

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REACTOR REGULATION  
WASHINGTON, D.C. 20555-0001

March 28, 2000

**NRC REGULATORY ISSUE SUMMARY 2000-07  
USE OF RISK-INFORMED DECISIONMAKING IN LICENSE  
AMENDMENT REVIEWS**

Addressees

All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

Intent

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to advise addressees of interim guidance on the use of risk information by the staff in its license amendment reviews, including reviews of license amendment requests that are not risk informed, and staff plans for finalizing this guidance. This RIS requires no action or written response on the part of an addressee.

Background Information

Commission policy, as presented in the Probabilistic Risk Assessment Policy Statement and the "Discussion on Safety and Compliance" (COMSAJ-97-008), indicates that it is the staff's responsibility to consider the change in risk, as well as compliance with the agency's regulations and other requirements, when reviewing license amendment requests. The use of risk information is clear when the action is a risk-informed license amendment request. However, the staff's responsibilities and authority for considering risk information and the Commission's policy regarding the use of risk information in regulatory decisionmaking are not explicitly stated or defined for license amendment requests that are not risk informed (i.e., their acceptability is based solely on meeting the Commission's deterministic rules and regulations).

The recent technical review of steam generator electrosleeves discussed in SECY-99-199, "Electrosleeve Amendment Issued to Union Electric Company for Callaway Plant, Unit 1," illustrates the difficulty of completing a review of a proposed license amendment request that is not risk informed and that satisfies existing design and licensing bases but introduces new potential risks. As a result of this experience, the staff proposed an approach for applying risk informed decisionmaking in similar technical reviews in SECY-99-246, "Proposed Guidelines for Applying Risk Informed Decisionmaking in License Amendment Reviews." In the related staff

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requirements memorandum, the Commission approved the approach and its implementation on an interim basis while the staff proceeds to engage stakeholders in the development of final guidance.

This RIS transmits the interim guidance on the use of risk information in regulatory decisionmaking regarding license amendment requests and describes the planned approach for finalizing this guidance.

### Summary of Issue

When a license amendment request complies with the regulations and other license requirements, there is a presumption by the Commission of adequate protection of public health and safety (Maine Yankee, ALAB-161, 6 AEC 1003 (1973)). However, circumstances may arise in which new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, such as identification of a design vulnerability or an issue that substantially increases risk. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety. Section 182.a of the Atomic Energy Act of 1954, as amended, and as implemented by 10 CFR 2.102, gives the NRC the authority to require the submittal of information in connection with a license amendment request if NRC has reason to question adequate protection of public health and safety. The applicant may decline to submit such information, but it would risk having the amendment request denied if NRC cannot find that the requested amendment provides adequate protection of public health and safety.

Under unusual circumstances that could introduce significant and unanticipated risks, the NRC staff would assume the burden of demonstrating that protection is not adequate or that additional license conditions are justified despite the fact that current regulatory requirements appear to be met. Instances in which the staff would question licensees regarding risk are expected to be relatively rare.

The guidelines presented in SECY-99-246 for identifying those situations in which risk implications are appropriate to consider and for deciding if undue risk exists are described in Attachment 1 to this RIS. These guidelines will be used on an interim basis while the staff proceeds to engage stakeholders in the development of final guidance.

The staff will develop final guidelines that articulate what constitutes a special circumstance in a clear and objective manner and modifications to relevant guidance documents to incorporate this guidance. In particular, the staff will modify the regulatory guidance found in Regulatory Guide (RG) 1.174 to describe the concept of special circumstances and the staff's role in reviewing the risk implications of license amendment requests that are not risk informed. The staff will also evaluate whether any regulatory guides or standard review plans in deterministic review areas need to be modified to sensitize the technical staff to identifying potential risk implications of licensing changes within their deterministic review scope. The staff will ensure that both internal and external stakeholders are meaningfully engaged in the development of the final guidelines and related guidance documents.

The staff will subsequently reflect this information in internal, office-level documents that establish the process for reviewing license amendment requests, such as Office of Nuclear Reactor Regulation Office Letter 803, "License Amendment Review Procedures." In modifying the process documents, the staff will be careful to clearly differentiate the concept of adequate protection from the numerical risk acceptance guidelines of RG 1.174.

