February 9, 1996

FOR:	The Commissioners
FROM:	James M. Taylor /s/ Executive Director for Operations
SUBJECT:	CHARTER OF THE COMMITTEE TO REVIEW GENERIC REQUIREMENTS (CRGR) - (PROPOSED REVISION 6)

PURPOSE:

To obtain Commission approval of a major revision to the CRGR Charter in order to:

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

BACKGROUND:

The CRGR Charter was last revised on April 18, 1991, for the purpose of clarifying its requirements and updating its procedures to reflect current policy and practice. The Charter is now in need of major revision, principally to address the issues referred to in (1), (2), and (3) above, and to again update and clarify existing provisions to better reflect current policy and practice. The proposed charter revision is provided in Attachment 1 Attachment 2 shows the proposed revision in the form of a markup to facilitate review of the changes involved. Proposed deletions are marked by line through and proposed additions are indicated by shading.

DISCUSSION:

- Substantial Increase Standard
- Scope of CRGR Review
- New Regulatory Analysis Guidelines
- Other Charter Revisions

Substantial Increase Standard

In a Staff Requirements Memorandum (SRM) dated June 30, 1993, on the subject of "SECY-93-086 -Backfit Considerations" (see Attachment 3), the Commission requested that the staff consider whether existing documents, such as the CRGR Charter or office letters, should be revised to better reflect the Commission's understanding of the "substantial increase" standard of the backfit rule, in particular with regard to consideration of qualitative factors in the justification of proposed backfits. The Commission also indicated that it would entertain a staff recommendation that separate guidance be drafted or other appropriate mechanisms for implementation be prepared, and noted that any document revisions or procedural mechanism changes that the staff considered advisable should be brought to the Commission for approval.

The staff believes that the CRGR Charter does need to be revised to better reflect the Commission's understanding of the "substantial increase" standard, as discussed in the June 30, 1993 SRM. Revisions to other documents, such as Management Directive 8.4 on plant-specific backfitting, will be prepared after Commission approval is obtained for the Charter revision.

The basic Commission understanding of the "substantial increase" standard is reflected most directly in new footnotes 13 and 14, on page 14 of the markup version of the Charter and in a new Attachment 3 to the Charter. Those additions provide, for the first time in the Charter, guidance on how to meet the "substantial increase" standard in cases where consideration of qualitative factors may be the determining factor for justifying a proposed backfit. The new guidance incorporated in the Charter relies upon, and reflects to a considerable extent, (1) previous guidance in the Statement of Considerations for the backfit rule, (2) the Commission's understanding, as discussed in the June 30, 1993 SRM, and (3) past experience with problematic cases. In this regard, it should be noted specifically that, while the Commission's SRM of June 30, 1993 explicitly addresses only rulemaking, the proposed Charter revisions would broaden the application of the principles set forth in that SRM, to include other types of legal requirements as well as staff positions, consistent with the full scope of the current Charter. (See further discussion in the Minutes of CRGR Meeting No. 269 - Attachment 4.)

Scope of CRGR Review

In an SRM dated June 15, 1994, on the subject of "SECY-94-109, Scope of Review for the Committee to Review Generic Requirements" (see Attachment 5), the Commission directed that: (1) the scope of the CRGR charter should not be reduced, (2) the staff should consider enlarging the scope of review of the CRGR to include proposed generic requirements in the nuclear materials area and provide a recommendation, and (3) the staff should look at measures which would lessen the time spent on CRGR reviews by individual CRGR members.

With regard to measures to lessen the time spent on CRGR reviews by individual CRGR members, the CRGR has adopted a practice of making more frequent use of a negative consent process and, in conjunction with this, emphasizing the elimination of dual reviews (i.e., review at both the proposed and final stages) when these measures seem to be appropriate based on a lack of controversy, low expected impact, or small potential for serious error. It is noted specifically, in this context, that more frequent use of a negative consent process (which is, in essence, an abbreviated review process) does not reduce the CRGR review scope. It is also recognized, however, that negative consent items are not subjected to synergistic consideration by the members as would occur when an item is reviewed formally at a CRGR meeting; thus this practice is limited to items of lesser significance. Some further detail regarding the bases and guidelines for application of these effort reduction measures is provided in Attachment 6.

