AN AMERICAN NATIONAL STANDARD

Quality Assurance Program Requirements for Nuclear Facilities

ANSI/ASME N45.2 - 1977

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(REVISION OF N45.2-1971)

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AMERICAN NATIONAL STANDARD

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This standard was approved by the American National Standards Committee N45 and its Secretariat, and it was subsequently approved and designated N45.2-1977/N46.2-1977 by the American National Standards Institute on April 7, 1977.

FOREWORD

(This foreword is not a part of American National Standard for Quality Assurance Program Requirements for Nuclear Facilities.)

This standard sets forth requirements for overall Quality Assurance Programs for nuclear facilities. The standard was developed by the American National Standards Committee N45, Reactor Plants and Their Maintenance.

On April 17, 1969, the Atomic Energy Commission (AEC) published in the Federal Register, Volume 34, No. 73, a proposed amendment to 10 CFR 50 which would add an Appendix B, "Quality Assurance Criteria for Nuclear Power Plants." Appendix B was officially issued on June 27, 1970, and published in the Federal Register, Volume 35, No. 125. Requirements of 10 CFR 50, Appendix B, apply directly to and place responsibility on the Applicant (plant owner) for the establishment and execution of the total Quality Assurance Program. Appendix B provides quality assurance requirements for the design, construction, and operation of those structures, systems, and components from which satisfactory performance is required to prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The requirements of Appendix B apply to all activities affecting the safety related functions of structures, systems, and components including designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

In May 1969, the ASME Boiler and Pressure Vessel Committee's Subcommittee on Nuclear Power expanded its scope of activities to include major components of the nuclear power system of a plant. A new Section III of the Boiler and Pressure Vessel Code was published as the 1971 Edition of the Code. The quality assurance provisions of that Code apply directly to owners, manufacturers, and installers of nuclear power system components and include provisions for the establishment and execution of a Quality Assurance Program for items and activities covered by the Code. The Quality Assurance Program requirements of Section III of the ASME Code are consistent with the requirements of this standard.

In May 1969, the American National Standards Committee N45 established an ad hoc Committee on Quality Assurance Program Requirements. The purpose of this committee was to prepare a standard for general industry use that would, among other things, satisfy the intent and amplify the requirements of the AEC quality assurance regulations and provide a basis for the development of detailed quality assurance practices and procedures. The ad hoc committee was composed of representatives of the AEC and key segments of the nuclear industry, including utilities, reactor suppliers, plant engineers, and constructors. In 1970 a new N45-2 Subcommittee on Nuclear Quality Assurance Standards was formed to provide for the preparation, coordination, and approval of this standard and other N45.2-series standards; the initial issue of N45.2-1971 resulted from the efforts of this subcommittee.

This standard sets forth the general provisions for planning, managing, and performing overall Quality Assurance Programs by the applicant or by any participating organization for the design, construction, and operation of safe and reliable nuclear facilities. This standard does not define specific or detailed technical requirements for achieving or verifying quality. Therefore, it may be necessary for supplementary general provisions or specific methods, procedures, or techniques to be added to the Quality Assurance Program required by this standard in order to comply with applicable codes, standards, or contract requirements for a particular segment of the facility. In addition to this standard, other nuclear quality assurance standards have been issued or are being developed as American National Standards. These standards set forth more detailed requirements and guidelines for certain activities to assure quality of nuclear power plants and are intended to be used in conjunction with this standard, where appropriate.

The ASME Code, as well as other American National Standards, have been considered in the development of this standard, and this standard is intended to be compatible with their requirements. However, this standard does not apply to activities covered by Section III and Section XI of the Code.

This revision to N45.2-1971 was prepared by the N45-2.7 Work Group in cooperation with the N45-2 Subcommittee to cover the following nuclear facilities: nuclear power plants, fuel reprocessing plants, plutonium processing plants, plutonium fuel fabrication plants, and spent fuel storage facilities. This revision was balloted by the N45-2, N45, N46, N46-2 and N18 Committees.

