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The document is being submitted as a revision to the current QA Program. The revisions are 1) company name change, 2) change of title from Regulatory Compliance Manager to Director, Regulatory Compliance, and 3) revision of the organizational chart.

The file is best printed on 8 1/2" by 11" paper.

Sincerely,

Richard Byars  
Director, Regulatory Compliance

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**Mission Statement:**

*To provide safe, compliant, and cost-effective radioactive waste management solutions through the innovative application of proven technologies.*

## NUKEM Corporation Quality Assurance Program

Signatures on file

<b>Title</b>	<b>Signature</b>	<b>Date</b>
<b>Quality Assurance</b>	<b>Richard Byars</b>	<b>8/14/06</b>
<b>President</b>	<b>John Raymont</b>	<b>8/14/06</b>

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## **FOREWORD**

This program defines and describes the basic policies and procedures used by NUKEM Corporation (NUKEM) to establish quality assurance requirements for all activities effecting safety related functions of NUKEM systems and components. NUKEM's top management has approved and fully supports adherence to the policies contained in this program.

The policies described in this program are intended to meet or exceed the appropriate requirements of 10 CFR 71, Subpart H; ANSI/ASME NQA-1; and 10 CFR 50, Appendix B. A graded approach to the quality requirements is used for the design, procurement, fabrication, use, maintenance, and repair of NUKEM equipment. The quality assurance requirements are differentiated in NUKEM specifications, procedures, and drawings appropriate to the circumstance.

Copies of the Quality Assurance Program will be issued to customers and government representatives, as required. Assigned copies of this program will be serialized and a record maintained showing the transmittal of each revision. Information copies of the program may be distributed without serialization and they will not be updated with revisions.

The Quality Assurance Program was established and implemented by the President of NUKEM Corporation. The Quality Assurance Program has the full support of NUKEM's management and all NUKEM's employees shall adhere to its provisions.

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John M. Raymont, Jr.  
President and Chief Executive Officer

## 1. ORGANIZATION

### 1.1 Structure

1.1.1 NUKEM Corporation (NUKEM) organization and facilities are located in Columbia, South Carolina (corporate office), Oak Ridge, Tennessee, and Wampum, Pennsylvania. The organizational structure that has been set up at NUKEM to establish and implement its Quality Assurance (QA) Program is shown in Figure 1. The authority and duties of the personnel performing activities affecting safety related functions are described below.

### 1.2 Regulatory Compliance/Quality Assurance Manager

1.2.1 The Director, Regulatory Compliance/Quality Assurance Manager (QA Manager) is the person responsible for establishing the QA program. He reports directly to the President of NUKEM. The President approves the QA program and any revisions thereto. The QA Manager approves all QA procedures and any revisions thereto.

1.2.2 The QA Manager is functionally independent of any group or individual directly responsible for the activities which he monitors including the lead engineer, discipline engineers and field operations personnel. He has the authority and organizational freedom to enforce QA requirements, identify quality problems and initiate, recommend or provide solutions to QA problems, and verify the implementation of the solutions and assure that further processing, delivery, installation, or use is controlled until proper disposition of the non-conformance, deficiency or unsatisfactory condition has occurred. The QA Manager has the authority to stop unsatisfactory work and the processing, delivery, or installation of nonconforming material. The QA Manager is responsible for auditing, inspecting, and testing, including field operations as required. The QA Manager has the following appropriate responsibilities on each project.

1.2.2.1 Prepares QA program plans and QA procedures for specific projects.

1.2.2.2 Verifies that participating suppliers have approved QA programs, as required.

1.2.2.3 Approves QA program plans of participating suppliers.

1.2.2.4 Verifies that participating suppliers have QA procedures, as required.

1.2.2.5 Assures that NUKEM design documents contain applicable QA requirements.

1.2.2.6 Approves quality related procurement documents, instructions, procedures, and drawings for inclusion of quality requirements. Signs certificates of compliance or conformance.

1.2.2.7 Assures that further processing, delivery, installation, or use of non-conforming items is controlled until proper disposition has occurred.

1.2.2.8 Performs audits to verify that QA requirements are being met.

### **1.3 Responsibilities**

1.3.1 When other organizations are delegated the tasks of establishing and executing the QA Program, NUKEM retains responsibility for equipment it owns and operates. The QA Manager, upon notification of need for further direction or resolution of QA problems, has the authority to communicate or direct communications with any firm doing business with NUKEM. Ordinarily, such communications will be through the NUKEM department having responsibility for the function provided by the firm.

### **1.4 Position Requirements**

1.4.1 A BS in Engineering (or equivalent experience) with a minimum of ten years QA experience in the commercial nuclear power industry is required. Preferred experience is QA related work within a service organization or prior work at a nuclear power plant at the QA supervisor level.

