AMERICAN NATIONAL STANDARD
REACTOR PLANTS AND THEIR MAINTENANCE

Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants

ANSI N45.2.13 - 1976

SECRETARIAT

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AMERICAN NATIONAL STANDARD

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This standard was approved by the American National Standards Committee N45 and its Secretariat, and it was subsequently approved and designated N45.2.13-1976 by the American National Standards Institute on February 27, 1976.

FOREWORD

(This foreword is not a part of American National Standard Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants.)

This standard deals with the control of activities that should be exercised for the procurement of items and services for nuclear power plants. The standard was developed by the American National Standards Committee N45 on Reactor Plants and Their Maintenance. This committee has been chartered to promote the development of standards for the location, design, construction, and maintenance of nuclear reactors and plants embodying nuclear reactors, including equipment, methods, and components specifically for this purpose.

In April of 1970, the N45 Standards Committee established a subcommittee N45-2, to guide the preparation of nuclear quality assurance standards. The subcommittee is responsible for establishing guidelines and policy to govern the scope and content of the various standards; monitoring the status of standards in process; recommending preparation of additional standards; and final approval of standards prior to their submittal to the N45 Committee for balloting.

In September of 1971, the N45-2 Subcommittee established a work group committee N45-2.13 on Quality Assurance Requirements for Control of Procurement of Items and Services. The purpose of this committee was to prepare a standard for industry use that would define requirements and guidelines for procurement planning; procurement document preparation, review, and change control; selection and surveillance of suppliers; and the control of purchased items and services.

Working with N45-2 Subcommittee and concurrently with the development of this standard by the N45-2.13 Work Group, other work groups of N45 are developing a series of standards that set forth both general and detailed technical provisions for certain activities to assure quality during the design, construction, and maintenance of nuclear power plants.

As of June 1975, these work groups had the responsibility for the following associated standards:

Work Group	Standard in Preparation or Issued	
N45-2.7	N45.2	Quality Assurance Program Requirements for Nuclear Power Plants
N45-2.1	N45.2.1	Cleaning of Fluid Systems and Associated Components During the Construction Phase of Nuclear Power Plants
N45-2.2	N45.2.2	Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Power Plants (During the Construction Phase)
N45-2.3	N45.2.3	Housekeeping During the Construction Phase of Nuclear Power Plants
N45-2.4 (IEEE SC8)	N45.2.4	Supplementary Quality Assurance Requirements for Installation, Inspection and Testing Requirements for Instrumentation and Electric Equipment During the Construction of Nuclear Power Generating Stations
N45-2.5	N45.2.5	Supplementary Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants
N45-2.6	N45.2.6	Qualifications of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants

N45-2.8	N45.2.8	Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for the Construction Phase of Nuclear Power Plants
N45-2.9	N45.2.9	Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants
N45-2.10	N45.2.10	Quality Assurance Terms and Definitions
N45-2.11	N45.2.11	Quality Assurance Requirements for the Design of Nuclear Power Plants
N45-2.12	N45.2.12	Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants
N45-2.4 (IEE SC8)	N45.2.14	Quality Assurance Program Requirements for the Design and Manufacture of Class 1E Instrumentation and Electric Equipment for Nuclear Power Generating Stations
N45-2.2	N45.2.15	Hoisting, Rigging, and Transporting of Items for Nuclear Power Plant Sites
N45-2.4 (IEEE SC8)		Supplementary Requirements for the Calibration and Control of Measuring and Test Equipment Used in the Construction and Maintenance of Nuclear Facilities
N45-2.5	N45.2.20	Supplementary Quality Assurance Requirements for Sub-Surface Investigations Prior to the Construction Phase of Nuclear Power Plants
ANS-57.6	N45.2.21	Quality Assurance Program Requirements for Nuclear Power Plant Fuels
N45-2.7	N45.2.22	Supplementary Requirements for Inspection of Dimensional Characteristics
N45-2.6	N45.2.23	Qualification of Quality Assurance Program Audit Personnel for Nuclear Facilities

Suggestions for improvement gained in the use of this standard will be welcomed. They should be sent to The American Society of Mechanical Engineers, 345 East 47th Street, New York, N.Y. 10017.

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QUALITY ASSURANCE REQUIREMENTS FOR CONTROL OF PROCUREMENT OF ITEMS AND SERVICES FOR NUCLEAR POWER PLANTS

1. INTRODUCTION

1.1 Scope

This standard describes requirements and provides guidelines for the control of activities to be exercised during procurement of items and services which affect the quality of nuclear power plants. These requirements and guidelines apply to procurement activities for items and services such as designing, purchasing, fabricating, handling, shipping, storing, cleaning, constructing, erecting, installing, inspecting, testing, maintaining, repairing, initial fueling, refueling, and modifying. This standard provides guidelines for application of quality assurance program requirements listed in ANSI N45.2 for various types of procurement such as; total system supply, hardware, services, or a combination thereof.

