Report Evaluation

Project Number:	REA 2023 Topical Report Chapter 11
Originating Organization:	Ridihalgh, Eggers & Associates 2219 Summit Street Columbus, Ohio 43201
Report Title:	Quality Assurance Plan for Design and Construction of REA 2023 Dry Storage Casks for Spent Fuel
Report Date:	May 6, 1982
Reviewed by:	Quality Assurance Branch, NRR

SUMMARY OF REPORT

REA 2023 Topical Report Chapter 11 describes the qual ty assurance (QA) program which Ridihalgh, Eggers & Associates (REA) applies to the design, procurement, and fabrication activities involving components of dry storage casks for spent fuel from nuclear power plants. REA 2023 Topical Report Chapter 11 commits REA to comply with the requirements of Appendix B to 10 CFR Part 50.

REA has provided for our evaluation a detailed organizational description of those individuals and groups involved in carrying out activities required by the QA program and a delineation of duties, responsibilities, and authority of those organizational elements involved in the QA program. REA Topical Report Chapter 11 contains a description of the measures used to carry out the QA program activities and describes how applicable requirements of Appendix B will be satisfied by the administration and implementation of these measures.

SUMMARY OF REGULATORY EVALUATION

We have evaluated the QA program and the organizations responsible for QA functions as described in REA 2023 Topical Report Chapter 11. We find that QA policy and direction originate at an acceptably high management level and are effectivly communicated to other parts of the organization. Those performing QA functions have responsibility and authority commensurate with their duties in implementing the QA program. We also find that measures have been established, to be implemented by written procedures and instructions, which address each of the criteria of Appendix B to 10 CFR Part 50 in an acceptable manner.

Our review was based on the QA checklist provided in the Haass to Rouse memorandum, "QA Checklist for Dry Storage Casks," dated July 13, 1982.

Based on our review and evaluation of REA 2023 Topical Report Chapter 11, we conclude that:

1. The organizations and persons performing QA functions within REA and its principal contractors have the required independence and authority to effectively carry out the QA program without undue influence from those directly responsible for costs and schedules, and

2. The REA QA program contains requirements, procedures, and controls which, when properly implemented, comply with the requirements of Appendix B to 10 CFR Part 50.

REGULATORY POSITION

It is the staff's position that the REA 2023 Topical Report Chapter 11, "Quality Assurance Plan for Design and Construction of REA Dry Storage Casks for Spent Fuel," is acceptable for use in the design, procurement and fabrication of dry storage casks for spent fuel from nuclear power plants.

QA Checklist
for
Dry Storage Casks

The applicant must establish a QA program for design and fabrication in accordance with 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." This program must be described to the extent of demonstrating how each criterion of Appendix B will be met. The acceptance criteria used by the QAB in its evaluation of this program are listed in the following eighteen subsections. If the QA program meets these acceptance criteria, the program is considered acceptable.

I. The Organization elements responsible for the QA program are acceptable if:

1. The responsibility for the QA program is retained and exercised by the applicant.

2. The QA/QC functions, performed by the applicant's QA organization or delegated to other organizations, are identified and described, providing controls to assure all elements of Appendix B will be implemented.

3. Clear and effective lines of communication between the QA organizations of the applicant and his suppliers are established to assure proper direction of the QA program and resolution of QA problems.

4. Organization charts demonstrate adequate management control over quality.

5. A high level of management is responsible for establishing the corporate or company QA policies, goals, and objectives and this management level maintains a continuing involvement in QA matters. Communication through any intermediate levels of management between this position and the Manager (or Director) of QA must be shown to be effective.

6. The applicant designates a position, to be filled by a qualified individual, to retain overall authority and responsibility for the QA program.

7. The authority and independence of the individual responsible for managing the QA program are such that he can direct and control the organization's QA/QC program, can effectively assure the conformance to quality requirements, and is independent of undue influences and responsibilities for schedules and costs. An acceptable organizational structure would have this individual report to at least the same organizational level as the highest line manager directly responsible for performing activities affecting quality.

