May 12, 2010

MEMORANDUM TO: Edwin M. Hackett, Executive Director
Advisory Committee on Reactor Safeguards

FROM: Charles E. Ader, Director /**RA**/
Division of Safety Systems and Risk Assessment
Office of New Reactors

SUBJECT: TRANSMITTAL OF DRAFT COMMISSION PAPER ON
RISK-INFORMED REGULATORY GUIDANCE FOR NEW REACTORS

In April and June 2009, the staff met with the Advisory Committee on Reactor Safeguards (ACRS) and its Subcommittee on Reliability and Probabilistic Risk Assessment, respectively, to discuss risk metrics for new light-water reactor risk-informed applications. A follow-up meeting with the ACRS is planned for June 10, 2010. In support of this meeting, the staff has prepared a draft Commission paper describing the related issues and the staff's planned approach. The staff intends, together with stakeholders, to identify appropriate changes to the existing risk-informed guidance for changes to the licensing basis, including operational programs, and to the Reactor Oversight Process.

The staff requests that this draft paper, which has been concurred on by the affected offices, be shared with the ACRS in advance of the June 10, 2010, meeting.

Enclosure: As stated

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FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: STATUS OF STAFF EFFORT TO EVALUATE THE RISK-INFORMED REGULATORY GUIDANCE FOR NEW REACTORS

PURPOSE:

Since publication of the Commission's Probabilistic Risk Assessment (PRA) Policy Statement in 1995, the U.S. Nuclear Regulatory Commission (NRC) staff has developed or endorsed numerous guidance documents to support risk-informed changes to the licensing basis and the reactor oversight process (ROP). The purpose of this paper is to provide the Commission a status of staff efforts to evaluate the risk-informed regulatory guidance (a) to recognize the lower risk profiles of new reactors[1] and (b) to prevent a significant decrease in the enhanced levels of safety provided by new reactors.

SUMMARY:

In early 2009, the staff provided the Commission a memorandum with a white paper enclosed. The 2009 paper identified potential issues with applying the current guidance for risk-informed changes to the licensing basis, including operational programs (e.g., risk-managed technical specifications), and the ROP to new reactors with lower risk estimates. In the memorandum, the staff informed the Commission about the staff's intent to engage external stakeholders in the development of potential options.

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[1] For the purpose of this paper, the term "new reactor" refers to evolutionary and advanced light-water reactors (LWRs) that have been certified or are under review as standard designs by the NRC.

Based on these interactions with stakeholders, the staff evaluated three approaches related to the risk-informed regulatory guidance for new reactors. The staff concluded that the best approach would be to continue to work with stakeholders to identify specific changes to the risk-informed guidance for the ROP and changes to the licensing basis that would prevent a significant decrease in the level of safety of the new reactor over its life. This approach supports the Commission's expectation for new plants.

BACKGROUND:

The regulatory interactions for new reactors, like operating reactors, in the areas of licensing and oversight rely upon a number of regulatory processes and guidance, some of which are risk-informed. The current framework that supports risk-informed regulation consists of guidance for reactors that can be grouped into four major categories:

- *Guidance for changes to a licensee's approved licensing basis without prior NRC approval.* In this category, the NRC's endorsement of Nuclear Energy Institute (NEI) 96-07 in Regulatory Guide (RG) 1.187 supports implementation of Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.59.
- *Risk-informed guidance to support changes to a licensee's approved licensing basis including operational programs with prior NRC approval.* In this category, RG 1.174 and associated guidance (e.g., RG 1.177 on risk-informed technical specifications) provide a risk-informed integrated decision-making framework.
- *Guidance to support implementation of risk-informed regulations.* In this category, NRC endorsement of Nuclear Management and Resources Council (NUMARC) 93-01 in RG 1.160 and RG 1.182 supports implementation of the Maintenance Rule (10 CFR 50.65).
- *Guidance to support implementation of the ROP.* Management Directive (MD) 8.13 documents the staff's regulatory oversight process under the ROP. Implementation of specific aspects of the ROP is found in the Inspection Manual Chapters (IMCs).

