

September 26, 2000

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: William D. Travers */RA/*
Executive Director for Operations

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

In SECY-99-246, "Proposed Guidelines for Applying Risk-Informed Decisionmaking in License Amendment Reviews," the staff proposed interim guidance for applying risk-informed decisionmaking in reviewing requests for non-risk-informed license amendments. Central to the decisionmaking process is determining whether the license amendment, if approved, could create "special circumstances" under which plant operation might pose an undue risk to public health and safety even though all other regulatory requirements appear to be satisfied. In the related staff requirements memorandum (SRM), the Commission approved the use of this guidance on an interim basis while the staff solicited comments from stakeholders and finalized the guidance. The staff has disseminated the interim guidance via Regulatory Issue Summary 2000-7.

The NRC plans to issue the guidance as a new appendix to Chapter 19 of the Standard Review Plan (SRP). 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 close of the comment period. The draft appendix was discussed with the Advisory Committee for Reactor Safeguards (ACRS) on May 11, 2000, and with the Committee to Review Generic Requirements on May 30, 2000. Comments on the appendix generally supported the guidance, but pointed out the need to clarify several areas. The staff then revised the appendix to address the comments. The ACRS considered the revisions during its July 2000 meeting and had no additional comments or concerns.

In accordance with the SRM, the final version of the appendix is provided as Attachment 1 for the Commission's information. Also included for information are a summary of the stakeholder comments and staff responses (Attachment 2), conforming changes to the main body of SRP Chapter 19 and Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Attachments 3 and 4), and draft conforming changes to Office Letter 803, "License Amendment Review Procedures" (Attachment 5). The changes to RG 1.174 and Office Letter 803 will be incorporated during the next planned revisions of these documents.

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415-1095

We will inform our stakeholders of the final guidance via a regulatory issue summary and use this guidance in future reviews.

Attachments:

1. Appendix D - Use of Risk Information in Review of Non-Risk-Informed License Amendment Requests
2. Responses to Stakeholder Comments
3. Revisions to Main Body of SRP Chapter 19
4. Revisions to Main Body of RG 1.174
5. Modifications to Office Letter 803, Revision 3

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APPENDIX D

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 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.