1.4.2 The QA Manager must be able to pass all tests and checks to allow unescorted access at customer sites (includes, but is not limited to, security/background investigation, drug and alcohol abuse testing, psychological screening, fitness for duty medical examination, and General Employee Training).

## **2. QUALITY ASSURANCE PROGRAM**

### **2.1 Quality Assurance Policies, Goals, and Objectives**

2.1.1 It is NUKEM's policy that all activities which are governed by the Code of Federal Regulations, licenses, Certificates of Compliance, Letters of Approval, or other regulatory requirements, be conducted in accordance with written, approved instructions, procedures, and drawings. These documents shall incorporate the regulatory requirements in a manner that is easily understood by the user/operator. Quality related activities shall be performed with specified equipment, under suitable environmental conditions and prerequisites shall be satisfied prior to inspection, operation, or testing. Adherence to the procedure requirements is mandatory for all NUKEM employees.

2.1.2 It is the goal of the NUKEM QA Program to provide those mechanisms and environments necessary to achieve a reliable QA Program for activities which affect public health and safety or are specified by a regulatory requirement. This goal is achieved through the use of instructions, procedures, and drawings and a system of internal audits that are designed to evaluate the effectiveness of this program.

2.1.3 Differences of opinion between QA personnel and other NUKEM departments shall be resolved in a meeting with the President of NUKEM.

### **2.2 Quality Assurance Manual Distribution**

2.2.1 Measures to control the distribution of the QA Program Manual and revisions thereto are described in Section 6 of this document.

## **2.3 NUKEM Implementing Procedures**

- 2.3.1 This QA Program incorporates the 18 criteria addressed in NQA-1; 10 CFR 71, Subpart H; and 10 CFR 50, Appendix B. Implementation of this program is accomplished through written approved procedures, instructions or drawings.
- 2.3.1.1 The NUKEM QA Manual is a generic program that identifies the requirements of in NQA-1; 10 CFR 71, Subpart H; and 10 CFR 50, Appendix B. Implementation of these requirements is provided through instructions, procedures, or drawings. Project specific QA Plans and procedures may be developed and implemented to identify the actions necessary to ensure quality objectives are achieved for the specific project.
- 2.3.1.2 The QA Manager, either directly or through QA personnel under his supervision, verifies that the provisions of the QA Program are being observed in all phases of the execution of a project. He also verifies that NUKEM suppliers meet the NUKEM QA requirements stated in applicable documents. The QA Manager maintains liaison with the quality assurance departments of NUKEM's clients.
- 2.3.1.3 This QA Program manual is prepared and kept up-to-date under the direction of the QA Manager. Changes in the QA Program may be proposed by all members of the NUKEM organization.
- 2.3.1.4 The QA Manager is responsible for developing and approving project QA Plans.

## **2.4 Personnel Training**

- 2.4.1 Personnel performing activities affecting quality are trained and indoctrinated in the purpose, scope, and proper implementation of the QA program, the specific QA Program Plan, and the project procedures to assure proficiency for the tasks that they are to perform. The proficiency of NUKEM personnel performing activities affecting quality is maintained through a program of on-the-job training, when applicable, and indoctrination meetings as required. When testing, inspecting, or auditing is delegated, the QA Manager is responsible for the training of individuals performing these functions. Training will be completed prior to the individual performing these functions.

## **3. DESIGN CONTROL**

- 3.1 The Design Control program at NUKEM ensures that design characteristics, especially those related to safety, are controlled, inspected, and tested; that designs developed by the NUKEM Engineering Department meet all applicable regulatory requirements; and that design activities are carried out in a planned, controlled, and orderly manner.
- 3.2 A comprehensive system of established procedures and policies is used for developing and implementing design projects, as well as controlling design documents and design document distribution.
- 3.3 The design shall be defined, controlled, and verified. Design adequacy shall be verified by individuals other than those who designed the item or computer program.

- 3.4 Design changes shall be governed by control measures commensurate with those applied to the original design.
- 3.5 Design changes are reviewed and approved by the same individuals or organizations that reviewed and approved the original documents.
- 3.6 The Design Control program provides for design reviews at regular intervals to ensure that design characteristics are controlled, inspected, and tested, and that inspection, test and acceptance criteria are identified. Formal design reviews may include the Cognizant Engineer, the Lead Designer, the QA Manager and any other individuals or groups involved in the development of the design. Design reviews may be called at any time a problem is identified. Records are kept of these design reviews, and measures are taken to ensure that design errors are corrected and not repeated. Design controls also extend to other individuals or groups in interfacing design organizations.
- 3.7 Procurement of materials parts, equipment, and processes are controlled as outlined in Section 7 of this document. The procurement documents specify all design base requirements including the applicable regulatory requirements, material and component requirements, drawings, specifications, codes, industry standards, test and inspection criteria, and special process instructions. No equipment is released to the requisitioning party until it meets the requirements specified in the purchase order. All materials, parts, and equipment are reviewed for suitability prior to selection.