The staff recognizes that when applying the above regulatory framework to plants licensed under 10 CFR Part 52, there are important considerations arising from Commission guidance regarding its expectations on enhanced safety for the new reactor designs. From the Policy Statement on "Severe Reactor Accidents Regarding Future Designs and Existing Plants," dated August 8, 1985 (50 *Federal Register* (FR) 32138), the Commission stated that it "fully expects that vendors engaged in designing new standard (or custom) plants will achieve a higher standard of severe accident safety performance than their prior designs." The Policy Statement on the "Regulation of Advanced Nuclear Power Plants," dated July 8, 1986 (and restated July 12, 1994; 59 FR 35461), further stated that "the Commission expects that advanced reactors will provide enhanced margins of safety and/or utilize simplified, inherent, passive, or other innovative means to accomplish their safety functions." This policy is effectively implemented by design certifications, which codify in rules the severe accident enhancements in the new reactor designs, and in environmental impact assessments, in which severe accident mitigation design alternatives are considered based on the lower risk profile estimates of the new reactor design.

In the staff requirements memorandum dated February 15, 1991, for SECY-90-377, "Requirements for Design Certification under 10 CFR Part 52," the Commission approved a process similar to 10 CFR 50.59 for making changes to Tier 2 information between combined license (COL) issuance and authorization for operation. The Commission stated that "the staff should ensure that this process requires preservation of the severe accident, human factors, and operating experience insights that are part of the certified design." Under Part 52, the process for changes and departures for each certified reactor design is found in Section VIII of the appendix that contains its design certification rule.

Furthermore, the Statement of Considerations (SOC) of the standard design certification for the Advanced Boiling Water Reactor (ABWR) design (62 FR 25800, 25810) highlights the Commission's position regarding the change process as it relates to the PRA and severe accidents as follows.

> [T]he Commission recognizes that the ABWR design not only meets the Commission's safety goals for internal events, but also offers a substantial overall enhancement in safety as compared, generally, with current generation of operating power reactors The Commission recognizes that the safety enhancement is the result of many elements of the design, and that much but not all of it is reflected in the results of the probabilistic risk assessment (PRA) performed and documented for them. In adopting a rule that the safety enhancement should not be eroded significantly by exemption requests, the Commission recognizes and expects that this will require both careful analysis and sound judgment, especially considering uncertainties in the PRA and the lack of a precise, quantified definition of the enhancement which would be used as the standard.

The Commission adds in the SOC that:

> [T]he Commission on its part also has a reasonable expectation that vendors and utilities will cooperate with the Commission in assuring that the level of enhanced safety believed to be achieved with this design will be reasonably maintained for the period of the certification (including renewal). This expectation that industry will cooperate with NRC in maintaining the safety level of the certified designs applies to design changes suggested by new information, to renewals, and to changes under section VIII.B.5 of the final rule. If this reasonable expectation is not realized, the Commission would carefully review the underlying reasons and, if the circumstances were sufficiently persuasive, consider the need to reexamine the backfitting and renewal standards in Part 52 and the criteria for Tier 2 changes under section VIII.B.5.

On February 12, 2009, the staff provided the Commission a memorandum with a white paper enclosed (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML090150636 and ML090160004, respectively). The 2009 paper identified potential issues with applying the current guidance for risk-informed changes to the licensing basis, including operational programs (e.g., risk-managed technical specifications), and the ROP to new reactors with lower risk estimates. In the memorandum, the staff informed the Commission

about the staff's intent to engage external stakeholders in the development of potential options. As discussed below, the staff held numerous dialogues with external stakeholders on the issues raised in the 2009 white paper.

DISCUSSION:

With the implementation of an enhanced level of severe accident prevention and mitigation design capability being confirmed through the review of applications for design certification for new LWRs, the staff is identifying potential issues that may arise with the transition to operations and the use of the existing risk-informed framework. While there are no specific provisions in RG 1.174 and the current ROP precluding their application to new reactor designs, both RG 1.174 and the ROP were implemented considering the risk profiles of currently operating plants. As discussed in the 2009 white paper, the staff identified a number of potential issues posed by the lower risk estimates of new reactors using the current risk-informed guidance that could potentially allow for a significant erosion of the enhanced safety as originally licensed. As a result, the staff is considering changes to RG 1.174 and the ROP in light of the differing risk profiles and the Part 52 process (e.g., design certification rulemaking on enhanced severe accident features). The staff is currently reviewing one application for risk-informed technical specifications initiatives 4b and 5b (completion times and surveillance test intervals, respectively) as part of the U.S. Advanced Pressurized Water Reactor (US-APWR) design certification. In addition, other industry representatives have expressed interest in pursuing risk-informed in service inspection of piping for new reactors, and staff expects additional risk-informed applications for new reactors in the future.

