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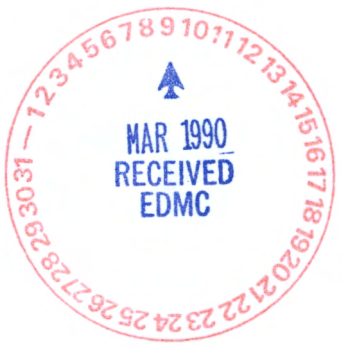
Quality Assurance Program Requirements for Nuclear Facilities



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The American Society of
Mechanical Engineers

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ASME issues written replies to inquiries concerning interpretations of technical aspects of this Standard. The interpretations will be included with the above addenda service. Interpretations are not part of the addenda to the Standard.

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FOREWORD

(This Foreword is not a part of ASME NQA-1–1989 Edition.)

Early in 1975, the American National Standards Institute (ANSI) assigned overall responsibility for coordination among technical societies, development, and maintenance of nuclear power quality assurance standards to the American Society of Mechanical Engineers (ASME). The ASME Committee on Nuclear Quality Assurance was constituted on October 3, 1975, and began operating under the ASME Procedures for Nuclear Projects. The ASME Committee on Nuclear Quality Assurance currently operates under the ASME Operating Procedures and Practices for Nuclear Codes and Standards Development Committees. This Committee prepared ANSI/ASME NQA-1, Quality Assurance Program Requirements for Nuclear Power Plants, which was first issued in 1979 as an American National Standard. The 1989 Edition consists of the 1986 Edition, with all approved revisions through the NQA-1c-1988 Addenda.

Parallel with the development of ANSI/ASME NQA-1, American National Standards N46-2 Subcommittee, under the sponsorship of the American Institute of Chemical Engineers, prepared Revision 1 to ANSI N46.2, Quality Assurance Program Requirements for Post Reactor Nuclear Fuel Cycle Facilities, which was issued as an American National Standard in 1978.

This Standard is an integration of ANSI/ASME NQA-1 and ANSI N46.2, Revision 1. It contains an Introduction, Basic Requirements, and Supplements. In addition, nonmandatory guidance is provided in the Appendices, which do not set forth requirements. The 18-criteria structure of Appendix B of 10 CFR Part 50 has been retained. The Introduction, Basic Requirements, and Supplements together are intended to meet and clarify the criteria of Appendix B of 10 CFR Part 50, dated January 20, 1975.

This document is based upon the contents of ANSI/ASME N45.2-1977, Quality Assurance Program Requirements for Nuclear Facilities; ANSI N46.2, Revision 1, Quality Assurance Program Requirements for Post Reactor Nuclear Fuel Cycle Facilities; and the following seven daughter Standards of ANSI/ASME N45.2.

N45.2.6	Qualifications of Inspection, Examination, and Testing Personnel for Nuclear Power Plants
N45.2.9	Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants
N45.2.10	Quality Assurance Terms and Definitions
N45.2.11	Quality Assurance Requirements for the Design of Nuclear Power Plants
N45.2.12	Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants
N45.2.13	Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants
N45.2.23	Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants

This document does not incorporate the technical requirements of ANSI/ASME NQA-2, which provides related quality assurance requirements and guidance.

This document sets forth requirements and nonmandatory guidance for the establishment and execution of quality assurance programs for the siting, design, construction, operation, and decommissioning of nuclear facilities. The arrangement of the basic and supplementary requirements permits judicious application of the entire document or only portions of the document. The extent to which this document should be applied, either wholly or in part, will depend upon the nature and scope of the work to be performed and the relative importance of the items or services being produced. The extent of application is to be determined by the organization imposing this document. For example, it may only involve the Basic Requirements; Basic Requirements in combination with selected Supplements; Basic Requirements in combination with Supplements with appropriate changes; or the entire document. This document is written to allow application to any structure, system, or component that is essential to satisfactory performance of the facility.

Requests for interpretation or suggestions for improvement of this Standard should be addressed to the Secretary of the ASME Committee on Nuclear Quality Assurance, American Society of Mechnical Engineers, 345 East 47th Street, New York, New York 10017.

PREPARATION OF TECHNICAL INQUIRIES TO THE NUCLEAR QUALITY ASSURANCE COMMITTEE

INTRODUCTION

The ASME Nuclear Quality Assurance Committee will consider written requests for interpretations and revisions to NQA Standards and develop new requirements or guidance if dictated by technological development. The Committee's activities in this regard are limited strictly to interpretations of the requirements and guidance, or to the consideration of revisions to the present Standard on the basis of new data or technology. As a matter of published policy, ASME does not "approve," "certify," "rate," or "endorse" any item, construction, proprietary device, or activity and, accordingly, inquiries requiring such consideration will be returned. Moreover, ASME does not act as a consultant on specific engineering problems or on the general application or understanding of the Standard requirements. If, based on the inquiry information submitted, it is the opinion of the Committee that the inquirer should seek assistance, the inquiry will be returned with the recommendation that such assistance be obtained.

All inquiries that do not provide the information needed for the Committee's full understanding will be returned.

INQUIRY FORMAT

Inquiries shall be limited strictly to interpretations of the requirements and guidance, or to the consideration of revisions to the present Standard on the basis of new data or technology.

Inquiries shall be submitted in the following format.

(a) Scope. The inquiry shall involve a single requirement/guidance or closely related requirements/guidance. An inquiry letter concerning unrelated subjects will be returned.

(b) Background. State the purpose of the inquiry, which would be either to obtain an interpretation of the Standard, or to propose consideration of a revision to the present Standard. Provide concisely the information needed for the Committee's understanding of the inquiry, being sure to include reference to the applicable Standard, Edition, Addenda, Basic Requirements, Supplements, Parts, Appendices, paragraphs, figures, and tables. If sketches are provided, they shall be limited to the scope of the inquiry.

(c) *Inquiry Structure*

(1) Proposed Question(s). The inquiry shall be stated in a condensed and precise question format, omitting superfluous background information, and, where appropriate, composed in such a way that "yes" or "no" (perhaps with provisos) would be an acceptable reply. The inquiry statement should be technically and editorially correct.

(2) Proposed Reply(ies). State what it is believed that the Standard requires. If, in the inquirer's opinion, a revision to the Standard is needed, recommended wording shall be provided.

(d) Submittal. The inquiry shall be submitted in typewritten form; however, legible, handwritten inquiries will be considered. It shall include the name and mailing address of the inquirer and be mailed to the following address:

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Nuclear Department
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I INTRODUCTION

1 PURPOSE

This Standard sets forth requirements for the establishment and execution of quality assurance programs for the siting, design, construction, operation, and decommissioning of nuclear facilities. Nonmandatory guidance is provided in the Appendices.

2 APPLICABILITY

The requirements of this Standard apply to activities which could affect the quality of structures, systems, and components of nuclear facilities. Nuclear facilities include facilities for power generation, spent fuel storage, waste storage, fuel reprocessing, and plutonium processing and fuel fabrication. These activities include the following:

(*a*) the performing functions of attaining quality objectives;

(*b*) the functions of assuring that an appropriate quality assurance program is established; and

(*c*) the function of verifying that activities affecting quality have been correctly performed.

Activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning. The application of this Standard, or portions thereof, shall be specified in written contracts, policies, procedures, or instructions.

3 RESPONSIBILITY

The organization invoking this Standard shall be responsible for specifying which Basic Requirements and Supplements, or portions thereof, apply, and appropriately relating them to specific items and services. The organization upon which this Standard, or portions thereof, is invoked shall be responsible for complying with the specified requirements.

4 DEFINITIONS

Terms used in this Standard that require unique definition are included in Supplement S-1, Terms and Definitions.

II BASIC REQUIREMENTS

1 ORGANIZATION

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. Persons or organizations responsible for assuring that an appropriate quality assurance program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

(1) identify quality problems;

(2) initiate, recommend, or provide solutions to quality problems through designated channels;

(3) verify implementation of solutions; and

(4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.

2 QUALITY ASSURANCE PROGRAM

A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Standard, or portions thereof. The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

The program shall provide for the planning and 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 provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality.

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

Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation.

3 DESIGN CONTROL

The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.

4 PROCUREMENT DOCUMENT CONTROL

Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.

5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

6 DOCUMENT CONTROL

The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

7 CONTROL OF PURCHASED ITEMS AND SERVICES

The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.

8 IDENTIFICATION AND CONTROL OF ITEMS

Controls shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner which assures that identification is established and maintained.

9 CONTROL OF PROCESSES

Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

10 INSPECTION

Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

11 TEST CONTROL

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated.

Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

13 HANDLING, STORAGE, AND SHIPPING

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.

14 INSPECTION, TEST, AND OPERATING STATUS

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or

other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators 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.

15 CONTROL OF NONCONFORMING ITEMS

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

16 CORRECTIVE ACTION

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.

17 QUALITY ASSURANCE RECORDS

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

18 AUDITS

Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

III SUPPLEMENTS

SUPPLEMENT S-1
TERMS AND DEFINITIONS

1 GENERAL

This Supplement contains definitions of certain quality-related terms used in this Standard or in ASME NQA-2.

2 TERMS AND DEFINITIONS

acceptance criteria — specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

audit — a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Certificate of Conformance — a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

certification — the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

characteristic — any property or attribute of an item, process, or service that is distinct, describable, and measurable.

commercial grade item — an item satisfying (a), (b), and (c) below:

(a) not subject to design or specification requirements that are unique to nuclear facilities;[1]

(b) used in applications other than nuclear facilities;

(c) is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog).

computer program[2, 3] — a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it.

condition adverse to quality — an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

corrective action — measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

design change — any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design input — those criteria, parameters, bases, or other design requirements upon which detailed final design is based.

design output — drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

design process — technical and management pro-

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[1] Nuclear facilities can be either nuclear power facilities or any other facilities subject to the requirements of 10 CFR Part 21. Additionally, any unique requirements which one nuclear facility may elect to apply, including the requirements of 10 CFR Part 21, does not necessarily impact the "commercial grade" status of the item for all nuclear facilities.

[2] Computer programs covered by this Standard are those used for:
(a) design analysis;
(b) operations or process control; or
(c) data base or document control registers when used as the controlled source of quality information for (a) or (b) above.

[3] This definition has been copied from ANSI/IEEE 729-1983, Glossary of Software Engineering Terminology, with the permission of IEEE.

cesses that commence with identification of design input and that lead to and include the issuance of design output documents.

deviation — a departure from specified requirements.

document — any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this Supplement.

external audit — an audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

final design — approved design output documents and approved changes thereto.

guideline — a suggested practice that is not mandatory in programs intended to comply with a standard. The word *should* denotes a guideline; the word *shall* denotes a requirement.

inspector — a person who performs inspection activities to verify conformance to specific requirements.

inspection — examination or measurement to verify whether an item or activity conforms to specified requirements.

internal audit — an audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

item — an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

measuring and test equipment (M & TE) — devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

nonconformance — a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

objective evidence — any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

Owner — the person, group, company, agency, or corporation who has or will have title to the nuclear power plant.

procedure — a document that specifies or describes how an activity is to be performed.

procurement document — purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Purchaser — the organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents.

qualification (personnel) — the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

qualified procedures — an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

quality assurance (QA) — all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

quality assurance record — a completed document that furnishes evidence of the quality of items and/or activities affecting quality.

receiving — taking delivery of an item at a designated location.

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 does not conform to the original requirement.

rework — the process by which an item is made to conform to original requirements by completion or correction.

right of access — the right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.

service — the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

special process — a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Supplier — any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

surveillance — the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

testing — an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

traceability — the ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

use-as-is — a disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

verification — the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

waiver — documented authorization to depart from specified requirements.