#### 4. **PROCUREMENT DOCUMENT CONTROL**

##### 4.1 **Procurement Documents**

- 4.1.1 This section defines the measures established to assure that applicable regulatory requirements, design bases, and other requirements necessary for adequate quality assurance are included in documents for procurement of items or services. These requirements include the following:
  - 4.1.1.1 **Scope of Work** – The scope of work at all tiers of supply level are adequately defined.
  - 4.1.1.2 **Technical Requirements** – Technical requirements by reference to appropriate specifications, codes, industry standards, and regulations are included that describe the items or services to be furnished. Test, inspection, and acceptance requirements are identified.
  - 4.1.1.3 **Applicable Quality Requirements** – The procurement documents shall identify the applicable quality requirements.
  - 4.1.1.4 **Right of Access** – At each tier of procurement, the procurement documents provide for the right of access to the supplier's facility for inspection and audit. The procurement documents specify events to be witnessed, schedule the hold and witness points, identify minimum advance notice of tests, and means of communication regarding these tests.
  - 4.1.1.5 **Special QA Requirements** – Special QA requirements are specified.

- 4.1.1.6 **Documentation Requirements** – Procurement documents specify documentation required and establish a submittal schedule.
- 4.1.1.7 **Nonconformance reports** – Requirements for reporting and approving disposition of nonconformances.
- 4.1.1.8 **Identification and Control of Records** – Those records to be retained, controlled, and maintained by the supplier and those records delivered to NUKEM prior to installation of hardware.

## 4.2 Procurement Document Review

- 4.2.1 Procurement documents such as the “Technical Specification”, “Purchase Order”, etc. are initiated and processed in accordance with NUKEM procedures. These procedures delineate the responsibilities of the various departments, including QA, which have the responsibility for the initiating, processing, and approving the procurement document.
- 4.2.2 Changes to procurement documents are reviewed and approved by the same organizations that performed the original review and approval. Approved changes are included in the applicable procurement documents prior to the implementation of the change.
- 4.2.3 During these reviews, the procurement documents are screened and applicable paragraphs relating to specific proprietary and manufactured items are highlighted for incorporation into a procurement specification. Resulting from these reviews, the Engineering, or Operations department prepares the procurement document and forwards them to the Purchasing Department.
- 4.2.4 The Quality Assurance reviewer examines the procurement document to assure that complete information is provided to identify:
  - 4.2.4.1 The applicable 10 CFR Part 50, Appendix B; NQA-1; or 10 CFR 71, Subpart H requirements which must be addressed,
  - 4.2.4.2 The design basis technical requirements including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, tests and inspection requirements, and special process instructions,
  - 4.2.4.3 Applicable inspection, witness, and hold points.

## 4.3 Procurement

- 4.3.1 The procurement of materials, components, or services affecting assemblies for use at customer sites or other licensed activities is accomplished with a written Purchase Order. Purchase Order forms are controlled by the Purchasing Department. Only the Purchasing Department is authorized to release Purchase Orders, and is responsible for conforming to established procurement and record keeping procedures. The sequence of events leading to Purchase Order issuance, and the associated record keeping activities comply with NUKEM written procedures.

- 4.3.2 Technical or quality requirement changes to procurement documents are processed in the same manner as the original documents.
- 4.3.3 Procurement documents for packaging licensed according to 10 CFR Part 71 shall contain the following:
  - 4.3.3.1 The manufacturer shall certify that the packaging (identifying model and serial number) was fabricated under the control of an USNRC approved QA program.
  - 4.3.3.2 Requires the manufacture to identify type of verification activities required during use and maintenance.
  - 4.3.3.3 The manufacture shall provide; a current copy of the USNRC Certificate of Compliance, as-built-drawings, maintenance procedures, operating procedures; inspection/test reports showing current compliance with current NRC Certificate of Compliance and a listing of safety related components and their approved supplier.

## **5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

- 5.1 Activities affecting quality are prescribed by instructions, procedures, or drawings appropriate to the circumstance and are accomplished in accordance with these instructions, procedures, or drawings. These instructions, procedures, or drawings provide the method for compliance with the applicable nationally recognized codes, standards and specifications.
- 5.2 Included in these instructions, procedures, or drawings are quantitative and/or qualitative acceptance criteria to permit the verification that activities affecting quality have been satisfactorily accomplished.
- 5.3 A QA representative reviews and approves project instructions, procedures, or drawings to verify inclusion of quality requirements. These documents may include but are not limited to specifications, procurement documents, and operating procedures.
- 5.4 Instructions, procedures, and drawings are maintained in active data files. Superseded instructions, procedures, and drawings are marked "HISTORY" and filed.
- 5.5 Suppliers are responsible for the destruction and voiding of all superseded documents upon the receipt of superseding documents.

