

QA Program (Procurement Control)

Procedure No.: 35746B

Issue Date: 10-1-76

SECTION I
INSPECTION OBJECTIVE

Ascertain whether the licensee has developed and implemented a QA Program relating to the control of procurement activities that is in conformance with Regulatory requirements, commitments in the application and industry guides and standards.

SECTION II
INSPECTION REQUIREMENTS

1. Program Review

a. Determine that administrative controls require that procurement documents for safety-related items provide for the following:

- (1) Specific identification of equipment, supplies, consumables (chemicals, welding rods, etc,) or services purchased.
- (2) Identify any test, inspection, and acceptance requirements and any special instructions for fabrication, packaging, shipping or storage.
- (3) Requisite technical requirements
- (4) Access to the supplier's plant or records for purposes of audit.

QA Program (Procurement Control)

Procedure No.: 35746B

Issue Date: 4/1/79

- (5) Requisite documentation to certify the item being procured.
 - (6) Requirement for the contractor/supplier to provide a QA program consistent with Appendix B to 10 CFR 50.
 - (7) Requirement that each procurement document for a system or component, when applicable, specifies that provisions of 10 CFR 21 apply (21.31).
- b. Verify that administrative controls provide measures and assign responsibilities in writing for:
- (1) Initiation of procurement documents
 - (2) Review and approval of specifications differing from the original design documents
 - (3) Review and approval of procurement documents
 - (4) Making changes to procurement documents
 - (5) Basis for designation of quality classification of procurement items
- c. Verify that administrative controls provide the following concerning bidders/suppliers:

- (1) An acceptable method is established for "qualifying" a vendor, supplier, or contractor providing goods or services as defined in the SAR.
- (2) Provision for purchaser's right of access to supplier's facilities and documents.
- (3) Maintenance of an "approved bidders" list, including methods for updating the list.
- (4) Maintenance of records of supplier qualification and audit.
- (5) Responsibilities are assigned for items (1) through (4), above.

2. Implementation

- *a. Verify that administrative control directives are available to those preparing, reviewing, and approving procurement documents.

- *b. Select a sample of 6 recently purchased safety-related items that have been received on-site. No more than two should be from any one of the following categories; mechanical, electrical, instrument/electronic, and consumables (chemicals, reagents, lubricants, filters, etc.). Verify the following for each item:
- (1) Procurement documents were prepared in accordance with administrative controls identified in 1.a. and b.
 - (2) The items were purchased from "qualified" vendors.
 - (3) The procurement documents contained requirements for the vendor/supplier to supply appropriate documentation of quality, including component tracability.

- *c. Verify that an approved bidders list is maintained in accordance with controls identified in 1.c.3.

- *d. Review results of a supplier audit or evaluation to determine the implementation of controls identified in 1.c.4.

- *e. Verify that personnel assigning/designating quality classification are cognizant of QA Program requirements.

SECTION III

GUIDANCE

References: ANSI N45.2.13-1976; Section 17.2.4 of FSAR;
10 CFR 50, Appendix B, Criteria IV, VII
and VIII.

1. Program Review

The inspection in this area should be directed at assuring that procurement of equipment and materials and selection of suppliers will be accomplished in accordance with the licensee's documented controls. The licensee may define two type of procurement controls; one for purchase of nonsafety related items and one for safety related items. If this is the case, it is important to recognize that the defined methods of control must be sufficiently definitive to prevent the non-conservative method of controls from being used for purchasing safety related items. The licensee may have

established defined channels for developing and approving procurement documents for major equipment but may also allow for direct procurement by onsite supervisor or other personnel. For example, onsite personnel may, in some cases, be assigned the responsibility or be permitted to directly purchase expendable supplies and materials, such as chemical, boron, lubricants, solvents, bar and plate stock, welding rod, etc. If this practice is permitted, the licensee's procedures should also define how these procurement activities will be controlled.

