13.0 QUALITY ASSURANCE

I. Review Objective

In this portion of the dry cask storage system (DCSS) review, the NRC evaluates the applicant's proposed quality assurance (QA) program, as described in the safety analysis report (SAR). In conducting this evaluation, the NRC staff seeks to ensure that the program provides adequate control over all activities related to the design, fabrication, assembly, testing, and use of DCSS structures, systems, and components (SSCs) that are important to safety.

To assess "adequate control," the staff determines whether the applicant's proposed QA program defines and assigns specific quality measures and controls to the various activities and SSCs. Moreover, the applicant should apply these quality measures and controls using a graded approach. The graded approach is described in NUREG/CR-6407[1]. That is, the effort expended on an activity or SSC should be consistent with its importance to safety. The QA program description provided in the SAR must identify both the procedures that the applicant will use to implement the QA program, as well as the activities and DCSS SSCs that are important to safety.

This evaluation should yield reasonable assurance that the applicant's proposed QA program will ensure that the DCSS will perform its intended functions in a satisfactory manner.

II. Areas of Review

This chapter of the DCSS Standard Review Plan (SRP) provides guidance for use in evaluating the applicant's proposed QA program. As described in Section V, "Review Procedures," a comprehensive evaluation involves examining the QA program in terms of the 18 criteria defined in 10 CFR Part 72[2], Subpart G, "Quality Assurance." Reviewers should obtain reasonable assurance that the applicant has implemented accepted QA principles in the design, fabrication, assembly, testing, and use of the DCSS SSCs. In addition, the SAR should address the assignment of specific QA levels to each activity and SSC important to safety.

It is essential that the SAR provide sufficient detail to enable the NRC staff to assess the adequacy of the proposed QA program. In addition, since many of the QA program controls may be detailed in other sections of the SAR, the description of the QA program in SAR Section 13 should reference other sections that contain relevant information. The QA program evaluation should therefore be coordinated with other aspects of the DCSS review. Such coordination will allow reviewers to derive a more accurate and complete assessment of the applicant's level of commitment to the overall QA program, the selection of quality criteria and quality levels, and the proposed implementation methods.

To control activities related to the design and development of the DCSS, the applicant must *first* establish and implement an effective design control program and associated QA program controls and implementing procedures. Consequently, in conducting the QA program evaluation, reviewers should emphasize the area of design control. An effective design control program will provide assurance that the proposed DCSS will be correctly designed and tested and will perform its intended function.

III. Regulatory Requirements

According to 10 CFR 72.24, "Contents of Application: Technical Information," the application must include, at a minimum, a description that satisfies the requirements of 10 CFR Part 72, Subpart G, "Quality Assurance," with regard to the QA program to be applied to the design, fabrication, construction, testing, and operation of the DCSS SSCs important to safety. Moreover, Subpart G states that the licensee shall establish the QA program at the earliest practicable time consistent with the schedule for accomplishing the activities.

IV. Acceptance Criteria

The SAR must provide a comprehensive description of the QA program that the applicant will establish, maintain, and execute to ensure control of all activities related to the design, fabrication, construction, testing, and use of DCSS SSCs that are important to safety. In addition, the QA program description in the SAR must identify the SSCs that are important to safety and must include information pertaining to managerial and administrative controls to ensure safe operation of the DCSS.

To be acceptable, the applicant should structure the QA program to apply QA measures and controls to all activities and SSCs using a graded approach in proportion to their importance to safety. Consequently, in identifying the activities and SSCs that are important to safety, the SAR should also identify the associated degree of importance for each. Those activities and SSCs that are highly important to safety should be covered by a high level of control, while those less important to safety may have a lower level of control.

An applicant may choose to apply the highest level of QA and control to all activities and SSCs without distinction. By contrast, a graded approach to QA requires applicant justification and reviewer acceptance. Consequently, the SAR should adequately describe the proposed graded approach.

Section V summarizes the acceptance positions that the NRC staff uses to evaluate an applicant's QA program as described in the SAR. These positions represent solutions and approaches that the staff finds acceptable, but they may not be the only possible solutions and approaches. Various alternatives to the detailed guidance in this SRP may be deemed acceptable, provided that the applicant adequately documents and justifies the deviations.