This standard applies to the work of any individual or organization participating in the procurement of those items and services from which satisfactory performance is required. The extent to which the individual requirements of this standard shall apply will depend upon the nature and scope of the work to be performed and the required quality of the items or services purchased.

The ASME Boiler & Pressure Vessel Code (hereafter referred to as the Code, as well as other American National standards, has been considered in the development of this standard, and this standard is intended to be compatible with Code requirements.

This standard does not, however, apply to activities covered by Section III Divisions 1 and 2 and Section XI of the Code for those activities covered by the Code.

1.2 Responsibility

1.2.1 General. The responsibilities for Purchaser and Supplier are identified with recognition that an organization can be either a Purchaser or a Supplier depending upon the level of procurement. However, for any given procurement action the organization is one or the other and this standard applies accordingly. For example, an organization may be a supplier but may have to purchase items or services from a subtier level.

1.2.2 Purchaser's Responsibility

a. Establishment and implementation of a procurement control process consistent with the requirements and guidelines of this standard.

b. Incorporation of quality assurance program requirements, appropriate to the scope of work, into procurement documents.

c. Evaluation of Supplier's quality assurance program to assure that it is appropriate and satisfies the requirements for the items or services being purchased.

d. Where interfacing, but separate, procurement actions are initiated by a single Purchaser to purchase the design, manufacture, shop assembly and test, field installation and field test of equipment or a system, the single Purchaser shall assure that the quality assurance requirements incorporated in separate procurement documents, in conjunction with the Purchaser's quality assurance program, will collectively satisfy the requirements of ANSI N45.2 and applicable supplementary standards as applicable to the total items and services procured. An example of this is the case where one Supplier has responsibility for design, manufacture, shop assembly and test; another Supplier has responsibility for field assembly; and a third Supplier has responsibility for field tests.

1.2.3 Supplier's Responsibility

a. Establish and implement a documented quality assurance program that complies with procurement document requirements.

b. Permit Purchaser review of Supplier's quality assurance program and its implementation.

c. Incorporate appropriate quality assurance program requirements in subtier procurement documents.

1.3 Definitions

The following definitions are provided to assure a uniform understanding of selected terms as they are used in this standard. Other terms and their definitions are contained in ANSI N45.2.10.

Designated Representative–An individual or organization authorized by the Purchaser to perform functions in the procurement process.

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.

Quality Assurance Program Requirements–Those individual requirements listed in ANSI N45.2 which when invoked in total or in part establish the requirements of a quality assurance program.

Quality Assurance Records–Those records which furnish documentary evidence of the quality of items and of activities affecting quality.

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.

Services–The performance by a Supplier of activities such as design, fabrication, inspection, non-destructive examination, repair, or installation.

Subtier Procurement–Procurement by a Supplier from a subsupplier of items or services.

Supplier–Any individual or organization who furnishes items or services to a procurement document. It includes the terms Vendor, Seller, Contractor, Subcontractor, Fabricator, Consultant, and subtier levels.

Surveillance–The physical presence to monitor by observation the designated activities to assure that they are performed in a specified manner.

1.4 Referenced Documents

Documents that are required to be included as part of this standard are identified at the point of reference and described in Section 13 of this standard. The issue or edition of the referenced document that is required will be specified either at the point of reference or in Section 13 of this standard unless otherwise specified in the procurement document.

2. PLANNING

Measures established for the control of the procurement of items or services shall include planning. Control of the procurement process requires the identification of organizations involved in the execution of the activity and the delineation of each organization's responsibility. Planning shall determine the following objectives:

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.

These objectives shall be accomplished as early as practicable and no later than 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 the following:

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.
f. Control of Nonconformances.
g. Corrective Action.
h. Acceptance of Item or Service.
i. Quality Assurance Records.
j. Audit of Procurement Program.

Subsequent sections discuss these activities and their control in accordance with the general requirements of ANSI N45.2 (and this standard) in greater detail. These activities shall be capable of being verified and their effectiveness determined by audit. Where any of the procurement activities are delegated or applicable to subtier Suppliers, the appropriate controls and requirements of this standard shall also apply.