Risk-Informed Changes to the Licensing Basis and Operational Programs

RG 1.174 provides an approach for using PRA in risk-informed decisions on plant-specific changes to the licensing basis for current reactors. This guide is the foundation on which many other risk-informed programs (e.g., risk-informed inservice testing, risk-informed inservice inspection of piping, and risk-managed technical specifications) are based.

RG 1.174 describes five principles for making risk-informed decisions. Specifically, the proposed change should be shown to:

- Meet current regulations, unless the change is explicitly related to a requested exemption
- Be consistent with the defense-in-depth philosophy
- Maintain sufficient safety margins
- Result in an increase in core damage frequency (CDF) or risk that is small and consistent with the intent of the Commission's Safety Goal Policy Statement
- Include monitoring using performance measurement strategies.

Figures 3 and 4 of RG 1.174 provide acceptance guidelines as to what constitutes "small changes" in CDF (ΔCDF) and large early release frequency (ΔLERF), respectively. For most new LWRs which have baseline CDF estimates at or substantially below 10^{-6} per year (/yr), a ΔCDF of 10^{-6} or even 10^{-7} would no longer constitute a "small change" *on a relative basis*. A change that is considered a "small increase" for current reactors under RG 1.174 may not have the same ramifications when applied to new reactors. Furthermore, RG 1.174 does not

explicitly consider the impact of changes on the enhanced severe accident safety features included in new reactor designs. RG 1.174 also does not address whether changes in large release frequency (LRF), the metric used in new reactor licensing, should be considered when evaluating "small changes."

In addition, a number of important operational programs also have close ties to the current risk-informed regulatory framework. The extent of the reliance of these operational programs on quantitative risk metric guidelines varies. In risk-informed technical specifications initiative 4b, the derived *completion times* have a strong relationship to PRA results, although they contain deterministic *backstops* that protect against very small risk impacts leading to non-conservative operational decisions. In other cases, the analysis may rely on less mathematical rigor. For example, under 50.65(a)(4) the licensee "shall assess and manage the increase in risk that may result from the proposed maintenance activities" before performing the maintenance. The maintenance risk can be assessed using risk insights that are qualitative or quantitative in nature. Here again, the question regarding what constitute "small changes" in CDF and risk when applied to new reactors for these and other operational programs needs to be addressed. Without changes to the guidance documents for risk-informed changes to the licensing basis and operational programs, the Commission's expectations for new plants may not be met.

Reactor Oversight Process

The regulatory framework for reactor oversight is a risk-informed, tiered approach to ensuring plant safety. There are three key strategic performance areas: reactor safety, radiation safety, and security. Within each strategic performance area, there are cornerstones that reflect the essential safety aspects of facility operation. Satisfactory licensee performance in the cornerstones provides reasonable assurance of safe facility operation and that the NRC's safety mission is being accomplished. Within this framework, the ROP provides a means of collecting information about licensee performance, assessing the information for its safety significance, responding to degraded licensee performance, and ensuring that licensees take appropriate corrective actions. Because there are many aspects of facility operation and maintenance, the NRC inspects utility programs and processes on a risk-informed sampling basis to obtain representative information.

With regard to setting numerical thresholds, SECY-99-007 discusses a close link to RG 1.174. SECY-99-007 states, in part:

> The concept for setting performance thresholds includes consideration of risk and regulatory response to different levels of licensee performance. The approach is intended to be consistent with other NRC risk-informed regulatory applications and policies as well as consistent with regulatory requirements and limits…(2) the thresholds should be risk informed to the extent practical, but should accommodate defense in depth and indications based on existing regulatory requirements and safety analyses; (3) the risk implications and regulatory actions associated with each performance band and associated threshold should be consistent with other NRC risk applications, and based on existing criteria where possible (e.g., Regulatory Guide 1.174).

