POLICY ISSUE
NOTATION VOTE

July 21, 2005 SECY-05-0130

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: POLICY ISSUES RELATED TO NEW PLANT LICENSING AND STATUS OF THE TECHNOLOGY-NEUTRAL FRAMEWORK FOR NEW PLANT LICENSING

PURPOSE:

To obtain Commission approval of staff recommendations for resolving the policy issues pertaining to (1) the level of safety and (2) the integrated risk posed by multiple and modular future reactors at a single site.

To inform the Commission on the status of the technology-neutral framework specifically addressing the staff's effort (1) to develop a definition of defense-in-depth and (2) to develop options and recommended positions for resolving the issue of containment functional performance requirements and criteria for new plant licensing.

SUMMARY:

This paper contains recommendations for Commission consideration on two policy issues (i.e., level of safety and integrated risk) that are needed to support near term pre-application reviews of new reactor designs and the development of the technology-neutral framework. The resolution of these policy issues establishes the safety expectation for formulating the technical basis of the technology-neutral framework, and therefore, the development of technology-neutral requirements for future rulemaking. The staff has briefed the Advisory Committee on Reactor Safeguards on these two issues. The Committee, for now, has decided not to send us a letter on these issues; however, they plan to revisit the issues at their September 2005 meeting. A draft of the technology-neutral framework was issued for public review and

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comment to start engaging stakeholders early in the process, and a three-day workshop was held in March 2005. During the workshop and from formally submitted letters, the staff has received a significant number of substantive, detailed and constructive comments from stakeholders. Many of the stakeholders expressed the general belief that further development of the framework is needed to assist the stakeholders in better understanding the staff's proposed definition of defense-in-depth and options for containment functional performance requirements and how both would be implemented. This paper does not address the assessment of possible modifications to emergency preparedness requirements as part of the work to develop a description of defense-in-depth.

BACKGROUND:

In SECY-03-0047, "Policy Issues Related to Licensing Non-Light-Water Reactor Designs," dated March 28, 2003 (ML030160002), the staff discussed options and provided recommendations for Commission consideration on seven policy issues fundamental to licensing non-light-water reactor (non-LWR) designs. The staff stated in that paper that the resolution of these issues would be included in the development of the technology-neutral framework of the regulatory structure for new plant licensing. Two of the issues included:

- How should the Commission's expectations for enhanced safety be implemented for future non-LWRs?

- Under what conditions, if any, can a plant be licensed without a pressure-retaining containment building?

The June 26, 2003, staff requirements memorandum (SRM) in response to SECY-03-0047 provided direction on the seven policy issues. On the above two issues, the Commission (1) approved the staff's recommendation on implementation of the Commission's expectation for enhanced safety in future non-LWRs, but requested the staff to provide further details on the options for, and associated impacts of, requiring that modular reactor designs account for the integrated risk posed by multiple reactors and (2) did not believe there was sufficient information to prejudge the best options and make a decision on the viability of a confinement building, and requested the staff to develop containment functional performance standards and submit options and recommendations to the Commission.

In SECY-04-0103, "Status of Response to the June 26, 2003, Staff Requirements Memorandum on Policy Issues Related to Licensing Non-Light-Water Reactor Designs," dated June 23, 2004 (ML041140521), the staff provided a status report on the staff's work on integrated risk from modular reactors and containment performance standards.

In SECY-04-0157, "Status of Staff's Proposed Regulatory Structure for New Plant Licensing and Potentially New Policy Issues," dated August 30, 2004 (ML042370388), the staff provided a status paper on the regulatory structure for new plant licensing including a summary of the technology-neutral framework. The staff also alerted the Commission to potentially new policy issues one of which included level of safety. The staff stated that it would provide preliminary recommendations on the new policy issues in December 2004, and final recommendations after a public review and comment period to ensure that the staff considered public input.

In SECY-05-0006, “Second Status Report of Staff’s Proposed Regulatory Structure for New Plant Licensing and Policy Issues Related to Licensing Non-Light-Water Reactor Designs,” dated January 7, 2005 (ML043560093), the staff provided an update to the Commission. Specifically, SECY-05-0006 reported on (1) the staff's effort regarding a regulatory structure for new plant licensing, (2) the incorporation of the policy issues (approved in the SRM to SECY-03-0047) into the proposed regulatory structure for new plant licensing, (3) the staff’s proposed positions on the two policy issues pertaining to integrated risk of modular reactors and containment performance, and (4) new policy issues for Commission information. In addition, in SECY-05-0006, the staff said it will (1) provide options and recommendations to the Commission in June 2005 on level of safety, integrated risk and containment performance to support the pre-application reviews for new plants and the development of the technology-neutral framework, and (2) provide in December 2005, for Commission approval, a definition of defense-in-depth to be incorporated into the Commission’s policy statement on “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities” (60 FR 42622, dated August 16, 1995).

DISCUSSION:

Technology-Neutral Framework

A working draft of the technology-neutral framework was released for public review and comment in January 2005 to start soliciting stakeholder input with the expectation that a second draft would be provided in December 2005 for public review and comment. This second draft would include a definition of defense-in-depth which the staff would provide to the Commission for consideration and subsequent incorporation into the probabilistic risk assessment (PRA) policy statement.

On March 14-16, 2005, a public workshop was held with stakeholders to discuss the draft technology-neutral framework and the staff’s proposed positions on the three policy issues. At the workshop, attendees provided a significant number of substantive, detailed and constructive comments directed at both further developing, clarifying and completing the draft framework and describing the policy and technical issues and evaluating the options. The staff has also since received additional significant formal written comments from a number of stakeholders.

The participants at the workshop expressed their appreciation to have the opportunity for detailed technical dialogue and to provide comments to the staff early in the process of developing the technology-neutral framework. They also expressed their desire for similar meetings in the future, particularly as the other policy and technical issues are further developed in the framework. Because of the complexity of the issues and the substantive public comments received to date, the staff has agreed to hold additional public meetings, each focused on a specific policy and technical issue. The staff believes that this approach (i.e., focused meetings rather than fewer broader meetings) is a more effective way to engage the public. It directly implements the Commission’s strategies to (1) “obtain early public involvement on issues most likely to generate substantial interest and promote two-way communication to enhance public confidence in the NRC’s regulatory process,” and (2) ensure that “transparency in its [the NRC’s] communications” is achieved.

In using this approach to engage the public and to address the comments received, the staff anticipates a delay in completing the draft framework for public review and comment from

December 2005 to June 2006. This delay would also postpone the revision of the PRA policy statement to include the definition of defense-in-depth to June 2006. However, given the level of public involvement, the staff believes that the development of the framework will be enhanced and will result in a more effective public review and comment process. Further, this delay will not impact the schedule for the pre-application reviews.

As discussed in SECY-05-0006, development of the Technology-Neutral framework is Part 1 of the effort to develop a Regulatory Structure for New Plant Licensing. The remaining parts include development of:

- a proposed set of technology-neutral requirements
- a technology-specific framework (provides the guidance for how to apply the technology-neutral framework on a technology-specific basis)
- technology-specific regulatory guides (provides the guidelines for how to meet the technology-neutral requirements for a specified technology)

Development of the technology-neutral framework is an iterative process; that is, as the other parts of the regulatory structure for new plant licensing are developed, the technology-neutral framework may need to be revised. The work to date has focused on development of the technology-neutral framework. Work is starting on the other three parts to gain insights regarding where the framework may need to be revised.

In SECY-05-0006, the staff said it would continue to review security for new plant licensing as part of the framework and would provide a recommendation to the Commission in the spring of 2005. In SECY-05-0120, "Security Design Expectations for New Reactor Licensing Activities," the staff recommended to the Commission that security be integrated with safety in the framework to ensure a coherent approach to safety and security. As security is integrated into the technology-neutral framework, the guidelines and criteria developed in the framework may also change given security considerations.

Containment Functional Performance Requirements and Criteria

In its SRM related to SECY-03-0047, the Commission asked the staff to "develop performance requirements and criteria working closely with industry experts (e.g., designers, EPRI [Electric Power Research Institute], etc.) and other stakeholders regarding options in this area, taking into account such features as core, fuel, and cooling systems design. The staff should pursue the development of functional performance standards and then submit options and recommendations to the Commission on this important policy decision."