With regard to expansion of the CRGR's scope of review to include proposed new requirements in the nuclear materials area, the staff recommends that, for a one-year trial period, the Committee review selected items in the nuclear materials area at the recommendation of the Director, NMSS or at the EDO's request. (See further discussion in the Minutes of CRGR Meeting No. 269 - Attachment 7.) In addition, in an SRM dated March 22, 1995, on the subject of "Briefing on Status of Action Plan for Fuel Cycle Facilities" (see Attachment 8), CRGR was directed by the Commission to review the proposed major revision to the existing 10 CFR Part 70 for regulation of activities at the large SNM processing facilities.

During the proposed one-year trial period, the Committee will assess for each such item submitted whether CRGR attention was warranted and whether or not value was added by CRGR review. These assessments will be included in the meeting minutes for each item reviewed and will be reported to the EDO in the Weekly Items of Interest, which are forwarded to the Commission. At the end of the trial period, based on these assessments, the Committee will make a recommendation regarding whether CRGR review of materials items should be continued, discontinued or expanded.

New Regulatory Analysis Guidelines

In an SRM dated June 30, 1995, on the subject of "SECY-95-028, Issuance of Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission," the Commission approved publication of the new Guidelines (subject to specific caveats that were addressed satisfactorily by the staff). The new Guidelines (NUREG/BR-0058, Revision 2, dated November 1995) contain comprehensive guidance to the NRC staff for preparation of regulatory analyses in support of proposed regulatory actions by the NRC, including specifically proposed backfitting actions in accordance with 10 CFR 50.109 and proposed information requests to licensees in accordance with the criteria of 10 CFR 50.54(f). The new Guidelines also contain detailed guidance for addressing the Commission's safety goals in connection with those proposed actions, where appropriate. Proposed Revision 6 to the CRGR Charter has been modified to incorporate by reference and appropriately reflect the applicable provisions of the new Guidelines.

Other Charter Revisions

Several other revisions of a lesser nature, which are appropriate for purposes of clarification and updating, are also proposed. These include:

- A new instruction that changes to reporting requirements, such as those contained in 10 CFR 50.72 and 10 CFR 50.73, should be justified by evaluation against criteria similar to those in 10 CFR 50.54(f). (See footnote 11 on page 11 of the markup version of the proposed revision.)
- A specific procedure for CRGR review of immediately effective actions promptly after they are issued. (See the new guidance on page 7 of the markup version of the proposed revision.)
- A new instruction that CRGR review packages should include the staff's evaluation of public comments (in order to make the handling of comments more apparent to the public). (See new item j. and footnote 12 on page 13 of the markup version of the proposed revision.)
- A confirmation that CRGR review is not necessary in standard plant reviews conducted under 10 CFR Part 52. (See footnote 5 on page 4 of the markup version of the proposed revision.)
- A change in the reference provided for the companion document (Handbook) to the new Regulatory Analysis Guidelines, i.
 e., draft NUREG/BR-0184 instead of NUREG/CR-3568. The draft NUREG has been developed in parallel with the
 new Guidelines and is considered by the cognizant group in RES to be the more appropriate reference that contains the
 most current information to supplement the guidance provided in the new Guidelines document. The final NUREG/BR-0184
 is expected to be published in 1996. (See item v. on page 9 and footnote 8 on page 10 of the markup version of
 the proposed revision.)

CONCLUSION:

The CRGR Charter should be revised (1) to include guidance that clearly reflects the Commission's understanding of the "substantial increase" standard of the backfit rule, specifically regarding the consideration of qualitative factors in the justification of proposed backfits; (2) to expand the CRGR review scope, on a trial basis, to include selected items in the nuclear materials area; and (3) to reflect approval by the Commission recently of the new Regulatory Analysis Guidelines (Revision 2 to NUREG/BR-0058). Other revisions of a lesser nature for the purpose of updating and clarifying various other provisions are also warranted at this time, as indicated in the attached markup (Attachment 2).