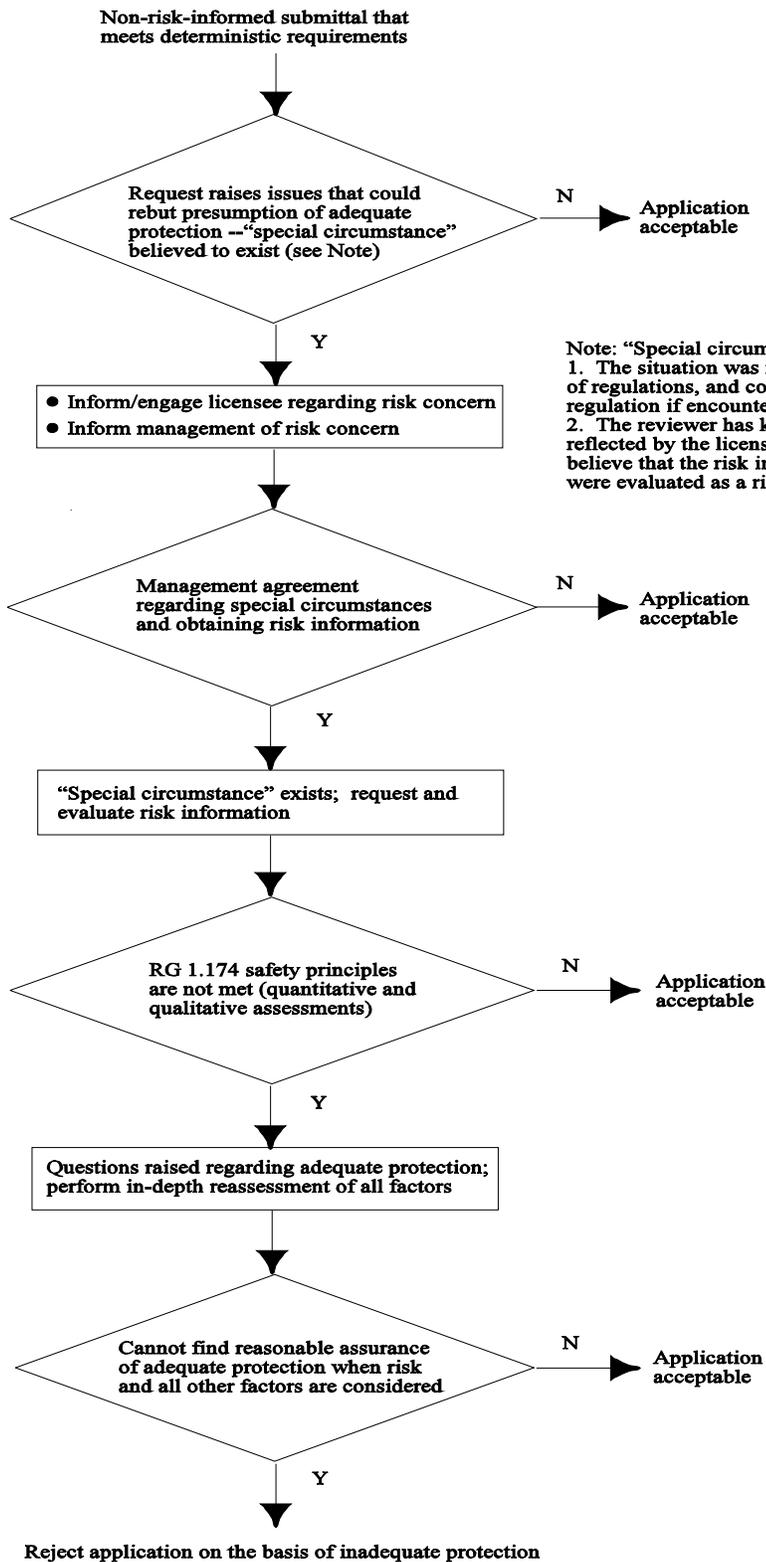
Evaluation Findings

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



Responses to Stakeholder Comments

1. Comment: Clarify the flowchart to describe the point at which NRC would notify the licensee of potential risk issues (NEI 2).

Response: We agree that the guidance should clarify when NRC should notify the licensee of potential risk issues. The text has been modified to indicate that *“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.”* The flow chart has also been modified to include this step.

2. Comment: Clarify the flowchart to describe the level of NRC management that would determine the existence of “special circumstances” (NEI 2).

Response: We agree that the guidance should identify the level of management involvement for establishing whether a license amendment comprises a special circumstance, and for rejecting non-risk informed license amendment requests on the basis of risk. We believe that use of the Risk Informed Licensing Panel (RILP) would provide an appropriate level of management and technical oversight of the subject process and is consistent with the RILP charter. RILP is composed of Division Directors of all divisions within NRR, as well as representatives from the Office of Research and the Office of General Counsel. This panel has been empowered to resolve technical differences as well as issues associated with implementing risk-informed policy. The need to elevate the issue to a higher management level or to inform the Commission would be specifically addressed by the RILP if a special circumstance is determined to exist. The appendix has been modified to include the following additional guidance in this area:

Under Review Guidance and Procedures:

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 regulatory requirements in question, and licensing project management, as well as the Office of General Counsel. Review by the 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.

Under Evaluation Findings:

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.

3. Comment: Clarify whether one or both of the criteria for identifying special circumstances need to be met in order to be considered a special circumstance (Workshop).

Response: The guidance includes the following two criteria for determining whether a special circumstance may exist: (1) the 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, and (2) the reviewer has knowledge that the risk impact is not reflected by the licensing basis analysis, and reason to believe that the risk increase would warrant denial if the request were evaluated as a risk-informed application. The appendix has been modified to include the following clarification: *If one criterion is met, the second would generally be met as well. However, in view of the judgment involved in these determinations, cases where one of the criteria is not clearly met should still be elevated for management consideration.*

4. Comment: The particular examples of situations that could create special circumstances should be reconsidered or clarified since they do not clearly represent cases where adequate protection does not exist. For example: (1) two of the examples have been the subject of considerable staff review and sufficient guidance has been developed to preclude concerns of significant risk impacts, and (2) for the example concerning SSCs that are not required by the regulations, it is unclear what licensing actions would be pursued absent regulatory requirements (NEI 5, ComEd, APS 3).

