COMNJD-03-0002

September 8, 2003

MEMORANDUM TO: Commissioner Edward McGaffigan
Commissioner Jeffrey S. Merrifield

FROM: Nils J. Diaz ***/RA/***

SUBJECT: STABILIZING THE PRA QUALITY EXPECTATIONS AND REQUIREMENTS

It is my view that we must clarify Commission policy and expectations of the role, applicability, and characteristics of PRA quality for NRC's risk-informed regulatory decisionmaking. A policy decision is needed to stabilize the PRA quality expectations and requirements and enable its broader and more predictable use in safety-related applications. This need has become pressing with the 50.69 and 50.46 rulemakings, and their SRM statement on PRA quality.

I believe that implementing a phased approach to PRA quality would provide a path towards predictability and increased use of risk insights, thus enhancing safety. The proposed initial phases would establish PRA quality requirements that are commensurate with a specific application or type of application, in a manner similar to the current approach. In the next phase, an acceptable level of PRA quality is specified for all currently envisioned uses, or an "all-applications" phase. In the final phase, the NRC would expect a fully-quantified approach to PRA quality in which PRAs are as good as can reasonably be expected, within the state-of-the-art.

The enclosed proposal entitled "Regulatory Decisionmaking and PRA Quality" presents, for your consideration, a path forward for defining an acceptable and pragmatic means of achieving the requisite PRA quality for regulatory purposes. It describes a phased approach to PRA quality, supportive of and in-phase with the Option 2 and Option 3 activities for risk-informing of our regulations. I ask for your consideration and approval.

Enclosure: As stated

SECY: Please track

Regulatory Decisionmaking
and
PRA Quality

The NRC staff, licensees, and other stakeholders need an improved definition of the Commission's expectations and requirements of acceptable PRA quality for regulatory applications. I believe that the implementation of a phased approach would provide a path towards predictability and increased use of risk insights, thus enhancing safety. The proposed initial phases would establish PRA quality requirements that are commensurate with a specific application or type of application, in a manner similar to the current approach. In the next phase, an acceptable level of PRA quality is specified for all currently envisioned uses, or an "all-applications" phase. In the final phase, the NRC would expect a fully-quantified approach to PRA quality in which PRAs are as good as can reasonably be expected, within the state-of-the-art.

I recommend that the Commission support and encourage continued progress in PRA methodologies and their application through a phased approach to achieving progressively increasing levels of PRA quality, while allowing practical uses of PRA.

Although a PRA is only one element in a risk-informed approach, there is a well known and increasing need to address the issue of "PRA quality" and its relationship to risk-informed decisionmaking. As the utilization and the importance of risk-informed decisionmaking grow and interact with other elements of the NRC regulatory infrastructure, a clear definition of "PRA quality" becomes an enabling factor for the NRC and licensees alike. An unclear definition becomes an unnecessary regulatory obstacle. The issue of PRA quality and appropriate regulatory decisionmaking were discussed extensively during the development of Regulatory Guide (RG) 1.174, and this RG provides guidance on how PRA quality should be addressed in the limited case of license amendment applications.

The approach to PRA quality used in RG 1.174 can be described as a practical and sufficient approach for its intended use, making the best use of the available risk information and insights, and supplementing them, to the extent necessary, with other information, extensive staff review, and conservative decisionmaking. In this context, the original purpose of the industry peer review process and the ASME PRA standard were to make detailed staff reviews of PRAs unnecessary and remove some of the excess conservatism from the decisions to be made, while maintaining acceptable quality for a particular application. In this practical approach, the PRAs only need to be as good as necessary to support the decisions being made.

Recent important Commission activities in risk-informed regulation, specifically the SRMs for 50.69 and 50.46, directly address PRA quality. Subsequently, ACRS letters appear to diverge

from the practical approach of RG 1.174.[1] The Commission SRMs, which call for "high quality" PRAs or for "...a level 2 internal- and external-initiating event all mode PRA, which has been subjected to a peer review process and submitted to and endorsed by the NRC," have set expectations of PRA quality that need to be addressed with increased definition.

