QUALITY ASSURANCE PROGRAM

FOR

RADIOACTIVE MATERIAL PACKAGES

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BABCOCK & WILCOX COMPANY
NNFD RESEARCH LABORATORY

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REVISIONS	SECTION NO. ii
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DATE	DESCRIPTION
12/78	ORIGINAL RELEASE
01/80	REVISION 1 - Revised to include NRC's comments of 11/01/79.
05/80	REVISION 2 - Added index to Section 2.0 per NRC's comments of 03/14/80.
08/85	REVISION 3 - Updated implementing procedure listing. Revised to reflect changes in reporting responsibilities of Quality Assurance Administrator, SNM Accountability Specialist, and Health Physics.
10/86	REVISION 4 - Updated implementing procedure listing. Revised Section 1.0 to reflect changes in reporting responsibilities of the LRC Quality Assurance Administrator and the Manager, Safety and Licensing.
11/87	REVISION 5 - Complete revision to reflect changes due to transfer of responsibility from the R&DD to NNFD.
11/88	REVISION 6 - Updated implementing procedure listing.
08/90	REVISION 7 - Updated implementing procedure listing, revised position titles and made minor text changes.

INTRODUCTION

This manual describes the Quality Assurance (QA) Program for shipping packages which transport certain quantities of radioactive material that is currently in effect at the Babcock & Wilcox Company NNFD Research Laboratory (Site). The QA Program imposes standards of quality through the development of policies, procedures and instructions, and the implementation of effective plans and disciplines.

This manual meets the requirements of 10 CFR Part 71, Subpart H, "Quality Assurance." It should be noted that for any specific package, not all of the sections of this manual will necessarily be imposed. The QA Program, however, requires the development of a formal QA Plan which shall specify the applicable sections of this manual.

The Quality Assurance Administrator has the responsibility and authority for the administration and assurance of conformance with the requirements of the program described in this manual. He has the authority and responsibility to require corrective action for shipping packages which do not conform to the objectives and policies outlined in this manual. Compliance with the intent of these objectives is also required of suppliers to the Site through requirements transmitted in procurement documents.

The safety of employees, the public, and Company operations are of paramount importance to the Company. An Industrial Safety and Health Program has been established at the NFD-RL to assure safe practices and implement accident prevention. Operations are performed according to guidelines contained in the NNFD-RL Industrial Safety Manual.

ORGANIZATION

Implementation and maintenance of the QA Program for manufacture, use, and repair of radioactive material shipping containers is the responsibility of Site management. Containers for shipment of NRC licensed material may be designed and constructed by a Site approved contractor or designed, constructed, purchased, repaired or used by the Site. However, responsibility for quality assurance resides with Site management.

The Site is organized as shown in the organization chart (Figure 1). Written procedures listed in Table 1 (see Section 2.0) delineate the function and responsibilities of the organizations at the Site.

All personnel performing shipping container QA functions are considered to be qualified in this area because current programs for the application of 10 CFR 50, Appendix B are in effect. All verifications of conformance to established requirements are accomplished by individuals or groups who do not have direct responsibility for performing the work being verified. Trained, qualified personnel at the Site shall determine if functions delegated to suppliers are being accomplished.

The principle responsibilities and authorities of the Site Quality Assurance Program for Shipping Packages are vested in the following positions at the Site.

