

December 20, 2016

MEMORANDUM TO: Edwin M. Hackett, Chairman  
Committee to Review Generic Requirements

FROM: Andrew P. Averbach, Solicitor **/RA/**  
Office of the General Counsel

SUBJECT: SUMMARY OF COMSECY-16-0020 RECOMMENDATION ON  
REVISION OF GUIDANCE CONCERNING CONSIDERATION OF  
COST AND APPLICABILITY OF COMPLIANCE EXCEPTION TO  
BACKFIT RULE

BACKGROUND:

On June 9, 2016, the Executive Director for Operations issued a tasking memorandum (ML16133A575) directing the Committee to Review Generic Requirements (CRGR) to address the adequacy of NUREG-1409 as well as associated Management Directive 8.4. The CRGR was directed to assess the training and management related to backfitting generally and to coordinate its response with, among others, the Office of the General Counsel (OGC). So as to avoid confusion among interested parties concerning proper application of the compliance exception, OGC undertook a reexamination of the extent to which costs are appropriately considered when the agency imposes a requirement on a licensee that implicates the backfit rule, as well as related issues.

OGC recommended to the Commission in COMSECY-16-0020 that existing guidance concerning consideration of costs and use and scope of the compliance exception be revised. On November 29, 2016, the Commission instructed the Staff to be “familiar with and operate in a manner consistent with” OGC’s conclusions, and it likewise directed that the staff maintain consistency with OGC’s analysis in completing the tasking memorandum issued to the CRGR. This memorandum summarizes the recommendations of OGC in COMSECY-16-0020 that the Commission approved in SRM-COMSECY-16-0020. The CRGR and the Staff may separately adopt the contents of this summary for meetings and discussions with the public regarding planned updates and revisions to backfit guidance.

DISCUSSION:

I. Consideration of Cost When Considering Exceptions to Backfit Rule

In COMSECY-16-0020, OGC made two recommendations for the Staff to follow when analyzing exceptions to the backfit rule under 10 C.F.R. § 50.109(a)(4). OGC made these recommendations in light of recent judicial precedent, including the Supreme Court’s decision in *Environmental Protection Agency v. Michigan*, 135 S.Ct. 2699 (2015).

First, when the Staff has reached a new or changed position with respect to whether a particular requirement has been satisfied, the Staff should consider, as a threshold matter, whether regulatory action is necessary to ensure adequate protection. If it is, then no further explanation is necessary to justify such action – it is required by the Atomic Energy Act and must be implemented without consideration of cost (though cost may be considered in selecting among different ways of achieving adequate protection, in accordance with 10 C.F.R. § 50.109(a)(7)). The compliance exception should be pursued only in those circumstances where the requirement that the Staff seeks to impose exceeds the level necessary to achieve adequate protection (or, at a minimum, where the Staff cannot demonstrate that compliance is necessary to ensure adequate protection).

Second, if the Staff is invoking the compliance exception, it need not provide a demonstration, as would otherwise be required by 10 C.F.R. § 50.109(a)(3), of a substantial increase in overall protection of public health and safety or the common defense and security, or that the direct and indirect costs of implementation are justified in view of this increased protection. However, it still must include at least *some* consideration of cost. Although the extent of the consideration required will necessarily be fact-specific, one of the factors that may be relevant is the amount of time that has elapsed since the approval that is now claimed to be the subject of a mistake or omission. Where the potential for a compliance backfit is identified relatively shortly after the licensing decision or the imposition of a regulatory requirement, a simple cost estimate of imposing the backfit that does not quantify benefits or perform any balancing beyond that which was originally considered is likely all that will be necessary. But when many years have passed before the Staff determines that a regulation or requirement is not satisfied, identifying the benefits of compliance and comparing them to the cost of implementation will likely be appropriate to ensure that costs have been adequately addressed.

## II. Scope of the Compliance Exception to the Backfit Rule

### A. Omission or Mistake of Fact

The Statement of Considerations accompanying the 1985 revision to the backfit rule explains that

[t]he compliance exception is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard.

