January 30, 1998 SECY-98-015

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: FINAL GENERAL REGULATORY GUIDE AND STANDARD REVIEW PLAN FOR RISK-INFORMED REGULATION OF POWER REACTORS

PURPOSE:

(1) To request Commission approval for the publication and use of Regulatory Guide 1.174 (formerly DG-1061) and Standard Review Plan Chapter 19, which provide general guidance regarding the submittal and review of risk-informed proposals that would change the licensing basis for a power reactor facility; and

(2) To respond to requests the Commission has made in Staff Requirements Memoranda dated June 5, 1997, and November 18, 1997.

SUMMARY:

The staff has completed final versions of Regulatory Guide (RG) 1.174 (DG 1061 in its draft form) and Standard Review Plan (SRP) Chapter 19, which provide general guidance to reactor licensees and the NRR review staff on the use of probabilistic risk assessment in plant-specific licensing basis changes. This paper summarizes changes made to the documents, provides the final versions of the guide and SRP chapter and a proposed *Federal Register* notice announcing their availability, and addresses related issues provided in Staff Requirements Memoranda. The regulatory guide and SRP chapter are based on a set of policy issues discussed in SECY-97-287. Commission approval is requested to publish and use the final versions of RG 1.174 and SRP Chapter 19.

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BACKGROUND:

The Commission's June 5, 1997, Staff Requirements Memorandum (SRM) approved publication of four draft RGs, three draft SRPs, and one draft NUREG document for comment by the public.

These guidance documents support the implementation of risk-informed regulation in the following areas:

- General Guidance (DG-1061 and SRP)
- Inservice Testing (DG-1062 and SRP)
- Graded Quality Assurance (DG-1064)
- Technical Specifications (DG-1065 and SRP), and
- The Use of PRA in Risk-Informed Applications (draft NUREG-1602)

The 90-day public comment period closed on September 30, 1997. During the comment period, a three-day public workshop was held (on August 11-13, 1997). The workshop was well attended; the commenters offered a number of constructive comments, some criticisms, and some suggestions for changing the guidance. By the end of the comment period, the staff received formal written comments from approximately forty sources, most of which were associated with the nuclear industry.

In reviewing the comments on the general guidance, the staff found similar comments from many different commenters, and what emerged was a set of specific concerns as follows:[1]

- According to the draft guide, all issues treatable with a risk-informed approach require NRC review and approval. This means that items of little or no safety significance still require considerable resource allocations by industry and staff.[2]

- The NRC's proposed guideline of not allowing changes involving *any* increase in risk in plants with a baseline core damage frequency (CDF) greater than or equal to 10^{-4} per reactor year is too conservative and too rigid when applied to proposals involving very small changes in risk. In addition, the approach for consideration of uncertainties was interpreted by some commenters as being unnecessarily complex.

- The guidance in the draft documents (including draft NUREG-1602) with respect to scope, level of detail, and quality of a PRA is viewed as being appropriate for treating

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[1] A more complete discussion of comments received and staff responses is provided in the draft *Federal Register* notice (Attachment 1) announcing the publication and availability of RG 1.174 and the final version of the SRP Chapter 19 and in a staff document (Attachment 6) which provides a summary and analysis of the comments.

[2] The staff believes that this comment is better addressed in its ongoing consideration of revisions to the NRC's current criteria in 10CFR 50.59 for determining when NRC review and approval of a facility change is appropriate. As such, this issue is not discussed in RG 1.174.

only the broadest, most complex issues. A roadmap for performing simplified analysis for the many simpler issues that licensees are considering was not provided.

- The NRC's proposed acceptance guidelines apply equally to issues involving either power operation or shutdown operation and issues involving either temporary changes to the facility or permanent facility changes. However, differences between these conditions warrant treatment with separate guidelines.

- The guidance in the draft documents implies that an onerous level of effort will be required on the part of licensees to perform and document risk analyses, and establish and maintain a follow-up performance monitoring program in support of proposed changes of little safety significance.

In parallel with the public comment process, the staff has completed related activities which have also helped to shape the final form of the guidance documents. These activities included:

- Pilot review activities associated with the risk-informed technical specification and graded quality assurance pilot applications,

- Responses to issues raised in Staff Requirements Memoranda dated January 22, 1997, March 7, 1997, April 15, 1997, June 5, 1997 and November 18, 1997,

- Discussions with the Advisory Committee on Reactor Safeguards (ACRS) and its Subcommittee on Probabilistic Risk Assessment (PRA), the Committee to Review Generic Requirements (CRGR), and the staff of the Office of General Counsel, and

- Development of a Commission paper (SECY 97-287, dated December 12, 1997) describing the key policy issues associated with the final version of RG 1.174 and associated staff recommendations.

The staff has chosen to finalize the general guidance documents (RG and SRP) at this time, to ensure that the key policy issues are identified, discussed, and resolved prior to finalization of the application-specific guidance documents (which are now due to the Commission at the end of March 1998, except for the guide/SRP on inservice inspection (ISI), which are due at the end of April 1998).

DISCUSSION:

The staff has developed final versions of DG 1061 (called RG 1.174 in its final form) and SRP Chapter 19 (Attachments 2 and 3). The significant changes the staff has made to these documents, in response to all of the activities noted above, are discussed below. Following that discussion, responses are provided on related issues the Commission has raised in Staff Requirements Memoranda dated June 5, 1997, and November 18, 1997.

Scope of the General Guidance Documents

The description of the scope of the regulatory guide has been slightly modified to make clear that it applies only to changes in those parts of the "current licensing basis," as defined in

10 CFR Part 54, which require NRC review and approval. The RG and SRP have been modified to make clear that the term "current licensing basis" is being used for convenience and is not intended to imply any change in the regulatory status of commitments.

Principles of Risk-Informed Regulation

The staff has made significant modifications to two of the five principles of risk-informed regulation that must be satisfied for the staff to approve a change (as well as clarifications to others). In the draft guidance documents, Principle 4 states: "Proposed increases in risk, and their cumulative effect are small and do not cause the NRC Safety goals to be exceeded." This has been changed in the proposed final guidance to read: "Proposed increases in core damage frequency and risks are small and *are consistent with the intent of the Commission's Safety Goal Policy Statement."* This change is necessary because the original wording could be interpreted to mean that the demonstration of this principle must involve a comparison of PRA results with the Safety Goal quantitative health objectives(QHOs). In fact, the guide and SRP focus on comparisons with acceptance guidelines for core damage frequency (CDF) and large early release frequency (LERF), which are subsidiary objectives to the safety goals. Thus, for purposes of this regulatory guide, a proposed change which meets the acceptance guidelines is considered to have met the intent of the policy statement.

In addition, the staff has removed the reference to *implementation* from Principle 5. The principle now focuses clearly on the importance of monitoring the impact of risk-informed changes. Implementation is treated as a step in the process of making a risk-informed change, and discussed as part of the staff's expectations.

Acceptance Guidelines for Very Small Changes in Risk and Treatment of Uncertainties

A large number of public comments suggested that, under some conditions, the quantitative acceptance guidelines in the draft guidance documents are unnecessarily restrictive. This is considered to be a policy issue by the staff, as discussed in SECY-97-287. As discussed in that paper, and subject to Commission approval, the staff has revised the guideline that would apply to plants with CDFs above 10^{-4} per reactor year and/or LERFs above 10^{-5} per reactor year. The original guideline forbids increases of any size, while the new one permits very small calculated increases in these measures. In quantitative terms, "very small" in this context means an increase of less than 10^{-6} per reactor year in core damage frequency or 10^{-7} per reactor year in large early release frequency. These values represent one percent of the baseline CDF/LERF guidelines, and are considered by the staff to be reasonable guideline values given typical calculated frequencies of core damage and LERF, typical calculated frequencies of important accident sequences, the guidance contained in the Commission's Regulatory Analysis Guidelines, and the margin between the CDF and LERF values and the QHOs. This change will increase opportunities for licensees to propose changes which have very little significance to CDF/LERF but could reduce regulatory burdens, making this more consistent with the philosophy of risk-informed regulation, as expressed in the PRA Policy Statement. To ensure that such changes do not lead to large cumulative changes in CDF/LERF, which is contrary to Principle 4, licensees are required to track cumulative changes in these measures and report them each time they propose a new change for review. In addition, licensees must address why compensatory changes that result in a net reduction in CDF and LERF cannot be made. Guidance for staff review of cumulative changes has been incorporated into SRP Chapter 19.

The staff's approach to treatment of uncertainties is also considered to be a policy issue, and is discussed in SECY-97-221 and SECY-97-287. These papers discussed several alternative approaches to treating uncertainties in the context of licensing basis changes. In SECY-97-287, the staff recommended that the basic approach for treating uncertainties contained in the draft version of the guide be retained in the final version, but be clarified to provide a better description of what the licensee should consider and address in his submittal to identify and account for the important sources of uncertainty. For "very small" CDF/LERF increases (as defined above), this will limit uncertainty analysis to that associated with the changes in CDF and LERF and the use of sensitivity analysis to test the changes in CDF and LERF against the acceptance guidelines. For larger CDF/LERF increases uncertainty and sensitivity analysis will also apply to the baseline CDF and LERF. The attached guide and SRP chapter reflect these changes to this guidance, subject to Commission approval of the policy recommendation.

Acceptance Guidelines for Shutdown Operations and Temporary Plant Conditions

SECY-97-287 also discusses two policy issues on acceptance guidelines for shutdown operations and temporary plant conditions. With respect to the former, public comment on DG-1061 noted that conditions relating to the definition of large early release frequency can be quite different for shutdown conditions versus power operations. Thus, the LERF definition developed using perspectives of full power accidents may be inapplicable for shutdown accidents. This comment is consistent with the staff's current understanding of shutdown risk. As such, the staff plans to give consideration to possible additional acceptance guidelines for shutdown conditions as part of its research program beginning in FY 1999. In the interim, and subject to Commission approval, the current CDF and LERF guidelines in RG 1.174 will remain applicable for shutdown conditions. However, if the proposed CLB change involves equipment used in shutdown operations when containment functions are not available, licensees will have the flexibility to propose a reasonable definition for LERF considering the reduced radionuclide inventory or to rely solely on an assessment of core damage (i.e., CDFs below the 10^{-5} per reactor year) as a way to limit the release frequency.

Comments received on the draft guidance suggest that an additional set of guidelines may be appropriate to limit the conditional CDF and LERF during certain temporary plant conditions, e.g., with equipment failed or found to be out of service. The staff has considered these comments and believes that they merit additional assessment, and recommended in SECY-97-287 that such an assessment be undertaken, but not as part of the finalization of DG-1061.

Integrated Decision Making

RG 1.174 has been revised to provide additional information on the factors included when "increased management attention" is called for in decision making and the conditions under which proposed licensing basis changes can be submitted in combinations. With respect to the former, the set of factors has been modified to clarify that PRA Level 3 (offsite health effect risk) information can be used and that the benefit of proposed changes will be considered commensurate with the proposed increase in CDF or LERF.

With respect to the latter, the guide now provides guidance with respect to what types of combinations of proposed licensing basis changes will normally be considered by the staff (Section 2.3 of RG 1.174).

Scope, Level of Detail, and Quality of a PRA

In response to many comments received on DG-1061, SRP Chapter 19 and draft NUREG-1602, the staff has revised its guidance to licensees for performing a PRA in support of a risk-informed change to the CLB and its guidance to the NRC reviewers of such PRAs. Specifically, the staff has:

- Removed the reference to draft NUREG-1602 in RG 1.174 and SRP Chapter 19 and provided a summary discussion on PRA quality in the RG and SRP.

- Made clear in RG 1.174 and SRP Chapter 19 that licensees should determine the appropriate scope, level of detail and quality of the PRA based on the application being treated;

- Incorporated additional guidance in RG 1.174 for determining the appropriate scope and depth of uncertainty analysis and sensitivity studies for an application specific PRA;

- Clarified guidance to staff reviewers in SRP Chapter 19 for judging the acceptability of PRAs on an application specific basis; and

- Acknowledged that for purposes of addressing PRA quality, the staff will accept as one element for review the results of licensee sponsored peer reviews, cross-comparison studies, and certification programs, provided that the standards that have been applied in those reviews, studies, and programs are described in the submittal.

Performance Monitoring and Documentation

The staff has clarified its guidance regarding monitoring the performance of systems, structures, components (SSC) that have been affected by a risk-informed change. RG 1.174 makes clear the staff's expectation that performance monitoring programs should be structured such that SSCs are monitored commensurate with their safety importance, i.e., monitoring for SSCs categorized as low safety significance may be less rigorous than that for SSCs of high safety significance. The staff has also added guidance that encourages licensees to integrate, or at least coordinate, their monitoring for risk-informed changes with existing programs for monitoring equipment performance and other operating experience on their site and throughout the industry, such as monitoring covered under the Maintenance Rule.

The staff has reviewed the documentation section of DG-1061 to identify requested information that in all likelihood would not normally be necessary to complete many reviews. This review revealed several information requests that were considered unnecessary and were removed from the guidance. The staff has also supplemented the documentation section to clarify the staff's guidance that licensees track and report cumulative changes in CDF/LERF and describe the specific information that should be included in a licensee's submittal.

Staff Response to SRM dated June 5, 1997

In a Staff Requirements Memorandum dated June 5, 1997 (Attachment 4), the Commission requested that the staff: (1) continue to evaluate the proposed decision criteria and methods of

ensuring conformance to the criteria included in the guidance; and (2) develop guidance on how to confirm the assumptions and analyses used to justify risk-informed changes to the licensing basis. These are addressed in the following two paragraphs, respectively.

Since issuing the draft guidance documents for comment, the staff has given additional consideration to the proposed acceptance guidelines and methods for ensuring conformance to these guidelines. These considerations are discussed in depth in the staff's recent paper on acceptance guidelines and consensus standards for use in risk-informed regulation (SECY-97-221) and the staff's more recent paper on the remaining policy issues associated with final regulatory guidance on risk-informed regulation (SECY-97-287). The changes that have resulted from these considerations are summarized above in the discussion of changes to the draft guidance documents.

In RG 1.174 and SRP Chapter 19, the staff has provided guidance for performance monitoring of SSCs as the principal means to ensure that the engineering evaluation conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of SSCs that have been evaluated. In addition, the staff has made it clear in RG 1.174 that a PRA performed in support of risk-informed changes to the CLB should reflect the actual design, construction, operational practices, and operational experience of the plant, and has provided guidance in SRP Chapter 19 to permit the staff to determine if a licensee's PRA is acceptable in this regard. It should be noted that this guidance permits licensees to take credit in their analysis for voluntary actions. However, if these voluntary actions are later modified, licensees are expected to assess the impact on previous staff approvals. On the other hand, the guidance clarifies that systems, structures or components 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 the decisionmaking may be identified. The guidance states that, in such cases, an appropriate level of regulatory requirement should be determined and reflected in the licensing basis.

Staff Response to SRM dated November 18, 1997

In a Staff Requirements Memorandum dated November 18, 1997 (Attachment 4), the Commission requested that the staff discuss the amount of variability and the degree of uncertainty that can be tolerated for regulatory purposes in PRAs performed by licensees within the risk-informed regulatory framework. These issues are addressed below.

The amount of variability that can be tolerated is addressed in two ways in RG 1.174 and SRP Chapter 19. First, there will be variability in PRAs when they are used for different purposes. That is, for some applications a simplified PRA model will suffice, while for others a more detailed model is necessary. RG 1.174 and SRP Chapter 19 make clear statements with respect to the need to have the PRA performed match its intended use.

Second, there will be variability which results from the use of different scopes, methods, and assumptions. Absent PRA standards at this time, the staff's approach to addressing this form of variability has two parts. The shorter-term part is being addressed directly by the regulatory guides and SRPs and as part of the ongoing risk-informed pilot programs.

In risk-informed processes governed by RG 1.174 and SRP Chapter 19, variability in PRAs will be managed through the use of the standards that have been incorporated implicitly, in the SRP especially, regarding the scope, level of detail, and quality of the PRA. Specifically, the guidance suggests that licensees subject their PRA to a peer review, an industry PRA certification process, or PRA cross-comparison study. Such processes and studies will help eliminate, or at least identify the sources of variability that are not the result of differences in the design, construction, or operation. As discussed in SRP Chapter 19, the staff will review the

application of these programs, including the industry standards that have been applied and the qualifications of the personnel involved. In addition to this, the staff's own independent technical review per SRP Chapter 19 will ultimately provide a check on PRA quality. Specifically, Appendix A of SRP Chapter 19 discusses the key elements expected in the PRA, such as: initiating events, event trees, fault trees, data, common cause failures, human performance and sequence quantification. The safety evaluation reports resulting from these reviews will document the staff's assessment of quality and thus help to define the needed quality for specific applications.

The longer-term part of the staff's approach for addressing model and assumption variability is the development of PRA standards. As discussed in the October 1997 quarterly update of the PRA Implementation Plan (SECY-97-234), the staff is working with ASME to develop such standards. Once developed and found acceptable, it is the staff's intention to endorse the standard in a revision to RG 1.174.

The issue of the degree of uncertainty that can be tolerated for regulatory purposes in PRAs has been the subject of considerable discussion between the staff and the ACRS Subcommittee on PRA, much of which has been documented in response to previous SRMs.[3] This work has culminated in the three-pronged approach to treatment of uncertainty that the staff has included in RG 1.174:

- Address parametric uncertainty and any explicit model uncertainties in the assessment of mean values;

- Identify sources of uncertainty related to modeling and perform sensitivity studies to evaluate the impact of using alternate models for the principal implicit model uncertainties; and

- Identify the sources of uncertainty related to incompleteness and use quantitative analyses or qualitative analyses as necessary to explore the impact of incompleteness as appropriate to the decision and the acceptance guidelines.

This approach has the major advantage that it is consistent with the state of the art of PRA methods. The approach avoids the value judgements of the analysts being implicitly incorporated in the results, which can contribute to unwarranted variability in results of PRAs. The method also makes the evidence used in making a decision more visible in that it focuses attention on the assumptions and approximations made by the analysts. Decision making in

[3]Responses are provided in SECY-97-221 and SECY-97-287.

light of these uncertainties then becomes a matter of weighing the different issues that can impact the decision in addition to the comparison of calculated numbers with the acceptance guidelines. This approach recognizes explicitly that it is not just the numerical values of the various measures of CDF/LERF and their changes that are important, but that it is also important to understand what contributes to the PRA results, and how the various sources of uncertainties impact those results.

COORDINATION:

RG 1.174 and SRP Chapter 19 have been reviewed by the ACRS and their views were provided in a letter dated December 11, 1997 (Attachment 5). CRGR has reviewed both documents and in a meeting with the staff on December 11, 1997 indicated their approval for publication of the documents in final form for use. The Office of the General Counsel has reviewed both documents and has no legal objection to them being issued for use.

RECOMMENDATION:

That the Commission approve for publication and use RG 1.174 and SRP Chapter 19, as provided in Attachments 2 and 3, using the *Federal Register* announcement provided as Attachment 1.

L. Joseph Callan
Executive Director
for Operations

Attachments:
1. Federal Register notice announcing publication of final RG 1.174
2. Regulatory Guide 1.174
3. Standard Review Plan Chapter 19
4. Staff Requirements Memoranda dated June 5, 1997, and November 18, 1997
5. Letter from ACRS regarding "Proposed Final Regulatory Guide 1.174 and Standard Review Plan Chapter 19 for Risk-Informed, Performance-Based Regulation," dated December 11, 1997.
6. Memorandum from M. Cunningham to M. Hodges, dated January 7, 1998, "Summary of the Resolution of the Overall Comments Received on the General Risk-Informed Draft Regulatory Guide and Standard Review Plan"

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The Commissioners

Attachment 1

Federal Register notice announcing publication of final RG 1.174 and SRP Chapter 19

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Use of PRA in Plant Specific Reactor Regulatory Activities:

Final Regulatory Guide and Standard Review Plan section

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of final documents.

SUMMARY: In June 1997, the Nuclear Regulatory Commission issued for public comment a series of draft regulatory guides and Standard Review Plan Sections, and a draft NUREG document addressing the use of PRA in support of risk-informed regulatory activities. The preparation of these documents follows from the Commission's August 16, 1995 Policy Statement on the Use of PRA Methods in Nuclear Regulatory Activities (60 FR 42622). The draft guidance documents provide examples of acceptable approaches for using probabilistic risk assessment (PRA) information in support of plant-specific changes to plant licensing bases. The use by power reactor licensees of such PRA information and guidance is voluntary, and alternative approaches may be proposed. The Commission conducted a workshop on August 11-13, 1997, during the comment period, to provide an overview of the draft documents, to answer questions regarding their intended application, and to solicit comments and suggestions. Comments received from the workshop have been considered in preparing a final general regulatory guide (R.G. 1.174) and its accompanying Standard Review Plan (Chapter 19), for risk-informed applications, and the issuance of these two documents is the subject of this notice. Comments received from the workshop on application-specific guidance documents for technical specifications, inservice testing, and graded quality assurance are currently being considered. These guidance documents will be issued at a later date.

EFFECTIVE DATE: [insert the date 30 days from publication of this notice.]

Comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time. Written comments may be submitted to the Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Copies of the regulatory guide and standard review plan section are available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street N.W. (Lower Level), Washington, D.C. 20555-0001. A free single copy of these documents may be requested by writing to the Office of Administration, Attention: Printing, Graphics and Distribution Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, or by Fax to (301) 415-5272. Final regulatory guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

I. Background

On August 16, 1995, the Commission published in the Federal Register a final policy statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities (60 FR 42622). The policy statement included the following policy regarding expanded NRC use of PRA:

1. The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and

supports the NRC's traditional defense-in-depth philosophy.

2. PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support proposals for additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

3. PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

4. The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

It was the Commission's intent that implementation of this policy statement would improve the regulatory process in three areas:

1. Enhancement of safety decision making by the use of PRA insights,
2. More efficient use of agency resources, and
3. Reduction in unnecessary burdens on licensees.