Additionally, consistent with the principles of RG 1.174, SECY-99-007 provides the framework for meeting cornerstone objectives with minimal reduction in safety margin.

The ROP is established to respond to a decline in performance, focusing inspections on activities where potential risks are greater at nuclear power plants. If the ROP were strictly *risk-based,* relying entirely on quantification of ΔCDF and ΔLERF to establish performance, then one might argue the fact that a new reactor has a lower risk profile than currently operating reactors is a characteristic in its favor, allowing greater *relative* degradation in performance before reaching various bands of performance calling for increased NRC oversight.

The concern is that the existing ROP may not provide for meaningful regulatory oversight for new reactors that supports NRC's response and inspection as performance declines. The current risk-informed baseline inspection program and risk-informed thresholds for performance indicators may not trigger a regulatory response before significant erosion occurs to the enhanced defense in depth and safety margins of the plant.

Interactions with Stakeholders

The staff developed an initial set of possible options for risk metrics for new reactors in early 2009. Through subsequent public meetings, the staff engaged stakeholders including the Advisory Committee on Reactor Safeguards (ACRS) to further assess these options. Industry representatives expressed the opinion that new and currently operating reactors be treated the same with respect to risk-informed changes to the licensing basis and the ROP (*status quo*). NEI issued its own white paper describing why it believes that the current metrics are technically justified and appropriate for all plants, based on reasonable assurance of public health and safety, including operation at a prudent margin above adequate protection. A Union of Concerned Scientist (UCS) representative expressed the opinion that it was premature to consider any options so far in advance of reactor construction and operation. Furthermore, the UCS representative stated that while new reactors appeared to be safer than the currently operating fleet, the public should get the benefit of this through the implementation of more stringent acceptance guidelines for licensing and thresholds in the ROP.

Approach for Modifying the Risk-Informed Regulatory Guidance

Based on the interactions with stakeholders, the staff evaluated three approaches related to the guidance for risk-informed initiatives for new reactors. The staff considered issues associated with the ROP for new reactors because of the link to RG 1.174 and the goal of maintaining consistency with other risk applications. The staff evaluated each alternate approach for consistency with Commission direction regarding its expectations for enhanced severe accident safety performance for new reactors. These expectations relate to risk-informed changes to the licensing basis that could be viewed as constituting voluntary changes to the design or operational programs (e.g., risk-managed technical specifications and risk-informed in-service inspection of piping), as well as to the risk-informed elements of the ROP for new reactors.

The first approach staff evaluated involved no changes to the current regulatory guidance, or *status quo.* Under this approach, the staff considered using the existing risk-informed framework for licensing changes and the ROP. This approach could provide incentive to build

reactors with enhanced severe accident safety features; applicants and licensees who invest in and maintain additional safety features would have more flexibility to operate the plants with a reduction in regulatory interactions. The staff concluded, however, that this approach did not meet Commission expectations in that this option may not prevent significant decrease in enhanced safety through changes to the licensing basis and plant operations over plant life. In addition, this approach may not provide for meaningful regulatory oversight that supports NRC's response and inspection.

The staff also considered modifying the risk-informed guidance to include a new risk metric for the ROP and changes to the licensing basis. This approach would support the Commission's expectation that new plants have enhanced severe accident safety performance and that advanced reactors provide enhanced margins of safety. The staff considered, however, that this approach goes beyond the Commission's expectation by essentially *requiring* the continued maintenance of the enhanced margin of safety. Moreover, this approach may be inconsistent with the Commission's statement on the Regulation of Advanced Reactors in 2008 that the "policy statement does not state that advanced reactor designs must be safer than the current generation of reactors." This approach would create a risk-informed framework that is, in effect, inconsistent with the underlying technical basis for the current thresholds that are derived from the Commission Safety Goals and implemented in RG 1.174. This approach could also have unintended consequences in that new reactors with enhanced safety features would have less operational flexibility than the current fleet of reactors; applicants who invest in additional safety features expect more flexibility in operation.