Quality Assurance Administrator

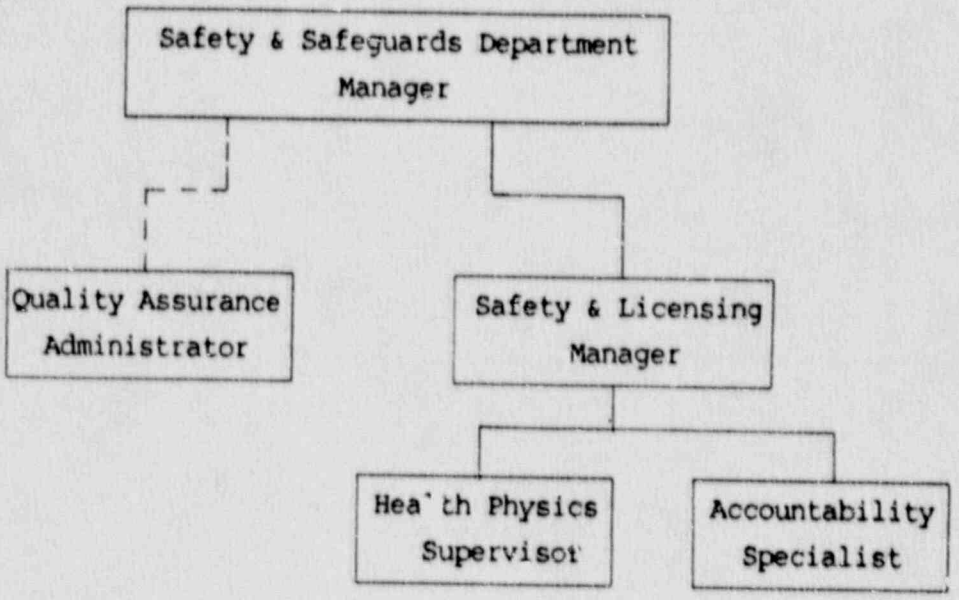
The responsibility for implementing the Quality Assurance Program lies with the Quality Assurance Administrator. He reports to the Manager, Safety & Safeguards Department. He is separated from all other groups, thus assuring independence in carrying out the functions of inspecting, auditing, and verifying conformance to 10 CFR 71, Sub-part H criteria. He is responsible for the implementation of the QA Program, including review and approval of vendor quality assurance programs. He has the authority to withhold from further processing or use the materials, parts, or components which do not meet the applicable requirements. The qualifications

for Quality Assurance Administrator include a B.S. degree or equivalent, or the ability to substitute equivalent experience; and a minimum of two years quality related experience in industry.

Health Physics Supervisor

The Health Physics Supervisor is responsible for the shipment of licensed material. He is assisted in this activity by members of the Health Physics Group or the SNM Accountability Specialist. Typical duties include determining shielding requirements, selecting and ordering shipping containers, obtaining permits, scheduling shipments, radiation surveys, labelling of shipping containers, and generation of documentation.

FIGURE 1



QUALITY ASSURANCE PROGRAM

The Site Quality Assurance Program for Radioactive Material Packages documented in this manual is in accordance with Corporate Quality Assurance policies, goals, and objectives. The QA Program regulates activities associated with the design, procurement, manufacture, production, testing, inspection, preservation, and handling of nuclear components and services. Compliance with the requirements of this QA Program is mandatory for all Site organizations and personnel.

A Quality Assurance Plan shall be developed for projects that require the application of QA according to the guidelines in this Program. It should be noted that all sections of this Program may not be required for each project. The project leader and Quality Assurance shall prepare a QA plan that imposes the ^ equirements for a specific project.

Implementation of quality assurance is primarily the responsibility of the project leader. The project leader shall assure that the required activities and training are performed and documented, and that inspections are performed by persons independent of the activity process.

Indoctrination and training programs require:

a. Instruction of organizations and personnel responsible for performing quality related activities. Instruction includes the purpose, scope, and mandatory implementation of the quality related manuals, instructions, and procedures.

b. Personnel performing quality related activities be trained and qualified in the principles, techniques, and regulato requirements of the activity being performed.

c. The scope, the objective, and the method of implementing the indoctrination and training program be documented.

d. Proficiency of personnel performing quality related activities be maintained by retraining, and/or re-certifying.

Safety related structures, systems, and components controlled by the QA Program shall include, as a minimum, structural requirements to maintain container integrity, radiation shielding, and neutron absorbents.

Controls shall be maintained over suppliers and consulting organizations to assure that 10 CFR 71, Subpart H is implemented.

Management reviews of the QA Program are conducted periodically to assess its scope, implementation, and effectiveness.

