

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

January 18, 2001

**NRC REGULATORY ISSUE SUMMARY 2001-02  
GUIDANCE ON 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 final 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. This guidance supercedes the interim guidance transmitted in RIS 2000-07. 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 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 requirements memorandum, the Commission approved the approach and its implementation on

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an interim basis while the staff proceeds to engage stakeholders in developing final guidance. The interim guidance on risk-informed decisionmaking in license amendment reviews was disseminated to industry via RIS 2000-07.

A draft version of the appendix was published in the *Federal Register* for public comment on April 10, 2000, and the NRC held a public workshop to discuss the appendix on May 16, 2000, before the end of the comment period. The staff discussed the draft appendix with the Advisory Committee for Reactor Safeguards on May 11, 2000, and with the Committee to Review Generic Requirements on May 30, 2000. The staff provided a final version of the appendix to the Commission on September 26, 2000. Provisions in the guidance on Commission notification were clarified in a November 12, 2000, memorandum (COMSECY-00-0038). In the related staff requirements memorandum, the Commission approved issuance of the final guidance, and approved its implementation in future reviews, subject to the clarification noted in COMSECY-00-0038 (i.e., the staff will notify the Commission of the first few amendments judged to create special circumstances, and thereafter will use the Risk Informed Licensing Panel to provide a recommendation to upper management on whether Commission notification is appropriate). The NRC plans to issue the guidance as a new Appendix D to Chapter 19 of the Standard Review Plan (SRP).

#### 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.

Guidance to the staff for identifying those situations in which risk implications should be considered and for deciding whether undue risk exists is provided in Attachment 1 to this RIS. This guidance will be used in future license amendment reviews.

The staff plans to issue this guidance as a new Appendix D to SRP Chapter 19 and to incorporate conforming changes in the planned future revisions of Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," and Office of Nuclear Reactor Regulation Office Letter 803, "License Amendment Review Procedures."

### 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 on this RIS 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. Furthermore, the guidance described in the RIS was previously issued for public comment, and stakeholder feedback has been considered in developing the final version of the guidance.

### PAPERWORK REDUCTION ACT STATEMENT

This RIS does not request any information collection.

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

***/RA by Scott F. Newberry Acting For/***  
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#### Attachments:

1. Use of Risk Information in Review of Non-Risk-Informed License Amendment Requests (Appendix D to Chapter 19 of the Standard Review Plan)
2. List of Recently Issued NRC Regulatory Issue Summaries

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**USE OF RISK INFORMATION IN REVIEW OF  
NON-RISK-INFORMED LICENSE AMENDMENT REQUESTS  
(APPENDIX D TO CHAPTER 19 OF THE STANDARD REVIEW PLAN)**

**Areas of Review**

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 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 licensee 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 reviewers would assume the burden of demonstrating that the presumption of adequate protection is not supported by the bases for the existing staff positions despite the fact that currently specified regulatory requirements are met. Instances in which license amendment requests meet all regulatory requirements yet raise significant risk concerns are rare. The process used for identifying those situations in which risk implications are appropriate to consider and for deciding if undue risk exists is depicted in Figure 1. This process can be used in the 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 (i.e., non-risk-informed requests).

License amendment requests will be screened for potential risk implications as part of the license amendment review process. Office-level license amendment review procedures provide guidance on which license amendment requests should be examined at the level of the integrated risk model because of the potential for significant impacts on plant risk. In accordance with the guidance, the risk implications of a non-risk-informed submittal would be discussed with a risk analyst if the submittal --

- significantly changes the allowed outage time (e.g., outside the range previously approved at similar plants), the probability of the initiating event, the probability of successful mitigative action, the functional recovery time, or the operator action requirement;
- significantly changes functional requirements or redundancy;
- significantly changes operations that affect the likelihood of undiscovered failures;
- significantly affects the basis for successful safety function; or

- could create “special circumstances” under which compliance with existing regulations may not produce the intended or expected level of safety and plant operation may pose an undue risk to public health and safety.

Non-risk-informed license amendment requests judged to have the potential to significantly affect risk would be referred for a more detailed risk evaluation as part of the license amendment review.

### **Review Guidance and Procedures**

For license amendment requests referred for a risk review, the reviewers should assess the requested changes, and the need for and the 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 (LERF) and the manner in which the acceptance guidelines should be applied in the review and decisionmaking process. Reviewers should note that 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 reviewers will explore in more detail the underlying engineering issues contributing to the risk concern, and the potential risk significance of the license amendment request. The staff should inform and engage the licensee as early as possible in the evaluation process when it believes that a special circumstance may exist and is considering the need for risk information.

