Rockwell International
Atomics International Division

SUPPORTING DOCUMENT

NUMBER	REV LTR/CHG NO.
N001PP000002	SEE SUMMARY OF CHG

DOCUMENT TYPE: QA Program Plan

KEY NOUNS: QA, Packaging, Licensed Radioactive Material

ORIGINAL ISSUE DATE:

PROGRAM TITLE: QA Program for Packaging Licensed Radioactive Material for Shipment

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GO NO.	S/A NO.	PAGE 1 OF TOTAL PAGES	REV DATE
A11	A11	24	3-7-80

PREPARED BY/DATE	DEPT	MAIL ADDR
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IR&D PROGRAM? YES ☐ NO ☒ IF YES, ENTER TPA NO. _____

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SECURITY CLASSIFICATION

(CHECK ONE BOX ONLY)	DOE	DOD
UNCL	☐	☐
CONF.	☐	☐
SECRET	☐	☐

(CHECK ONE BOX ONLY)	
RESTRICTED DATA	☐
DEFENSE INFO.	☐

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754-B.20/sjd

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NO ASTERISK, TITLE PAGE/SUMMARY OF CHANGE PAGE ONLY

ABSTRACT

10 CFR 71.51 requires each NRC licensee to establish and maintain a QA program for the design, fabrication, assembly, testing, use, and maintenance of packaging for licensed radioactive material for shipment. This document describes the requirements which apply to all activities affecting the components of the packaging which are significant to safety, including designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying.

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1.0 INTRODUCTION

Effective October 18, 1977, the Nuclear Regulatory Commission (NRC) amended its regulations for packaging and transport of radioactive material. These amendments, published as changes to CFR Part 71, upgrade requirements for quality assurance in the design, fabrication, assembly, testing, use, and maintenance of packagings for shipping and transporting licensed radioactive material. In general, the upgrading consists of applying the 18 criteria of 10 CFR 50 Appendix B to the packaging of radioactive material; the criteria are published as 10 CFR 71 Appendix E.

2.0 SCOPE

This QA program applies to all organizations and personnel who perform activities affecting the safety-related functions associated with designing, fabricating, maintaining, and using packages for licensed radioactive material. It does not apply to packages used only for onsite shipments (i.e., where the vehicle never leaves ESG or government-owned land), to license-exempt activities (e.g., where ESG has a GOCO (Government owned-contractor operated) contract with Department of Energy (DOE), or to shipments in government-owned, government-escorted vehicles.

3.0 APPLICATION

In determining how to apply the requirements of this program to a particular activity, responsible management shall consider:

1) The importance of malfunction or failure of the item to safety;
2) The design or fabrication complexity or uniqueness of the item;
3) The need for special controls or surveillance over processes and equipment;
4) The degree to which functional compliance can be demonstrated by inspection or test; and
5) The quality history and degree of standardization of the item.

Any change to design documents that changes conditions specified in the NRC approval of a package or container must also be approved by NRC.

When ESG purchases materials or services, measures to assure adequate quality shall be included in the procurement documents. Subtier contractors shall be required to provide quality assurance programs to the extent necessary to assure adequate quality. The degree to which QA requirements are passed down to subtier suppliers shall specifically be considered by Engineering and QA personnel during P.O. initiation and review.

This program is implemented at ESG by the instructions and procedures listed in N001QFP810001.

4.0 QUALITY ASSURANCE PROGRAM

The subsections below describe ESG's Quality Assurance program for packaging licensed radioactive materials for shipment. The subsections are numbered as in N001QFP810001, which describes the ESG procedures that implement this program.

4.1 ORGANIZATION

4.1.1 The responsibility for the QA program is retained and exercised by Energy Systems Group (ESG) of Rockwell International.

4.1.2 The QA/QC functions, performed by ESG or delegated to other organizations, are identified and described, providing controls to assure all elements of Appendix E will be implemented.