In response to the above SRM, the staff has developed and evaluated alternative functional performance criteria for reducing radionuclide releases to the environs. These were discussed in detail at the March 14-16, 2005, public workshop. The participants at the workshop (and in subsequent written comments) encouraged the staff to:

- not finalize functional performance requirements and criteria until the technology-neutral framework is more completely developed. For example, the criteria and guidance for defense-in-depth and event selection being developed in the technology-neutral

framework are key drivers for the development of the technology-neutral containment performance requirements and criteria. Further development of the framework will assist stakeholders in better understanding and assessing the proposed requirements and criteria and how they would be implemented on a design-specific analysis basis.

- address other containment functions (e.g., physical protection, protection from external events) in the consideration of options.

Contrary to a prior commitment, the staff is not providing a recommendation to the Commission at this time for the following reasons. The public requested the staff not to provide recommendations on functional performance requirements and criteria so that a fully integrated framework could be developed. Further, resolution of this issue is not needed in the near term to support the current pre-application reviews. The staff will continue to develop the technology-neutral framework using an integrated system approach by determining containment performance functions from overall safety requirements rather than just basing it on radiological considerations. The staff will seek further stakeholder comment in resolving this issue. Therefore, the staff plans to submit the final options and recommendation on this issue in coordination with submitting the draft of the technology-neutral framework in June 2006.

Policy Issues

The staff has incorporated into the technology-neutral framework the Commission's direction regarding the approved policy issues and the staff's proposed positions on the policy issues of level of safety and integrated risk. The relationship of these two issues to the framework is shown in Figure 1 of the attachment. The staff also intends to apply the Commission decisions on these policy issues, where applicable, to new plant licensing decisions. Applying these policy decisions prior to completion of the framework or within the existing regulatory regime will ensure consistency in regulatory decision making.

In assessing options and developing recommendations for the policy issues related to level of safety and integrated risk, the staff used the following general guidelines (as stated in SECY-03-0047):

- Keep the risk to the population around a nuclear power plant consistent with the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants" (51 FR 28044, dated August 4, 1986).

- Use a risk-informed and performance-based approach, wherever practical, consistent with the Commission's policy statement on the "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities;" SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," dated June 22, 1998 (ML992880068); and Yellow Announcement #019, "Commission Issuance of White Paper on Risk-Informed and Performance-Based Regulation," dated March 11, 1999.

- Use a technology-neutral approach.

- Use the Commission's performance goals to assess the advantages and disadvantages of the options and to develop a recommendation.

- Consider previous Commission guidance on these issues.

- Consider the practicality of the options and recommendations.

Application of these guidelines, and input from stakeholders, resulted in the following recommendations as discussed below. However, as noted earlier in the paper, integration of security may effect the guidelines and criteria being developed in the framework. Consequently, the recommendations by the staff on the two policy issues may be impacted given security considerations. Nonetheless, the staff plans to move forward since it is also expected that the guidelines and criteria in the framework may change as the other parts of the regulatory structure for new plant licensing are developed.

Issue 1: Level of Safety

The staff recommends that the Commission approve:

- the implementation of enhanced safety for new plants by specifying a minimum level of safety (i.e., level of risk) that new plants must meet, and that this minimum safety level will be the Quantitative Health Objectives (QHOs) documented in the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants."

With these recommendations, the technology-neutral framework would be developed to meet this minimum level of safety for new plant licensing. In implementing the framework, the technology-neutral regulations would be developed to achieve at least the safety goal level of safety. Approving this recommendation would implement the Commission's expectations for safety as expressed in the policy statements on "Regulation of Advanced Nuclear Power Plants" (59 FR 35461, dated July 12, 1994) and "Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138, dated August 8, 1985). This recommendation also provides a standard to assess whether new reactor designs meet the Commission's expectations prior to completion and implementation of the framework.

The policy statement on "Regulation of Advanced Nuclear Power Plant" states that the Commission "expects that advanced reactors will provide enhanced margins of safety . . . to accomplish their safety functions. The Commission also expects that advanced reactor designs will comply with the Commission's safety goal policy statement."

The policy statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants states that "the Commission encourages the development and commercialization of any standard designs that might realize safety benefits . . . to enhance safety, reliability and economy." It further states that "Although in the licensing of existing plants the Commission has determined that these plants pose no undue risk to public health and safety, this should not be viewed as implying a Commission policy that safety improvements in new plant design should not be actively sought. The Commission 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."

Embodying the QHO's (as the minimum safety level) in the technology-neutral requirements, and in reactor design reviews conducted using the existing regulatory framework, will make the regulatory decision-making process more scrutable. It would eliminate subjective judgment in determining whether the Commission's expectation for enhanced safety has been achieved.

This issue is discussed in detail in the Attachment.

Issue 2: Integrated Risk from Multiple Reactors at a Single Site

The staff recommends that the Commission approve:

- the criterion that the integrated risk only associated with new reactors (i.e., modular or multiple reactors) at a site does not exceed the risk expressed by the QHOs established in the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants."

With this recommendation, the integrated risk posed by all new reactors at a single site would not exceed the risk expressed by the QHOs and is complementary to the minimum level of safety recommended above in Issue 1.

If the Commission approves the recommendations for Issue 1 and Issue 2, the technology-neutral regulations for new plant licensing would be developed to ensure that both (1) the risk from each new reactor (individually) and (2) the integrated risk for all new reactors at a single site, do not exceed the risk expressed by the QHOs. Additionally, if approved, the staff will ensure that both the individual risk of each new reactor and the integrated risk from the new reactors, associated with a future combined license application, do not exceed the risk expressed by the QHOs.

This recommendation would not require that the integrated risk from existing reactors, where there are multiple reactors at a single site, meet the risk expressed by the QHOs, even though the site may be considered for new reactors. In the policy statement on "Severe Reactor Accidents Regarding Future Designs and Existing Plants," the Commission "concludes that existing plants pose no undue risk to public health and safety and sees no present basis for immediate action on generic rulemaking or other regulatory changes for these plants ...." This statement is supported by the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants" that states "that current regulatory practices are believed to ensure that the basic statutory requirement, adequate protection of the public, is met." In considering new plants at a site with or without existing plants, it should be assured that the new plants pose no undue risk to the public. Limiting the integrated risk for new plants to the risk expressed by the QHOs (and thereby imposing enhanced safety for these new plants), ensures that the new plants pose no undue risk to the public (see Issue #1).

This issue is discussed in detail in the Attachment.

Communicating the above issue to the public could be a significant challenge. The public may find it difficult to understand why the risk from existing plant(s) on a site would not be accounted for in the integrated risk consideration.

RESOURCES:

The plans discussed in this paper (i.e., implementation of these policy issues for new plant licensing and incorporation in the development of a final draft of the technology-neutral framework) do not require additional resources for implementation. Specifically, the current RES budget has 1 FTE and $500K in FY 2005 for this activity, and 1 FTE and $400K in FY

2006. In addition, the NRR budget includes sufficient resources to support RES in developing the technology-neutral framework. Beyond FY 2006, resources will be requested through the NRC's Planning, Budgeting and Performance Management process.

The current effort on the framework is part of the planned activities and as such, no other currently planned work will be affected.

The technology-neutral framework is scheduled to be completed in FY 2007. Once completed, the staff will notify the Commission of the additional resources that would be needed to develop the regulations and regulatory guidance to implement the technology-neutral framework.

The information on resources and schedule reflects the current environment. If a significant amount of time (greater than 30 days) passes or the Commission provides the staff direction that differs from or adds to the staff's recommended action(s), this section of the paper would need to be revisited after issuance of the draft SRM.

COORDINATION:

The Office of the General Counsel has no legal objection concerning this paper. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

COMMITMENTS:

Listed below are the actions or activities committed to by the staff in this paper.

(1) The staff will issue a draft of the technology-neutral framework in June 2006.

(2) The staff, in issuing the draft of the framework, will provide

- options, and a recommendation for Commission approval on the containment functional performance requirements and criteria,
- for Commission approval a definition of defense-in-depth to be incorporated into the Commission's PRA policy statement,
- for Commission information any new policy issues associated with implementing the technology-neutral framework for new plant licensing.