3. PROCUREMENT DOCUMENT PREPARATION, REVIEW AND CHANGE CONTROL

3.1 General

The Purchaser shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements (including specific issue dates and applicable addenda) which are necessary to assure adequate quality are included or invoked by reference in the documents for procurement of items and services. Procurement document changes shall be subject

to the same degree of control as utilized in the preparation of the original documents.

3.2 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:

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

3.2.2 Technical Requirements. Technical requirements shall be specified in the procurement documents by reference to the specific drawings, specifications, codes, regulations, procedures or instructions including revisions thereto that describe the items or services to be furnished. The procurement documents shall identify or provide for later identification of test, inspection and acceptance requirements, and any special instructions and requirements for such activities as designing, identification, fabrication, cleaning, erecting, packaging, handling, shipping and extended storage. All such technical requirement documents shall be prepared, reviewed and released under the requirements established by ANSI N45.2.11.

3.2.3 Quality Assurance Program Requirements. Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of ANSI N45.2 as well as applicable quality assurance program requirements of other nationally recognized codes and standards. (The Appendix provides an explanation and examples of logic and considerations which may be used to decide how and to what extent quality assurance program requirements shall be specified in procurement documents. The Appendix is not a part of this standard.)

The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.

3.2.4 Right of Access. At each tier of a procurement, the procurement document shall provide, as deemed necessary by the Purchaser, 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. The provisions should include a statement of the minimum time of advance notice and the method of communication of such notice. They should include or provide for the later identification (see Section 6.2) of the events such as witness and hold points established or considered appropriate for the Purchaser's presence at the Supplier's facility.

3.2.5 Documentation Requirements. The procurement documents at all tiers shall identify the documentation required to be submitted, including quality assurance records for information, review, or approval of the Purchaser. The time of submittal shall also be established. The Purchaser shall prescribe to the Supplier those quality assurance records of compliance for which retention responsibility remains with the Supplier. ANSI N45.2.9 provides guidance for retention and disposition of quality assurance records.

3.2.6 Nonconformances. The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances. Section 8 of this standard provides further guidelines on handling nonconformances.

3.3 Procurement Document Review

A review of the procurement documents shall be made to assure that documents transmitted to the prospective Suppliers for bid or contract purposes include appropriate provisions to assure items or services meet the specified requirements.

a. Such reviews shall be performed prior to release for bid and contract award and shall assure that the documents are complete and contain the applicable requirements specified in Section 3.2 of this standard.

b. Changes made in the procurement documents 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.

1) Appropriate requirements specified in Section 3.2.

2) Determination of any additional or modified design criteria imposed after preparation of the procurement documents.

3) 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.

c. 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.

d. Performance of reviews shall be documented to provide objective evidence of accomplishment.

3.4 Procurement Document Control

Procurement documents shall be controlled in accordance with ANSI N45.2 Section 7.

4. SELECTION OF PROCUREMENT SOURCES

4.1 General

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.

4.2 Selection Measures

Procurement source evaluation and selection measures shall be adopted by the Purchaser and shall provide for identification of the Purchaser's organizational responsibilities for determining Supplier capability. This may require integrated action involving one or more organizations (e.g., engineering, construction, manufacturing, operations, purchasing, or quality assurance) based upon the item or service being procured.

Methods to be utilized in evaluation of Supplier sources, and the results therefrom, shall be documented and shall include any or all of the following:

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

1) Experience of users of identical or similar products of the prospective Supplier.

2) 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, physical conditions of the manufacturing facility and equipment, and management attitude towards 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 shall be requested to submit information on a similar item or service for evidence of his current capabilities.

b. The Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated. This would include review and evaluation of the Supplier's Quality Assurance Program, Manual, and Procedures, as appropriate.

c. The 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.

5. BID EVALUATION AND AWARD

5.1 General

A documented system for reviewing and evaluating the bids and awarding of contracts shall be established by the Purchaser.

5.2 Conformance to Procurement Document

The Purchaser shall establish measures to assure that the bid conforms to the procurement document requirements.

The bid evaluation shall be made by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

a. Technical considerations.
b. Quality assurance requirements.
c. Research and development effort.
d. Suppliers' personnel.
e. Suppliers' production capability.
f. Suppliers' past performance.
g. Alternates.
h. Exceptions.

Other considerations such as warranties, schedule, price, price adjustments, commercial terms and conditions, although not quality related, are recognized as factors affecting bid evaluation.

5.3 Preaward Evaluation

Prior to the award of the contract, the Purchaser shall have performed a preaward evaluation of the Supplier as described in Section 4.2 of this standard.