In parallel with the development of Commission policy on uses of risk assessment methods, the NRC developed an agency-wide implementation plan for application of probabilistic risk assessment insights within the regulatory process (SECY-95-079). This implementation plan included tasks to develop a series of Regulatory Guides (R.G.) and Standard Review Plans (SRP) in the areas of:

- general guidance,
- inservice inspection (ISI),
- inservice testing (IST),
- technical specifications (TS), and
- graded quality assurance (GQA).

The general regulatory guide (R.G. 1.174) and its accompanying SRP section (Chapter 19), are intended to help implement the Commission's August 1995 policy on the use of risk information in the regulatory process. The subject of this notice is the finalization of these two general documents, the first in the series of risk-informed guidance documents. Together, they provide the basic framework for an acceptable approach for use by power reactor licensees in preparing proposals for plant-specific changes to their licensing bases using risk information. The Commission conducted a workshop on August 11-13, 1997, during the comment period, to provide an overview of the draft documents, to answer questions regarding their intended application, and to solicit comments and suggestions. Comments received from the workshop have been considered in preparing the final general regulatory guide (R.G. 1.174) and its accompanying Standard Review Plan (Chapter 19) for risk-informed applications. Application-specific guidance documents for risk-informed TS, IST, and GQA are currently being revised to address the public comments that were received, and these documents are scheduled to be issued in early 1998. Guidance for ISI is also being developed on a slightly later schedule. It is intended that the guidance documents will provide examples of acceptable approaches for use in risk-informed programs, and alternative approaches may be proposed.

II. Public comment summary and resolution.

The public comment period for the draft regulatory guidance documents on risk-informed applications expired on September 30, 1997. In addition to comments received at the workshop, the NRC staff has received approximately 40 sets of written comments. Some of the more extensive comments were provided by the Nuclear Energy Institute (NEI), in a letter dated September 29, 1997, which provided comments on behalf of the nuclear industry. In its letter, NEI commended the NRC staff for its efforts in developing the draft documents, stating that the industry recognized the significance of the drafts in articulating a framework for the use of risk information in regulatory decisionmaking, and that the documents represent a milestone in the evolution of the regulatory process. In addition, the NEI letter expressed concern regarding four highlighted policy issues, the resolution of which NEI said they believe to be essential to the continued viability and the expansion of risk-informed regulation. The issues cited by NEI were:

- Overall cost benefit
- Use of numerical acceptance guidelines
- Treatment of uncertainty, and
- PRA attributes and quality considerations

Each of these areas highlighted by NEI will be addressed in the following discussion of the principal issues.

Comment letters were also received from the Electric Power Research Institute (EPRI), the American Society of Mechanical Engineers (ASME), the owner's groups for the four reactor vendors (General Electric, Westinghouse, Combustion Engineering and Babcock and Wilcox), one vendor (Westinghouse), 18 electric utilities, one national laboratory (Oak Ridge), five technical organizations, five other private industry organizations or individuals, and two anonymous commenters. The following discussion addresses the resolution of the principal issues raised by the commenters. A more complete discussion of the comments received overall is given in the attachment to a memorandum from Mr. Mark A. Cunningham (Chief, Probabilistic Risk Analysis Branch, Division of Systems Technology, Office of Nuclear Regulatory Research) to Mr. M. Wayne Hodges (Director, Division of Systems

Technology, Office of Nuclear Regulatory Research) dated January 7, 1998. The discussion in the attachment covers the resolution of the NRC's specific requests for comment included in the Federal Register notice for the workshop (62 FR 34321) and the resolution of the other issues raised by the commenters as well as the principal issues discussed in this announcement. The January 7, 1998, memorandum is also available in the Commission's Public Document Room.

Principal Issues

1. Use of 10^{-4} Per Reactor-Year Core Damage Frequency (CDF) As An Acceptance Guideline

Issue: Comments were received indicating that the use of 10^{-4} per reactor-year core damage frequency (10^{-4}/RY CDF) as an acceptance guideline was overly conservative, that the Commission's Safety Goal Policy quantitative health objectives (QHOs) would be more appropriate for use as goals, and that it was not clear how closely staff reviewers would hold applications to this numerical criteria.

Resolution: Revised Section 2.4.2.2 , "Acceptance Guidelines," of R.G. 1.174 addresses the use of 10^{-4}/RY CDF as a guideline in evaluating the acceptability of risk-informed applications. The use of 10^{-4}/RY CDF as a subsidiary goal is consistent with past Commission guidance. The guidelines for assessing risk, contained in the Regulatory Guide and SRP, are based upon the QHOs contained in the Commission's Safety Goal Policy and upon previous Commission guidance related to implementation of the Safety Goal Policy and Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 2). Specifically, the guideline value of 10^{-4}/RY for CDF is based upon a June 15, 1990 memorandum from the Commission to the NRC staff on implementation of the Safety Goal Policy which established a 10^{-4}/RY CDF as a benchmark objective for accident prevention. The guideline value on $\triangle$CDF of 10^{-5}/RY is based upon the guidance in the Commission's Regulatory Analysis Guidelines which establishes a 10^{-5}/RY $\triangle$CDF as a cutoff below which the significance of safety issues is not large enough to warrant backfit analysis, assuming a reasonable accident mitigation capability.

Accident mitigation capability is addressed via guidelines on large early release frequency (LERF). The guideline value of 10^{-5}/RY for LERF contained in R. 1.174 is based upon risk analysis results presented in NUREG-1150, which calculated offsite health risks for five nuclear power plants and compared them to the Safety Goal QHOs. Analyses for all five plants calculated health risks well below the QHOs. However, if the results of this analyses were adjusted so that the offsite health risks just met the early fatality QHO (the most limiting QHO), with allowance for the unanalyzed modes of operation (shutdown) and, in some cases external events, a corresponding LERF value of 10^{-5}/RY is the result for those plants whose calculated offsite health risks are closest to the QHOs.

Site to site variations in LERF were judged to not be a large factor (this was also confirmed in a study reported by the Advisory Committee for Reactor Safeguards in a September 19, 1997 letter to Chairman Jackson) and thus a single value for all plants is used. The guideline value of 10^{-6}/RY for $\triangle$LERF is based upon the Regulatory Analysis Guidelines which, when used in conjunction with the $\triangle$CDF guidelines discussed above, establishes a cutoff below which the significance of safety issue is not large enough to warrant backfit analysis.

Figures 3 and 4 of Section 2.4.2.2 illustrate acceptance guidelines for CDF and containment large early release frequency (LERF) and indicate that for each of these metrics, three regions have been identified for use in screening acceptability of proposed changes in current licensing bases. Region III, shown in the figures and discussed in the text, has been identified as representing a sufficiently low CDF or LERF increase that, in general, program changes associated with this region may be permitted without a detailed assessment of the baseline CDF/LERF. As discussed in R.G. 1.174, if there are indications that the baseline CDF and/or LERF are above the guideline values, additional evaluation would be needed even though the calculated changes in CDF or LERF are small and in Region III. In Section 2.4.2.3, “Comparison of PRA Results with the Acceptance Criteria,” it is stated that the acceptance guidelines (lines separating the regions) are not to be interpreted in an overly prescriptive manner and that they are intended to provide an indication, in numerical terms, of what is considered acceptable. Graduated shading has been added to the guideline figures to indicate regions in which proposed changes will be subject to gradually more

intensive NRC technical and management review. Regarding the use of the QHOs, in Section 2.1, "Risk-Informed Philosophy," it is stated that the use of the QHOs in lieu of LERF in support of risk-informed applications is an acceptable approach provided that appropriate consideration is given to the methods and assumptions used in the analysis and in the treatment of uncertainties. Also, in Section 2.4.3, "Integrated Decision-Making," it is noted that Level 3 PRA information can be submitted and will be considered in support of those cases in which increased NRC management attention is needed during the review (e.g., when the calculated CDF/LERF changes and baseline values are close to the acceptance guidelines).

2. Definition of Risk Neutral

Issue: A number of comments were received indicating that there was a need for a definition of risk neutral applications and that increased NRC management and technical review should not be required for risk increases below some threshold.

Resolution: See responses to Issues Number 1 and 3 addressing very small increases in risk.

3. Allowance for Very Small Increases in Risk

Issue: Comments received stated that facilities with CDFs greater than 10^{-4}/RY should be allowed small risk increases and that the level of effort and information required in submittals was excessive for small risk increases.

Resolution: Section 2.4.2.2, "Acceptance Guidelines," addresses the treatment of small increases in risk using the metrics of CDF and LERF. As noted in the discussion for Issue Number 1, this section has been revised and now includes a special category of application in which the estimated level of CDF/LERF increase associated with the application is sufficiently low such that, in general, program changes associated with this region may be permitted without a detailed assessment of the baseline CDF/LERF. This category is displayed in Figures 3 and 4 of Section 2.4.2.2.

4. Treatment of Uncertainties

Issue: Comments received stated that inclusion of uncertainty could lead to confusion regarding the decision criteria and that the use of PRA inherently takes care of uncertainty.

Resolution: Several approaches were reconsidered for the treatment of uncertainties, and it was concluded that the approach that was described in the draft regulatory guide (DG-1061) appeared to be the most practical and useful approach at this time, although there was a need to clarify the text for this subject. Uncertainty is addressed in Section 2.4.2.3, "Comparison of PRA Results with the Acceptance Guidelines," in Regulatory Guide 1.174. In this section, it is noted that it is important when interpreting the results of a PRA to develop an understanding of the impact of a specific assumption or choice of model on the prediction. PRA only inherently takes care of those uncertainties modeled in the analysis. Others must be qualitatively or quantitatively addressed. The impact of using alternative assumptions and models may be reasonably evaluated using appropriate sensitivity studies. The major sources of uncertainty should be understood, but it is not, in all cases, necessary to perform elaborate uncertainty evaluations (e.g, propagation of uncertainty distributions).

5. Quality of PRA

Issue: Numerous comments were received indicating concern that the PRA standards included in draft NUREG-1602 were unnecessarily high for many risk-informed applications. It was also indicated that the requirements for PRA quality were not clear and that graded levels of PRA quality should be provided for different applications.

Resolution: The issue of PRA quality is addressed in revised Section 2.4.2.1 of R.G. 1.174, "Scope, Level of Detail, and Quality of the PRA." In this section it is stated that PRA quality should be commensurate with the application for which it is intended and with the role that PRA results play in the integrated decision process. A PRA used in a risk-informed application should be performed in a manner that is consistent with accepted practices, and be commensurate with the scope and level of detail which are also discussed in Section 2.4.2.1 of R.G. 1.174. The

NRC has not developed its own formal standard nor endorsed an industry standard for PRA quality, however, it supports such a standard and expects that one will be available in the future. Draft NUREG-1602, "Use of PRA in Risk-Informed Applications," was cited in draft Regulatory Guide DG-1061 as a potential reference for PRA methods that could be used to support regulatory decision making. There were a number of comments indicating that the "PRA standard" represented by draft NUREG-1602 was excessive for many risk-informed applications not requiring sophisticated or state-of-the-art methods. While it was not intended that draft NUREG-1602 be used universally as a PRA standard, it is recognized that it would be more useful to have a standard that addresses the differing needs for PRA scope and detail depending on the application. Accordingly, draft NUREG-1602 has been removed as a reference in R.G. 1.174, and a separate discussion on PRA quality has been added. This includes addressing PRA quality by the use of peer review or PRA cross comparisons. PRA peer review activities such as those that are presently being done under various industry PRA certification programs are examples. Neither peer review nor a PRA certification or cross comparison, replaces a staff review in its entirety, and licensees need to provide justification why the PRA is adequate for the proposed application. In the interim, until a consensus PRA standard is available, the NRC staff will evaluate PRAs submitted in support of specific applications using the guidelines given in Chapter 19 of the Standard Review Plan.

6. Low Safety Significant Components Monitoring Needs

Issue: Comments received indicated that the draft guidance placed too much importance on monitoring of low safety significant components (LSSCs). It was also indicated that monitoring performed under the Maintenance Rule should be acceptable for risk-informed programs.

Resolution: Section 2.5, "Element 3: Define Implementation and Monitoring Program," has been revised to clarify monitoring needs for LSSCs. While details for monitoring LSSCs will be provided in the application-specific guidance documents, the following principal needs should be satisfied for all applications. Monitoring programs should be proposed that are capable of adequately tracking the performance of equipment which when degraded could alter

the conclusions that were key to supporting the acceptance of the program. It follows that monitoring programs should be structured such that SSCs are monitored commensurate with their safety significance. Monitoring that is performed as a part of the Maintenance Rule implementation can be used in cases where the monitoring performed under the Maintenance Rule is sufficient for the SSCs affected by the risk-informed application.

7. Shutdown and Temporary Plant Condition

Issue: Several commenters noted that the guidelines proposed did not distinguish between power operation and shutdown and did not address temporary plant conditions. Separate guidelines for these conditions were suggested.

Resolution: In response to these comments, Section 2.4.2.2 of R.G. 1.174 has been expanded to address the shutdown condition. Specific guidance for temporary plant conditions has not been added, but will be considered in a future update of R.G. 1.174.

8. Documentation Needs

Issue: Many commenters stated that the documentation requirements in the drafts were excessive and unmanageable, particularly for proposals involving small changes in risk. It was also suggested that certain documentation items should not be required to be submitted for the staff's initial review, provided that more complete documentation be maintained at the utility if the need were to arise later for its review.

Resolution: In response to the comments received, Section 3 of R.G. 1.174 has been reevaluated to determine what items listed in the draft were not necessary. As a result, a number of documentation items, particularly with regard to the PRA, have been removed in the final regulatory guide, and the SRP has been revised to be consistent.

9. Overall cost benefit

Issue: This issue was highlighted by NEI in its comment letter and was also included in a number of other comment

letters. A concern was expressed that the resources required by licensees to prepare proposals and to subsequently implement NRC approved risk-informed changes to the CLB will be too high considering the benefit in terms of burden reduction.

Resolution: The question of how cost beneficial it will be for utilities to prepare proposals for risk-informed changes to their current licensing bases and to implement such programs after review and approval by the NRC will only be fully answered after the industry and the NRC gain further experience in these types of programs. Certainly, the pilot plant program proposals that are currently being reviewed for application to technical specifications, graded quality assurance, and inservice testing and inspection, will provide useful insights into the potential cost savings available through these programs. While it is not the NRC's responsibility to ensure that such risk-informed programs are cost beneficial, it is believed that such programs can enhance safety by better focusing utility and NRC resources on the most important safety areas in reactors, and this philosophy is consistent with the Commission's Policy Statement on the use of PRA methods in nuclear regulatory activities. During the preparation of the final regulatory guide and standard review plan section for general guidance, attention was paid to those areas where utility resource needs could be reduced thus improving the cost-beneficial aspects of the risk-informed process while still maintaining an appropriate level of safety. Examples of sections in R.G. 1.174 where this is reflected in the final guidance are Section 2.4.2.1, Quality and Scope of the PRA, in which it is stated that the level of detail required to support an application can vary depending on the application, and that not all applications require that an expensive, detailed PRA be acquired; Section 2.4.2.2, Acceptance Guidelines, where a special category of risk-informed proposal has been identified as having a sufficiently low estimated risk increase, that generally for such cases, the proposed program will be considered without a detailed assessment of baseline CDF/LERF (i.e., Region III of Figures 3 and 4 in R.G. 1.174); and in Section 3, Documentation, where some of the items that were identified in the draft regulatory guide and SRP as being needed in program submittals have been removed since they were not believed necessary.

Dated at Rockville, Maryland, this _____ day of _____ 1997.

For the Nuclear Regulatory Commission.

Malcolm R. Knapp, Acting Director
Office of Nuclear Regulatory Research

Attachment 2

Regulatory Guide 1.174

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH
REGULATORY GUIDE

Predecisional

REGULATORY GUIDE 1.174
(Draft Guide DG-1061)

AN APPROACH FOR USING PROBABILISTIC RISK ASSESSMENT IN RISK-INFORMED DECISIONS ON PLANT-SPECIFIC CHANGES TO THE CURRENT LICENSING BASIS

Draft 1/7/98

1. PURPOSE AND SCOPE

1.1 Introduction

The NRC's policy statement on probabilistic risk analysis (PRA)(Ref. 1) encourages greater use of this analysis technique to improve safety decisionmaking and improve regulatory efficiency. The NRC staff's PRA Implementation Plan (Ref. 2) describes activities now under way or planned to expand this use. These activities include, for example, providing guidance for NRC inspectors on focusing inspection resources on risk-important equipment, as well as reassessing plants with relatively high core damage frequencies for possible backfits.

Another activity under way in response to the policy statement is the use of PRA in support of decisions to modify an individual plant's current licensing basis (CLB). This regulatory guide provides guidance on the use of PRA findings and risk insights in support of licensee requests for changes to a plant's current licensing basis (e.g., request for license amendments and technical specification changes under 10 CFR 50.90-92). It does not address licensee-initiated changes to the current licensing basis which do NOT require NRC review and approval (e.g., changes to the facility as described in the FSAR which are the subject of 10 CFR 50.59). Licensee-initiated CLB changes which 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 be expected to submit risk information in support of the proposed change. Licensee-initiated CLB 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 CLB change is not provided to the staff, the staff will review the information provided by the licensee to determine if the application can be approved based upon the information provided using traditional methods and will either approve or reject the application based upon the staff's review. For those licensee-initiated CLB changes which a licensee chooses to support (or is requested by the staff to support) with risk information, this regulatory guide describes an acceptable method for assessing the nature and impact of proposed CLB 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 chosen approaches and methods (whether they are quantitative or qualitative, and traditional or probabilistic), data, and criteria for considering risk are appropriate for the decision to be made.

Finally, the guidance provided here does not preclude other approaches for requesting changes to the CLB. Rather, this regulatory guide is intended to improve consistency in regulatory decisions in areas in which the results of risk analyses are used to help justify regulatory action. As such, the principles, process, and approach discussed herein also provide useful guidance for the application of risk information to a broader set of activities than plant-specific changes to a plant's CLB (i.e., generic activities), and licensees are encouraged to utilize this guidance in that regard.

1.2 Background

During the last several years, both the NRC and the nuclear industry have recognized that probabilistic risk assessment (PRA) has evolved to the point where it can be used increasingly as a tool in regulatory decisionmaking. In August 1995, the NRC adopted the following policy statement regarding the expanded use of PRA.

- The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

- PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

- PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

- The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on need for proposing and backfitting new generic requirements on nuclear power plant licensees.

In its approval of the policy statement, the Commission articulated its expectation that implementation of the policy statement will improve the regulatory process in three areas: foremost, through safety decisionmaking enhanced by the use of PRA insights; through more efficient use of agency resources; and through a reduction in unnecessary burdens on licensees.

In parallel with the publication of the policy statement, the staff developed an implementation plan to define and organize the PRA-related activities being undertaken. These activities cover a wide range of PRA applications and involve the use of a variety of PRA methods (with variety including both types of models used and the detail of modeling needed). For example, one application involves the use of PRA in the assessment of operational events in reactors. The characteristics of these assessments permit relatively simple PRA models to be used. In contrast, other applications require the use of detailed models.

The activities described in the PRA Implementation Plan relate to a number of agency interactions with the regulated industry. With respect to reactor regulation, activities include, for example, guidance development for NRC inspectors on focusing inspection resources on risk-important equipment, and a reassessment of plants with relatively high core damage frequencies for possible backfit.

This regulatory guide focuses on the use of PRA in a subset of the applications described in the staff's implementation plan. Its principal focus is the use of PRA findings and risk insights in decisions on proposed changes to a plant's CLB.[4]

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[4]For convenience this regulatory guide uses the definition of current licensing basis in 10 CFR 54.3. That is, "Current Licensing Basis (CLB) is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation with in applicable NRC requirements and the plant-specific design basis (including all

The regulatory guide also makes use of the Commission's Safety Goal Policy Statement (Ref. 4). As discussed below, one key principle in risk-informed regulation is that proposed increases in core damage frequency and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement. The safety goals (and associated quantitative health objectives (QHOs)) define an acceptable level of risk which is a small fraction (0.1%) of other risks to which the public is exposed. The acceptance guidelines defined in this regulatory guide (in Section 2.4.2) are based on subsidiary objectives derived from the Safety Goals and their QHOs.

1.3 Purpose of this Regulatory Guide

Changes to many of the activities and design characteristics in a nuclear power plant's current licensing basis require NRC review and approval. This regulatory guide provides the staff's recommendations for utilizing risk information in support of licensee-initiated CLB changes requiring such review and approval. The guidance provided here does not preclude other approaches for requesting CLB changes. Rather, this regulatory guide is intended to improve consistency in regulatory decisions in areas in which the results of risk analyses are used to help justify regulatory action. As such, this regulatory guide, the use of which is voluntary, provides general guidance concerning one approach that the NRC has determined to be acceptable for analyzing issues associated with proposed changes to a plants's current licensing bases (CLB) and for assessing the impact of such proposed changes on the risk associated with plant design and operation. This guidance does not address the specific analyses needed for each nuclear power plant activity or design characteristic that may be amenable to risk-informed regulation.

1.4 Scope of this Regulatory Guide

This regulatory guide describes an acceptable approach for assessing the nature and impact of proposed CLB changes by considering engineering issues and applying risk insights. Assessments should consider relevant safety margins and defense-in-depth attributes, including consideration of success criteria as well as equipment functionality, reliability, and availability. The analyses should reflect the actual design, construction, and operational practices of the plant. Acceptance guidelines for evaluating the results of such assessments are provided also. This guide also addresses implementation strategies and performance monitoring plans associated with CLB changes that will help ensure assumptions and analyses supporting the change are verified.