SUPPLEMENT 1S-1
SUPPLEMENTARY REQUIREMENTS FOR ORGANIZATION

1 GENERAL

This Supplement provides amplified requirements for organization. It supplements the requirements of Basic Requirement 1 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 RESPONSIBILITY

2.1 Purpose

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

(a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and

(b) quality achievement is verified by persons or organizations not directly responsible for performing the work.

2.2 Delegation of Work

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefor.

2.3 Nonconforming Items

Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing.

3 MULTIPLE ORGANIZATIONS

3.1 Responsibility

Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.

3.2 Interface Control

3.2.1 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.

3.2.2 Interface responsibilities shall be defined and documented.

SUPPLEMENT 2S-1
SUPPLEMENTARY REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL

1 GENERAL

This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement do not apply to the qualification of personnel for performance of nondestructive examination.

2 CERTIFICATION

2.1 Qualification Requirements

The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities.

When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this Standard may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.

2.2 Personnel Selection

Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.

2.3 Indoctrination

Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed.

2.4 Training

The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests.

2.5 Determination of Initial Capability

The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration.

2.6 Evaluation of Performance

The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of para. 2.5 above. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of 1 year shall be reeval-

uated by a redetermination of required capability in accordance with the requirements of para. 2.5 above.

2.7 Certificate of Qualification

The qualification of personnel shall be certified in writing in an appropriate form, including the following information:

(a) employer's name;

(b) identification of person being certified;

(c) activities certified to perform;

(d) basis used for certification, which includes such factors as:

(1) education, experience, indoctrination, and training

(2) test results, where applicable

(3) results of capability demonstration

(e) results of periodic evaluation;

(f) results of physical examinations, when required;

(g) signature of employer's designated representative who is responsible for such certification;

(h) date of certification and date of certification expiration.

2.8 Physical

The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

3 RECORDS

3.1 Record Files

Records of personnel qualification shall be established and maintained by the employer. These records shall include the information required by para. 2.7 above.

SUPPLEMENT 2S-2
SUPPLEMENTARY REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

1 GENERAL

This Supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak testing (LT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 CERTIFICATION

2.1 Applicable Documents

The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this Supplement.

2.2 Program

The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.

2.3 Records

Records of personnel qualification shall be established and maintained by the employer.

SUPPLEMENT 2S-3
SUPPLEMENTARY REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

1 GENERAL

This Supplement provides amplified requirements for the qualification of an audit team leader, henceforth identified as a *Lead Auditor,* who organizes and directs audits, reports audit findings, and evaluates corrective action. This Supplement also provides amplified requirements for the qualifications of individuals, henceforth referred to as *Auditors,* who participate in an audit, such as technical specialists, management representatives, and auditors-in-training. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 QUALIFICATION OF AUDITORS

2.1 Responsibility of Auditing Organization

The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below:

(a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results;

(b) training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

3 QUALIFICATION OF LEAD AUDITORS

An individual shall meet the requirements of paras. 3.1 through 3.4 below prior to being designated a Lead Auditor.

3.1 Communication Skills

The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.

3.2 Training

Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor.

3.2.1 Knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.

3.2.2 General structure of quality assurance programs as a whole and applicable elements as defined in this Standard.

3.2.3 Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.

3.2.4 Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.

3.2.5 On-the-job training to include applicable elements of the audit program.

3.3 Audit Participation

The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification.

3.4 Examination

The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in para. 3.2 above. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5 of this Supplement.

4 MAINTENANCE OF QUALIFICATION

4.1 Maintenance of Proficiency

Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s). Based on annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.

4.2 Requalification

Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of para. 3.2 above, reexamination in accordance with para. 3.4 above, and participation as an Auditor in at least one nuclear quality assurance audit.

5 ADMINISTRATION

5.1 Organizational Responsibility

Training of auditors shall be the responsibility of the employer. The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit. The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

5.2 Qualification Examination

The development and administration of the examination for a Lead Auditor required by para. 3.4 above is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration to this Standard. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of Section 6 below.

6 RECORDS

6.1 General

Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer.

6.2 Certification of Qualification

Each Lead Auditor shall be certified by his employer as being qualified to lead audits. This certification shall, as a minimum, document the following:

(a) employer's name;
(b) Lead Auditor's name;
(c) date of certification or recertification;

(d) basis of qualification (i.e., education, experience, communication skills, training, examination, etc.);

(e) signature of employer's designated representative who is responsible for such certification.

6.3 Updating of Lead Auditors' Records

Records for each Lead Auditor shall be maintained and updated annually.

SUPPLEMENT 2S-4
SUPPLEMENTARY REQUIREMENTS FOR PERSONNEL INDOCTRINATION AND TRAINING

1 GENERAL

This Supplement provides amplified requirements for the indoctrination and training of personnel performing or managing activities affecting quality. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 APPLICABILITY

This Supplement applies to personnel performing or managing activities affecting quality. Personnel to be indoctrinated or trained shall be identified. The extent of indoctrination and training shall be commensurate with the following:

(a) the scope, complexity, and nature of the activity; and

(b) the education, experience, and proficiency of the person.

Activities affecting quality include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

3 INDOCTRINATION

Personnel shall be indoctrinated in the following subjects as they relate to a particular function:

(a) general criteria, including applicable codes, standards, and company procedures;

(b) applicable quality assurance program elements; and

(c) job responsibilities and authority.

4 TRAINING

Training shall be provided, if needed, to:

(a) achieve initial proficiency;

(b) maintain proficiency; and

(c) adapt to changes in technology, methods, or job responsibilities.

5 RECORDS

Records of the implementation of indoctrination and training may take the form of:

(a) attendance sheets;

(b) training logs; or

(c) personnel training records.

SUPPLEMENT 3S-1
SUPPLEMENTARY REQUIREMENTS FOR DESIGN CONTROL

1 GENERAL

This Supplement provides amplified requirements for design control. It supplements the requirements of Basic Requirement 3 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 DESIGN INPUT

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled.

3 DESIGN PROCESS

The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall be adequate to support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall:

(a) be relatable to the design input by documentation in sufficient detail to permit design verification; and

(b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.1 Design Analyses

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.

(a) Computer programs may be utilized for design

analysis without individual verification of the program for each application provided:

(1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

(2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above.

(b) Documentation of design analyses shall include (1) through (6) below:

(1) definition of the objective of the analyses;

(2) definition of design inputs and their sources;

(3) results of literature searches or other applicable background data;

(4) identification of assumptions and indication of those that must be verified as the design proceeds;

(5) identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem;

(6) review and approval.

4 DESIGN VERIFICATION

Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. Verification of computer programs shall include appropriate testing. The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be clearly documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this Standard.

Verification shall be performed in a timely manner. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

4.1 Extent of Design Verification

The extent of the design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Standard, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

4.2 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.

4.2.1 Design Reviews. These are critical reviews to provide assurance that the final design is correct and satisfactory. Where applicable, (a) through (f) below shall be addressed.

(a) Were the design inputs correctly selected?

(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?

(c) Was an appropriate design method used?

(d) Were the design inputs correctly incorporated into the design?

(e) Is the design output reasonable compared to design inputs?

(f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

4.2.2 Alternate Calculations. These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

4.2.3 Qualification Tests. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate 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. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met.

If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.

5 CHANGE CONTROL

Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the structure, system, or component are still valid. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the Owner or his designee shall designate a new responsible organization which could be the Owner's engineering organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

6 INTERFACE CONTROL

Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

7 DOCUMENTATION AND RECORDS

Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Standard, shall be collected, stored, and maintained in accordance with documented procedures.

The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.

SUPPLEMENT 4S-1
SUPPLEMENTARY REQUIREMENTS FOR PROCUREMENT DOCUMENT CONTROL

1 GENERAL

This Supplement provides amplified requirements for procurement document control. It supplements the requirements of Basic Requirement 4 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 CONTENT OF THE PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.

2.1 Scope of Work

A statement of the scope of the work to be performed by the Supplier shall be in the procurement documents.

2.2 Technical Requirements

Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the Purchaser for monitoring and evaluating the Supplier's performance.

2.3 Quality Assurance Program Requirements

Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Standard. The extent of the program required shall depend upon the type and use of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.

2.4 Right of Access

At each tier of a procurement, the procurement documents shall provide for access to the Supplier's plant facilities and records for inspection or audit by the Purchaser, his designated representative, and/or other parties authorized by the Purchaser.

2.5 Documentation Requirements

The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established. When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.

2.6 Nonconformances

The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances.

2.7 Spare and Replacement Parts

The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies.

3 PROCUREMENT DOCUMENT REVIEW

A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements.

Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award.

Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations:

(a) appropriate requirements specified in Section 2 of this Supplement;

(b) determination of any additional or modified design criteria;

(c) analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.

Reviews required by this Section shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4 PROCUREMENT DOCUMENT CHANGES

Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.

SUPPLEMENT 6S-1
SUPPLEMENTARY REQUIREMENTS FOR DOCUMENT CONTROL

1 GENERAL

This Supplement provides amplified requirements for a document control system. It supplements the requirements of Basic Requirement 6 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

The documents which shall be controlled in accordance with this Supplement are only those documents which specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings.

The term *document control* used throughout this Supplement is defined as the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

2 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

The control system shall be documented and shall provide for (a) through (c) below:

(a) identification of documents to be controlled and their specified distribution;

(b) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;

(c) review of documents for adequacy, completeness, and correctness prior to approval and issuance.

3 DOCUMENT CHANGES

3.1 Major Changes

Changes to documents, other than those defined as minor changes in para. 3.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

3.2 Minor Changes

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

SUPPLEMENT 7S-1
SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF PURCHASED ITEMS AND SERVICES

1 GENERAL

This Supplement provides amplified requirements for control of purchased items and services. It supplements the requirements of Basic Requirement 7 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. This Supplement includes requirements for source selection, bid evaluation, Supplier performance evaluation, and verification of conformance.

2 PROCUREMENT PLANNING

Procurement activities shall be planned and documented to assure a systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities.

Planning shall determine the following:

(a) what is to be accomplished;
(b) who is to accomplish it;
(c) how it is to be accomplished;
(d) when it is to be accomplished.

Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process.

Planning shall result in the documented identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning shall provide for the integration of (a) through (i) below:

(a) procurement document preparation, review, and change control;
(b) selection of procurement sources;
(c) bid evaluation and award;
(d) Purchaser control of Supplier performance;
(e) verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points;
(f) control of nonconformances;
(g) corrective action;
(h) acceptance of item or service;
(i) quality assurance records.

3 SUPPLIER SELECTION

3.1 Source Evaluation and Selection

The selection of Suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract.

Procurement source evaluation and selection measures shall be implemented by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability.

Measures for evaluation and selection of procurement sources, and the results therefrom, shall be documented and shall include one or more of (a) through (c) below:

(a) evaluation of the Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The Supplier's history shall reflect current capability.

(b) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated;

(c) Supplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.

4 BID EVALUATION

Bid evaluation shall determine the extent of conformance to the procurement documents. This evaluation shall be performed by individuals or organi-

zations designated to evaluate the following subjects, as applicable to the type of procurement:

(a) technical considerations
(b) quality assurance requirements
(c) Supplier's personnel
(d) Supplier's production capability
(e) Supplier's past performance
(f) alternates
(g) exceptions

Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable quality conditions resulting from the bid evaluation.

5 SUPPLIER PERFORMANCE EVALUATION

The Purchaser of items and services shall establish measures to interface with the Supplier and to verify Supplier's performance as deemed necessary by the Purchaser. The measures shall include (a) through (f) below:

(a) establishing an understanding between Purchaser and Supplier of the provisions and specifications of the procurement documents;

(b) requiring the Supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements;

(c) reviewing Supplier documents which are generated or processed during activities fulfilling procurement requirements;

(d) identifying and processing necessary change information;

(e) establishing method of document information exchange between Purchaser and Supplier;

(f) establishing the extent of source surveillance and inspection activities.

