

3.0 QUALITY ASSURANCE

3.1 Purpose of Review

The purpose of this review is to establish that the applicant's quality assurance (QA) program meets the NRC QA requirements of 10 CFR 76.93. The applicant's QA program should apply to all items¹ and activities relied upon for safety to provide reasonable assurance that they will perform their safety function in a satisfactory manner to provide adequate protection of the health and safety of the public, the workers, and the environment.

3.2 Responsibility for Review

Primary: Quality Assurance (QA) Engineer/Specialist

Secondary: Certification Project Manager

Supporting: Reviewers of Standard Review Plan (SRP) Chapters 2.0 and 6.0

3.3 Areas of Review

This chapter of the SRP is written to direct the review of an application with regard to gaseous diffusion plant (GDP) items and/or activities that are relied on for safety. A graded QA program commensurate with importance to safety should be applied to provide reasonable assurance of the availability and reliability of items and activities that are relied on for safety.

The QA program description should specify the applicable regulatory acceptance criteria, the basis on which the criteria were selected, where they are described in the application, if not in the QA Section, and the proposed method for implementation.

The application should describe the QA program, and the primary reviewer should examine the QA program description in terms of the acceptance criteria given in SRP Section 3.5. The review objective is to obtain reasonable assurance of the implementation of accepted QA principles in the operation, maintenance, modification, and decommissioning phases of a GDP facility's life. Fundamental to this effort is the applicant's application of QA to the items and activities identified as being relied on for safety.

The application should define the levels of QA to be applied to items and activities relied upon for safety and continue to describe the relationship among the programs for QA, maintenance, and configuration management. The application should assign each item and activity that is relied on for safety to a QA level. The application should address the applicant's approach to

¹ Items include structures, systems, components; materials (including consumable materials); parts; measuring and test equipment; computers; computer programs (software and firmware); etc., as appropriate.

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determining the relative risk, or relative safety importance, of the various items and activities to be treated by the QA program. This safety importance ranking should determine the level of QA to be applied to individual items and activities relied upon for safety.

Many of the regulatory acceptance criteria that an applicant's QA program should control may be detailed in other parts of the application (for example, SRP Section 2.1, "Organizational Structure," and Section 2.6, "Records Management"), and Section 3, "Quality Assurance," of the application may reference these other parts of the application that present information relevant to the QA program. The application of quality levels commensurate with the risk involved should parallel the risk levels established for the maintenance program addressed in Section 2.7, "Maintenance," of this SRP.

3.4 Review Procedures

3.4.1 Acceptance Review

The staff review should start with the primary reviewer's determination that sufficient information has been provided in the contents of the application to satisfy the requirements in 10 CFR 76.35, "Contents of Application," and 10 CFR 76.36, "Renewals," with respect to the description of the QA program—see SRP Section 3.5.1, "Regulatory Requirements"—and that the topics discussed in SRP Section 3.3, "Areas of Review," have been addressed, including proposed or unreported changes to the applicant's QA program.

If significant deficiencies are identified in the application, the applicant should be requested to submit additional material before the staff resumes the application review.

3.4.2 Evaluation

The primary staff reviewer should review the QA program description, including changes, with respect to each of the acceptance criteria in SRP Section 3.5. The review should result in a determination that there is reasonable assurance that the applicant's QA program adequately addresses the acceptance criteria, that the applicant's QA, configuration management, and maintenance programs are coordinated, and that the QA program is an integral part of everyday work activities. The review should confirm that there is reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of the QA program and will make needed adjustments on a timely basis.

When an applicant's QA program references other parts of the application, the primary reviewer should review these other parts to determine the applicant's commitment to the overall QA program, the selection of acceptance criteria and quality levels, and the proposed method for implementation. The primary reviewer should focus on the QA and management controls applied to criticality, personnel health and safety and environmental safety. The application of quality levels commensurate with the risk involved should parallel the risk levels established for the maintenance program.

The secondary staff reviewer should report to the primary reviewer any changes to the applicant's QA program that have not been submitted in the application, and the primary reviewer should follow-up through the Project Manager to have the application modified as necessary. The secondary staff reviewer should maintain familiarity with the applicant's (and the principal contractor's) QA program and determine whether ongoing activities are in agreement with the program.

