APPENDIX A
SAMPLE CHECKLIST FOR EVALUATING QUALITY ASSURANCE PROGRAM ELEMENTS FOR DRY CASK STORAGE SYSTEMS

Within the context of "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," Subpart G of 10 CFR Part 72 specifies 18 criteria that must be addressed in a quality assurance (QA) program. To be found acceptable, the applicant's proposed QA program should include provisions for meeting each of the following acceptance criteria:

1. Quality Assurance Organization

The SAR should describe the structure, interrelationships, and areas of functional responsibility and authority for all organizational elements that will perform activities related to quality and safety. Acceptability of these organizational elements is contingent upon the following criteria:

a. The applicant should retain and exercise responsibility for the QA program. The assignment of responsibility for the overall QA program in no degree relieves line management of their responsibility for the achievement of quality.

b. The application should identify and describe the QA functions, performed by the applicant's QA organization or delegated to other organizations, that will provide controls to ensure implementation of the applicable elements of the QA criteria.

c. Clear management controls and effective lines of communication should exist between the applicant's QA organizations and suppliers to ensure proper direction of the QA program and resolution of QA problems.

d. Organization charts should identify onsite and offsite organizational elements that will function under the purview of the QA program and the lines of responsibility.

e. High-level management should be responsible for documenting and promulgating the applicant's QA policies, goals, and objectives, and this management level should maintain a continuing involvement in QA matters. The application should also describe the lines of communication between intermediate levels of management and between this position and the Manager (or Director) of QA.

f. The applicant should designate a position that retains overall authority and responsibility for the QA program.

g. The authority and independence of the individual responsible for managing the QA program should be such that he or she can direct and control the organization's QA program, can effectively ensure conformance to quality requirements, and can remain sufficiently independent of undue influences and responsibilities of 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.

h. Individuals or groups responsible for defining and controlling the content of the QA program and related manuals should have appropriate organizational position and authority, as should the management level responsible for final review and approval.

I. The qualification requirements for the principal QA management positions should demonstrate management and technical competence commensurate with the responsibilities of these positions.

j. Conformance to established requirements should be verified 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 activities.

k. Persons and organizations performing QA functions should have direct access to management levels that will ensure accomplishment of quality-affecting activities. These individuals should have sufficient authority and organizational freedom to perform their QA functions effectively and without reservation. In addition, they should be able to identify quality problems; initiate, recommend, or provide solutions through designated channels; and verify implementation of solutions.

l. Designated QA individuals or organizations should have the responsibility and authority, delineated in writing, to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material. In addition, the application should describe how stop-work requests will be initiated and completed.

m. The extent of QA controls should be determined by the QA staff in combination with the line staff and should depend upon the specific activity or item complexity and level of importance to safety.

2. Quality Assurance Program

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

a. The applicant should specify measures used to ensure that the QA program meets applicable acceptance criteria.

b. Management should commit to regularly assess the effectiveness of the QA program. In addition, the applicant should describe how management (above and beyond the QA organization) will regularly assess the scope, status, adequacy, and compliance of the QA program to the requirements of 10 CFR Part 72. These measures should include frequent contact with program status through reports, meetings, and audits, as well as performance of a periodic assessment that is planned and documented with corrective action identified and tracked.

c. The applicant should specify measures used to ensure that trained, qualified personnel within the organization will be assigned to determine that functions delegated to contractors are properly accomplished.

d. The applicant should briefly summarize the corporate QA policies, goals, and objectives and should establish a meaningful channel for transmittal of these policies, goals, and objectives down through the levels of management.

e. The applicant should designate responsibilities for implementing the major activities addressed in the QA manuals.

f. The applicant should establish provisions to control the distribution of the QA manuals and revisions.

g. The applicant should establish provisions for communicating to all responsible organizations and individuals that policies, QA manuals, and procedures are mandatory requirements.

h. The applicant should provide a comprehensive listing of QA procedures, plus a matrix of these procedures cross-referenced to each of the QA criteria, to demonstrate that the QA program will be fully implemented by documented procedures.