These verification activities shall be conducted as early as practicable. The Purchaser's verification activities, however, shall not relieve the Supplier of his responsibilities for verification of quality achievement.

5.1 Extent of Activities

The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of Suppliers.

5.2 Records

Activities performed to verify conformance to requirements of procurement documents shall be recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented.

The Purchaser shall assure that his documentation is evaluated to determine the Supplier's quality assurance program effectiveness.

6 CONTROL OF SUPPLIER GENERATED DOCUMENTS

Supplier generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to assure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

7 CONTROL OF CHANGES IN ITEMS OR SERVICES

The Purchaser and Supplier shall assure that measures to control changes in procurement documents are established, implemented, and documented and are in accordance with this Standard.

8 ACCEPTANCE OF ITEM OR SERVICE

8.1 General

Methods shall be established for the acceptance of an item or service being furnished by the Supplier. Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use.

8.2 Methods of Acceptance

Purchaser methods used to accept an item or related service from a Supplier shall be Supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility site, or a combination thereof.

8.2.1 Certificate of Conformance. When a Certificate of Conformance is used, the minimum criteria of (a) through (f) below shall be met.

(a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.

(b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

(c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

(d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.

(e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.

(f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

8.2.2 Source Verification. When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and it shall be implemented to monitor, witness, or observe activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.

8.2.3 Receiving Inspection. When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall be performed in accordance with established procedures and inspection instructions, to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanness. Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

8.2.4 Post-Installation Testing. When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.

8.3 Acceptance of Services Only

In certain cases involving procurement of services only, such as third party inspection; engineering and consulting services; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:

(a) technical verification of data produced;

(b) surveillance and/or audit of the activity;

(c) review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc.

9 CONTROL OF SUPPLIER NONCONFORMANCES

The Purchaser and Supplier shall establish and document methods for disposition of items and services

that do not meet procurement documentation requirements.

These methods shall contain provision for (a) through (e) below:

(a) evaluation of nonconforming items;

(b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., *use-as-is* or *repair*) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition:

(1) technical or material requirement is violated;

(2) requirement in Supplier documents, which has been approved by the Purchaser, is violated;

(3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework;

(4) the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired;

(c) Purchaser disposition of Supplier recommendation;

(d) verification of the implementation of the disposition;

(e) maintenance of records of Supplier-submitted nonconformances.

10 COMMERCIAL GRADE ITEMS

Where the design utilizes commercial grade items, the following requirements are an acceptable alternate to other requirements of this Supplement, except as noted in (b) below and the requirements of Supplement 4S-1.

(a) The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.

(b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance to safety, shall be in accordance with para. 3.1 of this Supplement.

(c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (for example, catalog number).

(d) After receipt of a commercial grade item, the Purchaser shall determine that:

(1) damage was not sustained during shipment;

(2) the item received was the item ordered;

(3) inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer's published requirements;

(4) documentation, as applicable to the item, was received and is acceptable.

SUPPLEMENT 8S-1
SUPPLEMENTARY REQUIREMENTS FOR IDENTIFICATION AND CONTROL OF ITEMS

1 GENERAL

This Supplement provides amplified requirements for identification and control of items. It supplements the requirements of Basic Requirement 8 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 IDENTIFICATION METHODS

2.1 Item Identification

Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of the items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

2.2 Physical Identification

Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.

2.3 Markings

Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

3 SPECIFIC REQUIREMENTS

3.1 Identification and Traceability of Items

When specified by codes, standards, or specifications that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall be designed to provide such identification and traceability control.

3.2 Limited Life Items

Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

3.3 Maintaining Identification of Stored Items

Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as:

(1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging;

(2) protection of identifications on items subject to excessive deterioration due to environmental exposure;

(3) provisions for updating existing plant records.

SUPPLEMENT 9S-1
SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF PROCESSES

1 GENERAL

This Supplement provides amplified requirements for control of processes. It supplements the requirements of Basic Requirement 9 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 PROCESS CONTROL

Processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained.

3 SPECIAL PROCESSES

Each special process shall be performed in accordance with appropriate instructions which include or reference procedure, personnel, and equipment qualification requirements.

3.1 Responsibility

It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.

3.1.1 Qualification of personnel, procedures, and equipment shall comply with specified requirements.

3.1.2 Conditions necessary for accomplishment of the process shall be included in procedures or instructions. These conditions shall include proper equipment, controlled parameters of the process, and calibration requirements.

3.2 Acceptance Criteria

The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions.

3.3 Records

Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.

3.4 Special Requirements

For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.

SUPPLEMENT 10S-1
SUPPLEMENTARY REQUIREMENTS FOR INSPECTION

1 GENERAL

This Supplement provides amplified requirements for inspection of items and activities. It supplements the requirements of Basic Requirement 10 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 PERSONNEL

2.1 Reporting Independence

Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

2.2 Qualification

Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task.

Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.

3 INSPECTION HOLD POINTS

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

4 INSPECTION PLANNING

4.1 Planning

Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results.

4.2 Sampling

Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.

5 IN-PROCESS INSPECTION

5.1 Inspection

Inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality. 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.

5.2 Combined Inspection and Monitoring

5.2.1 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

5.2.2 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

6 FINAL INSPECTIONS

6.1 Resolution of Nonconformances

Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

6.2 Inspection Requirements

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformances of the item to specified requirements. Quality records shall be examined for adequacy and completeness if not previously so examined.

6.3 Acceptance

The acceptance of the item shall be documented and approved by authorized personnel.

6.4 Modifications, Repairs, or Replacements

Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

7 INSERVICE INSPECTION

7.1 Planning and Performance

Required inservice inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for operation.

7.2 Methods

Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

8 RECORDS

Records shall, as a minimum, identify (a) through (f) below:

(a) item inspected
(b) date of inspection
(c) inspector
(d) type of observation
(e) results or acceptability
(f) reference to information on action taken in connection with nonconformances

SUPPLEMENT 11S-1
SUPPLEMENTARY REQUIREMENTS FOR TEST CONTROL

1 GENERAL

This Supplement provides amplified requirements for test control. It supplements the requirements of Basic Requirement 11 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents.

3 TEST PROCEDURES

Tests procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.

In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.

4 TEST RESULTS

Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied.

5 TEST RECORDS

Test records shall, as a minimum, identify (a) through (g) below:

(a) item tested
(b) date of test
(c) tester or data recorder
(d) type of observation
(e) results and acceptability
(f) action taken in connection with any deviations noted
(g) person evaluating test results

SUPPLEMENT 11S-2
SUPPLEMENTARY REQUIREMENTS FOR COMPUTER PROGRAM TESTING

1 GENERAL

This Supplement provides amplified requirements for testing of computer programs and associated computer systems. It supplements the requirements of Basic Requirement 11 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents.

2.1 Verification Tests

Verification tests shall demonstrate the capability of the computer program to produce valid results for test problems encompassing the range of permitted usage defined by the program documentation. Acceptable test problem solutions are as follows:

(a) hand calculations;

(b) calculations using comparable proven programs; or

(c) empirical data and information from technical literature.

For programs used for operational control, testing shall demonstrate required performance over the range of operation of the controlled function or process.

Depending on the complexity of the computer program being tested, testing may range from a single test of the completed computer program to a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test. Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

2.2 In-Use Tests

Test problems shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. Test problems shall be run whenever the computer program is installed on a different computer, or when significant hardware or operating system configuration changes are made. Periodic in-use manual or automatic self-check routines shall be prescribed and performed for those applications where computer failures or drift can affect required performance.

3 TEST PROCEDURES

Test procedures or plans shall specify the following, as applicable:

(a) required tests and test sequence

(b) required ranges of input parameters

(c) identification of the stages at which testing is required

(d) criteria for establishing test cases

(e) requirements for testing logic branches

(f) requirements for hardware integration

(g) anticipated output values

(h) acceptance criteria

(i) reports, records, standard formatting, and conventions

4 TEST RESULTS

Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

5 TEST RECORDS

(a) Verification test records shall identify (1) through (10) below.

(1) computer program tested

(2) computer hardware used

(3) test equipment and calibrations, where applicable

(4) date of test

(5) tester or data recorder

(6) simulation models used, where applicable

(7) test problems

(8) results and acceptability

(9) action taken in connection with any deviations noted

(10) person evaluating test results

(b) In-use test results shall identify (1) through (6) below.

(1) computer program tested

(2) computer hardware used

(3) test equipment and calibrations, where applicable

(4) date of test

(5) tester or data recorder

(6) acceptability

SUPPLEMENT 12S-1
SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF MEASURING AND TEST EQUIPMENT

1 GENERAL

This Supplement provides amplified requirements for control of measuring and test equipment. It supplements the requirements of Basic Requirement 12 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 SELECTION

Selection of measuring and test equipment shall be controlled to assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

3 CALIBRATION AND CONTROL

3.1 Calibration

Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.

3.2 Control

The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. When measuring and test equipment is 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. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspect.

3.3 Commercial Devices

Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

4 HANDLING AND STORAGE

Measuring and test equipment shall be properly handled and stored to maintain accuracy.

5 RECORDS

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

SUPPLEMENT 13S-1
SUPPLEMENTARY REQUIREMENTS FOR HANDLING, STORAGE, AND SHIPPING

1 GENERAL

This Supplement provides amplified requirements for handling, storage, and shipping. It supplements the requirements of Basic Requirement 13 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 INSTRUCTION

Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

3 REQUIREMENTS

3.1 General

When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified.

3.2 Procedures

When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

3.3 Tools and Equipment

Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained.

3.4 Operators

Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment.

4 MARKING

Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

SUPPLEMENT 15S-1
SUPPLEMENTARY REQUIREMENTS FOR THE CONTROL OF NONCONFORMING ITEMS

1 GENERAL

This Supplement provides amplified requirements for the control of nonconforming items. It supplements the requirements of Basic Requirement 15 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 IDENTIFICATION

(a) Identification of nonconforming items shall be by marking, tagging, or other methods which shall not adversely affect the end use of the item. The identification shall be legible and easily recognizable.

(b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.

3 SEGREGATION

(a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

(b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

4 DISPOSITION

4.1 Control

Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel.

4.2 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.

4.3 Personnel

Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

4.4 Disposition

The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented.

Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation.

4.5 Repaired or Reworked Items

Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

SUPPLEMENT 17S-1
SUPPLEMENTARY REQUIREMENTS FOR QUALITY ASSURANCE RECORDS

1 GENERAL

This Supplement provides amplified requirements for quality assurance records. It supplements the requirements of Basic Requirement 17 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

The requirements of this Supplement apply to quality assurance records which have been completed.

The term *records*, used throughout this Supplement, is to be interpreted as *Quality Assurance Records*.

2 RECORDS ADMINISTRATION

2.1 Records System

A records system(s) shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this Supplement. The records system(s) shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.

2.2 Generation of Records

The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the Owner. Documents that are designated to become records shall be legible, accurate, and completed appropriate to the work accomplished.

2.3 Record Validation

Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies.

2.4 Index

The records shall be indexed. The indexing system(s) shall include, as a minimum, record retention times and the location of the record within the record system.

2.5 Distribution

The records shall be distributed, handled, and controlled in accordance with written procedures.

2.6 Identification

Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies.

2.7 Classification

Records shall be classified as *Lifetime* or *Nonpermanent* by the Owner, or his agent when authorized, in accordance with the criteria given in paras. 2.7.1 and 2.7.2 below.

2.7.1 Lifetime Records. Lifetime records are those that meet one or more of the following criteria:

(a) those which would be of significant value in demonstrating capability for safe operation;

(b) those which would be of significant value in

maintaining, reworking, repairing, replacing, or modifying an item;

(c) those which would be of significant value in determining the cause of an accident or malfunction of an item;

(d) those which provide required baseline data for in-service inspections.

Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.

2.7.2 Nonpermanent Records. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

2.8 Retention of Records

Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing.

2.9 Corrected Information in Records

Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction.

3 RECEIPT

3.1 Responsibility

The individual or organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession.

3.2 Receipt Control

Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.

As a minimum, a receipt control system shall include the following:

(a) a method for designating the required records;

(b) a method for identifying records received;

(c) procedures for receipt and inspection of incoming records;

(d) a method for submittal of completed records to the storage facility without unnecessary delay.

3.3 Status

Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

4 STORAGE, PRESERVATION, AND SAFEKEEPING

4.1 Storage

The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies.

Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure shall include, as a minimum, (a) through (g) below:

(a) a description of the storage facility;

(b) the filing system to be used;

(c) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible;

(d) a method of verifying that the records are those designated (see para. 3.2 above);

(e) the rules governing access to and control of the files;

(f) a method for maintaining control of and accountability for records removed from the storage facility;

(g) a method for filing supplemental information (see para. 2.9 above) and disposing of superseded records.

4.2 Preservation

Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records, the requirements of (a) through (c) below shall apply.

(a) Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.

(b) Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers.

(c) Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

4.3 Safekeeping

Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.

Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.

4.4 Facility

Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

(a) natural disasters such as winds, floods, or fires;

(b) environmental conditions such as high and low temperatures and humidity;

(c) infestation of insects, mold, or rodents.

There are two satisfactory methods of providing storage facilities, single or dual.

4.4.1 Single Facility. Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below:

(a) reinforced concrete, concrete block, masonry, or equal construction;

(b) floor and roof with drainage control. If a floor drain is provided, a check valve (or equal) shall be included.

(c) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating;

(d) sealant applied over walls as a moisture or condensation barrier;

(e) surface sealant on floor providing a hard wear surface to minimize concrete dusting;

(f) foundation sealant and provisions for drainage;

(g) forced air circulation with filter system;

(h) fire protection system;

(i) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampered to comply with the minimum 2 hr fire protection rating.

The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing.

If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.

4.4.2 Alternate Single Facilities. The following are acceptable alternatives to the criteria of para. 4.4.1 above for a single facility:

(a) 2 hr fire rated vault meeting NFPA 232-1986 or NFPA 232AM-1986 or both;[1]

(b) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both;[1] or

(c) 2 hr fire rated file room meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both[1] with the following additional provisions:

(1) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station;

(2) records storage in fully enclosed metal cabinets;

(3) adequate access and aisle ways;

(4) prohibition in the room of work not directly associated with record storage or retrieval;

(5) prohibition in the room of smoking, eating, or drinking;

(6) 2 hr fire rated dampers or doors in all boundary penetrations.

4.4.3 Temporary Storage. When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1 hr fire rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying 1 hr fire protection or be certified by a person competent in the technical field of fire protection.

4.4.4 Dual Facilities. If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either para. 4.4.1 or para. 4.4.2 above, but shall meet the other requirements of this Standard.

[1] NFPA 232-1986 and NFPA-232AM-1986 are published by the National Fire Protection Association, Batterymarch Park, Quincy, MA 02269.

5 RETRIEVAL

Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type.

A list shall be maintained designating those personnel who shall have access to the files.

Records maintained by a Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the Owner.

6 DISPOSITION

Records accumulated at various locations, prior to transfer, shall be made accessible to the Owner directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this Standard.

Various regulatory agencies have requirements concerning records that are within the scope of this Standard. The most stringent requirements shall be used in determining the final disposition.

The Supplier's nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied:

(a) items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed;

(b) regulatory requirements are satisfied;

(c) operational status permits;

(d) warranty consideration is satisfied;

(e) Purchaser's requirements are satisfied.

SUPPLEMENT 18S-1
SUPPLEMENTARY REQUIREMENTS FOR AUDITS

1 GENERAL

This Supplement provides amplified requirements for quality assurance audits. It supplements the audit requirements of Basic Requirement 18 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.

2 SCHEDULING

Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

3 PREPARATION

3.1 Audit Plan

The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

3.2 Personnel

The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

3.3 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit.

4 PERFORMANCE

Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

5 REPORTING

The audit report shall be signed by the audit team leader and issued, and it shall include the following information, as appropriate:

(a) description of the audit scope;

(b) identification of the auditors;

(c) identification of persons contacted during audit activities;

(d) summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited;

(e) description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

6 RESPONSE

Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.

7 FOLLOW-UP ACTION

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

8 RECORDS

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

IV APPENDICES

APPENDIX 1A-1
NONMANDATORY GUIDANCE ON ORGANIZATION

1 GENERAL

This Appendix provides nonmandatory guidance on organization as specified in Basic Requirement 1 and Supplement 1S-1.

2 ORGANIZATIONAL STRUCTURE

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. The quality assurance group, however, should be designated to describe, integrate, and monitor the agreed-upon quality assurance activities of the various disciplines.

Quality assurance encompasses many functions and extends to various levels in all participating organizations, from the top executive to workers, such as designers, welders, inspectors, facility operators, craftsmen, and auditors, who perform activities affecting quality.

Different organizational structures may be effective, depending on the portion of the project or job in which the implementing organization is involved.

APPENDIX 2A-1
NONMANDATORY GUIDANCE ON THE QUALIFICATIONS OF INSPECTION AND TEST PERSONNEL

1 GENERAL

This Appendix provides nonmandatory guidance on the qualifications of inspection and test personnel. This Appendix may be used in conjunction with Basic Requirement 2 and Supplement 2S-1.

2 FUNCTIONAL QUALIFICATIONS

Three levels of qualification may be utilized depending on the complexity of the functions involved. The recommendations for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional activities.

2.1 Level I Personnel Capabilities

A Level I person should be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices as defined in user's written procedures.

2.2 Level II Personnel Capabilities

A Level II person should have all of the capabilities of a Level I person for the inspection or test category or class in question. Additionally, a Level II person should have demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment, as appropriate; in supervising or maintaining surveillance over the inspections and tests; in supervising and certifying lower level personnel; and in evaluating the validity and acceptability of inspection and test results.

2.3 Level III Personnel Capabilities

A Level III person should have all of the capabilities of a Level II person for the inspection or test category or class in question. In addition, the individual should also be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this Appendix.

3 EDUCATION AND EXPERIENCE QUALIFICATIONS

These education and experience recommendations should be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the activity may provide reasonable assurance that a person can competently perform a particular task. Other factors which may demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. These factors and the basis for their equivalency should be documented.

3.1 Level I

3.1.1 Two years of related experience in equivalent inspection or testing activities; or

3.1.2 High school graduation and 6 months of related experience in equivalent inspection or testing activities; or

3.1.3 Completion of college level work leading to an associate degree in a related discipline plus 3 months of related experience in equivalent inspection or testing activities.

3.2 Level II

3.2.1 One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or

3.2.2 High school graduation plus 3 years of related experience in equivalent inspection or testing activities; or

3.2.3 Completion of college level work leading to an associate degree in a related discipline plus 1 year of related experience in equivalent inspection or testing activities; or

3.2.4 Graduation from a 4 year college plus 6 months of related experience in equivalent inspection or testing activities.

3.3 Level III

3.3.1 Six years of satisfactory performance as a Level II in the corresponding inspection or test category or class; or

3.3.2 High school graduation plus 10 years of related experience in equivalent inspection or testing activities; or high school graduation plus 8 years of experience in equivalent inspection or testing activities with at least 2 years as a Level II and with at least 2 years associated with nuclear facilities — or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

3.3.3 Completion of college level work leading to an associate degree and 7 years of related experience in equivalent inspection or testing activities with at least 2 years of this experience associated with nuclear facilities — or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

3.3.4 Graduation from a 4 year college plus 5 years of related experience in equivalent inspection or testing activities with at least 2 years of this experience associated with nuclear facilities — or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

APPENDIX 2A-2
NONMANDATORY GUIDANCE ON QUALITY ASSURANCE PROGRAMS

1 GENERAL

This Appendix provides nonmandatory guidance on establishment of a quality assurance program as specified in Basic Requirement 2.

2 TIMING

(a) The primary reason for establishing a quality assurance program is to assure that structures, systems, and components are designed, manufactured, constructed, and operated in compliance with specified requirements. To achieve this objective, control and verification measures should be planned, documented, and implemented at predetermined points throughout the life of the project. The program should evolve with the project from design definition to plant decommissioning.

(b) The quality assurance program should specify an orderly and timely sequence for the implementation of applicable requirements and standards. As a nuclear project moves through the definition stage into design, construction, pre-operational testing, commercial operations, and finally decommissioning, activities affecting quality will change as the type of work dictates.

3 PLANNING

3.1 Purpose

Activities should be planned and documented to assure a systematic approach. Planning should result in the documented identification of methods and organizational responsibilities. Planning should determine the following:

(a) what is to be accomplished;
(b) who is to accomplish it;
(c) how it is to be accomplished;
(d) when it is to be accomplished.

Planning should be performed as early as practical and no later than the start of those activities which are to be controlled to assure interface compatibility and a satisfactory approach to quality assurance.

3.2 Planning for Quality Assurance Programs

Planning for the quality assurance program should consider (a) through (f) below, as appropriate:

(a) the quality requirements, including applicable codes, standards, and practices;
(b) the need for special procedures, work instructions, controls, processes, equipment, tools, or skills required to attain quality;
(c) the review of specifications, drawings, and other working documents to verify that prerequisites have been met and that the activity affecting quality can be accomplished as specified;
(d) the documentation needed;
(e) the assignment of responsibility for each task;
(f) the method to be used to verify conformance to quality requirements.

4 DEGREE OF CONTROL AND VERIFICATION

Since items and services differ with regard to relative importance, the program may need to require varying degrees of control and verification to assure compliance with applicable requirements. Some factors that should be considered in determining appropriate control and verification are given in (a) through (f) below:

(a) the consequence of malfunction or failure of the item;
(b) the design and fabrication complexity or uniqueness of the item;
(c) the need for special controls and surveillance over processes and equipment;

(d) the degree to which functional compliance can be demonstrated by inspection or test;

(e) the quality history and degree of standardization of the item;

(f) the difficulty of repair or replacement of the item.

APPENDIX 2A-3
NONMANDATORY GUIDANCE ON THE EDUCATION AND EXPERIENCE OF LEAD AUDITORS

1 GENERAL

This Appendix provides nonmandatory guidance relative to the education and experience which may be used for the qualification of Lead Auditors. This Appendix may be used in conjunction with Basic Requirement 2 and Supplement 2S-3.

2 EDUCATION AND EXPERIENCE

The prospective Lead Auditor should have verifiable evidence that a minimum of ten (10) credits under the following score system have been accumulated.

2.1 Education (4 Credits Maximum)

Associate degree from an accredited institution: score one (1) credit or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score two (2) credits; or

A bachelor's degree from an accredited institution: score two (2) credits or, if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three (3) credits; in addition, score one (1) credit for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.

2.2 Experience (9 Credits Maximum)

Technical experience in engineering, manufacturing, construction, operation, or maintenance: score one (1) credit for each full year with a maximum of five (5) credits for this aspect of experience.

If 2 years of this experience have been in the nuclear field, score one (1) additional credit; or

If 2 years of this experience have been in quality assurance, score two (2) additional credits; or

If 2 years of this experience have been in auditing, score three (3) additional credits; or

If 2 years of this experience have been in nuclear quality assurance, score three (3) additional credits; or

If 2 years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits.

2.3 Other Credentials of Professional Competence (2 Credits Maximum)

For certification of competency in engineering science, or quality assurance specialties issued and approved by a State Agency or National Professional or Technical Society: score two (2) credits.

2.4 Rights of Management (2 Credits Maximum)

The Lead Auditor's employer may grant up to two (2) credits for other performance factors applicable to auditing which may not be explicitly called out in this Appendix. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses.