## **6. DOCUMENT CONTROL**

- 6.1 NUKEM establishes and implements procedures to control the issuance of NUKEM documents which prescribe activities affecting quality. These procedures define document control measures to assure adequate review, approval, release, and distribution of original documents and subsequent revisions. These documents may include but are not limited to design specifications, drawings, procurement documents, special process, test, and operating procedures. When required by customer requirements, a specific QA plan is prepared identifying the persons, groups, and/or organizations responsible for reviewing and approving documents and their revisions for that project.

- 6.2 Changes to documents are reviewed and approved by the same organizations that performed the original review and approval. Approved changes are included in the applicable instructions, procedures, drawings, or other documents prior to the implementation of the change.
- 6.3 Documents are available at the location where activities affecting quality are performed prior to commencing the work.
- 6.4 Document control for suppliers shall be handled as follows;
  - 6.4.1 Subcontractors and suppliers are required to maintain an effective drawing control system when drawings are provided to NUKEM as part of the contractual requirements.
  - 6.4.2 Procurement of items to NUKEM's design requires a document control system that includes assurance of notification changes to the subcontractor or supplier, verification of change incorporation and appropriate identification of those items on which the change is incorporated.
  - 6.4.3 Procurement of items of subcontractor's or supplier's design requires a document control system that assures notification of NUKEM by the subcontractor or supplier of the proposed change, approval of the change by NUKEM and appropriate notification of the items on which the change is incorporated.

## **7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES**

### **7.1 Supplier Evaluation**

- 7.1.1 NUKEM Engineering and Quality Assurance personnel participate in evaluation of suppliers. Recommendations for suppliers are based on these evaluations. Results of supplier evaluations performed prior to contract award are documented and filed. These evaluations cover review of capabilities and facilities for technical, manufacturing, and quality performance, and include any or all of the following as appropriate:
  - 7.1.1.1 Historical performance data, particularly in product quality and delivery,
  - 7.1.1.2 Review and comment on supplier's quality assurance program,
  - 7.1.1.3 Audits to verify supplier's QA plan implementation,
  - 7.1.1.4 Supplier qualification programs.
- 7.1.2 The evaluation considerations include the applicable elements of the QA criteria listed in 10 CFR 50, Appendix B; NQA-1; or 10 CFR 71, subpart H to the extent these elements are applicable to the equipment being procured. Actions to correct deficiencies in the supplier's QA program are resolved with the supplier's management prior to fabrication of ordered items.

### **7.2 Procurement Requirements**

- 7.2.1 Requirements to be met by the supplier are detailed in procurement documents which may include procurement specifications. Procurement specifications detail

the required aspects of the supplier's QA Program, for example, inspection reports, provisions for inspection, equipment calibration prior to use, and provisions for inspection after component repair. The procurement specification may also require the successful bidder to submit the following for NUKEM's review:

- 7.2.1.1 Special process procedures for performing welding, heat treating, and nondestructive examination,
- 7.2.1.2 Recommended inspection point program,
- 7.2.1.3 Appropriate documentation required by applicable codes, standards, and procurement documents,
- 7.2.1.4 Notices of nonconformances and their disposition,
- 7.2.1.5 Test procedures in accordance with applicable codes and standards.

### **7.3 Supplier Surveillance**

- 7.3.1 NUKEM's QA Department is responsible for conducting and documenting supplier surveillances. Surveillance activities typically include:
  - 7.3.1.1 Witnessing test inspections, nondestructive examinations and various special process operations,
  - 7.3.1.2 Monitoring heat treating, welding, cleaning, preserving, and packaging activities,
  - 7.3.1.3 Verifying supplier conformance with established procedures such as:
    - 7.3.1.3.1 Use of NUKEM accepted drawings and procedures,
    - 7.3.1.3.2 Use of accepted product and process quality planning,
    - 7.3.1.3.3 Document change control,
    - 7.3.1.3.4 Material identification and traceability control,
    - 7.3.1.3.5 Control and calibration of measuring and test equipment,
    - 7.3.1.3.6 Control of major repair welding.
    - 7.3.1.3.7 Reviewing completed product quality documentation (including supplier nonconformances) and/or checklists prior to release of equipment for shipment. This documentation includes material test reports, inspection and test reports, Nondestructive examination reports, and applicable code data reports.
- 7.3.2 The frequency and extent of the surveillance are consistent with the complexity and quantity of the item or service being furnished.