A standard, N18.7-1972 (ANS 3.2) entitled "Administrative Controls for Nuclear Power Plants", has been prepared under the sponsorship of the American Nuclear Society with cognizance of the American National Standards Committee N18. This standard includes, among other things, requirements for certain activities to assure quality of nuclear power plants during operation. This standard is intended to supplement the requirements of N45.2-1971 during reactor operation. A revision to N18.7-1972 is being prepared with the intent to provide or reference, in a single document, quality assurance requirements during the operations phase of nuclear power plants. When this revision to N18.7 is issued, this standard will be appropriately amended.

Suggestions for improvement gained in the use of this standard will be welcome. They should be sent to the Secretary, ASME Committee on Nuclear Quality Assurance, The American Society of Mechanical Engineers, Nuclear Dept., United Engineering Center, 345 East 47th Street, New York, New York 10017.

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QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR NUCLEAR FACILITIES

1. INTRODUCTION

1.1 Scope

This standard provides general requirements and guidance for the establishment and execution of Quality Assurance Programs for the design, construction, and operation of structures, systems, and components of the following nuclear facilities: nuclear power plants, fuel reprocessing plants, plutonium processing plants, plutonium fuel fabrication plants, and spent fuel storage facilities. The requirements and guidance pertain to activities, including designing, procuring, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying, which affect the quality of structures, systems, and components.

1.2 Applicability

This standard is intended to apply to the facility owner, major contractors, such as the nuclear steam supply system designer or supplier, process equipment designer or supplier, the architect-engineer or facility designer, the constructor, and other organizations participating in activities affecting quality. The extent to which the individual sections and elements of this standard are applied will depend upon factors such as the nature and scope of activities to be performed and the required quality of items and services.

The ASME Boiler and Pressure Vessel Code, as well as other American National Standards have been considered in the development of the standard, and this standard is intended to be compatible with their requirements. However, this standard does not apply to activities covered by Section III and Section XI of the Code.

1.3 Responsibility

It is the responsibility of the facility owner to provide for the establishment and execution of a Quality Assurance Program for the facility consistent with the provisions of this standard. The facility owner or his designated representative and other organizations invoking this standard are responsible for identifying the structures, systems, and components and for specifying the extent to which the provisions of this standard apply. The facility owner or his designated representative and other organizations are also responsible for assuring that the necessary and appropriate requirements of this standard are invoked. The facility owner may delegate to other organizations the work of establishing and executing the Quality Assurance Program, or any part thereof, but shall retain responsibility for overall program effectivenesses. In no way shall the program operate to diminish the responsibility of any contractor for the quality of items or services furnished or for execution of the contractor's designated portion of the Quality Assurance Program.

1.4 Definitions

The following definitions are provided to assure a uniform understanding of select terms as they are used in this standard.

Characteristic – Any property or attribute of an item, process, or service that is distinct, describable, and measurable as conforming or nonconforming to specified quality requirements. Quality characteristics are generally identified in specifications and drawings which describe the item, process, or service.

Contractor – Any organization under contract for furnishing items or services. It includes the terms vendor, supplier, subcontractor, fabricator, and subtier levels of these where appropriate.

Documentation – Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Guidelines – Particular provisions which are considered good practice but which are not mandatory in programs intended to comply with this standard. The term *should* denotes a guideline, the term *shall* denotes a mandatory requirement.

Item – Any level of unit assembly, including structure, system, subsystem, subassembly, component, part, or material.

Nonconformance – A deficiency in characteristic, documentation, or procedure which renders the quality of an item unacceptable or indeterminate. Examples of nonconformance include: physical defects, test failures, incorrect or inadequate documentation, or deviations from prescribed processing, inspection or test procedures.

Objective Evidence – Any statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item or service based on observations, measurements, or tests which can be verified.

Owner – The person, group, company, or corporation who has or will have title to the facility or installation under construction.