For each of the activities and SSCs identified as important to safety, the applicant should identify and define the level of control to be applied to each of the following 18 elements of the QA program. Appendix A presents a sample checklist for use in evaluating each of these QA elements. The NRC intends that the attributes listed in the Appendix for each element are to be applied collectively only in the most stringent application of the QA program. Lesser quality requirements may be effected by modifying or eliminating some attributes from selected elements. The applicant's QA program, and associated QA program controls and implementing procedures regarding activities performed, must be in place before activities begin.

1. Quality Assurance Organization

The SAR should describe (and illustrate in an appropriate chart) the organizational structure, interrelationships, and areas of functional responsibility and authority for all organizations performing quality- and safety-related activities, including both the applicant's organization and principal contractors, if applicable. Persons or organizations responsible for ensuring that an appropriate QA program has been established and verifying that activities affecting quality have been correctly performed should have sufficient authority, access to work areas, and organizational freedom to carry out that responsibility.

2. Quality Assurance Program

The SAR should provide acceptable evidence that the applicant's proposed QA program will be well-documented, planned, implemented, and maintained to provide the appropriate level of control over activities and SSCs, consistent with their relative importance to safety.

3. Design Control

The SAR should describe the approach that the applicant will use to define, control, and verify the design and development of the DCSS. An effective design control program will provide assurance that the proposed DCSS will be appropriately designed and tested and will perform its intended function.

4. Procurement Document Control

Documents used to procure SSCs or services should include or reference applicable design bases and other requirements necessary to ensure adequate quality. To the extent necessary, these procurement documents should require that suppliers have a QA program consistent with the quality level of the SSCs or services to be procured.

5. Instructions, Procedures, and Drawings

The SAR should define the applicant's proposed procedures for ensuring that activities affecting quality will be prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate for the circumstances.

6. Document Control

The SAR should define the applicant's proposed procedures for preparing, issuing, and revising documents that specify quality requirements or prescribe activities affecting quality. These procedures should provide adequate control to ensure that only the latest documents are used. In addition, the applicant's authorized personnel should carefully review and approve the accuracy of all documents and associated revisions before they are released for use.

7. Control of Purchased Material, Equipment, and Services

The SAR should define the applicant's proposed procedures for controlling purchased material, equipment, and services to ensure conformance with specified requirements.

8. Identification and Control of Materials, Parts, and Components

The SAR should define the applicant's proposed provisions for identifying and controlling materials, parts, and components to ensure that incorrect or defective SSCs are not used.

9. Control of Special Processes

The SAR should describe the controls that the applicant will establish to ensure the acceptability of special processes (such as welding, heat treatment, nondestructive testing, and chemical cleaning) and that they are performed by qualified personnel using qualified procedures and equipment.

10. Licensee Inspection

The SAR should define the applicant's proposed provisions for inspection of activities affecting quality to verify conformance with instructions, procedures, and drawings.

11. Test Control

The SAR should define the applicant's proposed provisions for tests to verify that SSCs conform to specified requirements and will perform satisfactorily in service. The applicant should specify test requirements in written procedures, including provisions for documenting and evaluating test results. In addition, the applicant should establish qualification programs for test personnel.

12. Control of Measuring and Test Equipment

The SAR should define the applicant's proposed provisions to ensure that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals.

13. Handling, Storage, and Shipping Control

The SAR should define the applicant's proposed provisions to control the handling, storage, shipping, cleaning, and preservation of SSCs in accordance with work and inspection instructions to prevent damage, loss, and deterioration.

14. Inspection, Test, and Operating Status

The SAR should define the applicant's proposed provisions to control the inspection, test, and operating status of SSCs to prevent inadvertent use or bypassing of inspections and tests.

15. Nonconforming Materials, Parts, or Components

The SAR should define the applicant's proposed provisions to control the use or disposition of nonconforming materials, parts, or components.

16. Corrective Action

The SAR should define the applicant's proposed provisions to ensure that conditions adverse to quality are promptly identified and corrected and that measures are taken to preclude recurrence.

17. Quality Assurance Records

The SAR should define the applicant's proposed provisions for identifying, retaining, retrieving, and maintaining records that document evidence of the control of quality for activities and SSCs important to safety.