Consideration of the Commission's Safety Goal Policy Statement is an important element in regulatory decisionmaking. Consequently, this regulatory guide provides acceptance guidelines consistent with this policy statement.

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modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC
regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports." The use of this definition is not intended to imply any increase in the types of changes that are required to be submitted for NRC approval.

In theory, one could construct a more generous regulatory framework for consideration of those risk-informed changes which may have the effect of increasing risk to the public. Such a framework would include, of course, assurance of continued adequate protection (that level of protection of the public health and safety which must be reasonably assured regardless of economic cost). But it could also include provision for possible elimination of all measures not needed for adequate protection which either do not effect a substantial reduction in overall risk or result in continuing costs which are not justified by the safety benefits. Instead NRC has chosen, in this regulatory guide, a more restrictive policy which would permit only small increases in risk, and then only when it is reasonably assured, among other things, that sufficient defense in depth and sufficient margins are maintained. This policy is adopted because of uncertainties and to account for the fact that safety issues continue to emerge regarding design, construction, and operational matters notwithstanding the maturity of the nuclear power industry. These factors suggest that nuclear power reactors should operate routinely only at a prudent margin above adequate protection. The safety goal subsidiary objectives are used as an example of such a prudent margin.

Finally, this regulatory guide indicates an acceptable level of documentation that will enable the staff to reach a finding that the licensee has performed a sufficiently complete and scrutable analysis and that the results of the engineering evaluations support the licensee's request for a regulatory change.

1.5 Relationship to Other Guidance Documents

Directly relevant to this regulatory guide is the Standard Review Plan (SRP) designed to guide the NRC staff evaluations of licensee requests for changes to the CLB that apply risk insights (Ref. 3), as well as selected application-specific regulatory guides and the corresponding Standard Review Plan chapters. Related regulatory guides include DG-1062 (Ref. 5) on inservice testing, DG-1063 (Ref. 6) on inservice inspection, DG-1064 (Ref. 7) on graded quality assurance, and DG-1065 (Ref. 8) on technical specifications. An NRC contractor report (Ref. 9) is also available which provides a simple screening method for assessing one measure used in the regulatory guide--large early release frequency. The staff recognizes that the risk analyses necessary to support regulatory decisionmaking may vary with the relative weight that is given to the risk assessment element of the decisionmaking process. The burden is on the licensee requesting a change to their CLB to justify why the chosen risk assessment approach, methods, and data are appropriate for the decision to be made.

Regulatory guides are issued to describe to the public methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques used by the staff in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required.

The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget, approval number 3150-0011. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

2. AN ACCEPTABLE APPROACH TO RISK-INFORMED DECISIONMAKING

2.1 Risk-Informed Philosophy

In its approval of the policy statement on the use of PRA methods in nuclear regulatory activities, the Commission stated an expectation that "the use of PRA technology should be increased in all regulatory matters...in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy." The use of risk insights in licensee submittals requesting CLB changes will assist the staff in the disposition of such licensee proposals.

The staff has defined an acceptable approach to analyzing and evaluating proposed CLB changes. This approach supports the NRC's desire to base its decisions on the results of traditional engineering evaluations, supported by insights (derived from the use of PRA methods) about the risk significance of the proposed changes. Decisions concerning proposed changes are expected to be reached in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors as well as quantitative analyses and information.

In implementing risk-informed decisionmaking, changes are expected to meet a set of key principles. Some of these principles are written in terms typically used in traditional engineering decisions (e.g., defense-in-depth). While written in these terms, it should be understood that risk analyses techniques can be, and are encouraged to be, used to help ensure and show that they are met. These principles are:

1. The proposed change meets the current regulations unless it is explicitly related to a requested exemption or rule change.

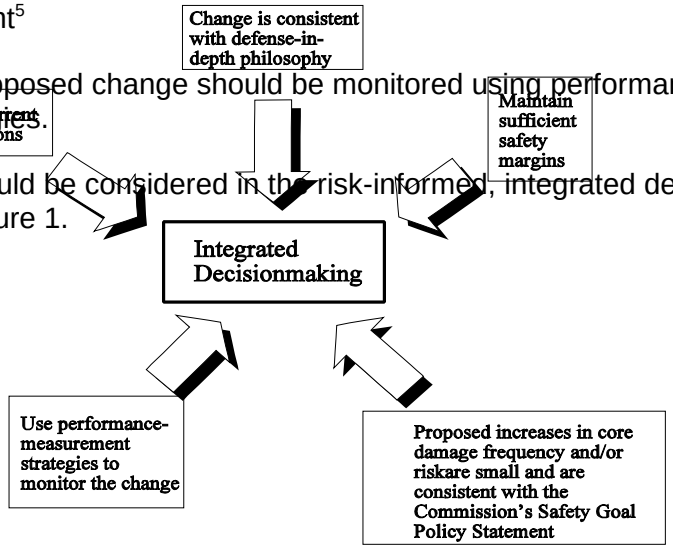
2. The proposed change is consistent with the defense-in-depth philosophy.

3. The proposed change maintains sufficient safety margins.

4. When proposed changes result in an increase in core damage frequency and/or risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement[5]

5. The impact of the proposed change should be monitored using performance measurement strategies.

Each of these principles should be considered in the risk-informed, integrated decisionmaking process, as illustrated in Figure 1.



[5] For purposes of this guide, a proposed CLB change which meets the acceptance guidelines discussed in Section 2.4.2 is considered to have met the intent of the policy statement.

Figure 1. Principles of Risk-Informed Regulation

The staff's proposed evaluation approach and acceptance guidelines follow from these principles. In implementing these principles, the staff expects that:

- All safety impacts of the proposed change are evaluated in an integrated manner as part of an overall risk management approach in which the licensee is using risk analysis to improve operational and engineering decisions broadly by identifying and taking advantage of opportunities for reducing risk, and not just to eliminate requirements the licensee sees as undesirable. For those cases where risk increases are proposed, the benefits should be described and should be commensurate with the proposed risk increases. The approach used to identify changes in requirements should be used to identify areas where requirements should be increased,[6] as well as where they could be reduced.

- The scope and quality of the engineering analyses (including traditional and probabilistic analyses) conducted to justify the proposed CLB change should be appropriate for the nature and scope of the change, should be based on the as-built and as-operated and maintained plant, and should reflect operating experience at the plant.

- The plant-specific PRA supporting licensee proposals has been subjected to quality controls such as an independent peer review or certification.[7]

- Appropriate consideration of uncertainty is given in analyses and interpretation of findings, including using a program of monitoring, feedback, and corrective action to address significant uncertainties.

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[6] The staff is aware of, but does not endorse here, guidelines which have been developed (e.g., by NEI/NUMARC) to assist in identifying potentially beneficial changes to requirements.

[7] As discussed in Section 2.4.2 below, such a peer review or certification is not a replacement for NRC review. Certification is defined as a mechanism for assuring that a PRA, and the process of developing and maintaining that PRA, meet a set of technical standards established by a diverse group of personnel experienced in developing PRA models, performing PRAs, and performing quality reviews of PRAs. Such a process has been developed and integrated with a peer review process by, for example, the BWR Owners Group and implemented for the purpose of enhancing quality of PRAs at several BWR facilities.

- The use of core damage frequency (CDF) and large early release frequency (LERF)[8] as bases for probabilistic risk assessment acceptance guidelines is an acceptable approach to addressing Principle 4. Use of the Commission's Safety Goal QHOs in lieu of LERF is acceptable in principle and licensees may propose their use. However, in practice, implementing such an approach would require an extension to a Level 3 PRA, in which case the methods and assumptions used in the Level 3 analysis, and associated uncertainties, would require additional attention.

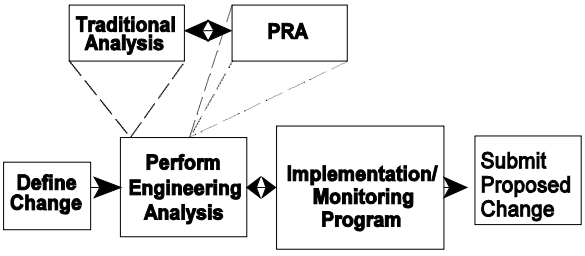
- Increases in estimated CDF and LERF resulting from proposed CLB changes will be limited to small increments; the cumulative effect of such changes should be tracked and considered in the decision process.

- The acceptability of proposed changes should be evaluated by the licensee in an integrated fashion that ensures that all principles are met.[9]

- Data, methods, and assessment criteria used to support regulatory decisionmaking must be well documented and available for public review.

2.2 A Four-Element Approach to Integrated Decisionmaking

Given the principles of risk-informed decisionmaking discussed above, the staff has identified a four-element approach to evaluating proposed CLB changes. This approach, which is presented graphically in Figure 2, acceptably supports the NRC's decisionmaking process. This approach is not sequential in nature; rather it is iterative.



[8] In this context, LERF is being used as a surrogate for the early fatality QHO. It is defined as the frequency of those accidents leading to significant, unmitigated releases from containment in a time frame prior to effective evacuation of the close-in population such that there is a potential for early health effects. Such accidents generally include unscrubbed releases associated with early containment failure at or shortly after vessel breach, containment bypass events, and loss of containment isolation. This definition is consistent with accident analysis used in the safety goal screening criteria discussed in the Commission's Regulatory Analysis Guidelines. An NRC contractor's report (Ref. 9) describes a simple screening approach for calculating LERF.

[9] One important element of integrated decisionmaking can be the use of an "expert panel." Such a panel is not a necessary component of risk-informed decisionmaking; but when it is used, the key principles and associated decision criteria presented in this regulatory guide still apply and must be shown to have been met or to be irrelevant to the issue at hand.

Figure 2. Principal Elements of Risk-Informed, Plant-Specific Decisionmaking

2.3 Element 1: Define the Proposed Change

Element 1 involves three primary activities. First, the licensee should identify those aspects of the plant's licensing bases that may be affected by the proposed change, including, but not limited to, rules and regulations, final safety analysis report (FSAR), technical specifications, licensing conditions, and licensing commitments. Second, the licensee should identify all SSCs, procedures, and activities that are covered by the CLB change under evaluation and consider the original reasons for inclusion of each program requirement.

When considering CLB changes, a licensee may identify regulatory requirements or commitments in its licensing bases that it believes are overly restrictive or unnecessary to ensure safety at its plant. Note that the corollary is also true; that is, licensees are expected also to identify possible cases where design and operational aspects of the plant should be enhanced consistent with an improved understanding of their safety significance. Such enhancements should be embodied in appropriate CLB changes which reflect these enhancements. With this staff expectation in mind, the licensee should, third, identify available engineering studies, methods, codes, applicable plant-specific and industry data and operational experience, PRA findings, and research and analysis results relevant to the proposed CLB change. With particular regard to the plant-specific PRA, the licensee should assess the capability to use, refine, augment, and update system models as needed to support a risk assessment of the proposed CLB change.

The above information should be used collectively to provide a description of the CLB change and to outline the method of analysis. The licensee should describe the proposed change and how it meets the objectives of the Commission's PRA Policy Statement, including enhanced decisionmaking, more efficient use of resources, and reduction of unnecessary burden. In addition to improvements in reactor safety, this assessment may consider benefits from the CLB change such as reduced fiscal and personnel resources and radiation exposure. In addition, the licensee should affirm that the proposed CLB change meets the current regulations, unless the proposed change is explicitly related to a proposed exemption or rule change (i.e., a 50.12 "specific exemption" or a 2.802 "petition for rulemaking").

Combined Change Requests

Licensees may make proposals which include several individual changes to the CLB that have been evaluated and will be implemented in an integrated fashion. The staff expects that with respect to the overall net change in risk, combined change requests (CCRs) will fall in one of two broad categories, each of which may be acceptable:

1. those for which any individual change increases risk;

2. those for which each individual change decreases risk.

For the first category, the contribution of each individual change in the CCR must be quantified in the risk assessment and the uncertainty of each individual change must be addressed. For CCRs in the second

category, qualitative analysis may be sufficient for some or all individual changes. Guidelines for use in developing CCRs are discussed below.

The changes that make up a CCR should normally be related to one another, for example by affecting the same single system or activity, the same safety function or the same accident sequence or group of sequences, or by being of the same type (e.g., changes in TS allowed outage time). However, this does not preclude unrelated changes being accepted. When CCRs are submitted to the staff for review, the relationships among the individual changes and how they have been modeled in the risk assessment should be addressed in detail, since this will control the characterization of the net result of the changes. Licensees should evaluate not only the individual changes but also the changes taken together against the safety principles and qualitative acceptance guidelines in Section 2.1 and Section 2.4.1, respectively, of this regulatory guide. In addition, the acceptability of the cumulative impact of the changes that make up the CCR with respect to the quantitative acceptance guidelines discussed in Section 2.4.2.2 of this guide should be assessed.

In implementing CCRs in category 1, it is expected that the risk from significant accident sequences will not be increased and that the frequencies of the lower ranked contributors will not be increased so that they become significant contributors to risk. In addition, it is expected that no significant new sequences or cutsets will be created. Also, in assessing the acceptability of CCRs, the following should be considered: (1) risk increases related to the more likely initiating events (e.g., steam generator tube ruptures) should not be traded against improvements related to unlikely events (e.g., earthquakes) even if, for instance, they involve the same safety function; and (2) risk should be considered in addition to likelihood. The staff also expects that CCRs will lead to safety benefits such as simplifying plant operations or focusing resources on the most important safety items.

Proposed changes which modify one or more individual components of a previously approved CCR, need to also address the impact on the previously approved CCR. Specifically, the question of would the proposed modification now cause the previously approved CCR to not be acceptable needs to be addressed. If the answer is yes, the submittal should address what actions the licensee is taking with respect to the previously approved CCR.

2.4 Element 2: Perform Engineering Analysis

As part of the second element, the licensee will evaluate the proposed CLB change with regard to the principles that adequate defense-in-depth is maintained, that sufficient safety margins are maintained, and that proposed increases in core damage frequency and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement.

The staff expects that the scope and quality of the engineering analyses conducted to justify the proposed CLB change will be appropriate for the nature and scope of the change. The staff also expects that appropriate consideration will be given to uncertainty in the analysis and interpretation of findings. The licensee is expected to use its judgment of the complexity and difficulty of implementing the proposed CLB change to decide upon appropriate engineering analyses to support regulatory decisionmaking. Thus, the licensee should consider the appropriateness of qualitative and quantitative analyses, as well as analyses using traditional engineering approaches and those techniques associated with the use of PRA findings. Regardless of the analysis methods chosen, the licensee must show that the principles set forth in Section 2.1 have been met through the use of scrutable acceptance guidelines established for making that determination.

Some proposed CLB changes can be characterized as involving the categorization of SSCs according to safety significance. An example is grading the application of quality assurance controls commensurate with the safety significance of equipment. Like other applications, the staff's review of CLB change

requests for applications involving safety categorization will be according to the acceptance guidelines which are associated with each key principle and which are presented in this regulatory guide, unless equivalent guidelines are proposed by the licensee. Since risk importance measures are often used in such categorizations, guidance on their use is provided in Appendix A of this regulatory guide. For such CLB changes, guidelines associated with the adequacy of programs (in this example, quality controls) implemented for different safety significant categories (e.g., more safety significant and less safety significant) are addressed in other application-specific guidance documents. Licensees are encouraged to apply risk-informed findings and insights to decisions (and potential CLB requests).

2.4.1 Evaluation of Defense-in-Depth Attributes and Safety Margins

One aspect of the engineering evaluations is to show that the fundamental safety principles on which the plant design was based are not compromised. Design basis accidents (DBAs) play a central role in nuclear power plant design. DBAs are a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response. During the design process, plant response and associated safety margins are evaluated using assumptions which are intended to be conservative. National standards and other considerations such as defense-in-depth attributes and the single failure criterion constitute additional engineering considerations that influence plant design and operation. Margins and defenses associated with these considerations may be affected by the licensee's proposed CLB change and, therefore, should be reevaluated to support a requested CLB change. As part of this evaluation, the impact of the proposed CLB change on affected equipment functionality, reliability, and availability should be determined.

2.4.1.1 Defense-in-Depth

The engineering evaluation conducted should evaluate whether the impact of the proposed CLB change (individually and cumulatively) is consistent with the defense-in-depth philosophy. In this regard, the intent of the principle is to assure that the philosophy of defense-in-depth is maintained, not to prevent changes in the way defense-in-depth is achieved. The defense-in-depth philosophy has traditionally been applied in reactor design and operation to provide multiple means to accomplish safety functions and prevent the release of radioactive material. It has been and continues to be an effective way to account for uncertainties in equipment and human performance. Where a comprehensive risk analysis can be done, it can be used to help determine the appropriate extent of defense-in-depth (e.g., balance among core damage prevention, containment failure and consequence mitigation) to ensure protection of public health and safety. Where a comprehensive risk analysis is not or cannot be done, traditional defense-in-depth considerations should be used or maintained to account for uncertainties. The evaluation should consider the intent of the general design criteria, national standards, and engineering principles such as the single failure criterion. Further, the evaluation should consider the impact of the proposed CLB change on barriers (both preventive and mitigative) to core damage, containment failure or bypass, and the balance among defense-in-depth attributes. As stated earlier, the licensee should select the engineering analysis techniques, whether quantitative or qualitative and traditional or probabilistic, appropriate to the proposed CLB change.

The licensee should assess whether the proposed CLB change meets the defense-in-depth principle. Defense-in-depth consists of a number of elements, as summarized below. These elements can be used as guidelines for making that assessment. Other equivalent acceptance guidelines may also be used.

- Consistency with the defense-in-depth philosophy is maintained if:
    - a reasonable balance among prevention of core damage, prevention of containment failure, and consequence mitigation is preserved

- over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided
- system redundancy, independence, and diversity are preserved commensurate with the expected frequency, and consequences of challenges to the system and uncertainties (e.g., no risk outliers)
- defenses against potential common cause failures are preserved and the potential for introduction of new common cause failure mechanisms is assessed
- independence of barriers is not degraded
- defenses against human errors are preserved
- the intent of the General Design Criteria in 10 CFR Part 50, Appendix A is maintained.

2.4.1.2 Safety Margins

The engineering evaluation conducted should assess whether the impact of the proposed CLB change is consistent with the principle that sufficient safety margins are maintained. Here also, the licensee is expected to choose the method of engineering analysis appropriate for evaluating whether sufficient safety margins would be maintained if the proposed CLB change were implemented. An acceptable set of guidelines for making that assessment are summarized below. Other equivalent acceptance guidelines may also be used.

- Sufficient safety margins are maintained if:
  - codes and standards or alternatives approved for use by the NRC are met
  - safety analysis acceptance criteria in the current licensing basis (e.g., FSAR, supporting analyses) are met, or proposed revisions provide sufficient margin to account for analysis and data uncertainty

Application-specific guidelines reflecting this general guidance may be found in the application-specific regulatory guides (Refs. 5-8).

2.4.2 Evaluation of Risk Impact, Including Treatment of Uncertainties

As noted in Section 2.1, the licensee's risk assessment may be used to address the principle that proposed increases in core damage frequency and risk are small and are consistent with the intent of the Commission's Safety Goal Policy Statement. For purposes of implementation, the licensee should assess the expected change in core damage frequency (CDF) and large early release frequency (LERF). The necessary sophistication of the evaluation, including the scope of the PRA (e.g., internal events only, full power only), depends on the contribution the risk assessment makes to the integrated decision-making, which depends to some extent on the magnitude of the potential risk impact. For some CLB changes for which a more substantial impact is possible, an in-depth and comprehensive PRA analysis of appropriate scope to derive a quantified estimate of the total impact of a proposed CLB change will be necessary to provide adequate justification. In other applications, calculated risk importance measures or bounding

estimates will be adequate. In still others, a qualitative assessment of the impact of the CLB change on the plant's risk may be sufficient.

The remainder of this section discusses the use of quantitative PRA results in decision making. This discussion has three parts:

- A fundamental element of NRC's risk-informed regulatory process is a PRA of sufficient quality and scope for the intended application. Section 2.4.2.1 discusses the staff's expectations with respect to the needed PRA quality and scope.

- PRA results are to be used in this decisionmaking process in two ways - to assess (for some situations) the overall baseline CDF/LERF of the plant and to assess the CDF/LERF impact of the proposed change. Section 2.4.2.2 discusses the acceptance guidelines to be used by the staff for each of these measures.

- One of the strengths of the PRA framework is its ability to provide a means of characterizing the impact of uncertainty in the analysis, and it is essential that these uncertainties be recognized when assessing whether the principles are being met. To provide a vehicle for consistency between submittals and the review of those submittals, Section 2.4.2.3 provides guidelines on how the uncertainty is to be addressed in the decision-making process.

The staff's decision on the proposed CLB change will be based on its independent judgment and review of the entire application.

2.4.2.1 Scope, Level of Detail, and Quality of the PRA

The scope, level of detail, and quality required of the PRA is commensurate with the application for which it is intended and on the role the PRA results play in the integrated decision process. The more emphasis that is put on the risk insights and on PRA results in the decision-making process, the more requirements have to be placed on the PRA, both in terms of scope and in terms of how well the risk and/or the change in risk is assessed.

Conversely, if a proposed change to the CLB results in a risk decrease or is very small, or if the decision could be based mostly on traditional engineering arguments, or if compensating measures are proposed such that it can be convincingly argued that the change is very small, then emphasis on the PRA scope and quality can be reduced.

Since this regulatory guide is intended for a variety of applications, the required quality and level of detail may vary. One overriding requirement is that the PRA performed should realistically reflect the actual design, construction, operational practices, and operational experience of the plant and its owner. This should include licensee voluntary actions as well as regulatory requirements and the PRA used to support risk-informed decisionmaking should also reflect the impact of previous changes made to the CLB.

Scope

Although the scope of the assessment of the risk implications in light of the acceptance guidelines discussed in Section 2.4.2.2 requires that all plant operating modes and initiating events be addressed, it is not necessary to have a PRA that treats all these modes and initiating events. A qualitative treatment of the missing modes and initiators may be sufficient in many cases. Section 2.4.2.3 discusses this further.