4.1.3 Clear and effective lines of communication between the QA organization and principal contractors are established to assure proper direction of the QA program and resolution of QA problems.

4.1.4 Organization charts identify the organizational elements which function under the control of the QA program (such as Design Engineering, Procurement, Manufacturing, Construction, Inspecting (QC), Testing, and QA) and demonstrate adequate control over quality aspects within and between organizations.

4.1.5 The interface relationships and QA responsibilities of each organizational element identified in Item 4.1.4 above are described and demonstrate assignment of responsibilities for requirements of Appendix E.

4.1.6 ESG's President is responsible for establishing the corporate or company QA policies, goals, and objectives and maintains a continuing involvement in QA matters. The Director of QA reports directly to the President.

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

4.1.8 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.

4.1.9 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.

4.1.10 The person responsible for directing and managing the QA program at the construction site has appropriate organizational position, responsibilities, and authority to exercise proper control over these functions. This individual is free of non-QA duties and can thus give full attention to assuring that the QA program at the plant site is being effectively implemented.

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

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

4.1.13 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:

1) Identify quality problems
2) Initiate, recommend, or provide solutions through designated channels
3) Verify implementation of solutions.

4.1.14 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.

4.2 QUALITY ASSURANCE PROGRAM

4.2.1 Measures are provided by ESG and principal contractors, as appropriate, that demonstrate how their QA program meets 10 CFR Part 71, Appendix E criteria.

4.2.2 Management regularly assesses the scope, status, implementation, and effectiveness of the QA program to assure that the program is adequate and complies with 10 CFR Part 71, Appendix E criteria.

4.2.3 Measures are provided by ESG to assure that trained, qualified personnel within his organization are assigned to determine that functions delegated to his principal contractors are being properly accomplished.

4.2.4 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.

4.2.5 The QA program procedures are derived from QA policies, goals, and objectives.

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

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

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

4.2.9 A listing of the QA procedures plus a matrix of these procedures cross referenced to each criterion of Appendix E to 10 CFR Part 71 demonstrates that Appendix E provisions are fully implemented by documented procedures.

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

4.2.11 ESG reviews and documents agreement with the QA program provisions of his principal contractors to the extent that he can be assured that Appendix E will be implemented.

4.2.12 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.

4.2.13 An indoctrination and training program is established such that:

1) Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.
2) Personnel performing quality-affecting activities are trained and qualified in the principles and techniques of the activity being performed.
3) The scope, the objective, and the method of implementing the indoctrination and training program are documented.
4) Proficiency of personnel performing quality-affecting activities is maintained by retraining, reexamining, and/or recertifying.

4.2.14 (Deleted. Discussion of the PSAR is not applicable to ESG's activities under 10 CFR 71.)

4.2.15 Quality-related activities are performed with specified equipment and under suitable environmental conditions, and prerequisites have been satisfied prior to inspection and test.

4.2.16 ESG and his principal contractors, as appropriate, demonstrate that their QA programs comply with 10 CFR 71 Appendix E or describe acceptable alternatives in equivalent detail.

4.2.17 (Deleted. Applicable only to reactor plants.)

4.2.18 (Deleted. Discussion of the PSAR is not applicable to ESG's activities under 10 CFR 71.)

4.2.19 Provisions are provided for keeping the QA program current.

4.2.20 (Deleted. Discussion of Reg. Guide 1.28 is not applicable to ESG's activities under 10 CFR 71.)

4.3 DESIGN CONTROL

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

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

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

4.3.4 Suitable design controls are applied to such activities as reactor physics; seismic, stress, thermal, hydraulic, radiation, and accident analyses; compatibility of materials; and accessibility for inservice inspection, maintenance, and repair.

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

4.3.6 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.

4.3.7 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.

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

4.3.9 Design and specification changes, including field changes, are subject to the same design controls and approvals that were applicable to the original design unless ESG designates another qualified responsible organization.