Response: Based on past experience, license amendment requests that meet all regulatory requirements yet raise significant risk concerns are rare. As a result, several of the examples are based on hypothetical situations. The examples were selected to reflect situations where adequate protection may be called into question rather than situations where adequate protection clearly does not exist. We agree that the examples need to be clarified consistent with the stated expectation that these situations would be rare, and significant enough to question whether adequate protection is assured. The examples of potential special circumstances have been clarified as noted below.

- *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 for 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/reliability of SSCs that are risk-significant but not required by regulations, e.g., amendment requests that, as an unintended consequence, compromise the effectiveness of the Mark I hardened wetwell vent system in protecting against containment over-pressure failures in accidents beyond the design basis, or the diversity of the turbine-driven AFW 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, e.g., power uprate requests that would increase operating power well beyond the levels approved in previous uprates, and introduce or substantially increase the frequency of risk-significant core damage sequences.*

5. Comment: A licensee should be required to provide a risk-informed evaluation only where the requested change creates “special circumstances” under which compliance with the regulations does not produce the intended or expected level of safety, and plant operation poses an undue risk to the public health and safety (APS 1).

Response: The guidance is consistent with this comment. In accordance with the guidance, licensees would not be requested to provide a risk-informed evaluation unless the license amendment request creates a special circumstance. The decision that a special circumstance exists would involve an assessment of the underlying engineering issues contributing to the risk concern, the particular circumstances that could rebut the normal presumption that compliance with existing requirements assures adequate protection, and the potential risk significance of the amendment request. The decision to request risk information must be supported by NRC management as discussed above.

6. Comment: Clarify how identification of a special circumstance would impact the “no significant hazards consideration” finding under 10 CFR 50.91 (Workshop).

Response: If identified as a potential special circumstance during initial processing, the amendment request should be noticed with an opportunity for a hearing with no comments concerning significant hazards considerations. These amendments would not meet the categorical exclusion criteria from 10 CFR 51.22 and require an Environmental Assessment. If determined to be a special circumstance after the staff has noticed the amendment request with a determination that no significant hazards consideration is involved, the amendment request should be renoticed pursuant to 50.91(a)(7). This guidance is not appropriate for inclusion in the SRP, but will be included in the future revision to Office Letter 803.

7. Comment: Continue the interim policy of informing the Commission whenever a license amendment request is judged to meet the “special circumstances” standard (NEI 1).

Response: We agree that it may be appropriate to inform the Commission if it is determined that a license amendment application meets the “special circumstances” standard, but do not believe that every such instance would rise to the level that the Commission would need or want to be informed. Rather than make this a required part of the process, the staff has adopted a more flexible approach in the revised guidance. The guidance will be modified to state that the RILP should specifically address the need to inform the Commission if a special circumstance is determined to exist. (See addition under item 2 above.)

8. Comment: The SRP should acknowledge the burden likely to be incurred by the licensee in responding to risk questions raised by the NRC (NEI 6).

Response: We agree that the burden incurred by the licensee in responding to risk questions raised by the NRC should be considered in weighing the need and extent of such information. The guidance will be modified to state that the RILP should ensure that the burden imposed on the licensee is justified in view of the potential safety significance of the issue to be addressed in the requested information. (See addition under item 2 above.)

9. Comment: In situations where the staff has determined that special circumstances exist, a review similar to the process for an information request through a Generic Letter is recommended including, for example, review by a panel established for this purpose (NUBARG 2).

Response: The process for considering risk in license amendment reviews has been modified to include oversight by the RILP, as discussed above.

10. Comment: The quantitative acceptance guidelines of RG 1.174 were specifically not developed to establish a measure of adequate protection. Thus, exceeding the numerical guidelines in RG 1.174 is not sufficient reason to conclude that adequate protection is not maintained. Quantitative guidelines appropriate to this purpose should be developed (NEI 7, APS 2).

Response: It is important to note that the quantitative guidelines are only one of several factors in the integrated decisionmaking process; the others address compliance with the regulations, defense-in-depth, safety margins, and performance monitoring. Although the quantitative acceptance guidelines of RG 1.174 were not developed to establish a measure of adequate protection, we believe that they provide an appropriate set of criteria to be used in the process for evaluating adequate protection, and that a separate set of quantitative guidelines are not required in order to make judgments regarding adequate protection. Situations that exceed the numerical guidelines or violate the other safety 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 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 PRA results with numerical acceptance guidelines.