8. Positions or groups responsible for defining and controlling the content of the QA program and related manuals and the management level responsible for final review and approval have appropriate organizational position and authority.

9. The qualification requirements for the principal QA/QC management positions demonstrate competence commensurate with the responsibilities of these positions.

10. Verification of conformance to established requirements is accomplished by individuals or groups who do not have direct responsibility for performing the work being verified.

11. Persons and organizations performing QA/QC functions have direct access to management levels which will assure accomplishment of quality-affecting activities. These personnel have sufficient authority and organizational freedom to perform their QA/QC functions effectively and without reservation. They can:

    a. Identify quality problems.
    b. Initiate, recommend, or provide solutions through designated channels.
    c. Verify implementation of solutions.

12. Designated QA individuals have the responsibility and authority, delineated in writing, to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material.

II. The Quality Assurance Program description is acceptable if:

1. Measures are provided by the applicant that demonstrate how the QA program meets 10 CFR Part 50, Appendix B criteria.

2. Management regularly assess the effectiveness of the QA program.

3. Measures are provided by the applicant to assure that trained, qualified personnel within his organization are assigned to determine that functions delegated to his contractors are being properly accomplished.

4. A brief summary of the Company's corporate QA policies, goals, and objectives is given and a meaningful channel for transmittal of these policies, goals, and objectives down through the levels of management is established.

5. QA/QC responsibilities are designated for the implementation of the major activities contained in the QA manuals.

6. Provisions are established to control the distribution of the QA manuals and revisions thereto.

7. Provisions are established for communicating to all responsible organizations and individuals that quality policies, QA manuals, and procedures are mandatory requirements.

8. A listing of the QA procedures plus a matrix of these procedures cross referenced to each criterion of Appendix B to 10 CFR Part 50 demonstrate that Appendix B provisions are fully implemented by documented procedures.

9. The safety-related structures, systems, and components controlled by the QA program are identified.

10. The applicant reviews and documents agreement with the QA program provisions of his suppliers to the extent that he can be assured that Appendix B will be implemented.

11. Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA/QC personnel and other department (engineering, procurement, manufacturing, etc.) personnel.

12. An indoctrination and training program is established such that:

    a. Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

    b. Personnel performing quality-affecting activities are trained and qualified in the principles and techniques of the activity being performed.

    c. Proficiency of personnel performing quality-affecting activities is maintained by retraining, reexamining, and/or recertifying.

III. Activities related to Design Control are acceptable if:

1. Measures are established to carry out design activities in a planned, controlled, and orderly manner.

2. Measures are established to correctly translate the applicable regulatory requirements and design bases into specifications, drawings, written procedures, and instructions.

3. Quality standards are specified in the design documents, and deviations and changes from these quality standards are controlled.

4. Designs are reviewed to assure that (1) design characteristics can be controlled, inspected, and tested and (2) inspection and test criteria are identified.

5. Internal and external design interface controls are established. These controls include the review, approval, release, distribution, and revision of documents involving design interfaces with participating design organizations.

6. Proper selection and accomplishment of design verification or checking processes such as by design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, a qualification test of a prototype unit under adverse design conditions shall be used.

7. Individuals or groups responsible for design verification are other than the original designer and the designer's immediate supervisor.

8. Design and specification changes are subject to the same design controls and approvals that were applicable to the original design.

9. Errors and deficiencies in the design, including the design process, that could adversely affect safety-related structures, systems, and components are documented; and corrective action is taken to preclude repetition.

10. Materials, parts, and equipment which are standard, commercial (off the shelf) or which have been previously approved for a different application are reviewed for suitability prior to selection.

11. The positions or groups responsible for design reviews and other design verification activities and their authority and responsibility are identified and controlled by written procedures.