Procurement Documents – Contractually binding documents that identify and define the requirements which items or services must meet in order to be considered acceptable by the purchaser.

Quality Assurance – All those planned or systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service.

Quality Control – Those quality assurance actions which provide a means to control and measure the characteristics of an item, process, or facility to established requirements.

Repair – The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still may not conform to the original requirement.

Rework – The process by which a nonconforming item is made to conform to a prior specified requirement by completion, remachining, reassembling, or other corrective means.

1.5 Referenced Documents

Other documents that are required to be included as part of this standard will be identified at the point of reference.

2. QUALITY ASSURANCE PROGRAM

A documented Quality Assurance Program which complies with the applicable sections and elements of this standard shall be established at the earliest practical time consistent with the schedule for accomplishing the activities for the nuclear facility. The establishment of the program shall include considerations of the technical aspects of the activities to be performed. The program shall contain provisions to assure identification of and compliance with requirements of pertinent ANSI and other recognized and appropriate engineering codes, standards, requirements, and practices.

The program shall define the organizational structure within which the Quality Assurance Program is to be planned and implemented and shall clearly delineate the responsibility and authority of the various personnel and organizations involved.

The program shall identify the items and services to which this and other standards apply. Since items and services will differ in regard to relative safety, reliability, and performance importance, various methods or levels of control and verification may be used to assure adequate quality. Regardless of the methods or levels used, the program shall provide for the assurance of quality consistent with applicable codes, standards, and other requirements. Some factors to be considered in assigning methods or levels of quality assurance are as follows:

(1) the consequence of malfunction or failure of the item
(2) the design and fabrication complexity or uniqueness of the item
(3) the need for special controls and surveillance over processes and equipment
(4) the degree to which functional compliance can be demonstrated by inspection or test
(5) the quality history and degree of standardization of the item
(6) the difficulty of repair or replacement

The program shall provide assurance that activities affecting quality are documented within a document control system and accomplished in accordance with written instructions, procedures, or drawings.

The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

The program shall provide for the accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality and the need for verification of quality by inspection, examination, or test.

The program shall provide for the regular review, by management of organizations participating in the program, of the status and adequacy of that part of

the Quality Assurance Program for which they have designated responsibility.

3. ORGANIZATION

The organizational structure, functional responsibilities, levels of authority, and lines of internal and external communication for management, direction, and execution of the Quality Assurance Program shall be documented. Where multiple organizational arrangements exist, the responsibility of each organization shall be clearly established.

The authority and responsibility of persons and organizations performing activities affecting quality shall be clearly established. Persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to:

(1) identify quality problems;
(2) initiate, recommend, or provide solutions, through designated channels;
(3) verify implementation of solutions; and
(4) control further processing, delivery, or installation of a nonconforming item, deficiency, or unsatisfactory condition until proper dispositioning has occurred.

The person or organization responsible for defining and measuring the overall effectiveness of the Quality Assurance Program shall be designated, shall be sufficiently independent from the pressures of production, shall have direct access to responsible management at a level where appropriate action can be required, and shall report regularly on the effectiveness of the program.

The organizational structure and the functional responsibility assignments shall be such that:

(1) attainment of quality objectives is accomplished by those who have been assigned responsibility for performing work; e.g., the designer, the welder, or the nuclear facility operator. This may include interim examinations, checks, and inspections of the work by the individual performing the work.
(2) verification of conformance to established quality requirements is accomplished by those who do not have direct responsibility for performing the work; e.g., the design reviewer, the checker, the inspector, or the tester.

In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group. For example, it may be more appropriate for design engineers to perform design reviews rather than quality assurance engineers because of the special competence required to perform these reviews. Quality assurance encompasses many functions and activities and extends to various levels in all participating organizations, from the top executive to all workers whose activities may influence quality.

