

## **Guidance for Deciding When to Request the Committee to Review Generic Requirements Review of a Rulemaking Package**

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

The lead office for a rulemaking should apply the following criteria and guidance, in consultation with the CRGR, to determine whether or not to request a CRGR review of the rule. Specifically, the office should consider requesting CRGR review of a rulemaking when the staff and the CRGR agree that one or more of the following criteria are met:

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

The following implementing guidance provides instruction on identifying whether a particular condition has been met.

1. The staff indicated, in the rulemaking plan, that the rulemaking would not constitute backfitting. However, in developing the proposed rule, the staff identifies that a backfit is possible.

Self-explanatory.

Enclosure

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

When qualitative factors are used to justify a rulemaking that would incur significant costs, the staff should consult with the CRGR to determine the necessity and effectiveness of the rulemaking.

In addition, security-related rulemakings currently rely only on qualitative factors and do not consider any quantitative factors (because the likelihood of a security event is always postulated as 1.0). Therefore, for every security-related rulemaking, the staff should engage the CRGR to determine whether CRGR review is warranted.

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

Staff should consider engaging the CRGR when there is substantial uncertainty in the statistical values used to support the rulemaking. Substantial uncertainty results when there are large ranges in the possible values of the input parameters driving the cost-benefit calculations of the regulatory analysis. As a result of these large ranges in input parameter values, the results of the regulatory analysis could differ from the mean estimate to a significant degree, indicating the conclusion of the regulatory analysis is also subject to high variability (i.e., uncertainty).

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

Self-explanatory.

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

The concerns raised may be regarding known backfitting issues (i.e., questions concerning compliance versus a change in staff position) associated with the rulemaking, the staff should identify and review past concerns raised or related regulatory matters and determine if they are directly or indirectly connected to backfitting. In addition, the staff should consider the discussion in the current [CRGR Charter](#) on relaxations, specifically “mandatory relaxations” (page 3, footnote 5 of the current CRGR charter), when considering backfitting issues associated with a proposed rule. If backfitting issues exist, then the staff should consult with the CRGR to determine whether or not to request CRGR review of the rule.

Furthermore, the staff should determine whether or not any external stakeholders have raised significant concerns regarding the backfit analysis or the regulatory analysis. These concerns may include lack of documentation related to the backfit or regulatory analyses or improper or incomplete development of backfit and regulatory analyses.

The staff should attempt to address and resolve any such concerns through normal NRC processes. The staff should consult with the CRGR to determine whether or not to request

CRGR review of the rule, even in those cases where the staff believes it has adequately addressed any stakeholder concerns about backfitting.

If any staff has initiated the non-concurrence process or differing professional opinion process related to backfitting or directly related to the responsibilities of the CRGR as outlined in the current [CRGR Charter](#) regarding a particular rulemaking, then the staff should inform the CRGR of the nature of the non-concurrence and recommend whether the CRGR should be further engaged.