October 12, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: PROPOSED GUIDELINES FOR APPLYING RISK-INFORMED DECISIONMAKING IN LICENSE AMENDMENT REVIEWS

PURPOSE:

To propose interim guidance for applying risk informed decisionmaking in license amendment reviews, and request Commission approval for implementing this guidance.

BACKGROUND:

Although the Commission's 1995 Probabilistic Risk Assessment (PRA) Policy Statement indicated that the staff should increase the use of PRA in its regulatory activities, no specific requirement currently exists for licensees to perform risk analyses in support of license amendment requests submitted for NRC staff review and approval, nor is there any explicit requirement for a licensee to have and maintain a PRA for their plant. The Commission guidance contained in risk informed regulatory guidance, such as Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis", only defines the process and criteria in situations in which the licensee voluntarily chooses to support license amendment requests with risk information.

Commission policy, as presented in the PRA Policy Statement, the "Discussion on Safety and Compliance" (COMSAJ-97-008), and other policy guidance, indicates that it is the staff's responsibility to consider the change in risk as well as to consider compliance with the agency's regulations and other requirements when reviewing license amendment requests. The licensee's responsibility 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 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).

Policy Issue 4 in SECY-98-300, "Options for Risk Informed Revisions to 10 CFR Part 50Domestic Licensing of Production and Utilization Facilities," describes the advantages and disadvantages of clarifying the NRC's authority to question the risk implications of proposed changes to the license or licensing basis, and to potentially reject proposed changes in instances in which risk considerations indicate the change would be unacceptable from the perspective of adequate protection. While concluding that additional direct authority does not need to be stated in Part 50 itself, the staff recommended that additional guidance be developed with respect to the use of risk informed approaches in regulatory activities, including activities beyond licensee-initiated (voluntary) risk informed license amendment requests. The staff would utilize such guidance in deciding if undue risk exists, even when all other regulatory requirements appear to be satisfied. In the staff requirements memorandum (SRM) related to SECY-98-300, the Commission approved the recommendation and directed the staff to submit the clarifying guidance for Commission approval.

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 in completing a review of proposed license amendment requests that are not risk informed, that satisfy existing design and licensing bases, but that introduce new potential risks. As a result of that review and a lessons-learned review, the staff separately committed to prepare an interim position for the Commission concerning how the staff intends to proceed to address similar technical reviews.

This paper transmits the proposed guidance with respect to the staff's authority to obtain and use risk information in regulatory decisionmaking regarding license amendment requests, and a planned approach for implementing this guidance. The guidance also reflects the interim position that the staff intends to follow in future technical reviews of steam generator issues, as indicated in SECY-99-199. The same process and logic may be applied in other types of licensing reviews, where appropriate.

DISCUSSION:

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 the case of the Callaway electrosleeve amendment, the licensee introduced a new material into the design which the current regulations did not consider when they were promulgated. 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.

For cases in which the staff determines that a license amendment request does not meet NRC design-basis requirements, the request would be denied. In practice, licensees often prefer to modify or withdraw their request when it becomes clear that it would likely be denied. For those cases in which the

licensee meets the design-basis requirements, the request would normally be approved. However, under unusual circumstances which 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 design basis requirements appear to be met. Stated otherwise, the staff would have to rebut the presumption that compliance with existing requirements alone is, in this circumstance, sufficient to provide adequate protection. To clarify the process and logic for identifying those situations in which risk implications are appropriate to consider and for deciding if undue risk exists, the staff proposes to adopt the guidelines described below for use in regulatory decisionmaking regarding license amendment requests. The staff also proposes to modify the current license amendment review procedures to aid in identifying license amendment requests that warrant further evaluation from a risk perspective since they could create "special circumstances" under which compliance with existing regulations would not produce the intended or expected level of safety.

The revised review procedure together with the decisionmaking guidelines would provide a process by which the risk implications of proposed license amendment requests are assessed and controlled. The proposed process, depicted in Figure 1, would be used for 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 same process and logic may be applied in other types of licensing reviews, where appropriate.

GUIDELINES FOR USING RISK INFORMATION IN REGULATORY DECISIONMAKING

The staff recommends that the requested changes, and the need for and effectiveness of any compensatory measures that might be warranted because of risk considerations, be addressed by evaluating the changes relative to the safety principles and integrated decisionmaking process defined in RG 1.174. The following safety principles, which are articulated in the regulatory guide, should be met: (1) the proposed change meets current regulations unless it is explicitly related to a requested exemption, (2) the proposed change is consistent with the defense-in-depth philosophy, (3) the proposed change maintains sufficient safety margins, (4) when proposed changes result in an increase in risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement, and (5) the impact of the proposed change should be monitored using performance measurement strategies. 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. The guidelines serve as a point of reference for gauging risk impact but are not legally binding requirements.