“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. In such situations, undue risk may exist even when all regulatory requirements are satisfied. In general, a special circumstance may exist if (1) the situation was not identified or specifically addressed in the development of the current set of regulations and could be important enough to warrant a new regulation (e.g., a risk-informed regulation) if such situations were encountered on a widespread basis and (2) the reviewer has knowledge that the risk impact is not reflected by the licensing basis analysis and has reason to believe that the risk increase would warrant denial or attaching conditions to the staff’s approval if the request were evaluated as a risk-informed application. If one criterion is met, the second would generally be met as well. However, in view of the judgment involved in these determinations, cases in which one of the criteria is not clearly met should still be elevated for management consideration as discussed below.

“Special circumstances” may include but not be limited to license amendment requests that, if approved, could --

- substantially increase the likelihood or consequences of accidents that are risk significant but are beyond the design and licensing basis of the plant, for example, proposed changes to steam generator (SG) allowable leak rates that meet 10 CFR Part 100 limits based on the design basis source term but result in a large early release given a severe accident source term; or use of new materials for SG repairs that provide acceptable performance under normal and design basis accident conditions but a reduced capability to maintain SG tube integrity in high-temperature, severe accident scenarios.
- degrade multiple levels of defense, or cornerstones in the reactor oversight process, through plant operations or situations not explicitly considered in the development of the regulations, for example, advanced applications of digital instrumentation and controls in which the licensee does not address or comply with regulatory guidance concerning evaluation of defense in depth and diversity in digital instrumentation and control systems.
- significantly reduce the availability or reliability of structures, systems, or components that are risk significant but are not required by regulations, for example, amendment requests that as an unintended consequence compromise the effectiveness of the Mark I hardened wetwell vent system in protecting against containment overpressure failures in accidents beyond the design basis, or the diversity of the turbine-driven auxiliary feedwater pumps provided in response to NUREG-0737, Section II.E.1.1.
- involve changes for which the synergistic or cumulative effects could significantly impact risk, for example, power uprate requests that would increase operating power well beyond the levels approved in previous uprates and would introduce or substantially increase the frequency of risk-significant core damage sequences.

If, upon further consideration, it is believed that approval of the request would compromise the safety principles described in RG 1.174 and substantially increase risk relative to the risk acceptance guidelines contained in the regulatory guide, the reviewers should inform NRC management of the risk concerns and the need to further evaluate the risk associated with the request. In such instances, the reviewers, with management concurrence, should ask the licensee to address the safety principles and the numerical guidelines for acceptable risk increases contained in RG 1.174 in its submittal. The reviewers may alternatively ask the licensee to submit the information needed in order for the NRC staff to make an independent risk assessment.

The appropriate level of management involvement would depend on the nature and significance of the issue. In general, the decision regarding whether a license amendment request creates a special circumstance should, at a minimum, be supported by the division directors responsible for probabilistic safety assessment, the technical issue and the regulatory requirements in question, and licensing project management, as well as the Office of the General Counsel. Review by the Risk-Informed Licensing Panel (RILP) should be considered for this purpose. The need to elevate the issue to a higher management level or to inform the Commission should be specifically addressed by the RILP if a special circumstance is determined to exist. The RILP should ensure that the burden imposed on the licensee in responding to risk questions raised by the NRC is justified in view of the potential safety significance of the issue to be addressed in the requested information.

If a licensee does not choose to address risk, the reviewers should not issue the requested amendment until they have sufficiently assessed the risk implications 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 reviewers 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.