TABLE 1. INDEX CROSS-REFERENCING APPENDIX 9 CRITERIA WITH IMPLEMENTING PROCEDURES

Criteria	Procedures Applicable to NNFD Research Laboratory
1. Organization	RL-IP-0101-02 NNFD-RL Purpose and Responsibilities
2. Quality Assurance Program	RL-IP-1702-01 Operational Quality Program (OQP) for the NNFD Research Laboratory RL-IP-1702-03 Preparation of Quality Assurance Program Plans RL-IP-1702-04 Operational Quality Program (OQP) for Radioactive Material Packages NNFD-RL Industrial Safety Manual
3. Design Control	RL-IP-0405-01 Design Review Program RL-IP-1704-02 Preparation of Project Technical Plans RL-IP-1704-03 Independent Technical Reviews RL-IP-1704-04 Documentation and review of Calculations
4. Procurement Document Control	NNFD-AP-1211-01 Requisitions RL-IP-1705-01 Procurement Document Control
5. Instructions, Procedures and Drawings	RL-IP-0101-09 Preparation, Review, Authorization and Issuance of Implementing Procedures RL-IP-1706-01 Technical Procedures RL-IP-1706-02 Drawing Preparation and Control RL-IP-1706-08 Preparation of Calibration Procedures RL-IP-1706-10 Procedures Required for Compliance with Federal Regulations RL-IP-1709-03 Route Sheets RL-IP-1711-01 Inspection Checklist
6. Document Control	RL-IP-0101-09 Preparation, Review, Authorization and Issuance of Implementing Procedures RL-IP-1702-03 Preparation of Quality Assurance Program Plans RL-IP-1702-04 Operational Quality Program (OQP) for Radioactive Material Packages RL-IP-1704-02 Preparation of Project Technical Plans RL-IP-1706-01 Technical Procedures RL-IP-1706-02 Drawing Preparation and Control RL-IP-1706-10 Procedures Required for Compliance with Federal Regulations RL-IP-1709-03 Route Sheets RL-IP-1711-01 Inspection Checklist

Criteria	Procedures Applicable to NNFD Research Laboratory
7. Control of Purchased Material, Equipment, and Services	(NNFD-AP) 1211-01 Requisitions RL-IP-1214-01 Receiving RL-IP-1216-01 Shipping RL-IP-1216-03 Transportation of Radioactive Materials RL-IP-1708-01 Supplier Control RL-IP-1708-02 Approved Supplier List RL-IP-1714-01 Receiving Inspection Reports
8. Identification and Control of Materials, Parts, and Components	RL-IP-1217-09 Government-Owned Equipment RL-IP-1709-01 Material Identification Tags RL-IP-1709-02 Control of Customer Furnished Property RL-IP-1709-03 Route Sheets RL-IP-1715-01 Inspection Acceptance Tag RL-IP-1715-02 Discrepancy Tag
9. Control of Special Processes	RL-IP-1706-01 Technical Procedures
10. Inspection	RL-IP-1711-01 Inspection Checklist RL-IP-1711-02 Inspection RL-IP-1714-01 Receiving Inspection Reports RL-IP-1715-01 Inspection Acceptance Tag RL-IP-1715-02 Discrepancy Tag
11. Test Control	RL-IP-1706-01 Technical Procedures RL-IP-1706-10 Procedures Required for Compliance with Federal Regulations RL-IP-1712-01 Test Control RL-IP-1712-03 Logbooks/Laboratory Notebooks
12. Control of Measuring and Test Equipment	RL-IP-1706-01 Technical Procedures RL-IP-1706-08 Preparation of Calibration Procedures RL-IP-1713-01 Measuring Equipment Control and Calibration System RL-IP-1713-02 Out-of-Calibration Report RL-IP-1713-04 Use of Thermocouples RL-IP-1713-05 Manometers RL-IP-1713-06 Strain Gages RL-IP-1718-01 Instrument Service Log
13. Handling, Storage and Shipping	RL-IP-1214-01 Receiving RL-IP-1216-01 Shipping RL-IP-1216-03 Transportation of Radioactive Material RL-IP-1217-01 Equipment Storage RL-IP-1706-01 Technical Procedures RL-IP-1711-01 Inspection Checklist
14. Inspection, Test, and Operating Status	RL-IP-1714-01 Receiving Inspection Reports RL-IP-1715-01 Inspection Acceptance Tag RL-IP-1715-02 Discrepancy Tag

Criteria	Procedures Applicable to NNFD Research Laboratory
15. Nonconforming Materials, Parts or Components	(B&W AP) 1208-A5 Implementation of the Requirements of 10 CFR 21
	(B&W AP) 1716-A1 Reporting of Defects and Noncompliances Concerning Substantial Safety Hazards (10 CFR 21)
	RL-IP-1715-02 Discrepancy Tag
	RL-IP-1716-01 Control of Nonconforming Items
	RL-IP-1716-02 Reporting of Defects and Noncompliance Pursuant to 10 CFR 21
	RL-IP-1717-01 Corrective Action System
16. Corrective Action	RL-IP-1716-02 Reporting of Defects and Noncompliance Pursuant to 10 CFR 21
	RL-IP-1717-01 Corrective Action System
	RL-IP-1719-01 Quality Assurance Audits (Internal)
17. Quality Assurance Records	RL-IP-1718-03 Quality Assurance Records
	(B&W AP) 1311-A2 Records Retention
18. Audits	RL-IP-1717-01 Corrective Action System
	RL-IP-1719-01 QA Audits (Internal)
	RL-IP-1719-02 QA Audits (Supplier)
	RL-IP-1719-04 Lead Auditor Qualification