4.3.10 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.

4.3.11 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.

4.3.12 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.

4.3.13 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.

4.3.14 (Deleted. Discussion of Reg. Guide 1.64 is not applicable to ESG's activities under 10 CFR 71.)

4.4 PROCUREMENT DOCUMENT CONTROL

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

4.4.2 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.

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

4.4.4 Procurement documents identify the applicable 10 CFR Part 71, Appendix E requirements which must be complied with and described in the supplier's QA program. This QA program or portions thereof shall be reviewed and concurred with by qualified personnel in QA prior to initiation of activities affected by the program.

4.4.5 Procurement documents contain or reference the design basis technical requirements including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions.

4.4.6 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.

4.4.7 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.

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

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

4.4.10 Procurement documents for spare or replacement parts of safety-related structures, systems, and components are subject to controls at least equivalent to those used for the original equipment.

4.4.11 (Deleted. Discussion of procurement of nuclear power plant items is not applicable to ESG's activities under 10 CFR 71.)

4.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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

4.5.2 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.

4.5.3 Methods for complying with each of the 18 criteria of 10 CFR Part 71, Appendix E are specified in instructions, procedures, and drawings.

4.5.4 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.

4.5.5 The QA organization reviews and concurs with inspection plans; test, calibration, and special process procedures; drawings and specifications; and changes thereto or acceptable alternatives are described.

4.6 DOCUMENT CONTROL

4.6.1 The review, approval, and issue of documents (such as listed in Item 4.6.8 below) and changes thereto, prior to release, are procedurally controlled to assure they are adequate and the quality requirements are stated.

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

4.6.3 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 ESG.

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

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

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

4.6.7 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.

4.6.8 The documents that are controlled under this subsection are identified, including:

1) Design specifications.
2) Design, manufacturing, construction, and installation drawings.
3) Procurement documents.

4) QA manuals.
5) (Deleted. PSAR's are NA.)
6) Manufacturing, inspection, and testing instructions.
7) Test procedures.
8) Design change requests
9) Nonconformance reports.

4.7 CONTROL OF PURCHASED MATERIALS, EQUIPMENT, AND SERVICES

4.7.1 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.

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

1) The supplier's capability to comply with the elements of 10 CFR Part 71, Appendix E or 10 CFR 50, Appendix B, that are applicable to the type of material, equipment, or service being procured.
2) A review of previous records and performance of suppliers who have provided similar articles of the type being procured.
3) 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.

4.7.3 The results of supplier evaluations are documented and filed.

4.7.4 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:

1) 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.
2) 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.

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

1) Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items.
2) 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.

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

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

1) The material, component, or equipment is properly identified and corresponds with the identification on receiving documentation.
2) Material, components, equipments, and acceptance records are inspected and judged acceptable in accordance with predetermined inspection instructions, prior to installation or use.

3) Inspection records or certificates of conformance attesting to the acceptance of material, components, and equipment are available prior to installation or use.
4) 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.

4.7.8 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.

4.7.9 Spare or replacement parts of safety-related structures, systems, and components are subject to controls at least equivalent to those used for the original equipment.

4.7.10 (Deleted. Discussion of procurements for nuclear power plants does not apply to ESG's activities under 10 CFR 71.)

4.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

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

4.8.2 Identification requiremnts are determined during generation of specifications and design drawings.

4.8.3 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.

4.8.4 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.

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

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

4.9 CONTROL OF SPECIAL PROCESSES

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

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

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

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

4.9.5 (Deleted. NA to ESG's activities under 10 CFR 71.)

4.10 INSPECTION

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

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

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

1) Identification of characteristics and activities to be inspected.
2) Identification of the individuals or groups responsible for performing the inspection operation.
3) Acceptance and rejection criteria.
4) A description of the method of inspection.
5) Recording evidence of completing and verifying a manufacturing, inspection, or test operation.
6) Recording inspector or data recorder and the results of the inspection operation.