5.4 Award

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

6. PURCHASER EVALUATION OF SUPPLIER PERFORMANCE

6.1 General

Purchasers at all tiers shall retain the responsibility of monitoring and evaluating Supplier performance to the specified requirements of the procurement document. In exercising this responsibility, the Purchaser of items and services shall establish measures to verify Supplier's performance. As deemed necessary by the Purchaser, the methods shall include:

a. Establishing an understanding between Pur-

chaser 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 documents which are generated or processed during activities fulfilling procurement requirements.

d. Identifying and processing necessary change information.

e. Establishing exchange method of document information between Purchaser and Supplier.

6.2 Planning and Coordination

Depending on the complexity or scope of the item or service, the Purchaser shall initiate pre- and post-award activities. These activities may take the form of meetings or other forms of communication to establish an understanding between the Purchaser and Supplier of the procurement requirements; the intent of the Purchaser in monitoring and evaluating the Supplier's performance; and the planning, manufacturing techiques, tests, inspections, and processes to be employed by the Supplier in meeting procurement requirements. Purchaser notification points, including hold and witness points, should be identified and documented based upon mutual agreement between Purchaser and Supplier. These activities shall be implemented as early as practicable in the procurement process. The depth and necessity of pre- and post-award activity depends on the uniqueness, complexity, procurement frequency with the same Supplier and past Supplier performance for the specific items or services covered by the procurement document.

6.3 Control of Supplier Generated Documents

The Purchaser and Supplier shall assure that established measures for the control, handling and approval of Supplier generated documents are implemented, and that the submittal time and frequency for these documents is accomplished in accordance with the procurement documents. These measures shall provide for the acquisition, processing and recorded evaluation of inspection and test data against acceptance criteria.

6.4 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 ANSI N45.2 Section 7.

7. VERIFICATION ACTIVITIES BY PURCHASER

7.1 General

Measures shall be established and implemented for verification activities (surveillance, inspection, and audit) as appropriate, to assure conformance of procured items and services to identified requirements. Purchaser verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit or witness the activities of Suppliers. These verification activities shall be conducted as early as practicable to preclude subsequent activities from preventing disclosure of deficiencies. The Purchaser's verification activities are not intended to relieve the Supplier of his responsibilities for verification of quality requirements.

7.2 Planning

Planning shall be an integral part of verification activities. The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item procured and the Supplier's quality performance. See Section 10 of this standard for guidance in selecting verification methods.

7.2.1 Source Verification Planning. The verification activity plans shall, relative to fabrication sequence and assembly processes, identify the appropriate inspections, tests, prerequisites and inspection sequence, hold and witness points, acceptance criteria, and the documentation required by the procurement document.

7.2.2 Receiving Inspection Planning. The receiving inspection plans shall identify the characteristics to be verified and documentation to be reviewed at receiving inspection. For characteristics to be considered during receiving inspection, see ANSI N45.2.2.

7.3 Implementation

7.3.1 Source Verification Activities. When planning requires Purchaser source surveillance, it shall be implemented to monitor, witness or observe activities. Similarly, source inspection shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Source surveillance and inspection may require the assignment of personnel to a Supplier's facilities.

When conformance to procurement requirements is verified by audit, such audits shall be conducted in accordance with established methods.

7.3.2 Receiving Inspection. When planning requires

Purchaser receiving inspection, it shall be implemented and coordinated with source verifications performed. During receiving inspection, emphasis shall be placed on assuring that items have not sustained damage in shipment that would influence subsequent fabrication, construction, installation, or end use. Sampling may be utilized during receiving inspection when conducted in accordance with established procedures or recognized standards. Receiving inspection measures shall include provisions for receiving documentation (such as drawings, certifications, test results and other materials) offered as objective evidence in satisfaction of requirements. These measures shall also include provisions for dispositioning (i.e., accept, reject or hold) and handling of items received and services performed. See ANSI N45.2.2 for additional requirements.

7.4 Measuring and Test Equipment

7.4.1 Selection. Inspection, examination, and testing equipment utilized to implement the requirements of this standard shall be selected to have accuracy and tolerance sufficient to determine conformance to specified requirements.

7.4.2 Calibration and Control. As appropriate, measuring and test equipment shall be adjusted and calibrated at prescribed intervals against certified equipment having known valid relationships to nationally recognized standards. If no standards exist, the basis for calibration shall be documented. Records shall be maintained and equipment suitably marked to indicate calibration status or the records shall be traceable to the equipment. When inspection, measuring and test equipment are found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.

7.5 Personnel Qualifications

Personnel responsible for performing verification activities shall be qualified in accordance with ANSI N45.2.6 as applicable.