## **7.4 Receiving Inspection**

- 7.4.1 Receipt inspections shall be performed on purchased items (including spare or replacement parts) to ensure that:
  - 7.4.1.1 Material, components, or equipment are properly identified and correspond to purchase order requirements,
  - 7.4.1.2 Inspection records or certificates of conformance attesting to the acceptance of material, components or equipment were received,
  - 7.4.1.3 Items accepted and released are identified with their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.

## **7.5 Acceptance By Test**

- 7.5.1 Acceptance based on testing after installation of an item shall be mutually agreed to with the supplier prior to use.

# **8. IDENTIFICATION AND CONTROL OF COMPONENTS AND MATERIALS**

## **8.1 Components and Materials**

- 8.1.1 The inspection status of components and materials shall be maintained by use of travelers, marking, tagging, or stamping components or materials at the appropriate stages of fabrication or installation. The inspection status is not changed without NUKEM QA concurrence.
- 8.1.2 Identification of components and materials shall be accomplished with a method that will provide legible identification without adverse effect on the life and utility of the items.
- 8.1.3 Components or materials not suitable for individual marking shall be individually tagged, or placed in an identified container.
- 8.1.4 The storage area shall contain only components or materials, which have been inspected and accepted. Surveillance shall be maintained over the storage areas to assure that material subject to certification control or age limit requirements are properly segregated, dated, and controlled. This surveillance shall also include checking for conformance to proper standards of packaging and storage of components, materials, parts, and assemblies.

## **8.2 Identification**

- 8.2.1 Identification requirements shall be determined during generation of specifications and design drawings. Identification of materials and parts for safety related systems or components shall be traceable to the appropriate documentation, such as drawings, specifications, purchase orders, manufacturing and inspection documents, nonconformance reports and physical and chemical material test reports.

## **9. CONTROL OF SPECIAL PROCESSES**

### **9.1 Personnel Certification**

9.1.1 Personnel responsible for performance, inspection, and control of special processes and operations, which require special skills and have an effect upon quality, shall be certified (e.g. welding, nondestructive examination, heat treating, etc.). Personnel for these processes or operations shall be trained and qualified in accordance with the codes and/or standards applicable to the process. The effective period for all certifications shall be specified and each individual shall be recertified at the end of such period as required by applicable standards. Inspection results and quality audits shall be used as indicators of the need for additional training and recertification of fabrication, installation, and inspection personnel without regard for established recertification periods. A record of the names of certified personnel, their skills, and certification periods shall be kept current and maintained on file for review at the facility performing the special process.

### **9.2 Subcontractor Control**

9.2.1 Special processes performed by NUKEM's subcontractors and suppliers shall be specified in procurement documents and shall be monitored by QA for conformance to NUKEM requirements.

### **9.3 Procedures**

9.3.1 All special fabrication, installation, and inspection processes, which have an effect upon the quality of the component, system, or fabrication operation, shall be controlled by special process procedures.

9.3.2 Special process procedures shall be reviewed and approved by Quality Assurance to ensure their adequacy. Special process procedures shall include the method, qualification requirements, equipment, and associated control parameters.

## **10. INSPECTION**

10.1 Measures are established and implemented to inspect materials, parts, processes, or other activities affecting quality to verify conformance with documented instructions, procedures, specifications, drawings, or other procurement documents. Personnel other than those who performed the activity being inspected shall perform these inspections. Inspectors shall be qualified in accordance with the applicable codes and standards. Inspector qualifications and certifications shall be maintained current, and these records shall be retained.

10.2 Inspections are performed in accordance with approved, written instructions and procedures. The instructions and procedures shall include:

- acceptance criteria;
- identify the characteristics and activities being inspected;
- identify the individuals or groups responsible for performance of the inspection;

- describe the method of inspection;
- record evidence of completion and verification of manufacture, inspection or test;
- measures to ensure that nonconformances noted earlier have been resolved;
- measures to ensure inspected item is identifiable and traceable to specified records (e.g. drawings, test specifications, purchase order requirements, etc.);
- record the identity of the inspector or data recorder and the results of the inspection.

10.3 When direct inspection is not possible; provisions are established for indirect control by monitoring processing methods, equipment, and personnel.

10.4 Modifications and/or repairs to and replacements of safety related components or equipment are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

### **10.5 Hold Points**

10.5.1 The procurement documents, drawings, quality plans, transportation, and operating procedures shall establish any required mandatory hold points, which shall be reflected in the fabrication or operation schedule. Hold points shall be designated points in the fabrication or operation schedule beyond which the operations shall not proceed without the concurrence of the QA Department because of witnessing required examinations, inspections, or tests.

