

February 7, 1996

FOR: The Commissioners
 FROM: James M. Taylor /s/
 Executive Director for Operations
 SUBJECT: TWO ISSUES FOR DESIGN CERTIFICATION RULES

PURPOSE:

To request the Commission's approval of the staff's position on two major issues raised by the Nuclear Energy Institute (NEI **(EXIT)**) in its comments on the proposed design certification rules. While the staff believes that the final design certification rules will resolve most of the major issues, there remains fundamental disagreement on applicable regulations and verification of inspections, tests, analyses, and acceptance criteria (ITAAC).

SUMMARY:

The staff reevaluated the need for applicable regulations, in accordance with the Commission's guidance dated March 17, 1995, and continues to believe that new applicable regulations are necessary and desirable for the final design certification rules. Also, the staff disagrees with the industry's request to add a provision to the design certification rules that would restrict the matters to be considered in verifying ITAAC determinations.

APPLICABLE REGULATIONS

BACKGROUND:

In implementing the goals of Part 52 of Title of the Code of Federal Regulations (10 CFR Part 52), the staff set out to achieve a higher level of safety performance for both evolutionary and passive LWR designs in the area of severe accidents and in other selected areas. In response to Commission guidance in 1989, the staff proposed new requirements to implement these goals in various Commission papers, such as SECY-90-016, "Evolutionary LWR Certification Issues and Their Relationship to Current Regulatory Requirements," and SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced LWR Designs." These new requirements deviate from or are not embodied in existing regulations. The staff selected the new requirements that were applicable to each evolutionary design and evaluated the design information presented by the applicants for design certification that described how those requirements were met. The staff documented the results of its evaluations in the final safety evaluation reports (FSERs) for the U.S. ABWR (NUREG-1503) and System 80+ (NUREG-1462) designs. In the proposed rule for each design, the NRC has identified these requirements as new applicable regulations in order to completely identify the requirements (safety bases) for these designs that are applicable and in effect at the time the certification is issued for the purposes of 10 CFR 52.48, 52.54, 52.59, and 52.63.

The staff has been developing these new applicable regulations in parallel with its review of the design certification applications, in accordance with Commission guidance, since 1988. For example, in the statements of consideration for 10 CFR Part 52 (*proposed* 53 FR 32060, 32063 and *final* 54 FR 15372, 15373, 15375-76), the Commission stated that new safety standards may be required to address new design features and directed the staff to advise the Commission of the need for criteria for judging the safety of designs offered for certification that are different from or supplementary to current standards. In SECY-88-248, "Implementation of the Severe Accident Policy for Future LWRs," the staff recommended initiation of rulemaking to implement severe accident performance requirements and modification of 10 CFR 50.34(f). In SECY-90-016 and SECY-93-087, the staff requested the Commission's approval of new requirements that went beyond current regulations. In the staff requirements memorandum (SRM) on SECY-90-016, dated June 26, 1990, the Commission agreed that in those cases in which the proposed requirements departed from current regulations, consideration should be given to incorporating these requirements into the regulations. In SECY-92-287, "Form and Content for a Design Certification Rule," the staff requested the Commission's approval of having the resolution of selected design-specific technical and severe accident issues be approved in the rule that certifies the standard design. In SECY-92-287A, "Form and Content for a Design Certification Rule," the staff stated that these new regulations in the design certification rule would become part of the Commission's baseline of regulations that were "applicable and in effect at the time the certification was issued," and without this baseline of applicable regulations, the staff could not perform reviews in accordance with 10 CFR 52.59 and 52.63.

In its SRM on SECY-95-023, dated March 17, 1995, the Commission directed the staff to add a question to the Federal Register Notices to solicit comments on whether each new applicable regulation is justified and requested the staff to give special attention to the resolution of comments received, particularly regarding the inclusion of applicable regulations in the rule, and to reevaluate, as necessary, the need for their inclusion in the final design certification rules.

DISCUSSION:

In response to the proposed design certification rules, dated August 4, 1995, NEI submitted detailed comments (Section II of Attachment B) on the need for new applicable regulations. The applicants for design certification and 16 other industry organizations support NEI's comments. In its first group of comments, NEI stated that there is no requirement in 10 CFR Part 52 that compels the Commission to adopt these new applicable regulations, that the new applicable regulations are not necessary for adequate protection or to improve the safety of the standard designs, and that the applicable regulations are inconsistent with the Commission's SRM, dated September 14, 1993.

Although the Commission was not compelled to adopt new applicable regulations, it has been developing them in accordance with the goals of 10 CFR Part 52 (see background discussion herein) and in order to achieve the purposes of 10 CFR 52.48, 52.54, 52.59, and 52.63. The staff has been developing the new applicable regulations consistent with Commission guidance. The Commission chose design-specific rulemaking rather than generic rulemaking for the new technical and severe accident issues. The Commission adopted this approach early in the design certification review process because it was concerned that generic rulemakings would cause significant delay in the design certification reviews and it was thought that the new requirements would be design-specific. In its SRM on SECY-91-262, dated January 28, 1992, the Commission approved the staff's recommendation to proceed with design-specific rulemakings through individual design certifications to resolve these technical and severe accident issues for the ABWR and System 80+ designs and has continued to support this approach, as stated in its SRM on SECY-93-226, dated September 14, 1993. However, the Commission delayed its decision on the need for generic rulemaking for advanced LWRs. It is this later guidance that NEI appears to have misunderstood.