RECOMMENDATIONS:

The staff recommends that the Commission approve:

- the implementation of enhanced safety for new plants by specifying a minimum level of safety (i.e., level of risk) that new plants must meet, and that this minimum safety level will be the Quantitative Health Objectives (QHOs) documented in the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants."

- the criterion that the integrated risk only associated with new reactors (i.e., modular or multiple reactors) at a site does not exceed the risk expressed by the QHOs established in the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants."

/RA/

Luis A. Reyes
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for Operations

Attachment: Detailed Discussion Regarding
Policy Issues for New Plant Licensing

LEVEL OF SAFETY AND INTEGRATED RISK

Issue 1: What shall be the minimum level of safety that new plants need to meet to achieve enhanced safety?

Issue 2: How shall the risk from multiple reactors at a single site be accounted for?

BACKGROUND:

Both of the above issues relate to the policy issue on Expectations for Safety (i.e., "How to implement the Commission's expectations for enhanced safety in future non-light-water reactors (non-LWRs)"), which was initially raised to the Commission in SECY-02-0139, dated July 22, 2002. (ML021790610).

In SECY-02-0139, the staff provided a plan for resolving policy issues related to licensing non-LWR designs. It was noted in the paper that the current regulations had been developed over the past 40 years and reflect the experience gained from many years of LWR design and operation. The regulations contain many provisions of a generic nature (independent of reactor technology), but also contain provisions that are specific to LWR design and technology. The regulations have served as the underlying basis for licensing the current generation of plants as well as certifying the Advanced Boiling Water Reactor (ABWR), System 80+ and AP-600. In the past, when NRC reviewed or licensed non-LWR designs (e.g., Ft. St. Vrain, the Clinch River Breeder Reactor) the staff had to determine the applicability of the regulations to these designs and the need for exemptions and/or additional requirements to address the unique aspects of these designs. These determinations were made on a case-by-case basis and were implemented by exemptions and/or license conditions, to address areas where the current regulations did not apply. Accordingly, it is possible to review and license future plants, regardless of the technology, using a similar case-by-case approach. However, the staff noted that this approach may not be the most efficient or effective for non-LWRs, particularly if there will be more than one of a kind.

To facilitate licensing of new reactor designs substantially different than current generation LWRs, the Commission has encouraged interactions between NRC and designers at the preapplication stage to identify, early in the process, key safety and licensing issues and a path to their resolution. The results of such interactions could then be used by the staff and the designers as guidance in the preparation and review of an actual application. Recently, the staff completed the AP-1000 design certification review. The staff may begin interacting with PBMR Pty, Limited, to identify key issues related to the pebble bed modular reactor (PBMR) and an approach for their resolution. In addition, the Department of Energy is considering licensing issues in ITS Generation IV reactor development program.

In addition, the staff has had interactions with the Nuclear Energy Institute (NEI) regarding the possible development of a generic (technology-neutral) risk-informed, performance-based framework for future plant licensing. NEI submitted a white paper (letter dated May 7, 2002, to Chairman Meserve) containing "A Risk-Informed, Performance-Based Regulatory Framework for Power Reactors" (NEI-02-02) on this topic for Commission consideration.

Attachment

The staff also stated in SECY-02-0139 that the staff believes it is appropriate that reactor design-related policy issues with potential generic implications be provided to the Commission for guidance so as to facilitate the reviews of non-LWRs and to help determine to what extent, if any, generic, risk-informed and performance-based requirements should be developed. The items identified as policy issues are those that affect traditional approaches to achieving safety, such as defense-in-depth, and those related to the application of existing Commission policies and practices to non-LWRs.

It is also likely that the resolution of these policy issues will affect the viability of certain future non-LWR designs and will need to be addressed in establishing regulatory requirements for those designs, regardless of whether the requirements are established on a technology-specific basis or are technology-neutral, such as suggested by NEI. However, no decision has been made regarding the need for a technology-neutral licensing approach for future plants, and the number and type of future non-LWR plant applications is uncertain. Nevertheless, the early establishment of guidance in key areas will benefit all stakeholders by improving the effectiveness, efficiency, and predictability of the review process.

In SECY-03-0047, "Policy Issues Related to Licensing Non-Light-Water Reactor Designs," dated March 28, 2003 (ML030160002), the staff provided options and recommendations for the policy issues discussed in SECY-02-0139. With regard to the policy issue on expectations for enhanced safety, the staff recommended that the Commission approve implementation of enhanced safety through a process similar to that used in the evolutionary LWR and advanced light-water reactor (ALWR) design certification reviews (i.e., reactor designers are expected to propose designs with enhanced safety characteristics and the staff reviews each design on its own merits and on an as-needed basis, recommends additional enhancements in areas of high uncertainty subject to Commission endorsement). Such enhancements could include additional design features, additional testing by the designer, or additional confirmatory testing and oversight by NRC in areas of large uncertainty, and would be recommended with the intent to achieve a level of safety and confidence similar to that achieved in the evolutionary and ALWR design certifications.

In implementing the above, the staff also recommended in SECY-03-0047 that the following considerations be applied:

- When using probabilistic or risk information, modular reactor designs should account for the integrated risk posed by multiple reactors necessary to achieve the overall electrical output desired.

- The incremental risk to the surrounding population from adding additional units to an existing site is expected to be small due to the enhanced safety characteristics of new designs.

The above recommendations were intended to help ensure that the intent of the Commission's policy statement on “Safety Goals for the Operation of Nuclear Power Plants” (51 FR 30028, August 21, 1986) would be met.

In the June 26, 2003, staff requirements memorandum (SRM) in response to SECY-03-0047, the Commission approved the staff’s recommendation on the implementation of the Commission’s expectation for enhanced safety in future non-LWRs, with the exception of accounting for the integrated risk posed by multiple reactors. The Commission requested that

the staff provide further details on options for, and associated impacts of, requiring that modular reactor designs account for the integrated risk (i.e., cumulative effect on risk to the population around a site) posed by the use of multiple small reactors to equal the power output of one large reactor. These reactor modules generally would be located in close proximity to one another on a single site. Further, near-term licensing applications may involve sites with existing nuclear power reactors, possibly including multiple units.

Traditionally, risk calculations related to the safety goal quantitative health objectives (QHOs) have been done on a per reactor basis and the guidelines developed and used in the risk-informed process were based on the risk from an individual reactor. However, in applying the QHOs, the policy statement for the "Safety Goals for the Operation of Nuclear Power Plants" refers to "The risk to an average individual in the **vicinity of a nuclear power plant** [emphasis added]..." and "The risk to the population in the **area near a nuclear power plant** [emphasis added]..." Hence the safety goal policy could be interpreted to mean that the risk should be calculated on a per site basis. This also has implications for the level of safety for new plant licensing.

The QHOs are defined in the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants" as:

- "The risk to an average individual[1] in the vicinity of a nuclear power plant of prompt fatalities[2] that might result from reactor accidents should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accident to which members of the U.S. population are generally exposed."

[1]The Safety Goal Policy further states that the average individual in the vicinity of the plant is defined as the average individual biologically (in terms of age and other risk factors) and who resides within a mile from the plant site boundary. This means the dose conversion factors (DCFs) that translate exposure to dose (and hence risk) are for an average adult person (i.e., infant DCFs, etc. are not evaluated). In addition the average individual risk is found by accumulating the estimated individual risks and dividing by the number of individuals residing in the vicinity of the plant. (The statement also states that if there are no individuals residing within a mile of the plant boundary, an individual should, for evaluation purposes, be assumed to reside 1 mile from the site boundary).