4. DESIGN CONTROL

4.1 General

Measures shall be established and documented to assure that the applicable specified design requirements, such as design bases, regulatory requirements, codes, and standards are correctly translated into specifications, drawings, procedures, or instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included or referenced in design documents. Changes or deviations from specified design requirements or quality standards shall be identified, documented, and controlled. Records of implementation of these design control measures shall be available for review.

Design control measures shall provide for design analyses, such as physics, stress, thermal, hydraulic, accident; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the function of the structure, system, or component.

4.2 Interface Control

Design control measures shall be applied as necessary to identify and control design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

4.3 Design Verification

Design control measures shall be applied to verify or check the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who perform the original design but who may be from the same organization.

Verifying or checking should consist of, as a minimum, reviewing the design, spot-checking the calculations or analyses, and assessing the results against the original design bases and functional requirements. The responsible design organization shall identify the particular design verification methods utilized.

There are many ways of performing design reviews, and various depths of reviews may be required depending upon the importance and complexity of the design being reviewed, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. Regardless of the degree of standardization or similarity to previously proven designs, the applicability of standardized or previously proven designs with respect to meeting pertinent design requirements shall be verified for each application. The methods for design review can range from a formalized, multi-organization review to an informal, single-person review. The depth of review can range from a detailed check of the complete design to a limited check of such things as the design approach and the results obtained in the original design.

In those cases where the adequacy of a design is to be verified by tests, the testing shall be identified. Testing shall demonstrate adequacy of performance under the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. If testing indicates that modifications to the item are necessary to obtain acceptable performance, the item shall be modified and retested as necessary to assure satisfactory performance.

4.4 Change Control

Design changes, including field changes, shall be governed by design control measures commensurate with those applied to the original design. It is the intent of this standard that design changes be reviewed and approved by the organizations that performed the original design, review, and approval. In the event that it is not practical for the original organizations to perform the required review or approval, other responsible design organizations may be designated, provided the designated organizations have access to pertinent background information, have demonstrated competence in the specific design area of interest, and have adequate understanding of the requirements and intent of the original design.

5. PROCUREMENT DOCUMENT CONTROL

Measures shall be established and documented to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are included or referenced in the documents for procurement of items and services. Changes in procurement documents shall be subject to the same degree of control as was utilized in the preparation of the original document. To the extent necessary, procurement documents shall require contractors to provide a Quality Assurance Program consistent with the pertinent requirements of this standard.

Procurement documents shall include provisions for the following, as applicable:

(1) *Supplier Quality Assurance Program.* Identification of quality assurance requirements and the elements of the program applicable to the items or services procured. This may be accomplished in various ways, such as the following:

(a) invoking this standard by reference, or
(b) invoking applicable sections or elements of this standard, or
(c) invoking other specific requirements which meet the intent of this standard.

(2) *Basic Technical Requirements.* Drawings, specifications, codes and industrial standards with applicable revision data, test and inspection requirements, and special instructions and requirements, such as for designing, fabricating, cleaning, erecting, packaging, handling, shipping, and, if applicable, extended storage in the field; and for test equipment.

(3) *Source Inspection and Audit.* Provisions for access to the plant facilities and records for source inspection and audit when the need for such inspection or audit has been determined.

(4) *Documentation Requirements.* Records to be prepared, maintained, submitted, or made available for review, such as drawings, specifications, procedures, procurement documents, inspection and test records, personnel and procedure qualifications, and material, chemical, and physical test results. Instruction on record retention and disposition shall be provided.

(5) *Lower Tier Procurements.* Provisions for extending applicable requirements of procurement documents to lower tier subcontractors and suppliers, including purchaser's access to facilities and records.

6. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall

be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative criteria for determining that important activities have been satisfactorily accomplished.

The activity may be prescribed in job specifications, work instructions, shop construction drawings, job tickets, planning sheets, operating or procedure manuals, test procedures, or any other type of written form, provided that the activity is adequately described. Quantitative criteria, such as dimensions, tolerances, and operating limits, and qualitative criteria, such as comparative workmanship samples, shall be specified, as appropriate, for determining satisfactory work performance and quality compliance.