I. The applicant should identify the structures, systems, and components (SSCs) that are important to safety and therefore will be controlled by the QA program.

j. The applicant should review and document agreement with the QA program provisions of its suppliers to ensure implementation of a program meeting the QA criteria.

k. The applicant should establish provisions for the resolution of disputes involving quality, arising from a difference of opinion between QA/QC personnel and personnel from other departments (engineering, procurement, manufacturing, etc.).

l. The applicant should establish indoctrination, training, and qualification programs that will fulfill the following criteria:

- Personnel responsible for performing activities affecting quality should be instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.
- Personnel performing activities affecting quality should be trained and qualified in the principles and techniques of the activities being performed.
- The applicant should maintain the proficiency of personnel performing quality-affecting activities by retraining, reexamining, and recertifying.
- The applicant should describe specific documentation of completed training and qualification.
- Qualified personnel should be certified in accordance with accepted codes and standards.

3. Design Control

The SAR should describe the approach that the applicant will use to define, control, and verify the design and development of the dry cask storage system (DCSS). Acceptability of activities related to design control is contingent upon the following criteria:

a. The applicant should establish measures to carry out design activities in a planned, controlled, and orderly manner.

b. The applicant should establish measures to correctly translate the applicable regulatory requirements and design bases into specifications, drawings, written procedures, and instructions.

c. The applicant should specify quality standards in the design documents, and should control deviations and changes from these quality standards.

d. The applicant should review designs to ensure that design characteristics can be controlled, inspected, and tested and that inspection and test criteria are identified.

e. The applicant should establish both internal and external design interface controls. These controls should include review, approval, release, distribution, and revision of documents involving design interfaces with participating design organizations.

f. The applicant should properly select and perform design verification processes, such as design reviews, alternative calculations, or qualification testing. When a test program is to be used to verify the adequacy of a design, the applicant should use a qualification test of a prototype unit under adverse design conditions.

g. Design verification constitutes confirmation that the design of the SSC is suitable for its intended purpose. Consequently, design verification requires a level of skill at least equal to that of the original designer, while design checking can be performed by a less experienced person. (As an example, design checking, which must also be performed, includes 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 should be performed by persons other than those performing design checking. In addition, individuals or groups responsible for design verification should not include the original designer, and normally should not include the designer's immediate supervisor.

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

I. The applicant should document all errors and deficiencies in the design, or the design process, that could adversely affect SSCs important to safety. In addition, the applicant should take adequate corrective action, including root cause evaluation of significant errors and deficiencies, to preclude repetition.

j. Before selecting materials, parts, and equipment that are standard, commercial (off-the-shelf), or have been previously approved for a different application, the applicant should review their suitability for the intended application.

k. The applicant should implement written procedures to identify and control the authority and responsibilities of all individuals or groups responsible for design reviews and other design verification activities.

l. The applicant should establish measures that include the use of valid industry standards and specifications for the selection of suitable materials, parts, equipment, and processes for SSCs that are important to safety.

4. Procurement Document Control

Documents used to procure SSCs or services should include or reference applicable design bases and other requirements necessary to ensure adequate quality. Acceptability of the proposed procurement document controls is contingent upon the following criteria:

a. The applicant should establish procedures that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents.

b. Qualified personnel should review and concur with the adequacy of quality requirements stated in procurement documents. This review should ensure that the 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.

c. The applicant should document the review and approval of procurement documents before they are released, and the documentation should be available for verification.

d. Procurement documents should identify the applicable QA requirements that must be compiled with and described in the supplier's QA program. In addition, the applicant should review and concur with the supplier's QA program.

e. Procurement documents should contain or reference the regulatory requirements, design bases, and other technical requirements.

f. Procurement documents should 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.

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

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

i. Changes and revisions to procurement documents should be subject to the same or equivalent review and approval as the original documents.

5. Instructions, Procedures, and Drawings

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

a. Activities affecting quality should be prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

b. The applicant should establish provisions that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, and drawings.

c. The instructions, procedures, and drawings should specify the methods for complying with each of the applicable QA criteria.

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

e. The QA organization should review and concur with the procedures, drawings and specifications related to inspection plans, tests, calibrations, and special processes, as well as any subsequent changes to these documents.