3 RECORDS

The sample form shown in Fig. 2A-3.1 is provided for utilization as a record of Lead Auditor qualification.

RECORD OF LEAD AUDITOR QUALIFICATION	Name	Date	
EMPLOYER:			
QUALIFICATION POINT REQUIREMENTS			CREDITS
Education – University/Degree Date		4 Credits Max.	_____
1. Undergraduate Level 2. Graduate Level			
Experience – Company/Dates		9 Credits Max.	_____
Technical (0-5 credits) and Nuclear Industry (0-1 credit), or Quality Assurance (0-2 credits), or Auditing (0-4 credits)			
Professional Accomplishment – Certificate/Date		2 Credits Max.	_____
1. P.E. 2. Society			
Management – Justification/Evaluator/Date		2 Credits Max.	_____
Explain: Evaluated by: (Name and Title)		_____ Date	
		Total Credits:	_____
AUDIT COMMUNICATION SKILLS			
Evaluated by: (Name and Title)		_____ Date	
AUDIT TRAINING COURSES			
Course Title or Topic: 1. 2.			Date

AUDIT PARTICIPATION

	Location	Audit	Date
	1.		
	2.		
	3.		
	4.		
	5.		

EXAMINATION:	PASSED:	DATE:
AUDITOR QUALIFICATION CERTIFIED BY: (Signature and Title)		Date Certified

ANNUAL EVALUATION (Signature and Date)					

FIG. 2A-3.1 SAMPLE FORM FOR RECORD OF LEAD AUDITOR QUALIFICATION

APPENDIX 3A-1
NONMANDATORY GUIDANCE ON DESIGN CONTROL

1 GENERAL

This Appendix provides nonmandatory guidance on design control as specified in Basic Requirement 3 and Supplement 3S-1.

2 DESIGN PROCESS

The design activities may be prescribed in job specifications, work instructions, planning sheets, procedure manuals, test procedures, or any other typed or written form that provides adequate control and permits reviewing, checking, or verifying the results of the activity.

3 DESIGN CONTROL PROGRAM

Some factors to be considered in establishing the design control program may include (a) through (d) below:

(a) nature of the organization, such as the power plant owner, major equipment designer, or power plant designer, and the nature of the design interfaces among them;

(b) importance of design activity to safety;

(c) state of the art such as experimental, developmental, or standard design;

(d) nature of design activity, such as conceptual, preliminary, detailed design, or field engineering.

4 PROCEDURES

4.1 Drawings

Subjects normally covered by procedures for the preparation and control of drawings include the following:

(a) drafting room standards
(b) standardized symbols
(c) identification system
(d) indication of status
(e) checking methods
(f) review and approval requirements
(g) issuance and distribution
(h) storage and control of originals or master copies
(i) revisions
(j) as-built drawings

4.2 Specifications and Other Design Documents

Subjects normally covered by procedures for the preparation and control of specifications and other design documents include the following:

(a) format requirements
(b) identification system
(c) review and approval requirements
(d) issuance and distribution
(e) revisions
(f) indication of status
(g) storage and control of originals or master copies

5 DESIGN INPUT

Design inputs include many characteristics and functions of an item or system. These inputs vary depending on the application; however, the nuclear industry has found it desirable to consider at least the following listed inputs as they apply to specific items or systems:

(1) basic functions of each structure, system, and component;

(2) performance requirements such as capacity, rating, and system output;

(3) codes, standards, and regulatory requirements including the applicable issue and/or addenda;

(4) design conditions such as pressure, temperature, fluid chemistry, and voltage;

(5) loads such as seismic, wind, thermal, and dynamic;

(6) environmental conditions anticipated during storage, construction, and operation such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure;

(7) interface requirements including definition of the functional and physical interfaces and the effects of cumulative tolerances involving structures, systems, and components;

(8) material requirements including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance;

(9) mechanical requirements such as vibration, stress, shock, and reaction forces;

(10) structural requirements covering such items as equipment foundations and pipe supports;

(11) hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities;

(12) chemistry requirements such as provisions for sampling and limitations on water chemistry;

(13) electrical requirements such as source of power, voltage, raceway requirements, electrical insulation, and motor requirements;

(14) layout and arrangement requirements;

(15) operational requirements under various conditions such as plant startup, normal plant operation, plant shutdown, plant emergency operation, special or infrequent operation, and system abnormal or emergency operation;

(16) instrumentation and control requirements including indicating instruments, controls, and alarms required for operation, testing, and maintenance. Other requirements such as the type of instrument, installed spares, range of measurement, and location of indication are included.

(17) access and administrative control requirements for plant security;

(18) redundancy, diversity, and separation requirements of structures, systems, and components;

(19) failure effects requirements of structures, systems, and components including a definition of those events and accidents which they must be designed to withstand;

(20) test requirements including pre-operational and subsequent periodic in-plant tests and the conditions under which they will be performed;

(21) accessibility, maintenance, repair, and inservice inspection requirements for the plant including the conditions under which these will be performed;

(22) personnel requirements and limitations including the qualification and number of personnel available for plant operation, maintenance, testing, and inspection, and radiation exposures to the public and plant personnel;

(23) transportability requirements such as size and shipping weight, limitation, and I.C.C. regulations;

(24) fire protection or resistance requirements;

(25) handling, storage, cleaning, and shipping requirements;

(26) other requirements to prevent undue risk to the health and safety of the public;

(27) materials, processes, parts, and equipment suitable for application;

(28) safety requirements for preventing personnel injury including such items as radiation safety, criticality safety, restricting the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems;

(29) quality and quality assurance requirements;

(30) reliability requirements of structures, systems, and components including their interactions, which may impair functions important to safety;

(31) interface requirements between plant equipment and operation and maintenance personnel;

(32) requirements for criticality control and accountability of nuclear materials.

6 DESIGN VERIFICATION

Design verification for some designs or specific design features may be achieved by suitable qualification testing of a prototype or initial production unit. Qualification testing may be used in combination with other verification methods. For example, it may be most effective to verify that an instrumentation cabinet is designed to withstand the maximum earthquake-caused vibratory motions by actually subjecting the cabinet and its associated components to shaker tests which correspond to these vibratory motions. The shaker tests will not, however, verify that the circuitry is designed correctly or that the component in the cabinet will perform its intended function. Other tests or verification means are required to confirm that remaining design functions are adequately performed by the instrumentation and that

those components perform the intended functions for the varying conditions to which they are subjected.

7 FORMATS

Examples of formats that may be used for division of responsibilities and drawing control are shown in Figs. 3A-1.1, 3A-1.2, and 3A-1.3.

SYSTEM/COMPONENT/STRUCTURE: Seismic Design—All Systems

PROJECT:

CONTRACT/PURCHASE ORDER:

LEGEND
OWNER
ARCHITECT/ENGINEER (A/E)
REACTOR MANUFACTURER (NSSS)
SUBCONTRACTOR (SUB)

Activity / Responsibility	Seismic/ Criteria Specifications	Dynamic Model	Preliminary Design	Seismic Analysis & Confirmation	Base Response Curves	Equip. Level Response Curves	Seismic Confirmation Report	Review & Approval
1. Reactor Pressure Vessel and Internals	Owner-NSSS	NSSS	NSSS	A/E-NSSS	—	NSSS	NSSS	Owner
2. Reactor Building	Owner	A/E	A/E	A/E-NSSS	A/E	A/E	A/E	Owner
3. NSSS Piping	Owner	NSSS	NSSS	NSSS	—	—	NSSS	Owner
4. NSSS Piping Restraints and Supports	Owner	NSSS	A/E-NSSS	A/E-NSSS	—	—	A/E-NSSS	Owner
5. Non-NSSS Piping	Owner	A/E	A/E	A/E	—	—	A/E	Owner
6. Non-NSSS Piping Restraints & Supports	Owner	A/E	A/E	A/E	—	—	A/E	Owner
7. NSSS Subcontracted Equipment	NSSS	SUB	SUB	SUB	—	A/E	SUB	NSSS-Owner
8. Non-NSSS Subcontracted Equipment	A/E	SUB	SUB	SUB	—	A/E	SUB	A/E-Owner

EXAMPLE

FIG. 3A-1.1 DIVISION OF RESPONSIBILITIES

SEISMIC INTERFACE CHART

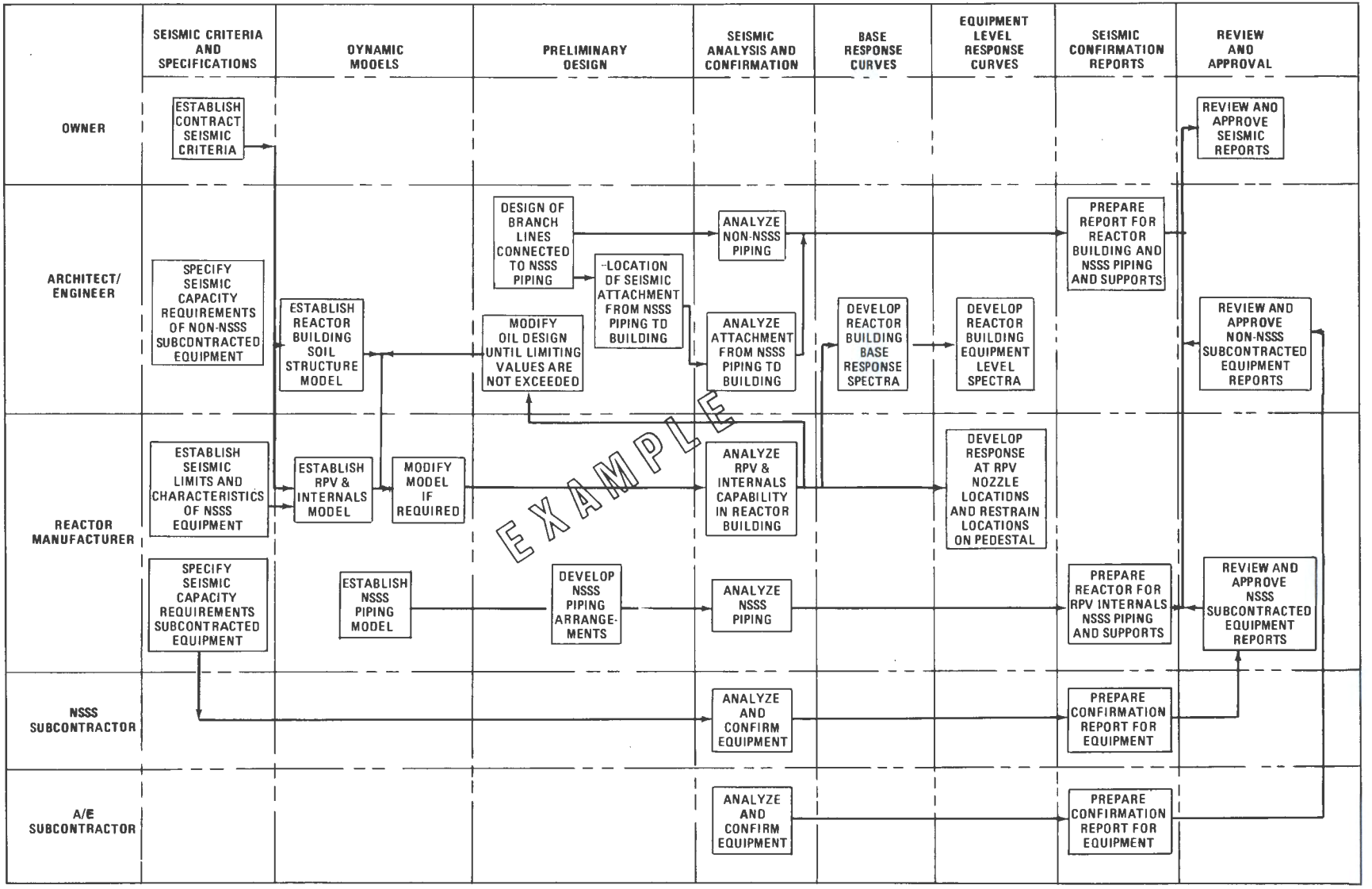

FIG. 3A-1.2 DIVISION OF RESPONSIBILITIES

PROJECT_____

DRAWING ISSUE CHECKLIST

JOB ORDER NUMBER *9999-1*

TO *JOHN DOE – CONST. SUPT.*

DATE *12-31-72*

FROM *JOHN SMITH – PROJECT ENGINEER*

THE FOLLOWING DRAWINGS HAVE BEEN SENT TO YOU SINCE *11-30-72* PLEASE REVIEW YOUR RECENT RECEIPTS OF DRAWINGS AND CHECK THE APPROPRIATE COLUMN AS TO WHETHER YOU HAVE RECEIVED THEM OR NOT. INITIAL AND DATE THIS FORM WHERE INDICATED. RETURN THE MARKED ORIGINAL TO ME IMMEDIATELY; KEEP THE COPY FOR YOUR RECORDS.

