UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

ACRSR-2267

September 26, 2007

The Honorable Dale E. Klein
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

SUBJECT: DEVELOPMENT OF A TECHNOLOGY-NEUTRAL REGULATORY FRAMEWORK

Dear Chairman Klein:

During the 545th meeting of the Advisory Committee on Reactor Safeguards (ACRS), September 6-8, 2007, we completed our review of draft NUREG-1860, "Framework for Development of a Risk-Informed, Performance-Based Alternative to 10 CFR Part 50." We met with the NRC staff and discussed this matter during our 540th meeting, March 8-9, 2007. In addition, our Subcommittee on Future Plant Designs reviewed this document on March 7, 2007. We had the benefit of the documents referenced. In our May 16, 2007, report we stated that there were issues, critical to the development of a framework, that were still being debated within the ACRS. This report provides our view on some issues important to the development of a conceptual framework.

CONCLUSIONS AND RECOMMENDATIONS

1. We concur with the staff that the safety objective of the framework should be to ensure that advanced reactors, as a minimum, provide at least the same degree of protection of the public and the environment that is required for current-generation light water reactors (LWRs), and that advanced reactor designs comply with the Commission's safety goal quantitative health objectives (QHOs).

2. We concur with the staff that a set of licensing-basis events (LBEs) is needed as part of the licensing basis to structure the interactions between the staff and the applicant and to focus the conduct of mechanistic analyses. Identifying the LBEs by using the probabilistic risk assessment (PRA) reduces the risk that licensing-basis requirements will divert attention from events of real safety significance.

3. The use of a frequency-consequence (F-C) curve is an appropriate way to establish a range of regulatory requirements to limit radiation exposure to the public. However, a sequence-specific F-C curve, such as that developed in NUREG-1860, may not be a sufficient licensing criterion. A complementary cumulative distribution function (CCDF) F-C curve ("risk curve") that sums the contributions to risk from the entire spectrum of accident sequences establishes limits on risk better than the LBE F-C curve.

4. We are concerned that extension of the F-C curves to very low dose levels may unduly increase requirements for the scope and level of detail in the PRA performed to demonstrate compliance with the F-C curve. It may also detract attention from accidents which could have a more significant impact on public health and safety.

5. The framework should recognize accident prevention as a fundamental regulatory goal and should specify a quantitative limit on the frequency of an accident. In technology-neutral terms, an accident can be defined as the release of radionuclides within the plant significantly in excess of normal operating limits.

DISCUSSION

The framework proposed by the staff is intended to provide the conceptual basis for the development of a technology-neutral regulatory system. This system is intended to achieve a level of safety considering all modes of operation that is consistent with the expectations stated in the Commission's policy statement entitled, "Regulation of Advanced Nuclear Power Plants." The policy statement states that the Commission expects that advanced reactors will provide enhanced margins of safety and that advanced reactor designs will comply with the Commission's Safety Goal Policy Statement (Safety Goals). The Commission also expects that advanced reactors should provide, as a minimum, at least the same degree of protection of the public and the environment that is required for current-generation LWRs.

Reactors must be designed and operated in a manner that ensures "adequate protection" to the public. Lower levels of risk are desirable and can be considered in terms of cost benefit. The Safety Goals define a level of risk below which no additional risk reductions need to be considered. The objective of the framework is to help develop requirements for future reactors that will ensure there is only a small chance that the risk will exceed that defined by the Safety Goals. Since all risks may not be recognized or fully evaluated in the design certification and licensing process, the regulatory system should also address situations or conditions at operating reactors in which the risks could exceed the Safety Goals.

For application to a site, the framework states that the integrated risk from all new reactors at the site must meet the QHOs. We concur with the staff that this is an appropriate level of expectation for safety in new reactors and an appropriate treatment of risk at a site.

Compliance with the QHOs depends, in part, upon site characteristics. For design certification, it is convenient to have criteria that minimize dependence on site characteristics. The approach taken in the framework to define criteria that can be used by the designer is to provide limits on dose at certain distances from the plant boundary. The staff assumes that these dose limits are sufficiently conservative to provide a high degree of confidence that a design which meets these limits will meet the QHOs and other regulatory limits at most sites. Although such dose limits will in fact be technology dependent, we concur with this approach for developing guidance for designers.