7. DOCUMENT CONTROL

Measures shall be established and documented to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organizations shall have access to pertinent background information upon which to base its approval and shall have adequate understanding of the requirements and intent of the original document.

Those participating in an activity shall be made aware of and use proper and current instructions, procedures, drawings, and engineering requirements for performing the activity. Participating organizations shall have procedures for control of the documents and changes thereto to preclude the possibility of use of outdated or inappropriate documents.

Document control measures shall provide for:

(1) identification of individuals or organizations responsible for preparing, reviewing, approving, and issuing documents and revisions thereto;
(2) identifying the proper documents to be used in performing the activity;
(3) coordination and control of interface documents;
(4) ascertaining that proper documents are being used;
(5) establishing current and updated distribution lists.

8. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Measures shall be established and documented to assure that purchased items and services, whether purchased directly or through contractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection and audit at the source, and examination of items upon delivery.

Measures for evaluation and selection of procurement sources include the use of historical quality performance data, source surveys or audits, or source qualification programs.

Source inspection or audit shall be performed as necessary to assure the required quality of an item. Source inspection or audit may not be necessary when the quality of the item can be verified by review of test reports, inspection upon receipt, or other means.

Where required by code, regulation, or contract requirements, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use of such items. This documentary evidence shall be retained at the nuclear facility site and shall be sufficient to identify the specific requirements such as codes, standards, and specifications met by the purchased item. Where not precluded by other requirements, such documentary evidence may take the form of written certifications of conformance which identify the requirements met by the items, provided means are available to verify the validity of such certifications.

The effectiveness of the control of quality shall be assessed by the purchaser at intervals consistent with the importance, complexity, and quality of the item or service.

9. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Measures shall be established and documented for the identification and control of materials, parts, and components including partially fabricated subassemblies. These measures shall provide for assuring that only correct and accepted items are used and installed, and relating an item of production (batch, lot, component, part) at any stage, from initial receipt through fabrication, installation, repair or modification, to an applicable drawing, specification, or other pertinent technical document. Physical identification shall be used to the maximum extent possible. Where physical identification is either impractical or insuf-

ficient, physical separation, procedural control, or other appropriate means shall be employed. Identification may be either on the item or on records traceable to the item, as appropriate.

Where identification marking is employed, the marking shall be clear, unambiguous, and indelible, and shall be applied in such a manner as not to affect the function of the item. Markings shall be transferred to each part of an item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

When codes, standards, or specifications require traceability of materials, parts, or components to specific inspection or test records, the program shall be designed to provide such traceability.

10. CONTROL OF SPECIAL PROCESSES

Measures shall be established and documented to assure that special processes, including welding, heat treating, cleaning, and nondestructive examination, are accomplished under controlled conditions in accordance with applicable codes, standards, specifications, criteria, and other special requirements, using qualified personnel and procedures. Qualification of personnel, procedures, and equipment shall comply with the requirements of applicable codes and standards. Documentation shall be maintained for currently qualified personnel, processes, or equipment in accordance with the requirements of pertinent codes and standards. For special processes not covered by existing codes or standards, or where item quality requirements exceed the requirements of established codes or standards, the necessary qualifications of personnel, procedures, or equipment shall be defined.

11. INSPECTION

A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance to the documented instructions, procedures, and drawings for accomplishing the activity. Inspection activities to verify the quality of work shall be performed by appropriately trained persons other than those who performed the activity being inspected. Such persons shall not report directly to the immediate supervisors who are responsible for the work being inspected.

Examinations, measurements, or tests of items processed shall be performed for each work operation where necessary to assure quality. Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices and shall provide adequate justification for the sample size and selection process.

If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both.

If mandatory inspection hold points, which require witnessing or inspecting by the purchaser's designated representative and beyond which work shall not proceed without the consent of the purchaser's designated representative, are required, the specific hold points shall be indicated in appropriate documents. Such consent shall be documented prior to the continuation of work beyond the designated hold point.