DESIGN CONTROL

Design activities at the Site are conducted in accordance with procedures which assure applicable quality standards and design features are translated into specifications, drawings, procedures, and instructions. Any deviations or changes from these quality standards are controlled. Design reviews are made by individuals or groups other than those involved in the original design and are specifically directed to those items critical to the quality of the component or system being designed. Suitable design controls are applied to such activities as seismic, stress, thermal, hydraulic, radiation, and accident analysis, compatibility of materials, and accessibility for in-service inspection, maintenance and repair. Designs are also reviewed to assure (1) design characteristics can be controlled, inspected, and tested, and (2) inspection and test criteria are identified. Materials, parts, and equipment which are standard, commercial, or which have been previously approved for a different application are reviewed for suitability prior to selection. Measures are established for the selection of suitable materials, parts, equipment, and processes for safety related structures, systems, and components including the use of valid industry standards and specifications.

Selection and accomplishment of design verification or checking processes by design reviews, alternative calculations or qualification testing are performed. When a test program is used to verify the adequacy of a design, a qualification test of a prototype unit under adverse operating conditions shall be used.

Design interface controls include the review, approval, release, distribution and revision of documents with participating design organizations. Design and specification changes are subject to the same design controls and approvals applicable to the original design. Errors or deficiencies in the design, including the design process, that could adversely affect safety related structures, systems, and components are documented and handled in accordance with Section 16.0 of this manual.

PROCUREMENT DOCUMENT CONTROL

Quality Assurance shall review and approve purchasing documents prior to release to verify inclusion of basic technical requirements, provisions for access to the suppliers facility for source inspection or audit, documentation submittal and retention requirements, quality assurance program requirements, provisions for extending applicable requirements to lower tier suppliers, requirements for material certifications or certificates of conformance, and other applicable 10 CFR Part 71, Subpart H requirements.

Quality Assurance shall verify the proposed supplier has been evaluated and approved according to the provisions of Section 7.0 of this manual and shall notify Purchasing if an approved supplier must be used for a purchase.

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

Changes to purchase requisitions or purchase orders shall receive the same level of approval as the original document.

INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities at the Site are directed by documented instructions, procedures, and drawings appropriate to the circumstances to which they are applied.

Fabrication Drawings are prepared by the appropriate organizations and checked for safety, functional and structural adequacy, and dimensional accuracy for critical components. Drawings are reviewed by responsible groups to verify design requirements. Revision level and approvals are applied to the drawings prior to release for fabrication. Revisions to drawings are subject to the same level of approval as original drawings prior to implementation of changes.

If Quality Assurance determines fabrication, assembly, or process control is required, the drawings shall contain a note stating that route sheets are required.

Route Sheets shall reference the drawing and revision number to be used, indicate the sequence of operations to be followed, provide a place for recording data, reference technical procedures (including revision) to be used in performing the operation, identify acceptance criteria (if not on the drawing or in the technical procedure), and provide for the initials of the person completing the operations. If an independent inspection function is to be employed, the route sheet shall provide for initials of the inspector evaluating the operation.

Inspection Checklists are used for verifying recording of physical characteristics considered critical to the component. Checklists can be used in place of route sheets when the inspection is performed after the part has been completed with no in-process control of fabrication.

Implementing Procedures are used to implement policies and to direct the activities of one or more organizations. They describe interface requirements and provide the detailed work instructions for recurring functions.

Area Operating Procedures and Technical Procedures are used to direct specific technical activities such as the performance of experiments or tests, calibration of equipment, error analysis, or special process control; (i.e., welding, nondestructive examination, etc.). When used as test performance procedures, the technical procedures shall include provisions for assuring test prerequisites have been met (refer to Section 11.0), provisions for recording data either on test data sheets or in test logs, and provisions for customer witnessing of the test are met as required. When material control is required during the performance of a test or experiment, the test procedures shall direct the handling and identification of the controlled material.