In addition to the QHOs, the current regulations have other limits on the release of radioactive material and on radiation doses to the public during normal operation and hypothetical accidents. In the staff's current approach to a framework, these requirements have been used to develop an F-C curve where the frequency is frequency of an individual PRA sequence and the consequence is the dose associated with that sequence, calculated at prescribed distances that vary with the frequency. Such an approach can also be viewed as a defense-in-depth measure that sets high-level requirements for reliability and inspection. Limits on the frequencies of smaller releases on this F-C curve control the allowable degradation of "barriers" that prevent the inadvertent release of radioactive material to the environment.

In the development of such an F-C curve, the goal is to provide consistency with 10 CFR Part 50, 10 CFR Part 20, Environmental Protection Agency requirements, and the QHOs. NUREG-1860 presents a candidate F-C curve. Some judgment was required to assign frequencies to the various dose ranges. An alternative candidate F-C curve is discussed in EPRI TR-1013582, "Technical Elements of a Risk-Informed, Technology-Neutral Design and Licensing Framework for New Nuclear Plants." It is premature to determine whether either of these curves is the most appropriate expression of the current requirements.

In addition to the requirement that each PRA sequence meet the F-C curve limits, the PRA results must demonstrate that the total integrated risk satisfies the QHOs. There are also some additional cumulative dose limits for sequences with frequencies greater than 10^{-3}/year. However, the current framework as described in NUREG-1860 does not contain a complete definition of risk in terms of a CCDF F-C curve, which describes the frequency of exceeding a given dose summed over all PRA sequences ("risk curve"). A CCDF F-C curve establishes better limits on risk. A candidate CCDF F-C curve that attempts to provide consistency with the QHOs, other regulatory requirements, and reflects experience with current operating reactors is discussed in EPRI TR-1013582. However, development of an appropriate CCDF F-C curve will require additional effort.

The F-C curve, the QHOs, and a CCDF F-C curve prescribe limits on the release of radioactive material from the plant. The framework currently does not have a quantitative requirement for accident prevention corresponding to the core damage frequency (CDF) value currently used for LWRs. The discussion of surrogate measures such as CDF in NUREG-1860, notes their usefulness in balancing accident prevention and mitigation, but continues to focus on their usefulness as simplified representations of the QHOs. Accident prevention should be considered a fundamental goal of regulation. In technology-neutral terms, an accident can be defined as the release of radionuclides within the plant significantly in excess of normal operating limits. Although it may not be possible to relate a limit on the frequency of such accidents to the QHOs, it would be a reasonable extension of current regulatory practice to establish a quantitative limit on the frequency of such accidents. Such a requirement should be included in the framework.

The framework described in NUREG-1860 envisions a far more central role for PRA in the regulatory system and design process than in the current licensing process. Even though there will be significant issues of modeling uncertainty and completeness associated with new designs, PRA methods provide the best tool to identify vulnerabilities that challenge design assumptions. For LWRs, the scope of PRAs has been focused on estimates of the frequency of beyond-design-basis accidents. For future reactor designs, the PRA approach described in the framework provides estimates of the frequencies of sequences with consequences that range from small releases to severe accidents with large releases of radioactive materials. We are concerned that extension of the F-C curve to very low dose levels may unduly increase requirements for the scope and level of detail in the PRA performed to demonstrate compliance with the F-C curve. It may also detract attention from accidents which could have a more significant impact on public health and safety.

In NUREG-1860, it is proposed that the PRA be used to identify a set of LBEs that encompass a whole spectrum of off-normal events (including frequent, infrequent, and rare initiating events and event sequences) and include a spectrum of radioactive material releases from minor to major. An additional defense-in-depth LBE is imposed to ensure that a postulated release of radioactive material from the fuel and the reactor will not exceed the 10 CFR Part 100 limits.

The LBEs play a role akin to design-basis accidents (DBAs) in 10 CFR Part 50. However, there are important differences. LBEs are based on sequence frequencies, not initiating event frequencies. They are not artificially limited to considerations of single failure, and thus allow considerations of vulnerabilities associated with a relatively frequent initiating event cascading through a series of failures to an event with significant consequences.