[2]An accident that results in the release of a large quantity of radionuclides to the environment can result in acute doses to specific organs (e.g., red blood marrow, lungs, lower large intestine, etc.) in individuals in the vicinity of the plant. These acute doses can result in prompt (or early) health effects, fatalities and injuries. Doses that accumulate during the first week after the accidental release are usually considered when calculating these early health effects. The possible pathways for acute doses are: inhalation, cloudshine, groundshine, resuspension inhalation, and skin deposition. Cloudshine and inhalation are calculated for the time the individual is exposed to the cloud. Groundshine and resuspension inhalation doses for early exposure are usually limited to one week after the release. The doses accumulated during this early phase can be significantly influenced by by emergency countermeasures such as evacuation and sheltering of the affected population. Early fatality is generally calculated using a 2-parameter hazard function. A organ dose threshold is incorporated into the hazard function such that below the threshold the hazard is zero. (For example, the default value of the threshold for acute dose to red marrow is 150 rem in (Ref. B.1). An early fatality is defined as one that results in death within 1 year of exposure.

"The risk to the population in the area of nuclear power plant of cancer fatalities[3] that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks resulting from all other causes."

These QHOs have been translated into two numerical objectives, as follows:

Early Fatality —

The individual risk of a prompt fatality from all "other accidents to which members of the U.S. population are generally exposed," such as fatal automobile accident, etc., is about $5x10^{-4}$ per year. One-tenth of one percent of this figure implies that the individual risk of prompt fatality from a reactor accident should be less than $5x10^{-7}$ per reactor year (ry). The "vicinity" of a nuclear power plant is understood to be a distance extending to 1 mile from the plant site boundary. The individual risk is determined by dividing the number of prompt or early fatalities (societal risk) to 1 mile due to all accidents, weighted by the frequency of each accident, by the total population to 1 mile and summing over all accidents.

Latent Fatality —

"The sum of cancer fatality risks resulting from all other causes" is taken to be the cancer fatality rate in the U.S. which is about 1 in 500 or $2x10^{-3}$ per year. One-tenth of one percent of this implies that the risk of cancer to the population in the area near a nuclear power plant due to its operation should be limited to $2x10^{-6}$/ry. The "area" is understood to be an annulus of 10-mile radius from the plant site boundary. The cancer risk is also determined on the basis of an individual, i.e., by evaluating the number of latent cancers (societal risk) due to all accidents to a distance of 10 miles from the plant site boundary, weighted by the frequency of the accident, dividing the total population to 10 miles, and summing over all accidents.

[3] Lifetime 50-year committed doses can result in latent cancer fatalities. These doses occur during the early exposure phase (within one week of the release) from the early pathways, i.e. cloudshine, groundshine, inhalation, and resuspension inhalation, and the long-term phase from the long-term pathways that include groundshine, resuspension inhalation, and ingestion (from contaminated food and water). Just as early exposure can be limited by protective actions such as evacuation during the early phase, chronic exposure during the long-term phase can also be limited by actions such as population relocation, interdiction of contaminated land for habitation if it cannot be decontaminated in a cost-effective manner (within a 30-year period), food and crop disposal, and interdiction of farmland. A piecewise linear dose-response model is generally used to estimate cancer fatalities. A dose and dose rate reduction factor is used at low dose rates (<0.1 Gy per hour) and for low doses (< 0.2 Gy) to estimate cancer fatalities based on the recommendations of the International Commission on Radiation Protection in their ICRP 60 report. Up to 20 organs are included for estimation of latent cancers (e.g., lungs, red bone marrow, small intestine, lower large intestine, stomach, bladder wall, thyroid, bone surface, breast, gonads, etc.)

With regard to the level of safety for new plant licensing, using a process to achieve enhanced safety similar to that used in the evolutionary LWR and ALWR designs is appropriate if future designs are to be licensed using 10 CFR Part 50 regardless of the plant power output. In this process, case-by-case determinations are made regarding the applicability of requirements of the design and the need for additional requirements to account for the unique aspects of the design, including uncertainties. However, the proposed regulatory structure for new plant licensing, as currently being developed, requires a minimum level of safety for its development and the development of the requirements that would be established to achieve the Commission's expectation of enhanced safety (i.e., what is the level of safety that the requirements should be written to?). This structure and relationship is shown below in Figure 1.

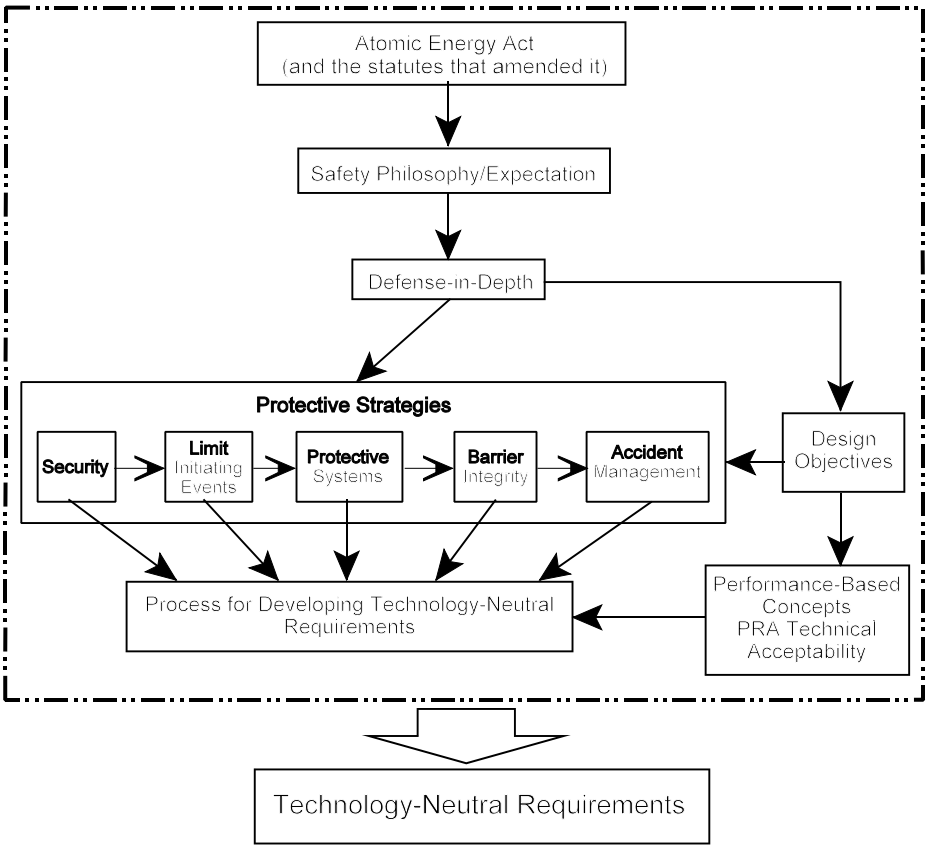

Figure 1. Technology-Neutral Framework Elements

The framework uses an hierarchal approach, as illustrated in the above figure, to establish the process by which the technology-neutral requirements for ensuring the protection of the public health and safety are derived. The various elements of the framework provide the guidelines and criteria for writing a set of technology-neutral requirements:

- Safety Philosophy/ Expectation: Sets at a high level the safety expectation that the regulations are meant to ensure by defining the minimum "level of safety."

- Defense-in-Depth: Provides the systematic approach for ensuring safe and reliable design, construction and operation by explicitly addressing the uncertainties (e.g., incomplete or incorrect knowledge).

- Protective Strategies: Defines the safety fundamentals that are needed to protect the public health and safety in a defense-in-depth manner and defines the building blocks for developing technology-neutral requirements and regulations.

- Design Objectives: Defines the quantitative objectives for ensuring that the minimum level of safety is met, defines the process for identification and selection of the events that the design needs to withstand, defines the process for safety classification of the structures, systems and components, and defines the risk analysis needs to support the above objectives and processes.

- Performance-Based Concepts: Provides for measurable parameters/objective criteria, flexibility for licensees in meeting criteria, a structure such that failure to meet a criterion is not immediate safety concern.

- PRA Technical Acceptability: Defines process (and associated requirements) for risk analysis evolution that is consistent with design development.

- Technology-Neutral Requirements Process: Provides the process for how to implement and integrate the guidance and criteria of the other framework elements to develop a set of technology-neutral requirements.

To date the staff has developed preliminary guidance and criteria for the elements shown in the shaded region. Implementation of the guidance and criteria to develop a set of technology-neutral requirements is scheduled to start later this year.

