

April 2, 1998

FOR: The Commissioners

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

SUBJECT: FINAL APPLICATION-SPECIFIC REGULATORY GUIDES AND STANDARD REVIEW PLANS FOR RISK-INFORMED REGULATION OF POWER REACTORS

PURPOSE:

To request Commission approval for publication of the attached Federal Register Notice ([Attachment 1](#)) regarding Commission approval and final issuance of: Regulatory Guide (RG)-1.175 (formerly Draft Guide (DG)-1062) and Standard Review Plan (SRP) Chapter 3.9.7, related to inservice testing (IST) programs ([Attachments 2 and 3](#), respectively); RG-1.176 (formerly DG-1064), related to graded quality assurance (GQA) programs ([Attachment 4](#)); and RG-1.177 (formerly DG-1065) and SRP Chapter 16.1, related to technical specifications (TS, [Attachments 5 and 6](#), respectively). These RGs and SRP chapters provide guidance in their respective application-specific subject areas to reactor licensees and the NRR review staff regarding the submittal and review of risk-informed proposals that would change the licensing basis for a power reactor facility.

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: ⁽¹⁾

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- General Guidance (DG-1061 and draft SRP Chapter 19),
- Inservice Testing (DG-1062 and draft SRP Chapter 3.9.7),
- Graded Quality Assurance (DG-1064),
- Technical Specifications (DG-1065 and draft SRP Chapter 16.1), and
- The Use of PRA in Risk-Informed Applications (draft NUREG-1602).

The 90-day public comment period closed on September 30, 1997. Disposition of comments regarding the general guidance documents and the draft NUREG report, and the resulting changes made in those documents, were discussed in SECY-98-015, dated January 30, 1998. The concerns stated by those comments are also relevant to the application-specific guidance documents, and changes were made in the latter that are substantially identical to those made in the general guidance documents. However, in lieu of discussing those substantially identical changes in this paper for each of the application specific documents, the discussions in SECY-98-015 are referenced.

DISCUSSION:

This paper provides the final versions proposed by the staff of the aforementioned guidance documents. It also provides a proposed Federal Register Notice which announces their availability, references publically available memoranda that give the staff's disposition of public comments regarding those guidance documents ([Attachment 7](#)), and discusses changes the staff made to the documents in response to public comments and other activities related to the application-specific subject areas of those documents, which included:

- Review activities associated with risk-informed technical specification changes by pilot plants (discussed in SECY-97-095) and with risk-informed graded quality assurance program changes by volunteer plants (discussed in SECY-97-229);
- While not yet completed, the staff's review of the IST pilot plant's program;
- 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 the General Counsel;
- Development of SECY-97-287 describing the key policy issues associated with the final version of RG 1.174 and SRP Section 19 and associated staff recommendations; and
- Recent concerns regarding proper use of the term "Current Licensing Basis" (CLB) with regard to the types of changes to a plant's design, operation, and other activities that require NRC approval. The application-specific guidance documents have been edited to make it clear that

their issuance does not imply any increase in the types of changes that are required to be submitted for NRC approval, and to eliminate reference to the plants' CLB within the documents, thus avoiding any potential misinterpretation to the contrary that might result from such reference. The staff expects to make conforming changes to the generally applicable guidance documents (currently before the Commission for approval, SECY-98-015) upon receipt of the Commission's SRM for those documents.

The guidance contained in the attached final application specific Regulatory Guides and Standard Reviews Plans is consistent with the Commission's decisions on risk-informed policy issues (SECY-97-287) contained in the SRM dated March 19, 1998.

COORDINATION:

RGs 1.175 through 1.177 and SRP Sections 3.9.7 and 16.1 were reviewed by the ACRS Subcommittee on Reliability and Probabilistic Risk Assessment on February 19, 1998, and by the ACRS on March 3, 1998, and the ACRS' views were provided in a letter dated March 12, 1998 ([Attachment 8](#)). CRGR has reviewed the same documents and in a meeting with the staff on February 27, 1998, indicated their approval for publication of the documents in final form for use. The Office of the General Counsel has reviewed the documents and has no legal objection to their being issued for use.