The LBEs will be proposed by the applicant and reviewed and approved by the staff. The LBEs are chosen from the PRA by grouping similar accident sequences into an event class. An LBE is selected as the event from the class with the bounding consequence. It is assigned a frequency equal to the most frequent event in the class. There is no unique definition of a "sequence" in a PRA. This is recognized in NUREG–1860 and some guidance is provided to ensure that the sequences to be compared to the F-C curve and used to identify the LBEs are defined in a meaningful way. However, additional guidance would have to be provided in order to implement the framework. Since the PRA is envisioned as a living PRA, LBEs can be changed during the life of the plant based on operational experience or other additional knowledge.

Although the PRA provides the best characterization of the risk of the plant, we support the concept of the LBEs. The LBEs provide a useful check on the quality of the mechanistic analyses used in the PRA, provide additional margin, establish a well-defined commitment for the licensee, and set limits on regulatory attention and control. Since LBEs are based on the PRA, there is less chance that they will divert attention from events of real safety significance, as can be the case with the current DBA approach. The licensing basis may also include other metrics from the PRA such as importance measures.

The use of LBEs as the fundamental licensing basis reduces the dependence on the "bottom line" numbers of the PRA. The PRA is used primarily to identify the most significant sequences and not to provide "risk numbers" as part of the licensing basis.

Additional comments by ACRS members Thomas S. Kress, Dana A. Powers, and Graham B. Wallis are provided below.

Sincerely,

/RA/

William J. Shack
Chairman

Additional Comments by ACRS Member Thomas S. Kress

The Committee's report does not embrace two long-standing ACRS positions: (1) the criteria for design safety of new reactors should be consistent with a core damage frequency (CDF) of 10^{-5}/year and a large release frequency (LRF) of 10^{-6}/year; and (2) design and siting should be separated as much as practical in the regulatory process.

The report correctly considers that a frequency-consequence complementary cumulative distribution function (CCDF) design acceptance criterion would properly summate the risk. It should be a mandatory part of the framework. It is entirely possible to construct such a CCDF acceptance criterion that would make it consistent with any chosen values of CDF and LRF. The ACRS report should call for the inclusion of such a criterion for CDF of 10^{-5}/year and LRF of 10^{-6}/year for the following reasons:

- These values would ensure that several such plants placed on a greenfield site would meet the current QHOs with margin.
- The recommended values for CDF and LRF are consistent with current U.S. and international positions.
- Having a CCDF criterion that embodies both a CDF and a LRF provides for a balance between prevention and mitigation.
- Such a criterion would provide a consistent way to compare the safety status of new plants with that of the current plants.
- It would also provide a way to relate new regulatory requirements to the existing ones that utilize CDF and large early release frequency (LERF) (for example, the Backfit Rule).
- Societal risk is not addressed by either the framework or the ACRS report. The above recommended value for LRF is highly likely to be a good surrogate for acceptable societal risk.

In accepting the framework's LBE frequency-consequence figure-of-merit design curve which uses dose as the consequence measure, the Committee has compromised the principle of separation of design and siting. This curve requires the designer to utilize a surrogate characteristic site along with a level-3 PRA to determine the dose targets. This is an unnecessary burden to place on the design at the stage for which the actual site is not known especially since the use of equivalent curies released from containment will better serve the purpose and be simultaneously compatible with the CCDF LRF criterion that necessarily uses curies released as the consequence measure. This compatibility greatly enhances the design process that is envisioned to require iteration on the figure-of-merit acceptance curve to meet the real risk criteria embodied in the CCDF curve.

Additional Comments by ACRS Member Dana A. Powers

A well crafted, technology-neutral regulatory framework could facilitate the development of higher efficiency nuclear power technologies and innovative application of nuclear technologies to address the economic and security issues confronting our Nation. The overly complicated regulatory framework developed by the staff is not a useful first step in the needed evolution of the current regulatory system to become technology neutral.

The proposed framework is not well founded. My colleague, Professor Wallis, has gone to great lengths to point to questionable elements of the framework foundation. I note that staff did not take advantage of the current General Design Criteria (Appendix A, 10 CFR Part 50) many of which were defined before there was broad acceptance of LWR technology and are, consequently, technology neutral. Regulatory experience of the last 35 years might well suggest a few additional criteria or some amendment of current criteria. Together, these criteria would have provided a sound foundation for a technology-neutral regulatory framework useful to nuclear power plant designers, builders, and regulators.