A program for required inservice inspection of completed systems, structures, and components shall be planned and executed by or for the organization responsible for operation of the nuclear facility.

12. TEST CONTROL

A test program shall be established to assure that all testing required to demonstrate that the item will perform satisfactorily in service is identified and documented, and that the testing is performed in accordance with written test procedures which incorporate or reference the requirements and acceptance limits contained in applicable design documents. The test program shall cover all required tests, including, as appropriate, prototype qualification tests, proof tests prior to installation, preoperational tests, and operational tests to verify continued satisfactory performance during operation. Test requirements and acceptance criteria shall be provided by the organization responsible for the design of the item under test, unless otherwise designated.

Test procedures shall include provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, and that necessary monitoring is performed. Prerequisites include such items as calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. Test results shall be documented and evaluated by responsible authority to assure that test requirements have been satisfied.

13. CONTROL OF MEASURING AND TEST EQUIPMENT

Measures shall be established and documented to assure that tools, gages, instruments, and other in-

spection, measuring, and testing equipment and devices used in activities affecting quality are of the proper range, type, and accuracy to verify conformance to established requirements. To assure accuracy, inspection, measuring, and test equipment shall be controlled, calibrated, adjusted, and maintained at prescribed intervals or prior to use against certified equipment having known valid relationships to nationally recognized standards. If no national standards exist, the basis for calibration shall be documented. This requirement is not intended to imply a need for special calibration and control measures on rulers, tape measures, levels, and such other devices, if normal commercial practices provide adequate accuracy.

The method and interval of calibration for each item shall be defined and shall be based on the type of equipment, stability characteristics, required accuracy, and other conditions affecting measurement control. Special calibration shall be performed when accuracy of the equipment is suspect. When inspection, measuring, and test equipment are found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. If any inspection, measuring, or test equipment is consistently found to be out of calibration, it shall be repaired or replaced.

Records shall be maintained and equipment suitably marked to indicate calibration status.

14. HANDLING, STORAGE, AND SHIPPING

Measures shall be established and documented to control handling, storage, and shipping, including cleaning, packaging, and preservation of material and equipment in accordance with established instructions, procedures, or drawings to prevent damage, deterioration, and loss. When necessary for particular items, special coverings, special equipment, and special protective environments such as inert gas atmosphere, specific moisture content levels, and temperature levels shall be specified, provided, and their existence verified.

For critical, sensitive, perishable, or high-value articles, specific written procedures for handling, storage, packaging, shipping, and preservation should be used. Special handling tools and equipment should be provided and controlled as necessary to ensure safe and adequate handling.

Special handling tools and equipment shall be inspected and tested, in accordance with written procedures and at specified times, to verify that the tools and equipment are adequately maintained.

Special attention shall be given to providing adequate instructions for marking and labeling for packaging, shipment, and storage of items. Marking shall be adequate to identify, maintain, and preserve the shipment, including indication of the presence of special environments or the need for special control.

15. INSPECTION, TEST, AND OPERATING STATUS

Measures shall be established and documented to identify inspection and test status. Such measures shall provide means for assuring that required inspections and tests are performed and that the acceptability of items with regard to inspections and tests performed is known throughout manufacturing, installation, and operation. Nonconforming items shall be clearly identified.

The inspection and test status of items shall be maintained through the use of status indicators such as physical location and tags, markings, shop travelers, stamps, or inspection records. The measures shall provide for assuring that only items that have passed the required inspections and tests are used, installed, or operated. These measures shall include procedures for control of status indicators, including the authority for application and removal of tags, markings, labels, and stamps.

Measures shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.

16. NONCONFORMING ITEMS

Measures shall be established and documented to control items, services, or activities which do not conform to requirements. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures. The responsibility and authority for the disposition of nonconforming items shall be defined. Repaired and reworked items shall be reinspected in accordance with applicable procedures.

