January 30, 1998

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; andq

(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 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 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"

cc: SECY
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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.

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