Level of Detail Required to Support an Application

The level of detail required of the PRA is that which is sufficient to model the impact of the proposed change. The characterization of the problem should include the establishment of a cause-effect relationship to identify portions of the PRA affected by the issue being evaluated. For full scale applications of the PRA, this should be reflected in a quantification of the impact on the PRA elements. For applications like component categorization, sensitivity studies on the effects of the change may be sufficient. For other applications it may be adequate to define the qualitative relationship of the impact on the PRA elements or may only require an identification of which elements are impacted.

If the impacts of a change to the plant cannot be associated with elements of the PRA, the PRA should be modified accordingly. If this cannot be done, the impact of the change should be evaluated qualitatively as part of the decision-making process (or expert panel process). In any case, the effects of the changes on SSC reliability and unavailability or on operator actions should be appropriately accounted for.

PRA Quality

In the current context, quality will be defined as measuring the adequacy of the actual modeling. A PRA used in risk-informed regulation should be performed correctly, and in a manner that is consistent with accepted practices, commensurate with the scope and level of detail required as discussed above. One approach a licensee could use to assure quality is to perform a peer review of the PRA. In this case, the submittal should document the review process, the qualification of the reviewers, a summary of the review findings, and resolutions to these findings where applicable. Industry PRA certification programs and PRA cross-comparison studies could also be used to help ensure appropriate scope, level of detail and quality of the PRA. If such a program or studies are to be used, a description of the program, including the approach and standard or guidelines to which the PRA is compared, the depth of the review and the make-up and qualifications of the personnel involved should be provided for NRC review. Based on the peer review or certification process and on the findings from this process, the licensee should justify why the PRA is adequate for the present application in terms of scope and quality. Neither a peer review nor a certification or cross comparison replaces a staff review in its entirety, although the more confidence the staff has in the review that has been performed by or for the licensee, the less rigor should be expected of the staff review.

The NRC has not developed its own formal standard nor endorsed an industry standard for a PRA submitted in support of applications governed by this regulatory guide. However, the NRC supports ongoing initiatives to develop a standard and expects that one will be available in the future. In the interim, the NRC staff will evaluate PRAs submitted in support of specific applications using the guidelines given in Chapter 19 of its Standard Review Plan (Ref. 3). The staff expects to feed back the experience gained from these reviews into the standards development process so that ultimately a standard can be developed that is suitable for regulatory decisionmaking as described in this guide. In addition, the references and bibliography provide information that licensees may find useful in deciding on the acceptability of their PRA.

2.4.2.2 Acceptance Guidelines

The risk acceptance guidelines presented in this regulatory guide are based on the principles and expectations for risk-informed regulation discussed in Section 2.1, and are structured as follows. Regions are established in the two planes generated by a measure of the baseline risk metric (CDF or LERF) along the x-axis, and the change in those metrics (ΔCDF or ΔLERF) along the y-axis (Figures 3 and 4), and acceptance guidelines are established for each region as discussed below. These guidelines are intended for comparison with a full scope (including internal events, external events, full power, low power and

shutdown) assessment of the change in risk metric, and, when necessary, as discussed below, the baseline value of the risk metric (CDF or LERF). However, it is recognized that many PRAs are not full scope and the use of less than full scope PRA information may be acceptable as discussed in Section 2.4.2.3 of this regulatory guide.

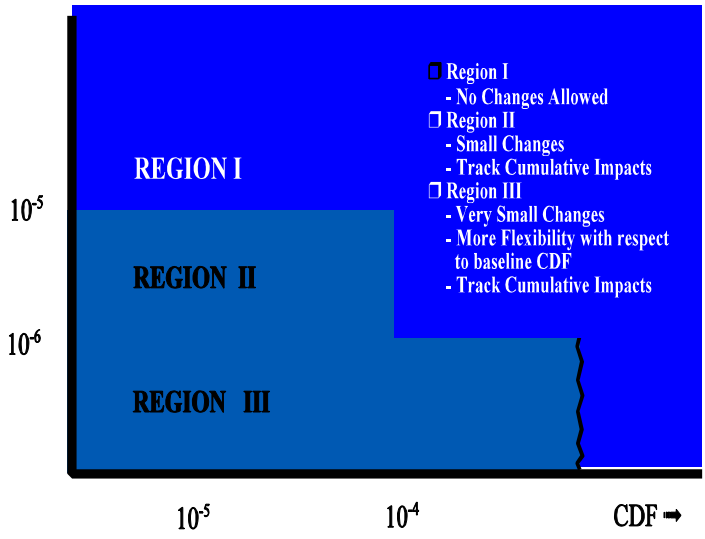


Figure 3 - Acceptance Guidelines* for Core Damage Frequency (CDF)

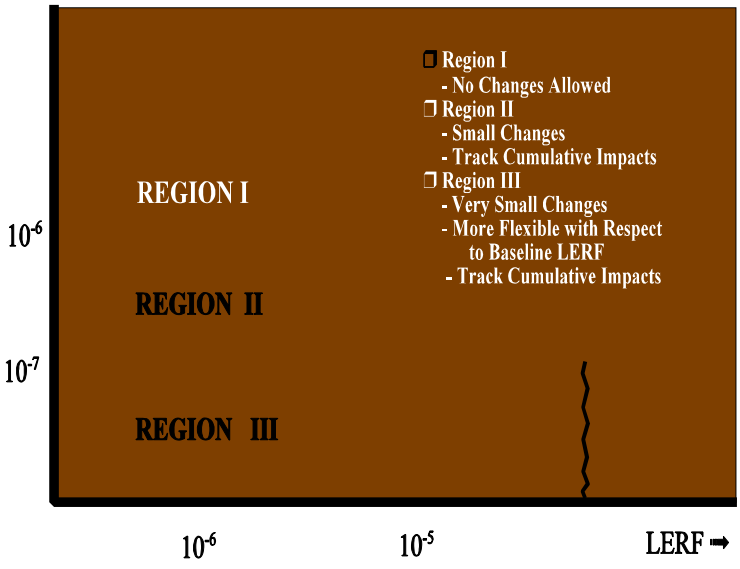


Figure 4 - Acceptance Guidelines* for Large Early Release Frequency (LERF)

* The analysis will be subject to increased technical review and management attention as indicated by the darkness of the shading of the figure. In the context of the integrated decision making, the boundaries between regions should not be interpreted as being definitive; the numerical values associated with defining the regions in the figure are to be interpreted as indicative values only.

There are two acceptance guidelines, one for CDF and one for LERF, both of which should be used.

The guidelines for CDF are:

- If the application can be clearly shown to result in a decrease in CDF, the change will be considered to have satisfied the relevant principle of risk-informed regulation with respect to CDF. (Because Figure 3 is drawn on a log scale, this region is not explicitly indicated on the figure.)

- When the calculated increase in CDF is very small, which is taken as being less than 10^{-6} per reactor year, the change will be considered regardless of whether there is a calculation of the total CDF (Region III). While there is no requirement to calculate the total CDF, should there be an indication that the CDF may be considerably higher than 10^{-4} per reactor year, the focus should be on finding ways to decrease rather than increase it. Such an indication would result, for example, if: (1) the contribution to CDF calculated from a limited scope analysis, such as the IPE, and, if appropriate the IPEEE, significantly exceeds 10^{-4}; (2) there has been an identification of a potential vulnerability from a margins type analysis; or (3) historical experience at the plant in question has indicated a potential safety concern.

- When the calculated increase in CDF is in the range of 10^{-6} per reactor year to 10^{-5} per reactor year, applications will be considered only if it can be reasonably shown that the total CDF is less than 10^{-4} per reactor year (Region II).

- Applications which result in increases to CDF above 10^{-5} per reactor year (Region I) would not normally be considered.

AND

The guidelines for LERF are:

- If the application can be clearly shown to result in a decrease in LERF, the change will be considered to have satisfied the relevant principle of risk-informed regulation with respect to LERF. (Because Figure 4 is drawn with a log scale, this region is not explicitly indicated on the figure.)

- When the calculated increase in LERF is very small, which is taken as being less than 10^{-7} per reactor year, the change will be considered regardless of whether there is a calculation of the total LERF (Region III). While there is no requirement to calculate the total LERF, should there be an indication that the LERF may be considerably higher than 10^{-5} per reactor year, the focus should be on finding ways to decrease rather than increase it. Such an indication would result, for example, if: (1) the contribution to LERF calculated from a limited scope analysis, such as that the IPE, and, if appropriate the IPEEE, significantly exceeds 10^{-5}; (2) there has been an identification of a potential vulnerability from a margins type analysis; or (3) historical experience at the plant in question has indicated a potential safety concern.

- When the calculated increase in LERF is in the range of 10^{-7} per reactor year to 10^{-6} per reactor year, applications will be considered only if it can be reasonably shown that the total LERF is less than 10^{-5} per reactor year (Region II).

- Applications which result in increases to LERF above 10^{-6} per reactor year (Region I) would not normally be considered.

These guidelines are intended to provide assurance that proposed increases in CDF and LERF are small and are consistent with the intent of the Commission's Safety Goal Policy Statement.

As indicated by the shading on the figures, the change request will be subject to an NRC technical and management review which becomes more intensive the closer the calculated results are to the region boundaries.

The guidelines discussed above are applicable for full power, low power and shutdown operations. However, during certain shutdown operations when the containment function is not maintained, the LERF guideline as defined above is not practical. In those cases, licensees may use more stringent baseline CDF guidelines (e.g., 10^{-5} per reactor year) to maintain an equivalent risk profile or may propose an alternate guideline to LERF that meets the intent of Principle 4.

The technical review that relates to the risk evaluation will address the scope, quality, and robustness of the analysis, including consideration of uncertainties as discussed in the next section. Aspects covered by the management review are discussed in Section 2.4.3, Integrated Decision Making, and include factors that are not amenable to PRA evaluation.

2.4.2.3 Comparison of PRA Results with the Acceptance Guidelines

The purpose of this section is to provide guidance on how to compare the results of the PRA with the acceptance guidelines described in Section 2.4.2.2. In the context of the integrated decisionmaking, the acceptance guidelines should not be interpreted as being overly prescriptive. They are intended to provide an indication, in numerical terms, of what is considered acceptable. As such, the numerical values associated with defining the regions in Figures 3 and 4 of this regulatory guide are approximate values that provide an indication of the changes that are generally acceptable. Furthermore, the state of knowledge, or epistemic, uncertainties associated with PRA calculations preclude a definitive decision with respect to which region the application belongs in based purely on the numerical results. The intent in making the comparison of the PRA results with the acceptance guidelines is to demonstrate with reasonable assurance that Principle 4, discussed in Section 2.1, is being met. This decision must be made based on a full understanding of the contributors to the PRA results, and the impacts of the uncertainties, both those that are explicitly accounted for in the results and those that are not. This is a somewhat subjective process, and the reasoning behind the decisions must be well documented. The following discussion provides guidance on what should be addressed. First, the types of uncertainty that impact PRA results, and methods typically used for their analysis are briefly discussed. More details can be found in the references in the bibliography.

Types of Uncertainty and Methods of Analysis

There are two facets to uncertainty that, because of their nature, must be treated differently when creating models of complex systems. They have recently been discussed under the terms aleatory and epistemic uncertainty. The aleatory uncertainty is that addressed when the events or phenomena being models are characterized as occurring in a "random," or "stochastic" manner, and probabilistic models are adopted to describe their occurrences. It is this aspect of uncertainty that gives the Probabilistic Risk Assessment the probabilistic part of its name. The epistemic uncertainty is that associated with the analyst's confidence

in the predictions of the PRA model itself, and is a reflection of his assessment of how well the PRA model represents the actual system being modeled. This has been referred to as state-of-knowledge uncertainty. In this section, it is the epistemic uncertainty that is discussed; the aleatory uncertainty is built into the structure of the PRA model itself. Because they are generally characterized and treated differently, it is useful to identify three classes of uncertainty that are addressed in, and impact the results of PRAs: parameter uncertainty, model uncertainty, and completeness uncertainty. Completeness uncertainty can be regarded as one aspect of model uncertainty, but because of its importance, it is discussed separately. The references in the bibliography may be consulted for additional information on definitions of terms, and approaches to the treatment of uncertainty in PRAs.

Parameter Uncertainty Each of the models that is used, either in developing the PRA logic structure, or to represent the basic events of that structure has one or more parameters. Typically, each of these models (e.g., the Poisson model for initiating events) is assumed to be appropriate. However, the parameter values for these models are often not known perfectly. Parameter uncertainties are those associated with the values of the fundamental parameters of the PRA model, such as equipment failure rates, initiating event frequencies, and human error probabilities that are used in the quantification of the accident sequence frequencies. They are typically characterized by establishing probability distributions on the parameter values. These distributions can be interpreted as expressing the analyst's degree of belief in the values these parameters could take, based on his state of knowledge, and conditional on the underlying model being correct. It is straightforward and within the capability of most PRA codes to propagate the distribution representing uncertainty on the basic parameter values to generate a probability distribution on the results (CDF, accident sequence frequencies, LERF, etc.) of the PRA. However, the analysis must be done to correlate the sample values for different PRA elements from a group to which the same parameter value applies (the so-called state-of-knowledge dependency - see Ref. 10).

Model Uncertainty The development of the PRA model is supported by the use of models for specific events or phenomena. In many cases, the industry's state of knowledge is incomplete, and there may be different opinions on how the models should be formulated. Examples include approaches to modeling human performance, common cause failures, and reactor coolant pump seal behavior upon loss of seal cooling. This gives rise to model uncertainty. In many cases, the appropriateness of the models adopted is not questioned and these models have become, de facto, the standard models to use. Examples include the use of Poisson and binomial models to characterize the probability of occurrence of component failures. For some issues where alternate models are well formulated, PRAs have addressed model uncertainty by using discrete distributions over the alternate models, with the probability associated with a specific model representing the analysts degree of belief in that model as being the most appropriate. A good example is the characterization of seismic hazard, where different hypotheses lead to different hazard curves, which can be used to develop a discrete probability distribution of the initiating event frequency for earthquakes. Other examples can be found in the level 2 analysis. Another approach to addressing model uncertainty has been to adjust the results of a single model through the use of an adjustment factor. However it is formulated, an explicit representation of model uncertainty can be propagated through the analysis as for parameter uncertainty. More typically, however, particularly in the level 1 analysis, the use of different models would result in the need for a different structure (e.g., where different thermal hydraulic models are used to determine success criteria). In such cases, uncertainties in the choice of appropriate model are typically addressed by making assumptions and/or, as in the case of the component failure models discussed above, adopting a specific model.

PRAs model the continuum of possible plant states in a discretized way, and are, by their very nature, approximate models of the world. This results in some random (aleatory) aspects of the 'world' not being addressed except in a bounding way, e.g., different realizations of an accident sequence corresponding to different LOCA sizes (within a category) are treated by assuming a bounding LOCA, time of failure of an operating component assumed to occur at the moment of demand, etc. These approximations introduce biases (uncertainties) into the results.

In interpreting the results of a PRA it is important to develop an understanding of the impact of a specific assumption or choice of model on the predictions of the PRA. This is true even in cases where the model uncertainty is treated probabilistically, since the probabilities, or weights, given to different models would be subjective. The impact of using alternate assumptions or models may be addressed by performing appropriate sensitivity studies, or they may be addressed using qualitative arguments, based on an understanding of the contributors to the results and how they are impacted by the change in assumptions or models. The impact of making specific modeling approximations may be explored in a similar manner.

Completeness Uncertainty Completeness is not in itself an uncertainty, but a reflection of scope limitations. The result is, however, an uncertainty about where the true risk lies. The problem with completeness uncertainty is that, because it reflects an unanalyzed contribution, it is difficult (if not impossible) to estimate its magnitude. Some contributions are unanalyzed not because methods are not available, but because they have not been refined to the level of the analysis of internal events. Examples are the analysis of some external events and the low power and shutdown modes of operation. There are issues however, for which methods of analysis have not been developed, and they have to be accepted as potential limitations of the technology. Thus, for example, the impact on actual plant risk from unanalyzed issues such as the influences of organizational performance cannot now be explicitly assessed.

The issue of completeness of scope of a PRA can be addressed for those scope items for which methods are in principle available, and therefore some understanding of the contribution to risk exists, by either supplementing the analysis with additional analysis to enlarge the scope, using more restrictive acceptance guidelines, or by providing arguments that, for the application of concern, the out-of-scope contributors are not significant. Acceptable approaches to dealing with incompleteness are discussed in the next section.

Comparisons with Acceptance Guidelines

The different regions of the acceptance guidelines require different depths of analysis. Changes resulting in a net decrease in the CDF and LERF estimates do not require an assessment of the calculated baseline CDF and LERF. Generally, it should be possible to argue on the basis of an understanding of the contributors and the changes that are being made that the overall impact is indeed a decrease, without the need for a detailed quantitative analysis.

If the calculated values of ΔCDF and ΔLERF are very small, as defined by Region III in Figures 3 and 4, a detailed quantitative assessment of the baseline value of CDF and LERF will not be necessary. However, if there is an indication that the CDF or LERF could considerably exceed 10^{-4} and 10^{-5} respectively, in order for the change to be considered, the licensee may be required to present arguments as to why steps should not be taken to reduce CDF or LERF. Such an indication would result, for example, if: (1) the contribution to CDF or LERF calculated from a limited scope analysis, such as the IPE, and, if appropriate the IPEEE, significantly exceeds 10^{-4} and 10^{-5} respectively; (2) there has been an identification of a potential vulnerability from a margins type analysis; or (3) historical experience at the plant in question has indicated a potential safety concern.

For larger values of ΔCDF and ΔLERF, which lie in the range used to define Region II, an assessment of the baseline CDF and LERF is required.

The level of detail required in the assessment of the values and the analysis of uncertainty related to model and incompleteness issues, to demonstrate compliance with the numerical guidelines, will both

depend on (1) the CLB change being considered, and (2) the importance of the demonstration that principle 4 has been met to the decision to grant the change. In Region III of Figures 3 and 4, the closer the estimates of ΔCDF or ΔLERF are to their corresponding acceptance guidelines, the more detail will be required. Similarly, in Region II of Figures 3 and 4, the closer the estimates of ΔCDF or ΔLERF and CDF and LERF are to their corresponding acceptance guidelines, the more detail will be required. In contrast, if, as an example, the estimated value of a particular metric is very small compared to the acceptance goal, a simple bounding analysis may suffice, with no need for a detailed uncertainty analysis.

Because of the way the acceptance guidelines were developed, the appropriate numerical measures to use in the initial comparison of the PRA results to the acceptance guidelines are mean values. The mean values referred to are the means of the probability distributions that result from the propagation of the uncertainties on the input parameters and those model uncertainties explicitly represented in the model. While a formal propagation of the uncertainty is the best way to correctly account for state-of-knowledge uncertainties that arise from the use of the same parameter values for several basic event probability models, under certain circumstances, a formal propagation of uncertainty may not be required if it can be demonstrated that the state-of-knowledge correlation is unimportant. This will involve, for example, a demonstration that the bulk of the contributing scenarios (cutsets or accident sequences) do not involve multiple events that rely on the same parameter for their quantification.

Consistent with the viewpoint that the guidelines are not to be used prescriptively, even if the calculated ΔCDF and ΔLERF values are such that they place the change in Region I or II, it may be possible to make a case that the application should be treated as if it were in Region II or III if, for example, it is shown that there are unquantified benefits that are not reflected in the quantitative risk results. However, care should be taken that there are no unquantified detrimental impacts of the change, such as an increase in operator burden. In addition, if compensatory measures are proposed to counter the impact of the major risk contributors, even though the impact of these measures may not be estimated numerically, then such arguments will be considered in the decision process.

While the analysis of parametric uncertainty is fairly mature, and is addressed adequately through the use of mean values, the analysis of the model and completeness uncertainties cannot be handled in such a formal manner. Whether the PRA is full scope or only partial scope, and whether it is only the change in metrics or both the change and baseline values that need to be estimated, it will be incumbent on the licensee to demonstrate that the choice of reasonable alternate hypotheses, adjustment factors, or modeling approximations or methods to those adopted in the PRA model would not significantly change the assessment. This demonstration can take the form of well formulated sensitivity studies, or qualitative arguments. In this context, "reasonable" is interpreted as implying some precedent for the alternate, such as use by other analysts, and also that there is a physically reasonable basis for the alternate. It is not the intent that the search for alternates should be exhaustive and arbitrary. For the decisions that involve only assessing the change in metrics, the number of model uncertainty issues to be addressed will be smaller than for the case of the baseline values, when only a portion of the model is affected. The alternates that would drive the result towards unacceptableness should be identified and sensitivity studies performed or reasons given as to why they are not appropriate for the current application or for the particular plant. In general, the results of the sensitivity studies should confirm that the guidelines are still met even under the alternate assumptions (i.e., change generally remains in the appropriate region). Alternatively, this analysis can be used to identify candidates for compensatory actions or increased monitoring. The licensee should pay particular attention to those assumptions which impact the parts of the model being exercised by the change.

When the PRA is not full scope, then it is necessary for the licensee to address the significance of the out-of-scope items. The importance of assessing the contribution of the out-of-scope portions of the PRA to the base case estimates of CDF and LERF is related to the margin between the as-calculated values and the acceptance guidelines. When the contributions from the modeled contributors are close to the

guidelines, the argument that the contribution from the missing items is not significant must be convincing, and in some cases may require additional PRA analyses. When the margin is significant, a qualitative argument may be sufficient. The contribution of the out-of-scope portions of the model to the change in metric may be addressed by bounding analyses, detailed analyses, or by a demonstration that the change has no impact on the unmodeled contributors to risk. In addition, it should also be demonstrated that changes based on a partial PRA do not disproportionally change the risk associated with those accident sequences that arise from the modes of operation not included in the PRA.