18. Audits

The SAR should define the applicant's proposed provisions for planning, scheduling, and conducting audits to verify compliance with all aspects of the QA program, and to determine the effectiveness of the overall program. The SAR should clearly identify responsibilities and procedures for conducting audits, documenting and reviewing audit results, and designating management levels to review and assess audit results. In addition, the SAR should describe the applicant's provisions for incorporating the status of audit recommendations in management reports.

V. Review Procedures

Except in cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, NRC staff reviewers should use the following methods and procedures to evaluate conformance of the applicant's proposed QA program with the Commission's regulations.

Begin the QA program review by determining whether the application includes the information required by 10 CFR Part 72 with regard to the QA program, as well as the topics discussed in this chapter of the DCSS SRP. If deficiencies are identified in the application, request that the applicant submit additional information before proceeding further with the QA program review.

Next, review each element of the QA program description with respect to the acceptance criteria in Section IV, above. The primary objective of this review is to ensure that the applicant has provided sufficient information to support a reviewer's conclusion that the proposed QA program meets the stated acceptance criteria. Consequently, the review should rely exclusively on an assessment of the information presented.

Determine whether the applicant has adequately planned the work to be accomplished, and whether the necessary policies, procedures, and instructions either are in place or will be in place before work begins. This review should provide reasonable assurance that adequate coordination exists among the applicant's QA, configuration management, and maintenance programs, and that the QA program is an integral part of everyday work activities. In addition, this review should provide 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.

Look beyond the existence of appropriate elements, and assess the effectiveness of the applicant's QA program design. Determine whether the applicant's QA program addresses the full scope of the application. The QA program description should specify the QA criteria, the basis on which the criteria were selected, how the criteria are apportioned within the sections of the application, and the proposed implementation method for each.

Write the related sections of the safety evaluation report (SER) summarizing the conduct of the review. Identify the material in the application that forms the basis for the finding of reasonable assurance with respect to the acceptance criteria, and present any recommendations for modification of the application that might be necessary to allow a finding of reasonable assurance.

VI. Evaluation Findings

The staff's review should verify that the application provided sufficient information to facilitate a thorough and comprehensive evaluation of the applicant's QA program. This information should demonstrate that the applicant has conceived and implemented adequate program provisions to ensure the quality of management control over procedures, processes, and SSCs important to the health and safety of workers and the public and the protection of the environment. In addition, the information provided in the application should be consistent with the guidance in this SRP and the related regulatory requirements.

The review record should demonstrate that the staff has reviewed the applicant's QA program for the design, fabrication, construction, testing, and operation of the DCSS, according to the guidance in this chapter of the SRP. In addition, the record should state the staff's finding that the application provided sufficient information, and that the review is sufficiently complete to support the following conclusions (in either the SER or a letter to the applicant):

> On the basis of the staff's detailed review and evaluation of the QA program described in the [topical report or safety analysis report (SAR)] for the [DCSS name], the NRC staff has reached the following conclusions:
>
> 1. The structure of the organization and the assignment of responsibility for each activity ensure that designated responsible parties will perform the necessary work to achieve and maintain the specified quality requirements. Conformance to established requirements will be verified by individuals and groups not directly responsible for performing the work. The organizations responsible for verifying quality report through a management hierarchy that allows the required authority and organizational freedom, including sufficient independence from influences of cost and schedule.
>
> 2. The QA program is well-documented and provides adequate control over activities affecting quality, as well as structures, systems, and components (SSCs) that are important to safety, to the extent consistent with their relative importance to safety. The QA program describes a management system and controls that, when properly implemented, will comply with the requirements of Subpart G to 10 CFR Part 72 and 10 CFR Part 21[3].
>
> 3. Accordingly, the staff concludes that the applicant's QA program complies with the applicable NRC regulations and industry standards and can be implemented for the [specify the application].

In addition, the SER should provide a brief description of the applicant's QA program, with highlights of the more important aspects of the program.

VII. References

1.NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," February 1996.

2.*U.S. Code of Federal Regulations*, Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," Title 10, "Energy,"

3.*U.S. Code of Federal Regulations*, Part 21, "Reporting of Defects and Noncompliance" Title 10, "Energy,".