The QA organization shall review and concur with technical procedures, inspection plans, drawings and specifications, and changes thereto. Area Operating Procedures are the responsibility of the Licensing and Compliance Officer.

DOCUMENT CONTROL

The documents affecting quality controlled by the provisions of this section are:

Implementing Procedures
Drawings
Inspection Checklists
Quality Assurance Manual
Quality Assurance Plans
Route Sheets
Technical Procedures
Area Operating Procedures

Implementing Procedures are prepared and revised by personnel reporting to the Manager, Safety & Safeguards Department. The resolution of conflicting requirements shall be the responsibility of the Manager, Safety & Safeguards Department. The editing, arranging, and issuing of procedures to authorized personnel is the responsibility of the QA Administrator. The QA Administrator is also responsible for obtaining approval signatures on the master file copy and for retention of historical file copies.

Drawings are to be prepared (as needed) by appropriate organizations and controlled by Plant Engineering. Revision level and approvals are reflected on the drawings and on status cards maintained by Plant Engineering. Original releases and revisions must be approved by the design engineer and the responsible personnel. The QA Administrator maintains a distribution list for each job requiring drawings to assure the latest approved revision applicable to a specific job is used. Drawings are retained as required by contract requirements or Site retention policy.

Inspection Checklists are prepared and revised by the responsible group and approved by the individual specifically responsible for the container. The checklists are issued to the person performing the verification. Completed checklists are returned to the responsible section for inclusion in the project file.

The Quality Assurance Program Manual is prepared by Quality Assurance and approved by the Manager, Safety & Safeguards Department. The Quality Assurance Administrator maintains the distribution lists and issues copies of the manual on a controlled and uncontrolled basis. Controlled manuals have an issue number assigned to each recipient and are kept up-to-date. Uncontrolled copies are issued on a one-time basis for information only. A record of recipients of uncontrolled copies shall be maintained. Revisions of the manual are subject to the same control as the original release.

Quality Assurance Plans for projects are prepared by the Quality Assurance Administrator with input from those personnel responsible for the use, repair, design or construction of the container. The responsible group maintains the distribution lists. Revisions are subject to the same control as the originals.

Route Sheets are prepared when fabrication, assembly, or process control is required. Route sheets shall be reviewed and approved by Quality Assurance prior to release to the project construction supervisor. Revisions to route sheets shall receive the same control as the originals.

Technical Procedure initiation and approval are the responsibility of the user organization. The originator is responsible for the technical content, revision, approvals, and identifying distribution. Quality Assurance shall provide the originator with a unique identification number. Once the procedure has been approved, Quality Assurance shall obtain final release, reproduce and distribute copies. Revisions require the same levels of approval as the original.

Area Operating Procedure initiation and approval are the responsibility of the Licensing and Compliance Officer. The Licensing and Compliance Officer is responsible for numbering, content, revision, approval and distribution. Once the procedure has been approved, the Licensing and Compliance Officer shall obtain final release, reproduce and distribute of copies. Revisions require the same levels of approval as the original.

CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

When required, pre-award audits and surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment and components will be planned and performed in accordance with written procedures to assure conformance to quality and purchase order requirements. These procedures provide for instructions specifying the characteristics or processes to be witnessed, inspected, or verified, and accepted; the method of surveillance and the extent of documentation required; and individuals responsible for implementing these instructions. Suppliers are periodically evaluated by audits, independent inspections, or test to assure their certificates of conformance are valid.

Source Evaluation and Selection

If evaluation and selection of suppliers is required by the Quality Assurance Plan, one of the following criteria shall be used:

a. The supplier must have a previous and continuous record of supplying acceptable items, processes, or services to the requirements of the Site procurement documents. For purposes of meeting this criterion, the Site may elect to use supplier quality history data obtained from other B&W divisions or other organizations in the nuclear industry provided the data is for similar items, processes, or services purchased.

b. If deemed necessary, an audit of the supplier's quality assurance system at his facility shall be performed to determine acceptability.

c. For commercial or "off the shelf" items, a receiving inspection should be performed to determine compliance with procurement document requirements.