### **10.6 Check Lists of Examinations, Tests and Inspections**

10.6.1 When required, prepared checklists shall include the document number and revision level for the examination, inspection or test being performed. The checklist shall have space provided for recording results of the examination, test or inspection and for witness signatures, initials or stamp, and date of activities witnessed.

## **11. TEST CONTROL**

### **11.1 Test Procedures**

11.1.1 Testing shall be performed in accordance with approved procedures, prepared by the responsible NUKEM department, and reviewed by QA in accordance with standards, procedures, or instructions that require inclusion of the following QA requirements, as applicable:

11.1.1.1 Test requirements and acceptance criteria as contained in the applicable design documents,

11.1.1.2 Detailed instructions for performing the test.

11.1.1.3 Test prerequisites, including, but not limited to the following:

11.1.1.3.1 Calibrated instrumentation,

- 11.1.1.3.2 Adequate and appropriate equipment,
- 11.1.1.3.3 Trained, qualified, and as appropriate, licensed and/or certified personnel,
- 11.1.1.3.4 Preparation, condition and completeness of the item being tested,
- 11.1.1.3.5 Suitable and, if required controlled environmental conditions.

11.1.1.4 Mandatory inspection hold points for witness by responsible individual,

11.1.1.5 Method for documenting or recording test data and results,

11.1.1.6 Designation of the individual(s) or group(s) responsible for evaluating and making decisions based on test results.

11.1.2 Test procedures shall be subject to document control requirements as outlined in this program. They shall be maintained current by revisions issued upon changes in specifications, documentation, drawings, or contracts.

## **11.2 Test Records**

11.2.1 Records of tests performed shall be prepared, showing the applicable drawing or procedure and revision level, identification of test performed, date, test data, and other essential test information.

11.2.2 The test record shall be signed by the individual performing the test and any test witness, if so required. Test records shall be retained in accordance with appropriate procedures.

## **11.3 Test Control for Procured Items**

11.3.1 Test control requirements are imposed on suppliers by procurement documents. They identify the tests being performed and stipulate that the supplier's test procedures be submitted to NUKEM for approval. Tests are conducted by groups within the supplier's organization, and test control systems are monitored by NUKEM QA during surveillances. Records of tests are reviewed for acceptability during the surveillance.

## **11.4 Modifications, Repairs and Replacements**

11.4.1 Modifications, repairs, and replacements shall be tested in accordance with the original design and test requirements or acceptable alternatives approved in the same manner as the original.

## **12. CONTROL OF MEASURING AND TEST EQUIPMENT**

12.1 Measures are established and implemented to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated and adjusted to maintain accuracy within necessary limits. These measuring devices are calibrated at scheduled intervals against certified equipment

having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented. All calibrations are performed in accordance with approved written procedures.

- 12.2 Measuring and test equipment are identified and traceable to the calibration records and are labeled or tagged indicating the next required calibration date. The required accuracy for calibration of measuring and test equipment shall be specified.
- 12.3 When measuring and test equipment is found to be out of calibration, measures are taken and documented to determine the validity of inspections performed during the period the equipment was out of calibration. The complete status of all measuring and test equipment under the calibration system is recorded and maintained.
- 12.4 Operational checks shall be performed on test equipment, as required, to assure that the equipment is still functioning properly prior to actual testing.

### **13. HANDLING, STORAGE AND SHIPPING**

#### **13.1 General**

13.1.1 Measures are established and implemented to assure that all materials, components, assemblies, spare parts, special tools, and equipment, including packaging for shipment of radioactive materials, are cleaned, handled, stored, preserved, packaged and shipped in a manner which prevents damage, loss of identity, or deterioration. These activities are carried out in accordance with written approved procedures. Procedures for these activities are established and issued to all project personnel involved in project implementation prior to carrying out any such activities on each project.

#### **13.2 Handling**

13.2.1 Material handling equipment is designed to preclude damage to both the equipment and its container. If special handling is needed, special requirements such as weights, sling locations, balance points, methods of attachments, maximum hoist line speeds, and other pertinent features for safe and proper handling shall be identified in procurement handling, and shipping documents, as necessary.

13.2.2 Engineering incorporates in their design protective measures to preclude handling damage.

13.2.3 Procurement specifications indicate necessary requirements for packaging and shipping to prevent damage or deterioration.

#### **13.3 Storage**

13.3.1 Normal storage is in the condition accepted by the owner or his agent. If crating or any other type of packing is required, this is accomplished prior to storage.

13.3.2 Components that are stored under the jurisdiction of NUKEM are periodically surveyed. Any damage or deterioration is handled as a non-conformance.

- 13.3.3 When necessary, storage procedures address special requirements for environmental protection such as inert gas atmospheres, moisture, temperature levels, etc.