6. Document Control

The SAR should define the applicant's proposed procedures for preparing, issuing, and revising documents that specify quality requirements or prescribe activities affecting quality. Acceptability of the proposed document control procedures is contingent upon the following criteria:

a. The application should identify all documents to be controlled under this subsection. As a minimum this should include design specifications; design and fabrication drawings; procurement documents; QA manuals; design criteria documents; fabrication, inspection, and testing instructions; and test procedures.

b. The applicant should establish procedures to control the review, approval, and issuance of documents and changes thereto, before release, to ensure that the documents are adequate and applicable quality requirements are stated.

c. The applicant should establish provisions to identify individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto.

d. Document revisions should be reviewed and approved by the same organizations that performed the original review and approval or by other qualified responsible organizations designated by the applicant.

e. Approved changes should be included in instructions, procedures, drawings, and other documents before the change is implemented.

f. The applicant should control obsolete or superseded documents to prevent inadvertent use.

g. Documents should be available at the location where the activity is performed.

h. The applicant should establish a master list (or equivalent) to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents. In addition, the applicant should update this list and distribute it to predetermined, responsible personnel to preclude use of superseded documents.

7. Control of Purchased Material, Equipment, and Services

The SAR should define the applicant's proposed procedures for controlling purchased material, equipment, and services to ensure conformance with specified requirements. Acceptability of the proposed controls is contingent upon the following criteria:

a. Qualified personnel should evaluate the supplier's capability to provide services and products of acceptable quality before the award of the procurement order or contract. The applicant's QA and engineering groups should participate in the evaluation of those suppliers providing critical items and services important to safety, and the applicant should define the responsibilities for each group's participation.

b. The applicant should evaluate suppliers on the basis of one or more of the following criteria:

- 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
- review of previous records and performance of suppliers who have provided similar articles or services of the type being procured
- a survey of the supplier's facilities and QA program to assess the capability to supply a product that meets applicable design, manufacturing, and quality requirements

c. The applicant should document and file the results of supplier evaluations.

d. The applicant should plan and perform adequate surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components in accordance with written procedures to ensure conformance to the purchase order requirements. These procedures provide the following information:

- 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
- procedures for audits and surveillance to ensure that the supplier complies with the quality requirements (surveillance should be performed for SSCs for which verification of procurement requirements cannot be determined upon receipt)

e. As a minimum, the supplier should furnish the following records to the purchaser:

- documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items
- documentation that identifies any procurement requirements that have not been met, together with a description of any nonconformances designated "accept as is" or "repair"

The applicant should describe the proposed procedures for reviewing and accepting these documents and, as a minimum, should ensure that this review and acceptance will be undertaken by a responsible QA individual.

f. The applicant should conduct periodic audits, independent inspections, or tests to ensure the validity of the suppliers' certificates of conformance.

g. The applicant should perform a receiving inspection of the supplier-furnished material, equipment, and services to ensure fulfillment of the following criteria:

- The material, component, or equipment should be properly identified in a manner that corresponds with the identification on the purchasing and receiving documentation.
- Material, components, equipment, and acceptance records should be inspected and judged acceptable in accordance with predetermined inspection instructions before installation or use.

- Inspection records or certificates of conformance attesting to the acceptance of material, components, and equipment should be available before installation or use.

- Items accepted and released should be identified as to their inspection status before they are forwarded to a controlled storage area or released for installation or further work.

h. The applicant should assess the effectiveness of suppliers' quality controls at intervals consistent with the importance to safety, complexity, and quantity of the SSCs procured.

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

The SAR should define the applicant's proposed provisions for identifying and controlling materials, parts, and components to ensure that incorrect or defective SSCs are not used. Acceptability of the proposed controls is contingent upon the following criteria:

a. The applicant should establish procedures to identify and control materials, parts, and components (including partially fabricated subassemblies).

b. The applicant should determine identification requirements during generation of specifications and design drawings.

c. The identification and control procedures should ensure that identification will be maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

d. Identification of materials and parts of important-to-safety items should be traceable to the appropriate documentation (such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports).

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

f. The applicant should verify and document the correct identification of all materials, parts, and components before releasing them for fabrication, assembly, shipping, and installation.

9. Control of Special Processes

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

a. The applicant should establish procedures to control special processes (such as welding, heat treating, nondestructive testing, and cleaning), for which direct inspection is generally impossible or disadvantageous. In addition, the applicant should provide a listing of these special processes.

b. The applicant should qualify procedures, equipment, and personnel connected with special processes, in accordance with applicable codes, standards, and specifications.

c. Qualified personnel should perform special processes in accordance with written process sheets (or the equivalent) with recorded evidence of verification.

d. The applicant should establish, file, and keep current qualification records of procedures, equipment, and personnel associated with special processes.