Approved Supplier List

Once a supplier has been evaluated and approved, Quality Assurance shall add the supplier's name to the Site Approved Supplier List. The list will be distributed to appropriate personnel at the Site and to the Purchasing Department. Purchase

orders for items requiring quality assurance according to this section must be placed with suppliers shown on the Approved Supplier List.

Supplier Audits

If an audit of a supplier's quality system is required by the Site, the audit shall be coordinated with Quality Assurance, Purchasing, and the cognizant project leader. The audit shall be performed in accordance with Section 18.0 of this manual. Supplier audits for DOT specification containers are not performed.

Source Inspection

When source inspection is required, an inspection plan shall be developed by the project leader and Quality Assurance. It will designate specific witness and hold points. Copies of the source inspection reports shall be maintained on file by the project leader and Quality Assurance. Surveillance shall be performed on items for which verification of procurement requirements cannot be determined upon receipt.

Receiving Inspection

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

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

b. Materials, components, equipment, and acceptance records are inspected and judged acceptable in accordance with pre-determined inspection instructions, prior to installation or use.

c. Inspection records or certificates of compliance attesting to the acceptance of materials, components, and equipment are available prior to installation or use.

d. Items accepted and released are identified by inspection status prior to forwarding to a controlled storage area or releasing for installation or fabrication.

Requirements for receiving inspection shall be noted on the purchase order. A copy of the purchase order shall be forwarded to the receiving group. Upon arrival, items shall be segregated and not released for use until accepted by inspection. If specific procedures are required to perform the inspection, they shall be provided to the inspector prior to commencement of the receipt inspection. A notation of special instructions and requirements shall be made on the purchase order.

Supplier Procedures

Requirements for suppliers to submit specific procedures for Site review and approval shall be included (as applicable) on the purchase order. When the procedures are received, they shall be routed to the project leader for review and approval. Supplier QA procedures shall be reviewed by Quality Assurance and the project leader. Supplier QA manuals shall be routed to QA for review, approval and retention.

Records

Suppliers shall furnish the following records:

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

b. Documentation identifying 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 QA Program and shall be undertaken by a responsible QA representative.

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

Material shall be controlled using a system of tags, route sheets, and technical procedures, as necessary, to assure accurate recording of traceability of material by part number, lot number, serial number, or heat number. Identification must be verified and documented. Identification requirements are determined during generation of specifications and design drawings.

Procedures direct the use of a tagging system to be applied to all controlled materials. When route sheets or technical procedures are used, material identification shall be transferred to route sheets, test data sheets, or test logs to maintain accountability and control during fabrication and assembly or during the performance of a test or experiment. Upon completion of the activity, the parts or material shall be re-identified to reflect their resulting condition. The location and the method of identification shall in no way affect the fit, function, or quality of the item being identified.

CONTROL OF SPECIAL PROCESSES

Special processing techniques used to support fabrication or performance of an experiment or test shall be documented in technical procedures with the requisite approvals. Qualification of the equipment to be used shall either be in accordance with the direction provided by the technical procedure or by standard calibration procedures used as a part of the normal measurement control program defined in Section 12.0 of this manual. If personnel qualifications are required (such as for welding), appropriate qualification records shall be maintained reflecting examination results, training records, and maintenance of proficiency. In most areas, the performance of a special process (for example, NDE) is by laboratory personnel directly engaged in the research aspects of the process who are, by nature of their work, qualified well above standards imposed on production facilities. When required in direct support of an experiment or test, appropriate process control records shall be maintained.

INSPECTION

Inspections are performed on those activities affecting quality to assure conformance with documented instructions, procedures, and drawings. The need for inspection is identified on the receiving copy of the purchase order, route sheets, technical procedures, and/or inspection checklists. Mandatory inspection hold points for witness by an inspector shall also be identified on these documents. Critical dimensions are identified on the drawings. Any modifications, repairs, or replacements shall be inspected in accordance with the original design and inspection requirements or acceptable alternatives. When direct inspection is not possible, indirect control shall be achieved by monitoring processing methods, equipment, personnel, etc.

Inspection shall be performed by a person(s) familiar with the operation being inspected. Inspectors shall be qualified in accordance with applicable codes, standards, and training program qualifications and certifications shall be kept current.