In its second group of comments, NEI stated that the applicable regulations are unnecessary because the staff has applied these technical positions in reviewing and approving the standard designs. In addition, each of these positions has corresponding staff-approved provisions in the respective design control documents (DCD), and these provisions already serve the purpose of applicable regulations for all of the situations identified by the staff. NEI's statement that information in the DCD will constitute an applicable regulation confuses the difference between design descriptions approved by rulemaking and the regulations (safety standards) that are used as the basis to approve the design. During a meeting on April 25, 1994 and in a letter from Mr. Crutchfield (NRC) to Mr. Rasin (NEI), dated July 25, 1994, the staff stated that design information cannot function as a surrogate for the new (design-specific) applicable regulations because this information describes only one method for meeting the regulation and would not provide a basis for evaluating proposed changes to the previously approved design descriptions. Also, the technical positions that form the basis for the new applicable regulations were used during the reviews because the design-specific rulemaking for the new applicable regulations has been established in parallel with the design certification rulemaking, in accordance with Commission guidance.

In its third group of comments, NEI is concerned that "broadly stated" applicable regulations could be used in the future by the NRC staff to impose backfits on applicants and licensees that could not otherwise be justified on the basis of adequate protection of public health and safety. However, NEI acknowledged in its comments that the NRC staff did not intend to reinterpret the applicable regulations to impose compliance backfits and since implementation of the applicable regulations was approved in the DCD, the staff could not impose a backfit on the approved implementation without meeting the standards in the change process. In response to NEI's comments, the staff intends for the final design certification rules to state that the standard designs meet the applicable regulations. Also, by approving the design information that describes how these regulations were met, the Commission minimized the potential for a differing interpretation of the regulations.

Finally, in response to question 4 in the proposed design certification rules, NEI provided additional comments on the specific wording of each new applicable regulation. The staff is currently reviewing these comments to determine whether the wording of the new applicable regulations can be improved without creating a conflict with the Commission's approval of the requirement or going beyond the previously approved implementation in the DCDs.

CONCLUSION:

In summary, there appears to be agreement that: (1) these new requirements go beyond existing regulations and improve safety; (2) the design descriptions that meet the proposed applicable regulations are binding on the applicants and licensees that reference these design certification rules in the same manner that other design descriptions are binding; (3) in evaluating the possible need for a compliance backfit, as permitted by Part 52, and in evaluating an application to renew or request to change a design certification, these new requirements will have no legal effect unless they are designated as applicable regulations; and (4) the need for these new applicable regulations must be resolved in the final design certification rule.

The staff believes the fundamental industry concern is that these new applicable regulations, precisely because they are new and have very limited implementation history, could be subject to future reinterpretations and rereviews, which could be the basis for backfits that undermine stability, thereby defeating a critical goal of the Commission's standardization policy. Industry has a point, in that future NRC reviewers could reinterpret and rereview against these new requirements and impose backfits, although it is certainly not the staff's intention to engage in frequent reinterpretations and rereviews. The staff's concern is with significant new information. If, at some future date while the design certifications are in effect, significant new information is developed which suggests that the safety improvements intended by the new requirements will not in fact be achieved by the designs, as described in the rule, the staff will be powerless to reinstate the level of safety originally intended if industry's position is adopted. In the industry's view, compliance with the new requirements, in this circumstance, will be a matter of discussion with the NRC and, while there is no intention to decrease safety, compliance would ultimately be voluntary. In essence, this issue poses a policy trade off between, on the one hand, possible loss of regulatory stability and, on the other, loss of the NRC's ability to assure a continued level of improved protection of the public health and safety, in the possible circumstance of significant new information.

Finally, the Commission's approval of the FSERs and final design approvals for the evolutionary designs were based on a wide range of technical and policy issues that were identified in a memorandum to the Commission, dated May 31, 1994. The staff's safety findings were based, in part, on the assumption that the Commission agreed with the staff's positions on these issues, including the use of new applicable regulations. If the Commission now disagrees with or provides alternative guidance on the use of applicable regulations, it is likely that certain review areas and safety conclusions will need to be reassessed and the FSERs revised, as stated in the Commission memorandum, dated June 9, 1994. Also, the design certification rules would need to be modified to reflect these changes.

ITAAC VERIFICATION

In its comments on the proposed design certification rules, dated August 4, 1995, NEI raised an industry concern regarding the matters to be considered by the NRC in verifying ITAAC determinations pursuant to [10 CFR 52.99](#), specifically quality assurance and quality control (QA/QC) deficiencies. NEI stated that this issue became a significant industry concern based on SECY-94-294, "Construction Inspection and ITAAC Verification," and related meetings with the staff. On page 59 of Attachment B to its comments, NEI stated:

[There are] industry concerns that in determining whether ITAAC have been satisfied, the NRC staff contemplates broad-ranging evaluations of quality assurance activities, e.g. adequacy of installation, training and test procedures, adequacy of procurement documentation, etc.