10. Licensee Inspection

The SAR should define the applicant's proposed provisions for inspection of activities affecting quality to verify conformance with instructions, procedures, and drawings. Acceptability of the proposed provisions is contingent upon the following criteria:

a. The applicant should establish, document, and conduct an inspection program that effectively verifies conformance of quality-affecting activities with requirements in accordance with written, controlled procedures.

b. Inspection personnel should be sufficiently independent from the individuals performing the activities being inspected.

c. Inspection procedures, instructions, and check lists should provide the following details:

- identification of characteristics and activities to be inspected
- identification of the individuals or groups responsible for performing the inspection operation
- acceptance and rejection criteria
- a description of the method of inspection
- procedures for recording evidence of completing and verifying a manufacturing, inspection, or test operation
- identification of the recording inspector or data recorder and the results of the inspection operation

d. The applicant should use inspection procedures or instructions with the necessary drawings and specifications when performing inspection operations.

e. The applicant should qualify inspectors in accordance with applicable codes, standards, and company training programs. Their qualifications and certifications should be kept current.

f. The applicant should inspect modifications, repairs, and replacements in accordance with the original design and inspection requirements or acceptable alternatives.

g. The applicant should establish provisions that identify mandatory inspection hold points for witnessing by a designated inspector.

h. The applicant should identify the individuals or groups who will perform receiving and process verification inspections, and should demonstrate that they have sufficient independence and qualifications.

i. The applicant should establish provisions for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is not possible.

11. Test Control

The SAR should define the applicant's proposed provisions for tests to verify that SSCs conform to specified requirements and will perform satisfactorily in service. Acceptability of the proposed provisions is contingent upon the following criteria:

a. The applicant should establish, document, and conduct a test program to demonstrate that the item will perform satisfactorily in service in accordance with written, controlled procedures.

b. Written test procedures should incorporate or reference the following information:

- requirements and acceptance limits contained in applicable design and procurement documents
- instructions for performing the test
- test prerequisites
- mandatory inspection hold points

- acceptance and rejection criteria
- methods of documenting or recording test data results

c. A qualified, responsible individual or group should document test results and evaluate their acceptability. When practicable, the applicant should test the SSC under conditions that will be present during normal and anticipated off-normal operations.

12. Control of Measuring and Test Equipment

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

a. Documented procedures should describe the calibration technique and frequency, maintenance, and control of all measuring and test equipment (instruments, tools, gauges, fixtures, reference and transfer standards, and nondestructive test equipment) that will be used in the measurement, inspection, and monitoring of SSCs that are important to safety.

b. Measuring and test equipment should be identified and traceable to the calibration test data.

c. The applicant should label, tag, or otherwise document measuring and test equipment to indicate the date of the next scheduled calibration and to provide traceability to calibration test data.

d. The applicant should calibrate measuring and test instruments at specified intervals on the basis of the required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions that could affect the accuracy of the measurements.

e. When measuring and test equipment is found to be out of calibration, the applicant should take and document measures to assess the validity of previous inspections.

f. The applicant should document and maintain the complete status of all items under the calibration system.

g. Reference and transfer standards should be traceable to nationally recognized standards; where national standards do not exist, the applicant should establish provisions to document the basis for calibration.

13. Handling, Storage, and Shipping Control

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

a. Qualified individuals should establish and accomplish special handling, preservation, storage, cleaning, packaging, and shipping requirements in accordance with predetermined work and inspection instructions.

b. The applicant should prepare procedures to 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).

14. Inspection, Test, and Operating Status

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

a. The applicant should know the inspection and test status of items throughout fabrication.

b. Established procedures should control the application and removal of inspection and welding stamps and operating status indicators (such as tags, markings, labels, and stamps).

c. Procedures under the cognizance of the QA organization should control bypasses of required inspections, tests, and other critical operations.

d. The applicant should specify the organization responsible for documenting the status of nonconforming, inoperative, or malfunctioning SSCs and identifying the item to prevent inadvertent use.