11. Comment: The SRP appendix should include the additional wording provided by the NRC staff at the May 11, 2000, meeting of the Advisory Committee on Reactor Safeguards to describe the threshold for determination of special circumstances (NEI 4).

Response: The following two criteria cited by NEI for determining whether a special circumstance may exist are already included in the text of the appendix: (1) the 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, and (2) the reviewer has knowledge that the risk impact is not reflected by the licensing basis analysis, and reason to believe that the risk increase would warrant denial if the request were evaluated as a risk-informed application. Based on discussions with the ACRS, this language will also be incorporated into Figure 1 of the appendix.

12. Comment: More work remains for the SRP revision to establish a clear definition for the threshold which triggers concerns of "significant and unanticipated risks" (NEI 3).

Response: Special circumstances are expected to be rare, and the underlying regulatory and safety concerns highly specific to the application. As such, it would be difficult if not impractical to develop a precise definition that would apply to all conceivable special circumstances. The staff believes that the criteria mentioned in the preceding comment, when used within the constraints of the process contained in the guidelines, provides an adequate characterization of special circumstances, and that the management involvement in the decision regarding the existence of special circumstances is sufficiently robust to provide reasonable controls on the staff's pursuit of risk information. No further definition of special circumstances is considered necessary.

13. Comment: The SRP appendix does not provide sufficient criteria for determining when adequate protection does not exist (APS 4).

Response: The guidance does not attempt to define or provide criteria for determining when adequate protection does not exist, as such criteria is not considered necessary or appropriate within the SRP. The guidance notes that for situations that exceed the numerical guidance or violate the other principles in RG 1.174, a more in-depth assessment of the special circumstances, the safety principles, and the issues identified for management attention in RG 1.174 should be made in order to reach a conclusion regarding the level of safety associated with the requested change. The guidance is careful to note that the numerical guidelines do not constitute a definition of adequate protection, and that the final acceptability of the proposed change should be based on a consideration of current regulatory requirements, as well as adherence to the safety principles, and not solely on the basis of a comparison of quantitative PRA results with numerical acceptance guidelines.

14. Comment: The guidance should include provisions for the NRC staff to follow the backfitting rule even though the licensee has initiated the license amendment request (NUBARG 1).

Response: In accordance with the process, risk information would not be requested by the staff unless the license amendment introduces technical issues that could rebut the normal presumption that compliance with existing requirements provides adequate protection, and thereby prevent the staff from concluding that adequate protection would be maintained. Under such a condition, 10 CFR 50.109(a)(4) states that backfit analysis is not required and the standards in 10 CFR 50.109(a)(3) do not apply. Thus, backfitting implications need not be addressed in implementing the guidance.

15. Comment: The process seems to place a lot of burden on the staff for potentially few instances. It is recommended that a better defined screening process be developed, otherwise weeks of review time are likely to be added to the license amendment review process (VP).

Response: Initial screening to determine potential risk implications would be performed by the plant project manager in accordance with guidance in Office Letter 803. This screening is already part of the license amendment review procedures and involves a quick, high-level assessment by the project manager. Only those non-risk informed license amendment requests judged to have the potential to significantly impact risk would be referred for a more detailed risk evaluation. Based on past experience, we would expect

that instances involving special circumstances would be rare, and that the majority of those requests referred for a risk evaluation would not proceed past the first step of the flow chart, i.e., be determined to be a special circumstance. Thus, the process would not typically add to the license amendment review time.

Revisions to Main Body of SRP Chapter 19

II. ACCEPTANCE CRITERIA

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To evaluate licensee-initiated LB changes which are consistent with currently approved staff positions (e.g., regulatory guides, standard review plans, or branch technical positions), the staff normally uses traditional engineering analyses. Licensees would not **generally** be expected to submit risk information in support of such proposed changes. **However, circumstances may arise in which new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, even when all regulatory requirements are met. 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. The use of risk information in the review of such license amendment requests is addressed in Appendix D of this SRP chapter.**

~~By contrast,~~ **To evaluate licensee-initiated LB changes which go beyond current staff positions,** the staff may use traditional engineering analyses as well as the risk-informed approach set forth in this SRP chapter.

