EFCOG Best Practice:

Procurement of Items and Services from Non-Nuclear Suppliers Using Part I of NQA-1

By the

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Safety Working Group

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1. ABSTRACT

The nuclear procurement process has been and continues to be challenging on NRC and DOE regulated nuclear projects. On first reading, NQA-1 2022 (most recent edition) appears to offer a dichotomous approach for procuring Safety Class (SC)/Safety Significant (SS) (DOE Projects) or Safety Related (SR) (NRC and some DOE Projects) items or services. In both cases, acceptance of the item or service can be via a Certificate of Conformance from an NQA-1 qualified (aka audited) supplier; alternatively, the item or service could be accepted via the commercial grade dedication (CGD) process. Historically, most NQA-1 users have incorrectly concluded that these are the only two acceptance methods allowed by NQA-1.

In addition to the acceptance methods identified above, a close reading of NQA-1 Requirement 7 reveals additional methods of acceptance for SC, SS, and SR items and services from commercial suppliers without using CGD. This paper illuminates a suite of acceptable procurement strategies which can be accommodated with the existing NQA-1 framework. While this best practice white paper provides new success paths for users, it in no way diminishes existing acceptance methods. Lastly, this best practice white paper is a living document and, as such, revisions will be made to document examples of implementation of the methodology identified herein.

Please note that while NQA-1 2022 is noted above, application of the methodology proposed herein is not limited to that standard year. A best practice approach to implementation is to closely coordinate with key stakeholders (e.g., DOE field office, management, affected organizations) to ensure seamless alignment prior to performance.

2. PURPOSE

The purpose of this paper is to discuss how NQA-1 Requirements 3, 4, and 7 can be applied to procure (SS/SC/SR) items from suppliers who do not implement a nuclear quality assurance program.

As a preface, a discussion on the basis for procurement acceptance requirements would aid as a lead in for the following discussion. Throughout the DOE for Hazard Category 1, Hazard Category 2, and Hazard Category 3 facilities, the typical order of precedence is as follows:

1) 10CFR830 Part I, Subpart A – Quality Assurance Requirements
2) DOE O 414.1D, Quality Assurance
3) NQA-1 2022, Quality Assurance Requirements for Nuclear Facility Applications. (citations herein are from the 2022 version of the Standard)

As the DOE directs contractors to select a standard by which the Rule and the Order can be implemented, this EFCOG Best Practice will focus on application of the most common nuclear quality standard, which is NQA-1.

3. PROCUREMENT PROCESS

Correctly implementing the NQA-1 standard in a coherent procurement program involves three main attributes, which are: design control, procurement document control, and acceptance processes. This paper will expand on how these requirements converge to accept items and services.

3.1 NQA-1 Requirement 3 Design Control:

NQA-1 Requirement 3, "Design Control," provides specific requirements which address the design process for SS/SC/SR items, stating:

> *"The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner…. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved."*

Design Control requirements (e.g., design bases, response spectra, specifications, qualification reports, calculations, drawings, and data sheets) form the technical foundation of the procurement process, irrespective of the supplier's quality program and/or reputation; additionally, they are an integral part of any acceptance method.

> *Design requirements including, but not limited to, codes (e.g., ASME, ASTM, and AISC), standards (e.g., ASTM, ANSI, IEEE, and UL), ratings (e.g., ANSI B16.5 and B15.34), qualification requirements (environmental and seismic), special material requirements (e.g., surface finish and electroless plating), welding (e.g., ASME Section IX, AWS, and heat input control), heat treatment (e.g., solution annealing), cleaning, setpoints, and software must be clearly specified and/or referenced in appropriate procurement documents. This will help ensure an adequate understanding by the supplier and project personnel. Such information may also be used for future decisions, analysis, inspections, testing activities, acceptance criteria, and tolerances. Any technical information should clearly be within the facility's design bases.*

3.2 NQA-1 Requirement 4 Procurement Document Control:

NQA-1: Requirement 4, "Procurement Document Control," provides specific requirements which address the procurement document preparation process for SS/SC/SR items, stating:

> *"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…. Quality assurance program requirements shall be specified in the procurement documents….consistent with the importance and/or complexity of the item or service being procured."*

Procurement Document Control is the bridge between the purchaser and the supplier. The importance of specifying the correct technical and quality requirements is implicitly addressed in the standard and their linkage to acceptance of the item or service. For example, invoking the supplier's quality assurance program in procurement documents. Lastly, it directly addresses flow-down of technical and quality requirements between the supplier and sub-suppliers along with rights of access for the purchaser.