12. Measures are established for the selection of suitable materials, parts, equipment, and processes for safety-related structures, systems, and components which include the use of valid industry standards and specifications.

IV. Activities related to Procurement Document Control are acceptable if:

1. Procedures are established that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents.

2. A review and concurrence of the adequacy of quality requirements stated in procurement documents is performed by qualified personnel. This review should determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with QA program requirements.

3. The review and approval of procurement documents are documented prior to release and available for verification.

4. Procurement documents identify the applicable QA requirements which must be compiled with and described in the supplier's QA program. This QA program or portions thereof shall be reviewed and concurred with by the applicant.

5. Procurement documents contain or reference the regulatory requirements, the design basis, and other technical requirements.

6. Procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to the purchaser for review and approval.

7. Procurement documents identify those records to be retained, controlled, and maintained by the supplier, and those delivered to the purchaser prior to use or installation of the hardware.

8. Procurement documents contain the procuring agency's right of access to supplier's facilities and records for source inspection and audit.

9. Changes and revisions to procurement documents are subject to at least the same review and approval as the original document.

V. Activities related to Instructions, Procedures, and Drawings are acceptable if:

1. Activities affecting quality are prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

2. Provisions are established which clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, and drawings.

3. Methods for complying with each of the 18 criteria of 10 CFR Part 50, Appendix B are specified in instructions, procedures, and drawings.

4. Instructions, procedures, and drawings include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria to verify that important activities have been satisfactorily accomplished.

5. The QA organization reviews and concurs with inspection plans; test, calibration, and special process procedures; drawings and specifications; and changes thereto.

VI. Activities related to Document Control are acceptable if:

1. The review, approval, and issue of documents (such as listed in item 8 below) and changes thereto, prior to release, are procedurally controlled to assure they are adequate and the quality requirements are stated.

2. Provisions are established which identify those individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto.

3. Changes to documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified responsible organizations delegated by the applicant.

4. Approved changes are included in instructions, procedures, drawings, and other documents prior to implementation of the change.

5. Obsolete or superseded documents are controlled to prevent inadvertent use.

6. Documents are available at the location where the activity will be performed prior to commencing the work.

7. A master list or equivalent is established to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents. This list is updated and distributed to predetermined, responsible personnel to preclude use of superseded documents.

8. The documents that are controlled under this subsection are identified. As a minimum this should include:

   a. Design specifications.
   b. Design and fabrication drawings.
   c. Procurement documents.
   d. QA manuals.
   e. Design criteria documents.
   f. Fabrication, inspection, and testing instructions.
   g. Test procedures.

VII. Activities related to Control of Purchased Material, Equipment, and Services are acceptable if:

1. Qualified personnel evaluate the supplier's capability to provide acceptable quality services and products before the award of the procurement order or contract. The QA and engineering groups participate in the evaluation of those suppliers providing critical components.

2. The evaluation of suppliers is based on one or more of the following:

   a. The supplier's capability to comply with the elements of 10 CFR Part 50, Appendix B that are applicable to the type of material, equipment, or service being procured.

   b. A review of previous records and performance of suppliers who have provided similar articles of the type being procured.

c. A survey of the supplier's facilities and QA program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

d. IE confirming letter.

e. CASE - Nuclear survey.

f. ASME "N"-stamp survey.

3. The results of supplier evaluations are documented and filed.

4. Surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components is planned and performed in accordance with written procedures to assure conformance to the purchase order requirements. These procedures provide for:

   a. Instructions that specify the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these instructions.

   b. Audits and surveillance which assure that the supplier complies with the quality requirements. Surveillance is performed on those items where verification of procurement requirements cannot be determined upon receipt.

5. The supplier furnishes the following records as a minimum to the purchaser:

   a. Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items.

   b. Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair."

   The review and acceptance of these documents shall be described in the purchaser's QA program and as a minimum shall be undertaken by a responsible QA individual.