Elements of PRA Quality

It is not possible today to define an acceptable level of PRA quality that is usable across-the-board. It is possible to define elements that are intrinsic to the definition of PRA quality, as well as to define the present and envisioned role of PRA quality in the regulatory process.

There is guidance (e.g., Regulatory Guides and Standard Review Plans) on each current type of application (e.g., RG1.174 for license amendments, RG 1.175 for Inservice Testing, RG 1.177 for Technical Specification changes, and RG 1.178 for Inservice Inspection (ISI), ...), and future application-specific guidance is expected. With this type of guidance and the normal NRC staff review and approval process, the issue of risk-informed regulatory guidance has been adequately addressed to date for these specific uses.

The more fundamental PRA quality issue that needs to be addressed is how to judge the elements relating to the baseline PRA (i.e., those independent of the intended application). In addition, it is clear that establishing an acceptable baseline PRA quality would be a major contribution to judging the acceptability of proposed changes.

There are two different sets of elements characterizing "PRA quality." One set consists of "PRA baseline elements" which contributes to characterizing the actual risk at the facility (i.e., they address the accuracy of the PRA in estimating the baseline CDF and LERF). The elements of baseline PRA quality contributing to the accuracy of the baseline estimates include:

- Scope of the PRA
- Fidelity in plant modeling
- Appropriate initiating-event and reliability data (e.g., plant specific vs. generic)
- Level of detail
- Realism in accident progression and success criteria
- Treatment of uncertainties
- Clarity of documentation

A second set consists of "risk-informed decisionmaking elements" that can be used to assess the effects of a change to the facility. The baseline PRA cannot assess plant changes and is therefore not usually utilized, by itself, in regulatory decisionmaking. Thus, in order to assess

[1] Attached is a background statement containing excerpts from pertinent ACRS letters. Additional background information entitled "Background - Statements and Positions on PRA Quality," is being provided to the Commission offices separately and contains direct quotes associated with PRA quality and decisionmaking from recent documents

the effects of proposed plant changes, the baseline PRA model or the input data, or both, need to be changed.

The risk-informed decisionmaking elements are more difficult to define since the role of the PRA, the scope and magnitude, and the safety significance of proposed changes vary so widely from one use to another. The following elements contribute specifically to the quality of risk-informed decisionmaking:

- The ability to understand and model the physical phenomena associated with the proposed change,
- The ability to characterize the proposed changes in terms of changes in the PRA model or its input data
- Level of detail in the areas affected
- Availability of data for the proposed condition
- The ability to assess safety margins and its acceptability
- The ability to assess defense-in-depth and its acceptability
- The ability to monitor the affects of approved changes

Clearly, these later elements are directly related to the regulatory decision being considered; they are, by definition, issue dependent, and they don't play a role in judging the quality of the baseline PRA.

Recommendations for Commission Policy:

In order to achieve the goal of stabilizing the expectations and requirements of PRA quality for risk-informed decisionmaking, and continuing progress on risk-informing NRC activities, the following Commission Policy Statement is proposed.

Commission Policy on Regulatory Decisionmaking and PRA Quality

The Commission endorses the following phased approach to PRA quality to allow the continued practical use of risk-informed methods and continued progress towards adoption of state-of-the-art methodologies.

Phase 1: An Application-Specific Phase of PRA Quality

The Commission continues to support risk-informed and performance based regulation including the current "application-specific" approach to regulatory decision-making. The current approach and guidance to PRA quality as addressed in the Commission's 1995 PRA Policy Statement and in Regulatory Guide 1.174 and Standard Review Plan Chapter 19 constitute "Phase 1", an application-specific quality approach. For the last several years, each risk-informed application and PRA analysis has been judged only in the context of the application for which it was being used (i.e., there has been no application-independent definition of PRA quality). This approach has been technically adequate and has been a practical way to advance the use of PRA, as called for in the Commission's 1995 PRA Policy Statement.

