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 x Hedges

MEMORANDUM FOR: John J. Linehan, Acting Chief  
 Repository Projects Branch  
 Division of Waste Management  
 Office of Nuclear Material Safety and Safeguards

FROM: G. Ted Ankrum, Chief  
 Quality Assurance Branch  
 Division of Quality Assurance, Vendor,  
 and Technical Training Center Programs  
 Office of Inspection and Enforcement

SUBJECT: SCHEDULE FOR REVIEW OF DOE DOCUMENTS

Your memorandum dated August 5, 1986 asked that the QA Branch review and comment on the DOE documents enclosed with the memorandum. Per your request, we are providing a schedule for this work. Based on a discussion between your Dale Hedges and my Jack Spraul, we plan to complete our review of the NNWSI documents before starting on the July 30 documents. Our proposed schedule is as follows:

Document Number, Rev, Subject	Review Period	Comments to NMSS
NNWSI-SOP-02-01, Rev. 1, QAPP Requirements	7/30 - 8/6	8/20
NNWSI-SOP-02-02, Rev. 1, QA Levels	8/6 - 8/11	8/25
NNWSI-SOP-03-03, Rev. 0, Data	8/12 - 8/15	8/29
NNWSI-SOP-15-01, Rev. 1, Nonconformances	8/18 - 8/19	9/2
OGR/B-3 Rev. 1, OGR QA Plan	8/20 - 8/25	9/8
Sup. 1, Rev. 0, Personnel	8/26 - 8/29	9/12
Sup. 2, Rev. 0, Overview	8/26 - 8/29	9/12
Sup. 3, Rev. 0, Q-List	8/26 - 8/29	9/12
Sup. 4, Rev. 0, Records	8/26 - 8/29	9/12
Sup. 5, Rev. 0, E & R Documents	8/26 - 8/29	9/12
Sup. 6, Rev. 0, Problem Reporting	8/26 - 8/29	9/12
Sup. 7, Rev. 0, Peer Review	8/26 - 8/29	9/12
Sup. 8, Rev. 0, Graded QA	8/26 - 8/29	9/12
SUP. 9, Rev. 0, Data Reliability	8/26 - 8/29	9/12
Sup. 11, Draft 7/86, Defense Wastes	8/26 - 8/29	9/12
-, Rev. 1, BWIP QA Plan	9/1 - 9/5	9/19
-, Rev. 0, SRPO QA Plan	9/8 - 9/12	9/26
BQARD, Rev. 0, BWIP QA Requirements	9/15 - 9/19	9/3

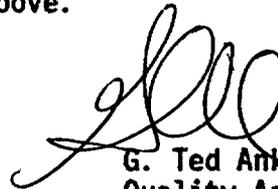
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John J. Linehan

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If this schedule is incompatible with your needs, please let me know. Note that the QA Branch is in the process of revising the review plan for QA programs for the high level waste repository program to incorporate the gist of recent changes to the review plan for QA program for ISFSIs (note the changes highlighted on the enclosed review plan). These revisions are being incorporated into our review of the documents listed above.



G. Ted Ankrum, Chief  
Quality Assurance Branch  
Division of Quality Assurance, Vendor,  
and Technical Training Center Programs  
Office of Inspection and Enforcement

Enclosure: SRP for ISFSIs

U.S. NUCLEAR REGULATORY COMMISSION  
Standard Review Plan for Quality Assurance Programs for an  
Independent Spent Fuel Storage Installation (ISFSI)  
10 CFR 72

**1.0 Introduction and Background**

As used in 10 CFR 72, quality assurance (QA) comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. QA includes quality control, which comprises those QA actions related to the physical characteristics of the item to predetermined quality requirements. A description of the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components important to safety of an ISFSI is required by 10 CFR 72. 10 CFR 72 also requires that this description identify structures, systems, and components important to safety and shows how the QA criteria will be applied to those components, systems, and structures in a manner consistent with their importance to safety.

The 10 CFR 72 definition of structures, systems, and components important to safety is significant to the entire formulation of the QA program and is reiterated here:

"Structures, systems, and components important to safety" means those features of the ISFSI whose function is: (1) To maintain the conditions required to store spent fuel safely, (2) to prevent damage to the spent fuel during handling and storage, or (3) to provide reasonable assurance that spent fuel can be received, handled, stored and retrieved without undue risk to the health and safety of the public.

It is essential that the applicant provide sufficient detail in its description of the planned QA program to enable the NRC to perform an adequate review of the QA program, since the acceptance by the NRC of the description of the QA program is a condition for the issuance of the license.