15. Nonconforming Materials, Parts, or Components

The SAR should define the applicant's proposed provisions to control the use or disposition of nonconforming materials, parts, or components. Acceptability of the proposed provisions is contingent upon the following criteria:

a. The applicant should establish procedures to control the identification, documentation, tracking, segregation, review, disposition, and notification of affected organizations regarding nonconforming materials, parts, components, services, or activities.

b. The applicant should have adequate documentation to identify nonconforming items and describe the nonconformance, its disposition, and the related inspection requirements. The documentation should also include signature approval of the disposition.

c. The applicant should establish provisions to identify those individuals or groups with the responsibility and authority for the disposition and closeout of nonconformances.

d. Nonconforming items should be segregated from acceptable items and identified as discrepant until properly dispositioned and closed out.

e. The applicant should verify the acceptability of reworked or repaired materials, parts, and SSCs by reinspecting and retesting the item as originally inspected and tested or by a method that is at least equal to the original inspection and testing method. In addition, the applicant should document the relevant inspection, testing, rework, and repair procedures.

f. Nonconformance reports designated "accept as is" or "repair" should be made part of the inspection records and forwarded with the hardware to the customer for review and assessment.

g. The applicant should periodically analyze nonconformance reports to show quality trends and to help identify root causes of nonconformances. Significant results should be reported to responsible management for review and assessment.

16. Corrective Action

The SAR should define the applicant's proposed provisions to ensure that conditions adverse to quality are promptly identified and corrected and that measures are taken to preclude recurrence. Acceptability of the proposed provisions is contingent upon the following criteria:

a. The applicant should evaluate conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material and equipment) in accordance with established procedures to assess the need for corrective action.

b. The applicant should initiate corrective action to preclude recurrence of a condition identified as adverse to quality.

c. The applicant should conduct followup activities to verify proper implementation of corrective actions and to close out the corrective action documentation in a timely manner.

d. The applicant should document significant conditions adverse to quality, as well as the root causes of the conditions, and the corrective actions taken to remedy the and preclude recurrence of the conditions. In addition, this information should be reported to cognizant levels of management for review and assessment.

17. Quality Assurance Records

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

a. The applicant should define the scope of the records program such that sufficient records will be maintained to provide documentary evidence of the quality of items and activities affecting quality. To minimize the retention of unnecessary records, the records program should list records to be retained by "type of data," rather than by record title.

b. QA records should 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.

c. Records should be identified and retrievable.

d. Requirements and responsibilities for record creation, transmittal, retention (such as duration, location, fire protection, and assigned responsibilities), and maintenance subsequent to completion of work should be consistent with applicable codes, standards, and procurement documents.

e. Inspection and test records should contain the following information, where applicable:

- a description of the type of observation
- the date and results of the inspection or test
- information related to conditions adverse to quality
- identification of the inspector or data recorder
- evidence as to the acceptability of the results
- action taken to resolve any noted discrepancies

f. Record storage facilities should be constructed, located, and secured to prevent destruction of the records by fire, flood, theft, and deterioration by environmental conditions (such as temperature or humidity). In addition, the facilities are to be maintained by, or under the control of, the licensee throughout the life of the DCSS or the individual product.

18. Audits

The SAR should define the applicant's proposed provisions for planning and scheduling audits to verify compliance with all aspects of the QA program, and to determine the effectiveness of the overall program. Acceptability of the proposed provisions is contingent upon the following criteria:

a. The applicant should perform audits in accordance with written procedures or checklists; qualified personnel tasked with performing these audits should not have direct responsibility for the achievement of quality in the areas being audited.

b. Audit results should be documented and reviewed with management having responsibility in the area audited.

c. The applicant should establish provisions for responsible management to undertake appropriate corrective action as a followup to audit reports. Auditing organizations should schedule and conduct appropriate followup to ensure that the corrective action is effectively accomplished.

d. The applicant should perform both technical and QA programmatic audits to achieve the following objectives:

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

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

e. Audits should be led by appropriately qualified and certified audit personnel from the QA organization. The audit team membership should include personnel (not necessarily QA organization personnel) having technical expertise in the areas being audited.

f. The applicant should schedule regular audits on the basis of the status and importance to safety of the activities being audited; such audits should be initiated early enough to ensure effective QA during design, procurement, and contracting activities.

g. The applicant should analyze and trend audit deficiency data. Resultant reports, indicating quality trends and the effectiveness of the QA program, should be given to management for review, assessment, corrective action, and followup.

h. Audits should objectively assess the effectiveness and proper implementation of the QA program and should address the technical adequacy of the activities being conducted.

i. The applicant should establish provisions requiring the performance of audits in all areas to which the requirements of the QA program apply.