One alternative to an analysis of uncertainty is to design the proposed CLB change such that the major sources of uncertainty will not have an impact on the decision-making process. For example, in the region of the acceptance guidelines where small increases are allowed regardless of the value of the baseline CDF or LERF, the proposed change to the CLB could be designed such that the missing modes of operation or missing initiating events that are missing from the analysis would not be affected by the change. In this case incompleteness ceases to be an issue . Similarly, in such cases, it will not be necessary to address all the model uncertainties, but only those that impact the evaluation of the change.

If just a Level 1 PRA is available, in general only the CDF is calculated and not the LERF. An approach is presented in Reference 9 which allows a subset of the core damage accidents identified in the Level 1 analysis to be allocated to a release category that is equivalent to a LERF. The approach uses simplified event trees that can be quantified by the licensee on the basis of the plant configuration applicable to each accident sequence in the Level 1 analysis. The frequency derived from these event trees can be compared to the LERF acceptance guidelines. The guidance in the approach described in Reference 9 may be used to estimate LERF in only those cases when the plant is not close to the CDF and LERF benchmark values.

2.4.3 Integrated Decision-Making

The results of the different elements of the engineering analysis discussed in Sections 2.4.1 and 2.4.2 must be considered in an integrated manner. None of the individual analyses is sufficient in and of itself. In this way, it can be seen that the decision will not be driven solely by the numerical results of the PRA. They are one input into the decisionmaking and help in building up an overall picture of the implications of the proposed change on risk. The PRA has an important role in putting the change into its proper context as it impacts the plant as a whole. The PRA analysis is used to demonstrate that principle 4 has been satisfied. As the discussion in the previous section indicates, both quantitative and qualitative arguments may be brought to bear. Even though the different pieces of evidence used to argue that the principle is satisfied may not be combined in a formal way, they need to be clearly documented.

In Section 2.4.2.2, it was indicated that the application would be given increased NRC management attention when the calculated values of the changes in the risk metrics, and their baseline values when appropriate, approached the guidelines. The issues addressed by management, and that would, therefore, be expected to be addressed in the submittal, will include:

- The cumulative impact of previous changes and the trend in CDF (the licensee's risk management approach);
- The cumulative impact of previous changes and the trend in LERF (the licensee's risk management approach);
- The impact of the proposed change on operational complexity, burden on the operating staff, and overall safety practices;
- Plant-specific performance and other factors, including, for example, siting factors, inspection findings, performance indicators, and operational events; and Level 3 PRA information, if available;
- The benefit of the change in relation to its CDF/LERF increase;
- The practicality of accomplishing the change with a smaller CDF/LERF impact; and

- The practicality of reducing CDF/LERF, in circumstances where there is reason to believe that the baseline CDF/LERF are above the guideline values (i.e., 10^{-4} and 10^{-5} per reactor year).

2.5 Element 3: Define Implementation and Monitoring Program

Careful consideration should be given to implementation and performance-monitoring strategies. The primary goal for this element is to ensure that no adverse safety degradation occurs because of the changes to the CLB. The staff's principal concern is the possibility that the aggregate impact of changes which affect a large class of SSCs could lead to an unacceptable increase in the number of failures due to unanticipated degradation, including possible increases in common cause mechanisms. Therefore, an implementation and monitoring plan should be developed to ensure that the engineering evaluation conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of SSCs that have been evaluated. This will ensure that the conclusions which have been drawn from the evaluation remain valid. Further details of an acceptable process for implementation in specific application areas are discussed in application-specific regulatory guides.

Decisions concerning implementation of changes should be made in light of the uncertainty associated with the results of the traditional and probabilistic engineering evaluations. Broad implementation within a limited time period may be justified when uncertainty is shown to be low (data and models are adequate, engineering evaluations are verified and validated, etc.), whereas a slower, phased approach to implementation (or other modes of partial implementation) would be expected when uncertainty in evaluation findings is higher and where programmatic changes are being made which potentially impact SSCs across a wide spectrum of the plant, such as in IST, ISI and graded QA. In such situations, the potential introduction of common cause effects must be fully considered and included in the submittal.

The staff expects licensees to propose monitoring programs that include a means to adequately track the performance of equipment which when degraded can affect the conclusions of the licensee's engineering evaluation and integrated decision-making that support the change to the CLB. The program should be capable of trending equipment performance after a change has been implemented to demonstrate that performance is consistent with that assumed in the traditional engineering and probabilistic analyses that were conducted to justify the change. This may include monitoring associated with non-safety related SSCs, if the analysis determines those SSCs to be risk significant. The program should be structured such that: (1) SSCs are monitored commensurate with their safety importance, i.e., monitoring for SSCs categorized as low safety significant may be less rigorous than that for SSCs of high safety significance; (2) feedback of information and corrective actions are accomplished in a timely manner; (3) degradation in SSC performance is detected and corrected before plant safety can be compromised. The potential impact of observed SSC degradation on similar components in different systems throughout the plant should be considered.

The staff expects that licensees will integrate, or at least coordinate, their monitoring for risk-informed changes with existing programs for monitoring equipment performance and other operating experience on their site and throughout the industry. In particular, monitoring that is performed as part of the Maintenance Rule implementation can be used in cases where the monitoring performed under the Maintenance Rule is sufficient for the SSCs affected by the risk informed application. If an application requires monitoring of SSCs not included in the Maintenance Rule, or have a greater resolution of monitoring than the Maintenance Rule (component vs. train or plant level monitoring), it may be advantageous for a licensee to adjust the Maintenance Rule monitoring program rather than to develop additional monitoring programs for risk-informed purposes. In these cases, the performance criteria chosen should be shown to be appropriate for the application in question. It should be noted that plant or licensee performance under actual design conditions may not be readily measurable. In cases where actual conditions cannot be monitored or measured, an approach should be implemented by striving to use

whatever information most closely approximates actual performance data. For example, a hierarchy for establishing a monitoring program with a performance based-feedback approach may consist of a combination of the following:

1. Monitoring performance characteristics under actual design bases conditions (e.g., reviewing actual demands on EDGs, reviewing operating experience)

2. Monitoring performance characteristics under test conditions that are similar to those expected during a design basis event

3. Monitoring and trending performance characteristics to verify aspects of the underlying analysis, research, or bases for a requirement (e.g., measuring battery voltage and specific gravity, inservice inspection of piping)

4. Evaluating licensee performance during training scenarios (e.g., emergency planning exercises, operator licensing examinations)

5. Component quality controls including developing pre- and post- component installation evaluations (e.g., environmental qualification inspections, RPS channel checks, continuity testing of BWR squib valves)

As part of the monitoring program, it is important that provisions for specific cause determination, trending of degradation and failures and corrective actions be included. Such provisions should be applied to SSCs in a way that is commensurate with their importance to safety as determined by the engineering evaluation that supports the CLB change. A determination of cause is needed when performance expectations are not being met or when there is a functional failure of an application-specific SSC which poses a significant condition adverse to quality. The cause determination should identify the cause of the failure or degraded performance to the extent that corrective action can be identified that would preclude the problem or ensure that it is anticipated prior to becoming a safety concern. It should address failure significance, the circumstances surrounding the failure or degraded performance, the characteristics of the failure, and whether the failure is isolated or has generic or common cause implications (as defined in Ref. 11).

Finally, in accordance with Criterion XVI of 10CFR Part 50, Appendix B, the monitoring program should identify any corrective actions to preclude recurrence of unacceptable failures or degraded performance below expectations. The circumstances surrounding the failure may indicate that the SSC failed because of adverse or harsh operating conditions (e.g., operating a valve dry, over-pressurization of a system) or failure of another component which caused the SSC failure. Therefore, corrective actions should also consider SSCs with similar characteristics with regard to operational, design, or maintenance conditions. The results of the monitoring need not be reported to the NRC, but should be retained onsite for inspection.

2.6 Element 4: Submit Proposed Change

Requests for proposed change to the plant's CLB 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: (i) carefully review the proposed CLB change in order to determine the appropriate form of the change request; (ii) assure that information required by the relevant regulations(s) in support of the request is developed; and (iii) 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. Where the licensee submits risk information in support of the CLB change request, that information 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 CLB change request. Where the licensee's proposed change to the CLB is consistent with currently-approved staff positions, the staff's determination will be based solely on traditional engineering analysis without recourse to risk information (although the staff may consider any risk information which is submitted by the licensee). However, where the licensee's proposed change goes beyond currently-approved staff positions, the staff will normally consider both information based upon traditional engineering analysis as well as information based upon risk insights. If the licensee does not submit risk information in support of a CLB change which 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 analysis and determine whether sufficient information has been provided to support the requested change.

In developing the risk information set forth in this regulatory guide, licensees will likely 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. It is expected that licensees will propose CLB changes that will subject these SSCs to appropriate level of regulatory oversight, consistent with the risk significance of each SSC. Specific information on the staff's expectations in this regard are set forth in the application-specific regulatory guides.

2.7 Quality Assurance

As stated in Section 2.4, the staff expects that the quality of the engineering analyses conducted to justify proposed CLB changes will be appropriate for the nature of the change. In this regard, it is expected that for traditional engineering analyses (e.g., deterministic engineering calculations) existing provisions for quality assurance (e.g., 10CFR50, Appendix B for safety-related SSCs) will apply and provide the appropriate quality needed. Likewise, when a risk assessment of the plant is used to provide insights into the decisionmaking process, the staff expects that the PRA will have been subject to quality control.

To the extent that a licensee elects to use PRA information to enhance or modify activities affecting the safety-related functions of SSCs, the following, in conjunction with the other guidance contained in this guide, describe an acceptable way to ensure that the pertinent quality assurance requirements of 10CFR50, Appendix B are met and that the PRA is of sufficient quality to be used for regulatory decisions:

- utilize personnel qualified for the analysis
- utilize procedures that ensure control of documentation, including revisions, and provide for independent review, verification or checking of calculations and information used in the analyses (an independent peer review or certification program can be used as an important element in this process)
- provide documentation and maintain records in accordance with the guidelines in Section 3 of this guide
- provide for an independent audit function to verify quality (an independent peer review or certification program can be used for this purpose)
- utilize procedures that ensure appropriate attention and corrective actions are taken if assumptions, analyses, or information used in previous decision making is changed (e.g., licensee voluntary action) or determined to be in error.

Where performance monitoring programs are used in the implementation of proposed change to the CLB, it is expected that those programs will be implemented utilizing quality provisions commensurate with the

safety significance of affected SSCs. An existing PRA or analyses can be utilized to support a proposed CLB change, provided it can be shown that the appropriate quality provisions have been met.

3. DOCUMENTATION AND SUBMITTAL

3.1 Introduction

To permit the staff's audit to ensure that the analyses conducted were sufficient to conclude that the key principles of risk-informed regulation have been met, documentation of the evaluation process and findings are expected to be maintained. Additionally, information submitted should include a description of the process used by the licensee to ensure quality and some specific information to support the staff's conclusion regarding the acceptability of the requested CLB change.

3.2 Archival Documentation

Archival documentation should include a detailed description of engineering analyses conducted and the results obtained, irrespective of whether they were quantitative or qualitative, or whether the analyses made use of traditional engineering methods or probabilistic approaches. This documentation should be maintained by the licensee, as part of the normal quality assurance program, so that it is available for examination. Documentation of the analyses conducted to support changes to a plant's CLB should be maintained as lifetime quality records in accordance with Regulatory Guide 1.33 (Ref. 12).

3.3 Licensee Submittal Documentation

To support the staff's conclusion that the proposed CLB change is consistent with the key principles of risk-informed regulation and NRC staff expectations, the following information is expected to be submitted to the NRC:

- A description of how the proposed change will impact the CLB (Relevant principle: CLB changes meet regulations.)

- A description of the components and systems affected by the change, the types of changes proposed, the reason for the changes, and results and insights from an analysis of available data on equipment performance (Relevant staff expectation: All safety impacts of the proposed CLB change shall be evaluated.)

- A reevaluation of the licensing basis accident analysis and the provisions of 10 CFR Parts 20 and 100, if appropriate (Relevant principles: CLB changes meet the regulations; sufficient safety margins are maintained; defense-in-depth philosophy.)

- An evaluation of the impact of the change in licensing bases on the breadth or depth of defense-in-depth attributes of the plant (Relevant principle: Defense-in-depth philosophy)

- Identification of how and where the proposed change will be documented as part of the plants licensing basis (e.g., FSAR, TS, licensing conditions). This should include proposed changes and/or enhancements to the regulatory controls for high risk-significant SSCs which an not subject to any requirements, or where the requirements are not commensurate with the SSCs risk-significance.

The licensee should also identify:

- Those key assumptions in the PRA that impact the application (e.g., licensee voluntary actions), elements of the monitoring program, and commitments made to support the application

- SSCs for which requirements should be increased

- A description of the information to be provided as part of the plant's licensing basis (e.g., FSAR, TS, licensing condition)

As discussed in Section 2.7 of this guide, if a licensee elects to use PRA as an element to enhance or modify its implementation of activities affecting the safety-related functions of SSCs subject to the provisions of Appendix B to 10 CFR Part 50, the pertinent requirements of Appendix B will also apply to the PRA. In this context, therefore, a licensee would be expected to control PRA activity in a manner commensurate with its impact on the facility's design and licensing basis and in accordance with all applicable regulations and its QA program description. An independent peer review can be an important element of ensuring this quality. The licensee's submittal should discuss measures used to ensure adequate quality, such as a report of a peer review (when performed) that addresses the appropriateness of the PRA model for supporting a risk assessment of the CLB change under consideration. The report should address any analysis limitations that are expected to impact the conclusion regarding acceptability of the proposed change. The licensee's resolution of the findings of the peer review, certification, or cross comparison, when performed, should also be submitted. For example, this response could indicate whether the PRA was modified or a justification as to why no change was necessary to support decisionmaking for the CLB change under consideration. As discussed in Section 2.4.2, the staff's decision on the proposed license amendment will be based on its independent judgment and review, as appropriate, of the entire application.

In order to have confidence that the risk assessment conducted is adequate to support the proposed change, a summary of the risk assessment methods used should be submitted. Consistent with current practice, information submitted to the NRC for its consideration in making risk-informed, regulatory decisions will be made publicly available, unless such information is deemed proprietary and justified as such. The following information should be submitted and is intended to illustrate that the scope and quality of the engineering analyses conducted to justify the proposed CLB change is appropriate to the nature and scope of the change:

- A description of risk assessment methods used;

- The key modeling assumptions necessary to support the analysis or that impact the application;

- The event trees and fault trees as necessary to support the analysis of the CLB change; and

- A list of operator actions modeled in the PRA that impact the application and their error probabilities.

Submitted information summarizing the results of the risk assessment should include:

- The effects of the change on the dominant sequences (sequences that contribute more than 5 percent to the risk) in order to show that the CLB change does not create risk outliers and does not exacerbate existing risk outliers.

- An assessment of the change to CDF and LERF, including a description of the significant contributors to the change.

- Information related to assessment of total plant CDF - the extent of the information required will depend on whether the analysis of the change in CDF is in Region II or Region III of Figure 3. The information could include quantitative (e.g., IPE or PRA results for internal initiating events, external event PRA results if available) and qualitative or semi-quantitative information (results of margins analyses, outage configuration studies).

- Information related to assessment of total plant LERF - the extent of the information required will depend on whether the analysis of the change in LERF is in Region II or Region III of Figure 4. The information could include quantitative (e.g., IPE or PRA results for internal initiating events, external event PRA results if available) and qualitative or semi-quantitative information (results of margins analyses, outage configuration studies).

- Results of analyses that show that the conclusions regarding the impact of the CLB change on plant risk will not vary significantly under a different set of plausible assumptions.

- A description of the licensee process to ensure PRA quality and a discussion as to why the PRA is of sufficient quality to support the current application.

Cumulative Risks

As part of evaluation of risk, licensees should understand the effects of the present application in light of past applications. Optimally, the PRA used for the current application should already model the effects of past applications. However, qualitative effects and synergistic effects are sometimes difficult to model. The tracking of changes in the risk (both quantifiable and non-quantifiable) due to plant changes would provide a mechanism to account for the cumulative and synergistic effects of these plant changes and would help to demonstrate that the proposing licensee has a risk management philosophy where PRA is not just used to systematically increase risk, but is also used to help reduce risk where appropriate and where it is shown to be cost effective. The tracking of cumulative risk will also help the NRC staff in the monitoring of trends.

Therefore, as part of the submittal, the licensee should track and submit the impact of all plant changes that have been submitted for NRC review and approval. Documentation should include:

- The calculated change in risk for each application (CDF and LERF) and the plant elements (SSCs, procedures, etc.) affected by each change;

- Qualitative arguments were used to justify the change (if any) and the plant elements affected by these arguments;

- Compensatory measures or other commitments used to help justify the change (if any) and the plant elements affected; and

- A summary of the results from the monitoring programs (where applicable) and a discussion on how these results have been factored into the PRA or into the current application

As an option, the submittal could also list past changes to the plant (but not submitted to the NRC) that reduced the plant risk, especially those changes that are related to the current application. A discussion of whether these changes are already included in the base PRA model should also be included.

3.4 Implementation Plan and Performance Monitoring Documentation

As described in Section 2.5, a key principle of risk-informed regulation is that proposed performance implementation and monitoring strategies reflect uncertainties in analysis models and data. Consequently, the submittal should include a description and rationale for the implementation and performance monitoring strategy for the proposed CLB change.

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1. USNRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," *Federal Register, Vol.* 60, p. 42622, August 16, 1995.

2. "Quarterly Status Update for the Probabilistic Risk Assessment Implementation Plan," SECY-97-234, October 14, 1997.[10]

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4. USNRC, "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement," *Federal Register,* 51 FR 30028, August 4, 1986.

5. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing," Draft Regulatory Guide DG-1062, June 1997.[8]

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7. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance," Draft Regulatory Guide DG-1064, June 1997.[8]

8. USNRC, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," Draft Regulatory Guide DG-1065, June 1997.[8]

9. W.T. Pratt, et al., "An Approach for Estimating the Frequencies of Various Containment Failure Modes and Bypass Events," Draft NUREG/CR-6595, December 1997.[8]

10. Apostolakis, G. and Kaplan, S., “Pitfalls in Risk Calculations”, Reliability Engineering, Vol. 2, pages 135-145, 1981.

11. A. Mosleh et al., "Procedures for Treating Common Cause Failures in Safety and Reliability Studies," NUREG/CR-4780, Volume 2, January 1989.[8]

12. USNRC, "Quality Assurance Program Requirements," Regulatory Guide 1.33, Revision 2, February 1978.[8]

[10] Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR’s mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

[11] Requests for single copies of draft or active regulatory guides or of draft NUREG documents (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Printing, Graphics and Distribution Branch, or by fax to (301)415-5272.

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1. S. Kaplan and B.J. Garrick, "On the Quantitative Definition of Risk", *Risk Analysis*, Vol. 1, pages 11 - 28, March 1981.

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3. G.A. Apostolakis, "Probability and Risk Assessment: The Subjectivist Viewpoint and Some Suggestions", *Nuclear Safety*, 19(3), pages 305 - 315, 1978.

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6. *Reliability Engineering and System Safety*, Vol 23, (1988), special issue on the meaning of Probability in Probabilistic Safety Assessment.

7. "Severe Accident Risks: An Assessment for Five U. S. Nuclear Power Plants", NUREG 1150, U. S. Nuclear Regulatory Commission, Washington D. C., January 1991.

8. "A Review of NRC Staff Uses of Probabilistic Risk Assessment", NUREG-1489, March 1994, Appendix C.6.

9. Proceedings of *Workshop I in Advanced Topics in Risk and Reliability Analysis, Model Uncertainty: Its Characterization and Quantification*, held in Annapolis, Maryland, October 20-22, 1993, University of Maryland Press, 1996.

10. *Reliability Engineering and System Safety*, Vol. 54, nos 2 and 3, November/December 1996, Special issue on Treatment of Aleatory and Epistemic Uncertainty.

12 The citations in this bibliography provide an overview of uncertainty analysis in PRA, and themselves contain extensive references.

Attachment 3

Standard Review Plan Chapter 19

Attachment 4

Staff Requirements Memoranda
dated June 5, 1997 and November 18, 1997

June 5, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-077 - DRAFT REGULATORY GUIDES, STANDARD REVIEW PLANS AND NUREG DOCUMENT IN SUPPORT OF RISK INFORMED REGULATION FOR POWER REACTORS

The Commission has approved publication of the draft regulatory guides, standard review plans and NUREG document for a 90-day public comment period.

(EDO) (SECY Suspense: 6/13/97)

The staff should provide the Commission information on its plans for conducting public workshops. The public workshop(s) to be conducted during the public comment period should be of sufficient duration and depth to provide meaningful insights into the approaches described in the documents.

In addition, the staff should provide the Commission information on its plans for training the NRC staff 1) on the risk-informed regulatory approach(es) contained in the regulatory guidance and standard review plan documents and 2) in overall PRA methods and techniques. Particular attention should be given to increasing basic user-level knowledge of PRA methods at the regional level.

(EDO) (SECY Suspense: 9/30/97)

The staff should continue to evaluate the proposed decision criteria and the methods of ensuring conformance to the criteria. The staff should also develop guidance on how to confirm the assumptions and analyses used to justify current licensing basis changes.

SECY NOTE: THIS SRM, SECY-97-077, AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

In particular, the staff should explore the following areas to add clarity and consistency to the process.

1. The feasibility of assigning assurance levels for conformance to decision criteria.

2. The use of point values for comparisons with decision criteria, without any explicit consideration of uncertainty (i.e., how consideration of uncertainty should be explicitly considered in conjunction with using point values -- for example, use of probability limits).

3. The implications of small increases in core damage frequency (CDF) and large early release frequency (LERF) codified in the guidance documents, as a function of the uncertainty associated with the PRA results.