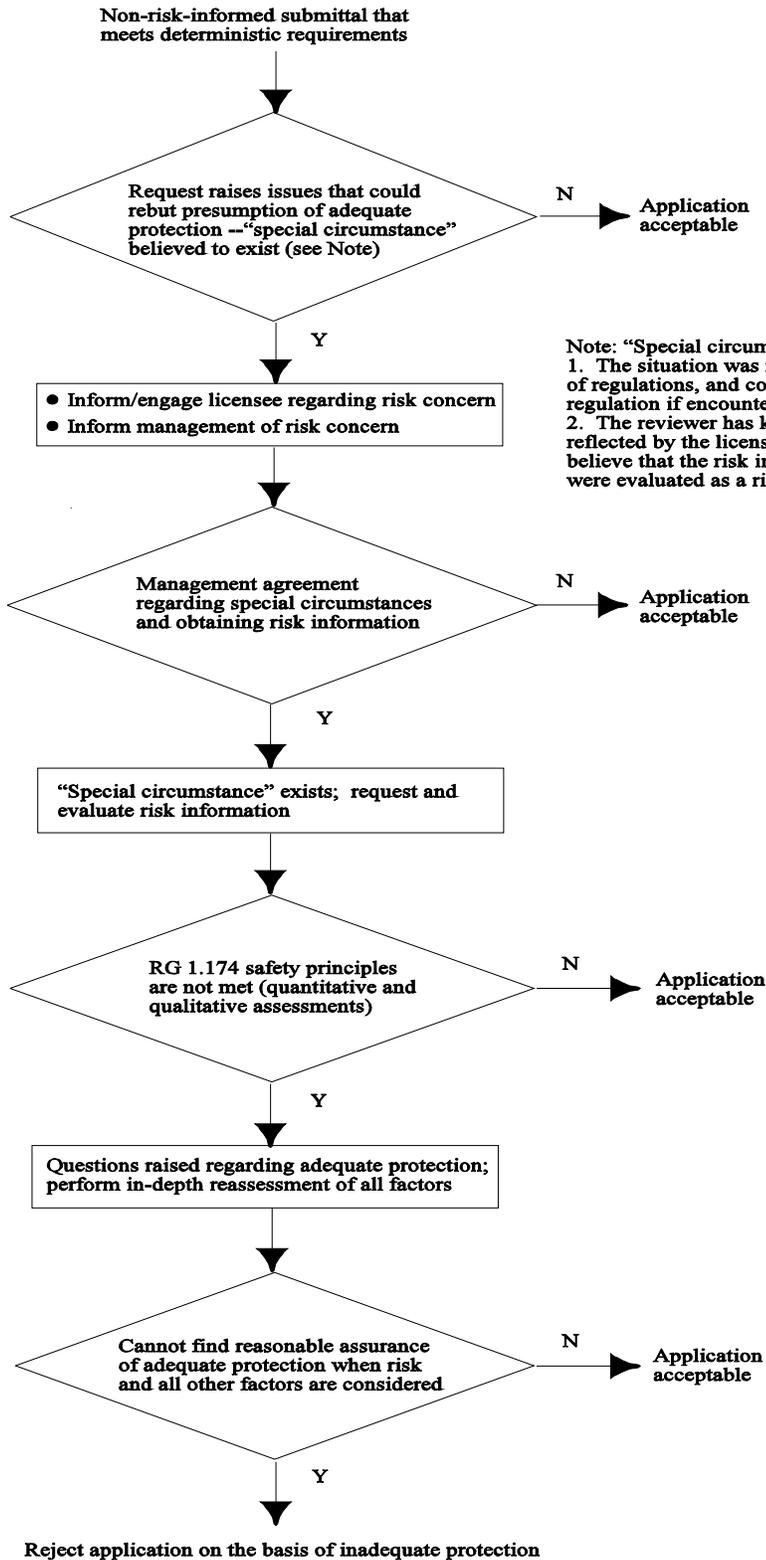
### **Evaluation Findings**

The numerical guidance for CDF and LERF and the safety principles provided in RG 1.174 are intended to provide a basis for finding that there is reasonable assurance of adequate protection. Therefore, situations that exceed these values or violate the other principles would 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 should then be made in order to reach a conclusion regarding the level of safety associated with the requested change.

In making this assessment, the reviewers should be mindful to clearly differentiate the concept of adequate protection from the numerical risk acceptance guidelines. The guidelines in themselves do not constitute a definition of adequate protection but provide an appropriate set of criteria to be used in the process for evaluating adequate protection. As discussed in RG 1.174, the uncertainty in the analyses must be considered in any finding that adequate protection is achieved.

The final acceptability of the proposed change should 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 decision to reject a non-risk-informed license amendment request on the basis of risk should be supported by the RILP and would be expected to be elevated to office-level management for a final decision. The authority provided by the Atomic Energy Act and current regulations requires rejection of a license amendment request if the NRC is unable to find that adequate protection is 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
2001-01	Eligibility of Operator License Applicants	01/18/01	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.
2000-25	Potential Deficiency in Qualification of Okonite Single-Conductor Electrical Control Cables	12/26/00	All holders of OLs for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel have been permanently removed from the reactor vessel
2000-24	Concerns about Offsite Power Voltage Inadequacies and Grid Reliability Challenges Due to Industry Deregulation	12/21/00	All holders of OLs for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel have been permanently removed from the reactor vessel
2000-23	Recent Changes to Uranium Recovery Policy	11/30/00	All holders of materials licenses for uranium and thorium recovery facilities
2000-22	Issues Stemming from NRC Staff Review of Recent Difficulties Experienced in Maintaining Steam Generator Tube Integrity	11/03/00	All holders of OLs for pressurized-water reactors (PWRs), except those who have permanently ceased operations and have certified that fuel have been permanently removed from the reactor vessel

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OL = Operating License  
CP = Construction Permit