Instead, staff has chosen to base its proposed regulatory framework on risk assessment. The proposed framework demands PRAs well beyond the current state of the art. It is plausible that future risk assessments, unlike those done today, could address all accident initiators under all modes of operation in some integrated way. It might be possible in some future time to do the comprehensive uncertainty analysis addressing both parameter uncertainty and model uncertainty to obtain mean values for comparison to the quantitative health objectives that the staff envisages in its proposed framework. But, the staff has gone well beyond even this plausible future to expand the scope of PRAs mandated for regulation to extremes not even imaginable today. The introduction of the frequency-consequence (F-C) curves extending down to very low dose levels will necessitate these vast expansions in the scope of risk assessments. Risk assessments will need to include events associated with drains in the plant chemistry laboratory to meet staff expectations communicated through the F-C curves. This expansion in scope will impose burdens on both licensees and regulators heretofore never imagined. It will detract from a focus on safety issues that really do pose significant threats to the public health and safety.

The complexity of the proposed framework may have arisen as the authors attempted to satisfy many skeptics. Preservation of the design basis accident (DBA) concept under the guise of "licensing basis events" (LBEs) is remarkable. The deficiencies of DBAs as a feature of the regulatory system have become apparent to us all since the Three-Mile Island accident in 1979. Staff proposes that all pretense of realistic regulation be abandoned for the LBEs. Like the current DBAs, these LBEs will be analyzed using very conservative methods. Staff hopes that such LBEs will be defined anew for each reactor technology and each change to each technology, and discounts the likelihood that LBEs will ossify much as have DBAs into a legalistic analysis framework disconnected from physical reality. The technology-neutral regulatory framework proposed by the staff is destined to descend into a concentration on a few stylized accidents driven as a result of the focus on very low probabilities and the consequent neglect of more probable events that actually pose risks to the public. Preservation of the DBA concept is all the more remarkable in the proposed framework since it appears to turn its back on the breadth of attention sought in the drive over the last few years to develop a risk-informed regulatory system.

All of the motivations for the preservation of the current regulatory approach via the LBEs are not entirely certain. It may be that the staff sought a mechanism to develop sufficient understanding to optimize application of inspection and monitoring resources to new types of nuclear power plants. It is remarkable that the authors elected not to use importance metrics derived from the risk assessments such as "risk achievement worth" and "risk reduction worth." The importance metrics are among the most powerful results that can be derived from risk assessments even when these risk assessments do not meet the extreme standards of scope envisaged in the proposed framework. The authors mandate construction of risk assessments of unbelievable scope and depth but make no use of the results beyond a rather effete comparison to "bottom line" risk results widely considered to be the most uncertain aspects of risk assessments. The importance metrics derived from the risk assessments provide a comprehensive examination of systems, structures, and components important to plant safety and an identification of those critical aspects of plants that merit close inspection and monitoring. The metrics do this without singling out particular types of accidents. The metrics are most reliable when they are derived from realistic analyses. The importance metrics of risk assessments have already been demonstrated to be a far more useful mechanism for the optimal allocation of safety resources by both the licensee and the regulator. Use of both risk reduction worth and risk achievement worth could be developed into a rational mechanism for introduction of defense-in-depth into safety regulation. Yet, importance metrics make no appearance in the proposed regulatory framework.

Some have suggested that the proposed framework be tested on a new reactor technology such as a gas-cooled nuclear power plant. I think this is not a good idea. Aside from the deficiencies of the proposed framework identified above and elsewhere, there is not a good phenomenological basis for assessing gas-cooled reactor safety. Even such a routine analysis as assessing the radionuclide release associated with expected depressurization events at gas-cooled reactors cannot be confidently done today as has been demonstrated in a Phenomena Identification and Ranking exercise recently undertaken by the NRC staff. This will assuredly handicap any application of a proposed regulatory framework focused as this one is on F-C curves and bottom-line risk results.

Additional Comments by ACRS Member Graham B. Wallis

My colleagues have made considerable progress on this important issue. However, there are still many features of some of the recommendations by them and by the staff for which the justification and implications have not been adequately evaluated.

The framework proposed by the staff in draft NUREG-1860 requires substantial revision to demonstrate that it responds to the needs of the Agency and that appropriate choices have been made. I have provided reasons and suggestions in a set of detailed comments which has been shared with the staff (Reference 6).