Final Rule, Revision of Backfitting Process for Power Reactors, 50 Fed. Reg. 38097, 38103 (Sept. 20, 1985).

To maintain consistency with this principle, the compliance exception should be limited to those situations in which

- (i) the Staff, whether by its own error or by licensee or third-party error or omission, at or before the time of its determination that a known and established standard of the Commission was satisfied, incorrectly perceived facts, performed or failed to recognize flawed analyses, or failed to properly draw direct inferences from those facts or analyses, as judged by standards and practices that were prevailing among

professionals or experts in the relevant area at the time of the determination in question; and

- (ii) those facts, analyses, or inferences have now been properly perceived, performed, or drawn.

By contrast, the compliance exception should not be applied to

- (i) failures of the Staff to extrapolate conclusions from facts, analyses, and direct inferences in ways that were not commonly recognized under such prevailing professional standards and practices at the time of the NRC determination; or
- (ii) recharacterizations of whether a particular set of otherwise understood circumstances satisfies the standard at issue based upon professional standards and practices developed or accepted after the time of the determination.

The “standards and practices that were prevailing” qualification is designed to make clear that the flaw in the Staff’s determination must be apparent based on methodologies existing and prevalent at the time the determination was made among professionals and knowledgeable persons within the specific field at issue, rather than on a retrospective assessment, fueled by new technologies and modes of analysis. In other words, the error must have been demonstrable at the time of the determination and not merely determined to be wrong based on an after-the-fact application of new advances. Thus, in each case, it must be determined whether the facts or conclusions upon which the Staff’s new position is based rests on methodologies or principles that were widely understood by professionals or experts in the relevant area at the time of the original approval yet were not in fact correctly implemented or whether they are the result of an intervening change in the prevailing understanding of the subject matter and associated phenomena. The compliance exception should be available in circumstances falling into the former, but not the latter, category.

#### B. Use of Compliance Exception To Mandate Consistency with General Design Criteria

General Design Criteria (GDCs) represent “minimum requirements” for the principal design criteria (PDCs) for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission. See 10 C.F.R. Part 50 App. A. Applicants for licenses issued under Part 50 (or Part 52, if they are not relying on already approved design certifications) are required to submit PDCs for approval. The two-step licensing process of Part 50 requires approval of the PDCs as a condition to the grant of a construction permit. Later, prior to issuance of an operating license and as a basis for its finding of reasonable assurance of adequate protection of public health and safety, the Commission must find that the facility has been built in accordance with the PDCs and any changes. See Final Rule, General Design Criteria for Nuclear Power Plants, 36 Fed. Reg. 3255, 3256 (Feb. 20, 1971) (“Principal design criteria established by an applicant and accepted by the Commission will be incorporated by reference in the construction permit. In considering the issuance of an operating license under Part 50, the Commission will require assurance that these criteria have been satisfied in the detailed design and construction of the facility and that any changes in such criteria are justified.”). Thus, for Part 50 licenses issued since 1971 (when the GDCs were promulgated), the Commission has already necessarily reached the conclusion

that the design basis of the plant, as reflected in the PDCs, meets or exceeds the minimum criteria set forth in the GDCs.

The approval process outlined above will typically yield more specific requirements than those set forth in the GDCs. However, the agency is not precluded from reliance on GDCs as the source of a "requirement" for purposes of invoking the compliance exception, in those cases where a GDC provides more than just a performance standard and has not been superseded through the approval of PDCs and requirements derived from those PDCs. Thus, a GDC can be regarded as a requirement in those circumstances in which the GDC is prescriptive in nature and the technical specifications and other licensee requirements derived from the PDCs do not speak to the matter in question.

Finally, it should be noted that in many cases, conditions that are outside the GDCs can be properly resolved as a matter of adequate protection, without the need to invoke the compliance exception. Consistent with the discussion in Part I above, the extent to which regulatory action is necessary to ensure adequate protection should be evaluated prior to any efforts to invoke the compliance exception to the backfit rule based on a requirement set forth in the GDCs.

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Office:	OGC	OGC	OGC	OGC
Name:	A. Averbach			
Date:	12/20/16			

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