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III.4 Element 4: Conduct Staff Evaluation of Submittal

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Licensees have a choice of whether to submit risk information in support of their LB change request. Where the licensee's proposed change is consistent with currently approved staff positions, reviewers should **generally** reach their determination solely on the basis of traditional engineering analyses without recourse to risk information. (Reviewers may, however, consider any risk information submitted by the licensee). Where the licensee's proposed change goes beyond currently approved staff positions **or appears to constitute a special circumstance as described in Appendix D**, reviewers should consider both information derived through traditional engineering analysis as well as information derived from risk insights. If the licensee does not submit risk information in support of an LB change which goes beyond currently approved staff positions, reviewers may request that the licensee provide this information. If the licensee chooses not to provide the risk information, reviewers will evaluate the proposed application using traditional engineering analysis and determine whether the licensee has provided sufficient information to support the requested change. **If the licensee does not choose to address risk for a situation believed to create a special circumstance as described in Appendix D, 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.**

In risk-informed change proposals, licensees are expected to identify SSCs with high risk significance which are not currently subject to regulatory requirements, or are subject to a level of regulation which is not commensurate with their risk significance, or voluntary actions that are key to decisionmaking.

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Revisions to Main Body of RG 1.174

1. PURPOSE AND SCOPE

1.1 INTRODUCTION

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Licensee-initiated LB changes that are consistent with currently approved staff positions (e.g., regulatory guides, standard review plans, branch technical positions, or the Standard Technical Specifications) are normally evaluated by the staff using traditional engineering analyses. A licensee would not **generally** be expected to submit risk information in support of the proposed change.

Licensee-initiated LB change requests that go beyond current staff positions may be evaluated by the staff using traditional engineering analyses as well as the risk-informed approach set forth in this regulatory guide. A licensee may be requested to submit supplemental risk information if such information is not submitted by the licensee. If risk information on the proposed LB change is not provided to the staff, the staff will review the information provided by the licensee to determine whether the application can be approved. Based on the information provided, using traditional methods, the NRC staff will either approve or reject the application.

However, licensees should be aware that special circumstances may arise in which new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, such as the identification of an issue related to the requested LB change that may substantially increase risk. In such circumstances, the NRC has the statutory authority to require licensee action above and beyond existing regulations, and may request an analysis of the change in risk related to the requested LB change to demonstrate that the level of protection necessary to avoid undue risk to public health and safety (i.e., "adequate protection") would be maintained upon approval of the requested LB change.

This regulatory guide describes an acceptable method for **the licensee and NRC staff to use in** assessing the nature and impact of LB changes ~~by a licensee~~ when the licensee chooses to support (or is requested by the staff to support) these changes with risk information. The NRC staff would review these **LB** changes by considering engineering issues and applying risk insights. Licensees submitting risk information (whether on their own initiative or at the request of the staff) should address each of the principles of risk-informed regulation discussed in this regulatory guide. Licensees should identify how their chosen approaches and methods (whether quantitative or qualitative, deterministic or probabilistic), data, and criteria for considering risk are appropriate for the decision to be made.

Additional guidance is provided to the NRC staff (in Appendix D to Chapter 19, Revision 1 of the Standard Review Plan, Ref. 3) regarding the circumstances and process under which NRC staff reviewers would request and use risk information in the review of non-risk-informed license amendment requests.

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2.4 ELEMENT 4: SUBMIT PROPOSED CHANGE

Requests for proposed changes to the plant's LB typically take the form of requests for license amendments (including changes to or removal of license conditions), technical specification changes, changes to or withdrawals of orders, and changes to programs pursuant to 10 CFR 50.54 (e.g., QA program changes under 10 CFR 50.54(a)). Licensees should (1) carefully review the proposed LB change in order to determine the appropriate form of the change request, (2) ensure that information required by the relevant regulations in support of the request is developed, and (3) prepare and submit the request in accordance with relevant procedural requirements. For example, license amendments should meet the requirements of 10 CFR 50.90, 50.91, and 50.92, as well as the procedural requirements in 10 CFR 50.4. Risk information that the licensee submits in support of the LB change request should meet the guidance in Section 3 of this regulatory guide.