7.6 Reporting

Measures shall be established to provide for the reporting of activities performed to verify conformance to requirements of procurement documents. These measures shall include reporting of source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions.

In addition, the Purchaser shall assure that these reports are evaluated to determine the Supplier's quality assurance program effectiveness.

8. CONTROL OF NONCONFORMANCES

8.1 General

The Purchaser and Supplier shall establish and document measures for the identification, control, and disposition of items and services that do not meet procurement document requirements.

8.2 Disposition

These measures shall contain provision for the following:

a. Review of nonconforming items.

b. Submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier recommended disposition (i.e., "use-as-is" or "repair") and technical justification. Nonconformances to the procurement requirements or Purchaser approved documents and 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 have 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 disposition.

e. Maintenance of records of Supplier nonconformances.

9. CORRECTIVE ACTION

9.1 General

The Purchaser shall establish and document measures that describe the method for the identification of and timely corrective action for conditions adverse to quality which occur during the procurement process and are the responsibility of the Purchaser.

9.2 Significant Conditions

In the case of significant conditions adverse to quality which may arise during the procurement process, the Purchaser's measures shall describe the method used to:

a. Identify and document deviations and nonconformances.

b. Review and evaluate the conditions to determine the cause, extent, and measures needed to correct and prevent recurrence.

c. Report the conditions and corrective action to the appropriate levels of management.

d. Assure corrective action is implemented and maintained as necessary.

9.3 Verification

The Purchaser's corrective action measures shall include verification of implementation of Supplier corrective action system. These measures shall determine that conditions adverse to quality such as deficiencies, deviations, defective items and nonconformances have had corrective action implemented and maintained as necessary.

10. ACCEPTANCE OF ITEM OR SERVICE

10.1 General

The Purchaser shall establish the method of 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 power plant site prior to installation or use of such items regardless of acceptance methods.

10.2 Certificate of Conformance

Where not precluded by other requirements, documentary evidence may take the form of written certificates of conformance which identify the requirements met by the items. Where certificates of conformance are used, the following minimum criteria shall be met:

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

b. The certificate should 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, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified should include any approved changes, waivers, or deviations applicable to the subject material or equipment.

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

d. The certificate should be attested to 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, should be described in the Purchaser's or Supplier's quality assurance program.

f. Means should 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 verifications should be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

(Section 7 of this standard provides requirements and guidance relative to the conduct of source verification activities and receiving inspections.)

10.3 Methods of Acceptance, Selection and Implementation

Purchaser methods used 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.

10.3.1 Acceptance by Source Verification. Acceptance by source verification should be considered when the item or service is—

a. vital to plant safety; or

b. difficult to verify quality characteristics after delivery; or

c. complex in design, manufacture, and test.

The source verification activities should include but not be limited to the following as applicable:

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

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

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

d. Nonconformances have been dispositioned as required.

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

Upon Purchaser acceptance by source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.

10.3.2 Acceptance by Receiving Inspection. Acceptance solely by receiving inspection is satisfactory when the items or services are–

a. relatively simple and standard in design, manufacture, and test; and

b. adaptable to standard or automated inspections and/or tests of the end product to verify quality characteristics after delivery; and

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

Receiving inspection should be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

10.3.3 Acceptance by Supplier Certificate of Conformance. In certain procurement actions which do not involve direct inspection by the Purchaser, the Purchaser may accept an item or service from a Supplier based only on 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 a minimum quality confidence level.

10.3.4 Acceptance by Post Installation Test at the Nuclear Power Plant Site. Acceptance by this method is satisfactory when performed following the accomplishment of at least one of the preceeding 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.

Post installation test requirements and acceptance documentation should be mutually established by the Purchaser and Supplier.

10.3.5 Acceptance of Services Only. The guidelines outlined in Section 10.3 above primarily deal with hardware items and related services. 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 may 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.

11. QUALITY ASSURANCE RECORDS

Measures shall be established and implemented for the control of:

a. Supplier–generated documents and records that are required to be submitted to the Purchaser or retained by the Supplier as specified by the procurement documents.

b. Purchaser–generated quality related documents and records.

The collection, storage, and maintenance of quality assurance records shall be in accordance with ANSI N45.2.9.

12. AUDIT OF PROCUREMENT PROGRAM

Periodic or random audits shall be performed to verify compliance with procurement activities described in this standard. The scope of planned auditing activity may cover individual operations, events, processes, or the complete quality assurance program. When deemed necessary by the Purchaser, audits of subtier Suppliers shall be carried out to assure that their quality assurance programs on procurement adequately translate the necessary requisites of the governing procurement documents to the items or services involved. The audits shall be conducted in accordance with established methods.