DRAWING NO. (EXCLUDING J.O.)	ISSUE NO.	DRAWING RECEIVED		DRAWING NO. (EXCLUDING J.O.)	ISSUE NO.	DRAWING RECEIVED		DRAWING NO. (EXCLUDING J.O.)	ISSUE NO.	DRAWING RECEIVED	
		YES	NO			YES	NO			YES	NO
12732	*B*										
27426	*D*										
44014	*C*										
32507	*E*										

EXAMPLE

I certify that the previous revisions of the documents, and drawings have been recalled or accounted for:

_____
Signature – Date

IMPORTANT →

FIELD CHECK BY

DATE

FIG. 3A-1.3 DRAWING ISSUE CHECKLIST

APPENDIX 4A-1
NONMANDATORY GUIDANCE ON PROCUREMENT DOCUMENT CONTROL

1 GENERAL

This Appendix provides nonmandatory guidance on controlling quality assurance requirements in procurement documents as specified in Basic Requirement 4 and Supplement 4S-1.

2 PROCUREMENT DOCUMENT REVIEW

The review of procurement documents should be performed as early in the document preparation as practical. Technical and quality assurance reviews should normally be performed on the procurement documents prior to issuance for bid.

3 TYPICAL SCOPE OF PROCUREMENT EFFORT

The complexity of a nuclear facility dictates the need for a multitude of tasks that should be performed during various phases of design, construction, testing, and operations. One of the major tasks is the procurement of items and services. Each major phase involves a procurement effort that should be responsive to the special needs of that phase and that should provide items and services which meet code, regulatory, and special requirements. Examples of the items and services procured during these phases are given in paras. 3.1 and 3.2 below.

3.1 Design, Construction, and Testing Phases

(a) Design and engineering services;

(b) Site investigations, such as those required to determine the engineering requirements for the structure (i.e., soil investigation, environmental studies, both field work and laboratory effort);

(c) Long-lead items such as the nuclear steam supply, process equipment, including major equipment fabrication and test, and high level waste storage tanks;

(d) Construction of the main structure of the facility, including structural steel erection and concrete production and placement;

(e) Specific site erection and installation tasks, such as piping, mechanical and electrical equipment;

(f) Services for nondestructive examination and required laboratory tests;

(g) Hardware, such as valves, piping, tanks, and miscellaneous hardware;

(h) Software, such as development of facility operating procedures, technical manuals, and computer codes;

(i) Services of various consultants to assist in setting up management systems (i.e., quality assurance program and operator training);

(j) Pre-operational and start-up tests;

(k) Baseline inspection equipment or services.

3.2 Operational Phase

(a) Fuel, equipment, and services for power plant fueling operations; special fuel grapples and cask yokes at reprocessing plants, fuel components, and subassemblies at fuel fabrication plants; chemicals used in fuel processing and reprocessing cycles; special packaging for nuclear materials, radioactive products, and radioactive by-products;

(b) Inservice inspection equipment or services;

(c) Items and services for facility maintenance, modifications, or changes;

(d) Special services such as environmental monitoring, radioactive waste disposal, and facility decontamination.

The examples given in para. 3.1 and (a) through (d) above are not meant to be all inclusive but only indicative of the wide variety of procurements for the above phases. Similarly, it should be realized that the phases and types of procurements listed above are not distinct in scope and timing and that there may be considerable overlapping depending upon the needs of a particular situation.

4 CATEGORIZATION OF PROCUREMENT ACTIONS

The types of procurements listed above may also be categorized in terms of what is supplied by the Supplier, i.e., hardware, services, installation, and total system supply or combinations thereof. Such a categorization, wherein the procurement efforts are grouped by what is supplied, can be of assistance in identifying the logical steps that should be performed in properly specifying the quality assurance requirements in the procurement documents. For example, the procurement of services, such as for soil investigations or pipe stress calculations, can have certain quality assurance program features in common which may be different for the program feature of a pure hardware procurement.

5 GENERAL LOGIC CONSIDERATIONS

The quality assurance requirements should be compatible to the particular type of item or service which is to be supplied. Certain items and services may require extensive controls throughout all stages of development, while others may require only a limited quality assurance effort in selected phases of development. The factors that determine the extent of a quality assurance effort are as follows.

5.1 Importance of Malfunction or Failure of the Item to Plant Safety

Each item to be procured should be evaluated to determine whether or not it is important to plant safety. For those items that are important to plant safety, applicable requirements of this Standard should be specified in the procurement document. This safety determination should be made by the engineering staff of the appropriate organization having primary responsibility for specifying the design requirements for the item.

5.2 Complexity or Uniqueness of the Item

In developing specific quality assurance requirements for a particular item, the complexity and uniqueness should be considered.

5.2.1 The extent of controls needed to assure the quality of those characteristics which are necessary for proper functioning and long-term performance may depend heavily upon the complexity of the item, the margin of safety incorporated into its design, and the industry experience, or lack thereof, in accomplishing the quality-related activity. Obviously, if a design effort is required to develop the item or accomplish the activity, design quality assurance requirements should be included in the procurement document.

5.2.2 Items which require a complex manufacturing plan may require extensive control over important characteristics. The control over important characteristics should extend beyond the manufacturing phase when it is necessary to preclude damage to those characteristics during packaging, shipping, handling, and storage.

5.2.3 In determining the extent of quality assurance to be applied, past experience in the development of similar items should be considered. An item being developed for the first time will probably require much more control over important characteristics than one which has had a past history of successful performance. The complexity or uniqueness of the item may also affect the extent of personnel training and indoctrination required.

5.3 Need for Special Controls and Surveillance Over Processes and Equipment

5.3.1 Certain work operations require the use of special processes such as a welding, nondestructive examination, passivation, brazing and soldering, hardness and tensile testing, protective coating, and heat treatment.

5.3.2 Special processes may also include certain in-process operations such as chemical batch process, plating operating, and electric insulation impregnation. These processes should be accomplished under specially controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions, definitive procedures, qualified personnel, and assurance that prerequisites have been satisfied.

5.4 Degree to Which Functional Compliance Can Be Demonstrated by Inspection and Test

It may be possible to demonstrate the quality of certain characteristics of an item by an appropriate inspection or test. In such cases, the in-process control effort may be reduced if any appropriate inspection and test will be sufficient to provide assurance of quality. A limiting case is an end product test which

can properly assess the degrees of compliance to quality requirements, thereby eliminating the need for in-process control.

5.5 Quality History and Degree of Standardization of the Item

The ability to use historical data in evaluating the quality experience of an item is based in part upon the degree of standardization of the item. If a manufacturer has been producing a particular standard item for a long period and if the operational quality history of the item indicates that its significant characteristics perform satisfactorily, the quality assurance program may be tailored to reflect this satisfactory performance history. Conversely, if certain characteristics are determined to be unsatisfactory based upon operational data, additional quality assurance effort may be required to correct these deficiencies.

The general logic considerations outlined above should be applied for each procurement action. If all or most of these considerations apply to a particular action, the overall method of para. 7.0.1 of this Appendix should be applied in specifying the quality assurance requirements in the procurement document. However, if these considerations have only limited applicability to a particular procurement action, the unique order method of para. 7.0.2 of this Appendix may be used to specify the quality assurance requirements of the procurement document.

6 LOGIC CHART

Figure 4A-1.1 provides a pictorial illustration of the logic process described in Section 5 of this Appendix. This chart illustrates an example for procurement of hardware items only; however, a similar logic flow can also be used for other types of procurements such as design, inspection, test, and installation services or total system supply. It should be noted that this chart is provided for guidance and illustration only, and does not necessarily present all considerations that have to be made for this type of procurement.

7 METHODS OF SPECIFYING QUALITY ASSURANCE PROGRAM REQUIREMENTS

There are various ways in which the Purchaser can specify and obtain suitable Supplier quality assurance program requirements. Two of the most prevalent methods are as follows.

7.0.1 Overall Method. The Purchaser may incorporate into the procurement documents a complete quality assurance program standard, such as this Standard, and require the Supplier to apply the requirements of the quality assurance standard as appropriate to the items or services being procured.

7.0.2 Unique Order Method. The Purchaser may incorporate into the procurement documents selected portions of a quality assurance standard, such as this Standard, that are unique to the items or services being procured. For example, when the Purchaser's order is limited to design work only, Basic Requirements 1, 2, 3, 5, 6, 16, 17, and 18 and requirements of Supplements 1S-1, 2S-1, 3S-1, 6S-1, 17S-1, and 18S-1 could be applied.

7.1 Example of Specifying the Overall Method

For procurement actions where the scope of work requires a broad range of skills and facilities to be furnished by the Supplier, most or all of the requirements of this Standard may apply in varying degrees to the item or service being procured. An example would be the procurement of a major primary coolant pump or valve which requires the Supplier to design, manufacture, inspect, and test the equipment in accordance with the Purchaser's engineering specification.

Typical Example

For the example given in para. 7.1 above, the overall method could be used to specify the quality assurance program required of the Supplier by use of the provisions given in (a) through (f) below.

(a) The Supplier shall establish and maintain a quality assurance program conforming to this Standard and all its applicable supplements.

(b) This Standard and its Supplements are applicable only to the extent that the Purchaser's order requires work that is governed by the sections and elements. For example, when the Purchaser's order does not require design work of the Supplier, the requirements of Basic Requirement 3 and Supplement 3S-1 do not apply.

(c) The Supplier shall document a quality assurance program sufficient to conform to the applicable requirements of this Standard and to the Purchaser's technical and administrative requirements contained in the purchase order and referenced documents.