Licensees are free to decide whether to submit risk information in support of their LB change request. If the licensee's proposed change to the LB is consistent with currently approved staff positions, the staff's determination **generally** will be based solely on traditional engineering analyses without recourse to risk information (although the staff may consider any risk information submitted by the licensee). **However, if** the licensee's proposed change goes beyond currently approved staff positions, the staff normally will consider both information based on traditional engineering analyses and information based on risk insights. If the licensee does not submit risk information in support of an LB change that goes beyond currently approved staff positions, the staff may request the licensee to submit such information. If the licensee chooses not to provide the risk information, the staff will review the proposed application using traditional engineering analyses and determine whether sufficient information has been provided to support the requested change. **However, if new information reveals an unforeseen hazard or a substantially greater potential for a known hazard to occur, such as the identification of an issue related to the requested LB change that may substantially increase risk (see Ref. 3), the NRC staff will request the licensee to submit risk-related information. The NRC staff will not approve the requested LB change until it has reasonable assurance that the public health and safety will be adequately protected if the requested LB change is approved.**

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Modifications to Office Letter 803, Revision 3

7.0 RISK-INFORMED LICENSING ACTION GUIDANCE

7.1 Introduction

Risk-informed regulation is the use of insights and results derived from Probabilistic Risk Assessments (PRAs) in combination with traditional engineering (deterministic) analyses to focus licensee and regulatory attention on issues commensurate with their importance to safety. It is the Commission's desire that the NRC and the industry make appropriate use of risk-informed regulation in their daily work. The objectives of risk-informed regulation are to enhance safety decisions and make more efficient use of industry and NRC resources. **This section provides guidance for processing risk-informed license amendment requests, as well as non-risk-informed amendment requests.**

7.2 Responsibilities

7.2.1 Definitions

Risk-informed licensing action

Any licensing action that uses quantitative or qualitative risk assessment insights or techniques to provide a key component of the basis for the acceptability or unacceptability of the proposed action. Mere mention of quantitative or qualitative risk insights does not in itself make a licensing action risk-informed.

Risk Informed Licensing Panel (RILP)

The Risk Informed Licensing Panel is made up of Division Directors in NRR that participate in licensing reviews, as well as representatives from the Office of General Counsel (OGC) and the Office of Nuclear Regulatory Research (RES). One of the main purposes of the panel is to streamline the review of risk-informed licensing actions by serving as a focal point for resolution of technical issues and for guidance on policy implementation to the NRR staff. This panel will provide a forum for the staff, licensee, owners groups, and the public to receive management attention on risk-informed issues. The panel will also monitor the overall implementation of risk-informed licensing actions.

Very low risk significance

An issue in which risk is expressed numerically is of very low risk significance if it results in a risk decrease, is risk neutral (i.e., it has no effect on risk or the change is too small to measure accurately), or results in an increase of less than $\sim 1E-6$ per reactor year (mean value) to core damage frequency (CDF) estimates, or an increase in large early release frequency (LERF) of less than $\sim 1E-7$ per reactor year.

Low to moderate risk significance

An issue in which risk is expressed numerically is of low risk significance if it results in an increase to CDF estimates in the range of $\sim 1\text{E-}6$ to $\sim 1\text{E-}5$ per reactor year (mean value) or an increase in LERF in the range of $\sim 1\text{E-}7$ to $\sim 1\text{E-}6$ per reactor year.

Substantial risk significance

An issue in which risk is expressed numerically is of substantial risk significance if it results in an increase to CDF estimates greater than $\sim 1\text{E-}5$ per reactor year (mean value) or an increase in LERF greater than $\sim 1\text{E-}6$ per reactor year. Note that a “substantial risk increase” should not normally be approved. In fact, approving a change that allows such a risk increase would result in a risk contribution meeting the criteria for consideration of a backfit analysis and possible action to correct the very situation. Guidance that would allow such a circular “approval” and “consideration for backfit” cycle would be inappropriate.

Special circumstances

Conditions or situations that raise concerns about whether there is adequate protection, and that could rebut the normal presumption that compliance with existing regulations provides adequate protection. In such situations, undue risk may exist even when all regulatory requirements are satisfied.

7.2.2 Division of Licensing Project Management

Project Managers should apply the guidance contained in this OL in determining SPSB involvement in the review of the submittal. Project Managers should consult SPSB when any questions arise concerning the submittal review.