The same general guidelines, as stated in SECY-03-0047, were used in assessing options and developing the recommendations for the policy issues related to level of safety and integrated risk:

- Keep the risk to the population around a nuclear power plant site consistent with the Commission's policy statement on “Safety Goals for the Operation of Nuclear Power Plants.”

- Use a risk-informed and performance-based approach, wherever practical, consistent with the Commission's 1995 policy statement on the “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities“ (60 FR 42622); SECY-98-144, “White Paper on Risk-Informed and Performance-Based Regulation,” dated June 22, 1998; and Yellow Announcement #019, “Commission Issuance of White Paper on Risk-Informed and Performance-Based Regulation,” dated March 11, 1999.

- Use a technology-neutral approach.

- Use the Commission's performance goals to assess the advantages and disadvantages of the options and to develop a recommendation.

- Consider previous Commission guidance on these issues.

- Consider the practicality of the options and recommendations.

The policy issues and proposed options are discussed below. Each option is assessed against the above guidelines, with consideration of stakeholder input, and with respect to its advantages and disadvantages. A staff recommendation follows the discussion of the options.

DISCUSSION

Issue 1: Level of Safety

The Commission formulation of the level of safety has evolved over the last two decades. The Commission has stated on numerous occasions, for example in the "Revision of Backfitting Process for Power Reactors (53 FR 20603, June 6, 1988), "that compliance with the Commission's regulations and guidance 'should provide a level of safety sufficient for adequate protection of the public health and safety and common defense and security under the Atomic Energy Act'." While clarifying the use of economic costs in making safety decisions, the Commission observed that it "is actively pursuing reliable quantitative measures of safety, and some quantitative and generally applicable definition of 'adequate protection' may eventually emerge as a byproduct of the Commission's efforts . . . to implement its general safety goals which take a partly quantitative form." (53 FR 20603, June 6, 1988).

In the policy statement on the "Safety Goals for the Operation of Nuclear Power Plants," the Commission also expressed its belief that improvement of current practices could lead to a more coherent and consistent regulation of nuclear power plants, a more predictable regulatory process, a public understanding of the regulatory criteria that the NRC applies, and public confidence in the safety of operating plants. In the SRM to SECY-89-0102, Implementation of Safety Goals, dated June 15, 1990, the Commission expressed its belief that "adequate protection is a case by case finding based on evaluating a plant and site combination and considering the body of our regulations." The policy statement on the "Regulation of Advanced Nuclear Power Plants" (59 FR 35461, July 7, 1994) states that the Commission "expects that advanced reactors will provide enhanced margins of safety" and that it also "expects that advanced reactor designs will comply with the Safety Goal Policy Statement." Further, the policy statement on "Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138, August 8, 1985) states that "the Commission encourages the development and commercialization of any standard designs that might realize safety benefits . . . to enhance safety, reliability and economy."

The staff considered these statements in developing options and noticed several points. The Commission has stated that current regulatory practices are believed to ensure that the basic statutory requirement of adequate protection of the public is met. However, the level of safety afforded by adequate protection is not necessarily at the level of safety specified in the QHOs. For plants where the risk is believed to be less than that expressed by the QHOs, the probabilistic risk assessments (PRAs) used to compare the risk of individual plants to the QHOs credit plant systems and practices that go beyond what is required by the current regulations. In other words, if the plant risk was calculated only crediting the systems and actions specified in the current regulations (i.e., those systems that are required to provide adequate protection), this risk is likely to be higher and may exceed the risk expressed in the QHOs. Therefore, regulating to the QHOs will provide a higher level of safety and will lead to enhanced margins.

The Commission's policy statement for "Regulation of Advanced Nuclear Power Plants" implies that the QHOs are meant to provide consistency and stability to the regulatory process, and that as reactor technology advances enhanced levels of safety are a reasonable expectation, i.e., as technology improves, it appears justifiable to establish safety levels or benchmarks which advanced reactors, but not current reactors, should meet. The Commission's policy statement on "Severe Reactor Accidents Regarding Future Designs and Existing Plants" states that "although in the licensing of existing plants the Commission has determined that these plants pose no undue risk to public health and safety, this should not be viewed as implying a Commission policy that safety improvements in new plant design should not be actively sought. The Commission 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." This expectation is consistent with advances in safety as practiced in other technologies. What may be reasonably practical for a new design in terms of additional risk reduction, may not be so for an existing operating reactor.

This issue was discussed at the March 14-16, 2005, public workshop. The stakeholder feedback from the workshop and subsequently provided in written comments were considered in evaluating the options. Four options for the level of safety for new plants have been identified and evaluated by the staff:

1. Adopt the process used for the evolutionary LWR and ALWR.
2. Define the minimum level of safety as the QHOs.
3. Develop other risk objectives for the minimum level of safety.
4. Develop new QHOs for the minimum level of safety.

The advantages and disadvantages for each option are discussed below.

Option 1: Adopt the process used for the evolutionary LWR and ALWR

For this option, a minimum level of safety is not explicitly defined for achieving enhanced safety. A case-by-case review is performed for each design. The staff determines on a case-by-case basis whether the design under consideration "will achieve a higher standard of severe accident safety performance than their prior designs" per the Commission's policy statement on "Severe Reactor Accidents Regarding Future Designs and Existing Plants."

In implementing this option, the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants" would be determined on a reactor-specific basis. In the near term, for ongoing activities, a minimum level of safety for specifying how the Commission's expectations regarding how enhanced safety is to be achieved would be determined on a case-by-case basis. In the longer term, a minimum level of safety would not be defined in the technology-neutral framework for new plant licensing. Consequently, in implementing the framework, the technology-neutral regulations would not be developed to achieve at least the safety goal level of safety.

Advantages

For this option, no changes are needed to the practice established for the case-by-case consideration of the various ALWRs. This option provides the maximum flexibility to the licensee. The risk of each plant design is not required to meet the QHOs or other pre-defined risk measures to demonstrate enhanced safety. Each applicant can propose how to achieve enhanced safety.

Disadvantages

The lack of a predefined minimum level of safety will not necessarily result in a technology-neutral risk-informed and performance-based approach. The criteria for determining that enhanced safety has been achieved would be developed for each individual applicant (and for at least each individual plant design) and is not likely to be quantitative. Without a quantitative criteria, the Commission's and staff's expression of safety aspirations will be restricted to qualitative statements about enhanced safety of advanced reactors. There is less assurance that such a qualitative approach can result in a uniform minimum acceptable safety standard which can be applied across all the potential new reactor technologies (i.e., technology-neutral), and also less likely to result in a risk-informed and performance-based standard.

It is not clear that this option supports the Commission's intention, as stated in its policy statement on "Regulations of Advanced Nuclear Power Plants," to "improve the licensing environment for advanced nuclear power reactors to minimize complexity and uncertainty in the regulatory process." Determining the criteria for whether safety enhancement has been achieved on a case-by-case basis, particularly for new reactor technologies, could lead to different results, even for very similar cases. Further, additional criteria or requirements may be needed to ensure enhanced safety for some of the individual cases, and the Commission may need to approve such additions individually. The results of such an approach may be more likely to be challenged by stakeholders during the rulemaking, design certification and combined licensed processes. This approach does not minimize the complexity and uncertainty of the regulatory process. It is not readily scrutable, relies on subjective judgment, and consequently, will likely not result in consistency and uniformity, and will likely not promote stability and predictability in the regulatory structure for new plant licensing.

Option 2: Define the minimum level of safety as the Quantitative Health Objectives

For this option, the Safety Goal QHOs (as expressed in the Commission's Safety Goal Policy) are selected as the minimum level of safety to demonstrate that enhanced safety has been achieved for new reactor designs.

In implementing this option, the method for achieving the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants" is defined. This option also provides a standard to assess whether new reactor designs meet the Commission's expectations prior to implementation of the framework. Further, the technology-neutral framework would be developed to meet this minimum level of safety for new plant licensing. In implementing the framework, the technology-neutral regulations would be developed to achieve at least the safety goal level of safety.

Advantages

Defining the minimum level of safety needed to achieve enhanced safety that applies regardless of reactor design will eliminate, on a case-by-case basis, defining the measures for determining enhanced safety. Therefore, it provides for a more efficient, scrutable and objective regulatory process. Further, as compared with Option 1, defining a specific minimum level of safety will increase the level of consistency and uniformity, and will promote stability and predictability in the regulatory structure for new plant licensing.