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

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

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

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

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

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

4.10.10 (Deleted, NA to ESG's activities under 10 CFR 71.)

4.11 TEST CONTROL

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

4.11.2 Modifications, repairs, and replacements are tested in accordance with the original design and testing requirements or acceptable alternatives.

4.11.3 Written test procedures incorporate or reference:

1) The requirements and acceptance limits contained in applicable design and procurement documents.
2) Instructions for performing the test.
3) Test prerequisites such as:
   a) Calibrated instrumentation
   b) Adequate and appropriate equipment
   c) Trained, qualified, and licensed or certified personnel
   d) Completeness of item to be tested
   e) Suitable and controlled environmental conditions
   f) Provisions for data collection and storage.
4) Mandatory inspection hold points for witness by owner, contractor, or inspector.
5) Acceptance and rejection criteria.
6) Methods of documenting or recording test data and results.

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

4.11.5 (Deleted. NA to ESG's activities under 10 CFR 71.)

4.12 CONTROL OF MEASURING AND TEST EQUIPMENT

4.12.1 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 measurement, inspection, and monitoring of safety-related components, systems, and structures.

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

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

4.12.4 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.

4.12.5 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.

4.12.6 Calibrating standards have an uncertainty (error) requirement 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."

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

4.12.8 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.

4.13 HANDLING, STORAGE, AND SHIPPING

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

4.13.2 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.

4.13.3 (Deleted. NA to ESG's activities under 10 CFR 71.)

4.14 INSPECTION, TEST, AND OPERATING STATUS

4.14.1 Identification of the inspection, test, and operating status of structures, systems, and components is known throughout manufacturing and installation.

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

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

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

4.15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

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

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

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

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

4.15.5 Acceptability 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.

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

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

4.16 CORRECTIVE ACTION

4.16.1 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.

4.16.2 Corrective action is initiated following the determination of a condition adverse to quality to preclude recurrence.

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

4.16.4 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.

4.17 QUALITY ASSURANCE RECORDS

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

4.17.2 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.

4.17.3 Records are identifiable and retrievable.

4.17.4 Requirements and responsibilities 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.

4.17.5 Inspection and test records contain the following where applicable:

1) A description of the type of observation.
2) Evidence of completing and verifying a manufacturing, inspection, or test operation.
3) The date and results of the inspection or test.
4) Information related to conditions adverse to quality.
5) Inspector or data recorder identification.
6) Evidence as to the acceptability of the results.

4.17.6 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.

4.17.7 (Deleted. NA to ESG's activities under 10 CFR 71.)

4.18 AUDITS

4.18.1 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.

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

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

4.18.4 Deficient areas are reaudited on a timely basis to verify implementation of corrective actions which minimize recurrence of deficiencies.

4.18.5 Audits include an objective evaluation of quality-related practices, procedures, and instructions and the effectiveness of implementation.

4.18.6 Audits include the objective evaluation of work areas, activities, processes, and items, and the review of documents and records.

4.18.7 Audits to assure that procedures and activities are meaningful and comply with the overall QA program are performed by:

1) The QA organization, to provide a comprehensive independent verification and evaluation of quality-related procedures and activities.
2) ESG and, as appropriate, principal subcontractors, to verify and evaluate their suppliers' QA programs, procedures, and activities.

4.18.8 Provisions are established requiring that audits be performed in those areas where the requirements of Appendix E to 10 CFR Part 71 are being implemented. Areas which are often neglected include those activities associated with:

1) (Deleted. NA to ESG's activities under 10 CFR 71.)
2) The preparation, review, approval, and control of early procurements.
3) Indoctrination and training programs.
4) Interface control among ESG and principal subcontractors.

4.18.9 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.

4.18.10 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.

4.18.11 The requirements and guidelines of ANSI N45.2.12 are complied with or acceptable alternatives are provided.

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