The PM should

- Determine if the submittal is risk-informed (using the above definition and guidance).
- Inform the lead PM for RILAs (or his/her designated representative) that the PM has received a RILA.
- Assign a TAC number and mark it as risk-informed (i.e., the review method should be TSR or PMR). Assign as a priority 2 unless other circumstances warrant a priority 1.
- Identify a lead review branch, with SPSB marked for PRA review support.
- Discuss the scope of the review required with the responsible technical branches.
- Send a copy of the submittal to SPSB.
- Ensure that RAIs are focused and are seeking a scope and depth of information in line with the risk significance of the licensing action.

- Send a completed Risk-Informed License Amendment Cumulative Risk Tracking Form (see pages 17 - 19 of SRP 19 or updated form if available) when the licensing action or activity is complete.
- Assess all non-risk-informed licensing action and activity submittals to seek to identify if there are any unaddressed, potentially significant risk effects (e.g., potentially significant changes in CDF, LERF, design margins, or defense-in-depth) that approval of the licensing action could precipitate. If the reviewer suspects that there is such a potential, the nature of the concern should be documented and forwarded along with the submittal to SPSB for joint review and consultation.
- Bring conflicts between branches, divisions, or offices regarding the risk-informed submittals to the risk-Informed Licensing Panel (RILP) by contacting SPSB.

7.2.3 The Lead Technical Review Branch

The branch chief should

- Ensure that RAIs dealing with a risk-informed submittal are sent to SPSB for review and concurrence. Note that review of RAIs is frequently delegated to section chiefs.
- **Ensure that potentially significant risk impacts of all non-risk-informed licensing actions are considered in the staff's review, and that SPSB has been consulted as appropriate.**

The NRR lead branch reviewer should

- Coordinate or consult with SPSB regarding determination of the risk significance of the issue.
- Work with SPSB to identify strengths and limitations of a licensee's risk evaluation.
- Follow the guidance of SRP 19. Note it is expected that the lead reviewer will use good judgment in developing a scope of review commensurate with the risk importance of the issue.
- Work with SPSB to determine an appropriate balance between traditional engineering (deterministic) and probabilistic review, based on the risk significance of the licensee's request.
- **Assess all non-risk-informed licensing action and activity submittals to seek to identify if there are any unaddressed, potentially significant risk effects (e.g., potentially significant changes in CDF, LERF, design margins, or defense-in-depth) that approval of the licensing action could precipitate. If the reviewer suspects that there is such a potential, the nature of the concern should be documented and forwarded to the PM for joint review and consultation with SPSB.**

7.2.4 SPSB

The branch chief should

- Be responsible for the timeliness of the SPSB review of the risk-informed submittal.
- Ensure that RAIs generated by SPSB are appropriate for the risk significance of the issue.
- Concur in the appropriate level of traditional engineering (deterministic) and probabilistic review. This function is normally delegated to section chiefs.
- Ensure the Risk-Informed License Amendment Cumulative Risk Tracking Form is correct and is attached to the safety evaluation report.
- Concur in any staff determination regarding the existence of “special circumstances,” and elevate the issue for review by the Risk Informed Licensing Panel as appropriate.

The SPSB reviewer should

- Help the lead reviewer determine the risk significance of the risk-informed submittal, or the risk-related issues associated with a non-risk-informed submittal.
- Help the lead reviewer determine the level of traditional engineering (deterministic) and risk review needed for the submittal, based on the risk significance of the issues involved.
- Provide a detailed review or audit of the risk-informed submittal, including a description of the depth and scope of the review performed.
- Assist PMs, as necessary, to complete the Risk-Informed License Amendment Cumulative Risk Tracking Form.

7.3 Guidelines for Using Risk Information in Regulatory Decisionmaking¹

Use of risk information should be considered in the staff review of both licensee-initiated risk informed license action requests, as well as license action requests in which the licensee chooses to not submit risk information.

The requested changes, and the need for and effectiveness of any compensatory measures that might be warranted because of risk considerations, should 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.

¹ See SECY-99-246, "Proposed Guidelines for Applying Risk-Informed Decisionmaking in License Amendment Reviews," Appendix D to SRP Chapter 19, and any subsequent documentation of NRC policies related to the staff's introduction of risk considerations into the review process for licensing actions.