13. AMERICAN NATIONAL STANDARDS REFERRED TO IN THIS DOCUMENT

When any of the following standards referred to in this document are superseded by a revision approved by the American National Standards Institute, the revision is not mandatory until it has been incorporated as a part of this standard.

Revisions to the referenced standards and revisions to this standard issued after the contract date, may be used by mutual consent of the Purchaser and the Supplier.

Number	Title	Issue
N45.2	–Quality Assurance Program Requirements for Nuclear Power Plants	1971
N45.2.2	–Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Power Plants (During the Construction Phase)	1972
N45.2.6	–Qualification of Inspection, Examination, and Testing Personnel for the Construction Phase of Nuclear Power Plants	1973
N45.2.9	–Requirements for Collection, Storage and Maintenance of Quality Assurance Records for Nuclear Power Plants	1974
N45.2.10	–Quality Assurance Terms and Definitions	1973
N45.2.11	–Quality Assurance Requirements for the Design of Nuclear Power Plants	1974

APPENDIX

(This APPENDIX is not a part of ANSI N45.2.13 Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants.)

1. General

This Appendix provides an explanation and example of logic and considerations necessary to decide how and to what extent quality assurance program requirements should be specified in procurement documents (Section 3.2.3).

There are various methods for specifying quality assurance program requirements depending on the type and scope of procurement action being undertaken. The following sections of this Appendix provide guidelines for:

a. Typical scope of procurement effort.
b. Categorization of procurement actions.
c. General logic or factors to be considered in specifying quality assurance program requirements in a procurement document.
d. Logic chart.
e. Methods of specifying quality assurance program requirements.

2. Typical Scope of Procurement Effort

The complexity of a nuclear power plant dictates the need for a multitude of tasks which should be performed during various phases of design, construction, testing and operations. Among these tasks is the procurement of items and services. Each major phase requires a procurement effort which will be responsive to the special needs of that phase and which will provide items and services which meet code, regulatory, and special requirements. Examples of the types of procurements required during each phase are as follows:

a. *Design–Construction Phase*

1) Design and engineering services.
2) 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).
3) Long-lead items such as the nuclear steam supply system, including major equipment fabrication and test.
4) Construction of the main structure of the plant, including structural steel erection and concrete production and placement.
5) Specific site erection and installation tasks; such as piping, mechanical and electrical equipment.
6) Services for non-destructive examinations and required laboratory tests.
7) Hardware such as valves, piping, tanks and miscellaneous materials.
8) Software such as development of plant operating procedures, technical manuals and computer codes.
9) Services of various consultants to assist in setting up management systems (i.e., quality assurance program and operator training).
10) Preoperational and startup tests.
11) Preservice base line inspection equipment and/or services.

b. *Operational Phase*

1) Reload fuel, equipment and services for refueling operations.
2) In-service inspection equipment or services.
3) Items and services for plant maintenance, modifications or changes.
4) Special services such as environmental monitoring, radioactive waste disposal, and plant decontamination.

The above-mentioned examples are not meant to be all inclusive but rather to provide an appreciation 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.

3. 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 which should be performed in properly specifying the quality assurance requirements in the procurement documents. For example, the procurement of services, whether for soil investigations or pipe stress calculations, has certain quality assurance program requirements in common which may be different from the program requirement of a pure hardware procurement.

4. General Logic Considerations

The quality assurance requirements shall 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 will require only a limited quality assurance effort in selected phases of development. The factors which determine the extent of a quality assurance effort are as follows:

a. *The importance of malfunction or failure of the item to plant safety*

Each item to be procured must be evaluated to determine whether or not it is important to plant safety. For those items which are important to plant safety, applicable requirements of ANSI N45.2 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.

b. *The complexity or uniqueness of the item*

In developing specific quality assurance requirements for a particular item, the complexity and uniqueness should be considered. 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 item's complexity and the industry experience, or lack of, 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. 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. 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.

c. *The need for special controls and surveillance over process and equipment*

Certain work operations may require the use of special processes such as welding, non-destructive examination, passivation, brazing and soldering, hardness and tensile testing, protective coating and heat treatment. Special processes may also include certain in-process operations such as chemical batch process, plating operations, and electric insulation impregnation. These processes shall 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.

d. *The 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 an appropriate inspection and test will be sufficient to provide an assurance of quality. A limiting case is an end-product test which can properly assess the degree of compliance to quality requirements, thereby eliminating the need for in-process control.

e. *The 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 of time 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 procurement action, the overall method of para-

graph 6.a 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 paragraph 6.b. of this Appendix may be used to specify the quality assurance requirements of the procurement document.