4. Codifying in the guidance documents the experience gained from the pilots to provide additional guidance on the "increased management attention" process when proposed changes approach the guidelines.

5. Clarifying the distinction between risk-informed and risk-informed, performance-based regulatory approaches.

The staff should continue to pursue the long range goal of improving the overall quality and consistency of PRAs performed by different licensees by promoting high quality standards.

The staff should continue its efforts to complete, in a timely manner, the pilot applications of risk-informed regulation, and to complete the draft regulatory guidance and standard review plan for inservice inspection.

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

IN RESPONSE, PLEASE
REFER TO: M971015

November 18, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle /s/

SUBJECT: STAFF REQUIREMENTS: BRIEFING ON PRA IMPLEMENTATION PLAN, 10:05 A.M. WEDNESDAY, OCTOBER 15, 1997, COMMISSIONERS CONFERENCE ROOM, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the NRC staff on recent accomplishments, the status of on-going activities, and future tasks in the staff's efforts to ensure timely and integrated agency-wide use of PRA technology and methodology in NRC regulatory activities. The Commission encouraged the staff to continue to improve the agency's PRA activities and to provide appropriate review and feedback mechanisms to ensure that PRA is appropriately used in a risk-informed regulatory framework and continues to foster a risk-informed regulatory process.

The Commission also requested that the staff:

- in their forthcoming paper identifying the issues raised during the workshop on NRC's draft guidance documents include a discussion of how much variability and what degree of uncertainty in PRAs performed by licensees can be tolerated for regulatory purposes in a risk-informed regulatory framework.

  (EDO) (SECY Suspense: 12/31/97)

- address at the next periodic briefing on the PRA Implementation Plan the extent to which the Commission's objective of establishing a risk-informed regulatory program has been communicated effectively to the NRC staff and to licensees and other external stakeholders.

  (EDO) (SECY Suspense: 5/06/98)

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO
CFO
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (by E-Mail)
PDR
DCS

Attachment 5

**Letter from Advisory Committee on Reactor Safeguards
regarding "Proposed Final Regulatory Guide 1.174 and Standard Review Plan Chapter 19
for Risk-Informed, Performance-Based Regulation," dated December 11, 1997**

Attachment 6

Memorandum from M. Cunningham to M. Hodges, dated January 7, 1998, "Summary of the Resulution of the Overall Comments Received on the General Risk-Informed Draft Regulatory Guide and Standard Review Plan"

MEMORANDUM TO: M. Wayne Hodges, Director
Division of Systems Technology
Office of Nuclear Regulatory Research

FROM: Mark Cunningham, Chief
Probabilistic Risk Analysis Branch
Division of Systems Technology
Office of Nuclear Regulatory Research

SUBJECT: SUMMARY OF THE RESOLUTION OF THE OVERALL COMMENTS RECEIVED ON THE GENERAL RISK-INFORMED DRAFT REGULATORY GUIDE AND STANDARD REVIEW PLAN

The purpose of this letter is to document the staff's overall review of the comments received from the public following the workshop held in August, 1997, to discuss the staff's draft guidance documents on risk-informed regulatory applications. Discussed herein are the comments received on draft Regulatory Guide DG-1061, "An Approach For Using Probabilistic Risk Assessment In Risk-Informed Decisions On Plant-Specific Changes To The Current Licensing Basis, " and the accompanying draft Standard Review Plan, Draft SRP Chapter 19, "Use Of Probabilistic Risk Assessment In Plant-Specific, Risk-Informed Decisionmaking: General Guidance."

In addition to the comments received at the workshop, the NRC staff has received approximately 42 sets of written comments. Attachment 1 is a list of the organizations and individuals that contributed to the public comments; however, it should be noted that some organizations commented on only a limited set of the documents issued for comment. Comment letters were received from the Nuclear Energy Institute, (NEI), the Electric Power Research Institute (EPRI), the American Society of Mechanical Engineers (ASME), the owner's groups for the four reactor vendors (General Electric, Westinghouse, Combustion Engineering and Babcock and Wilcox), one vendor (Westinghouse), 18 electric utilities, one national laboratory (Oak Ridge), five technical organizations, five other private industry organizations or individuals, and two anonymous commenters.

Attachment 2 is a discussion of the staff's resolution of the comments. The discussion is organized into three parts: (1) staff's resolution of major issues, (2) responses to individual comments and concerns from nuclear utilities, industry organizations and members of the general public, and (3) responses to the staff's questions in the areas specifically requested to be commented on in the Federal Register Announcement for the workshop (62 FR 34321). The discussion on the major issues in Attachment 2 is the same as that included in the Federal Register Notice for the final issuance of Regulatory Guide 1.174 and the accompanying SRP.

This document does not discuss the comments received on the application-specific draft guidance documents such as IST and Technical Specifications. Comments for these topics will be discussed separately when the application-specific regulatory guides and SRPs are finalized. Comments received on draft NUREG-1602, "The Use of PRA In Risk-Informed

Applications," are also not addressed since that document will not be finalized at this time, but will be used as input to staff PRA standards development activities.

Attachments: As stated

CF	Y	N
PDR	Y	N

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Attachment 1
COMMENTS ON REGULATORY GUIDES AND SRPs RECEIVED BY THE STAFF[13]

(listed by set of comments received)

1. Oak Ridge National Laboratory
2. Oak Ridge National Laboratory (additional comment set)
3. Detroit Edison
4. Jerry J. Cohen
5. TU Electric (Commanche Peak)
6. PLG, Inc.
7. Entergy
8. New York Power Authority
9. Northeast Utilities System
10. Combustion Engineering Owners Group
11. Southern California Edison
12. The B&W Owners Group
13. The Nuclear Energy Institute
14. Jebsen/Kukielka/Mattern
15. Performance Technology
16. Commonwealth Edison Company
17. Carolina Power & Light Company
18. Westinghouse
19. The Electric Power Research Institute
20. Baltimore Gas and Electric Company
21. North Atlantic Energy Service Corporation
22. Oak Ridge National Laboratory (additional comment set)
23. Holloway - Atomic Weapons Establishment
24. Detroit Edison (additional comment set)
25. PECO Nuclear
26. Tennessee Valley Authority
27. The Wesley Corporation
28. Westinghouse Owners Group
29. Duke Power Company
30. Houston Lighting & Power - South Texas
31. Arizona Public Service - Palo Verde
32. Patricia Campbell - Winston & Strawn
33. John G. Stampelos
34. Anonymous # 1
35. Anonymous # 2
36. Gregg E. Joss
37. Randy Fitsgerald - Winston & Strawn

13In some cases only a limited set of regulatory guides and SRPs were addressed in the comments, e.g., some commenters did not provide comments on DG-1061 or SRP Chapter 19.

38. Frank Krowzack - Commonwealth Edison Company
39. Boiling Water Reactors Owners Group
40. American Society of Mechanical Engineers
41. TU Electric - Commanche Peak (additional comment set)
42. Global Nuclear Alert Group

Attachment 2

DISCUSSION OF RESOLUTION OF PUBLIC COMMENTS

I. **PRINCIPAL ISSUES** This discussion is the same as that given in the Federal Register Notice for the finalization of Regulatory Guide 1.174 and the accompanying SRP.

1. Use of 10^{-4} Per Reactor Year Core Damage Frequency As An Acceptance Guideline

Issue: ***Comments were received indicating that the use of 10^{-4} per reactor year (ry) core damage frequency (10^{-4}/ry CDF) as an acceptance guideline was overly conservative, that the quantitative health objectives (QHOs) would be more appropriate for use as goals, and that it was not clear how closely staff reviewers would hold applications to this numerical criteria.***

Resolution: Revised Section 2.4.2.2 , "Acceptance Guidelines," of RG 1.174 addresses the use of 10^{-4}/ry CDF as a guideline in evaluating the acceptability of risk-informed applications. The use of 10^{-4}/ry CDF as a subsidiary goal is consistent with past Commission guidance. Figures 3 and 4 of Section 2.4.2.2 illustrate acceptance guidelines for CDF and containment large early release frequency (LERF) and indicate that for each of these metrics, three regions have been identified for use in screening acceptability of proposed changes in current licensing bases. Region III, shown in the figures and discussed in the text, has been identified as representing a sufficiently low CDF or LERF increase that, in general, program changes associated with this region may be permitted without a detailed assessment of the baseline CDF/LERF. As discussed in RG 1.174, if there are indications that the baseline CDF and/or LERF are above the guideline values, additional evaluation would be needed even though the calculated changes in CDF or LERF are small and in Region III. In Section 2.4.2.3, "Comparison of PRA Results with the Acceptance Criteria," it is stated that the acceptance guidelines (lines separating the regions) are not to be interpreted in an overly prescriptive manner and that they are intended to provide an indication, in numerical terms, of what is considered acceptable. Graduated shading has been added to the guideline figures to indicate regions in which proposed changes will be subject to gradually more intensive NRC technical and management review. Regarding the use of the QHOs, in Section 2.1, "Risk-Informed Philosophy," it is stated that the use of the QHOs in lieu of LERF is an acceptable approach provided that appropriate consideration is given to the methods and assumptions used in the Level 3 analysis and in the treatment of uncertainties. Also, in Section 2.4.3, "Integrated Decision-Making," it is noted that Level 3 PRA information can be submitted and will be considered in support of those cases in which increased NRC management attention is needed during the review (e.g., when the calculated CDF/LERF changes and baseline values are close to the acceptance guidelines).

2. Definition of Risk Neutral

Issue: ***A number of comments were received indicating that there was a need for a definition of risk neutral applications and that increased NRC management and technical review should not be required for risk increases below some threshold.***

Resolution: See responses to Issues Number 1 and 3 addressing very small increases in risk.

3. Allowance for Very Small Increases in Risk

Issue: ***Comments received stated that facilities with CDFs greater than 10^{-4}/ry should be allowed small risk increases and that the level of effort and information required in submittals was excessive for small risk increases.***

Resolution: Section 2.4.2.2, "Acceptance Guidelines," addresses the treatment of small increases in risk using the metrics of CDFand LERF. As noted in the discussion for Issue Number 1, this section has been revised and now includes a special category of application in which the estimated level of CDF/LERF increase associated with the application is sufficiently low such that, in general, program changes associated with this region may be permitted without a detailed assessment of the baseline CDF/LERF. This category is displayed in Figures 3 and 4 of Section 2.4.2.2.

4. Treatment of Uncertainties

Issue: ***Comments received stated that inclusion of uncertainty could lead to confusion regarding the decision criteria and that the use of PRA inherently takes care of uncertainty.***

Resolution: In response to this comment the staff considered several alternative approaches to the treatment of uncertainties, and it was concluded that the approach that was described in the draft regulatory guide (DG-1061) appeared to be the most practical and useful approach at this time although there was a need to clarify the text for this subject. Uncertainty is addressed in Section 2.4.2.3, "Comparison of PRA Results with the Acceptance Guidelines," in Regulatory Guide 1.174. In this section, it is noted that it is important when interpreting the results of a PRA to develop an understanding of the impact of a specific assumption or choice of model on the results. The impact of using alternative assumptions and models may be reasonably evaluated using appropriate sensitivity studies. The major sources of uncertainty should be understood, but it is not always necessary to perform elaborate uncertainty evaluations (e.g, propagation of uncertainty distributions).

5. Quality of PRA

Issue: ***Numerous comments were received indicating concern that the PRA standards included in draft NUREG-1602 were unnecessarily high for many risk-informed applications. It was also indicated that the requirements for PRA quality were not clear and that graded levels of PRA quality should be provided for different applications.***

Resolution: The issue of PRA quality is addressed in revised Section 2.4.2.1 of RG 1.174, entitled, "Scope, Level of Detail, and Quality of the PRA." In this section it is stated that PRA quality should be commensurate with the application for which it is intended and on the role that PRA results play in the integrated decision process. A PRA used in a risk-informed application should be performed in a manner that is consistent with accepted practices, and be commensurate with the scope and level of detail which are also discussed in Section 2.4.2.1 of RG 1.174.

The NRC has not developed its own formal standard nor endorsed an industry standard for PRA quality, however, it supports such a standard and expects that one will be available in the future. Draft NUREG-1602, "Use of PRA in Risk-Informed Applications," was cited in draft Regulatory Guide DG-1061 as a potential reference for PRA methods that could be used to support regulatory decision making. There were a number of comments indicating that the "PRA standard" represented by draft NUREG-1602 was excessive for many risk-informed applications not requiring sophisticated or state-of-the-art methods. While it was not intended that draft NUREG-1602 be used universally as a PRA standard, it is recognized that it would be more useful to have a standard that addresses the differing needs for PRA scope and detail depending on the application. Accordingly, draft NUREG-1602 has been removed as a reference in RG 1.174, and a standard is being planned in a joint effort with the

industry. Other means for addressing PRA quality include the use of peer review and PRA cross comparisons. PRA peer review activities such as those that are presently being done under various industry PRA certification programs are examples. Neither peer review nor a PRA certification or cross comparison replaces a staff review in its entirety, and licensees need to provide justification why the PRA is adequate for the proposed application. In the interim, until a consensus PRA standard is available, the NRC staff will evaluate PRAs submitted in support of specific applications using the guidelines given in RG 1.174 and Chapter 19 of the Standard Review Plan.

6. LSSC Monitoring Needs

Issue: ***Comments received indicated that the draft guidance placed too much importance on monitoring of low safety significant components (LSSCs). It was also indicated that monitoring performed under the Maintenance Rule should be acceptable for risk-informed programs.***

Resolution: Section 2.5, "Element 3: Define Implementation and Monitoring Program," has been revised to clarify monitoring needs for LSSCs. While details for monitoring LSSCs will be provided in the application-specific guidance documents, the following principal needs should be satisfied for all applications. Monitoring programs should be proposed that are capable of adequately tracking the performance of equipment which when degraded could alter the conclusions that were key to supporting the acceptance of the program. It follows that monitoring programs should be structured such that SSCs are monitored commensurate with their safety significance. Monitoring that is performed as a part of the Maintenance Rule implementation can be used in cases where the SSCs affected by the risk-informed application are also covered under the Maintenance Rule.

7. Shutdown and Temporary Plant Condition

Issue: ***Several commenters noted that the guidelines proposed did not distinguish between power operation and shutdown and did not address temporary plant conditions. Separate guidelines for these conditions were suggested.***

Resolution: In response to these comments, Section 2.4.2.2 of R.G. 1.174 has been expanded to address the shutdown condition. Specific guidance for temporary plant conditions has not been added, but will be considered in a future update of R.G. 1.174.

8. Documentation Needs

Issue: ***Many commenters stated that the documentation requirements in the drafts were excessive and unmanageable, particularly for proposals involving small changes in risk. It was also suggested that certain documentation items should not be required to be submitted for the staff's initial review, provided that more complete documentation be maintained at the utility if the need were to arise later for its review.***

Resolution: In response to the comments received, Section 3 of RG 1.174 has been reevaluated to determine what items listed in the draft were not necessary. As a result, a number of documentation items, particularly with regard to the PRA, have been removed in the final regulatory guide, and the SRP has been revised to be consistent.

9. Overall cost benefit

Issue: ***This issue was highlighted by NEI in its comment letter and was also included in a number of other comment letters. A concern was expressed that the resources required by licensees to prepare proposals and to subsequently implement NRC approved risk-informed changes to the CLB will be too high considering the benefit in terms of burden reduction.***

Resolution: The question of how cost beneficial it will be for utilities to prepare proposals for risk-informed changes to their current licensing bases and to implement such programs after review and approval by the NRC will only be fully answered after the industry and the NRC gain further experience in these types of programs. Certainly, the pilot plant program proposals that are currently being reviewed for application to technical specifications, graded quality assurance, and inservice testing and inspection, will provide useful insights into the potential cost savings available through these programs. While it is not the NRC's responsibility to ensure that such risk-informed programs are cost beneficial, it is believed that such programs can enhance safety by better focusing utility and NRC resources on the most important safety areas in reactors, and this philosophy is consistent with the Commission's policy statement on the use of PRA methods in nuclear regulatory activities. During the preparation of the final regulatory guide and standard review plan section for general guidance, attention was paid to those areas where utility resource needs could be reduced thus improving the cost-beneficial aspects of the risk-informed process while still maintaining an appropriate level of safety. Examples of sections in RG 1.174 where this is reflected in the final guidance are Section 2.4.2.1 entitled, "Quality and Scope of the PRA", in which it is stated that the level of detail required to support an application can vary depending on the application, and that not all applications require that an expensive, detailed PRA be acquired; Section 2.4.2.2, "Acceptance Guidelines", where a special category of risk-informed proposal has been identified as having a sufficiently low estimated increase in CDF and LERF, that generally for such cases, the proposed program will be considered without a detailed assessment of baseline CDF/LERF (i.e., Region III of Figures 3 and 4 in RG 1.174); and in Section 3, "Documentation", where some of the items that were identified in the draft regulatory guide and SRP as being needed in program submittals have been removed since they were not judged as necessary.

II. RESPONSES TO INDIVIDUAL COMMENTS AND CONCERNS EXPRESSED BY NUCLEAR UTILITIES, INDUSTRY ORGANIZATIONS AND THE GENERAL PUBLIC

The table below contains responses to public comments on draft general guidance documents that were issued for public comment in June 1997 (62 FR 34321). These documents included Draft Regulatory Guide DG-1061 and draft Standard Review Plan (SRP) Chapter 19. While all comments submitted to the staff have been reviewed, explicit responses are provided here for those comments that reflected significant issues and concerns regarding the staff's proposed approach, including differing views on an issue. In reviewing the comments received, the staff observed similar comments from multiple sources in many cases. In the table that follows, the text provided under the "Comment" heading in column 2 is taken from one source, and best captures the similar concerns or issues expressed by the other sources listed in column 3. The acronyms for the sources listed in column 3 of the table are defined below.

Acronym	Definition
APS	Arizona Public Service Co.
AWE	Atomic Weapons Establishment (United Kingdom)
B&WOG	Babcock and Wilcox Owners Group
BG&E	Baltimore Gas and Electric
BWROG	Boiling Water Reactors Owners Group
P. Campbell	Patricia Campbell
CEOG	Combustion Engineering Owners Group
CP&L	Carolina Power and Light
ComEd	Commonwealth Edison Co.
DEC	Detroit Edison Company
DPC	Duke Power Co.

EI	Entergy Operations Inc.
EPRI	Electric Power Research Institute
GNAG	Global Nuclear Alert Group
Jebsen et. al	Jebsen, Kukeilka & Mattern
NEI	Nuclear Energy Institute
NYPA	New York Power Authority
North Atlantic	North Atlantic Energy Service Corp.
Northeast Utilities	Northeast Utilities System
ORNL	Oak Ridge National Laboratory
Performance Technology	Performance Technology
PECO	PECO Energy Co.
PLG	PLG Inc.
SCE	Southern California Edison
WC	The Wesely Corporation
WOG	Westinghouse Owners Group/ Westinghouse Electric
workshop	Workshop Comments (from transcript)

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

Num.	Comment	Source	Subject	Staff Response
1	The commenter questions the validity of acceptance guidelines that are based on subsidiary objectives of the Safety Goal Policy Statement.	Performance Technology	acceptance guidelines	Staff maintains that core damage frequency and large early release frequency provide most practical and best available vehicles for ensuring that the intent of the Commission's Safety Goal Policy is met. However, use of the QHOs as acceptance guidelines is not precluded in RG 1.174[14].
2	Promulgation of acceptance guidelines will not be an effective regulatory tool.	Northeast Utilities	acceptance guidelines	Staff disagrees. Guidelines will help staff assure that increases in risk are small and consistent with the Commission's Safety Goal policy statement.
3	Plants with CDF above 1E-4/ry should still be allowed to have small risk increases.	B&WOG BWROG EPRI NYPA North Atlantic PL&G APS	acceptance guidelines	The staff agrees and has modified the regulatory guidance to permit such increases under certain conditions..