7.4 SPSB Involvement in Licensing Action Reviews

The general approach to determining the character of SPSB's role depends more on the technical content of the submittal than on the submittal type, although some generalities may be drawn based on historical analysis. Only a fraction of submittals need to be seen by SPSB, even in today's risk-informed environment. This results from several factors:

- ▶ Many submittals deal with legal or administrative changes, or simple inconsistencies in technical specifications, rather than substantive safety issues.
- ▶ Many submittals deal with technical issues whose resolution take place at a level of detail that lies below the level at which risk models are applied.
- ▶ Many submittals deal with licensing issues that are driven by safety concerns other than major core damage or large release.
- ▶ Many submittals are related to wholesale conversion of technical specifications, or to changes with such clear precedence that resources to review them in-depth cannot be justified.

A set of rules has been established, based on historical analysis of SPSB involvement in previous submittal reviews, that seek to identify licensing action requests that need to be examined at the level of the integrated risk model, which requires SPSB involvement. Such changes either qualitatively affect the set of possible scenarios, or affect the frequency at which existing scenarios occur, meaning that time, frequency, or probability parameters are changing. Changes that qualitatively affect the scenario are termed "configurational."

In order to apply these rules, the overall submittal must be summarized in terms of an issue or issues whose joint resolution are required for approval/disapproval of the submittal. A determination should be made as to SPSB involvement at each issue level. For example, a submittal may raise only an allowed outage time (AOT) issue; a complex submittal may argue that less redundancy is necessary in a particular system based on a thermal hydraulic (T/H) analysis. The latter submittal should be broken down into the following two issues: the validity of the T/H analysis and the risk implications of the proposed LCOs, given that the T/H analysis is valid. The former issue is called a "specialty topic" and needs to be resolved by the cognizant technical branch, while the latter issue may need to be resolved at the risk model level by SPSB, depending upon the details of the change requested. The decomposition of the submittal into discrete issues should be performed by the PM with assistance from SPSB, if required.

In rare situations, a license amendment request could introduce significant and unanticipated risks even when all regulatory requirements are satisfied. These situations, termed "special circumstances" represent conditions or situations that raise questions about whether there is adequate protection, and that could rebut the normal presumption of adequate protection from compliance with existing regulations. 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 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. Examples include 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, or 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. The process and controls for evaluating the existence of special circumstances, requesting risk information from the licensee, and using risk information in judging the acceptability of non-risk-informed license amendment requests are provided in Appendix D of SRP 19.

Identification of a special circumstance would impact the "no significant hazards consideration" finding under 10 CFR 50.91. If identified as a potential special circumstance during initial processing, the amendment request should be noticed with an opportunity for a hearing with no comments concerning significant hazards considerations. These amendments would not meet the categorical exclusion criteria from 10 CFR 51.22 and require an Environmental Assessment. If determined to be a special circumstance after the staff has noticed the amendment request with a determination that no significant hazards consideration is involved, the amendment request should be renoticed pursuant to 50.91(a)(7).

Table 4 provides general guidance to determine SPSB's role in review of the license action request. If any questions exist, SPSB should be consulted. Please consult SPSB with any questions concerning phenomenological basis, special circumstances, etc.

Table 4 - Guidance on SPSB Involvement in Reviews

Submittal Review Issue Identification		
<i>For each issue, consider the following questions</i>		
	Question	If yes, then...
If "NO," continue to next question.	Invokes RG 1.174, et al.?	Consult with SPSB
	Significantly changes the allowed outage time (e.g., outside the range previously approved at similar plants) Changes AOT, probability of initiating event, probability of successful mitigative action, functional recovery time, or operator action requirement?	Consult with SPSB
	Significantly c Changes functional requirements or redundancy?	Consult with SPSB
	Significantly changes operations that affect the undiscovered failures? Affects likelihood of undiscovered failures?	Consult with SPSB
	Significantly affects the basis for successful safety function Affects phenomenological basis for mission success?	Consult with SPSB
	Could create "special circumstances" under which compliance with existing regulations may not produce the intended level of safety, and plant operation may pose an undue risk Potential that "Special circumstances" exist?	Consult with SPSB
	Completely consistent with deterministic requirements?	Conventional review.