#### Backfit Discussion

This RIS requires no action or written response. Consequently, the staff did not perform a backfit analysis.

#### Federal Register Notification

The staff did not publish a notice of opportunity for public comment in the *Federal Register* because the RIS is informational and pertains to a staff position that does not represent a departure from current regulatory requirements and practice. NRC intends to work with the Nuclear Energy Institute, industry representatives, members of the public, and other stakeholders in developing final guidance and modifying related guidance documents.

If there are any questions about this matter, please contact the person listed below.

***/RA by Ledyard Marsh Acting For/***  
David B. Matthews, Director  
Division of Regulatory Improvement Programs  
Office of Nuclear Reactor Regulation

Technical Contact: Robert L. Palla, NRR  
301-415-1095  
E-mail: rlp3@nrc.gov

#### Attachments:

1. Interim Guidelines for Using Risk Information in Regulatory Decisionmaking
2. List of Recently Issued NRC Regulatory Issue Summaries

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\*See Previous Concurrence Accession #: ML003680058 Template #: NRR-052

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NAME	Rpalla:rmc*		RJBarrett*				GMHolahan*	
DATE	1/27/00		1/31/00		1/ 24 /00		2/4/00	

OFFICE	D:ADPT		OGC		REXB		DRIP/REXB		DRIP	
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## **Interim Guidelines for Using Risk Information in Regulatory Decisionmaking**

The process depicted in Figure 1 will be used in the staff review of both licensee-initiated risk-informed license amendment requests, as well as license amendment requests in which the licensee chooses to not submit risk information.

The staff will assess the requested changes and the need for and effectiveness of any compensatory measures that might be warranted because of risk considerations by evaluating the changes relative to the safety principles and integrated decisionmaking process defined in Regulatory Guide (RG) 1.174. The risk acceptance guidelines (Sections 2.2.4 and 2.2.5 of RG 1.174) describe acceptable levels of risk increase as a function of total core damage frequency (CDF) and large early release frequency and the manner in which the acceptance guidelines should be applied in the review and decisionmaking process. The guidelines serve as a point of reference for gauging risk impact but are not legally binding requirements.

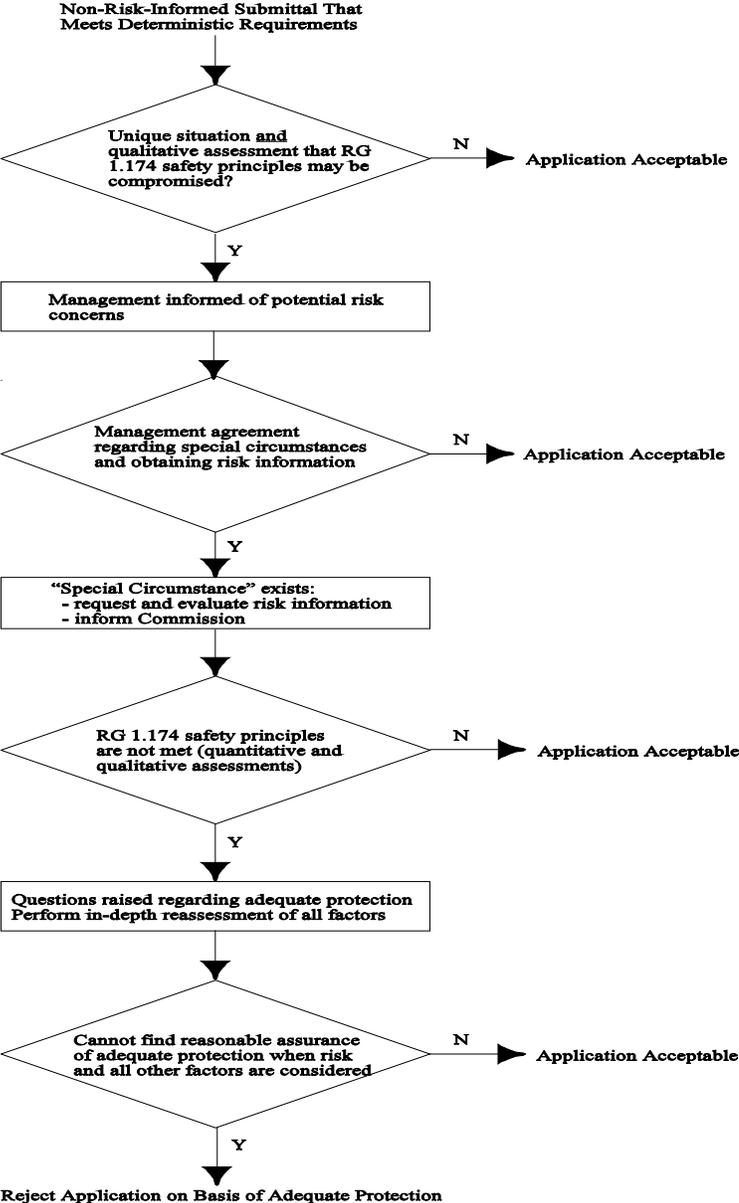
For non-risk-informed license amendment requests, the preliminary assessment would be qualitative with a decision based on engineering judgment since quantitative risk information would not generally be presented in submittals that are not risk informed. If “special circumstances” are believed to exist, the staff will explore in more detail the underlying engineering issues contributing to the risk concern, and the potential risk significance of the license amendment request. These “special circumstances” represent conditions or situations that would raise questions about whether there is adequate protection and that could rebut the normal presumption of adequate protection from compliance with existing requirements. The application and related issues would be given increased attention from the U.S. Nuclear Regulatory Commission management at this point.

