Public Workshop on Guidelines for Using Risk Information in License Amendment Reviews

May 16, 2000

Division of Systems Safety and Analysis
Office of Nuclear Reactor Regulation

MEETING OBJECTIVES

- Discuss and clarify proposed staff guidance (draft SRP appendix attached)
- Solicit and gather feedback and comments from stakeholders

MEETING STRUCTURE

- Overview presentation, with opportunity for clarifying questions
- Question and comment period (individuals should state their name and affiliation)
- Blank forms available for written comments (attached)
- Attendance sheet will be circulated - please sign

AGENDA

9:00	- 9:10	Introductory Remarks (NRC staff and others)
9:10	- 10:10	Overview presentation (NRC staff)
10:10	- 10:30	BREAK
10:30	- 12:00	Questions and comments (Industry & public)
12:00		ADJOURN

BACKGROUND

- 1995 PRA Policy Statement encourages increased use of PRA in regulatory activities
- Licensees are not required to consider/submit risk information
- Existing regulatory guidance (e.g., RG 1.174) is geared to situations in which the licensee voluntarily chooses to support licensing actions with risk information
- Policy and process guidance are needed to deal with proposed license actions that:
  - are not risk-informed, and
  - satisfy existing design and licensing bases, but
  - introduce significant and unanticipated risks
- Staff committed to provide clarifying guidance for Commission approval (SECY-98-300)

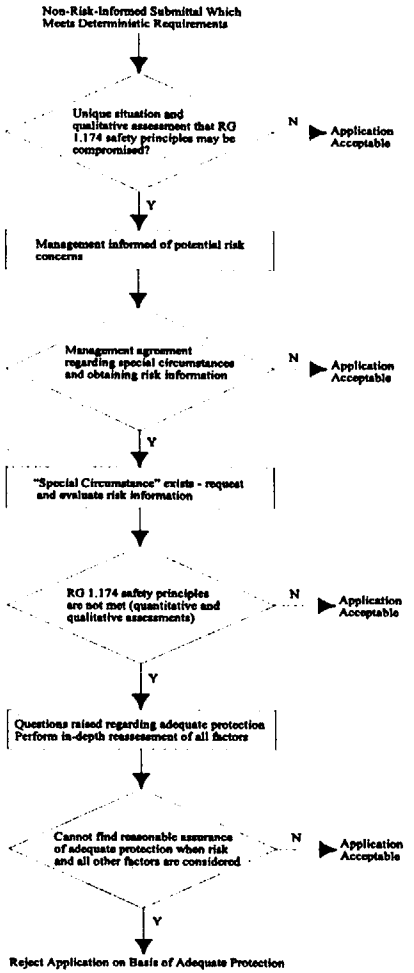
CHRONOLOGY

12/98	Staff recommends developing guidance to clarify its authority for applying risk-informed processes in non-risk informed licensing actions (Policy Issue 4 in SECY-98-300)
6/99	Commission approves development of clarifying guidance
8/99	Review of electrosleeve amendment for Calloway highlights the need for clear policy and process guidance (SECY-99-199)
9/99	Proposed guidance discussed with ACRS Full Committee
10/99	Staff submits proposed interim guidance to Commission (SECY-99-246)
1/00	Commission approves interim use of guidance while staff finalizes regulatory guidance documents
3/00	Industry informed of interim guidance via Regulatory Issue Summary 2000-07
4/00	Proposed SRP appendix issued for review and comment (ACRS, CRGR, public)

PROPOSED APPROACH (SECY-99-246)

- Establish concept that proposed license amendments could create "special circumstances" under which the regulations do not provide the intended or expected level of safety, and plant operation may pose an undue risk
- When "special circumstances" may be created, staff will:
  - explore underlying engineering issues contributing to risk concern
  - obtain management buy-in regarding risk concern
  - request additional information to address risk and RG 1.174 safety principles
  - not issue the amendment until it has assessed risk implications sufficiently to determine there is reasonable assurance of adequate protection
- Use safety principles and decisionmaking process in RG 1.174, and the standard of exceeding the acceptance guidelines as a trigger at which questions are clearly raised as to whether adequate protection is reasonably assured
- Further evaluate special circumstances, safety principles, and other factors if trigger is exceeded
- Base final acceptability on consideration of regulatory requirements and adherence to safety principles, and not solely on comparison with numerical acceptance guidelines

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



SRM ON SECY-99-246

- Commission approved the interim implementation of proposed guidance and directed the staff to:
  - develop final guidance that articulates what constitutes a special circumstance in a clear an objective manner
  - ensure stakeholders are meaningfully engaged in the development of the guidance documents, and provide final versions of the documents to the Commission for information
  - during interim implementation, inform the Commission if it determines an amendment request meets the special circumstances standard

MODIFICATIONS TO GUIDANCE DOCUMENTS

- New appendix to Chapter 19 of Standard Review Plan providing guidance to risk analyst on use of risk information in review of non-risk informed license amendments
- Limited modifications to text of SRP 19 and RG 1.174 to refer to new appendix
- Conforming changes to Office Letter 803, "License Amendment Review Procedures"

NEW APPENDIX TO SRP

- Mirrors SECY-99-246 approach and language rather than create new concepts or language
- Provides additional description of the threshold/criteria for an issue to be considered a "special circumstance"
  - situations not identified or addressed in development of regulations, and important enough to warrant a new regulation if encountered on a widespread basis
  - reviewer has: (1) knowledge that risk impact is not reflected by the licensing basis analysis, and (2) reason to believe that risk increase would warrant denial if the request were evaluated as a risk-informed application
- Includes examples of situations that could create "special circumstances"

SITUATIONS THAT COULD CREATE "SPECIAL CIRCUMSTANCES"

License amendment requests which, if approved, could:

- substantially increase the likelihood or consequences of accidents that are risk-significant but beyond the design and licensing basis of the plant
  - changes to SG allowable leak rates
  - use of new materials for SG repairs
- 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
  - advanced applications of digital I&C without due consideration of defense-in-depth
- significantly reduce the availability/reliability of SSCs that are risk-significant but not required by regulations
  - turbine driven AFW pumps, hardened vents
- involve changes for which the synergistic or cumulative effects could significantly impact risk
  - large power uprate requests

MODIFICATIONS TO TEXT OF SRP 19 AND RG 1.174

- Indicates that "special circumstances" may exist even when all regulatory requirements are met
- Indicates that in those situations staff may request risk related information and will not approve the requested change until it has determined that public health and safety will be adequately protected
- Refers to the new appendix regarding the use of risk information in the review of such requests

CHANGES TO OFFICE LETTER 803

- Guidance for processing license amendments is provided in OL 803, "License Amendment Review Procedures"
- Recent OL revision (Rev. 3, 12/99) added general guidance on types of amendment requests on which risk analyst should be consulted
  - screening questions based on analysis of previous amendment requests
  - includes "special circumstances" as one consideration
  - does not describe what constitutes special circumstances
- OL 803 update will include clarification regarding screening process and special circumstances

BREAK

1. **Is the proposed approach reasonable in terms of latitude and controls on questioning risk?**

   - explore underlying engineering issues contributing to risk concern
   - obtain management buy-in regarding risk concern
   - request licensee to address RG 1.174 safety principles and/or information necessary for staff to make an independent risk assessment
   - do not issue the amendment until risk implications have been sufficiently assessed to establish there is reasonable assurance of adequate protection

2. Is the threshold/criteria for an issue to be considered a "special circumstance" reasonable and sufficient?

- situation introduces significant and unanticipated risks and could rebut the normal presumption of adequate protection from compliance with existing requirements
- situation was not identified or addressed in development of regulations, and could be important enough to warrant a new regulation if encountered on a widespread basis
- reviewer has knowledge that risk impact is not reflected by the licensing basis analysis, and reason to believe that risk increase would warrant denial if the request were evaluated as a risk-informed application

3. Are the examples of potential "special circumstances" helpful?

- substantially increase the likelihood or consequences of accidents that are risk-significant but beyond the design and licensing basis of the plant, e.g., use of new materials for SG repairs
- 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, e.g., advanced applications of digital I&C without due consideration of defense-in-depth
- significantly reduce the availability/reliability of SSCs that are risk-significant but not required by regulations, e.g., turbine driven AFW pumps, hardened vents
- involve changes for which the synergistic or cumulative effects could significantly impact risk, e.g., large power uprate requests

4. Is the proposed decisionmaking process and approach reasonable?

- use the safety principles and decisionmaking process in RG 1.174
- use exceedance of acceptance guidelines as a "trigger" at which questions are raised whether adequate protection is reasonably assured
- base final acceptability on totality of information, not just comparison with numerical guidelines

SCHEDULE FOR COMPLETING GUIDANCE (per 2/14/00 response to SRM)

Issue Regulatory Issue Summary describing interim guidance	3/2000C
Develop mods to SRP 19 and RG 1.174	
▸ Transmit draft mods to ACRS, CRGR, public	4/2000C
▸ Meet with stakeholders, ACRS, CRGR	5/2000
▸ Resolve comments and transmit proposed final mods	7/2000
▸ Meet with ACRS and CRGR on proposed final mods	8/2000
Develop mods to Office Letter 803	9/2000
Transmit final mods to Commission (SRP 19, RG 1.174, OL 803)	9/2000

New Appendix D to SRP Chapter 19

USE OF RISK INFORMATION IN REVIEW OF NON-RISK-INFORMED LICENSE AMENDMENT REQUESTS

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 which 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 the reviewers would question licensees regarding risk are expected to be 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 due to the potential for significant impacts on plant risk[1]. 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), probability of initiating event, probability of successful mitigative action, functional recovery time, or 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 impact 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 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

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[1] Following approval of the subject SRP changes, the staff will update the license amendment review procedures to include supplemental information on "special circumstances" and other conforming changes.

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.

"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, these situations would not have been identified or specifically addressed in the development of the current set of regulations, and would be important enough to warrant the promulgation of a new regulation (e.g., a risk-informed regulation) if such situations were encountered on a widespread basis. "Special circumstances" may include but not be limited to license amendment requests which, if approved, could:

- substantially increase the likelihood or consequences of accidents that are risk-significant but beyond the design and licensing basis of the plant, for example: proposed changes to steam generator (SG) allowable leak rates that meet 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, e.g., advanced applications of digital instrumentation and controls without due consideration of defense-in-depth.

- significantly reduce the availability/reliability of SSCs that are risk-significant but not required by regulations, e.g., turbine driven AFW pumps provided in response to NUREG-0737, II.E.1.1, or hardened vents in Mark I containments that protect against containment over-pressure failures in accidents beyond the design basis.

- involve changes for which the synergistic or cumulative effects could significantly impact risk, e.g., large power uprate requests.

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 RG, the reviewers should inform NRC management of the risk concerns, and the need to further evaluate the risk associated with the request. The general criteria that should be met are that: (1) the reviewer has knowledge that indicates that the risk impact associated with the requested change is not reflected by the licensing basis analysis, and (2) the reviewer has reason to believe that the magnitude of the risk increase may be sufficient to warrant denial of the request or to warrant attaching conditions to its approval of the request, if the request were evaluated in the context of the existing guidance for approval of risk-informed applications.

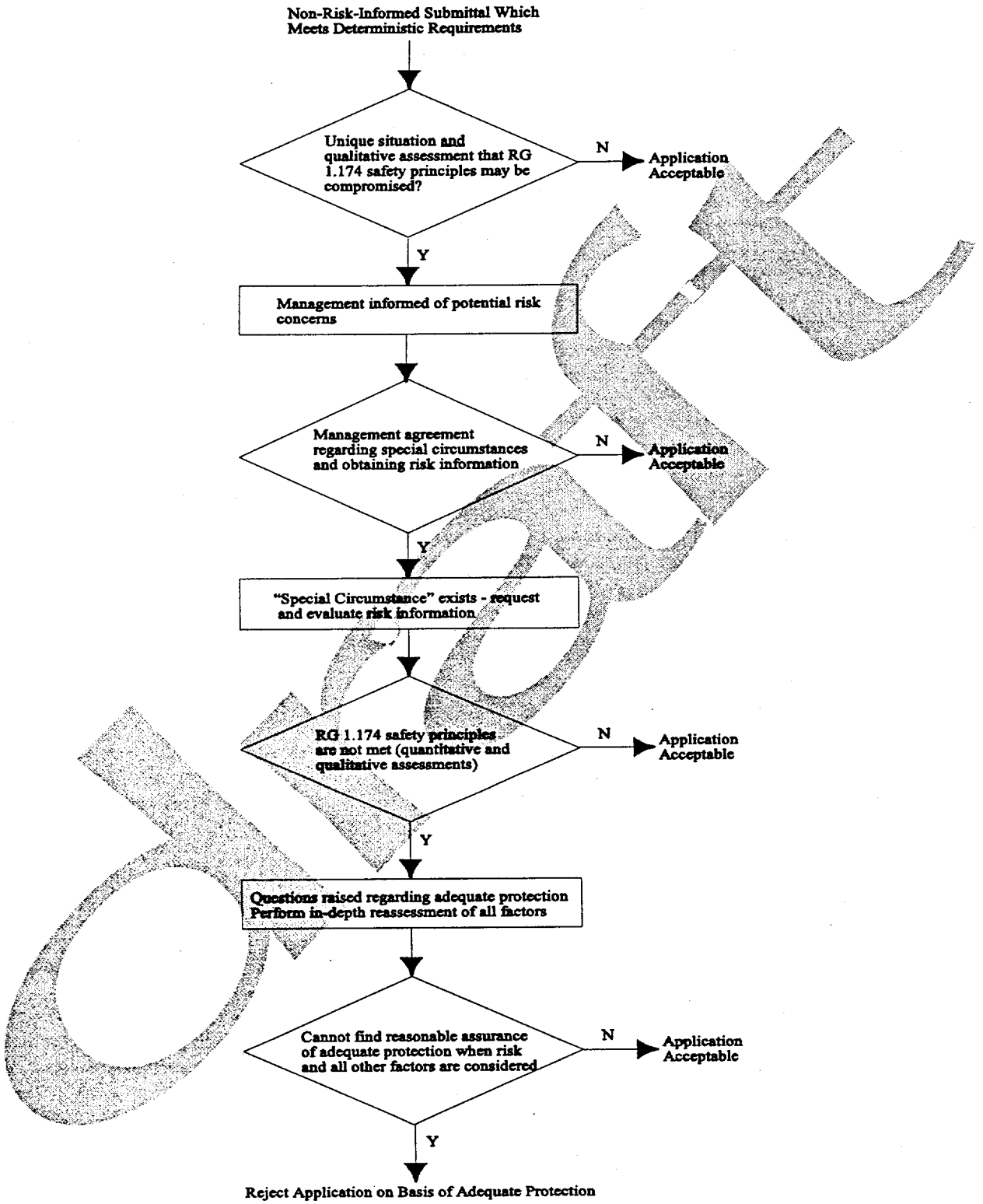
In such instances, the reviewers with management concurrence should ask the licensee to address the safety principles and the numerical guidelines for acceptable risk increases contained in RG 1.174 in their submittal. The reviewers may alternatively ask the licensee to submit the information needed for the NRC staff to make an independent risk assessment. If a licensee does not choose to address risk, the reviewers should not issue the requested amendment until they have 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 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 provided in RG 1.174 is 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.
It is not the NRC's policy or within the NRC's technical capabilities to allow risk to increase to a point where protection is almost, but not quite, inadequate. 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 PRA 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 is unable to find that adequate protection is provided.

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



United States
Nuclear Regulatory Commission

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May 16, 2000
Rockville, Maryland

Name:	Organization:
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Comments on the proposed guidelines:

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