RECOMMENDATION:

That the Commission approve for publication and use RGs 1.175 through 1.177 and SRP Sections 3.9.7 and 16.1, as provided in [Attachments 2 through 6](#), 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 RGs 1.175 through 1.177 and SRP Sections 3.9.7 and 16.1
 2. Regulatory Guide 1.175
 3. Standard Review Plan Section 3.9.7
 4. Regulatory Guide 1.176
 5. Regulatory Guide 1.177
 6. Standard Review Plan Section 16.1
 7. Details Regarding Disposition of Public Comments
 8. Letter from ACRS, "Proposed Final Standard Review Plan Sections and Regulatory Guides for Risk-Informed, Performance-Based Regulation for Inservice Testing, Graded Quality Assurance, and Technical Specifications," dated March 12, 1998.

ATTACHMENT 1

[7590-01-P]

NUCLEAR REGULATORY COMMISSION
Use of PRA in Plant Specific Reactor Regulatory Activities:
Final Application-Specific Regulatory Guides
and Standard Review Plan Sections

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 followed 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 provided 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 subject of this notice is the final issuance of five application-specific regulatory guidance documents: Regulatory Guide (RG)-1.175 (formerly Draft Guide (DG)-1062) and Standard Review Plan (SRP) Section 3.9.7, related to inservice testing (IST) programs; RG-1.176 (formerly DG-1064), related to graded quality assurance (GQA) programs; and RG-1.177 (formerly DG-1065) and SRP Section 16.1, related to technical specifications (TS). Together with the previously issued general guidance documents⁽²⁾, and the ISI guidance documents being developed on a separate, later schedule, this series of documents provides 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 as a partial basis.

In parallel with the public comment process, the staff has completed activities explicitly related to the application-specific documents which have also helped to shape their final form. These activities included:

- Review activities associated with risk-informed technical specification changes by pilot plants (discussed in SECY-97-095) and with risk-informed

graded quality assurance program changes by volunteer plants (discussed in SECY-97-229);

- While not yet completed, the staff's review of the IST pilot plant's program;
- A workshop conducted by the Commission 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;
- The application-specific guidance documents have been edited to make it clear that their issuance does not imply any increase in the types of changes that are required to be submitted for NRC approval, and to eliminate reference to the plants' CLB within the documents, thus avoiding any potential misinterpretation to the contrary that might result from such reference;
- 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;
- Development of SEC-97-287 describing the key policy issues associated with the final version of RG 1.174 and SRP Section 19 and associated staff recommendations; and
- Development of SECY-98-015 describing public comments on the general guidance documents and changes made to those documents.

In response to the concerns stated by the public comments⁽³⁾ and the additional activities noted above, the staff has developed final versions of RG-1.175 and SRP Section 3.9.7 related to IST programs, RG-1.176 related to GQA programs, and RG-1.177 and SRP Section 16.1 related to TS. The significant changes the staff has made to these documents are discussed in Section II of this Federal Register Notice.

EFFECTIVE DATE: Effective immediately.

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 (RGs) and Standard Review Plans (SRPs). Final issuance of the aforementioned five application-specific documents (three RGs and two SRPs) is the subject of this Federal Register Notice.

II. Changes Made to the Application-Specific Guidance Documents.

Changes Made to the IST RG and SRP:

- Guidance regarding the scope, level of detail, and quality of the PRA needed for RI-IST programs was modified to provide significantly more flexibility in meeting those requirements, i.e., "the quality required of the PRA is commensurate with the role it plays in the determination of test intervals and/or test methods, and the role the integrated decision-making panel plays in compensating for limitations in PRA quality."
- After initial RI-IST program approval by the NRC staff, the nature of minor changes that can be made to the RI-IST program without further staff review and approval was clarified. The cumulative effect of all RI-IST program changes (those made as part of the initially approved program, plus additional changes made subsequent to that approval) should comply with the acceptance guidelines in RG 1.174 and RG 1.175, or the licensee should obtain staff approval of the overall IST program (i.e., of the initially approved program plus any additional changes subsequently being considered) prior to implementing the additional changes.
- The relationship of the monitoring program for the IST program and the monitoring program for the Maintenance Rule was clarified, i.e., any performance monitoring that is done as part of the Maintenance Rule that fulfills the needs of the RI-IST program will not have to be repeated.
- Guidance regarding the performance monitoring program for high safety significant components (HSSCs) and low safety significant components (LSSCs) was clarified (i.e., the monitoring for both HSSCs and LSSCs is the component testing done as part of the RI-IST programs).
- Documentation requested for IST program submittal was significantly reduced and clarified.
- It was clarified that the assessment of the validity of failure rates assumed within the PRA can be performed periodically as opposed to "as failures occur." Also, the approach for assessing corrective actions is now specified in a less prescriptive way.
- The suggested periodicity for the reassessment of the RI-IST program (i.e., every two refueling cycles) was deleted.
- The previous "changes to test interval (only)" separate program option for implementing a RI-IST program has been deleted. Licensees may need to take credit for testing beyond that required by the ASME code as part of their RI-IST program.
- The maximum test interval was changed from the previous "5 years or 3 refueling outages (RFOs)" to "6 years or 3 RFOs," or as allowed by NRC-endorsed code cases.
- In most cases, relief requests that were approved prior to establishment of a RI-IST program do not need to be reevaluated by the NRC during review of proposed RI-IST programs.

Changes Made to the GQA RG:

- Discussion was added regarding the expectation that the quality of the PRA used in development of GQA programs must be consistent with its use. If the GQA program is developed with a well organized and documented categorization process, and includes sensitivity and bounding PRA studies and a robust performance monitoring and corrective actions program, then the staff's evaluation of PRA quality will concentrate on a finding that the PRA and the calculations are of sufficient quality for assigning SSCs into broad safety significant categories for consideration in an integrated decision making process.
- Discussion has been added that the evaluations performed to meet provisions of the Maintenance Rule can be used as part of the GQA evaluations needed to identify safety significant functions of SSCs, and that the monitoring performed as part of the Maintenance Rule implementation can be used in cases where that monitoring is sufficient for the SSCs affected by GQA. The discussion further suggests that since GQA could require monitoring of SSCs not included in the Maintenance Rule and requires 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 GQA purposes.
- Additional guidance has been provided regarding use of PRA for internal and external events and operating modes other than full power in the SSC categorization process. It states that PRA models for internal initiating events at full power should be used to support the categorization process, but that licensees may use qualitative studies of other initiating events and operational modes. It states that if importance measures from quantitative studies of external events or other operational modes are combined with measures generated from internal event analyses at full power, the licensee should ensure that the greater uncertainties inherent in the analysis of external events and the modeling of other operational modes (such as shutdown events) are fully considered during the final categorization.
- Reference was added to the South Texas Plant (STP) Commission paper and SER. Also, discussion was added of specific changes that will be allowed for QA controls for LSSCs (in section 5.2, from the staff's STP review), and a revised description was provided of the documentation

necessary to include in a GQA program submittal (per documentation that was accepted for the STP GQA program).

- Clarification was made that implementation can be focused on selected QA criteria (i.e., licensees are not required or expected to evaluate all SSCs for all QA criteria). The proposed program can be with regard to only certain specific criteria, and only the SSCs in certain specific systems can be selected for evaluation with respect to those criteria (i.e., a system-by-system approach to GQA programs is acceptable), but prior identification and bounding studies on all systems intended for eventual inclusion in the plant's GQA program are expected. However, for all SSCs not evaluated, QA controls will remain as-is.
- Discussion was added that monitoring failures of all SSCs whose QA requirements have been lessened is vital to acceptance of a licensee's proposed GQA program, but that for LSS failures, apparent cause screening reviews can be used in lieu of root-cause analyses, absent multiple observed failures.
- Discussion was added regarding development of performance monitoring thresholds (failure based) as alternatives to LSS degradation monitoring and living PRA.
- Provision was added that QA controls defined for LSSCs must be re-evaluated as necessary (i.e., as indicated by failures noted in the equipment monitoring program for LSS equipment).
- Discussion was added regarding 10 CFR 50.59 change control for GQA implementing procedures (section 5.4).
- Discussion was added regarding the QA controls needed for high safety significant, non-safety-related SSCs (section 5.1.2), making it clear that the licensee has the flexibility to justify acceptability of the level of such controls being proposed, and that the NRC is not requiring application of all controls described in 10 CFR 50, Appendix B.

Changes Made to the TS RG and SRP:

- Acknowledgment was added that TS changes beyond AOTs and STIs will be considered on their own merit if they follow key principles outlined in the TS RI-RG.
- The tone of the discussion regarding TS acceptance guidelines was changed to be consistent with the discussion in RG-1.174 and to address comments that the guidelines should not be used prescriptively.
- A discussion was added regarding some of the requirements and benefits of group submittals, such as the CE Owner's Group pilot application.
- The discussion was expanded regarding PRA quality to be consistent with RG-1.174 and to provide discussion, based on the pilot program, of acceptable means for determining PRA quality for TS applications. It was stated that industry PRA certification programs and PRA cross-comparison studies could be used to help ensure appropriate scope, level of detail and quality of the PRA, and that based on the peer review or other certification process and on the findings from this process, the licensee should justify why the PRA's scope and quality is adequate for the licensee's proposed TS application.
- The discussion was modified regarding PRA scope to provide more flexibility for cases when a PRA of sufficient scope is not available. It was stated that insufficient PRA scope will have to be compensated for by qualitative arguments, bounding analyses, or taking compensatory measures.

The discussion was modified regarding Tier 3 to incorporate pilot experience, including addition of TS Administrative Control program description for the Configuration Risk Management Program (CRMP) and section on key elements of the CRMP.

- The discussion was modified regarding the three-tiered process to allow elimination of the Tier 3 requirement for changes involving non-interactive systems.

Dated at Rockville, Maryland, this _____ day of _____ 1998.

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

ATTACHMENT 8

March 12, 1998

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission

Dear Chairman Jackson:

SUBJECT: PROPOSED FINAL STANDARD REVIEW PLAN SECTIONS AND REGULATORY GUIDES FOR RISK-INFORMED, PERFORMANCE-BASED REGULATION FOR INSERVICE TESTING, GRADED QUALITY ASSURANCE, AND TECHNICAL SPECIFICATIONS

During the 449th meeting of the Advisory Committee on Reactor Safeguards, March 2-4, 1998, we met with representatives of the NRC staff to review proposed final Standard Review Plan (SRP) sections and regulatory guides for risk-informed, performance-based regulation including individual applications for inservice testing, graded quality assurance, and technical specifications. We discussed the staff's reconciliation of public comments on the subject documents. Our Subcommittee on Reliability and Probabilistic Risk Assessment met with the staff and industry representatives on February 19, 1998, to discuss these matters. We also had the benefit of the documents referenced.

Conclusions and Recommendations

1. We recommend that Regulatory Guides 1.175 (Inservice Testing), 1.176 (Graded Quality Assurance), and 1.177 (Technical Specifications) and associated SRP sections be approved and issued for use.
2. We do not believe that Regulatory Guide 1.176 takes full advantage of the information that probabilistic risk assessment (PRA) provides. We recognize, however, that the lack of a model for assessing the quantitative impact of quality assurance requirements on PRA parameters makes this a particularly difficult document to write.
3. We recommend that the Office of Nuclear Regulatory Research consider a research project to assess the impact of quality assurance requirements on PRA parameters.
4. We recommend that the staff prepare a plan for improvements to Regulatory Guide 1.176 after experience with its application and related studies and brief the Committee sometime in the next two years.

As stated in our previous reports, we believe that the next major step in the process will be the use of these documents in practice. We urge the staff to move expeditiously to reach closure on the pilot risk-informed requests for changes to the current licensing basis that are currently under review. We were pleased to hear a presentation from the Nuclear Energy Institute on the new risk-informed initiative that it is sponsoring. We plan to follow developments in these activities with great interest.

Sincerely,
/s/

R. L. Seale
Chairman

References:

1. U.S. Nuclear Regulatory Commission, proposed final SRP Section 3.9.7, "Risk-Informed Inservice Testing," draft dated March 2, 1998 (Predecisional).
2. U.S. Nuclear Regulatory Commission, proposed final Regulatory Guide 1.175, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing," draft dated March 2, 1998. (Predecisional)
3. U.S. Nuclear Regulatory Commission, proposed final SRP Chapter 16.1, "Risk-Informed Decisionmaking: Technical Specifications," draft dated March 2, 1998 (Predecisional).
4. U.S. Nuclear Regulatory Commission, proposed final Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance," draft dated March 2, 1998 (Predecisional).
5. U.S. Nuclear Regulatory Commission, proposed final Regulatory Guide 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," draft dated March 2, 1998 (Predecisional).
6. Report dated March 17, 1997, from R. L. Seale, Chairman, ACRS, to Shirley Ann Jackson, Chairman, NRC, Subject: Proposed Standard Review Plan Sections and Regulatory Guides for Risk-Informed, Performance-Based Regulation.
7. Report dated December 11, 1997, from R. L. Seale, Chairman, ACRS, to Shirley Ann Jackson, Chairman, NRC, Subject: Proposed Final Regulatory Guide 1.174 and Standard Review Plan Chapter 19 for Risk-Informed, Performance-Based Regulation.
8. Memorandum dated October 30, 1997, from John C. Hoyle, Secretary of the Commission, to L. Joseph Callan, Executive Director for Operations, NRC, Subject: Staff Requirements Memorandum - SECY-97-229, "Graded Quality Assurance/Probabilistic Risk Assessment Implementation Plan for the South Texas Project Electric Generating Station."

9. Memorandum dated May 28, 1997, from John C. Hoyle, Secretary of the Commission, to L. Joseph Callan, Executive Director for Operations, NRC, Subject: Staff Requirements Memorandum- SECY-97-095, "Probabilistic Risk Assessment Implementation Plan Pilot Application for Risk-Informed, Performance-Based Regulation."

1. An application-specific regulatory guide and SRP chapter for inservice inspection (ISI) programs is being developed and will be reported to the Commission on a later schedule (DG-1063 and draft SRP Chapter 3.9.8, which will become RG-1.178 and SRP Chapter 3.9.8 in their final form).
2. A previous Federal Register Notice (FRN**) was published regarding the issuance of the generally applicable documents, i.e., a final general regulatory guide (RG 1.174) and its accompanying Standard Review Plan (Section 19, for risk-informed applications).
3. A discussion of the comments received is given in the attachments to three NRC Staff memoranda: (1) To Suzanne C. Black and Mark Cunningham, from Hugh W. Woods and Robert A. Gramm, "Resolution of Public Comments on Draft Risk-Informed Graded Quality Assurance Regulatory Guide (DG-1064)", dated March 11, 1998; (2) To Richard H. Wessman and Mark Cunningham, from David C. Fischer and W. Brad Hardin, "Resolution of Public Comments on Draft Risk-Informed Inservice Testing Regulatory Guide (DG-1062) and Standard Review Plan Section (SRP Section 3.9.7)", dated March 27, 1998; (3) To William D. Beckner from Nanette V. Gilles, "Resolution of Public Comments on Draft Risk-Informed Technical Specifications Regulatory Guide (DG-1065) and Standard Review Plan Chapter (SRP Chapter 16.1)", dated March 19, 1998. These memoranda are available in the Commission's Public Document Room.