14Previously identified as DG-1061

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

4	Acceptance guidelines should be based on ΔCDF and ΔLERF, not absolute CDF or LERF.	NEI GNAG TVA BWROG WOG B&W OG CEOG	acceptance guidelines	The staff finds this acceptable for only very small changes in risk. Acceptance guidelines on absolute CDF and LERF for very small changes have been removed from the guidance.
5	Point estimate for CDF or LERF ok for very small changes; use mean value from uncertainty analysis for larger increases.	SCE CEOG	acceptance guidelines	The staff agrees that point estimates may be sufficient for some applications and has reflected this in the final guidance documents. However, the burden is on the licensee to justify the use of point estimates as being appropriate.
6	NRC mgmt. & tech review process includes consideration of regulatory analysis guidelines which is inconsistent with plant specific nature of RG/SRP.	BWROG	acceptance guidelines	The staff disagrees. Some factors considered for generic decisions are valid for consideration in plant-specific decisions. For example, consideration of man-rem reduction or cost savings.
7	Requirement for licensees to track cumulative impact of all plant changes on risk should be better defined.	BWROG CEOG	acceptance guidelines	The staff has supplemented the documentation section of RG 1.174 to clarify the staff's guidance that licensees track and report cumulative changes in CDF/LERF and describe the related information that should be included in a licensee's submittal.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

8	All licensees will be in "increased management attention" group because of absolute CDF limit of 1E-04/ry.	NEI GNAG TVA BWROG CEOG	acceptance guidelines	The staff has revised its guidance so as to permit very small changes in risk without increased management and technical review.
9	Safety goals used as criteria in Principle 4; but subsidiary objectives used in guidelines; this is inconsistent.	B&WOG	acceptance guidelines	Staff has modified the statement of Principle 4 to more clearly reflect the relationship between the acceptance guidelines and the Safety Goal policy.
10	Allow option to perform level 3 PRA and compare results to QHOs.	DPC NEI GNAG TVA WOG APS	acceptance guidelines	Staff has revised its expectations in Section 2.1 of RG 1.174 to make it clear that the Level 3 option is available.
11	CDF = 1E-04/Ry should not be used as a fundamental goal or regulatory limit.	DPC APS	acceptance guidelines	Staff disagrees. Staff position is that avoiding core damage in a U.S. reactor is a premier NRC objective. Staff is currently considering whether or not they should recommend that the Commission develop a formal Safety Goal regarding core damage frequency.
12	1E-04/Ry guideline for core damage frequency is reasonable.	ComEd	acceptance guidelines	Staff agrees.
13	Provide guidance for "bundling changes."	CP&L WOG PL&G	acceptance guidelines	Staff has incorporated additional guidance in RG 1.174 and SRP Chapter 19 that addresses the integration of multiple changes to the CLB in a single submittal.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

14	In regards to change in risk: define the terms "small" and "very small".	CEOG P. Cambell	acceptance guidelines	Staff has defined "small" and "very small" changes in risk in quantitative terms in RG 1.174 and SRP Chapter 19. A change in CDF less than 1E-06/Ry or a change in LERF less than 1E-07/Ry are considered to be very small. Changes which are larger than these, and still permitted, are considered small.
15	Application of safety principles in combination with use of subsidiary objective in acceptance guidelines is too conservative.	B&WOG ComEd	acceptance guidelines	Staff disagrees. Staff position is that they compliment one another, i.e., acceptance guidelines provide an effective "roadmap" for satisfying principles.
16	Expand DG-1061 to treat temporary changes. Follow EPRI PSA Applications guide.	NEI GNAG TVA WC	define change	In the current versions of RG 1.174 and SRP Chapter 19 temporary changes are treated the same way as permanent changes. As discussed in SECY-97-287, staff agrees that additional consideration should be given to treating temporary changes separately. If new guidance is developed, it would be included in a revision to the risk-informed guidance documents or possibly in a separate guidance document.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

17	Use of 10CFR Part 54 definition of CLB not appropriate. Limit scope to regulations, orders, license conditions, exemptions and technical specifications.	NEI GNAG TVA PECO	define change	Staff disagrees. Staff has retained the 10 CFR Part 54 definition of CLB. However, to ensure that there is no legal ambiguity, the staff has expanded its explanation of the term "current licensing basis" in RG 1.174 to make clear to licensees that in the context of the RG 1.174 , the term "current licensing basis" is used only for convenience and is not intended to imply that there is any change in the types of licensee changes requiring NRC approval.
18	Provide guidance on the use of PRA for "10CFR 50.59" evaluations.	CP&L North Atlantic P. Campbell	define change	The staff intends to consider this issue as a part of larger considerations related to revisions to 10CFR 50.59.
19	Provide more discussion on application of the guide to exemptions.	Northeast Utilities	define change	Guidance for using PRA to support an exemption request is the same as for other changes to the CLB (same principles, expectations and acceptance guidelines apply). For this reason, additional "exemption-specific" guidance has not been provided in RG 1.174.
20	Legal requirements for using risk insights in changing the CLB should be discussed.	Jebsen et. al	define change	Using risk insights in support of changes to the CLB is voluntary; there are no legal requirements.
21	Staff should discuss how risk-informed changes to 10CFR Part 50, Appendix R and Appendix K would be handled.	Jebsen et. al	define change	Risk-informed changes to existing regulations would be treated most likely with a pilot review. Staff does not think it appropriate to speculate on the details of a potential future application of the regulatory guide.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

22	Clarify threshold for re-submittal when PRA changes. Propose only when there is significant error that invalidates conclusions of previous submittal.	BG&E	documentation	Actual thresholds will be application-dependent. However, staff has emphasized in the Performance Monitoring section of RG 1.174 that a licensees' monitoring program should be capable of identifying when conclusions drawn from an engineering evaluation (including a PRA) are no longer valid.
23	Documentation of PRA requested is far too much.	BG&E B&WOG CEOG APS	documentation	The staff has reviewed the documentation section of DG-1061 to identify requested information that in all likelihood would not normally be necessary to complete a majority of reviews. This review revealed several information requests that were considered unnecessary and were removed from the guidance.
24	Staff should make general submittal requirements consistent with those of Technical Specification (TS) pilot review.	SCE	documentation	In developing the final versions of RG 1.174 and SRP Chapter 19, the staff has considered the results of the completed pilot programs for Technical Specifications and Graded Quality Assurance and made appropriate revisions to the guidance documents.
25	Using the order of minimal cutsets as a measure of defense-in-depth may not always be effective since in some minimal cutsets all mitigators may be worthless	AWE (UK)	engineering evaluation	The staff recognizes the validity of this comment. The staff's guidance in SRP chapter 19 regarding defense-in-depth emphasizes the need for close scrutiny of the specific SSCs that show up in minimal cutsets. It is unlikely that worthless mitigators would not be identified in the staff's review.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

26	In light of the blended (deterministic and probabilistic) approach, the emphasis on numerical limits for PRA seems unnecessary.	WOG	general philosophy	The staff disagrees. Staff position is that guidance documents address a broad range of potential applications, some for which quantitative analysis will play a large role and others for which quantitative analysis will be de-emphasized and play a small role.
27	Too many "layers of conservatism and regulation" in documents to permit significant burden reduction and optimal application of scarce resources.	WOG APS	general philosophy	The staff disagrees with this perception. However, the staff acknowledges that a less restrictive approach could have been taken in developing the guidance. However, the staff adopted the more restrictive approach because of uncertainties and to account for the fact that safety issues continue to emerge notwithstanding the maturity of the nuclear power industry.
28	Expectation that licensee must be prepared to improve safety as well as relax requirements is appropriate.	WOG ComEd	general philosophy	The staff agrees. This view is consistent with the Commission's policy as stated in their policy statement on use of PRA in regulatory matters.[15]
29	RGs/SRPs should not call for increase in requirements, e.g., commitments to enhance IST methods.	SCE	general philosophy	The staff disagrees because such a position would be inconsistent with Commission policy as stated in their policy statment on use of PRA in regulatory matters.

1560 FR 42622; August 16, 1995.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

30	Acceptance criteria for use with importance measures not provided. PSA applications guide criteria should be used.	BWROG	importance measures	Appropriate acceptance criteria will be specified for each particular application that uses importance measures.
31	Include the "ALARP" principle in general guidance	AWE (UK)	integrated decision making	ALARP is a fundamental principle of reactor regulation in the United Kingdom. Its definition is: "Risks must be reduced until the further costs that would be incurred would be in gross disproportion to the risk reduction benefits." The staff has not included this as a key safety principle in large part because it is not a part of the Commission's current policy on use of PRA in regulatory matters. However, it should be noted that the Commission does do formal risk-based cost/benefit analysis when considering new generic requirements.
32	Guidance on using qualitative evaluations not sufficient; not clear how qualitative evaluations will be used in decision process.	NEI GNAG TVA	integrated decision making	Additional guidance may be provided in application-specific guidance documents. However, in general, licensees should provide qualitative analysis when it clearly supports the conclusion that a safety principle has been satisfied.
33	Want more guidance on how to integrate information from PRA and other sources in engineering evaluation.	workshop	integrated decision making	Additional guidance will be provided in application-specific guidance documents or in lead plant reviews as experience is gained in using the general guidance documents.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

34	Provide guidance on how much defense-in-depth is enough.	CP&L	integrated decision making	Same response as immediately above.
35	More guidance on the use of expert panels is requested.	WOG	integrated decision making	Same response as immediately above.
36	Can a licensee use PRA as basis for not taking action in response to a GL?	P Cambell	integrated decision making	A Licensee could use RG 1.174 as guidance in making a proposal that the change in *their* licensing basis due to an imposition of a generic position is not warranted. This would be analogus to using RG 1.174 to support a request for an exemption from a requirement.
37	Separate the guidance for applying PRA to decisions and the standard against which the PRA will be reviewed.	AWE (UK)	integrated decision making	The staff has applied this segregation to a degree (i.e., the guidance is in RG 1.174, and the standard for review is articulated in SRP Chapter 19).
38	The terms “adequate defense-in-depth”, “sufficient safety margins” are subjective and should be better defined.	STP	integrated decision making	These terms have been defined and exemplified in the final guidance documents. They will become more meaningful in the context of a particular application.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

39	Performing a PRA and evaluating the impact of the change on defense-in-depth are redundant. Evaluation regarding defense-in-depth should not be required	Performance Technology	integrated decision making	Staff disagrees. As discussed in section 2.4 or RG 1.174 the staff believes that the evaluations are complementary, i.e., PRA can be used to determine the extent of defense-in-depth.
40	Simplified level 2 approach is too conservative; utility level 2 models are more technically acceptable; insufficient to address containment flooding and RPV vent influences on LERF.	BWROG	Level 2	The Staff's bounding approach for level 2 PRA has been revised and included in NUREG/CR-6595, *An Approach for Estimating the Frequencies of Various containment Failure Modes and Bypass Events.* However, licensees are encouraged to use plant specific methods.
41	Appendix B of DG-1061 could help plants without Level 2 PRA; but method needs to be supported with plant specific data.	NEI GNAG TVA	Level 2	Staff agrees.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

42	Guides dictate need for costly expansion of PRA program at utility including: increased PRA scope, detailed, quality verification, lengthy submittal, support for RAIs, performance monitoring requirements, PRA updating, etc.	NEI GNAG TVA BWROG EI SCE PECO B&WOG CEOG Performance Tech. APS	licensee burden	The staff believes this will not be the case for most applications. The perceived implication of draft NUREG-1602 that a full scope, sophisticated and elaborate PRA will be required for each application, was not intended. The staff has revised its guidance for performance monitoring and documentation for the purpose of removing unnecessary licensee burden.
43	Performance of key SSCs credited in PRA should be monitored in terms of reliability and availability.	SCE	performance monitoring	Staff agrees. This objective has been incorporated in RG 1.174 .
44	What should a licensee do, if performance data is obtained such that there is a risk increase over what had been previously submitted?	STP	performance monitoring	10 CFR 50.9 requires complete and accurate reporting of information provided to the Commission, and reporting within two days of discovery of information that has a significant implication for public health and safety. In general, licensees would need to determine if the circumstances surrounding identified risk increase satisfied the threshold for reporting under 10 CFR 50.9. If this threshold was not met, the increase would normally be reported as part of the cumulative increase in risk when the next risk-informed submittal was made (per RG 1.174) or in the update for the safety analysis report (per 10CFR 50.71).

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

45	Don't need uncertainty analysis if you have performance monitoring. It will tell you if you made the wrong decision.	B&WOG	performance monitoring	Staff disagrees. Performance monitoring cannot resolve all uncertainties, (e.g., model and level 2 phenomena).
46	Performance monitoring of low safety significant SSCs is costly, will achieve insignificant risk reduction and should not be required.	NEI GNAG TVA SCE PECO B&WOG CEOG WOG APS	performance monitoring	As discussed in RG 1.174 , the staff's position is that with respect to performance monitoring, SSCs should be treated commensurate with their safety importance. In general this allows for a reduced level of effort in monitoring the performance of low safety significant SSCs.
47	Long term monitoring program should focus on changes in PRA that affect conclusions of previous changes to CLB, not assumptions in PRA; documentation and reporting of the latter would be burdensome for licensee and NRC.	SCE DPC ComEd	performance monitoring	Staff agrees in general. The nature of the application will dictate the specifics.
48	Scope of performance monitoring should be industry-wide.	ORNL	performance monitoring	RG 1.174 encourages licensees to incorporate industry-wide experience in their monitoring program

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

49	Guidance on performance monitoring and feedback is too general. It should be made clear what a licensee needs to do to satisfy the NRC.	NEI GNAG TVA	performance monitoring	Specifics will be defined for a given application.
50	Recognize industry peer review and certification process as acceptable alternatives to NUREG-1602 for ensuring PRA quality. Refine NUREG-1602 as a PRA standard and use a graded (by application type) approach in the interim.	NEI GNAG TVA WOG BWROG B&WOG ComEd	PRA quality	RG 1.174 and SRP Chapter 19 explicitly acknowledge the useful role peer review and PRA certification programs can play in developing a PRA of sufficient quality for risk-informed regulation. Draft NUREG-1602 is being finalized as part of standards development. References to the guidance in draft NUREG-1602 have been removed from RG 1.174 and SRP Chapter 19.
51	Consider IPERS[16] review process	WOG	PRA quality	The staff has considered the IPERS review process in its development of SRP Chapter 19.
52	Clarify intent of requesting an independent audit function to verify quality of PRA (for program or for each application?)	BG&E	PRA quality	This should be aimed at the program.

16IPERS stands for the International Atomic Energy Agency's *International Peer Review Service*.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

53	DG-1061 indicates in several places that the level of sophistication and detail of PRA can vary with application; but never indicates when the draft NUREG-1602 state-of-the art PRA is required. The suggestion is that the "trigger" is when the "increased management attention" region of the acceptance guidelines is entered.	BWROG SCE	PRA quality	As discussed in RG 1.174 , the staff expects the licensee to use its judgement of the complexity and difficulty of implementing the proposed CLB change to decide upon appropriate PRA to support the change. A key part of doing the engineering analyses expected by the staff is applying technical judgement in determining the quality and scope of the PRA, including the analysis of uncertainties, that is appropriate for the nature and scope of the proposed CLB change. The existence of a threshold for increased management attention in the staff's review should not be interpreted as a gauge for when to do a more rigorous or sophisticated analysis. The factors that will be considered when there is increased management attention are listed in section 2.4 of RG 1.174 . These factors will not be considered until after the staff has confidence in the numerical results the licensee has presented.
54	Should lower the standard of the PRA required to support application. Acknowledge and define a graded approach to PRA for applications.	NEI TVA WOG PECO APS	PRA quality	The staff acknowledges the acceptability of a graded approach; however, until more experience with risk-informed changes is gained and appropriate standards are developed, licensees must determine and propose the "grade" of the analysis for staff review. Insight regarding what may or may not be acceptable to the staff can be obtained by examining SRP Chapter 19.
56	How will staff ensure that previous changes to CLB have been incorporated in PRA?	B&WOG	PRA quality	The information that licensees are to submit in this regard is provided in section 3.3 of RG 1.174. Guidelines for the staff's review of this information are provided in section II of SRP Chapter 19. Ideally, the licensee will have incorporated the effects of all past applications into the model being used to analyze the current change.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

57	PRA quality "requirements" in DG-1061 inconsistent with TS pilot. Don't believe TS pilot meets DG-1061.	BG&E	PRA quality	Staff has clarified its previous guidance regarding PRA quality and incorporated additional guidance to ensure consistency with positions taken in pilot reviews.
58	PRA cross comparison used in TS pilot should be acceptable alternative for audits and peer review of PRA and specific changes to CLB.	SCE	PRA quality	Staff agrees. RG 1.174 and SRP Chapter 19 acknowledge the useful role that both of these techniques can play in developing a PRA of sufficient quality for risk-informed regulation.
59	Development of a national consensus PRA standard is a good goal but should not be in critical path of risk-informed regulatory guides.	NEI GNAG TVA	PRA quality	Staff agrees. Standards development is being pursued in a separate but related program.
60	Staff should not require independent peer review of PRA for risk-informed changes.	North Atlantic	PRA quality	Peer review is not required; however, staff encourages such review as an effective means of ensuring quality in the PRA.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

61	Guidance on quality assurance inconsistent with what has been required thus far in TS pilot.	SCE CEOG	QA	The staff acknowledges some inconsistency between pilot applications and RG/SRP development because of the schedules these activities have been on. However, the staff has reviewed the guidance for quality assurance and continues to believe that it reflects a reasonable approach. However, this does not preclude proposal of an alternate approach. It should also be noted that the staff has revised the guidance to include references to the use of the owners group cross comparison technique for incorporating quality in the PRA and has removed draft NUREG-1602 as a reference for PRA quality.
62	Guidelines on ensuring quality are reasonable, with exception of records retention.	NEI GNAG TVA CEOG	QA	Guidance on retention of quality records instructs licensees to follow RG 1.33 which the staff believes is appropriate. However, this does not preclude proposal of alternate approaches.
63	Clarify parenthetical re: peer review for quality assurance (DG-1061 pp. 22).	BG&E	QA	Verification of calculations is a necessary part of quality assurance. This may be done by those doing peer review or by others. There is no intent to dictate that the peer review team must check calculations.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

64	Change wording in DG-1061 section 2.7, i.e., remove the phrase "..provide documentation" from the third bullet, but leave in the phrase "maintain records".	CEOG	QA	Wording will stand. Intent is to make clear which documentation should be submitted to NRC and which documentation should be maintained on site as a quality record. Deficiencies in documentation submitted for review (excluding false and misleading information) are addressed with requests for additional information. They do not normally constitute violations of 10 CFR Part 50, Appendix B. In regard to corrective actions when errors are identified, the guideline in RG 1.174 as written is consistent with 10 CFR Part 50 Appendix B. Tests for significance of errors and corresponding corrective actions should be incorporated in the procedures developed to meet the guideline.
65	Clarify item 5) regarding quality assurance in section 2.7 of DG-1061. (Commenter questions the need to have procedures for determing corrective actions if an error is discovered in the bases for a previous risk-informed decision.)	APS	QA	The staff's concern here is with errors that impact conclusions which formed the basis for a previous change to the CLB approved by the NRC. There must be a process that evaluates the error to determine if previous facility changes should be reconsidered, if additional analysis is necessary or if the NRC should be informed per 10 CFR 50.9.
67	Formal program for qualifying personnel should be required.	BG&E	QA	Nuclear power plant personnel that provide engineering support in the development of risk-informed changes to the CLB should be trained in accordance with 10 CFR 50.120. Services of contractors should be obtained in accordance with 10 CFR Part 50, Appendix B.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

68	Quality assurance of PRA should be consistent with that of other licensing analysis.	EPRI	QA	Staff agrees. 10CFR Part 50, Appendix B provides the standard in both cases.
69	The safety principles are ok but subjectivity may cause burden on implementation.	B&WOG	safety principles	The staff acknowledges the potential for subjectivity. However, this concern should diminish as experience is gained in satisfying the principles.
70	Add a sixth key principle that reflects the desire to use resources efficiently in implementing risk-informed processes.	PL&G	safety principles	The staff recognizes that this is an important principle and notes that it is already highlighted in the Commission's policy statement on the use of PRA. Licensees are free to voice concerns at any time during any review (risk-informed or not) if they believe that this principle is not being adhered to in a reasonable manner. However, the staff has not included it in their key principles for risk-informed changes to the CLB because of its much broader application to regulatory matters.
71	Safety principals are reasonable set; need more guidance on what is required to satisfy them.	NEI GNAG TVA	safety principles	Some additional guidance for satisfying the principles has been included in the final guidance documents. Further guidance will be provided in application specific RGs and SRP Chapters.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

72	The requirement to "maintain" safety margins should be changed to say that margins should "remain acceptable"; this allows for small reductions in margin which will accompany some changes to CLB.	SCE	safety principles	Staff agrees. The principle now states that *sufficient* safety margins be maintained, which allows for reduction in a margin of safety as a result of a risk-informed application.
73	Most utilities don't have shutdown PRAs; should allow use of qualitative analysis based on generic studies in place of quantitative analysis for shutdown risk.	SCE	shutdown and external events	In its revised guidance the staff has made allowance for using less than a full scope PRA when the impact of the out-of-scope items on the decision at hand can be addressed in some other way (e.g., bounding analysis or valid arguments that there is no impact).
74	CDF and LERF for shutdown conditions are arbitrary quantities because of the variations in conditions.	NEI GNAG TVA	shutdown and external events	This staff has addressed this issue explicitly in SECY-97-287.
75	Consider separate decision guidelines for low-power and shutdown assessments.	workshop	shutdown and external events	This staff has addressed this issue explicitly in SECY-97-287.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

76	State-of-the art for shutdown and external events PRA not as advanced as for at-power conditions. Not practical to expect licensees to be able to quantify risks for those conditions.	NEI GNAG TVA WOG	shutdown and external events	This staff has addressed this issue explicitly in RG 1.174 with flexible guidelines that allow the use of qualitative analysis to address issues that are difficult to treat quantitatively.
77	Combining PRA results from power, shutdown, fire etc., which have very different levels of conservatism and uncertainty, will make result invalid and unrealistic.	EI	shutdown and external events	This staff has addressed this issue explicitly in RG 1.174 with flexible guidelines that allow the use of qualitative analysis to address issues that are difficult to treat quantitatively.
78	Level of uncertainty and conservatism in fire PRAs is much higher than in internal events PRAs making them of limited value in risk-informed regulation.	EI	shutdown and external events	Same as above
79	Guidelines will be used as limits by some reviewers; need to ensure that reviewers are trained on consistent application.	PECO	staff review process	The staff is developing comprehensive and detailed SRP Chapters to guide reviews and training reviewers on the use of these SRPs as well as the content of the risk-informed regulatory guides. Training for the staff is described in SECY-97-234.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

80	Staff needs to ensure consistent application of documents by reviewers. IPE and maintenance inspections have shown wide variability in interpretation of what is acceptable.	WOG	staff review process	Same as above.
81	Staff practice of requesting PRA information when a CLB goes beyond a currently-approved NRC staff position is inconsistent with voluntary nature of risk-informed regulation.	APS	staff review process	The staff agrees. However, this practice is a staff initiative derived from Commission policy which is to increase the use of PRA technology in all regulatory matters to the extent supported by the state-of-the art in PRA methods and data.
82	Some guidance lacks the detail necessary for licensees to know what is required; and thus, leaves the question of what's acceptable up to the whim of the reviewer.	NEI GNAG TVA BWROG WOG	staff review process	The staff is developing comprehensive and detailed SRP Chapters to guide reviews and training reviewers on the use of these SRPs as well as the content of the risk-informed regulatory guides. Training for the staff is described in SECY-97-234.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