**General Guidance**

The NRC considers the QA program to be a comprehensive closed-loop management control system. It is a management tool; a preventive program necessitating prior planning. Implementation of a QA program is not a panacea for management. The attainment of quality remains everyone's job and NRC studies have concluded that nothing replaces properly motivated, adequately trained, experienced employees in the attainment of quality. Management should ensure that line management retains its responsibility for the achievement of quality and that the QA organization provides for the assurance of that quality. An effective QA program should be oriented towards performance objectives and should attempt to exceed the 10 CFR 72 QA requirements which are minimum criteria for an effective management control system.

The applicant's management must realize that NRC's approval of the submitted QA program description does not relieve management of its responsibility for the

effective implementation of the QA program and that management must recognize the limited role of the NRC in identifying quality-related problems and ineffectively functioning QA programs.

### NRC Acceptance Criteria

The acceptance positions used by the NRC to evaluate an applicant's QA program that is to be described in the ISFSI safety analysis report are listed in the following subsections. These positions represent solutions and approaches that are acceptable to the NRC staff, but which may not be the only possible solutions and approaches. Various alternatives to the detailed guidance in this SRP may be found acceptable provided that the applicant documents and justifies these deviations.

#### A. General

A.1 The applicant's QA program description in the SAR must describe a QA program that will be established, maintained, and executed for the design, fabrication, construction, testing, and use of the structures, systems, and components of the ISFSI that are important to safety, including information pertaining to the managerial and administrative controls to assure safe operation of the ISFSI. The QA program description must identify the structures, systems, and components of the ISFSI which are important to safety.

A.2 For the applicant who has an NRC-approved 10 CFR 50 Appendix B QA program, the applicant may simply provide a commitment to apply the pertinent provisions of its Appendix B QA program to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of ISFSI items which are important to safety. Such applicants must also identify the structures, systems, and components of the ISFSI which are important to safety.

#### B. Acceptance Criteria

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. The assignment responsibility for the overall QA program in no degree relieves line management of their responsibility for the achievement of quality.
2. The QA functions, performed by the applicant's QA organization or delegated to other organizations, are identified and described, providing controls to assure the applicable elements of the QA criteria will be implemented.
3. Clear management controls and 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 identify:
  - a. "onsite" and "offsite" organizational elements which function under the cognizance of the QA program.

b. lines of responsibility.

5. A high level of management is responsible for documenting and promulgating the corporate or company QA policies, goals, and objectives and this management level maintains a continuing involvement in QA matters. Communication lines between any intermediate levels of management and between this position and the Manager (or Director) of QA must be described.
6. The applicant designates a position that retains 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 program, can effectively assure the conformance to quality requirements, and is sufficiently 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 management positions demonstrate management and technical 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. The quality control function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity.
11. Persons and organizations performing QA functions have direct access to management levels which will assure accomplishment of quality-affecting activities. These personnel shall have sufficient authority and organizational freedom to perform their QA 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 or organizations have the responsibility and authority, delineated in writing, to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material. The QA organization need not have authority to stop work

if the individual to whom the person responsible for managing the QA program reports has this authority. A description of how stop-work requests are initiated and completed is provided. Records of requests are retained until the ISFSI license is issued.

13. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, item complexity, and its importance to safety.

II. The Quality Assurance Program description is acceptable if:

1. Measures are provided by the applicant that describe how the QA program meets the QA criteria.
2. Management commits to regularly assess the effectiveness of the QA program. A description is provided for how management (above and outside the QA organization) will regularly assess the scope, status, adequacy, and compliance of the QA program to 10 CFR 72. These measures should include:
  - a. Frequent contact with program status through reports, meetings, and/or audits.
  - b. Performance of a periodic assessment which is preplanned and documented with corrective action identified and tracked.
3. Measures are provided by the applicant to assure that trained, qualified personnel within its 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 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 of the QA criteria demonstrates that provisions will be fully implemented by documented procedures.
9. The important to safety 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 a program meeting the QA criteria 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. Indoctrination, training, and qualification programs are established such that:
  - a. Personnel responsible for performing activities affecting quality are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.
  - b. Personnel performing activities affecting quality 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.
  - d. Specific documentation of completed training and qualification should be described in general terms.
  - e. Qualified personnel are certified in accordance with applicable codes and standards.

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:
  - a. Design characteristics can be controlled, inspected, and tested.
  - b. 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 processes such as by design reviews, alternate calculations, or qualification testing are performed. When a test program is to be 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 normally other than the designer's immediate supervisor. Design verification is confirmation that the design of the structure, system, or component is suitable for its intended purpose. Design checking, which must also be performed, includes such things as confirmation of the numerical accuracy of computations and the accuracy of data input to computer codes. Confirmation that the correct computer code has been used is part of design verification. Design verification requires a level of skill at least equal to that of the original designer, while design checking can be performed by less experienced persons. Design verification should be performed by persons other than those performing design checking.
  8. Design and specification changes are subject to the same design controls and the same or equivalent approvals that were applicable to the original design.
  9. Errors and deficiencies in the design, including the design process, that could adversely affect structures, systems, and components important to safety are documented; and corrective action, including root cause evaluation of significant errors and deficiencies, 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 that include the use of valid industry standards and specifications are established for the selection of suitable materials, parts, equipment, and processes for structures, systems, and components important to safety.
- 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 bases, 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 to be 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 the same or equivalent review and approval as the original documents.