The staff concluded that the best approach would be to continue to work with stakeholders to 1) identify specific changes to the risk-informed guidance for the ROP to provide for meaningful regulatory oversight and 2) identify specific changes to the guidance for risk-informed licensing-basis changes that would prevent a significant decrease in the level of safety of the new reactor over its life. This approach will support the Commission's expectation for new plants. The implementation details would differ for these two processes because of the differences in the scope of NRC and industry documents that would be affected and the general time frames for implementation of each process, as discussed below.

For changes to the licensing basis and operational programs, the staff will evaluate how to modify the risk-informed guidance to prevent a significant decrease in the level of safety provided by certified designs. Implementation of this approach will support the Commission's expectation regarding the maintenance of the level of severe accident safety performance of new designs. The staff will evaluate how to supplement the CDF and LERF acceptance guidelines to recognize the lower risk profiles of new reactors, including revisiting the definition of "small" change when implementing RG 1.174. Specifically, the staff will:

- Utilize stakeholder involvement in the evaluation and development of detailed changes to risk-informed regulatory guidance.
- Evaluate the merits of developing additional criteria (e.g., deterministic, defense in depth) to support the change process.

- Evaluate proposed changes to guidance to ensure that the changes do not create unintended consequences such as creating disincentives for safer designs on the one hand, or allowing degradation of passive safety system performance on the other hand. This would include developing guidance to implement Section VIII.B.5.c of the design certification rules.

For oversight, the staff will identify appropriate changes to the risk-informed elements of the ROP to reflect the enhanced level of severe accident safety performance of new reactors while providing for meaningful regulatory oversight that supports NRC's response and inspection. Specifically, the staff will:

- Utilize stakeholder involvement in the evaluation and development of changes to the guidance.
- Evaluate the criteria for plant placement in the action matrix to assess whether the current process would ensure that operational performance that results in significant reductions in the level of safety provided by the certified design is fully understood by the licensee and NRC and is effectively corrected.
- Evaluate the merits of developing additional criteria (e.g., deterministic, change in risk) to support NRC's response to findings and performance trends.
- Evaluate any potential ROP changes to avoid unintended consequences such as creating disincentives for safer designs on the one hand; or allowing degradation of passive safety system performance on the other hand; or diverting the attention of NRC inspectors from issues of higher safety significance on currently operating reactors.
- Consider the need to risk-weight or otherwise weight findings associated with passive systems to reflect the difficulty of recognizing the degradation of passive systems.
- Continue to independently assess licensee performance in the area of safety culture since safety culture addresses common underlying factors that affect plant safety.
- Evaluate maintaining or changing the current thresholds for green, white, yellow, red risk-significant findings and performance indicators, given that low-risk designs may rarely if ever cross the current white threshold.
- Consider the advantages and disadvantages of applying any potential changes to the ROP to currently operating reactors.

A key advantage of this approach is that it will reaffirm the Commission's expectation of enhanced severe accident safety performance for new reactors and the expectation that this level of enhanced safety will be reasonably maintained throughout plant life. Both plant design and operations are addressed, including licensing basis changes, operational programs, and oversight. Furthermore, this approach acknowledges that there are safety-margin and defense-in-depth considerations beyond the quantitative risk-informed thresholds. The staff will work to provide timely updates to guidance to support the staff's review of a number of risk-informed applications expected to be proposed by design certification and COL applicants, including risk-informed technical specifications initiatives 4b and 5b.

In addition to revision of RG 1.174, this approach will necessitate changes to associated guidance for specific risk-informed applications. Changes to the ROP, including MD 8.13 and a

number of IMCs, will be necessary. Several industry documents endorsed by the staff may also be affected.

CONCLUSION:

The staff will continue to interact with stakeholders to modify the risk-informed regulatory guidance to address the lower risk profiles to ensure that the Commission's expectation that there is "no significant decrease in the level of safety" over the life of the new reactor design is met. The staff believes that this approach will create a regulatory environment that encourages the design of new reactors with higher levels of severe accident safety performance, including greater redundancy of safety systems, which may allow for greater operational flexibility. Stakeholder involvement in the development of the new guidance for changes to the licensing basis and in the identification of potential changes to the risk-informed elements of the ROP is a key feature of this option. The staff will keep the Commission apprised of progress in the development of such guidance.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. A copy of this paper has been provided to the Advisory Committee on Reactor Safeguards.

R. W. Borchardt
Executive Director
for Operations