With management concurrence, the staff will question risk further if there is a reason to believe that the proposed change would compromise the safety principles described in RG 1.174 and would substantially increase risk relative to the risk acceptance guidelines contained in the regulatory guide. In such instances, the staff will ask the licensee to address the safety principles and the numerical guidelines for acceptable risk increases contained in RG 1.174 in the submittal. The staff may ask the licensee to submit the information it needs to make an appropriate risk assessment. If an applicant does not choose to address risk, the NRC staff will not issue the requested amendment until it has assessed the risk implications sufficiently to determine that there is reasonable assurance that the public health and safety will be adequately protected if the amendment request is approved. A licensee’s decision not to submit requested information could impede the staff’s review and could also prevent the staff from reaching a finding that there is reasonable assurance of adequate protection. A licensee’s failure to submit requested information could also be a basis for rejection pursuant to 10 CFR 2.108.

The staff will inform the Commission if it determines that a license amendment application meets the “special circumstances” standard, the basis for that determination, the licensee’s response to the staff’s determination, any delay in the license amendment review process, and any generic implications.

Situations that exceed RG 1.174 guidance could constitute a trigger point at which questions are raised as to whether the proposed change provides reasonable assurance of adequate protection. A more in-depth assessment of the special circumstances, the safety principles, and the issues identified for management attention in Section 2.2.6 of RG 1.174 would then be made in order to reach a conclusion regarding the level of safety associated with the requested change. The final acceptability of the proposed change would be based on a consideration of current regulatory requirements, as well as on adherence to the safety principles, and not solely on the basis of a comparison of quantitative probabilistic risk assessment results with numerical acceptance guidelines. The authority provided by the Atomic Energy Act and current regulations requires rejection of a license amendment request if the NRC finds that adequate protection is not provided.

Figure 1 - Process and Logic for Considering Risk in License Amendment Reviews



LIST OF RECENTLY ISSUED  
 NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2000-06	Consolidated Line Item Improvement Process for Adopting Standard Technical Specifications Changes for Power Reactors	03/20/2000	All holders of OLs for nuclear reactors, except for those licensees who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-05	Resolution of Generic Safety Issue 165, Spring-Actuated Safety and Relief Valve Reliability	03/16/2000	All holders of OLs for nuclear reactors, except for those licensees who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-04	Operating Reactor Licensing Action Estimates	03/16/2000	All power reactor licensees
2000-03	Resolution of Generic Safety Issue 158: Performance of Safety-Related Power-Operated Valves Under Design Basis Conditions	03/15/2000	All holders of OLs for nuclear reactors, except for those licensees who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-02	Closure of Generic Safety Issue 23, Reactor Coolant Pump Seal Failure	02/15/2000	All holders of OLs for nuclear reactors, except for those licensees who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel