



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

April 22, 1997

MEMORANDUM TO: John C. Hoyle
Secretary of the Commission

FROM: John T. Larkins, Executive Director
Advisory Committee on Reactor Safeguards

SUBJECT: ACRS MEETING WITH THE NRC COMMISSIONERS, MAY 2,
1997—SCHEDULE/BACKGROUND INFORMATION

The ACRS is scheduled to meet with the NRC Commissioners between 9:00 and 10:30 a.m. on Friday, May 2, 1997, to discuss the items listed below. Background materials related to these items are attached.

- A. Introduction - NRC Chairman 9:00 - 9:05 a.m.
- B.1
- (a) Risk-Informed, Performance-Based Regulation and Related Matters 9:05 - 9:20 a.m.
 - Dr. Apostolakis (pp. 1-9)
 - (b) Risk-Based Regulatory Acceptance Criteria for Plant-Specific Application of Safety Goals 9:20 - 9:35 a.m.
 - Dr. Kress (pp. 10-37)
2. Proposed Regulatory Approach Associated with Steam Generator Integrity 9:35 - 9:45 a.m.
 - Dr. Seale (pp. 38-50)
3. Low-Power and Shutdown Operations Risk 9:45 - 10:00 a.m.
 - Dr. Powers (pp. 51-62)
4. Status of ACRS Review of National Academy of Sciences/National Research Council Phase 2 Study Report on Digital Instrumentation and Control Systems 10:00 - 10:10 a.m.
 - Dr. Miller (pp. 63-68)
5. Human Performance Program Plan 10:10 - 10:20 a.m.
 - Dr. Apostolakis (pp. 69-77)

John C. Hoyle

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6. ACRS Report to Congress on
Nuclear Safety Research and
Regulatory Reform
- Dr. Powers (pp. 78-86)

10:20 - 10:25 a.m.

C. Closing Remarks - NRC Chairman

10:25 - 10:30 a.m.

Attachment: As stated

cc: ACRS Members
ACRS Technical Staff

ITEM B.1 (a):

**RISK-INFORMED, PERFORMANCE-BASED
REGULATION AND RELATED MATTERS**

(DR. APOSTOLAKIS)

ITEM B.1 (a): RISK-INFORMED, PERFORMANCE-BASED REGULATION AND RELATED MATTERS

During the December 6, 1996 meeting with the Commissioners, the ACRS discussed the staff's approach to codify risk-informed, performance-based regulation and related matters through development of Standard Review Plan (SRP) sections and associated regulatory guides.

Subsequent to the December 6, 1996 meeting with the Commission, the ACRS has continued its discussions with the staff regarding the proposed SRP sections and regulatory guides. The ACRS met with the staff and industry representatives on February 6-8 and March 6-8, 1997, to continue its discussion of the proposed SRP sections and regulatory guides. The ACRS Subcommittee on Probabilistic Risk Assessment (PRA) also heard presentations by and held discussions with representatives of the staff and of the industry on January 28, February 20 and 21, 1997. All ACRS members attended the February 20-21 Subcommittee meeting. During these meetings, the ACRS reviewed the following documents:

- 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," dated February 28, 1997
- Draft Regulatory Guide DG-1062, "An Approach for Plant-Specific, Risk-Informed, Decision Making: Inservice Testing," dated February 25, 1997
- Draft Regulatory Guide DG-1064, Revision 4, "An Approach for Plant-Specific, Risk-Informed Decision Making: Graded Quality Assurance," dated February 26, 1997
- Draft Regulatory Guide DG-1065, Revision 5, "An Approach for Plant-Specific, Risk-Informed Decision Making: Technical Specifications," dated February 24, 1997
- Draft SRP Chapter 19, Revision L, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," dated March 3, 1997
- Draft SRP Section 3.9.7, Revision 2C, "Standard Review Plan for the Review of Risk-Informed Inservice Testing Applications," dated February 25, 1997
- Draft SRP Chapter 16.1, Revision 12, "Risk-Informed Decision Making: Technical Specifications," dated February 24, 1997

The ACRS was provided with draft NUREG-1602, "Standards for Probabilistic Risk Assessment (PRA) to Support Risk-Informed Decisionmaking." Since it was being revised, the staff requested that the ACRS not comment on this document at this time. The ACRS plans to review this document after receiving a revised document.

The ACRS provided a report to the Commission on March 17, 1997. In this report the Committee made several comments and recommendations, including the following:

- The draft Regulatory Guide DG-1061 (General Guidance) and the associated SRP Chapter 19 that provide guidance for making risk-informed changes to the current licensing basis of individual plants constitute a significant achievement. These documents, and in particular the stated principles, provide the foundation for risk-informed regulatory philosophy that can better focus resources and can lead to a more coherent regulatory structure.

The staff formulated a list of questions to elicit public comments needed to refine and improve these draft documents. The ACRS agreed that these questions highlight important issues that need to be addressed. The ACRS recommended that the staff issue these documents for public comment.

- The draft Regulatory Guides DG-1062 (Inservice Testing) and DG-1065 (Technical Specifications) and the associated SRP sections have been developed consistent with the principles in DG-1061 (General Guidance). The ACRS recommended that these documents be issued for public comment.

The ACRS viewed proposed guidelines for allowed outage times to be acceptable in that they were based on incremental conditional probability of core damage and large, early release. The ACRS stated that such guidelines could also include limits on the maximum conditional annual core damage frequency (CDF) and large, early release frequency (LERF). This alternative is one of the questions included in the proposed Federal Register notice, and the ACRS believes that final resolution of this issue can be postponed until public comments on this matter have been received.

- The ACRS considered DG-1064 (Graded Quality Assurance) to have taken an unnecessarily timid approach toward focusing stringent quality assurance activities on highly risk-significant systems, structures, and components (SSCs) and defining adequate, but less exacting, quality assurance demands on areas of low risk significance. The Committee stated that there should be a clear justification based on PRA or other compelling reasons for classifying SSCs as belonging to the high-safety-significant category.

The ACRS stated that issuance of this draft Regulatory Guide, in this form, could reinforce the suspicion that risk-informed regulation is simply an additional layer of regulation imposing burden without tangible benefit. Since the staff agreed to revise this document to address the ACRS concerns and, since there is intense industry interest, the Committee stated that it has no objection to the staff proposal for issuing the revised document for public comment.

- The ACRS believes that the successful implementation of the risk-informed, performance-based regulatory philosophy will require a change in culture for both the NRC staff and the industry. The ACRS recommends that a vigorous program be established to communicate the risk-informed philosophy through workshops and other means planned by the staff.
- The ACRS recommends that the Commission consider issuing a statement inviting licensees to propose new and innovative approaches to risk-informed, performance-based regulation using the concepts articulated in DG-1061 (General Guidance). The review and approval processes may need to be revised to provide timely responses to licensee submittals, which will necessarily cross disciplinary and organizational lines.
- DG-1061 (General Guidance), Appendix B, provides a method for estimating LERF in the absence of a Level 2 PRA. The ACRS recommends that some approaches also be developed for estimating the contributions of external events to CDF and LERF, as well as from low-power and shutdown operations when detailed PRAs are not available.

The ACRS noted that frequent interactions between the ACRS and the staff on the draft SRP sections and associated regulatory guides were both valuable and constructive, and the staff was very cooperative during this long process.

The ACRS plans to continue its review of proposed SRP sections and regulatory guides for risk-informed, performance-based regulation. The ACRS Subcommittee on PRA plans to meet with the staff to discuss the proposed SRP section and associated regulatory guide for risk-informed inservice inspection in June 1997 with full Committee review during the July 9-11, 1997 ACRS meeting.

The Committee plans to meet with the staff to discuss the PRA Implementation Plan during its June 11-13, 1997 meeting, with emphasis on risk-informed initiatives in training and inspection. The ACRS also plans to meet with the staff to discuss ongoing staff initiatives for risk-based analysis of reactor operating experience and some special studies.

Attachment:

- Report dated March 17, 1997, from R. L. Seale, ACRS Chairman, to Shirley Ann Jackson, NRC Chairman, Subject: "Proposed Standard Review Plan Sections and Regulatory Guides for Risk-Informed, Performance-Based Regulation" (pp. 5-9)



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

March 17, 1997

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Chairman Jackson:

SUBJECT: PROPOSED STANDARD REVIEW PLAN SECTIONS AND REGULATORY GUIDES FOR RISK-INFORMED, PERFORMANCE-BASED REGULATION

During the 437th, 438th, and 439th meetings of the Advisory Committee on Reactor Safeguards, December 5-7, 1996, February 6-8, and March 6-8, 1997, respectively, we met with representatives of the NRC staff, industry, and other interested parties to review the proposed Standard Review Plan (SRP) sections, Regulatory Guides, and other matters associated with risk-informed, performance-based regulation. We discussed the staff's approach to codify risk-informed, performance-based regulation into a general guidance SRP section and an associated Regulatory Guide, as well as related documents for technical specifications, inservice testing, and graded quality assurance. We also discussed industry views and initiatives related to these matters. In addition, our Subcommittee on Probabilistic Risk Assessment (PRA) met with the staff and industry representatives to discuss these documents on October 31, November 1, 21, 22, 1996, and January 28, February 20 and 21, 1997. We also had the benefit of the documents referenced.

Conclusions and Recommendations

1. The draft Regulatory Guide DG-1061 (General Guidance) and the associated SRP Chapter 19 that provide guidance for making risk-informed changes to the current licensing basis of individual plants constitute a significant achievement. They, and in particular the stated principles, provide the foundation for risk-informed regulatory philosophy that can better focus resources and can lead to a more coherent regulatory structure. These documents should be issued for public comment. The staff has formulated questions that should elicit the public comments needed to refine and improve these draft documents.
2. The draft Regulatory Guides for application of risk-informed decisionmaking to technical specifications (DG-1065) and inservice testing (DG-1062) have been developed consistent with

the principles articulated in the General Guidance (DG-1061). These Regulatory Guides and associated SRP sections should be issued for public comment. The proposed guidelines for acceptability of allowed outage time changes are based on the incremental conditional probability of core damage and large, early release. Such guidelines could also include limits on the maximum conditional annual core damage frequency (CDF) and large, early release frequency (LERF). This alternative is one of the questions included in the proposed Federal Register notice, and we believe that final resolution of this issue can be postponed until public comments on this matter have been received.

3. The version of the Regulatory Guide that we reviewed for application of risk-informed decisionmaking to graded quality assurance (DG-1064) took an unnecessarily timid approach toward focusing stringent quality assurance activities on highly risk-significant systems, structures, and components (SSCs) and defining adequate, but less exacting, quality assurance demands on areas of low risk significance. There should be a clear justification based on PRA or other compelling reasons for classifying SSCs as belonging to the high-safety-significant category. Issuance of this draft Regulatory Guide in this form for public comment could erroneously reinforce the wide-spread suspicion that risk-informed regulation is simply an additional layer of regulation imposing burden without tangible benefit. The staff is currently working to revise this document, and we are confident that the revised version will, in large measure, address our concerns. Since there is intense industry interest in this Regulatory Guide, we have no objection to the staff's proposal for issuing this document for public comment.
4. The successful implementation of the new regulatory philosophy will require a change in culture for both the NRC staff and the industry. A vigorous program should be established to communicate the risk-informed philosophy through workshops and other means planned by the staff.
5. The Commission should consider issuing a statement inviting licensees to propose new and innovative approaches to risk-informed, performance-based regulation using the concepts articulated in the General Guidance (DG-1061). The review and approval processes may need to be revised to provide timely responses to licensee submittals, which will necessarily cross disciplinary and organizational lines.
6. Appendix B of DG-1061 provides a method for estimating LERF in the absence of a Level 2 PRA. We recommend that some approaches also be developed for estimating the contributions

of external events to CDF and LERF, as well as from low-power and shutdown operations when detailed PRAs are not available.

Discussion

It has been about 22 years since the Reactor Safety Study (WASH-1400) introduced PRA to the reactor safety community. During this time, PRA methods, especially those for internal events during power operations, have matured to the point that PRA insights are increasingly being utilized in risk management both by the staff and licensees. However, formal guidance as to how PRA results can be used in the regulatory arena has been lacking. The documents that the staff has prepared provide such guidance. They constitute a major step forward in the development of a more risk-informed regulatory process.

Formulation of the guidance in terms of a basic set of principles creates a foundation for the new regulatory philosophy. We believe this to be a sound and significant achievement. It provides the starting point for the integration of traditional engineering approaches to safety, such as defense-in-depth, and the new probabilistic approach. The implementation of the General Guidance will evolve as experience is gained. We are confident, however, that a good start has been made.

The efforts to understand how the concepts of defense-in-depth and safety margins can be considered in the context of PRA must be applauded and encouraged. They provide very useful insights regarding the intent of these cornerstones of traditional reactor safety philosophy and the extent to which they are reflected in the PRA results.

We agree with the use of an "integrated" process in risk-management situations. It is clearly recognized that decisionmaking cannot rely solely on numerical results from either the PRA or more traditional approaches. We note that this integrated approach to decisionmaking is akin to the concept of the inclusion of "deliberation" in reaching risk-management decisions, as discussed in a recent report by the National Research Council Committee on Risk Characterization.

A first reading of the proposed SRP sections and associated Regulatory Guides creates the impression that they impose an onerous burden and are difficult to understand. We believe that the potential benefits clearly outweigh this burden and merit the effort to implement the new philosophy.

At this time, many of the staff and the industry may still not believe that risk-informed regulation is real or may have difficulty in making the transition to risk-informed decision-making. We are, therefore, very pleased to hear that the staff

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plans to organize workshops and public meetings to explain the new regulatory philosophy.

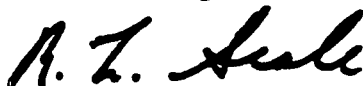
Interaction with industry is needed to ensure that the industry realizes its responsibility to provide the staff with the information needed to make meaningful risk-informed decisions. To a large extent, the benefits of a risk-informed approach will be in proportion to the attention to accuracy and completeness of the industry's PRAs. There probably are licensees that have not yet done enough with their current PRAs to be able to garner significant benefit from a risk-informed approach to regulation. The new approach may, in the beginning, require additional industry effort. This is understandable and should be considered in the context of potential increases in safety and reductions in regulatory burden.

Graded quality assurance is a quintessential subject for application of risk-informed decisionmaking. Risk information should be the rational basis for adjudicating the level of quality assurance effort needed to provide confidence that SSCs will perform their safety functions reliably. The staff is currently planning to use risk information only to reduce quality assurance requirements for SSCs in the low-safety-significant category. We believe there is a better approach to using risk information to classify SSCs according to quality assurance needs than that described in the draft Regulatory Guide. Greater discrimination among the quality assurance needs will better focus licensee and regulatory attention on risk-important topics. Such a focus may not be achieved by simply using risk information to define reductions in licensee burdens associated with quality assurance for low-safety-significant items.

The approach proposed in Appendix B of DG-1061 for estimating LERF in the absence of a Level 2 PRA needs to be supported with additional documentation. Although this approach may be appropriate for screening purposes, additional probabilistic analyses using plant-specific values may be necessary for plants that do not meet the LERF guidelines.

We express our appreciation for the staff's cooperation during this long process. We have had excellent discussions of both concepts and methods during our meetings. The staff was always willing to listen and debate with us. The frequent interactions between the staff and the Committee were very valuable and constructive.

Sincerely,



R. L. Seale
Chairman

References:

1. U.S. Nuclear Regulatory Commission, 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," dated February 28, 1997.
2. U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-1062, "An Approach for Plant Specific, Risk-Informed, Decision Making: Inservice Testing," dated February 25, 1997.
3. U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-1064, Revision 4, "An Approach for Plant-Specific, Risk-Informed Decision Making: Graded Quality Assurance," dated February 26, 1997.
4. U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-1065, Revision 5, "An Approach for Plant-Specific, Risk-Informed Decision Making: Technical Specifications," dated February 24, 1997.
5. U.S. Nuclear Regulatory Commission, Draft Standard Review Plan, Chapter 19, Revision L, "Use of Probabilistic Risk Assessment in Plant-Specific, Risk-Informed Decisionmaking: General Guidance," dated March 3, 1997.
6. U.S. Nuclear Regulatory Commission, Draft Standard Review Plan, Chapter 3.9.7, Revision 2C, "Standard Review Plan for the Review of Risk-Informed Inservice Testing Applications," dated February 25, 1997.
7. U.S. Nuclear Regulatory Commission, Draft Standard Review Plan, Chapter 16.1, Revision 12, "Risk-Informed Decision Making: Technical Specifications," dated February 24, 1997.
8. U. S. Nuclear Regulatory Commission, NUREG-75/014, "Reactor Safety Study, An Assessment of Accident Risks in U.S. Nuclear Power Plants," WASH-1400, October 1975.
9. National Research Council report, "Understanding Risk, Informing Decisions in a Democratic Society," 1996.

ITEM B.1 (b):

**RISK-BASED REGULATORY ACCEPTANCE CRITERIA
FOR PLANT-SPECIFIC APPLICATION OF SAFETY GOALS**

(DR. KRESS)

ITEM B.1 (b): RISK-BASED REGULATORY ACCEPTANCE CRITERIA FOR PLANT-SPECIFIC APPLICATION OF SAFETY GOALS

The Committee provided a report to the Commission, dated November 18, 1996, regarding "Plant-Specific Application of Safety Goals." In this report the Committee made several comments and recommendations, including the following:

- The safety goals and subsidiary objectives can and should be used to derive guidelines for plant-specific applications. It is, however, impractical to rely exclusively on the Quantitative Health Objectives (QHOs) for routine use on an individual plant basis. Criteria based on core damage frequency (CDF) and large, early release frequency (LERF) focus more sharply on safety issues and can provide assurance that the QHOs are met.
- The Safety Goals quantified "how safe is safe enough" for the population of U.S. plants. For an individual plant, however, the acceptable level of risk is determined by the concept of "adequate protection," which in the final analysis means compliance with the body of regulations. Risk-informed analyses would provide a more rational basis for making regulatory decisions regarding plant-specific requests for exemptions from the rules or for changes to the licensing basis, and the acceptability of new regulations.
- In the longer term, the agency should move beyond the evaluation of risk associated with proposed changes to individual plant licenses and apply the Safety Goals to assess the acceptability of plant-specific risk. This could be done in terms of the QHOs, along with the CDF, or in terms of the CDF and LERF. To use the QHOs directly, it would be necessary to have full-scope Level 3 probabilistic risk assessments (PRAs).

The Committee met with the Commissioners on December 6, 1996, and discussed the report mentioned above. During that meeting, the Committee committed to provide an example of how risk-acceptance criteria could be developed directly from the Safety Goals. In addition, in a Staff Requirements Memorandum dated January 14, 1997, the Commission asked for the ACRS views on the relationship between the concept of "adequate protection" as used in NRC regulations, and the NRC Safety Goals, from the standpoint of levels of risk.

The Committee discussed the concept of "adequate protection" and other related matters and provided a report to the Commission on April 11, 1997 regarding "Risk-Based Regulatory Acceptance Criteria for Plant-Specific Application of Safety Goals." In this report, the following two main points were emphasized.

1. The lower tier risk-acceptance criteria (CDF and LERF), now being proposed in 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," for use in making decisions regarding requested changes to a licensee's current licensing basis, should be derived directly from the prompt fatality QHO and should be of such a value as to bound all current sites.
2. In the long run for enforcement purposes, the prompt fatality QHO should be considered as the quantification of a risk level to replace "adequate protection."

Some of the discussion points concerning the derivation of lower tier risk-acceptance criteria included:

- A risk-informed, performance-based regulatory system ought not be implemented without the existence of top-level risk-acceptance criteria. The obvious choices for these criteria are the NRC Safety Goals.
- The subsidiary CDF goal should be elevated to the status of a fundamental goal. Elevating the CDF subsidiary goal to the status of a fundamental goal can be considered as a defense-in-depth principle that provides balance between prevention and mitigation.
- The understanding of risk associated with low-power and shutdown operations, or accidents initiated by external events in which emergency response is impeded, is not yet sufficient to draw definitive conclusions concerning the limiting QHO in these situations.

Some of the discussion points concerning adequate protection include:

- Since each licensed plant must, by definition, provide adequate protection, the licensed plant that poses the highest level of risk places a bound on the quantified level of risk to be associated with "adequate protection."
- Within the spectrum of risk, it is likely that there are plants with risk levels above the Safety Goals and other plants with risk levels below. If this is indeed the case, a single risk level that bounds "adequate protection" would be a risk level greater than the Safety Goal level.
- A long-term objective of replacing the "adequate protection" concept with a well articulated and quantified "acceptable level of risk" if achievable, would enhance the public's understanding and acceptance of the regulatory process and would lead to a more uniform level of protection for all individuals living in the vicinity of nuclear plants.

Additional comments attached to the April 11, 1997 ACRS report, provide examples of approaches that could be used to quantify lower tier acceptance criteria (i.e., LERF, or CDF and conditional containment failure probability), which would ensure that the early fatality QHO is met at each site.

Attachments:

- Report dated November 18, 1996, from T. S. Kress, ACRS Chairman, to Shirley Ann Jackson, NRC Chairman, Subject: Plant-Specific Application of Safety Goals (pp. 13-15)
- Staff Requirements Memorandum, dated January 14, 1997, from John C. Hoyle, Office of SECY, to John T. Larkins, ACRS Executive Director (pp. 16-17)
- Report dated April 11, 1997, from Robert L. Seale, ACRS Chairman, to Shirley Ann Jackson, NRC Chairman, Subject: Risk-Based Regulatory Acceptance Criteria for Plant-Specific Application of Safety Goals (pp. 18-37)



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

November 18, 1996

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Chairman Jackson:

SUBJECT: PLANT-SPECIFIC APPLICATION OF SAFETY GOALS

During the 436th meeting of the Advisory Committee on Reactor Safeguards, November 7-9, 1996, we discussed the application of Safety Goals on a plant-specific basis. This subject was also discussed at meetings of our Joint Subcommittees on Probabilistic Risk Assessment and Plant Operations on July 17-18, 1996, and of our Subcommittee on Probabilistic Risk Assessment on August 7, 1996. We also had the benefit of the documents referenced.

In a Staff Requirements Memorandum dated June 11, 1996, we were requested to provide recommendations on how the Commission's Safety Goals and Safety Goal Policy should be revised to make them acceptable for use on a plant-specific basis.

The Safety Goal Policy Statement made it clear that the Quantitative Health Objectives (QHOs) and the subsidiary Core Damage Frequency (CDF) goal were to provide standards for the NRC staff to judge the overall effectiveness of the regulatory system. That is, if the risk posed by the population of plants on the average proved to be less than the Safety Goals, then the staff (and presumably the public) would deem that the regulatory system had functioned appropriately to protect the health and safety of the public.

The Safety Goals quantified "how safe is safe enough" for the population of U. S. plants. For an individual plant, however, the acceptable level of risk is determined by the concept of "adequate protection," which in the final analysis means compliance with the body of regulations. Risk-informed analyses would provide a more rational basis for making regulatory decisions regarding plant-specific requests for exemptions from the rules or for changes to the licensing basis, and the acceptability of new regulations.

In our August 15, 1996 report, we stated: "the safety goals and subsidiary objectives can and should be used to derive guidelines for plant-specific applications. It is, however, impractical to rely exclusively on the Quantitative Health Objectives (QHOs) for routine use on an individual plant basis. Criteria based on core

damage frequency (CDF) and large, early release frequency (LERF) focus more sharply on safety issues and can provide assurance that the QHOs are met."

In developing plant-specific criteria, it is important to consider the regulatory needs in the near future and to ensure that the process will be evolutionary rather than so revolutionary that it might discourage the licensees from using this approach. It appears that most of the anticipated licensee requests for changes to their current licensing basis will deal with Level 1 probabilistic risk assessment (PRA) issues, e.g., inservice inspection, extension of allowed outage times. Furthermore, most licensees have only recently familiarized themselves with Level 1 PRA methodology for the narrow regime of power operations. They are just beginning to integrate findings of such Level 1 risk assessments with the safe operation of their plants. Even the NRC staff is still coming to grips with the implications of Level 1 risk assessment results for regulation of nuclear plants. Many licensees do not have access to the technologies for facile conduct of full-scope Level 2 or Level 3 PRAs that treat power operations, low power/shutdown operations, as well as accidents initiated by external events. Commonly accepted standards for such extensive, in-depth analyses do not exist.

An evolutionary and pragmatic approach for using Safety Goals on a plant-specific basis would be to use the CDF as the primary criterion for evaluating proposed changes along with a qualitative or quantitative evaluation of the possible Level 2 and Level 3 PRA issues raised by these changes. For a quantitative analysis, the following two options are offered:

- 1) Full-scope Level 2 PRA (with fission product transport capability).

To use this option, a conservative value for a LERF criterion must be determined. This value, along with the CDF criterion, will provide an acceptable basis for decisionmaking. We note that both the NRC staff and the Electric Power Research Institute, in its, "PSA Application Guide," are proposing the use of LERF as an acceptance criterion.

- 2) Full-scope Level 2 PRA (without fission product transport capability).

To use this option, conservative values for early containment failure frequency criteria for different reactor designs must be determined. These values, along with the CDF criterion, will provide an acceptable basis for decisionmaking.

In the longer term, we believe the agency should move beyond the evaluation of risk associated with proposed changes to individual plant licenses and apply the Safety Goals to assess the

acceptability of plant-specific risk. This could be done in terms of the QHOs, along with the CDF, or in terms of the CDF and LERF. To use the QHOs directly, it would be necessary to have full-scope Level 3 PRAs. We believe that the use of Level 3 PRAs in the future should be encouraged.

Sincerely,



T. S. Kress
Chairman

References:

1. Staff Requirements Memorandum dated June 11, 1996, from John Hoyle, Secretary, NRC, to John T. Larkins, Executive Director, ACRS, Subject: Meeting with ACRS, Friday, May 24, 1996
2. ACRS report dated August 15, 1996, from T. S. Kress, Chairman, ACRS, to Shirley Ann Jackson, Chairman, NRC, Subject: Risk-Informed, Performance-Based Regulation and Related Matters
3. Electric Power Research Institute Report TR-105396, "PSA Application Guide," prepared by ERIN Engineering and Research, Inc., August 1995



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
SECRETARY

January 14, 1997

IN RESPONSE, PLEASE
REFER TO: M961206A

MEMORANDUM TO: John T. Larkins, Executive Director
Advisory Committee on Reactor Safeguards

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - MEETING WITH ADVISORY
COMMITTEE ON REACTOR SAFEGUARDS (ACRS), 9:30
A.M., FRIDAY, DECEMBER 6, 1996,
COMMISSIONERS' CONFERENCE ROOM, ONE WHITE
FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO
PUBLIC ATTENDANCE)

The Commission was briefed by the ACRS on the following topics:

1. Digital Instrumentation and Control Systems
2. Office of Nuclear Regulatory Research (RES) Plan for Upgrading Thermal-Hydraulic Codes
3. Risk-Informed, Performance-Based Regulation and Related Matters
4. Potential Use of IPE/IPEEE Results to Compare the Risk of the Current Population of Plans with the Safety Goals
5. Use of Safety Goals on a Plant-Specific Basis
6. Use of RuleNet in the Regulatory Process.

ACRS should continue to be forward-looking to bring developing concerns to the Commission's attention and continue follow up on issues such as digital I&C and use of Safety Goals for regulatory purposes. In this regard, the Commission would be interested in the ACRS views on the relationship between the concept of "adequate protection," as used in the NRC regulations, and the NRC safety goals, from the standpoint of levels of risk.

On the issue of I&C design process and acceptable product performance, the staff was asked to reduce the use of standards referenced and to consider how a process and product specific QA could track requirements and ensure the acceptability criteria is pertinent and sufficient.

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance
DCS - P1-24



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

April 11, 1997

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Chairman Jackson:

SUBJECT: RISK-BASED REGULATORY ACCEPTANCE CRITERIA FOR PLANT-SPECIFIC
APPLICATION OF SAFETY GOALS

In our December 6, 1996 meeting with the Commission, we committed to provide an example of how risk-acceptance criteria could be developed directly from the Safety Goals. Additionally, in a Staff Requirements Memorandum dated January 14, 1997, the Commission asked for our views on the relationship between the concept of "adequate protection," as used in the NRC regulations, and the NRC Safety Goals, from the standpoint of level of risk.

During the 440th meeting of the ACRS, April 3-4, 1997, we completed our deliberations on plant-specific application of NRC Safety Goals and the relationship between the concept of "adequate protection" and the Safety Goals. In our November 18, 1996 report on this subject, we stated that "the safety goals and subsidiary objectives can and should be used to derive guidelines for plant-specific applications." We noted that full-scope Level 3 probabilistic risk assessments (PRAs) would be necessary to use the quantitative health objectives (QHOs) directly to assess the acceptability of plant-specific risk. We also stated that this assessment of risk could be done in terms of the QHOs, along with the core damage frequency (CDF), or in terms of the CDF and large, early release frequency (LERF).

This report further discusses the need for plant-specific application of risk-acceptance criteria and the appropriateness of these criteria being derived from the Safety Goal QHO on early fatalities. The additional comments to this report provide examples of approaches that could be used to quantify lower tier acceptance criteria (i.e., LERF, or CDF and conditional containment failure probability) that will ensure that the early fatality QHO is met at each site. Quantification of the LERF at each site is needed to ensure the appropriateness of the choice of the LERF acceptance criterion proposed in draft Regulatory Guide DG-1061 and draft Standard Review Plan sections that support risk-informed, performance-based regulation.

Need for Plant-Specific Application

The Safety Goal Policy Statement makes it clear that the QHOs and the subsidiary goal on CDF were intended only to provide standards for the NRC to judge the overall effectiveness of its regulatory system. The Policy Statement specifically precludes enforcement of the Safety Goals on a plant-specific basis.

In the development of draft Regulatory Guide DG-1061 and the associated draft Standard Review Plan sections in support of risk-informed, performance-based regulation, the staff has found it necessary to propose risk-acceptance guidelines that can be applied on a plant-specific basis. These guidelines would be used, along with other considerations and inputs, for making judgments on the acceptability of requested changes to a licensee's current licensing basis. Reviewing plant-specific license amendments by using risk-acceptance guidelines is a positive action toward risk-informed, performance-based regulation.

We also note that, in the longer term, the Commission may want to consider having a quantified acceptable risk level to replace the current concept of "adequate protection." This risk level could eventually serve as an objective risk-acceptance criterion for many enforcement decisions.

Risk-Informed, Performance-Based Regulation

The Commission has directed the staff to increase the use of PRA in the regulatory process. We have endorsed this because we believe that a risk-informed, performance-based regulatory approach will lead to increased coherence in the regulatory system, to enhanced decision-making ability, and to technically defensible bases for granting regulatory relief.

A risk-informed, performance-based regulatory system ought not be implemented without the existence of top-level risk-acceptance criteria. The obvious choices for these criteria are the NRC Safety Goal QHOs. As it is the responsibility of the NRC to license individual plants and ensure adequate protection, there seems to be no alternative to plant-specific applications.

Relationship Between Adequate Protection and the Safety Goals

Currently, licensing acceptance criteria are embodied in the concept of "adequate protection." With this concept, a plant that is licensed and complies fully with the applicable rules and regulations, is considered to meet the "adequate protection" standard. "Adequate protection" embodies protection of public health and safety against threats that can be quantified in terms of risk as well as threats, such as sabotage and diversion of special nuclear material, for which the risk cannot now be quantified. In the discussion that follows, the nonquantifiable aspects of adequate protection are set aside. Since there are many ways in which plants can be designed and operated within the confines of the regulations, the natural result is a spectrum of risk levels across the population of operating plants. This conclusion is consistent with the results of the recent Individual Plant Examination Program. Since each licensed plant

must, by definition, provide adequate protection, the licensed plant that poses the highest level of risk places a bound on the quantified level of risk to be associated with "adequate protection."

Within the spectrum of risk, it is likely that there are plants with risk levels above the Safety Goals and other plants with risk levels below. If this is indeed the case, a single risk level that bounds "adequate protection" would be a risk level greater than the Safety Goal level. For those plants with risk levels below the Safety Goals, the difference between the plant risk and the Safety Goals can be viewed as margin. It is from some portion of this margin that plant-specific regulatory relief could be granted. For those plants with risk levels greater than the Safety Goals, the challenge will be to eventually reduce their risk to below the Safety Goal level within the confines of the backfit rule.

Regulatory Transparency

The unquantified "adequate protection" concept is not well understood by the general public because the public is unfamiliar with the regulatory process, the body of nuclear regulations, and associated underlying technical bases. We believe that a long-term objective of replacing the "adequate protection" concept with a well articulated and quantified "acceptable level of risk" if achievable, would enhance the public's understanding and acceptance of the regulatory process and would lead to a more uniform level of protection for all individuals living in the vicinity of nuclear plants.

We note that the use of risk-acceptance criteria such as the QHOs will add stability to the regulatory process. This is because the Safety Goals are determined primarily from considerations of societal risk, while the NRC rules and regulations, which are now used to specify adequate protection, change with time as our understanding of reactor safety issues evolves.

Safety Goals as Risk-Acceptance Criteria

It is our opinion that the QHOs are the appropriate choices for risk-acceptance criteria for plant-specific applications. The Safety Goals are the expression by NRC for "how safe is safe enough." In our opinion, this is what risk-acceptance criteria ought to be. As we stated in our August 15, 1996 report, the subsidiary CDF goal should be elevated to the status of a fundamental goal. Elevating the CDF subsidiary goal to the status of a fundamental goal can be considered as a defense-in-depth principle that provides balance between prevention and mitigation.

The early fatality QHO generally controls the risks from nuclear plant operations. Our understanding of risk associated with low-power and shutdown operations, or accidents initiated by external events in which emergency response

is impeded, is not yet sufficient to draw definitive conclusions concerning the limiting QHO in these situations.

Additional comments by ACRS Member T. S. Kress are presented below.

Sincerely,



R. L. Seale
Chairman

Additional Comments by ACRS Member T. S. Kress

While I agree completely with the Committee's report, I think it could be augmented in two respects. First, it could make it clearer that, with respect to plant-specific application of the Safety Goals, we are making two related, somewhat radical proposals — the second more so than the first:

- 1) That lower tier risk-acceptance criteria (CDF and LERF), now being proposed in Draft Regulatory Guide DG-1061 for use in making decisions regarding requested changes to a licensee's current licensing basis, be derived directly from the prompt fatality QHO and be of such value as to bound all current sites.
- 2) That, in the long run for enforcement purposes, the prompt fatality QHO be considered as the quantification of a risk level to replace "adequate protection."

Second, guidance on how lower tier criteria are to be derived from the QHO is needed. Consequently, I am including two attachments to these additional comments (one developed by me and a complementary one developed by ACRS Senior Fellow Rick Sherry). These provide examples of how to more rigorously derive the lower tier criteria. It is suggested that the staff consider these for use if the first proposal above is to be implemented.

Attachments:

1. Kress, T. S., "Risk-Based Regulatory Acceptance Criteria for Plant-Specific Application of Safety Goals," March 1997
2. Sherry, R. R., "Methodology for Estimating Offsite Early Fatality Risk in the Absence of a Level 3 PRA," March 1997

References:

1. Staff Requirements Memorandum dated January 14, 1997, from John C. Hoyle, Secretary, NRC, to John T. Larkins, Executive Director, ACRS, Subject: Meeting with ACRS, 9:30 A.M., Friday, December 6, 1996, Commissioners' Conference Room.