6. Supplier's certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid.

7. Receiving inspection of the supplier-furnished material, equipment, and services is performed to assure:

   a. The material, component, or equipment is properly identified and corresponds with the identification on receiving documentation.

b. Material, components, equipment , and acceptance records are inspected and judged acceptable in accordance with predetermined inspection instructions prior to installation or use.

c. Inspection records or certificates of conformance attesting to the acceptance of material, components, and equipment are available at the nuclear power plant prior to installation or use.

d. Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.

8. The effectiveness of the control of quality by suppliers is assessed by the applicant at intervals consistent with the importance, complexity, and quantity of the item.

VIII. Activities related to Identification and Control of Materials, Parts, and Components are acceptable if:

1. Procedures are established to identify and control materials, parts, and components including partially fabricated subassemblies.

2. Identification requirements are determined during generation of specifications and design drawings.

3. The identification and control procedures assure that identification is maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

4. Identification of materials and parts important to the function of safety-related structures, systems, and components can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

5. The location and the method of identification do not affect the fit, function, or quality of the item being identified.

6. Correct identification of material, parts, and components is verified and documented prior to release for fabrication, assembling, shipping, and installation.

IX. Activities related to Control of Special Processes (17.1.9) are acceptable if:

1. Special processes such as welding, heat treating, nondestructive testing, and cleaning are procedurally controlled.

2. Procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards, and specifications.

3. Special processes are performed by qualified personnel and accomplished in accordance with written process sheets or equivalent with recorded evidence of verification.

4. Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

X. Activities related to Inspection are acceptable if:

1. An inspection program which verifies conformance of quality-affecting activities with requirements is established, documented, and accomplished in accordance with written controlled procedures.

2. Inspection personnel are independent from the individuals performing the activity being inspected.

3. Inspection procedures, instructions, and check lists provide for the following:

   a. Identification of characteristics and activities to be inspected.
   b. Identification of the individuals or groups responsible for performing the inspection operation.
   c. Acceptance and rejection criteria.
   d. A description of the method of inspection.
   e. Recording evidence of completing and verifying a manufacturing, inspection, or test operation.
   f. Recording inspector or data recorder and the results of the inspection operation.

4. Inspection procedures or instructions are used with necessary drawings and specifications when performing inspection operations.

5. Inspectors are qualified in accordance with applicable codes, standards, and company training programs; and their qualifications and certifications are kept current.

6. Modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternative.

7. Provisions are established that identify mandatory inspection hold points for witness by an inspector.

8. The individuals or groups who perform receiving and process verification inspections are identified and shown to have sufficient independence and qualifications.

9. Provisions are established for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is not possible.

XI. Activities related to Test Control are acceptable if:

1. A test program to demonstrate that the item will perform satisfactorily in service is established, documented, and accomplished in accordance with written controlled procedures.

2. Written test procedures incorporate or reference:

   a. The requirements and acceptance limits contained in applicable design and procurement documents.

   b. Instructions for performing the test.

   c. Test prerequisites.

   d. Mandatory inspection hold points.

   e. Acceptance and rejection criteria.

   f. Methods of documenting or recording test data and results.

3. Test results are documented, evaluated, and their acceptablility determined by a qualified, responsible individual or group.

XII. Activities related to Control of Measuring and Test Equipment are acceptable if:

1. Provisions, contained in procedures, describe the calibration technique and frequency, maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) which is used in the measurements, inspection, and monitoring of safety-related components, systems, and structures.

2. Measuring and test equipment is identified and traceable to the calibration test data.

3. Measuring and test equipment is labeled or tagged to indicate date of the next calibration.

4. Measuring and test instruments are calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

5. Measures are taken and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

6. Calibrating standards have an uncertainty (error) requirement of of no more than 1/4th of the tolerance of the equipment being calibrated. A greater uncertainty may be acceptable when limited by the "state-of-the-art."