TEST CONTROL

Test control is achieved by use of technical procedures (reference Section 5.0). Responsibility for preparation of the test program and the test performance procedure is assigned to the project leader, who also obtains the necessary document approvals. The revision and distribution control is described in Section 6.0 of this manual. Each test procedure shall include provisions for ensuring test prerequisites have been met. Prerequisites include items such as calibrated instrumentation, appropriate equip- ment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions and provisions for data acquisition. Written test procedures shall incorporate the following:

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

b. Instructions for performing the test.

c. Mandatory inspection hold points for witness by owner, contractor, or inspector.

d. Acceptance and rejection criteria.

Test data and results shall be documented using test logs, data sheets, or a computer data acquisition system. These data shall be analyzed by the project engineer and reviewed by his supervisor to ensure test objectives have been met.

CONTROL OF MEASURING AND TEST EQUIPMENT

A documented system is established and maintained to assure tools, gauges, instruments, inspection and measuring and test equipment used in activities affecting quality are of the proper range, type and accuracy to verify conformance to established requirements.

This system, as a minimum, meets the requirements of Specification MIL-STD-45662, "Calibration System Requirements."

The system includes calibration and certification [illegible] calibration procedures, and a recall system to assure equipment is calibr[illegible] established intervals. The accuracy of calibrated equipment is assured b[illegible] following:

a. Traceability to standards maintained by the National Institute of Standar[illegible] and Technology (NIST).

b. Comparison to natural physical phenomena.

c. The ratio type of self-calibration techniques.

Items within this system are given a unique serial number for traceability to calibration test data. Calibrations are recorded on a service log form showing the serial number of the item and the procedure to which it is calibrated. A label is applied to the item to indicate the calibration status, including calibration due date. The complete status of items under the calibration system is maintained.

If inspection and measuring and test equipment is found to be out of tolerance, an Out-of-Calibration Report is issued by the Instrument Group. An evaluation of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested is made and documented. If inspection and measuring or test equipment is consistently found to be out of calibration, it is repaired or replaced.

Calibration standards have an uncertainty (error) requirement of no more than one-fourth of the tolerance of the equipment being calibrated. A greater uncertainty may be acceptable when limited by "state-of-the-art."

HANDLING, STORAGE, AND SHIPPING

Special handling, storage, shipping, packaging, preservation, or cleaning instructions required for containers are identified by the project leader. The project leader either issues a technical procedure detailing these requirements or coordinates with the designers to have the requirements defined on drawings. The technical procedures include provisions for recording inspection data when such inspection is required. If drawings are used, the drawings shall require route sheets or inspection checklists to document accomplishment of tasks and the inspection (if necessary) of the activity.

Special handling and loading procedures for NRC approved containers are documented in the specification, certificate of compliance, or referenced procedure. Completion of these requirements is assured by the project leader and are documented.

INSPECTION, TEST, AND OPERATING STATUS

If required by contract or work order involving material control, a system of markings, tags, route sheets, inspection checklists, test data sheets, test logs, or inspection records are used to identify the inspection and test status. This system assures nonconforming items are clearly marked and only items having passed the required inspections or tests are used. This system includes written procedures for control of the above listed status indicators. Bypassing of required inspections, tests, and other critical operations is procedurally controlled under the cognizance of the Quality Assurance organization. When required, this system also includes a means for indicating operating status of test systems.

NONCONFORMING MATERIALS, PARTS OR COMPONENTS

Nonconforming items shall be tagged with a red "discrepancy" tag, segregated whenever possible, and the nonconformance documented on a Corrective Action Report (CAR). The CAR identifies the nonconforming item, describes the nonconformance, the disposition of the nonconformance, the inspection requirements, and includes signature approval of the disposition.

The project leader shall review nonconformances to determine adverse effects to the test results, finished products or repairs. The project leader shall approve actions taken to correct the nonconformance or to "use-as-is." Quality Assurance shall approve all Corrective Action Reports and, when the nonconformance is satisfactorily resolved, shall remove the "discrepancy" tag from the item.

In instances requiring a "repair" or "use-as-is" decision, the project leader shall determine whether such a decision causes a deviation to customer requirements or commitments made in the proposal or project technical plan. If a deviation exists, the project leader must obtain approval from the customer before implementing the "repair" or "use-as-is" decision. Acceptability of rework or repair of materials, parts, components, systems, and structures is verified by re-inspecting and re-testing 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 shall be documented.