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

RECOMMENDATION:

That the Commission approve (1) proposed Revision 6 to the CRGR Charter, and (2) the proposed trial program for CRGR review of selected issues and proposed new requirements in the nuclear materials area.

James M. Taylor Executive Director for Operations

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Attachments:	1. Proposed Revision 6 to the CRGR Charter ≽
	 Markup version of proposed Revision 6 showing proposed changes Staff Requirements Memorandum, dated June 30, 1993 Attachment 4 to the Minutes of CRGR Meeting No. 269
	 Staff Requirements Memorandum, dated June 15, 1994 CRGR Effort Reduction Measures
	 Attachment 2 to the Minutes of CRGR Meeting No. 269 Staff Requirements Memorandum, dated March 22, 1995

EXCERPT FROM THE MINUTES OF CRGR MEETING NO. 269 RELATING TO ADDITIONAL GUIDANCE ON SUBSTANTIAL INCREASE STANDARD

Attachment 4 to the Minutes of the CRGR Meeting No. 269 CRGR Charter Revision

February 14, 1995

- TOPIC
- BACKGROUND
- CONCLUSIONS\RECOMMENDATIONS

TOPIC

The Committee discussed resubmittal to the EDO of a revised draft Revision 6 to CRGR Charter. (An earlier version of this proposed charter revision was transmitted to the EDO in December 1993, but was returned without EDO action while the possible abolishment of CRGR was being considered by the EDO and Commission.) Various aspects of the current proposed charter revision were discussed by the Committee at CRGR Meetings Nos. 211, 233, 243, 246, 247, 248, 251, 255, and 259. The major changes incorporated in proposed Revision 6 include: (i) improved guidance on consideration of qualitative factors for justification of proposed backfits, and (ii) expansion of the scope of CRGR activities, on a trial basis, to include review of selected items in the nuclear materials area. In conjunction with the proposed changes to the CRGR Charter, the Committee also discussed possible means/mechanisms for reducing the level of effort by CRGR members in carrying out their CRGR duties.

BACKGROUND

- 1. Enclosure 4 to the Minutes of CRGR Meeting No. 233, dated November 24, 1992
- 2. SRM (SECY-93-086), dated June 30, 1993, "Backfit Considerations"
- 3. Commission Paper (SECY-94-109), dated April 21, 1994, "Scope of Review for the Committee to Review Generic Requirements (CRGR)"
- 4. SRM (SECY-94-109), dated June 15, 1994, "Scope of Review for the Committee to Review Generic Requirements (CRGR)"
- 5. Commission Paper (SECY-94-141), dated May 23, 1994, "Improvement of the Rulemaking Process"
- 6. SRM (SECY-94-141), dated June 28, 1994, "Improvement of the Rulemaking Process"
- 7. Enclosure 4 to the Minutes of CRGR Meeting No. 259, dated August 3, 1994
- 8. Draft package, dated February 1, for proposed Revision 6 to the CRGR Charter

CONCLUSIONS\RECOMMENDATIONS

- 1. The Committee endorsed for inclusion (as a new Attachment 3) in proposed Revision 6 to the Charter improved guidance on consideration of qualita-tive factors for justification of proposed backfits. (This CRGR action is in response to SRM (SECY-93-086) dated June 30, 1993 see Background Item 2.) The new guidance is more detailed than, and goes beyond, related guidance provided in proposed Revision 2 to the Regulatory Analysis Guidelines (NUREG/BR-0058) submitted recently for Commission approval. After careful deliberation on this point, the Committee believes that the new Charter guidance is a logical extension of the guidance provided in the new Guidelines, and is consistent with the Commission's objectives reflected in the SRM. The Committee believes that the guidance in the two documents is consistent, and does not believe it is necessary to revise the Guidelines at this point to provide identical guidance in both documents.
- 2. The Committee also endorsed for inclusion in proposed Revision 6 a change to the CRGR scope of review specifying that, on a trial basis, the Committee will review selected items in the nuclear materials area. (This CRGR action is in response to SRM (SECY-94-109) dated June 15, 1994 see Background Item 4) As discussed in Attachment 2 preceding, candidate items identified for CRGR review during the next year include: (i) licensing of dry cask storage of spent fuel; (ii) interim low-level waste storage issues (e.g., transportation of potentially flammable\ dispersible waste forms); and (iii) radiation safety\hazards consider-ations and criticality issues related to the fuel cycle facilities. As a part of the trial process, for each such items. The Committee's assessments in this regard will be included in the meeting minutes for each item and will be reported to the EDO in the Weekly Items of Interest, which are forwarded to the Commission.

