

April 8, 1997

FOR: The Commissioners

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

SUBJECT: DRAFT REGULATORY GUIDES, STANDARD REVIEW PLANS AND NUREG DOCUMENT IN SUPPORT OF RISK INFORMED REGULATION FOR POWER REACTORS

PURPOSE:

To request Commission approval to publish for comment four draft Regulatory Guides (RGs), three draft Standard Review Plan (SRP) sections and one draft NUREG that support implementation of risk informed regulation for power reactors.

BACKGROUND:

In a memorandum to the Chairman dated January 3, 1996, the staff outlined its plan to develop RGs and SRP sections to support risk informed regulation in the following areas:

- general guidance;
- inservice inspection (ISI);
- inservice testing (IST);
- technical specification (TS);
- graded quality assurance (GQA)

This plan was developed in response to the Commission's August 16, 1995, Policy Statement on the "Use of PRA Methods in Nuclear Regulatory Activities" and the Chairman's November 30, 1995, memorandum "Follow-up Requests in Probabilistic Risk Assessment and Digital Instrumentation and Control." Progress in implementing this plan has been reported in quarterly status updates on the PRA Implementation Plan and in semi-annual briefings to the Commission. The most recent quarterly update (SECY-97-009, dated January 13, 1997) indicated that the draft RGs/SRPs would be transmitted to the Commission by March 31, 1997, with the exception of the RG/SRP for inservice inspection, and that the SRP for graded quality assurance is being replaced by inspection guidance. Therefore, at this time four draft RGs and three draft SRPs corresponding to the remaining areas (general guidance, IST, TS, GQA) are ready for public comment, subject to Commission approval. In addition, one NUREG document, which has been prepared to provide reference information for licensees and staff, is also ready for public comment, subject to Commission approval.

CONTACT: Ashok Thadani, NRR
415-1274

The purpose of the RGs and SRPs is to provide guidance to power reactor licensees and NRC staff reviewers on an acceptable approach for utilizing risk information to support requests for changes in a plant's current licensing basis (CLB). In effect, they describe an alternate means which licensees can use to propose plant specific CLB changes under 10 CFR 50. The general RG/SRP have been developed to provide an overall framework and guidance that is applicable to any proposed CLB change where risk insights are used to support the change. The application specific RGs/SRPs (i.e., IST, TS, GQA) build upon and supplement the general guidance for proposed CLB changes in their respective technical areas. Each application specific RG/SRP references the general RG/SRP, states that the general guidance is applicable and then provides additional guidance specific to the technical area being addressed. For example, the RG/SRP on Technical Specifications provides additional guidance related to the conditional risk from changes in allowable outage times.

Since this guidance supports implementation of a policy statement, it is by its very nature voluntary for licensees and is not considered a backfit. However, to encourage their use, the staff intends to give priority to applications for burden reduction that use risk information as a supplement to traditional engineering analyses. All applications that improve safety will continue to receive high priority.

As part of the development process, four policy issues were identified and options and staff recommendations on each were provided in SECY-96-218, dated October 11, 1996. Commission guidance on these policy issues was received in a Staff Requirements Memorandum (SRM) dated January 22, 1997. The draft RGs/SRPs have been developed in accordance with the Commission guidance on these policy issues.

In conjunction with developing these RGs and SRPs, the staff has also been working with several licensees on pilot applications of risk informed regulation in the technical areas listed above. The knowledge gained to date in interacting with licensees on these pilot applications has been used to help define the content and guidance contained in these RGs/SRPs. Additional interactions are expected over the next several months as work on these pilots continues and the industry gets an opportunity to review the draft RGs/SRPs. The results of these additional interactions will be factored into the final RGs/SRPs.

The remainder of this paper describes, in general terms, the approach that has been taken in developing these draft RGs/SRPs and highlights key factors associated with their content and use.

DISCUSSION:

Attached to this paper are a proposed Federal Register Notice (FRN) announcing the availability of the draft RGs/SRPs for comment ([Attachment 1](#)), the draft RGs/SRPs ([Attachments 2-8](#)) and the draft NUREG ([Attachment 9](#)) which is a reference document to the RGs/SRPs. The draft RGs/SRPs are based on the Commission's August 16, 1995, PRA Policy Statement and an expectation that increased application of risk information in the regulatory process will lead to improved plant safety by focusing attention on the more important safety aspects of plant design and operation. They describe an approach that preserves existing fundamental principles of reactor safety (such as the defense-in-depth philosophy), includes an integrated review of the safety implications of proposed changes to a plant's CLB (including where safety improvement, as well as burden reduction, are appropriate), and ensures protection of public health and safety. Accordingly, in the long term, it is expected that the application of this approach will result in improved reactor safety, not just burden reduction. In addition, in the longer term the approach and guidelines proposed in the RG/SRPs could provide the foundation for the application of risk insights in other regulatory activities (i.e., both plant specific and generic actions).

In addition to considering the Commission's August 16, 1995, Policy Statement on PRA, the Commission's Safety Goal Policy Statement, Regulatory Analysis Guidelines (NUREG/BR-0058, Rev 2) and other related factors have also been considered in developing the proposed guidance. As mentioned above, the proposed guidance encourages licensees to utilize risk insights to improve safety, as well as to propose reductions of unnecessary burdens. The Commission's Safety Goals, their subsidiary objectives and the Regulatory Analysis Guidelines have been used to derive guidelines for judging the acceptability of any calculated risk increases associated with the proposed CLB change.

The staff is proposing a measured approach to reviewing and accepting changes to CLBs that increase risk. Specifically, the guidelines proposed would permit only small increases in risk and then only when it is reasonably assured, among other things, that sufficient defense in depth and safety margins are maintained. This practice is proposed because of the uncertainties in PRA 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. In addition, limiting risk increases to small values is considered prudent until such time as experience is obtained with the methods and applications discussed in the proposed RGs/SRPs. However, it should be noted that the use of the Commission's Safety Goals in this fashion (i.e., to define guidance against which to judge proposed increases in risk) represents a different use of the Safety Goals from that stated in the Commission's June 15, 1990, SRM, which was for use to judge "how safe is safe enough" when improving safety. This is considered to be consistent with the guidance provided in the Commission's January 22, 1997, SRM on emerging policy issues associated with risk-informed regulation. The following paragraphs provide additional detail regarding the proposed approach, safety principles and risk guidelines.

The approach described in each of the RGs/SRPs has four basic steps. These are:

- define the proposed change;
- perform an integrated engineering analysis (which includes both traditional engineering and risk analysis) and use of an integrated decision process;
- monitoring and feedback to verify assumptions and analysis; and
- document and submit proposed change.

Five fundamental safety principles are described which each application for a change in the CLB should meet. These are:

- the proposed change meets the current regulations. This principle applies unless the proposed change is explicitly related to a requested exemption or rule change (i.e., a 50.12 "specific exemption" or a 2.802 "petition for rulemaking");
- defense-in-depth is maintained;
- sufficient safety margins are maintained;
- proposed increases in risk, and their cumulative effect, are small and do not cause the NRC Safety Goals to be exceeded;
- performance-based implementation and monitoring strategies are proposed that address uncertainties in analysis models and data and provide for timely feedback and corrective action.

These principles represent fundamental safety practices which the staff believes must be retained in any change to a plant's CLB to maintain reasonable assurance that there is no undue risk to public health and safety. Each of these principles is to be considered in the integrated engineering analysis and decision making process.

The guidelines for assessing risk proposed in the RGs/SRPs are derived from the Commission's Safety Goal Quantitative Health Objectives (QHOs). Specifically, the staff proposes to use the subsidiary objectives of core damage frequency (CDF) and large early release frequency (LERF) as the measures of risk against which changes in the CLB will be assessed, in lieu of the QHOs themselves which require level 3 PRA information (offsite health effects). This is recommended so as to simplify the scope of PRA analysis needed, to avoid the large uncertainties associated with level 3 PRA analysis and to be consistent with previous Commission direction to decouple siting from plant design.

The values proposed as guidelines for CDF and LERF were selected to be consistent with the Safety Goal QHOs and previous Commission guidance. Specifically, a CDF value of $10^{-4}/RY$ is proposed as the guideline where further increases in CDF would not be acceptable (i.e., plants with $CDF \geq 10^{-4}/RY$ would be expected to propose changes that result in CDF decreases or are neutral). The CDF value of $10^{-4}/RY$ is the value endorsed by the Commission in its June 15, 1990, SRM as a benchmark objective for accident prevention. For plants with CDFs $< 10^{-4}/RY$, guidelines are proposed on changes in CDF (Δ CDF) that ensure increases in risk from CLB changes are made in small steps and that increased NRC management attention is provided for proposed changes that approach the guidelines (i.e., CDFs in the range $10^{-5}/RY$ to $10^{-4}/RY$ and Δ CDFs $> 10^{-6}/RY$). The use of small steps is consistent with a measured approach (allowing time for monitoring, feedback and corrective action) and the values chosen for Δ CDF are consistent with the Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 2).

The guidelines on LERF are derived from the Commission's Safety Goal QHO for early fatality risk. A LERF value of $10^{-5}/\text{RY}$ is proposed as the guideline where further increases in LERF would not be acceptable (i.e., plants with a LERF $> 10^{-5}/\text{RY}$ would be expected to propose changes that result in LERF decreases or are neutral). Similar to CDF, a range is proposed where increased NRC management attention is required if LERF approaches the guideline (i.e., LERF in the $10^{-6}/\text{RY}$ - $10^{-5}/\text{RY}$ range). The value of $10^{-5}/\text{RY}$ for the LERF guideline corresponds to that value, estimated from existing PRA results, necessary to ensure that the early fatality QHO would be met without undue conservatism. In effect, the guideline value for LERF is a surrogate for the Commission's QHO on early fatality risk. The Commission had also proposed in the Safety Goal Policy Statement a general performance guideline of $10^{-6}/\text{RY}$ for a large release of radioactive material to the environment. This guideline was proposed for staff evaluation and the results of the staff evaluation were reported in SECY-93-138, dated May 19, 1993. Although work on defining a large release at a frequency of $10^{-6}/\text{RY}$ was stopped (as reported in SECY-93-138), the staff believes that the management attention region defined above (LERF of $10^{-6}/\text{RY}$ - $10^{-5}/\text{RY}$) provides assurance that the intent of the Commission's general performance guideline is considered in the review of risk-informed changes to the CLB.

Guidelines for changes in LERF (Δ LERF) are also proposed that limit increases in risk to small values (i.e., Δ LERF $< 10^{-6}/\text{RY}$) to ensure that risk increases are made in small increments and are consistent with the Regulatory Analysis Guidelines. Increased management attention is also required when Δ LERF is $> 10^{-7}/\text{RY}$. In effect, the proposed guidelines on CDF/ Δ CDF and LERF/ Δ LERF define the terms "small" and "under certain conditions" as requested in the discussion of "Risk Neutral vs. Increase in Risk" in the Commission's January 22, 1997, SRM. It should also be noted that as a further initiative on using risk insights to improve safety the staff, as part of its planned followup activities from the Individual Plant Examination (IPE) program, plans to review plants whose CDF and/or LERF values approach the proposed guideline values discussed above to see if any additional safety improvements can be justified.

The CDF/ Δ CDF and LERF/ Δ LERF guidelines are intended for comparison with a full scope PRA (i.e., full power, low power and shutdown conditions and internal and external events). It is expected that the cumulative impact of previous CLB changes will also be reflected in the PRA. However, it is recognized that less than full scope PRA analysis will likely be acceptable for many proposed CLB changes and the RG/SRP guidance is intended to allow licensees flexibility to do analyses appropriate for their proposed change and to allow the use of qualitative factors in the decision process. In addition, mean values of CDF and LERF are to be compared against the guidelines. However, the closer the proposed change is to the guidelines, a more comprehensive uncertainty and sensitivity analysis is expected, including the consideration of qualitative factors. Only general guidelines on uncertainty/sensitivity analyses are included in the RGs/SRPs to allow licensees flexibility to provide analyses appropriate for their specific application. The need for additional guidance on the treatment of uncertainties has been identified as a specific topic for discussion during the public comment period. If appropriate, additional guidance will be provided in the final RGs/SRPs.

Finally, two other key items related to the scope and approach of the RGs/SRPs should be noted. First, since these RGs/SRPs would allow the use of risk information and monitoring programs to support CLB changes associated with safety related systems, structures and components (SSCs), it is reasonable to expect that the quality of these analyses and monitoring programs should be consistent with the quality of other analyses and activities associated with safety related SSCs (i.e., 10 CFR 50, Appendix B). Accordingly, the staff has included in the draft general RG guidance regarding quality assurance, including quality of the PRA. This guidance is intended to define the quality assurance provisions that should be applied so that the analyses, monitoring and documentation performed in conjunction with this guide, meet the pertinent requirements of 10 CFR 50, Appendix B. Because of the major implications associated with applying quality assurance provisions to a PRA (many of which are already completed), the staff has identified this as a specific topic for discussion during the public comment period. Second, in the draft RGs/SRPs the staff has used the definition of CLB that is currently in 10 CFR 54 "License Renewal." Although not officially incorporated in 10 CFR 50, the staff believes that this definition is appropriate for use in these RGs/SRPs, pending further consideration of whether a definition of CLB should be included in 10 CFR 50 (see Millstone Lessons Learned Report). This topic has also been specifically identified for discussion during the public comment period.

A proposed FRN ([Attachment 1](#)) has been prepared to announce the availability of the draft RGs, SRPs and NUREG for comment (a 90-day comment period is proposed) and to provide supplementary information on their purpose and content. Due to the nature and volume of the material on which comment is sought, the staff intends to conduct a public workshop during the comment period to explain the documents and answer questions with the purpose of facilitating the public review. The FRN discusses the staff's plan to conduct the workshop and includes a list of topics on which discussion and feedback are sought at the workshop.

COORDINATION:

The RGs/SRPs have been reviewed by ACRS and their views were provided in a letter dated March 17, 1997. As indicated in the March 17, 1997, ACRS letter, the staff has revised the RG on Graded QA subsequent to the March 6-8, 1997, ACRS Full Committee meeting to respond to the ACRS concerns. CRGR has reviewed the RGs/SRPs and has no objection to their publication for comment.

Their views on these documents are provided in [Attachment 10](#). OGC has no legal objection.

RECOMMENDATION:

That the Commission:

- 1) Approve publication of the attached draft FRN, RGs, SRPs and NUREG ([Attachments 1-9](#)) for a 90-day public comment period.
- 2) Note:

- a. Because the RGs are new, an "information collection requirement" will be submitted to OMB for review prior to their being published as final documents.
- b. A public announcement will be issued when the FRN is filed with the Office of the Federal Register.
- c. Copies of the FRN will be distributed to all power reactor permittees and licensees. The notice will be sent to other interested parties on request.
- d. A Backfit Analysis is not required because these RGs do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).
- e. The staff intends to conduct a public workshop during the comment period.

L. Joseph Callan
Executive Director for Operations

- Attachments:
- 1. Proposed Federal Register Notice
 - 2. Draft Regulatory Guide-DG-1061 - General Guidance
 - 3. Draft Regulatory Guide-DG-1062 - IST
 - 4. Draft Regulatory Guide-DG-1064 - Graded QA
 - 5. Draft Regulatory Guide-DG-1065 - Technical Specifications
 - 6. Draft Standard Review Plan - General Guidance
 - 7. Draft Standard Review Plan - IST
 - 8. Draft Standard Review Plan - Technical Specifications
 - 9. Draft NUREG-1602 - Use of PRA in Risk-Informed Applications
 - 10. CRGR Views

ATTACHMENT 1

NUCLEAR REGULATORY COMMISSION
Use of PRA in Plant Specific Reactor Regulatory Activities;
Proposed Regulatory Guides, Standard Review Plan Sections,
and Supporting NUREG

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability.

SUMMARY: The Nuclear Regulatory Commission has issued for public comment drafts of four regulatory guides, three Standard Review Plan Sections, and a NUREG document. These issuances follow publication of the Commission's August 16, 1995 (60 FR 42622) Policy Statement on the Use of PRA Methods in Nuclear Regulatory Activities. The NRC has developed draft guidance for power reactor licensees on acceptable methods for using probabilistic risk assessment (PRA) information and insights in support of plant-specific applications to change the current licensing basis (CLB). The use of such PRA information and guidance is voluntary.

DATE: Comment period expires (insert date 90 days after date of publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

WORKSHOP: To facilitate comment, the Commission intends to conduct a workshop during the comment period to explain the draft documents and answer questions. The exact time, location and agenda will be announced in a future issue of the Federal Register. Section VI of this notice provides additional information on the scope, purpose and topics for discussion at the workshop.

ADDRESSES: Mail written comments to: David L. Meyer, Chief, Rules Review and Directives Branch, Office of Administration, Mail Stop T-6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Deliver comments to 11545 Rockville Pike, Rockville, Maryland, between 7:30am and 4:15pm, Federal workdays.

Copies of the draft regulatory guides, standard review plan sections and NUREG may be obtained by contacting Mr. Mark Cunningham at the address below. These documents and comments received also may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level),

Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mark Cunningham, Office of Nuclear Regulatory Research, MS: T10-E50, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-6189.

SUPPLEMENTARY INFORMATION:

- [I. Background](#)
- [II. An Overview of Draft RGs, SRPs, and NUREG-1602](#)
- [III. Policy Issues](#)
- [IV. Structure, Guidelines and Rationale for RGs/SRPs](#)
- [V. Comments](#)
- [VI. Workshop](#)
- [VII. Paperwork Reduction Act Statement](#)
- [VIII. Public Protection Notification](#)

I. BACKGROUND

On August 16, 1995, (60 FR 42622) the Commission published in the Federal Register a final policy statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities. 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 Regulatory Guides (RG) and Standard Review Plans (SRP) in the areas of:

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

These RGs and SRPs are intended to help implement the Commission's August 1995 policy on the use of risk information in the regulatory process and to provide an acceptable approach for power reactor licensees to prepare and submit and NRC staff to review applications for proposed plant-specific changes to the current licensing basis that utilize risk information. Currently, draft RGs/SRPs have been developed and are ready for comment in the areas of general guidance, IST and TS. A draft RG for GQA has also been developed and is ready for comment. No SRP has been developed for GQA, since the NRC staff will utilize its inspection process in the GQA area. In addition, the NRC has prepared draft NUREG-1602, "Use of PRA in Risk-Informed Applications," to provide reference information for licensees and NRC staff and it is also ready for public comment. Each of these documents is discussed in more detail below.

II. AN OVERVIEW OF DRAFT RGS, SRPS, AND NUREG-1602

The specific documents available for comment are:

- 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 its companion SRP, Chapter 19,

- draft regulatory guide DG-1062 "An Approach for Plant-Specific, Risk-Informed, Decision Making: Inservice Testing" and its companion SRP, Chapter 3.9.7,
- draft regulatory guide DG-1064, "An Approach for Plant-Specific, Risk-Informed Decision Making: Graded Quality Assurance,"
- draft regulatory guide DG-1065, "An Approach for Plant-Specific, Risk-Informed Decision Making: Technical Specifications" and its companion SRP, Chapter 16.1, and
- draft NUREG-1602, "Use of PRA in Risk-Informed Applications."

The purpose of the RGs and SRPs is to provide guidance to power reactor licensees and NRC staff reviewers on an acceptable approach for utilizing risk information to support requests for changes in a plant's CLB. The purpose of NUREG-1602 is to provide reference information useful in making decisions on the scope and attributes of PRA. The RGs describe an alternate means by which licensees can propose plant-specific CLB changes under 10CFR50. Adopting the approach of these RGs is voluntary. Licensees submitting applications for changes to their CLB may use this approach or an alternative equivalent approach. To encourage the use of risk information in such applications, the staff intends to give priority to applications for burden reduction that use risk information as a supplement to traditional engineering analyses, consistent with the intent of the Commission's policy. All applications that improve safety will continue to receive high priority.

The general RG/SRP have been developed to provide an overall framework and guidance that is applicable to any proposed CLB change where risk insights are used to support the change. The application-specific RGs/SRPs (i.e., IST, TS, GOA) build upon and supplement the general guidance for proposed CLB changes in their respective technical areas. Each application-specific RG/SRP references the general RG/SRP, states that the general guidance is applicable and provides additional guidance specific to the technical area being addressed.

The guidance provided in these documents is designed to encourage licensees to use risk information by defining an acceptable framework for the use of risk information on a plant-specific basis, and by promoting consistency in PRA applications. It is expected that the long-term use of risk information in plant-specific licensing actions will result in improved safety by focusing attention on the more risk significant aspects of plant design and operation. The draft guidance provides flexibility to licensees by allowing them to define the scope of the analysis required to support their proposed change and to perform appropriate analysis to justify proposed changes to the plant's CLB.

In conjunction with developing these RGs and SRPs, the staff has also been working with several licensees on pilot applications of risk informed regulation in the technical areas listed above. The knowledge gained to date in interacting with licensees on these pilot applications has been used to help define the content and guidance contained in these RGs/SRPs. Additional interactions are expected over the next several months as work on these pilot applications continues and licensees and other interested persons have an opportunity to review the draft RGs/SRPs. The results of these additional interactions will be factored into the final RGs/SRPs.

III. POLICY ISSUES

On May 15, 1996, the Commission requested the staff to identify and recommend resolution of the following four policy issues associated with risk-informed changes to a plant's CLB:

- the role of performance-based regulation,
- plant-specific application of safety goals,
- risk neutral vs. increases in risk,
- implementation of changes to risk-informed IST and ISI requirements.

On January 22, 1997, the Commission provided the following guidance on these issues:

A. The role of performance-based regulation in the PRA Implementation Plan:

The Commission instructed the staff to include, where practical, performance-based strategies in the implementation of the risk-informed regulatory process. Furthermore, the Commission indicated that application of performance-based approaches should not be limited to risk-informed initiatives and that performance-based initiatives that do not explicitly reference criteria derived from PRA insights should not be excluded from consideration. The Commission also instructed the staff to include in the PRA Implementation Plan, or in a separate plan, how these performance-based initiatives will be phased into the overall regulatory improvement and oversight program and to solicit input from industry on (or develop on its own) additional performance-based objectives which are not amenable to probabilistic risk analysis but could be ranked according to, for example, a relative hazards analysis, and phase in these initiatives.

B. Plant-specific application of Safety Goals:

The Safety Goals policy statement, issued by the Commission in 1986, established two qualitative safety goals to help ensure that nuclear power plant operations do not significantly increase risk to individuals or to the society. The policy statement also defined two Quantitative Health Objectives (QHO) for use "in determining achievement of the qualitative goals." Subsequently, the Commission approved for use two subsidiary objectives derived from the Safety Goal QHOs, one on core-damage frequency and one on containment performance, for use in assessing reactor designs for generic actions. The Commission approved the Safety Goals for use in generic actions with the intent that they would define "how safe is safe enough" in deciding how far to go when proposing safety enhancements.

The staff has considered the need for risk guidelines to support regulatory decision-making in plant-specific circumstances, recognizing that the use of risk information remains complementary to traditional engineering analysis and judgment. Specifically, the staff recommended the development of guidelines for plant-specific applications, derived from the Commission's current Safety Goals and/or subsidiary objectives and requested Commission approval.

The Commission tentatively approved the plant-specific application of safety goals and/or their subsidiary objectives.

C. Risk neutral vs. increases in risk:

This policy issue is related to whether to allow small increases in calculated plant risk in approving a change to the CLB.

The Commission approved small increases in risk under certain conditions, for proposed changes to a plant's CLB. In giving this approval the Commission noted that the terms "small" and "under certain conditions" require more precise definition. The staff was requested to provide a sound rationale for judging small increases and provide for explicit consideration of uncertainties. Criteria for judging small increases in risk should be considered in the context of maintaining reasonable assurance that there is no undue risk to public health and safety.

Moreover, the Commission asked the staff that, in its development of risk-informed guidance and review of applications regarding risk-informed initiatives, to evaluate all safety impacts of proposed changes in an integrated manner including the use of risk insights to identify areas where requirements should be increased or improvements could/should be implemented.

D. Implementation of changes to risk-informed IST and ISI requirements:

This policy issue is related to identifying a means for implementing risk-informed inservice inspection and testing programs until rulemaking is complete. The alternatives are to treat proposed changes as exceptions to 10 CFR 50.55(a) or to treat them as authorized alternatives under the current rule. The Commission approved risk-informed ISI and IST changes as authorized alternatives under 10 CFR 50.55a(a)(3)(i) to approve the pilot plant applications, provided appropriate findings can be made. In addition, the Commission instructed the staff that in cases where the findings necessary to approve the alternative cannot be made, then the use of exemptions should be considered.

IV. STRUCTURE, GUIDELINES AND RATIONALE FOR RGS/SRPS

The approach described in each of the RGS/SRPs has four basic steps. These are:

- define the proposed change;
- perform an integrated engineering analysis (which includes both traditional engineering and risk analysis) and use of an integrated decision process;
- monitoring and feedback to verify assumptions and analysis; and
- document and submit proposed change.

Five fundamental safety principles are described which should be met in each application for a change in the CLB. These principles are:

- the proposed change meets the current regulation. This principle applies unless the proposed change is explicitly related to a requested exemption or rule change (i.e., a 50.12 "specific exemption" or a 2.802 "petition for rulemaking");
- defense-in-depth is maintained;
- sufficient safety margins are maintained;
- proposed increases in risk, and their cumulative effect, are small and do not cause the NRC Safety Goals to be exceeded;
- performance-based implementation and monitoring strategies are proposed that address uncertainties in analysis models and data and provide for timely feedback and corrective action.

These principles represent fundamental safety practices that the staff believes must be retained in any change to a plant's CLB to maintain reasonable assurance that there is no undue risk to public health and safety. Each of these principles is to be considered in the integrated engineering analysis and decision-making process.

The guidelines for assessing risk proposed in the RGS/SRPs are derived from the Commission's Safety Goal Quantitative Health Objectives (QHOs). Specifically, the subsidiary objectives of Core Damage Frequency (CDF) and Large Early Release Frequency (LERF) are used as the measures of risk against which changes in the CLB will be assessed, in lieu of the QHOs themselves, which require level 3 PRA information (offsite health effects). These were chosen to simplify the scope of PRA analysis needed, to avoid the large uncertainties associated with level 3 PRA analysis, and to be consistent with previous Commission direction to decouple siting from plant design.

The values used in the RGS/SRPs as guidelines for CDF and LERF were selected to be consistent with the Safety Goal QHOs and previous Commission guidance. Specifically, a CDF value of $10^{-4}/RY$ is proposed as the guideline where further increases in CDF would not be acceptable (i.e., plants with $CDF \geq 10^{-4}/RY$ would be expected to propose changes that result in CDF decreases or are neutral). The CDF value of $10^{-4}/RY$ is the value endorsed by the Commission in a Staff Requirements Memorandum dated June 15, 1990, as a benchmark objective for accident prevention. For plants with $CDFs < 10^{-4}/RY$, guidelines are proposed on changes in CDF (ΔCDF) that ensure increases in risk from CLB changes are made in small steps and that increased NRC management attention is provided for proposed changes that approach the guidelines (i.e., CDFs in the range $10^{-5}/RY - 10^{-4}/RY$ and $\Delta CDF > 10^{-6}/RY$). The use of small steps is consistent with a measured approach (allowing time for monitoring, feedback and corrective action) and the values chosen for ΔCDF are consistent with the Commission's Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 2).

The guidelines on LERF are derived from the Commission's Safety Goal QHO for early fatality risk. A LERF value of $10^{-5}/RY$ is proposed as the guideline where further increases in LERF would not be acceptable (i.e., plants with a LERF $\geq 10^{-5}/RY$ would be expected to propose changes that result in LERF decreases or are neutral). Similar to CDF, a range is proposed where increased NRC management attention is required if LERF approaches the guideline (i.e., LERF in the range of $10^{-6}/RY$ to $10^{-5}/RY$). The value of $10^{-5}/RY$ for the LERF guideline corresponds to that value, estimated from existing PRA results, necessary to ensure that the early-fatality QHO would be met without undue conservatism. In effect, the guideline value for LERF is a surrogate for the Commission's QHO on early fatality risk. Guidelines for changes in LERF (Δ LERF) are used that limit increases in risk to small values (i.e., Δ LERF $< 10^{-6}/RY$) to ensure that increases are made in small increments, are consistent with the Regulatory Analysis Guidelines and, similar to Δ CDF, require increased management attention when they approach the guideline value (i.e., Δ LERF in the range of $10^{-7}/RY$ to $10^{-6}/RY$).

The CDF/ Δ CDF and LERF/ Δ LERF guidelines are intended for comparison with a full-scope PRA (i.e., full power, low power and shutdown conditions and internal and external events). It is expected that the cumulative impact of previous CLB changes will also be reflected in the PRA. However, it is recognized that less than full-scope PRA analysis will likely be acceptable for many proposed CLB changes and the RG/SRP guidance is intended to allow licensees flexibility to do analyses appropriate for their proposed change and to allow the use of qualitative factors in the decision process. In addition, mean values of CDF and LERF are to be compared against the guidelines. However, when a proposed change is closer to the guidelines, a more comprehensive uncertainty and sensitivity analysis is expected that includes the consideration of qualitative factors. Only general guidelines on uncertainty/sensitivity analyses are included in the RGs/SRPs to allow licensees flexibility to provide analyses appropriate for their specific application.

Monitoring and feedback strategies are to be utilized in implementing the proposed CLB change to help verify assumptions and analysis and to allow for corrective action should performance be less than assumed in the analysis. In addition, NRC expects licensees to identify how and where their proposed changes will be documented as part of the plant's CLB. This should include documentation that clearly establishes the basis for the change, ensures that commitments are known and provides sufficient documentation to allow inspection and enforcement, if appropriate. Related to the above, since these RGs/SRPs allow the use of risk information and monitoring programs to support CLB changes associated with safety related systems, structures and components (SSCs), it is reasonable to expect that the quality of these analyses and monitoring programs should be consistent with the quality of other analyses and activities associated with safety related SSCs (i.e., 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"). Accordingly, DG-1061 includes guidance regarding quality assurance, including that associated with the PRA, that ensures the pertinent requirements of 10 CFR 50, Appendix B are met. In addition, the draft RGs/SRPs use the definition of CLB that is currently in 10 CFR 54 "License Renewal." Although not officially incorporated in 10 CFR 50, this definition is considered appropriate for use in these RGs/SRPs.

As mentioned above, the draft guidance encourages licensees to utilize risk insights to improve safety, as well as to propose reductions of unnecessary burdens. The Commission's Safety Goals, their subsidiary objectives and Regulatory Analysis Guidelines have been used to derive guidelines for judging the acceptability of any calculated risk increases associated with the proposed CLB change. In this regard, a measured approach to reviewing and accepting changes to CLBs that increase risk has been taken. Specifically, the guidelines used correspond to small calculated increases in risk. In theory, one could construct an even 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 contribute to a substantial reduction in overall risk or result in continuing costs which are not justified by the safety benefits. However, a more restrictive practice has been used 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 safety margins are maintained. This practice is used because of the uncertainties in PRA 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. In addition, limiting risk increases to small values is considered prudent until such time as experience is obtained with the methods and applications discussed in the RGs/SRPs.

V. COMMENTS

The staff is soliciting comments related to the guidance described in the draft RGs, SRPs and NUREG-1602. Comments submitted by the readers of this FRN will help ensure that these draft documents have appropriate scope, depth, quality, and effectiveness. Alternative views, concerns, clarifications, and corrections expressed in public comments will be considered in developing the final documents.

VI. WORKSHOP

The Commission intends to conduct a workshop to discuss and explain the material contained in the draft guides, SRPs and NUREG-1602, and to answer questions and receive comments and feedback on the proposed documents. The purpose of the workshop is to facilitate the comment process. In the workshop the staff will describe each document, its basis and solicit comment and feedback on their completeness, correctness and usefulness. Since these documents cover a wide range of technical areas, many topics will be discussed. Listed below are topics on which discussion and feedback are sought at the workshop:

1) OVERALL APPROACH:

- A) Is it appropriate to apply the Commission's Safety Goals and their subsidiary objectives on a plant specific basis?
- B) Is it appropriate to allow, under certain conditions, changes to a plant's CLB that increase CDF and/or LERF?
- C) 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.

- D) Are the four elements of the risk-informed process described in the Reg Guides and SRPs clear and sufficient?
- E) Is the guidance on the treatment of uncertainties clear and sufficient, or is additional guidance necessary? What additional guidance is needed?
- F) 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?
- G) 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?
- H) Should licensees be required to submit risk information in support of proposed changes to their CLB?
- I) 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?
- J) 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?
- K) What other areas, besides graded QA, Tech Specs, IST and ISI could this process and these guidelines be applied to?

2) ENGINEERING EVALUATION:

- A) Are the proposed safety principles clear and sufficient? What should be clarified and/or added?
- 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. 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?
 2. Should there be quantitative guidelines for determining the sufficiency of defense-in-depth and safety margins?
- C) Is the guidance associated with the probabilistic analysis sufficient? For example:
 1. Is additional guidance on the use of qualitative risk evaluations necessary? What additional guidance would be appropriate?
 2. 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?
 3. Is more specific or less detailed guidance needed on comparison of PRA results with the CDF and LERF and the Δ CDF and Δ LERF guidelines?
 4. Should there be additional guidance on the number of proposed risk increases which can be submitted in any given year?
 5. Should there be separate LERF guidelines for PWRs and BWRs? What should they be?
 6. Should there be separate LERF guidelines for shutdown conditions/external events? What should they be?
 7. Should there be a guideline on long term release frequency to supplement LERF? What should it be based upon?
 8. 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).
 9. 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?
 10. 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?
 11. Should a confidence level or uncertainty level be used to define the "management attention" region in, lieu of a CDF and LERF range?

3) PERFORMANCE MONITORING AND FEEDBACK:

- A) 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?
- B) Is performance monitoring and feedback an appropriate element of the risk-informed process? Should it be used to a greater or lesser degree?
- C) Is the guidance on performance monitoring and feedback clear and sufficient? What should be improved?

4) GRADED QUALITY ASSURANCE REGULATORY GUIDE (DG-1064):

- A) Is the approach for determining the safety-significance of plant SSCs appropriate? Is it sufficient to identify high and low safety significant categories? Is the amount of risk analysis overly burdensome relative to the potential benefits?
- B) Is the guidance in the proposed regulatory guide regarding the content of QA programs for low safety significant SSCs appropriate? What additional guidelines are needed, and/or what portions of the proposed guidelines should be deleted?
- C) Are there any quantitative data that can be used to assess the risk impact (i.e., CDF or LERF) of reducing QA controls on equipment performance?
- D) Is the proposed scope of graded QA, that includes safety-related and other important plant equipment as covered by the Maintenance Rule, appropriate?
- E) Is the guidance on equipment-performance-monitoring strategies sufficient?
- F) Is the guidance sufficient regarding the QA controls for safety-significant, but non-safety-related, equipment that should be included in the licensee's QA program? What guidance should be included?
- G) Should the guidance allow for further removal of QA requirements? In what areas should this be done and what guidance would be appropriate? For example, is it appropriate for a graded QA program to eliminate all requirements associated with some of the 18 criteria specified in 10 CFR 50, Appendix B?

5) TECHNICAL SPECIFICATIONS REGULATORY GUIDE (DG-1065) AND SRP

- A) Are the proposed acceptance guidelines on incremental conditional core damage probability and incremental conditional large early release probability from a single AOT change (5E-07 and 5E-08, respectively) appropriate?
- B) Should there be a guideline on maximum conditional CDF/LERF during an AOT? What should it be?

6) INSERVICE TESTING REGULATORY GUIDE (DG-1062) AND SRP

- A) PRA models of component unavailability typically use a parameter lambda (λ) to characterize the component's failure rate, and this parameter is often considered to be a constant value. Is the assumption of constant value for λ realistic? What different values might be more realistic and what evidence (data) supports the alternate values?
- B) Is it appropriate, as part of a risk-informed program, to require licensees to look outside the ASME code boundary and identify candidate components for testing and then apply ASME criteria to the conduct of those tests? What is a reasonable way to deal with relatively high-risk components that are not part of a currently prescribed IST program?
- C) Is it appropriate to use the "other acceptable methods" provision of 10 CFR 50.55a to implement changes to the CLB?

7) NUREG-1602

- A) Draft NUREG-1602 provides reference material on the scope and quality of a PRA. Is the information in draft NUREG-1602 complete and correct? Is it useful as reference material in making assessments on an application specific basis on the scope and quality of the risk assessment to support that particular application? How could it be improved? For example, should it specify acceptable PRA methods?
- B) Would draft NUREG-1602 be useful as a starting point to develop a national consensus standard on PRA? What would be needed?
- C) Is a national consensus standard on PRA needed or desirable?

VII. PAPERWORK REDUCTION ACT STATEMENT

These draft regulatory guides contain information collections that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). These regulatory guides will be submitted to the Office of Management and Budget for review and approval of the information collections before the final guides

are published.

VII. PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

Dated at Rockville, Maryland, this day of 1997.

For the Nuclear Regulatory Commission.
John C. Hoyle,
Secretary of the Commission.