Since almost all licensees have participated in the industry peer review process and have evaluated their PRAs against the NEI guidance document, PRA quality above this basic level has likely already been achieved. The Commission considers that this level of PRA quality is not fully satisfactory for the longer term since it would not promote efficiency in PRA reviews or fully support standards development activities. Although this approach is still adequate for the intended regulatory decisions, it is not justifiable for the long term and should eventually be phased out once more desirable approaches are achievable.

Phase 2: An Issue-Specific Phase of PRA Quality

The first step towards a more efficient approach should be to establish an "issue-specific" phase to PRA quality. During this "issue-specific" phase, each general topic (such as: risk-informed ISI applications, or risk-informed Tech Spec applications, or risk-informed 50.46 applications) should be addressed with a PRA that meet applicable consensus standards (e.g., ASME standard at Capability Category II). With respect to the critical issue of PRA scope, this phase should have PRAs that address all modes and all initiators applicable to the issue. Some modes and initiators could be addressed qualitatively but all significant modes and initiator, those that could change the regulatory decision substantially and that are applicable to the issue and within the scope of the change being considered, should to be quantified and should include an uncertainty analysis.

This phase should be supported by an informal NRC program to monitor PRA quality through the application reviews and through a periodic check of the licensee PRA against the NRC models (e.g., SPAR models and SDP Notebooks).

The issue-specific phase to PRA quality represents the state of affairs after the development and implementation of an issue-specific PRA standard and related peer review process; that is, the condition in which RG 1.174 and SRP Chapter are supplemented and supported by some standard and/or guidance for use in the technical areas of the issue. This phase addresses PRA quality in the context of specific types (or groups) of issues. It is clear that this level of PRA quality is widely supported by both the NRC and the industry, judging from the level of support for the various standards activities. Since standards and/or guidance is planned for each type of use, this phase should provide a specific basis to support each presently planned use, including the proposed 50.69. Full implementation of the proposed 50.69 could involve a broad spectrum of plant systems and require extensive quantification. However, system-by-system implementations could limit the need for quantitative analysis since not all initiators and modes affect every system.

The Commission endorses implementing this phase through consensus standards and revisions to Regulatory Guide 1.174, SRP Chapter 19 and related documents. Realistically, the Commission recognizes that this second phase will need to be approached over the short-term during which fewer and fewer cases following the phase 1 approach will be seen.

The Commission concludes that a rule to require a specific level of PRA quality is not presently necessary; however, to implement this Commission policy, the staff needs to give low priority or to return non-conforming applications because of their adverse affect on effectiveness and

efficiency. The staff has the Commission's approval to take those actions, as necessary, following a reasonable transition period.

Phase 3: An All-Applications Phase of PRA Quality

The Commission supports and encourages continued progress in PRA methodologies beyond Phase 2, with the goal of achieving a level of PRA quality consistent with using enhanced PRAs for all currently envisioned regulatory or operational uses. This phase therefore differs from Phase 2 in that a single base-line PRA should be fully capable of supporting currently envisioned uses and doing so in a manner consistent with all the applicable consensus standards.

With respect to the critical issue of PRA scope, this phase requires PRAs to consider all modes and all initiators applicable to the full range of currently envisioned issues. Since there are a wide variety of applications currently envisioned, this would likely correspond to all modes and all initiators reasonably applicable, that is, power operation, low-power and shutdown, internal and reasonable external events. Some modes and initiators could be addressed qualitatively but all significant modes and initiators (those that could change the regulatory decision substantially) should be quantified and should include an uncertainty analysis.

Currently envisioned uses include: license amendment requests, Maintenance Rule (a) (4), RI-ISI, RI-IST, 50.69 Special Treatment alternative, RI-50.46, and initiatives to risk-inform Part 50.

The all-applications phase has the advantage of providing the efficiencies associated with preparing and reviewing applications which are based on sound quality and well understood baseline PRA models. Reviews will require fewer resources and the rate of rejection would presumably be lower (another measure of efficience). The Commission expects that this approach will also contribute to increased confidence in the results, both among the staff and with other stakeholders. The Commission also recognizes that this approach will require substantial investments in time and resources on the part of the NRC staff and the licensee in order to get the quality baseline PRA. In addition, consensus will need to be developed around the issue of "reasonably foreseeable uses."

