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OFFICE OF THE
INSPECTOR GENERAL

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MEMORANDUM TO: R. William Borchardt
Executive Director for Operations

FROM: Stephen D. Dingbaum */RA/*
Assistant Inspector General for Audits

SUBJECT: OBSERVATION: NRC'S QUALITY ASSURANCE
INSPECTION GUIDANCE IS IMPRECISE

As part of the Office of the Inspector General's (OIG) audit of the U.S. Nuclear Regulatory Commission's (NRC) quality assurance (QA) planning for new reactors, auditors reviewed licensing and inspection guidance and identified an issue that warrants your attention. In particular, OIG auditors observed imprecise language in some of the guidance for NRC QA inspections. As a result, NRC inspectors must perform a workaround to accommodate the imprecise language. NRC staff stated that they did not know of any instances where the imprecise language contributed to an inadequate assessment of compliance with QA requirements or inappropriate staff conclusions.

BACKGROUND

NRC regulations require applicants of a combined license (COL), which includes a nuclear power plant construction permit and an operating license, to submit a description of the QA program.¹ The tenets of the QA program are described in Appendix B to Title 10 Code of Federal Regulations (10 CFR), Part 50, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants* (Part 50).

¹ Nuclear power plants have structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The purpose of the QA program is to provide adequate confidence that these structures, systems, and components will perform satisfactorily in service.

As of May 2009, NRC had received 17 license applications for 26 new nuclear power plants. The applications that NRC received were provided under 10 CFR Part 52, *Licenses, Certifications, and Approvals for Nuclear Power Plants* (Part 52). Part 52 references the QA program requirements described in Part 50. Also, Part 52, which provides the process for issuing COLs, requires each combined license applicant to submit a final safety analysis report that includes a description of the applicant's QA program.

As part of NRC's regulatory oversight of applicants seeking to build new nuclear power plants, NRC inspects the applicants' implementation of their QA programs. NRC's QA inspections for new reactors are conducted under Inspection Manual Chapter 2502, *The Construction Inspection Program: Pre-Combined License Phase*, using Inspection Procedure 35017, *Quality Assurance Implementation Inspection*.

ISSUE FOR CONSIDERATION

While observing NRC QA inspections, OIG auditors noted that some of the guidance for NRC QA inspectors contains imprecise language. Inspectors should have clear and accurate guidance to ensure they inspect applicants consistently and in a manner compliant with both regulations and management expectations. However, an NRC inspection procedure and an NRC inspection manual chapter that are used for inspections contain imprecise language. Inspectors were observed to accept this imprecise guidance and to work around it. Although management was aware of this issue, and stated that they had guided the inspectors on how to conduct the inspection through inspection planning activities, no action was taken to revise the inspection procedure prior to the actual inspection.

Inspection Guidance Contains Imprecise Language

Some of the guidance for conducting inspections of COL applicants' QA programs contains imprecise language. Specifically, Inspection Procedure 35017 and Inspection Manual Chapter 2502 both make incorrect references to "NRC-approved QA programs." The references are incorrect because NRC does not approve licensee QA programs, but does review and approve QA program descriptions.

OIG observed inspectors using Inspection Procedure 35017 and interpreting the phrase "NRC-approved QA program" in the inspection procedure as actually referring to the QA program *description*. However, NRC regulations clearly differentiate between the QA program and the QA program description. For example:

- 10 CFR Part 50, Appendix B requires that a description of the applicant's QA program be included in the application. The QA program itself is defined in Appendix B and includes the written policies, programs, and instructions necessary to meet Appendix B quality requirements.

- 10 CFR Part 52.79(a)(25) requires submission of a description of the QA program to the NRC and clearly differentiates the program from the description of it. Specifically, the regulation requires a “description of the quality assurance program, applied to the design, and to be applied to the fabrication, construction, and testing, of the structures, systems, and components of the facility. Appendix B to 10 CFR Part 50 sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant must include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied, including a discussion of how the quality assurance program will be implemented.” Essentially, the agency requires applicants to submit a QA program description to the NRC for approval as part of the COL application. However, the QA program is not required to be submitted to NRC.

NRC guidance also provides a specific definition for the QA program description. NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants*, states that the QA program description is a top-level policy document in which a facility's management sets the tone and establishes the manner in which quality is to be achieved. It is a product of senior-level management, and represents an organization's overall philosophy regarding quality. This is in contrast to the program itself, which contains the detailed program policies, programs, instructions, and procedures that are to be carried out by staff members at all levels of an organization.

Another issue with Inspection Procedure 35017 is that it specifies that NRC's inspection is to be done while the early site permit, standard design certification, or COL application is under review and to verify that the “NRC-approved QA program” was appropriately translated into implementing procedures. However, the QA program description is not yet approved at the time the Inspection Procedure 35017 inspection is called for; in fact, Inspection Procedure 35017 states in its objective that the inspection is to occur prior to the approval of the COL. Because the description of the QA program is typically submitted as part of the COL, it would normally not be approved when NRC is conducting its inspection.

Inspection Manual Chapter 2502 also contains imprecise language. Specifically, it directs the inspector to verify the applicant's implementation of the “NRC-approved QA program” during a post-docketing inspection. However, as described above, NRC has not approved the QA program description at this point in the COL process and NRC does not approve QA programs.

Imprecise Guidance Results in Workarounds

To use the relevant inspection guidance, NRC inspectors must perform a workaround to accommodate the imprecise language in the inspection procedure and manual. That is, inspectors must interpret “NRC-approved QA program” to mean “NRC-approved QA

program description.” Moreover, NRC inspectors must overlook the fact that the QA program descriptions reviewed may not be approved by NRC prior to inspection because the QA program descriptions for new reactor applications are typically approved as part of the COL application.

The three COL applicants that OIG observed during NRC QA inspections utilized QA program descriptions that were, to varying degrees, unapproved. One applicant chose to utilize an unapproved QA program description that was submitted with the COL application for ongoing quality-related activities while the application was under review. Another applicant used the approved QA program description of the operating nuclear power plant located on the same site. However, that approved QA program description was supplemented by a document generated specifically to address new reactor issues not covered by the operating plant QA program description. Moreover, the supplementary document had not been approved by NRC. The third applicant also utilized the QA program description of the operating reactors on the same site, but also relied on the unapproved QA program description submitted with its COL application. This applicant referenced the fact that it was using the operating nuclear power plant’s QA program description in its final safety analysis report submitted with the COL application. None of these avenues of meeting the requirement to inspect against an applicant’s “NRC approved QA program” was described in Inspection Procedure 35017 or Inspection Manual Chapter 2502. However, NRC found all of these approaches to be acceptable in the inspections that OIG observed.

Regulatory Guide 1.206, *Regulatory Position Part I: Standard Format and Content of Combined License Applications*, states that an applicant may use an existing OA program description, as was done in two of the three cases with some exceptions as noted above. This option for fulfilling the requirement for an approved QA program description is not referenced in Inspection Procedure 35017 or Inspection Manual Chapter 2502.

NRC and the nuclear industry have not utilized the Part 52 licensing process in the manner originally envisioned. Inspection Procedure 35017 and Inspection Manual Chapter 2502 were likely written in light of NRC’s expectation of how the NRC and industry would utilize Part 52. This guidance, as written, does not contemplate industry using unapproved QA program descriptions. Consequently, to use the guidance, NRC inspectors must work around the reference to the “NRC-approved QA program.”