The QHOs are technology-neutral, risk-informed and performance-based. They do not need any reactor technology-specific parameters for implementation. They do not prescribe any particular implementation approach to how the QHOs are to be met. Therefore, defining the QHOs as a minimum level of safety is, unlike Option 1, in keeping with the desirable objective of a technology-neutral, risk-informed, and performance-based metric.

This option would implement the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants." Defining a minimum level of safety as the QHOs will provide and demonstrate, unlike Option 1, that "at least the same degree of protection to the public," that "enhanced margins of safety" and that "a higher standard of severe accident safety performance" has been achieved.

Use of the QHOs is clearly consistent with the Commission's expectations, as expressed in the policy statement on Advanced Nuclear Power Plants, where it is stated that the Commission "expects that advanced reactor designs will comply with the Commission's Safety Goal Policy." Use of the QHOs as the minimum level of safety is consistent with the level of safety adopted by the industry in their own design and regulatory initiatives (e.g., NEI-02-02, "A Risk-Informed, Performance-Based Framework for Power Reactors," dated May 2002).

This option would also allow the use of other risk measures to demonstrate the QHOs have been met. One possible acceptable set of risk measures would be defined via regulatory guides on a technology-specific basis. However, the applicant may propose a different set of risk measures or demonstrate that the QHOs are met through a Level 3 PRA, thereby providing greater flexibility to both the staff and the applicant.

Disadvantages

Two approaches are available to the licensees to demonstrate that the QHOs have been met: (1) a Level 3 PRA, i.e., a probabilistic consequence assessment in terms of health effects, or (2) other risk measures which are defined on a technology-specific basis. While this option provides flexibility for the licensee to make a specific safety case that is based on considerations besides those of meeting the QHOs, this option may result in inconsistent approaches for similar designs, and therefore, reduce efficiency in NRC review and increase the needed resources.

Option 3: Develop other risk objectives for the minimum level of safety

For this option, other risk objectives would be developed for the QHOs on a technology-neutral basis. These other risk objectives may be similar to the QHO risk surrogates, core damage frequency (CDF) and large early release frequency (LERF), that have been developed for the current operating LWRs.

In implementing this option, the method is defined for achieving the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants." This option also provides a standard to assess whether new reactor designs meet the Commission's expectations prior to implementation of the framework. Further, the technology-neutral framework would be developed to meet this minimum level of safety for new plant licensing. In implementing the framework, the technology-neutral regulations would be developed to achieve some risk objective that is tied to the Commission's safety goals.

Advantages

Like Option 2, defining the minimum level of safety needed to achieve enhanced safety that applies regardless of reactor design will eliminate, on a case-by-case basis, defining the measures for determining enhanced safety. Defining these measures would obviate the need to develop new risk objectives on a per applicant basis. This approach provides for a more efficient, scrutable and objective regulatory process, provides for consistency and uniformity, and promotes stability and predictability in the regulatory structure for new plant licensing.

Option 2 allows the licensee to make a specific safety case that is based on considerations besides those of meeting the QHOs, which could result in inconsistent approaches for similar designs and reduce efficiency and increase resources. With this option, uniformity is achieved because the framework would specify these new risk objectives. If the risk objectives can be established, efficiency would not be reduced and resources would not be increased.

Assuming that appropriate risk objectives (see below) can be established, this option (unlike Option 2) would eliminate the need for carrying out probabilistic assessments all the way to the health effect level, thus saving resources. Presumably the calculation of the new risk measures could be accomplished with less effort than the calculation of the health effects, much like the calculation of CDF and LERF in risk assessments for current reactors requires less effort than a Level 3 consequence assessment for these reactors.

This option, like Option 2, would implement the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants." Defining risk objectives based on the QHOs as a minimum level of safety will provide "at least the same degree of protection to the public," will demonstrate that "enhanced margins of safety" and "a higher standard of severe accident safety performance" has been achieved.

Disadvantages

There are the significant uncertainties regarding the feasibility of this approach. The risk measures used in the Safety Goal Policy for the QHOs are the consequential health effects of reactor accidents, prompt (or early) fatalities and latent cancers. The quantitative objectives for the risk measures are the associated frequencies of the health effects expressed on annual basis. It is not apparent that technology-neutral risk measures tied to the QHOs can be developed. It is likely that such risk measures and associated quantitative objectives can only be possible on a technology-specific basis.

For operating LWRs, other risk measures that are surrogates to the QHOs have been identified. These risk measures are based on LWR technology and on detailed LWR PRAs (including

Level 2 and 3 PRAs), and provide assurance that the QHOs are met. The surrogates include the risk measures of CDF and LERF with quantitative objectives of 1E-4 and 1E-5/ry, respectively.

CDF is a surrogate for the latent cancer QHO and expresses a risk measure related to accident prevention, and LERF is a surrogate for the prompt fatality QHO and can be considered a risk measure related to accident mitigation, both of which are LWR specific. For other reactor technologies such as PBMR, a core damage risk measure, for example, may not be applicable, because of the fundamentally different characteristics of such reactors. The technical definition of core damage used for LWRs does not apply to a PBMR. In a PBMR, the fuel temperature during normal operation exceeds the temperature criteria for core damage in an LWR. Although temperature excursions, where part of the fuel pebbles in the core experience higher than normal temperatures, can be postulated for a PBMR, no scenarios have been identified where a large fraction of core inventory would be released, comparable to an LWR core damage event. Therefore, in PBMR PRAs performed to date, the risk metrics used are the frequency of specific release categories and comparisons of individual risk to the QHOs, and not CDF and LERF. For non-LWRs, a risk measure for accident prevention that is analogous to CDF and a risk measure for accident mitigation that is analogous to LERF remains to be identified, especially on a technology-neutral basis.

For currently operating LWRs, quantitative objectives of 1E-4/ry and 1E-5/yr have been established for the surrogate risk measures of CDF and LERF that assure that the latent cancer and early fatality QHOs are met, respectively. Derivation of the 1E-4/yr value as an acceptable minimal value for CDF and 1E-5/yr for LERF awas based on the specific characteristics of the currently operating LWRs, and made use of the experience gained from a substantial number of Level 3 PRAs of such types of reactors. For example, based on the results from numerous LWRs, it can be shown that the latent cancer fatality risk is dominated by accidents where there is the equivalent of a large opening in containment and an unscrubbed release. The results from these numerous PRAs also provide a conditional probability of an individual becoming a latent fatality (within 10 miles) for internal initiators for these accidents. Assuming this conditional probability (4E-3) with a CDF goal of 1E-4/ry yields an individual latent risk that is less than the latent QHO with substantial margin. Using the results from numerous PRAs, a similar process is used to demonstrate that a LERF goal of 1E-5/ry yields a prompt fatality risk that is less than the prompt QHO also with substantial margin.

It is possible that with more data and experience gained from PRAs of new and advanced reactor designs, surrogate risk measures for the new designs, which will provide assurance that the QHOs are met, will be identified. However, it is likely that such an identification will only be possible on a technology-specific basis, and even on a technology-specific basis other risk measures may only be established after considerable experience has been accumulated, i.e., after years of reactor and plant operation.

Option 4: Develop new QHOs for the minimum level of safety

For this option, new QHOs, which are more stringent than the ones defined in the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants," would be developed to define the minimum level of safety.

In implementing this option, the method is defined for achieving the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants." This option also provides a standard to assess whether new reactor designs meet the Commission's expectations prior to implementation of the framework. Further, the technology-neutral framework would be developed to meet this minimum level of safety for new plant licensing. In implementing the framework, the technology-neutral regulations would be developed to achieve a level of safety that is more stringent than the Commission's safety goals.

Advantages

Developing new QHOs for the minimum level of safety that is needed to achieve enhanced safety that applies regardless of reactor design will, like Options 2 and 3, also eliminate, on case-by-case, defining measures for determining enhanced safety. This approach provides for a more efficient transparent and objective regulatory process and provides for consistency and uniformity, and promote stability and predictability in the regulatory structure for new plant licensing.

This option, also like Options 2 and 3, would implement the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants." Defining more stringent QHOs as a minimum level of safety will provide "at least the same degree of protection to the public," will demonstrate that "enhanced margins of safety" and "a higher standard of severe accident safety performance" has been achieved.

Disadvantages

Developing new QHOs would require considerable time and staff resources to develop alternate QHOs, solicit stakeholder input and address policy level considerations. For example, developing new QHOs would involve defining new objectives (early and latent fatality objectives) and their goals (e.g., one tenth of one percent). What would be considered more stringent would need to be defined along with consideration of their uncertainties. Since the current QHOs are widely accepted, it is likely that there would be significant concerns and questions from external stakeholders in developing new and more stringent ones. Further, how the current plants compare to the existing QHOs would need to be understood.

Recommendation

For the reasons stated above, the staff recommends that Option 2 be selected: the QHOs of the safety goal policy should be the minimum level of safety for new plant licensing in achieving the Commission's expectations for enhanced safety. Such a minimum level of safety, which is expressed in quantitative terms, will provide for the uniform application of a safety level across all potential reactor technologies and thus will promote stability and predictability in the regulatory structure for new plant licensing.

This option provides a level of safety that is technology-neutral, risk-informed and performance-based. It implements the Commission's expectations for safety as expressed in the policy statements on "Advanced Nuclear Power Plants" and "Severe Reactor Accidents Regarding Future Designs and Existing Plants" and is consistent with the level of safety adopted by the industry in their own design and regulatory initiatives. This option allows greater flexibility to both the staff and the applicant. In addition, this option is feasible and its implementation has the least impact on time and staff resources to implement.

Issue 2: Integrated Risk

Although the staff is not currently reviewing an application for design certification that involves multiple and modular reactor designs, it is anticipated that future applications may involve such designs. The use of multiple and, in particular, modular reactor designs is considered by some plant designers to be an attractive alternative to large single units because of potential inherent safety characteristics that are associated with some modular designs (e.g., passive decay heat removal) and potential economic advantages (e.g., increased use of factory fabrication and stepwise construction and operation bringing modules online as needed). The use of modular designs could result in a large number of reactors on a single site. It is also recognized that new reactors may be constructed on either new sites or existing sites (i.e., sites that have one or more operating reactors). Therefore, the issue of integrated risk applies to both design and siting reviews.

It has been the staff's practice in making risk-informed decisions to consider risk on a per reactor basis. This practice has been considered reasonable because of the small number of reactors on a site and because of the low risk generally posed by currently operating reactors as indicated by staff and industry studies (e.g., NUREG-1150, Individual Plant Examination Program). However, it is recognized that the population around a site is exposed to the hazard of everything that is on that site. In promulgating the safety goal policy in 1986, the terms "plant" and "plant site" were used by the Commission, especially in specifying how the QHOs were to be assessed. Whether these terms were intended to address integrated risk is not clear, but is a consideration with respect to how to treat integrated risk. Nevertheless, with the potential for multiple and/or modular reactors at a site in the future, it is appropriate to consider when and how (if at all) integrated risk should be addressed since the number of reactors on a specific site could be significantly more than currently licensed.

In SECY-03-0047, the staff recommended and the Commission approved in an SRM a process for licensing future reactors that parallels that used in the design certification of the evolutionary and advanced LWRs. This process is based upon the Commission's expectation that future reactor designs will be substantially safer than currently operating LWRs, will comply with the Commission's safety goal policy, and that the need for additional design features to address uncertainties will be determined on a reactor-specific basis, with Commission approval. Accordingly, it is expected that the addition of a single new reactor to a site with currently operating reactors would not add substantially to the integrated site risk. However, in making the recommendation in SECY-03-0047, the staff recognized that the use of a modular reactor design to a site could add a large number of reactors to the site. The staff, therefore, recommended modular reactors be treated differently in that their integrated site risk be considered. The Commission, in its SRM, requested that the staff provide further details and options for this recommendation.

In response to the Commission's SRM, the staff has also reviewed previous dockets for sites where multiple reactors were approved to see if and how the issue of integrated risk was addressed. NRC has issued operating licenses to a site for three reactors (Palo Verde) and granted construction permits for four reactors at several sites (Shearon Harris, North Anna, Surry, Hartsville, and Vogtle). These construction permits were granted on the basis of preliminary safety evaluations and environmental impact statements. However, these preliminary safety evaluations and environmental impact statements did not consider the risk (individually or integrated) from accidents and, therefore, are not considered potential precedents. In all cases, the integrated effect of reactor impacts on the environment from normal operation (e.g., thermal discharges, radiological releases from routine operation) was considered, but not the integrated risk from reactor accidents. In addition, in assessing the environmental impact of license renewal, the staff developed a generic environmental impact statement (NUREG-1437) that considered the risk from reactor accidents. However, the risk was considered on an individual reactor basis, not on an integrated site basis.

In addressing integrated risk one important issue that needs to be considered and analyzed at the outset. This issue concerns the risk measures for assessing integrated risk. The risk measures used for the QHOs are the consequential health effects of reactor accidents, prompt (or early) fatalities and latent cancers. The quantitative objectives for the risk measures are the associated frequencies of the health effects expressed on an annual basis. For operating LWRs, other risk measures that are surrogates to the QHOs have been identified. These risk measures are based on LWR technology and on detailed LWR PRAs (including Level 2 and 3 PRAs), and provide assurance that the QHOs are met. The surrogates include the risk measures of CDF and LERF with quantitative objectives of 1E-4 and 1E-5/ry, respectively. For non-LWRs, a risk measure for accident prevention that is analogous to CDF and a risk measure for accident mitigation that is analogous to LERF remain to be identified, especially on a technology-neutral basis. It is possible that with more data and experience from PRAs of new and advanced reactor designs, surrogate risk measures will be identified for the new designs to provide assurance that the QHOs are met. However, it is likely that the surrogate risk measures will only be possible on a technology-specific basis, and even on a technology-specific basis other risk measures may only be established after considerable experience has been accumulated, i.e., after years of reactor operation.

In the technology-neutral options discussed below for consideration of integrated risk, only risk measures corresponding to the QHOs are considered. As pointed out above, technology-neutral surrogate risk measures (akin to CDF and LERF for LWRs) that address notions of accident prevention and mitigation, will very likely need to be developed to provide assurance that the QHO are met.

Since the QHOs are the risk measures proposed for addressing the integrated risk from either modular or multiple reactors, the number of reactors (or modules) and their individual power levels are not factors in the development of the options. As noted above, the policy statement for the qualitative objectives states that the "intent is to require such a level of safety that individuals **living or working near nuclear power plants** [emphasis added] should be able to go about their daily lives without special concerns by virtue of their [emphasis added]." For the QHOs, the policy statements states that the "risk to an average individual in the **vicinity of a nuclear power plant** [emphasis added]" and the "risk to the population in the **area near a nuclear power plant** [emphasis added]" This language could be interpreted to mean that the risk should be calculated on a per site basis. Therefore, the risk should consider the entire site.

This issue was discussed at the March 14-16, 2005 public workshop. The stakeholder feedback from the workshop and provided subsequently in written comments were considered in the evaluation of the options. Three options for integrated risk have been identified and evaluated by the staff.

1. No consideration of integrated risk
2. Quantification of integrated risk at the site from new reactors
3. Quantification of integrated site risk

The advantages and disadvantages of each option are discussed below.

Option 1: No consideration of integrated risk.

For this option, the status quo is essentially maintained in that, in using risk information in regulatory decisions related to reactors (licensing, license amendments or oversight), the risk information is developed and evaluated on a per reactor basis, not a per site basis.

In implementing this option, the staff will also use this guidance in reviews conducted using the existing regulatory requirements. Consequently, the staff will not consider integrated risk for new reactors. In addition, the criteria and guidelines in the technology-neutral framework would not consider the integrated risk for new reactors at a single site. Therefore, the technology-neutral regulations would be developed without any consideration of integrated risk.