Following approval by the Commission, Revision 6 to the Charter will be distributed to all licensees. Appropriate modifications will be made to Management Directive 5.14 to provide consistent and standardized proced-ures for implementation by the NRC program offices and regional staff; and training sessions will be conducted for regional and program office staff in support of implementation of the revised Charter.

- 3. In addition to the major revisions discussed in the preceding, the Committee recommended a number of additional changes for the purpose of further updating and clarifying the Charter. All of the changes made to the Charter in proposed Revision 6 are reflected in Attachment 4A.
- 4. In conjunction with its consideration and endorsement of proposed Revision 6, CRGR has also adopted the practice of making use of the negative consent process where possible, and has been emphasizing the elimination of dual reviews (i. e., review at both the proposed and final stages), when these measures seem to be appropriate based on a lack of controversy. (These measures were implemented in response to SRM (SECY-94-109), dated June 15, 1994, which requested the Committee to explore possible means/measures to lessen the amount of time spent on CRGR reviews by individual CRGR members.) The Committee noted specifically, in adopting these measures, that they do not reduce the scope of CRGR review.

- BACKGROUND
- GUIDELINES

BACKGROUND

On April 21, 1994, the EDO transmitted to the Commission SECY-94-109 proposing to reduce the basic scope of CRGR review to:

- 1. "review of 'high impact' and 'controversial' generic correspondence and rules before public comment,"
- 2. "review of items for which the staff has difficulty resolving issues after public comment,"
- 3. "review of emergency and urgent generic correspondence, and"
- 4. "review of significant proposals with highly expedited schedules."

On June 15, 1994 the Commission provided a staff requirements memorandum (SRM) directing that:

- 1. "... the scope of the CRGR Charter should not be reduced."
- "... the staff should consider enlarging the scope of review of the CRGR to include proposed generic requirements in the nuclear materials area and recommend a course of action."
- 3. "The staff should look at measures which would lessen the time spent on CRGR reviews by individual CRGR members."

GUI DELI NES

The CRGR has considered measures to lessen the time spent by individual members on CRGR reviews and adopted the following guidelines:

- 1. The Charter has not changed with regard to defining what categories of documents are subject to CRGR review.
- 2. It is appropriate to make more frequent use of a negative consent process. (In this process, the CRGR staff reviews a package submitted for CRGR review, summarizes the issues and the staff's responses to the issues and, if appropriate, recommends to the members that further review and discussion at a meeting are not needed. If the members agree, no further review is performed.) It is noted that more frequent use of negative consent (which, in essence, is an abbreviated review) does not reduce the scope of CRGR review.
- 3. In conjunction with negative consent, it is appropriate to emphasize reducing the number of dual reviews (i.e., review at both the proposed and final stage). Specifically:
 - a. At the proposed (public comment) stage:

When it seems appropriate, based on a lack of controversy, low expected impact or small potential for error, the CRGR Chairman may agree to defer the CRGR's review pending public comment on the proposal. It has been a longstanding practice to do this occasionally for special situations; however, this approach will now be emphasized.

As an alternative, the CRGR Chairman may agree to a negative consent approach. This would be appropriate in cases where it appears that there are only narrow, minor questions that need to be brought to the attention of the CRGR.

Otherwise, the proposal will be scheduled for a regular review.

b. At the final (implementation) stage for items which the CRGR has previously reviewed, including items reviewed by negative consent:

When it seems appropriate, based on a lack of controversy, low expected impact or small potential for error, the CRGR Chairman may agree to forgo a second CRGR review.

As an alternative, the CRGR Chairman may agree to a negative consent approach. This would be appropriate when it appears that there are only narrow, minor questions that need to be brought to the attention of the CRGR.