5. Logic Chart

The attached chart provides a pictorial illustration of the logic process described in paragraph 4 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 which have to be made for this type of procurement.

6. 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:

a. *Overall Method*

The Purchaser may incorporate into the procurement documents a complete quality assurance program standard, such as ANSI N45.2, and shall require the Supplier to apply the requirements of the quality assurance standard as appropriate to the items or services being procured. The Supplier's quality assurance program shall be evaluated by the Purchaser to assure that it is appropriate to the items or services being purchased.

b. *Unique Order Method*

The Purchaser may incorporate into the procurement documents selected portions of a quality assurance program standard, such as ANSI N45.2, that are unique to the items or services being procured. For example, when Purchaser's order is limited to design work only, selected requirements of ANSI N45.2 or ANSI N45.2.11 would be applied. Supplier's quality assurance program shall be reviewed by the Purchaser to assure that it is appropriate to the items or services being purchased. Purchaser may also incorporate requirements equivalent to those referred to in ANSI N45.2 which are unique to the items or services being purchased.

6.1 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 ANSI N45.2 will apply in varying degree to the item or service being purchased. 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.

For the above example, the overall method could be used to specify the quality assurance program required of the Supplier by use of the following provisions:

a. Supplier shall establish and maintain a quality assurance program conforming to the applicable sections and elements of ANSI N45.2.

b. Sections and elements of ANSI N45.2 are applicable only to the extent that Purchaser's order requires work that is governed by the sections and elements. For example, when Purchaser's order does not require design work of Supplier, the requirements of ANSI N45.2, paragraph 4, Design Control, do not apply.

c. Supplier shall document a quality assurance program sufficient to conform to the applicable requirements of ANSI N45.2 and to Purchaser's technical and administrative requirements contained in the purchase order and referenced documents.

d. Supplier shall submit a description of his quality assurance program to Purchaser with Supplier's bid response for Purchaser's review. If Supplier's description of his quality assurance program has been previously submitted, the Supplier should update it or submit a statement that the quality assurance program has not changed since the last evaluation. Where the Supplier holds a valid Certificate of Authorization for ASME Code, Section III, 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 Manual shall be supplemented, as appropriate, to satisfy the Purchaser's procurement requirements.

e. Purchaser shall evaluate the program of the successful bidder and provide comments if modifications to the program are required. Supplier shall resolve Purchaser's comments and implement the resolution of them prior to the start of any work affected by the comments.

f. Supplier shall, during the performance of the requirements of the procurement document, submit

all changes to his quality assurance program to the Purchaser for information prior to implementing the changes.

g. The Supplier shall identify and pass on to subtier Suppliers all applicable quality assurance program requirements.

6.2 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 ANSI N45.2 may apply to the item or service being purchased. An example of such a scope of work might be as follows:

Supplier Scope of Work

a. Perform independent design review of

1) the equipment described by the drawings and specifications of enclosure (1) of this purchase order, and

2) the equipment design and stress calculations contained in enclosure (2) of this purchase order.

The purpose of this design review is to verify that equipment meets the design rules of ASME Boiler and Pressure Vessel Code Section III Class I, 1974 Edition.

b. Establish a procedure and technique, and conduct, subject to 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 100–200 F. Purchaser will provide Supplier with the equipment to be tested.

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

For the above example, the unique order method could be used to specify the quality assurance program required of the Supplier by use of the following provisions:

a. Supplier shall establish and maintain a documented quality assurance program conforming to those sections and elements of ANSI N45.2, Quality Assurance Program Requirements for Nuclear Power Plants (latest published edition as of the date of placement of this order) which are listed below. These sections and elements should be applied to the extent that Purchaser's order requires work that is governed by the sections and elements.

Section 1–Introduction
Section 2–Quality Assurance Program
Section 3–Organizaton
Section 4–Design Control
Section 6–Instructions, Procedures, and Drawings
Section 7–Document Control
Section 12–Test Control
Section 13–Control of Measuring and Test Equipment
Section 17–Corrective Action
Section 18–Quality Assurance Records
Section 19–Audits