NEI recommended that a provision be included in the final rules that clearly specifies that compliance with the ITAAC shall be determined by verifying that the required inspections, tests, and analyses specified in the ITAAC have been performed and that based solely (emphasis added) on the performance thereof, the corresponding acceptance criteria have been met. The staff believes that the term, "solely," is intended by the industry to preclude NRC consideration of any information not specifically identified in the ITAAC, such as QA/QC deficiencies, in the NRC's determination whether ITAAC have been successfully completed. This subject was not discussed in the statements of consideration (SOC) for the proposed rules. However, in view of the industry comment and the seriousness that they accord to this issue, the staff believes that this issue should be discussed in the SOC for the final rules.

The staff disagrees with the industry's apparent assertion that QA/QC deficiencies have no relevance to the NRC determination whether ITAAC have been successfully completed. Simply confirming that an ITAAC had been performed and a result obtained apparently showing that the acceptance criteria had been met would not be sufficient to support a determination that the ITAAC had been successfully completed; the *manner* in which an ITAAC is performed is relevant to the results of the ITAAC. The staff's position can be demonstrated by using the example ITAAC set forth in NEI's comment (Attachment B, p. 59). In NEI's example, the design commitment is for a pump flow rate of 100 gpm, a test is designed to demonstrate the commitment, and the acceptance criteria is "pump flow rate equal to or greater than 100 gpm." In conducting the required pump flow test, it is logical, even if not explicitly specified in the ITAAC, that the gauge used to verify the pump flow rate must be calibrated in accordance with relevant QA/QC requirements, and that the test configuration is representative of the final as-built plant conditions (i.e., valve or system line-ups,

gauge locations, system pressures, or temperatures). Otherwise, the 100 gpm acceptance criteria in the ITAAC could apparently be met while the actual flow rate in the system could be much less than that required by the approved design. However, if one were to adopt the industry argument, the NRC would be precluded from considering a QA/QC deficiency showing either that the gauge was not properly calibrated, or that the test conditions specified in the test procedures during the initial test program were not followed.

In contrast to the industry position, the staff believes that a QA/QC deficiency may be considered in determining whether an ITAAC has been successfully completed, if the QA/QC deficiency is directly related to one or more aspects of the relevant ITAAC (or supporting Tier 2 information), and the deficiency (considered by itself, with other deficiencies, or with other information known to the NRC) leads the NRC to question whether there is a reasonable basis for concluding that the relevant aspect of the ITAAC has been successfully completed. This approach is consistent with our current methods for verifying initial test programs. The staff recognizes that there may be programmatic QA/QC deficiencies which are not relevant to one or more aspects of a given ITAAC under review and, therefore, should not be relevant to or considered in the NRC's determination as to whether an ITAAC has been successfully completed. Similarly, individual QA/QC deficiencies unrelated to the aspect of the ITAAC in question would not form the basis for an NRC determination that an ITAAC has not been met, unless a direct logical nexus had been established. Again, using the NEI example, a specific QA deficiency in the calibration of pump gauges would not preclude a NRC determination of successful ITAAC completion if the licensee could demonstrate that the original deficiency was properly dispositioned (including a root cause determination, scope of effect, and corrective action), or that the deficiency could not have affected the test in question.

In the staff's view, the fundamental principle underlying the industry's position is a mechanistic and literal interpretation of the nature of the ITAAC and the determination of successful completion: i.e., if a specific type of information is not explicitly set forth in the words of the ITAAC, then it is not part of the ITAAC and may not be considered in determining whether the ITAAC has been successfully completed. However, the ITAAC were not reviewed and approved by the staff with that understanding, in accordance with the wishes of the applicants and industry representatives. During the ITAAC development, the applicants complained that it was impossible (or extremely burdensome) to provide all details relevant to verifying all aspects of ITAAC (e.g., QA/QC) in Tier 1 or Tier 2. Therefore, the staff accepted the applicants' proposal that top-level design information be stated in the ITAAC to ensure that it was verified, with an emphasis on verification of the design and construction details in the "as-built" facility. Thus, the staff reviewed and approved the ITAAC under an industry understanding which is inconsistent with the industry's current position. If we could modify the ITAAC to specify in detail every requirement (such as QA/QC) that the staff believes must be addressed in coming to a determination that an ITAAC has been successfully completed, in order to accommodate the industry's current position, it would result in a considerable expansion of the design control document and a reopening of the design reviews.

COORDINATION:

The Office of the General Counsel concurs in this paper.

RECOMMENDATIONS:

That the Commission approve the use of new applicable regulations in the design certification rules.

That the Commission approve the staff's approach to the matters that could be considered in making an ITAAC determination.

That the Commission release this paper 10 working days after its issuance.

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