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 PRA results with numerical acceptance guidelines. 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. Examples include amendment requests that have a substantial risk increase (exceeding the risk acceptance guideline), are not effectively abated by compensatory measures, and do not meet other safety principles. 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 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.

Although the concept of "adequate protection" is clarified by several NRC guidance documents (such as COMSAJ-97-008) and is the basis for our safety determination, the term "adequate protection" and the equivalent phrase "no undue risk" are not explicitly and concisely defined in the Atomic Energy Act[(1)]. Quantitative (absolute) risk estimates serve as an important measure of plant safety, but do not embody the full range of considerations that enter into the judgment regarding adequate protection. The judgment regarding adequate protection derives from a more diverse set of considerations, such as acceptable design, construction, operation, maintenance, modification, and quality assurance measures, together with compliance with NRC requirements including, license conditions, orders, and regulations. In consideration of this as well as feedback from stakeholders regarding the need to clarify our safety policy, the staff had recommended, in SECY 99-191, that a feasibility study be carried out to develop a set of high level safety principles which, among other things, would attempt to address adequate protection concepts. If undertaken and successful, this work could be useful in developing guidance related to adequate protection determinations, and could help promote consistency and a better understanding regarding the basis for such determinations.

The recommended approach is to control changes to risk and to complement the risk information with consideration of other factors important to the judgment regarding acceptability, unless a more precise definition of adequate protection is developed to deal with these special circumstances. The risk change associated with a license amendment request is a more focused and more reliable measure of the impact of the request than is comparison of total (absolute) risk with a risk threshold, since PRA modeling (in areas unaffected by the request) and PRA completeness are less relevant. The acceptance guidelines for change in risk found in Section 2.2.4 of RG 1.174 are a convenient and logical point of reference for gauging risk impact and serving as a trigger for questioning whether adequate protection is assured. These acceptance guidelines, derived in large part from the Regulatory Analysis Guidelines used for backfit analysis in accordance with 10 CFR 50.109, have been widely reviewed and accepted within the agency, and are generally consistent with decision criteria/thresholds in use within industry.

The safety principles articulated in RG 1.174 address additional considerations relevant to adequate protection that are not directly or fully captured in PRA (e.g., maintaining sufficient safety margins and monitoring performance). The use of these principles as part of an integrated decisionmaking process is already described in the regulatory guide. Accordingly, the staff believes that use of the RG 1.174 safety principles and integrated decisionmaking process, supplemented by any other information relevant to the application (e.g., new information, operating experience), provides an appropriate means for questioning whether a license amendment request may represent an undue risk, regardless of whether the request is or is not risk informed[(2)]. The decision on whether or not to approve the application would then be based upon consideration of the totality of information, including risk implications and other factors such as described in RG 1.174, and a judgement as to whether or not adequate protection is maintained.

PROCESS FOR IDENTIFYING "SPECIAL CIRCUMSTANCES" AND CONTROLLING RISK

To further ensure that the risk implications of both risk informed and non-risk informed license amendment requests are appropriately addressed, the

staff believes that the decisionmaking process needs to include the following elements:

(1) guidance for screening license amendment requests to identify "special circumstances" that warrant evaluation from a risk perspective,

(2) a methodology for assessing the risk implications of potentially risk-significant license amendment requests, and

(3) guidelines for determining the acceptability of the licensing action, which factor in risk considerations.

Several of these process elements are already in place; others need further development or formalization for the process to be fully effective.

The staff currently screens license amendment requests for risk implications, although this screening is done on an ad hoc basis without specific risk guidance. The staff envisions several review procedure changes to gain more consistency in this process, as described below. The staff considers the existing body of guidance contained in risk informed RGs 1.174 through 1.178 and Standard Review Plans (SRPs) 3.9.7, 3.9.8, 16.1, and 19.0 to provide an appropriate methodology for analyzing and evaluating the risk implications of proposed changes. Accordingly, no additional methodology development efforts are envisioned. Insofar as guidelines for determining the acceptability of the licensing action are concerned, the staff considers the safety principles and integrated decisionmaking process presented in RG 1.174 (and as supplemented by other relevant information) to be the appropriate basis for decisionmaking as previously discussed.

The current process for reviewing license amendment requests is established by several office-level guidance documents, such as NRR Office Letter 803 ("License Amendment Review Procedures") and the NRR "Project Manager's Handbook". These documents offer some guidance concerning the review of requests that are classified as risk informed license amendment requests, but the guidance does not address risk implications of non-risk informed license amendment requests. The staff proposes to modify the appropriate license review process documents to provide additional guidance to aid in identifying license amendment requests that could create "special circumstances" under which plant operation may pose an undue risk to public health and safety. 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. 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 -- the risk acceptance guidelines are not intended to define adequate protection.

The staff will also modify the risk informed regulatory guidance found in SRP Chapter 19 and RG 1.174 to reflect the staff's role in reviewing the risk implications of license amendment requests that are not risk informed. Staff review could include evaluation of a licensee's risk assessment, review of supporting thermal-hydraulic/accident progression calculations, or independent staff risk assessments or severe accident analyses. The staff will also evaluate whether any RGs or SRPs in deterministic review areas need to be modified to sensitize technical staff to identifying potential risk implications of licensing changes within their deterministic review scope.

Instances in which the staff would question licensees regarding risk are expected to be relatively rare. On the basis of a recent sampling of about 700 licensing submittals, about 10 percent involved proposed changes whose effects may reach the threshold to be considered at the integrated risk model level. Of those, only a few are expected to have a substantial impact on risk. The staff's experience leads it to expect that the majority of the issues would be resolved through internal review and limited dialogue with the licensee, and that only a small number of submittals would involve more extensive requests for risk-related information and analysis. Amendment requests involving use of new or different approaches, methods, and materials to address technical issues or meet regulatory requirements, such as the use of new materials for steam generator tube repair, are representative of the type of amendments that might involve "special circumstances" and warrant a detailed review for risk implications.

When "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. For non-risk informed license amendment requests, this preliminary assessment would be a qualitative assessment with a decision based on engineering judgment since quantitative risk information would not generally be presented in submittals that are not risk informed. The application and related issues would be given increased NRC management attention at this point. 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 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.

RESOURCES:

The staff estimates that the effort to modify the related guidance documents and to support meetings with stakeholders, the Advisory Committee on Reactor Safeguards (ACRS), and the Committee to Review Generic Requirements (CRGR) would take approximately 9 months and would be done with in-house resources (approximately 0.5 FTE combined from Nuclear Reactor Regulation (NRR), Office of Nuclear Regulatory Research (RES), and Office of the General Counsel (OGC)). These resources are within the resources presently budgeted for staff activities to risk inform 10 CFR Part 50.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection to its content. The Office of the Chief Financial Officer has reviewed

this paper for resource implications and has no objections to its content.

The proposed guidance contained in this paper has been discussed with the Risk-Informed Licensing Panel, the PRA Steering Committee, and the ACRS.

RECOMMENDATIONS:

The staff requests that the Commission:

1. Approve the use of the concepts described above for identifying and evaluating risk significant license amendment requests.

2. Approve the staff proceeding with modification of the related guidance documents and issuance of the proposed guidelines for comment, meetings with stakeholders, and review by the ACRS and the CRGR.

3. Approve the use of the approach on an interim basis, if needed, while the staff proceeds to engage stakeholders, the ACRS, and the CRGR.

4. Note that, if and when the Commission should decide to more precisely define the term adequate protection, this guidance would be revised accordingly.

Upon Commission approval, the staff will inform industry of the interim position via a separate communication, such as a Regulatory Issue Summary. The staff will inform the Commission of the results of its discussions with stakeholders before it finalizes and issues the modified guidance documents.

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1. Under AEC and NRC case law, reasonable assurance of adequate protection of public health and safety has long been defined by the Commission's health and safety regulations themselves -- there is reasonable assurance of adequate protection of public health and safety when the applicant or licensee demonstrates compliance with the Commission's regulations applicable to the particular issue Maine Yankee , ALAB-161, 6 AEC 1003, 1010.

2. Although a license amendment request may be approved using this process, nothing in this approval would preclude separate future application of the backfit rule in instances in which the cost-benefit criteria of 10 CFR 50.109 are met. Instances in which the staff would approve an amendment request and subsequently modify or revoke the approval based on backfit considerations and application of the backfit process are unlikely since the staff would have to show that there is a substantial increase in overall protection if the license amendment were modified or revoked.