7. The complete status of all items under the calibration system is recorded and maintained.

8. Reference and transfer standards are traceable to nationally recognized standards, or, where national standards do not exist, provisions are established to document the basis for calibration.

XIII. Activities related to Handling, Storage, and Shipping are acceptable if:

1. Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by qualified individuals in accordance with predetermined work and inspection instructions.

2. Procedures are prepared which control the cleaning, handling, storage, packaging, shipping, and preservation of materials, components, and systems in accordance with design and specification requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

XIV. Activities related to Inspection, Test, and Operating Status are acceptable if:

1. Identification of the inspection and test status of structures, systems, and components is known throughout fabrication.

2. The application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps are procedurally controlled.

3. Bypassing of required inspections, tests, and other critical operations is procedurally controlled under the cognizance of the QA organization.

4. The status of nonconforming, inoperative, or malfunctioning structures, systems, or components is identified to prevent inadvertent use.

XV. Activities related to Nonconforming Materials, Parts, or Components are acceptable if:

1. The identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components, or services are procedurally controlled.

2. Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition.

3. Provisions are established identifying those individuals or groups delegated the responsibility and authority for the disposition and approval of nonconforming items.

4. Nonconforming items are segregated from acceptable items and identified as discrepant until properly dispositioned.

5. Acceptablity of rework or repair of materials, parts, components, systems, and structures is verified by reinspecting and retesting the item as originally inspected and tested or by a method which is at least equal to the original inspection and testing method. Inspection, testing, rework, and repair procedures are documented.

6. Nonconformance reports dispositioned "accept as is" or "repair" are made part of the inspection records and forwarded with the hardware to the utility for review and assessment.

7. Nonconformance reports are periodically analyzed to show quality trends, and the results are reported to management for review and assessment.

XVI. Activities related to Corrective Action are acceptable if:

1. Evaluation of conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material and equipment) is conducted to determine the need for corrective action in accordance with established procedures.

2. Correction action is initiated following the determination of a condition adverse to quality to preclude recurrence.

3. Follow-up reviews are conducted to verify proper implementation of corrective actions and to close out the corrective action documentation.

4. Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken are reported to cognizant levels of management for review and assessment.

XVII. Activities related to Quality Assurance Records are acceptable if:

1. Sufficient records are maintained to provide documentary evidence of the quality of items and the activities affecting quality.

2. QA records include operating logs; results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment, and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective action reports.

3. Records are identified and retrievable.

4. Requirements and responsibilites for record transmittals, retention (such as duration, location, fire protection, and assigned responsibilities), and maintenance subsequent to completion of work are consistent with applicable codes, standards, and procurement documents.

5. Inspection and test records contain the following where applicable:

   a. A description of the type of observation.

   b. The date and results of the inspection or test.

   c. Information related to conditions adverse to quality.

   d. Inspector or data recorder identification.

   e. Evidence as to the acceptability of the results.

6. Record storage facilities are constructed, located, and secured to prevent destruction of the records by fire, flooding, theft, and deterioration by environmental conditions such as temperature or humidity.

XVIII. Activities related to Audits are acceptable if:

1. Audits are performed in accordance with preestablished written procedures or check lists and conducted by trained personnel not having direct responsibilities in the areas being audited.

2. Audit results are documented and then reviewed with management having responsibility in the area audited.

3. Responsible management takes the necessary action to correct the deficiencies revealed by the audit.

4. Audits are performed by the QA organization to:

   a. Provide a comprehensive independent verification and evaluation of quality-related procedures and activities.

   b. Verify and evaluate suppliers' QA programs, procedures, and activities.

5. Audits are regularly scheduled on the basis of the status and safety importance of the activities being performed and are initiated early enough to assure effective quality assurance during the design, procurement, and contracting activities.

6. Audit data are analyzed and the reports, which indicate quality trends and the effectiveness of the QA program, are reported to management for review and assessment.