(d) The Supplier shall submit a description of his quality assurance program to the Purchaser with the Supplier's bid response for the Purchaser's review. If the Supplier's description of his quality assurance program has been previously submitted, the Supplier shall update it or submit a statement that the quality assurance program has not

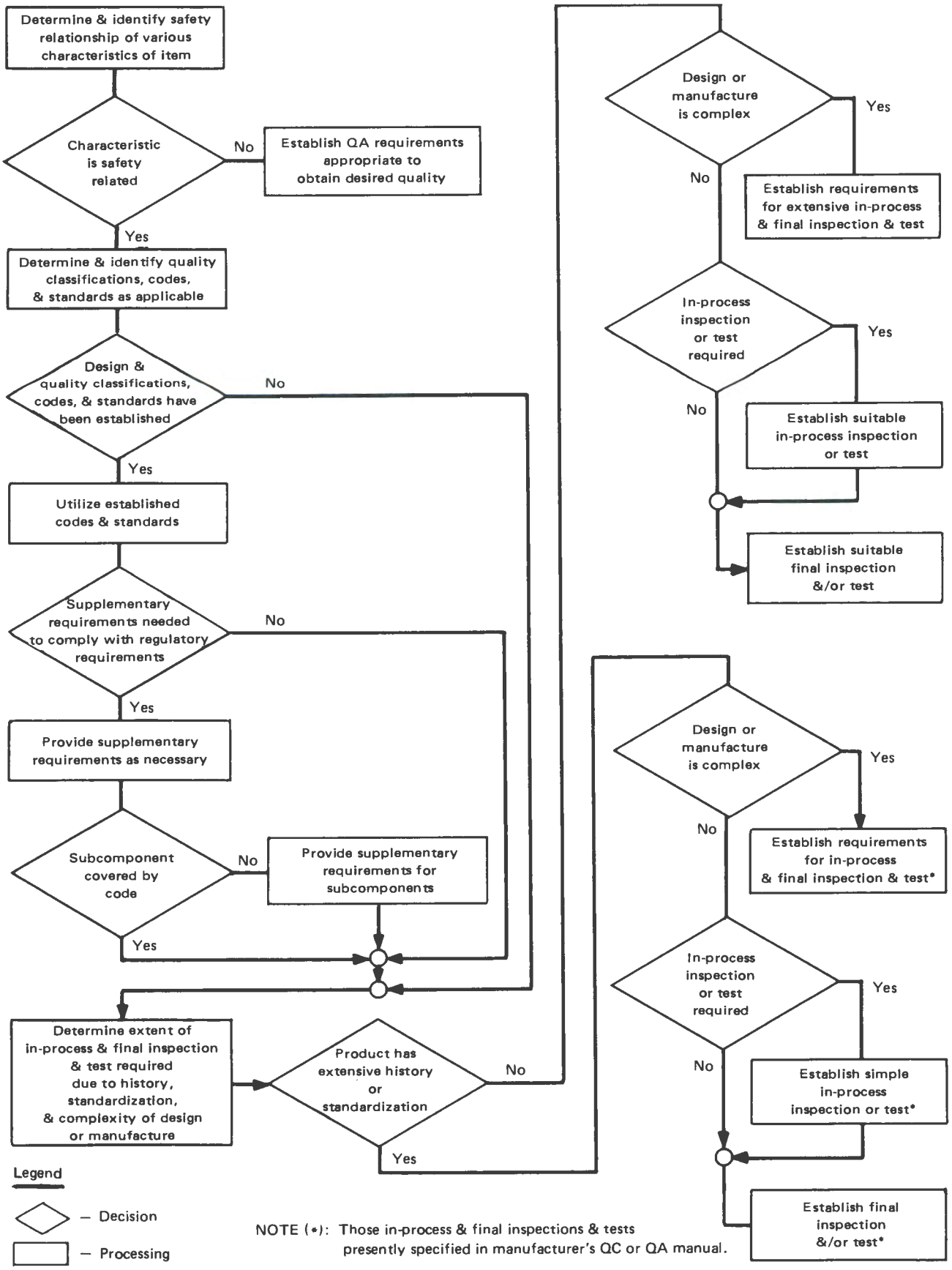

FIG. 4A-1.1 LOGIC CHART FOR DETERMINING APPROPRIATE QUALITY REQUIREMENTS

changed since the last evaluation. Where the Supplier holds a valid Certificate of Authorization for ASME Code Section III, the Supplier's ASME Quality Assurance Manual containing a copy of the Certificate of Authorization may be submitted to satisfy the requirements for a documented quality assurance program description. The Supplier's ASME Quality Assurance Program should be supplemented to extend the quality assurance requirements to other activities not covered by the Code as necessary to satisfy the Purchaser's procurement requirements.

(e) The Purchaser shall evaluate the program of the successful bidder and provide comments if modifications to the program are required. The Supplier should resolve the Purchaser's comments and implement them prior to the start of any work affected by the comments. Subsequent changes to the Supplier's program shall be subject to the same degree of Purchaser control.

(f) The Supplier shall identify and pass on to the subtier Suppliers all applicable quality assurance program requirements.

7.2 Example of Specifying the Unique Order Method

For procurement actions where the scope of work requires only limited, even though specialized, skills and facilities to be furnished by the Supplier, only part of the requirements of this Standard may apply to the item or service being purchased.

Typical Example

An example of the scope of work described in para. 7.2 above might be as in (a) through (d) below.

(a) Perform an independent design review of the following:

(1) the equipment described by the drawings and specifications referenced in this purchase order; and

(2) the equipment design and stress calculations submitted with this purchase order.

(b) Establish a procedure and technique and conduct, subject to the Purchaser's approval, an experimental test to determine stress levels at representative locations of the equipment under conditions corresponding to 100% system design pressure and coolant temperature of 100°F–200°F. The Purchaser will provide the Supplier with the equipment to be tested.

(c) Prepare a complete report describing the work performed in (a) and (b) above. The report should confirm whether the equipment meets the specified design requirements and make recommendations as to further investigations or design requirements considered necessary.

(d) For the above example, the unique order method could be used to specify the quality assurance program required of the Supplier by use of provisions given in (1) through (5) below.

(1) The Supplier shall establish and maintain a documented quality assurance program conforming to the Basic Requirements and Supplements of this Standard which are listed below. These requirements and the associated Supplements shall be applied to the extent that the Purchaser's order requires work which is governed by the Basic Requirements and Supplements.

Basic Requirements

1	Organization
2	Quality Assurance Program
3	Design Control
5	Instructions, Procedures, and Drawings
6	Document Control
11	Test Control
12	Control of Measuring and Test Equipment
15	Control of Nonconforming Items
16	Corrective Action
17	Quality Assurance Records
18	Audits

Supplements

S-1	Terms and Definitions
1S-1	Supplementary Requirements for Organization
2S-1	Supplementary Requirements for the Qualification of Inspection and Test Personnel
3S-1	Supplementary Requirements for Design Control
6S-1	Supplementary Requirements for Document Control
11S-1	Supplementary Requirements for Test Control
12S-1	Supplementary Requirements for Control of Measuring and Test Equipment
15S-1	Supplementary Requirements for the Control of Nonconforming Items
17S-1	Supplementary Requirements for Quality Assurance Records
18S-1	Supplementary Requirements for Audits

(2) The Supplier shall submit his quality assurance program description to the Purchaser with the Supplier's bid response for the Purchaser's review. If the Supplier's quality assurance program description has been previously submitted, the Supplier shall update it or submit a statement that the quality assurance program has not changed since the last evaluation.

(3) The Purchaser shall evaluate the program of the successful bidder and will provide comments if changes or supplements are required. The Supplier shall resolve the Purchaser's comments and implement them prior to the start of any work affected by the comments.

(4) The Supplier shall, during the performance of the order, submit all proposed changes of his quality assurance program to the Purchaser for information prior to implementing the changes to the Purchaser's order.

(5) The Supplier shall identify and pass on to the Supplier's subtier Suppliers all applicable quality program requirements.

APPENDIX 7A-1
NONMANDATORY GUIDANCE FOR CONTROL OF PURCHASED ITEMS AND SERVICES

1 GENERAL

This Appendix provides nonmandatory guidance on the control of procurement activities as specified in Basic Requirement 7 and Supplement 7S-1.

2 SUPPLIER SELECTION

One method most commonly used to assure the suitability of Supplier selection is source evaluation prior to selection. Where the evaluation involves more than one organization of the Purchaser, it is desirable to develop interface descriptions and sufficient program procedures to control the evaluations and define responsibilities.

There are many ways available for use in evaluating a potential Supplier. Some of the most common are given in paras. 2.1 through 2.3 below.

2.1 Performance History

Evaluate the Supplier's history of providing a product which performs satisfactorily in actual use. Information evaluated should include the following:

(a) the experience of users of identical or similar products of the prospective Supplier; or

(b) the Purchaser's records that have been accumulated in connection with previous procurement actions and product operating experience.

Quality performance is highly dependent upon the Supplier's personnel capabilities, the physical conditions of the manufacturing facility and equipment, and management attitude toward quality. Historical data should be representative of the Supplier's current capability. If there has been no recent experience with the Supplier or if he is a new Supplier, the prospective Supplier should be requested to submit information on a similar item or service for evidence of his current capabilities.

2.2 Quality Records

Objectively evaluate the Supplier's current quality records supported by documented qualitative and quantitative information. This may include review and evaluation of the Supplier's Quality Assurance Program, Manual, and Procedures, as appropriate.

2.3 Facility Survey

Evaluate the Supplier's technical quality capability, which is determined by a direct evaluation of his facilities and personnel, and the implementation of his quality assurance program.

3 PURCHASER/SUPPLIER COMMUNICATIONS

Depending on the complexity or scope of the item or service, the Purchaser may initiate pre- and post-award activities. These activities may take the form of meetings or other communications to establish that the Supplier understands the procurement requirements; the intent of the Purchaser in monitoring and evaluating the Supplier's performance; and the planning and manufacturing techniques, tests, inspections, and processes to be employed by the Supplier in meeting procurement requirements. When Purchaser notification points, including hold and witness points, are required, they should be identified at this time. The depth and necessity of pre- and post-award communication depend on the uniqueness, complexity, and frequency of procurement with the same Supplier, and past Supplier performance for the specific items or services covered by the procurement document.

4 PRODUCT ACCEPTANCE

Among the methods used in the nuclear industry to accept an item or service from a Supplier are source

verification, receiving inspection, Supplier Certificate of Conformance, post-installation test at the nuclear power plant site, or a combination thereof.

4.1 Source Verification

Acceptance by source verification may be most desirable when the item or service is as follows:

(a) vital to plant safety; or

(b) difficult to verify quality characteristics after delivery; or

(c) complex in design, manufacture, and test.

Source verification may not be necessary when the quality of the item can be verified by review of test reports, inspections upon receipt, or other means.

The source verification activities may include the following checks.

4.1.1 Documentation has been submitted as required and provides verification of approvals, material, applicable inspections, and tests.

4.1.2 Fabrication procedures and processes have been approved and complied with and the applicable qualifications, process records, and certifications are available.

4.1.3 Components and assemblies have been inspected, examined, and tested as required and applicable inspection, test, and certification records are available.

4.1.4 Nonconformances have been dispositioned as required.

4.1.5 Components and assemblies are cleaned, preserved, packed, and identified in accordance with specified requirements.

4.2 Receiving Inspection

Acceptance solely by receiving inspection should be considered only when the items or services are as follows.

4.2.1 Relatively simple or standard in design, manufacture, and test; and

4.2.2 Adaptable to standard or automated inspections and/or tests of the end product to verify quality characteristics after delivery; and

4.2.3 Such that receiving inspection does not require operations which could adversely affect the integrity, function, or cleanness of the item.

4.3 Certificate of Conformance

In certain procurement actions which do not involve source verification by the Purchaser, the Purchaser may accept an item or service from a Supplier based on a receiving inspection and a Supplier's Certificate of Conformance that the specified requirements have been met. However, specific supplemental documentation, such as material certificates or reports of tests performed, may be required by procurement documents. Acceptance by this method is satisfactory when the item or service is of simple design and involves standard materials, processes, and tests. Such items may be fabricated subject to selected qualification, sample, or batch testing to establish or maintain maximum quality.

4.4 Post-Installation Testing

Acceptance by post-installation test is satisfactory when performed following the accomplishment of at least one of the preceding methods and when:

(a) it is difficult to verify the quality characteristics of the item without it being installed and in use; or

(b) the item requires an integrated system checkout or test with other items to verify its quality characteristics; or

(c) the item cannot demonstrate its ability to perform its intended function except when in use.

5 COMMERCIAL GRADE ITEMS

The following precautions should be taken when commercial grade items are purchased.

5.1 Suitability

Verify that the requirements needed to satisfy the design function can be met by a product which is commercially available.