Otherwise, the proposal will be scheduled for a regular CRGR review.

c. At the final (implementation) stage for items which the CRGR has not previously reviewed:

When it seems appropriate, based on a lack of controversy, low expected impact or small potential for error, the CRGR Chairman may agree to a negative consent approach which is, in essence, an abbreviated review.

Otherwise, the proposal will be scheduled for a regular review.

ATTACHMENT 7

EXCERPT FROM THE MINUTES OF CRGR MEETING NO. 269 RELATING TO INCREASE IN CRGR SCOPE OF REVIEW

Attachment 2 to the Minutes of the CRGR Meeting No. 269 Proposed Expanded Scope of CRGR Review to Include Nuclear Materials Issues

February 14, 1995

- TOPIC
- BACKGROUND

The CRGR discussed with R. Bernero, Director, NMSS the possible expansion of CRGR review scope to include proposed new requirements in the nuclear materials area. NMSS proposed that the CRGR review of materials items be limited to selected nuclear materials items on a trial basis. This discussion was in response to the June 15, 1994 Commission directive (Background Item 2 below) that the staff consider expanding the scope of the CRGR review to include proposed requirements in the nuclear materials area. (This topic was also discussed previously by the Committee at Meeting No. 259.)

BACKGROUND

- 1. Commission Paper (SECY-94-109), dated April 21, 1994, "Scope of Review for the Committee to Review Generic Requirements (CRGR)"
- 2. SRM (SECY-94-109), dated June 15, 1994, "Scope of Review for the Committee to Review Generic Requirements (CRGR)"
- 3. Enclosure 4 to the Minutes of CRGR Meeting No. 259, dated August 3, 1994

CONCLUSIONS\RECOMMENDATIONS

R. Bernero, Director, NMSS identified several nuclear materials areas that might benefit from CRGR review; selected topics for future CRGR consideration discussed with the Committee included the following:

- 1. Dry cask storage of spent fuel I tems such as certification of multi-purpose (storage as well as transportation) canister systems through rulemaking.
- 2. 40 vs 100 year licensing of monitored retrievable storage sites east of Yucca Mountain (proposed legislation is currently pending before Congress).
- Interim on-site low-level waste storage issues Currently there are no generic requirements for on-site storage of low-level waste. A joint NRR-NMSS generic letter on the subject, addressing concerns related to potentially flammable and \or dispersible waste forms, is currently being considered.
- Radiation\chemical safety\hazards considerations and criticality issues related to the low-enrichment-uranium (LEU) fuel fabrication facilities. The planned revision of 10 CFR Part 70 was identified as a likely topic for CRGR review in this context.
- 5. NMSS indicated that the Committee's perspective and advice on structural, electrical, and mechanical aspects of the regulation of spent fuel and waste storage/transportation operations, and LEU fuel fabrication facilities (from the systems, rather than process, perspective) could be helpful.
- 6. With regard to proposed new requirements that are risk\performance-based, the Committee can provide a useful independent assessment of under-regulation or over-regulation in the nuclear materials area. For example, in the NRC-regulated states, if the implementation of alarming rate meters (under current 10 CFR 34 requirements) is shown to result in fewer radiographer over-exposure events, that finding may reduce the value of, and thus eliminate the need for, the proposed two-man rule and certification provisions in the proposed Part 34 revision under consideration.

The Committee agreed that the selected nuclear materials areas proposed by NMSS are appropriate topics for CRGR review, on a trial basis. The CRGR Charter revision, now under preparation, will be modified to reflect this proposed change in CRGR review scope. After a trial period of about one year, the Committee will examine the experience from CRGR reviews of nuclear materials items. Specifically, the Committee will assess the value added by CRGR reviews, and based on that assessment will make appropriate recommendations to the EDO regarding whether or not the Committee should continue review of nuclear materials items. The Committee's assessment of whether or not the items that were identified by the staff for CRGR review, actually warranted CRGR attention and, if so, whether there was significant value added by the COM the EDO in the CRGR Weekly Items of Interest to be reported to the Commission.