#### **13.4 Shipping**

- 13.4.1 NUKEM policy requires that items are packaged and shipped in a manner that will prevent damage during transit. Items are packaged in accordance with appropriate codes, manufacturer's standards, contractual requirements, and other shipping requirements.
- 13.4.2 Procurement documents contain relevant shipping instructions and requirements.
- 13.4.3 Items received and inspected at NUKEM facilities are repackaged in accordance with appropriate requirements for final shipment to the job site.
- 13.4.4 Shipping procedures assure that all conditions of the Certificate of Compliance are satisfied prior to delivery of radioactive material to a carrier for transport in an approved package.
- 13.4.5 When required, shipping documentation shall be completed prior to shipping.

### **14. INSPECTION, TEST AND OPERATING STATUS**

#### **14.1 Equipment Status**

- 14.1.1 The inspection, test and operating status of systems and components used for processing or transportation of radioactive material shall be known at all times during manufacturing and operation.
- 14.1.2 Transportation and operating procedures shall include reporting requirements which establish the equipment status at key events (after unloading, prior to shipment, etc.)
- 14.1.3 Equipment status will be maintained by operating personnel who are responsible for critical inspection, test, and operating activities. QA personnel shall verify equipment status and compliance with procedures. Bypassing of required tests or other critical operations shall be procedurally controlled under the cognizance of QA personnel with the concurrence of the QA Manager or his designee.

#### **14.2 Examination of Process Status**

- 14.2.1 Measures shall be established to indicate during receiving, fabrication and equipment operation the status of examinations and tests performed on items, systems and components. These measures shall provide identifications of those items, which conform to examination and test requirements and those that do not conform.

#### **14.3 Inspection Status**

- 14.3.1 NUKEM inspection stamps, tags, or authorized Quality Assurance signature shall be applied to documentation and/or materials, items, systems, and components

to indicate the inspection status and to provide traceability to the individual performing the inspection.

14.3.2 Procedures shall be established to control the application and removal status indicators.

## **15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS**

15.1 Materials, parts, or components that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, evaluation, segregation when practical, disposition of nonconformance, and for notification to affected organizations.

15.2 Nonconforming items shall be identified by legible marking, tagging, segregation, or other method not detrimental to the item.

### **15.3 Non-Conformance During Receiving Inspection**

15.3.1 If items are found not in conformance with specifications, the inspector attaches a Reject/Hold tag to the nonconforming item and segregates it from accepted items where practical. A nonconformance report shall be issued by the inspector. The report indicates the reason for the nonconformance and recommended corrective action, if any.

### **15.4 Subcontractor Control**

15.4.1 Subcontractors shall promptly notify NUKEM of all deviations from the procurement requirements, such as deviations from the required codes or approved drawings. A nonconformance report shall be initiated by the subcontractor in accordance with NUKEM procedures. After detection of the deviation, further fabrication shall not be performed until the nonconformance report has been dispositioned.

### **15.5 Verification of Rework or Repair Acceptability**

15.5.1 Acceptability of rework or repair of materials, parts, or components, shall be verified by reinspection and/or retesting the item to the original criteria, or by a method, which is at least equal to the original inspection and testing method. Inspection, testing, rework, and repair records shall be documented and filed in NUKEM quality records files.

### **15.6 Nonconformance Disposition**

15.6.1 The individual or groups (e.g. project engineer or Operations Dept.) identified on the nonconformance report shall have the responsibility and authority for disposition of the nonconforming item. NUKEM QA is responsible for reviewing, approving and verifying the disposition of nonconforming item.

### **15.7 Assessment of Non-conformance's**

15.7.1 Nonconformance reports shall be analyzed periodically to show quality trends and the results reported to NUKEM management for review and assessment.

## **16. CORRECTIVE ACTION**

- 16.1 Conditions adverse to quality (i.e., nonconformances, failures, malfunctions, deficiencies, deviations, defective materials, etc.) shall be evaluated to determine the need for corrective action in accordance with established procedures.
- 16.2 Corrective action shall be promptly initiated when it is determined that an existing non-conformity in a material, a process, or a component is due to an assignable cause and is repetitive in nature.
- 16.3 The corrective action shall include:
- 16.3.1 Investigation of deviation,
  - 16.3.2 Determination of cause,
  - 16.3.3 Corrective action taken,
  - 16.3.4 Evaluation of corrective action.
- 16.4 The appropriate departments shall be assigned the responsibility for corrective actions. Corrective action includes, but is not limited to, procurement or manufacturing operations, design, construction, and operation. The results of corrective actions shall be documented. QA shall review records to verify proper implementation of corrective action. Effectiveness of corrective actions shall be continuously monitored as a function of quality surveillance. Significant conditions adverse to quality, the cause of such conditions, and the corrective action taken shall be reported to cognizant levels of NUKEM management for review and assessment. Corrective actions shall be tracked to closure.
- 16.5 When corrective action requests affect a NUKEM supplier, the supplier shall be required to provide the following information:
- 16.5.1 A description of factors contributing to the deficiency,
  - 16.5.2 A description of corrective actions taken to prevent recurrence of the discrepancy in future production.