- 1.a. ANSI N45.2.13 provides guidance concerning items which are required to be included in procurement documents for safety-related items.
- 1.a.(5) In regard to quality certification (10 CFR 50, Appendix B, Criterion VII), when quality documentation in the form of certification is used at the site in lieu of original records establishing quality of materials or components important to safety, the following guidelines should be used:
 - ° The certification should specifically identify the purchased material or equipment, such as by the purchase order number.

QA Program (Procurement Control)

Procedure No.: 35746B

Issue Date: 10-1-76

- The certification 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 procurement specifications or drawings, together with a suitable conformance statement. The procurement requirements identified should include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- The certification should identify any procurement requirements which have not been met, together with an explanation and the means used to resolve the nonconformances.
- The certification should be attested to by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.

QA Program (Procurement Control)

Procedure No.: 35746B

Issue Date: 4/1/79

- ° 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 QA program.
- ° Means should be provided by the Licensee to verify the validity of certificates, and to determine the effectiveness of the certification system when desired, such as during the performance of audits.

Typical certifications are manufacturer's certifications that a product (usually consumables, such as weld rod and fly ash), if tested, would exhibit the product characteristics shown on the certification document. Typical certifications are acceptable only if the using-agency can demonstrate that the product was manufactured under a process control system which provides for Product control and process records which can establish that the product was manufactured within the characteristic limits identified on the typical certification.

- 1.a.(7) Each procurement document issued by a purchaser for a "Basic Component" must specify that the provisions of 10 CFR 21 apply.

- 1.b The licensee's formal controls should define the organizational unit(s) responsible for assuring the requirements of 1.a. are satisfied.
- 1.b.2. & 3. Review and approval of changes to procurement documents should be by the same individual/organization that approved the original document unless another qualified organization is formally designated.
- 1.c. Selection and qualification methods should be described in the QA manual and key features of these defined controls should be compared with commitments made in the application. Requirements should also be established in the QA manual for documenting the measures, checks, etc., used to qualify each vendor, supplier, or contractor. Section 5.2.13 of ANSI N18.7-1976 provides guidance relating to qualification of vendors for spare parts at older facilities.
- The licensee should have a supplier surveillance program to verify conformance of procured services to procedures,

drawings, specifications, procurement documents and other specified requirements. The licensee should also have responsibilities assigned to assure that surveillance activities when required, will be accomplished by authorized personnel assigned to check, inspect, audit, or witness the activities of supplier's furnishing services.

Approval and qualification of bidders is generally an off-site function and is generally accomplished by a branch of corporate engineering or purchasing. Procedures relating to the selection and audit of suppliers may be held by the corporate office.

- 2.b Procurement documents may contain some of or all of the requirements identified in part 1.a, depending on the item or service procured.

QA Program (Procurement Control)
Procedure No.: 35746B
Issue Date: 10-1-76

Criterion IV of Appendix B to 10 CFR 50, requires that "...to the extent necessary, procurement documents shall require contractors or subcontractors to provide a QA program ..." Judgement of "to the extent necessary" is required. Procurement documents for items purchased from well-known industry vendors may not show such a statement and still be acceptable. Specific test or packaging requirements, for example, may not be necessarily included in the procurement document if none are required for the item in question.

- 2.b(3) Approved bidders lists may be maintained by the corporate office. The inspector may need to have the licensee transmit these to the site or make an inspection trip to the corporate office to satisfy this item.

2.c. Results of supplier audit or evaluation will probably not be on-site, requiring arrangements with the corporate office.

Quality documentation would not be required for catalogue or off-the-shelf items such as light bulbs, resistors, and gaskets .

Note: 1. Only single * requirements need be inspected when the reactor facility for which the application is being made for an operating license is located at the same site and will use the same site management that was inspected within the previous 24 months.

2. The program review function should be completed during the operational preparedness phase of MC 2513.

3. A Procurement Control Program for plant operation is not required until the facility license is

QA Program (Procurement Control)
Procedure No.: 35746B
Issue Date: 10-1-76

issued. Therefore, inspection of program implementation may be deferred if necessary but should be completed within the first six-month period of operation.

4. For record keeping purposes, the program review and program implementation phases of the inspection will be assigned 50% of the total inspection effort.