5.1.1 Consider applicability of national codes and standards.

5.1.2 Consider critical operating requirements such as temperature, pressure, flow, seismic factors, structure, power supply, cycling, etc.

5.1.3 Identify the attributes that should be traceable to the item.

5.1.4 Verify that the item meets the definition of commercial grade given in Supplement S-1. The manufacturer's published product description should

specify what documents, if any, are supplied with the item. When documentation is required beyond that indicated in the manufacturer's published product description, and when such information is not available for all items with the same part number obtained from the same manufacturer, the item does not meet the definition of commercial grade.

5.2 Reordering

The requirements applicable to the initial procurement of an item should be documented to facilitate reordering. Appropriate catalog pages may be retained or catalog descriptions copied.

APPENDIX 17A-1
NONMANDATORY GUIDANCE ON QUALITY ASSURANCE RECORDS

1 GENERAL

This Appendix provides nonmandatory guidance on records as specified in Basic Requirements 17 and Supplement 17S-1.

1.1 Records System

A procedure describing the records system(s) should include control of records withdrawn from storage which may be required during the completion of work activity.

1.2 Generation of Records

Documents which may later become records should be maintained and processed in a prudent manner to avoid unnecessary delay and/or expense when the record is needed.

1.3 Records Stored on Magnetic or Optical Media

Provisions should be made for the capability to retrieve information stored on magnetic or optical media. Compatible processing systems should be available, or information should be transferred to other readable media.

2 LOST OR DAMAGED RECORDS

If replacement or restoration of lost or damaged records is not practical, action should be taken to assure the quality of items or activities affecting quality, e.g., reexamination or investigation by alternate means.

3 LIST OF TYPICAL LIFETIME RECORDS

The following is a list of typical lifetime records. The nomenclature of these may vary. Records not identified on this list are nonpermanent.

3.1 Design Records

Applicable codes and standards used in design
Computer programs or corresponding mathematical model
Design drawings
Design calculations and record of checks
Approved design change requests
Design deviations
Design reports
Design verification data
Design specifications and amendments
Safety analysis report
Stress reports for code items
Systems descriptions
Systems process and instrumentation diagrams
Technical analysis, evaluations, and reports

3.2 Procurement Records

Procurement specification
Purchaser order (unpriced) including amendments

3.3 Manufacturing Records

Applicable code data reports
As-built drawings and records
Certificate of compliance
Eddy current examination final results
Electrical control verification test results
Ferrite test results
Heat treatment records
Liquid penetrant examination final results
Location of weld filler material
Magnetic particle examination final results
Major defect repair records
Material properties records
Nonconformance reports
Performance test procedure and results records
Pipe and fitting location report
Pressure test results (hydrostatic or pneumatic)

Radiograph review records
Ultrasonic examination final results
Welding procedures

3.4 Installation Construction Records

3.4.1 Receiving and Storage — Nonconformance Reports

3.4.2 Civil

Check-off sheets for tendon installation
Concrete cylinder test reports and charts
Concrete design mix reports
Concrete placement records
Inspection reports for channel pressure tests
Material property reports on containment liner and accessories
Material property reports on metal containment shell and accessories
Material property reports on reinforcing steel
Material property reports on reinforcing steel splice sleeve material
Material property reports on steel embedments in concrete
Material property reports on structural steel and bolting
Material property reports on tendon fabrication material
Pile drive log
Pile loading test reports
Procedure for containment vessel pressure proof test and leak rate tests and results
Reports for periodic tendon inspection
Reports of high strength bolt torque testing
Soil compaction test reports

3.4.3 Welding

Ferrite test results
Heat treatment records
Liquid penetrant test final results
Material property records
Magnetic particle test final results
Major weld repair procedures and results
Radiograph review records
Ultrasonic test final results
Weld location diagrams
Weld procedures

3.4.4 Mechanical

Cleaning procedures and results
Code data reports
Installed lifting and handling equipment procedures, inspection, and test data
Lubrication procedures
Material properties records
Pipe and fitting location reports
Pipe hanger and restraint data
Pressure test results (hydrostatic or pneumatic)
Safety valve response test procedures

3.4.5 Electrical and I & C

Cable pulling tension data
Cable separation data
Cable splicing procedures
Cable terminating procedures
Certified cable test reports
Relay test procedures
Voltage breakdown test results on liquid insulation

3.4.6 General

As-built drawings and records
Final inspection reports and releases
Nonconformance reports
Specifications and drawings

3.5 Pre-Operational and Start-Up Test Records

Automatic emergency power source transfer procedures and results
Final system adjustment data
Pressure test results (hydrostatic or pneumatic)
Initial heatup, hot functional, and cooldown procedures and results
Initial plant loading data
Initial reactor criticality test procedures and results
Instrument AC system and inverter test procedures and reports
Main and auxiliary power transformer test procedures and results
Off-site power source energizing procedures and test reports
On-site emergency power source energizing procedures and test reports
Plant load ramp change data
Plant load step change data
Power transmission substation test procedures and results
Pre-operational test procedures and results
Primary and secondary auxiliary power test procedures and results
Reactor protection system tests and results
Start-up logs
Start-up test procedures and results
Station battery and DC power distribution test procedures and reports
Water chemistry report

3.6 Operation Records

Records and drawing changes identifying facility design modifications made to systems and equipment described in the Final Safety Analysis Report
New and irradiated fuel inventory, fuel transfers, and assembly fuel-depletion history records
Off-site environmental monitoring survey records
Spent fuel shipment records
Facility radiation and contamination survey results
Radiation exposure records for individuals entering radiation control areas
Records of gaseous and liquid radioactive material released to the environs
Records of transient or operational cycles for those facility components designed for a limited number of transients or cycles
Training and qualification records for current members of the plant operating staff
In-service inspection records
Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments
Meeting minutes of the plant nuclear safety committee and company nuclear review board
Surveillance activities, inspections, and calibrations required by the technical specifications records
Records of reactor tests and experiments
Changes made to operating procedures
Low level radioactive waste shipments records
Sealed source leak test results
Records of annual physical inventory of all sealed source material
Logs of facility operation covering time interval at each power level
Records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and components
Water chemistry reports
Operational, shift supervisor, and control room logs
Licensee event reports
Fire protection records
Nonconformance reports
Plant equipment operations instructions
Security plan and procedures
Emergency plan and procedures
Quality Assurance and Quality Control Manuals
Records of activities required by the security plan and procedures
Records of activities required by the emergency plan and procedures
Applicable records noted in other sections of this Appendix for any modifications or new construction applicable to structures, systems, or components
Evaluation of results of reportable safety concerns as required by regulations
Annual environmental operating report
Annual plant operating report
Records to support licensing conditions such as safeguards and special nuclear material accountability

APPENDIX 18A-1
NONMANDATORY GUIDANCE ON AUDITS

1 GENERAL

This Appendix provides nonmandatory guidance on quality assurance audits as specified in Basic Requirement 18 and Supplement 18S-1.

2 AUDIT ADMINISTRATION

2.1 Purpose

Quality assurance audits should be performed to:

(a) determine that an effective quality assurance program has been developed and documented;

(b) verify by examination and evaluation of objective evidence whether quality assurance program elements, items, processes, work areas, or records, as appropriate, conform to specified requirements;

(c) assess the effectiveness of controls and verification activities;

(d) report audit findings of deficiencies to all levels of management who should be informed and who should take corrective action;

(e) verify that corrective action has been planned, initiated, or completed.

2.2 Elements

Elements of audit administration should include (a) through (g) below:

(a) a management policy statement or procedure which establishes organizational independence and authority of the auditors and commits the organization to executing an effective audit system;

(b) manpower, funding, and facilities to implement the audit system;

(c) identification of audit personnel and their qualifications;

(d) provisions for reasonable and timely access of audit personnel to facilities, documents, and personnel necessary in the planning and performance of the audits;

(e) methods for reporting audit findings to responsible management of both the audited and auditing organizations;

(f) provision for access by audit teams to levels of management of the auditing and audited organizations that have the responsibility and authority to assure corrective action;

(g) methods for verification of effective corrective action on a timely basis.

2.3 Frequency of Audits

Frequency of regularly scheduled internal and external audits should be based upon evaluation of all applicable and active elements of the quality assurance programs. These evaluations should include an assessment of the effectiveness of the applicable and active elements of the program based upon such information as the following:

(a) previous audit results and corrective actions;

(b) nonconformance reports;

(c) independent information (e.g., from other sources such as generic experience of the nuclear industry, ASME, peer organizations, regulating bodies, etc.).

2.4 Supplemental Audits

Regularly scheduled audits should be supplemented by additional audits for one of the reasons given in (a) through (f) below:

(a) to determine the capability of a Supplier's quality assurance program prior to awarding a contract or purchase order;

(b) when, after award of a contract, sufficient time has elapsed for implementing the quality assurance program and it is appropriate to determine that the organization is adequately performing the functions as defined in the quality assurance program description, codes, standards, and other contract documents;

(c) when significant changes are made in functional areas of the quality assurance program such as significant reorganization or procedure revisions;

(d) when it is suspected that the quality of an item is in jeopardy due to deficiencies in the quality assurance program;

(e) when a systematic, independent assessment of program effectiveness is considered desirable;

(f) when it is necessary to verify implementation of required corrective action.

3 PREPARATION FOR AUDITING

3.1 Team Selection

In selecting personnel for audit assignments, consideration should be given to special abilities, specialized technical training, prior experience, personal characteristics, and education.

3.2 Team Familiarization

To ensure that the audit team is prepared prior to initiation of audit, pertinent information, including policies, procedures, standards, instructions, codes, regulatory requirements, and prior audit reports, should be made available for review by the auditors. During the orientation phase of the audit, particular attention should be directed toward an understanding of internal and external organization and contractual interfaces and responsibilities of the organization to be audited.

3.3 Audit Notification

Involved organizations should be notified of an audit a reasonable time before the audit is to be performed except for unannounced audits. This notification should be in writing and include such information as the scope and schedule of the audit and the names of the audit team leader and team members, if known. If unannounced audits are to be performed, prior agreement should be obtained by the parties involved.

4 PERFORMANCE

4.1 Pre-Audit Conference

A pre-audit conference should be conducted with the management of the organization to be audited. The purpose of the conference should be to confirm the audit scope and planned dates, meet counterparts, discuss the sequence and duration of the audit, set the time for the post-audit conference, and establish channels of communication. During the conference, there should be an agreed-to agenda for the audit.

4.2 Methods

Audits should be performed using the methods given in (a) through (e) below, as appropriate:

(a) review of procedures and work instructions for completeness and adequacy;

(b) examination in work areas for evidence of implementation of procedures and instructions;

(c) examination of personnel training and qualifications records where special skills are required;

(d) reexamination of selected work which has been accepted, such as products, design calculations, and drawings, and comparison of findings with applicable requirements and the previous basis for acceptance;

(e) examination of process controls and records to determine conformance with specification.

4.3 Post-Audit Conference

At the conclusion of the audit, a post-audit conference should be held by the audit team with management of the audited organization to present audit results and clarify misunderstandings. It is desirable that agreement be reached on audit results at the post-audit conference.

5 REPORTING

The audit report should be issued within 30 days and include a requested date for response by the audited organization. The audit report should be distributed to responsible management of both the auditing and the audited organizations.

6 RESPONSE

The audited organization should respond to the report prior to the requested date. The response should clearly state the corrective action taken to prevent recurrence. In the event that corrective action cannot be taken immediately, the audited organization's response should include a scheduled date for initiation and completion of corrective action. The audited or-

ganization should report periodically on the status of corrective action taken and the date corrective action was completed.

7 FOLLOW-UP ACTION

Follow-up action by the audit team leader or management of the auditing organization should verify the following:

(a) timely written response to the audit report;

(b) adequacy of the response;

(c) corrective action accomplishment as scheduled.