CORRECTIVE ACTION

There are three facets to the corrective action system. The first is the corrective action obtained for a specific hardware nonconformance (see Section 15.0). Quality Assurance shall verify the appropriate corrective action has been taken before final acceptance of the Corrective Action Report.

The second facet is corrective action obtained during formal audits. Quality Assurance performs periodic audits as described in Section 18.0 of this manual. When quality system deficiencies are detected, they are identified in the audit report. The response to audit findings is evaluated by Quality Assurance for adequacy. After the time for implementation of the corrective action has elapsed, Quality Assurance shall verify the action was taken and is effective.

The third facet of corrective action is a quality system deficiency detected by means other than a specific nonconformance or audit finding. When an incident has occurred or a condition exists which could jeopardize the attainment of Quality Assurance objectives, Quality Assurance shall initiate a Corrective Action Report describing the deficiency and shall forward the report to the cognizant project leader, group supervisor or section manager. Note: Deficiencies involving multiple projects, tests, programs or sections shall be reported to the appropriate section manager(s) for corrective action. The recipient shall (1) conduct an investigation of the cause of the incident or condition, (2) document on the report form the results of the investigation and the corrective action, and (3) forward the report to Quality Assurance. Quality Assurance shall follow up within a reasonable time to assure the corrective action has been implemented and is effective.

If a quality system deficiency is considered to be significant, Quality Assurance will immediately notify the cognizant project leader, group supervisor, section manager, and laboratory manager and shall require a work stoppage in the affected area of operation until the condition has been corrected. A report of this action shall be made to the Manager, Safety & Safeguards Department within forty-eight hours.

QUALITY ASSURANCE RECORDS

The Site has a system for preparation, collection and retention of records sufficient to provide documentary evidence of activities affecting quality and (where applicable) of the acceptability of materials, parts, or assemblies having an effect on the validity of the test or experiment. These records shall be consistent with applicable codes, standards, specifications, and contracts and shall be adequate for use in managing the program. The records shall be identifiable and retrievable.

The system encompasses those records required by each section of the manual, but specific records shall be generated only if the applicable section of this manual is invoked by the Quality Assurance Plan for the project. QA records may include (as applicable) results of reviews, inspections, tests, audits, material analyses and monitoring of work performance, qualifications of personnel, procedures, and equipment, and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, nonconformance reports, and corrective action reports.

Inspection and test records shall, as a minimum, identify the inspector or person recording data, the type and date of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

Permanent retention of records shall be in accordance with B&W policy and as required by contract work order or applicable codes, standards or specifications. B&W policy provides for permanent record retention in an established storage facility located and secured to prevent destruction of the records by fire, flooding, theft, and deterioration by environmental conditions such as temperature or humidity.

AUDITS

Quality Assurance shall implement a system of audits to verify compliance with the Quality Assurance Program and to include an objective evaluation of quality related practices, procedures, and instructions and the effectiveness of implementation. Audits shall, more specifically, consist of an objective evaluation of work areas, activities, processes, and items and the review of comments and records. The audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel having no direct responsibilities in the areas being audited. The audit team may employ other personnel with additional technical expertise to ensure a comprehensive assessment of the activity.

Internal audits shall be performed on individual projects to verify compliance with the Quality Assurance Plan. Audits shall also be performed on selected systems which apply to more than one project. Project audits shall be performed at least once during the project or at least once annually, whichever is the shorter interval.

Supplier audits shall be performed when required by the provisions of Section 7.0 of this manual. Site procurements do not require long supplier production runs; therefore, the Site policy is to perform a pre-award evaluation and then monitor the supplier's quality system using selected source inspections and receiving inspection data. Supplier audits must be performed at intervals consistent with the importance, complexity, and quantity of the item.

Audit findings shall be documented in a formal audit report and transmitted to the project leader and group supervisor (for project audits), the cognizant section manager (for generic system audits), or to the supplier. If deficiencies have been found, the recipient of the audit report shall be required to take the necessary corrective action and report the action taken (or scheduled) to QA within ten working days. Quality Assurance shall follow up to verify the committed corrective action has been taken and is effective.

Supplementing the formal audits is a program of informal surveillance conducted by Quality Assurance during the course of a project. The Quality Assurance Administrator shall monitor the activities to assure the project is being conducted in accordance with the QA Plan. Any deficiencies requiring formal corrective action shall be documented on a Corrective Action Report and resolved in accordance with Section 16.0 of this manual.