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 applicable QA criteria 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 activities important to safety have been satisfactorily accomplished.
5. The QA organization, as part of a multi-functional review, 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 the documents 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 items and services important to safety and the responsibilities for each group's participation are provided.
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 the QA criteria 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 the capability to supply a product that 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 the purchasing and 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 of important to safety structures, systems, and components are traceable 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 are acceptable if:

1. Special processes such as welding, heat treating, nondestructive testing, and cleaning are procedurally controlled. A complete as possible listing of special processes, which are generally those processes where direct inspection is impossible or disadvantages, is provided.
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 sufficiently independent from the individuals performing the activity being inspected (see item B.I.10).
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. 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 alternatives.
7. Provisions are established that identify mandatory inspection hold points for witness by a designated 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 results.

3. Test results are documented, evaluated, and their acceptability determined by a qualified, responsible individual or group. When practicable, testing must test the structure, system, or component under conditions which will be present during normal and anticipated off-normal operations.

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 important to safety structures, systems, and components.
2. Measuring and test equipment is identified and traceable to the calibration test data.
3. Measuring and test equipment is labeled or tagged or otherwise documented to indicate the due date of the next calibration and to provide traceability to calibration test data.
4. Measuring and test instruments are calibrated at specified intervals based on the required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions which could affect the measurement.
5. Measures are taken and documented to determining 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 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 documented 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 operating 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 documented, and the item is identified to prevent inadvertent use. The organization responsible for this function is identified.

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

1. The identification, documentation, tracking, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components, services, or activities 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 the close out of nonconformances.
4. Nonconforming items are segregated from acceptable items and identified as discrepant until properly dispositioned and closed out.

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.
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 to help identify root causes of nonconformances. Significant results are reported to responsible management for review and assessment.

XVI. Activities related to Corrective Action are acceptable if:

1. Conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material and equipment) are evaluated in accordance with established procedures to determine the need for corrective action.
2. Correction action is initiated following the determination of a condition adverse to quality to preclude recurrence.
3. Follow-up actions are conducted to verify proper implementation of corrective actions and to close out the corrective action documentation in a timely manner.
4. Significant conditions adverse to quality, the root cause of the conditions, and the corrective action taken to remedy the immediate adverse conditions and to preclude repetition of the adverse conditions are documented and reported to cognizant levels of management for review and assessment.

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

1. The scope of the records program is defined such that sufficient records are maintained to provide documentary evidence of the quality of items and the activities affecting quality. To aid in minimizing the retention of unnecessary records, the records program should list records to be retained by "type of data" rather than by record title.
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; design review and peer review reports; nonconformance reports; and corrective action reports.
3. Records are identified and retrievable.
4. Requirements and responsibilities for record creation, transmittal, 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.
  - f. Action taken to resolve any discrepancies noted.
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. The facilities are to be maintained by or under the control of the licensee throughout the life of the ISFSI or the individual product.

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 for the achievement of quality in the areas being audited.
2. Audit results are documented and then reviewed with management having responsibility in the area audited.
3. Provisions exist such that appropriate follow-up corrective action to audit reports is undertaken by responsible management. Auditing organizations schedule and conduct appropriate follow-up to assure that the corrective action is effectively accomplished.
4. Both technical and QA programmatic audits are performed to:
  - a. Provide a comprehensive independent verification and evaluation of procedures and activities affecting quality.
  - b. Verify and evaluate suppliers' QA programs, procedures, and activities.
5. Audits are led by appropriately qualified and certified audit personnel from the QA organization. The audit team membership includes personnel (not necessarily QA organization personnel) having technical expertise in the areas being audited.
6. Audits are regularly scheduled on the basis of the status and the importance to safety of the activities being performed and are

initiated early enough to assure effective QA during the design, procurement, and contracting activities.

7. Audit deficiency data are analyzed and trended. Resultant reports, which indicate quality trends and the effectiveness of the QA programs, are given to management for review, assessment, corrective action, and follow-up.
8. Audits objectively assess the effectiveness and proper implementation of the QA program and address the technical adequacy of the activities being conducted.
9. Provisions are provided such that audits are required to be performed in all areas where the requirements of the QA program are applicable.

END