Advantages

The status quo is essentially maintained in that, in using risk information in regulatory decisions related to reactors (licensing, license amendments or oversight), the risk information is developed and evaluated on a per reactor basis, not a per site basis. This approach has been judged acceptable for currently operating reactors given that current sites in the U.S. have a relatively small number of reactors and many currently operating reactors achieve a level of safety comparable to that expressed in the Commission's safety goal policy, thus ensuring the integrated risk is small. If, for example, future new reactor designs have significantly less risk (perhaps an order of magnitude less based upon insights from reviews completed to date) than current operating reactors, then neither modular designs nor larger multiple reactor designs would individually contribute significant additional risk. This option would not distinguish between large and small size reactors and would be reasonable if the number of multiple or modular reactors added to a site was limited, since this would limit integrated risk. Also, it can be argued that uncertainties in risk assessments could be larger than the cumulative risk obtained by combining the risk from all reactor modules. However, since uncertainties are to be considered in risk-informed decisions, this should not be a reason to ignore integrated effects.

Disadvantages

There would be no quantitative assessment of or limit on integrated site risk since the reviews of applications to construct and operate one or more new reactors at a site (either new or existing) would continue to be done on a per reactor basis. As a result, if multiple or a large number of modular reactors were sited together, the risk to the individuals near a reactor site could be greater than the QHOs. The decision not to consider integrated risk may be difficult to justify and communicate to the public.

Option 2: Quantification of integrated risk at the site from new reactors

For this option, the integrated risk solely associated with new reactors (i.e., modular or multiple reactors) at a site does not exceed the risk expressed by the QHOs established in the Commission's safety goal policy statement.

In implementing this option, he staff will use this guidance in the short term for reviews conducted using the existing regulatory requirements. For example, the staff will ensure that the integrated risk associated with a future combined license application does not exceed the risk expressed by the QHOs. In the longer term, the criteria and guidelines in technology-neutral framework would be developed considering the integrated risk for new reactors at a single site. In implementing this framework, the technology-neutral regulations would be developed so that the integrated risk posed by new reactors would not exceed the risk expressed by the QHOs. Specifying that the integrated risk posed by all new reactors at a site does not exceed the risk expressed by the QHOs is consistent with the minimum level of safety recommended above for Issue 1. For Issue 1, the technology-neutral regulations for new reactor licensing will ensure that the risk from each new reactor will not exceed the risk expressed by the QHOs. This issue requires that the integrated risk from new reactors not exceed the risk expressed by the QHOs.

Advantages

This option qualitatively assesses and limits the total integrated site risk. Unlike Option 1, there would be assurance that the integrated risk associated with new reactors constructed at a particular site would not exceed the risk expressed by the QHOs established in the Commission's safety goal policy statement.

This option takes into account the integrated risk posed by the proposed new reactor(s), while preserving regulatory stability and predictability for existing reactors. Specifically, previous regulatory decisions regarding the safety of existing reactors would not be revisited using a new regulatory framework.

Disadvantages

Significant effort would be required to develop regulatory guidance for assessing integrated site risk in a manner that allows comparison to the QHOs. This guidance would need to address commonalities among reactors (e.g., shared support systems and initiating events, such as loss of offsite power and seismic events, that simultaneously impacts all reactors at a given site) and public health effects. In addition, to separate the review of a proposed reactor design from the review of the site(s) where it could be located, it would be necessary for the staff and industry to collectively develop a realistically conservative description of a generic site for the purpose of assessing public health effects.

This option would increase the resources required by applicants to prepare and the staff to review combined operating license (COL) applications because of the need to demonstrate that the integrated risk meets the QHOs. COL applicants must submit a final PRA of public health consequences (i.e., a Level 3 PRA) that addresses (1) all systems, structures, and components (specifically including those not included within the boundary of the certified standard design), (2) all new reactors on site (specifically including any shared systems or other interconnections among individual reactors), and (3) unique site characteristics (e.g., meteorology and

demographics). Although some issues pertaining to integrated risk may be addressed during reviews of applications for early site permits (ESPs) and standard design certifications (e.g., the identification of potential interconnections among individual reactors such as a shared offsite power system), the staff believes that this option would increase the number and scope of items deferred to the COL application.

A full quantitative assessment of the integrated risk at the site from all the reactors (both existing and new) is not performed.

For this option, the public may find it difficult to understand why the risk from existing plants on the site is not included in the integrated risk consideration; that is, why existing reactors should not be held to the higher level of safety that is proposed for the new reactors

Option 3: Quantification of integrated site risk

For this option, unlike Options 1 and 2, the integrated risk associated with existing and new reactors (i.e., modular reactors or multiple reactors) at a site is quantified and does not exceed the risk expressed by the QHOs established in the Commission's safety goal policy statement.

In implementing this option, the staff will use this guidance in the short term for reviews conducted using the existing regulatory requirements. For example, the staff will ensure that the integrated risk from both the risk from the existing reactors and the risk associated with a future combined license application does not exceed the risk expressed by the QHOs. In the longer term, the criteria and guidelines in the technology-neutral framework would be developed considering the integrated risk for all (existing and new) reactors at a single site. In implementing this framework, the technology-neutral regulations would be developed so that the integrated risk posed by all reactors would not exceed the risk expressed by the QHOs. Specifying that the integrated risk posed by all reactors at a site does not exceed the risk expressed by the QHOs is consistent with the minimum level of safety recommended above for Issue 1. For Issue 1, the technology-neutral regulations for new reactor licensing will ensure that the risk from each new reactor will not exceed the risk expressed by the QHOs.

Advantages

For this option, there would be a complete quantitative assessment of integrated risk, including the risk from existing reactors and new reactors located at the site. In addition, the integrated risk would be limited by the QHOs established in the Commission's safety goal policy statement. Hence, it would be relatively straightforward to communicate to the public the suitability of the site/reactor combination in a consistent and systematic way from a risk standpoint, thereby supporting the Commission's expectation of improved public confidence in our regulatory decision-making.

Disadvantages

Similar to Option 2, this option would increase the resources required by applicants to prepare and the staff to review combined operating license (COL) applications because of the need to demonstrate that the integrated risk meets the risk expressed in the QHOs. COL applicants must submit a final PRA of public health consequences (i.e., a Level 3 PRA) that addresses (1) all systems, structures, and components (including those not within the boundary of the certified standard design), (2) all reactors on site (specifically including any shared systems or other

interconnections among individual reactors), and (3) unique site characteristics (e.g., meteorology and demographics). Although some issues pertaining to integrated risk may be addressed during reviews of applications for early site permits (ESPs) and standard design certifications (e.g., the identification of potential interconnections among individual reactors such as a shared offsite power system), the staff believes that this option would also increase the number and scope of items deferred to the COL application. The cost of implementing this option, however, would be notably higher than for Option 2 because of the need to consider existing reactors in addition to new reactors.

Significant effort would be required to develop regulatory guidance for assessing integrated site risk in a manner that allows comparison to the QHOs. This guidance would need to address commonalities among reactors (e.g., shared support systems and initiating events, such as loss-of-offsite power and seismic events, that simultaneously impact all reactors at a given site) and public health effects.

If applicants propose to construct new reactors at existing sites, this option creates additional burdens (compared to the other options) on applicants to prepare and the staff to review new plant licensing applications because it requires applicants to assess the integrated risk of all (existing and new) reactors on the proposed site. It should be noted that the burden of this option is the same as for Option 2 if applicants propose to construct new reactors at new sites.

Recommendation

For the reasons stated above, the staff recommends that Option 2 is selected: the integrated risk solely associated with new reactors (i.e., modular or multiple reactors) at a site not exceed the risk expressed by the QHOs established in the Commission's safety goal policy statement. The new reactors that are designed, constructed, and operated to the safety goal level of safety are demonstrating enhanced safety. Further, since their integrated risk must also meet the QHOs, any additional risk to a site with existing reactors would not be significant. Existing reactors that are licensed to operate under the existing regulatory structure have been extensively evaluated and have been found to pose no undue risk to public health and safety. Option 2 provides a risk-informed, performance-based approach that considers practicality and current licensing commitments.

This option qualitatively assesses and limits the total integrated site risk. Further, it takes into account the integrated risk posed by the proposed new reactor(s), while preserving the regulatory stability and predictability for existing reactors. This option allows greater flexibility to both the staff and the applicant and its implementation has the least impact on time and staff resources to implement.