Measures which control further processing, delivery, or installation of a nonconforming or defective item pending a decision on its disposition shall be established and maintained. Nonconforming items may be disposed of by acceptance *as is*, by scrapping or repairing the defective item, or by rework to complete or correct to a drawing or specification. Such measures shall provide assurance that the item is identified as nonconforming and controlled. The measures shall require documentation verifying

the acceptability of nonconforming items which have the disposition of *repair* or *use as is*. A description of the change, waiver, or deviation that has been accepted shall be documented to record the change and denote the as-built condition.

As a guideline, control of nonconforming items by tagging, marking, or other means of identification is acceptable where physical segregation is not practical, although physical segregation and marking are preferred.

17. CORRECTIVE ACTION

Measures shall be established and documented to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected as soon as practicable. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of significant conditions adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

18. QUALITY ASSURANCE RECORDS

Sufficient records shall be prepared as work is performed to furnish documentary evidence of the quality of items and of activities affecting quality. Records shall be consistent with applicable codes, standards, specifications, and contracts and shall be adequate for use in management of the program.

The records shall include the results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, and facility operating logs. The records shall also include, as appropriate, closely related data such as qualifications of personnel, procedures, and equipment and other documentation required by the applicable parts of this standard. Inspection and test records shall, as a minimum, identify the date of inspection or test, the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Required records shall be legible, identifiable, and retrievable.

Requirements and responsibilities for record transmittal, retention, and maintenance subsequent to completion of work shall be established and documented consistent with applicable codes, standards, and procurement documents.

In general, records which correctly identify the *as-built* conditions of items in the nuclear facility shall be maintained for the life of the particular item while it is installed in the nuclear facility and stored for future use by or for the owner. These records should include material certification and test data for traceability and quality verification; reports of inspections, examinations, and test results for conformance verification; drawings, specifications, procedures, and instructions for use in control of configuration; and records of nonconformances and their resolution. These records shall be indexed, filed, and maintained in facilities that provide suitable environment to minimize deterioration or damage and to prevent loss.

19. AUDITS

A comprehensive system of planned and documented audits shall be carried out to verify compliance with all aspects of the Quality Assurance Program. The audits shall be performed in accordance with written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility in the area audited. Responsible management shall take necessary action to correct the deficiencies revealed by the audit.

Audits should be performed:

(1) to provide an objective evaluation of compliance with established requirements, methods, and procedures;
(2) to assess progress in assigned tasks;
(3) to determine adequacy of Quality Assurance Program performance; and
(4) to verify implementation of recommended corrective action.

Deficient areas should be re-audited until corrections have been accomplished.

Audits should include an evaluation of quality assurance practices, procedures, and instructions; the effectiveness of implementation; and conformance with policy directives. In performing this evaluation, the audits should include evaluation of work areas, activities, processes, and items; and review of documents and records.

An audit plan should be developed to provide information about the audit, such as the functional areas to be audited, the names and assignments of those who will perform the audit, the scheduling arrangements, and the method of reporting findings and recommendations.

Audits should be conducted periodically or on

a random, unscheduled basis, or both. It is desirable to conduct audits when one or more of the following conditions exist:

(1) When it is necessary to determine the capability of a subcontractor's Quality Assurance Program prior to awarding of contract or purchase order.

(2) When, after award of contract, sufficient time has elapsed for the implementation of the Quality Assurance Program, and it is appropriate to determine that the organization is performing the functions as defined in the Quality Assurance Program description, codes, standards, and other contract documents.

(3) When significant changes are made in functional areas of the Quality Assurance Program, including significant reorganizations and procedure revisions.

(4) When it is suspected that safety, performance, or reliability of the item is in jeopardy due to deficiencies and nonconformances in the Quality Assurance Program.

(5) When a systematic, independent assessment of program effectiveness or item quality or both is considered necessary.

(6) When it is considered necessary to verify implementation of required corrective actions.