Phase 3 is seen as a goal for the time beyond our near-term goals of implementing Phase 1 and Phase2. Implementation of this phase will require enhanced consensus standards and revisions to NRC guidance documents.

Phase 4: A Fully-Quantified Phase of PRA Quality

The Commission also expects that, ultimately, PRA quality will more and more nearly approach the available state-of-the-art capabilities, with full-scope, full quantification and full uncertainty analysis, all based on realistic models and abundant data. Advancement toward this high level of PRA quality should be a continuing process in which the PRA quality would increase as the state-of-the-art progressed.

The fully-quantitative approach to PRA quality will require significant developmental efforts and time prior to its implementation. One major impediment to this approach is the current lack of PRA consensus standards in the areas of low-power and shutdown, seismic analysis, flooding and fires. This lack of consensus standards will probably involve several years of effort after Phase 3 is developed and proven. In addition, the need for NRC review and approval of more than 70 PRAs would make this phase very resource intensive, and thus the Commission recommend that resources for pursuing Phase 4 be allocated after Phase 2 and Phase 3 have established a functional framework.

Pertinent programs and activities need to be evaluated to determine if current staff positions and guidance are consistent with the approaches described above. Where necessary, activities will need to be redirected to be compatible with the policy.

The Commission is establishing this policy to support the goals of continued near-term progress in enhancing safety through the use of available risk-informed methods while striving for increased effectiveness and efficiency in the longer term. The Commission also concludes that the increased clarity of its goals and its commitment to quality and progress will contribute to increased confidence among stakeholders and enable increased utilization of risk-informed decisionmaking.

Background Information Containing Excerpts From Pertinent ACRS Letters Referred to in Footnote 2

The ACRS letter on "Draft Final Revision 1 to Reg Guide 1.174 and to Chapter 19 of the SRP," 7/23/02 is an example of the present controversy on acceptable PRA quality, which discusses the advantages and disadvantages of a less pragmatic approach. A few key statements from this letter are quoted below:

> "The publication of RG 1.174 and associated SRP Chapter 19 in 1998 was a major milestone in the NRC initiative to risk informing the regulations. RG 1.174 introduced the concept of an integrated decisionmaking process that had as inputs risk information, considerations of defense-in-depth, and sufficient safety margins . . .
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> ... the Guide did not determine acceptance in terms of strict numerical values for DCDF and DLERF and did not specify how to integrate various inputs to the decisionmaking process. Also, the Guide stated that the scope, level of detail, and technical acceptability of the PRA should be commensurate with the application.
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> Although this approach has been successful in the development of some risk-informed licensing changes, such as risk-informed inspection programs, it had the unfortunate consequence that it did not encourage the development of full-scope PRAs for all operational modes nor the use of rigorous methods in developing risk information.
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> Incomplete and less-than-rigorous PRAs undermine the credibility of the entire risk-informed regulatory process. We believe that the slow progress of risk-informed initiatives can be attributed, in part, to this lack of credibility . . .
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> ... the revised guidance should specify that a licensee who wishes to take advantage of risk information produce such information using methods consistent with rigorous consensus standards and include all significant sources of risk from all plant modes. Such a provision would bolster the credibility of risk-informed decisions and reduce the staff and licensee effort required to assess risk implications of licensing changes . . . "
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> Additional comments were provided by ACRS Members Dana A. Powers and John D. Sieber, showing the diversity of opinions on the issue:
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> "Our colleagues have the laudable desire to encourage improvements in the scope and depth of probabilistic risk assessments being utilized by licensees especially when they seek risk-informed changes to licensing bases. Our colleagues are, however, seeking improvements with such demands for rigor and stringency, regardless of need, that they may alienate some applicants. Such demands will increase the burdens associated with RG 1.174 and SRP Chapter 19 for both applicants and the NRC staff."