## **17. QUALITY ASSURANCE RECORDS**

### **17.1 General**

- 17.1.1 This section presents guidelines for the collection, storage and retention of quality assurance records associated with the design, procurement, manufacture, delivery, and start-up of NUKEM supplied systems, components, and services.
- 17.1.2 For safety-related components, equipment, and services, a program is established and implemented to assure that sufficient written records are maintained to furnish evidence of activities affecting quality. These records include but are not limited to design records, records of use, and the results of reviews, in-process assembly, and final inspections, packaging and shipping inspections, tests, audits, monitoring of work performance, materials analyses,

and related records such as qualifications of personnel, equipment, and procedures for special processes.

17.1.3 The procurement specifications identify those records to be transmitted to NUKEM for retention at NUKEM and those to be retained by the supplier in accordance with the procurement document requirements described in this manual. The records shall be identified, indexed, and stored in accessible locations.

17.1.4 Maintenance of records at NUKEM is in accordance with written approved procedures. These procedures address duration of storage, responsibilities for safekeeping, preservation, and disposition of lifetime and non-permanent records. Maintenance of records at participating organizations is in accordance with their approved program.

## **17.2 Responsibility**

17.2.1 The responsibility for obtaining all required QA documentation for a particular project rests with the Project Manager in charge.

17.2.2 Guidelines defining the scope of the required quality assurance documentation are established by the Quality Assurance Manager, amplified or modified for each project by contractual requirements. Requirements for submittal of quality assurance records are contained in procurement documents.

## **17.3 Lifetime Records**

17.3.1 Lifetime records shall contain as a minimum: design specifications, stress reports or stress calculations, "as built" and interface control drawings, copies of material test reports, tabulation of materials for "as built" configuration, nondestructive examination reports, including examination results, and disposition reports.

## **17.4 Non-permanent Records**

17.4.1 Records pertaining to NRC approved packages shall be retained for 3 years after the shipment.

17.4.2 All non-permanent records required verifying compliance with the applicable codes and the supplier's or subcontractor's QA Program shall be maintained until project completion, unless otherwise stipulated.

## **17.5 Record Storage Facilities**

17.5.1 Record storage facilities or containers shall be constructed, located and/or secured to prevent destruction of records by fire, flood, theft, and deterioration. As an alternative duplicate sets of documentation may be maintained in separate locations.

## **17.6 Record Replacement**

17.6.1 Measures shall be established for prompt replacement of a record that is lost or damaged.

## **18. AUDITS**

18.1 Planned audits shall be performed to provide comprehensive, independent verification, and evaluation of the NUKEM or supplier activity being audited. The audit scope shall encompass evaluation of quality system practices and/or procedures and the effectiveness of their implementation, monitoring of operations and activities, and a review of pertinent documents and their control and maintenance. Audit checklists shall be prepared prior to conducting an audit.

### **18.1.1 Audit Schedule**

18.1.1.1 Internal audits shall normally be conducted at least once every 12 months. However, unscheduled audits may be performed more frequently in specific areas, if deemed necessary by QA and/or when the need is indicated by the existence of chronic problems. Supplier audits shall be conducted at least once every 36 months.

### **18.1.2 Audit Personnel**

18.1.2.1 Audits shall be performed by NUKEM personnel with no direct line responsibility for the function audited. The audit personnel shall have the required level of technical capability to accomplish the audit functions. When required, representatives from various NUKEM departments may be called upon for technical advice or assistance.

## **18.2 Audit Reports**

18.2.1 A verbal presentation of the findings, conclusions, and recommendations of the audit shall be made to management personnel affected by the audit.

18.2.2 A written report containing the findings and recommendations (if any) presented in the verbal report is prepared and distributed to the responsible departments and appropriate management.

18.2.3 Audits shall include an assessment as to how well the QA Program meets regulatory or other requirements.

## **18.3 Audit Follow-Up**

18.3.1 The originator of an audit report or a designated alternate is required to follow an open finding until action is taken to satisfy the audit item. Follow-up actions are taken to verify corrective actions are implemented and effective.

18.3.2 Responsible management personnel shall evaluate each audit report item and correct deficiencies as promptly as possible after they are revealed.

## **18.4 Management Review**

18.4.1 The QA Program shall be reviewed by NUKEM's management at least once a year to ensure conformance to current practices and requirements.

Figure 1