Supporting staff reviewers should review the applicant's QA program, including changes, to ensure there is no contradiction between the QA program and their primary review areas. They should also ensure that the scope of the program includes the items and activities relied upon for safety that are in their primary review areas.

On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in SRP Section 3.5.

The final step in the review is the primary staff reviewer's writing of a Compliance Evaluation Report that summarizes the conduct of the review, identifies what material in the application forms the basis for a finding of reasonable assurance with respect to the acceptance criteria, identifies issues with the applicant's QA program that could affect a finding of reasonable assurance, and presents any recommendations for certificate conditions to achieve reasonable assurance.

3.5 Acceptance Criteria

The regulatory requirements, regulatory guidance, and regulatory review criteria applicable to this SRP section are listed in the following sections.

3.5.1 Regulatory Requirements

1. 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," Section 76.35(d), "Contents of Application," requires that the application for certification include a QA program that meets the requirements of 10 CFR 76.93, "Quality Assurance."
2. 10 CFR 76.93 requires that the corporation establish, maintain, and execute a QA program satisfying each of the applicable requirements of American Society of Mechanical Engineering (ASME) NQA-1-1989, "Quality Assurance Program Requirements for Nuclear Facilities," or satisfying acceptable alternatives to the applicable requirements. It also requires that the corporation execute the criteria in a graded approach to an extent that is commensurate with the importance to safety.
3. 10 CFR 76.36, "Renewals," requires that the corporation must submit applications for certification renewal to the NRC not less than every 5 years.

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3.5.2 Regulatory Guidance

No regulatory guidance has been developed by the NRC in this area.

3.5.3 Regulatory Review Criteria

The staff should use the regulatory review criteria, or information demonstrating acceptable alternatives, in its review of the application. Acceptability should be based on the basic and supplemental requirements in ASME NQA-1-1989 as specified in 10 CFR 76.93.

3.6 Evaluation Findings

The staff's review should verify that sufficient information has been provided in the application to satisfy the intent of requirements in 10 CFR 76.35, "Contents of Application," and 10 CFR 76.36, "Renewals," with respect to the QA program and that the information provided is consistent with the guidance in this SRP. On the basis of this information, the staff should be able to conclude that this evaluation is complete.

The staff could document the evaluation of the application as follows:

The staff has reviewed the QA program for [name of facility] according to SRP Sections 3.3, 3.4, and 3.5 and finds that: (1) the applicant has a QA organization responsible for developing, implementing, and assessing the QA program for ensuring a safe facility and safe facility operations in accordance with the acceptance criteria of Section 3.5 of the SRP, (2) the applicant committed to a plant QA program for items and activities relied upon for safety, with acceptable administrative controls for staffing, functioning, assessing findings, and implementing corrective actions, (3) the applicant has developed a process for preparation, review, approval, documentation, and control of written administrative plant procedures, including procedures for evaluating changes to procedures, equipment, tests, and processes relied on for safety, (4) the applicant has established and documented a surveillance, test, and inspection program to ensure satisfactory performance of items and activities relied on for safety, (5) the applicant has committed to conduct periodic independent audits to determine the effectiveness of the management controls program. Management controls will provide for documentation of audit findings and implementation of corrective actions, (6) the applicant has committed to establish and document training programs to provide employees with the skills to perform their jobs safely. Management controls will provide for evaluation of the effectiveness of the training programs against predetermined objectives and criteria, (7) the organizations and persons performing QA functions will have the required independence and authority to effectively carry out the QA program without undue influence from those directly responsible for process operations, and (8) the QA program covers all items and activities identified as relied on for safety, with controls established to prevent hazards from becoming pathways to accidents.

On the basis of its review, the NRC staff has concluded that the quality assurance program description is acceptable to support the recertification.

3.7 References

American Society of Mechanical Engineering (ASME). ASME NQA-1-1989, "Quality Assurance Program Requirements for Nuclear Facilities." ASME: New York. 1989.

Code of Federal Regulations, *Title 10, Energy*, Part 76, "Certification of Gaseous Diffusion Plants."