At an early point in the revised document, the following questions should be answered by providing convincing analysis and rationale:

- Are the QHOs the only top level regulatory criteria? Should they be supplemented by additional metrics such as those describing societal and environmental risk? (There are disparate assessments of the health effects of the Chernobyl event, but little doubt of the consequences for the livelihood of farmers and herders in the northern U.K. and Scandinavia).

- The QHOs are probabilistic criteria. They depend on the PRA results. With what confidence should they be met? Is the level of technical representation of accident scenarios in the PRA adequate to form the sole major basis for regulation?

- Are the QHOs realistic requirements? They have not been used in previous regulation. The example in Appendix E appears to show that a current LWR would fail to meet them. The latent cancer QHO is equivalent to 4 mrem/Ry; this can all be consumed by a few frequent events of insignificant consequence which would not now be modeled in the PRA. Multiple-reactor sites might fail to meet this requirement under present normal operating conditions.

- Do the QHOs need to be supplemented by requirements for additional "deterministic" analyses of the type represented by 10 CFR 50.46? How will these differ from the mechanistic analyses in the PRA? To what degree should this requirement be specified? How is it decided how much is enough?

- Should defense-in-depth requirements, such as for a containment/confinement, multiple barriers and a coolable geometry, be imposed? If so, shouldn't they be described as part of the basis of the framework and not hidden in a few lines of text?

- Should anything be specified about the allowable frequency-consequence spectrum of accidents? What functions will this serve? What is the best choice of format?

- What will be used to describe the overall safety status of the plant? CDF and LERF now play this role. Can the QHO metrics be used instead?

- Will the PRA technical analysis incorporate tools such as the thermal-hydraulic codes used in the current analysis of DBAs, as appears to be indicated in Appendix F? Does this require major technical and computational research and development?

- Besides requiring that a licensee meet the QHOs by summing up the latent cancer and fatality metrics from the PRA outputs, and perhaps also meet some defense-in-depth criteria, are any secondary requirements desirable? Some, such as for PRA quality, may be justified in the interest of effectiveness and efficiency in meeting the primary ones. Do some other requirements in Part 50 and other existing regulations influence the design of the framework? Are these compatible with the QHOs?

- What regulatory functions does the framework satisfy at the design certification stage, the combined license (COL) stage, and later stages of regulation such as approval of changes to the plant? Are there needs for inspection and enforcement which require that additional or modified features be specified in some parts of the framework? Will there be additional site- and technology-specific requirements?

- What will the "licensing basis" of a plant look like under the new framework? Will the Safety Analysis Report (SAR) be significantly better focused, more economical for the Agency and the licensee, and clearer to the informed public than under the present system?

<u>References:</u>

1. Memorandum dated April 3, 2007, from Farouk Eltawila, Director, Division of Risk Assessment and Special Projects, RES, to Frank P. Gillespie, Executive Director, ACRS, Subject: Transmittal of Proposed "Technology Neutral Framework" for Advisory Committee on Reactor Safeguards Review.
2. Report dated April 20, 2007, from William J. Shack, Chairman, ACRS to Dale E. Klein, Chairman, NRC, Subject: Technology-Neutral Framework for Future Plant Licensing.
3. Report dated May 16, 2007, from William J. Shack, Chairman, ACRS to Dale E. Klein, Chairman, NRC, Subject: Draft Commission Paper on Staff Plan Regarding a Risk-Informed and Performance-Based Revision to 10 CFR Part 50.
4. U.S. Nuclear Regulatory Commission Policy Statement on "Regulation of Advanced Nuclear Power Plants," published July 12, 1994, 59 FR 35461.
5. EPRI-1013582, "Technical Elements of a Risk-Informed, Technology-Neutral Design and Licensing Framework for New Nuclear Plants," December 2006.
6. Letter dated July 24, 2007, from Graham B. Wallis, ACRS to Luis A. Reyes, Executive Director for Operations, NRC, Subject: Comments on Draft NUREG-1860, "Framework for Development of a Risk-Informed, Performance-Based Alternative to 10 CFR Part 50."

References:
1. Memorandum dated April 3, 2007, from Farouk Eltawila, Director, Division of Risk Assessment and Special Projects, RES, to Frank P. Gillespie, Executive Director, ACRS, Subject: Transmittal of Proposed "Technology Neutral Framework" for Advisory Committee on Reactor Safeguards Review.
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