83	Don't require PRA be docketed and updated regularly. Licensee should address impact on previously approved changes when PRA changes substantially.	NEI GNAG TVA	staff review process	Some information from the PRA needs to be docketed so that the public can have access to the bases for the staff's conclusions in the safety evaluation report. The information that needs to be docketed is clearly described in RG 1.174.
84	Describe review process when "increased management attention " is warranted.	B&WOG	staff review process	A discussion of this topic has been incorporated into RG 1.174 and SRP Chapter 19.
85	NRC review process inefficient; should be streamlined; should consider matrix review organization; ensure reviewers are properly trained; make process public.	NEI GNAG TVA	staff review process	The staff is developing comprehensive and detailed SRP Chapters to guide reviews and training reviewers on the use of these SRPs as well as the content of the risk-informed regulatory guides. The staff's training program is summarized in SECY-97-234.
86	Application review process should ensure that major issues with staff are aired and addressed before detailed review begins.	NEI GNAG TVA	staff review process	The staff routinely meets in public with licensees and their contractors to discuss plans and schedules for submittals, including approaches being considered for resolution of significant safety and compliance issues.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

87	Construct pilot so advanced review and approval not required after pilot completed except where there is an explicit requirement, e.g., a techincal specification.	NEI GNAG TVA	staff review process	The staff intends to consider this issue as a part of larger considerations related to revisions to 10CFR 50.59.
88	Existing guidance for treatment of uncertainties is not sufficient. Simplify treatment of uncertainty. Use deltas only for guidelines. Focus should be on plant specific point estimates. Uncertainty intervals similar for most plants and won't add much value to decision.	NEI GNAG TVA	uncertainty	The basic approach for treating uncertainties contained in the draft version of the guide has been retained in the final version; however, it has been clarified to provide a better description of what the licensee should consider and address in his submittal to identify and account for the important sources of uncertainty. The staff's approach to uncertainty is fully discussed in SECY-97-221 and SECY-97-287.
89	Draft documents focus to much on treatment of PRA uncertainty; strength of PRA is in best estimate analysis.	PECO	uncertainty	The staff's approach to uncertainty is fully discussed in SECY-97-221 and SECY-97-287. The approach recognizes explicitly that it is not just the numerical values of the various measures of CDF/LERF and their changes that are important, but that it is also important to understand what contributes to the PRA results, and how the various sources of uncertainties impact those results.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

90	Accommodating uncertainty with implementation and monitoring is inappropriate.	PECO	uncertainty	Staff disagrees. Implementation and monitoring offer excellent mechanisms for treating uncertainty due to incompleteness in the PRA.
91	Don't need to specify confidence levels PRA results; just use mean values.	NEI GNAG TVA B&WOG	uncertainty	Staff agrees. See discussion in SECY-97-221 and SECY-97-287.
92	NUREG-1150 style propagation of uncertainties not necessary if point estimates are developed correctly.	EPRI	uncertainty	Staff acknowledges that this may be true for some applications. See SECY-97-221 and SECY-97-287.
93	Want more guidance on treating uncertainty of Level 2	WOG	uncertainty	Additional guidance provided in draft NUREG/CR 6595 which replaces the Appendix B included in DG-1061.
94	NRC and industry should have pilot project for treating uncertainty.	WOG ComEd	uncertainty	Formal pilot not necessary. Experience applying RG 1.174 and SRP Chpater 19 will serve same purpose.
95	Applying uncertainties to calculated results is redundant to maintaining the safety principles.	NYPA	uncertainty	Staff disagrees because calculated results may serve as partial basis for approving reductions in safety margin or the level of defense-in-depth.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

96	Level 2 uncertainty approach in draft NUREG-1602 and that in DG-1061 are in conflict. DG-1061 approach is reasonable and well thought out.	BWROG	uncertainty	References to draft NUREG-1602 have been removed from the final versions of the RG 1.174 and SRP Chapter 19.
97	Parametric uncertainty propagation in DG-1061 is felt to be not necessary.	BWROG	uncertainty	Staff acknowledges that this may be true for some applications. In those cases it will not be required.
98	Sensitivity analysis should be permitted as surrogate for uncertainty analysis for small changes in risk.	SCE	uncertainty	Staff agrees. See response to comment immediately above.
99	There is no guidance provided for utilizing the results of uncertainty analysis for small changes in risk.	SCE B&WOG	uncertainty	Guidance for treating very small changes has been incorporated in RG 1.174. For "very small" CDF/LERF increases (as defined above), uncertainty analysis is limited to that associated with the *changes* in CDF and LERF and the use of sensitivity analysis to test the changes in CDF and LERF against the acceptance guidelines.
100	Treatment of model uncertainty undefined and open-ended.	B&WOG	uncertainty	The basic approach for treating uncertainties contained in the draft version of the guide has been retained in the final version. It has been clarified to provide a better description of what the licensee should consider and address in his submittal to identify and account for the important sources of uncertainty. The basis for the staff's approach to uncertainty is fully discussed in SECY-97-221 and SECY-97-287.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chapter 19

101	Given increases in risk must be small (Principle 4), and there is a large margin between CDF=10E-4 and safety goals, uncertainty analysis not needed to show that true mean lies below safety goals.	B&WOG	uncertainty	Staff acknowledges that this may be true in some cases. The staff has revised its guidance such that the calculation of mean values for CDF and LERF are no longer required for very small increases in risk.
102	Costs of doing uncertainty analysis could be very high; not worth the effort.	WOG B&W OG	uncertainty	Guidance for treating uncertainties has been revised to make clear the staff's expectations regarding the treatment of uncertainties, including the expectation that different treatments will apply to different applications. The staff's basis for the guidance on treatment of uncertainties is fully explained in SECY-97-287.

Table A-1
Staff Responses to Public Comments on DG-1061 and draft SRP Chap

III. RESPONSES TO SPECIFIC REQUESTS FOR COMMENT ON PROPOSED DRAFT REGULATORY GUIDE AND SRP

Public responses to the following questions were specifically requested in the Federal Register Announcement for the workshop (62 FR 34321), and the questions were also included in the handout materials for the workshop attendees. The questions were categorized into the areas of (1) Overall Approach, (2) Engineering Evaluation and (3) Draft NUREG-1602.

NEI was the only organization that provided a complete point-by-point response to the questions posed in the Federal Register Notice for the workshop. The staff believes that, in general, the NEI responses reflect the views of the industry on the topics for which the staff requested input. The responses are briefly summarized below. For each question/issue, a cross reference to the applicable comments and responses in Table A-1 is provided along with a brief statement regarding the current resolution of the issue, usually in RG 1.174. Many of the issues included in the staff's question list were addressed as principal issues in Section I above, and for such cases, reference will be made to the discussion in Section I.

Questions for the inservice testing, technical specifications and graded quality assurance risk-informed activities were also included in the Federal Register Notice, but those areas will not be discussed here. Comment resolution for those topics will be addressed when their regulatory guides and SRP sections are finalized in early 1998.

1) **<u>Overall Approach</u>:**

A) Question: ***Is it appropriate to apply the Commission's Safety Goals and their subsidiary objectives on a plant specific basis?***
Applicable Comments and Responses: See comment(s) 1 and 9 in Table A-1.
Response: In the response to this question, it is noted that the industry has acknowledged a role for the Safety Goals on a plant specific basis in the screening criteria of the EPRI PSA Applications Guide. A concern is given that the staff appears to be planning to use the CDF subsidiary objective as a risk "cap" or ceiling rather than a goal.
Resolution: See discussion for Item 1 under Section I, where it is indicated that the staff proposes to allow for some flexibility in the use of the subsidiary objectives for screening applications.

B) Question: ***Is it appropriate to allow, under certain conditions, changes to a plant's CLB that increase CDF and/or LERF?***
Applicable Comments and Responses: See comment(s) 3,4,12 and 14 in Table A-1.
Response: Yes. A demonstrated substantial margin often exists between computed risk levels and the QHOs.
Resolution: Figures 3 and 4 of RG 1.174 indicate conditions in which increases in CDF or LERF may be acceptable to the staff.

C) Question: ***Is the level of detail in the guidance contained in the proposed regulatory guides and SRPs clear and sufficient, or is more detailed guidance necessary? What level of detail is needed?***

Applicable Comments and Responses: See comment(s) 32 through 35 and, 37, 38 and 82 in Table A-1.

Response: The level of detail is, in many instances, insufficient, vague or open ended thus being subject to the discretion of the specific NRC reviewer involved in reviewing a licensee's proposal.[17] Also, guidance is not always consistent with what has been required of the pilot plants.
Resolution: The staff has made an attempt to clarify the guidance throughout RG 1.174 based on the comments received. The pilot plants that are still under review are being reviewed against the current guidelines in the final version of RG 1.174 (revised from the draft DG-1061). The application-specific guidance documents (e.g., IST, TS) are presently being rewritten to respond to comments received during and after the workshop and to also be consistent with the final guidelines in RG 1.174. The pilot plant applications that are still under review will also be reviewed against the revised application-specific guides, and so there should not be inconsistency. In many areas the staff's review of the pilots has provided insights for revising the draft.

D) Question: ***Are the four elements of the risk-informed process described in the regulatory guides and SRPs clear and sufficient?***

Applicable Comments and Responses: See comments 26 through 29 in Table A-1.
Response: The four elements are appropriate, but the clarity and sufficiency of the accompanying guidance is not consistent from application to application.
Resolution: The finalization of the application-specific regulatory guides and SRP sections is ongoing. In revising these documents, it is intended to improve the clarity of each guide based on the comments received and to ensure that the guidance in each is consistent with RG 1.174.

E) Question: ***Is the guidance on the treatment of uncertainties clear and sufficient, or is additional guidance necessary? What additional guidance is needed?***

Applicable Comments and Responses: See comment(s) 88 through 102 in Table A-1.
Response: No; the guidance is not clear in this area. In the response, an approach is suggested for dealing with uncertainty.
Resolution: See Item 4 in Section I.

F) Question: ***Is guidance on the acceptability and treatment of temporary changes in the CLB (i.e., temporary changes in risk) needed? If so, what guidance and acceptance guidelines should be included? Should the guidance be different for full-power operation vs. a shutdown condition?***

Applicable Comments and Responses: See comment(s) 16 in Table A-1.
Response: Guidelines on the treatment of temporary changes in risk are essential to some applications. In the Response, some ideas about how this might be done are proposed.
Resolution: See Item 7 in Section I.

G) Question: ***Is it appropriate to use the definition of "current licensing basis" included in 10 CFR 54 "License Renewal" in these RGs/SRPs? What other definition would be more appropriate?***

Applicable Comments and Responses: See comment(s) 17 in Table A-1.

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17 It should be noted that there were other comments made that the draft guidance was too specific in some areas not allowing enough flexibility for licensees to use different approaches.

Response: The response states that it is not believed that the use of the 10 CFR 50.54 definition is appropriate. The definition should be limited to NRC regulations, orders, license conditions, exemptions and technical specifications.
Resolution: 10 CFR 50.54 ("Conditions of licenses") is not the correct reference for the definition of current licensing basis, and the staff believes that the limited definition given above is not sufficient. The correct reference for the definition is 10 CFR Part 54 (more specifically 10 CFR 54.3) which is the definition given in Section 1.2 of RG 1.174. RG 1.174 has been clarified to make clear that the term "current licensing basis" from 10 CFR Part 54 is being used for convenience and that it is not intended to imply any change in the regulatory status of commitments.

H) Question: ***Should licensees be <u>required</u> to submit risk information in support of proposed changes to their CLB?***

Applicable Comments and Responses: See comment(s) 22 through 24 and comment 81 in Table A-1.
Response: No, not as a matter of policy. PRA information should be used as appropriate to the change being considered.
Resolution: Section 1.1 of RG 1.174 dicusses this in more detail.

I) Question: ***Are the guidelines for quality described in DG-1061 sufficient to ensure appropriate quality in those activities that support proposed changes to the CLB for safety related systems, structures and components? Are the appropriate provisions from 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" applied to the PRA?***

Applicable Comments and Responses: See comment(s) 61 through 68 in Table A-1.
Response: The draft guidelines appear to be consistent with most current utility programs with the possible exception of the record retention requirements. However, additional guidance is needed.
Resolution: In risk-informed processes governed by RG 1.174 and SRP Chapter 19, quality in PRAs will be assured in the near future through the use of the acceptance criteria that have been incorporated in the SRP. Specifically, the guidance suggests that licensees subject their PRA to a peer review, an industry PRA certification process, or PRA cross-comparison study. Such processes and studies will help eliminate, or at least identify the sources of variability in PRAs that are not the result of differences in the design, construction, or operation. As discussed in SRP Chapter 19, the staff will review the application of these programs, including the industry standards that have been applied and the qualifications of the personnel involved. The safety evaluation reports resulting from these reviews will document the staff's assessment of quality and thus help to define the needed quality for specific applications.

The longer-term part of the staff's approach for addressing PRA quality is the development of PRA standards. As discussed in the October 1997 quarterly update of the PRA Implementation Plan (SECY-97-234), the staff is working with ASME to develop such standards. Once developed and found acceptable, it is the staff's intention to endorse the standard in a revision to RG 1.174.

J) Question: ***Should a licensee's PRA be required to be included in the NRC's docket file and updated as necessary to reflect previous changes and recent operating experience?***

Applicable Comments and Responses: See comment(s) 22 through 24 and comment 83 in Table A-1.

Response: No, however, in some cases, it may be necessary to re-evaluate risk-informed programs when major changes are made to the plant or to the PRA.
Resolution: Information relevant to this issue is provided in Section 3 of RG 1.174.

K) Question: ***What other areas, besides graded QA, Tech Specs, IST and ISI could this process and these guidelines be applied to?***

Applicable Comments and Responses: See comment(s) 13, 16, 18, 21, 36, and 87 in Table A-1.
Response: In the Response, it is stated that two other areas might be fruitful: (1) use of PRA to support discretionary enforcement and (2) use of PRA in evaluating USQs under 10 CFR 50.59.
Resolution: The staff is considering the need for specific activities in these areas as part its implementation of PRA in support of the inspection program.

2) **Engineering Evaluation:**

A) Question: ***Are the proposed safety principles clear and sufficient? What should be clarified and/or added?***

Applicable Comments and Responses: See comment(s) 69 through 72 in Table A-1.
Response: The principles themselves are reasonable, but the guidance regarding them is insufficient in some areas.
Resolution: The discussion of the safety principles given in Section 2.1 in RG 1.174 has been revised to clarify the guidance regarding what is needed to demonstrate that they have been satisfied.

B) ***Is sufficient guidance provided regarding the intent, scope, and level of detail requested in the submittal with respect to the evaluation of the safety principles? What should be added? For example:***

1. Question: ***Should there be different guidance on defense-in-depth for those items analyzed in the PRA versus those not analyzed? What should the differences be?***

Applicable Comments and Responses: See comment(s) 34 in Table A-1.
Response: The PRA provides information relative to frequency of occurrence and consequences of events for use in complementing traditional defense in depth considerations.
Resolution: Section 2.4.1.1 in RG 1.174 has been revised to clarify the guidance for defense in depth.

2. Question: ***Should there be quantitative guidelines for determining the sufficiency of defense-in-depth and safety margins?***

Applicable Comments and Responses: See comment(s) 38 and 39 in Table A-1.
Response: It is not clear how such quantitative guidelines could be developed.
Resolution: The sections addressing defense in depth (2.4.1.1) and safety margins (2.4.1.2) in RG 1.174 have been revised to clarify the guidance. Quantitative criteria are not proposed.

C) ***Is the guidance associated with the probabilistic analysis sufficient? For example:***

1. Question: ***Is additional guidance on the use of qualitative risk evaluations necessary? What additional guidance would be appropriate?***

Applicable Comments and Responses: See comment(s) 32 in Table A-1.
Response: This topic has insufficient guidance.
Resolution: The areas where qualitative information is discussed (including defense in depth and safety margins) have been reviewed and, in some areas, revised to clarify the guidance. The evaluation of the proposed pilot plant programs and the safety evaluations for those programs will help to evaluate the adequacy of the present guidance on qualitative factors, and the regulatory guidance can be revised as necessary in the future as more is learned.

2. Question: ***Are the proposed acceptance guidelines for CDF and LERF and changes in CDF and LERF appropriate? Are they too restrictive or too liberal? What guidelines would be more appropriate?***

Applicable Comments and Responses: See comment(s) 4 through 12 in Table A-1.
Response: The guidelines are ambiguous and suggest that even those proposals involving infinitesimal changes in risk will present an undue burden of effort by both the staff and the licensees. This is due to the use of the baseline CDF and LERF values in the proposed acceptance guidelines where it appears that every application will have to undergo increased NRC management and technical review.
Resolution: See responses in Section I to principal issues 1 and 3.

3. Question: ***Is more specific or less detailed guidance needed on comparison of PRA results with the CDF and LERF and the ΔCDF and ΔLERF guidelines?***

Applicable Comments and Responses: See comment(s) 77, 79,91, 95, 99 and 101 in Table A-1.
Response: Guidance is generally insufficient.
Resolution: See responses in Section I to principal issues 1 and 3.

4. Question: ***Should there be additional guidance on the number of proposed risk increases which can be submitted in any given year?***

Applicable Comments and Responses: See comment(s) 7 and 13 in Table A-1.
Response: No; this is not relevant to the risk-informed process in which the magnitude of the proposed changes and the insights gained by the changes are what are important.
Resolution: There are no limits given in RG 1.174 regarding the number of risk increases that can be submitted in any given year provided that the acceptance guidelines are not violated. However, the cummulative impact of risk changes will be monitored by the staff.

5. Question: ***Should there be separate LERF guidelines for PWRs and BWRs? What should they be?***

Applicable Comments and Responses: None in Table A-1.
Response: No, the general definition of LERF is equally applicable to all U.S. LWRs.
Response: The set of LERF guidelines included in RG 1.174 does not distinguish between BWRs and PWRs.

6. Question: ***Should there be separate LERF guidelines for shutdown conditions/external events? What should they be?***

Applicable Comments and Responses: See comment(s) 73 through 78 in Table A-1.
Response: Reference is made to the response to Question 1 F.
Resolution: Section 2.4.2.2 of R.G. 1.174 has been expanded to address the shutdown condition, including treatment of LERF.

7. Question: ***Should there be a guideline on long term release frequency to supplement LERF? What should it be based upon?***

Applicable Comments and Responses: None in Table A-1.
Response: For cases in which long term release is the only concern, such guidance would be useful although this case is not expected to occur very often.
Resolution: Guidelines for such cases will be addressed in the future if and when the need occurs.

8. Question: ***Is the guidance in Appendix B of DG-1061 for estimating LERF sufficient? What else is needed? (It should be noted that the staff intends to expand this guidance to cover shutdown conditions and external events).***

Applicable Comments and Responses: See comment(s) 40 and 41 in Table A-1.
Response: The value of the present guidance in Appendix B is unclear. Most licensees have Level 2 PRAs. The simplified approach seems quite tedious and could provide misleading results unless augmented with plant specific data. While such simplified approaches can be beneficial, they need to be derived from plant specific data and not generic. Two concerns regarding the approach are given in the response.
Resolution: Appendix B has been removed from RG 1.174. It is being revised and will published separately in a NUREG/CR report as reference material.

9. Question: ***Should there be acceptance guidelines for the use of PRA level 3 (segment of PRA that includes estimation of consequences/health effects and risk to the public) information? What guidelines would be appropriate?***

Applicable Comments and Responses: See comment(s) 10 in Table A-1.
Response: Such guidance would be useful for plants having Level 3 PRA information, however, its development should not delay the issuance of the current guidance.
Resolution: The discussion regarding principle issue 1 discusses how Level 3 QHO calculations may be used in lieu of LERF comparisons. Additional guidance for the use of Level 3 information in risk-informed activities will be considered for future revisions to RG 1.174.

10. Question: ***Should the acceptance guidelines specify a confidence level that the PRA results should meet when being compared to the risk guidelines? What is an appropriate confidence level?***

Applicable Comments and Responses: See comment(s) 5, 88 and 91 in Table A-1.

Response: This is not necessary. Since the Safety Goals and subsidiary objectives are based on mean values, mean values should also be used for developing the guidelines.
Resolution: Confidence levels are not used in RG 1.174.

11. Question: ***Should a confidence level or uncertainty level be used to define the "management attention" region in lieu of a CDF and LERF range?***

Applicable Comments and Responses: None in Table A-1.
Response: No.
Resolution: Such levels have not been used in RG 1.174.

3) <u>Performance Monitoring and Feedback</u>:

A) Question: ***Should the use of performance monitoring be more widely applied in regulation and regulatory practice, or is it sufficient to implement it through the elements described in the proposed regulatory guides?***

Applicable Comments and Responses: None in Table A-1.
Response: In the comments, it is stated that performance monitoring as an implementation of performance-based regulation has a much broader applicability than just for risk-informed regulation, and it should be extended to other regulatory practices as a regulatory improvement.
Resolution: Broader use of performance monitoring is being given further consideration in a separate Commission initiative on performance based regulation.

B) Question: ***Is performance monitoring and feedback an appropriate element of the risk-informed process? Should it be used to a greater or lesser degree?***

Applicable Comments and Responses: See comment(s) 43 and 46 through 49 in Table A-1.
Response: Yes, it is an appropriate element, however, it should only be applied when there is a demonstrated concern over perfomance such as when the margin of safety could be significantly impacted.
Resolution: See resolution to Principal Issue 6 in Section I.

C) Question: ***Is the guidance on performance monitoring and feedback clear and sufficient? What should be improved?***

Applicable Comments and Responses: See comment(s) 49 in Table A-1.
Response: No, the expectations are too general.
Resolution: See resolution to Principal Issue 6 in Section I. Also, additional information on performance monitoring will be provided when the application-specific guidance documents are revised to reflect the received comments in early 1998.

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