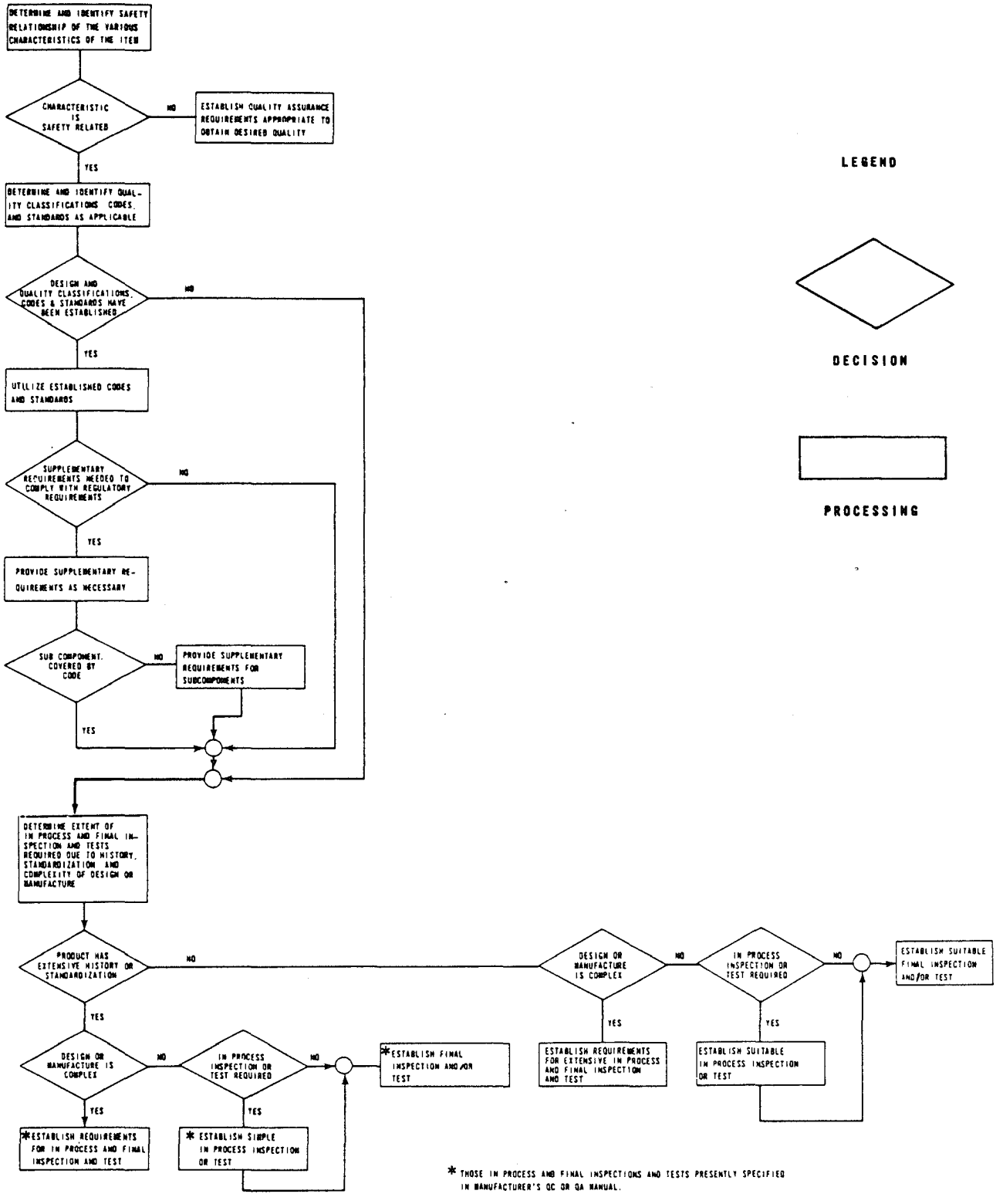
b. Supplier shall submit his quality assurance program description to Purchaser with Supplier's bid response for Purchaser's review. If Supplier's quality assurance program description has been previously submitted, Supplier shall update it or submit a statement that the quality assurance program has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

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

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

e. The Supplier shall identify and pass on to Supplier's subtier Suppliers all applicable quality program requirements.

There is an alternate approach which can be considered for specifying the required Supplier quality assurance program for the above work example, which is basically a "design and test only" scope of work. This alternate approach would be to utilize a different ANSI quality assurance standard such as ANSI N45.2.11, Quality Assurance Requirements for the Design of Nuclear Power Plants. This standard may be applicable to the above work example in greater degree than all portions of ANSI N45.2. Consequently, ANSI N45.2.11 could be incorporated into the procurement documents by provisions similar to paragraphs a. through e. above except that ANSI N45.2.11 would be referred in its entirety rather than referring to parts of ANSI N45.2.



LOGIC CHART FOR DETERMINING APPROPRIATE QUALITY REQUIREMENTS