Requirement 4 details preparation of procurement documents for SS/SC/SR items. Several key points from this section will be discussed that will aid the reader in how procurement documents can be tailored to enable multiple means of acceptance. Paragraph 100 from Requirement 4 is a summary of the requirement and contains language (see bolded sections) that will be further discussed below.

> **Requirement 4, Para 100:**
>
> *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**.*

3.3 "Design Bases" Requirements

Regardless of whether the supplier has a quality program, the design bases requirements necessary for the procured items to adequately perform their function must be included in procurement documents. This information can be found in safety bases documents, technical requirements (e.g., engineering specification, calculations, analysis), drawings, system design descriptions, technical evaluations, P&IDs, codes, and standards. These documents should completely define the scope of work and acceptance of the end item to be delivered to the purchaser. In many cases, the included codes and standards have quality requirements (i.e., required tests, inspections, and associated documentation) for acceptance. The purchaser's engineering organization must be aware of these requirements when determining what additional quality measures are required to accept the item or service.

As appropriate, technical requirements should be included in the procurement documents to enable the supplier to adequately complete the scope of work defined.

3.4 "Other Requirements Necessary to Assure Adequate Quality"

Quality requirements are often embedded in design requirements, such as codes or standards. These codes and standards can have quality program, testing, and documentation requirements. The purchaser's engineering organization should be conscious of these requirements and may specify additional documentation, tests, and inspection beyond what the design codes and standards specify. Awareness by the purchaser's engineering organization of these technical and quality requirements within the codes and standards is necessary to ensure clearly communicated requirements within purchasing documents. Additional requirements necessary to assure adequate quality may include supplier submittals, witness and hold points, supplier surveillance, and additional tests and inspections.

3.5 "Quality requirements consistent with this standard" and "To the extent necessary"

Describing the application of these requirements best explains their meaning. When developing a procurement specification, the practitioner typically compiles design bases requirements as the first step in preparing the specification. Inclusive in these requirements can be quality requirements that emanate from the items' design bases requirements (e.g., codes and standards). These quality requirements can range from required inspections and tests, along with the associated test documentation in accordance with quality program requirements. If included in design bases requirements, the purchaser must assure compliance either by meeting those requirements via actions they take or by requiring the supplier to meet those requirements via the procurement specification.

Incorporation of these requirements is performed irrespective of the purchaser's selected procurement method. After the purchaser's initial compilation of quality requirements included in design bases, the subsequent quality requirements incorporated in the procurement documents is dependent on the purchaser's selection of the methods of acceptance provided in Requirement 7, Paragraph 502. The following discusses incorporation of additional quality requirements dependent upon the purchaser's selection of acceptance method(s).

Acceptance criteria for supplier submittals and deliverables should be clearly defined in procurement documents. Specification of acceptance criteria should be based on the design bases requirements.

NQA-1 Supplier Certificate of Conformance: Should the purchaser elect to procure the item via this method, quality program requirements must be incorporated into the procurement specification. The most typical approach employed for this method is to require the supplier to meet the requirements of NQA-1. To accomplish this method of acceptance, the purchaser must verify that the supplier's program is compliant with those quality requirements and is effectively implementing the associated quality program.

Supplier Certificate of Conformance from a non-NQA-1 supplier: Alternatively, the purchaser may select an alternate quality standard or define quality standard requirements that the supplier must adhere to. Regardless of the chosen approach, verification of compliance and effective implementation of those quality requirements remains the responsibility of the purchaser. In both cases, the supplier is required to provide a Certificate of Conformance in accordance with Requirement 7, Paragraph 503, which the purchaser may employ as the sole means of acceptance of specified items or services.

Source Verification: When source verification is selected as the sole method of acceptance, verification of quality controls is limited to purchaser specified activities (e.g., in process inspection, factory acceptance, or functional testing) in the procurement documents. This is typically accomplished by requiring the supplier to submit procedures implemented to control processes such as those described above. In some cases, the purchaser may define the parameters of the required activities and witness performance of those activities to determine acceptability and subsequent acceptance of the associated items or services. In any case, application of this method does not require the supplier to implement a specific quality program, nor is the purchaser required to verify effective implementation of the supplier's quality program.

Receiving Inspection: Application of receipt inspection and/or post installation testing (PIT) as the primary methods of acceptance requires that the purchaser perform design bases required tests and inspections to achieve adequate confidence that the purchased items will perform their safety functions.

Post Installation Testing (PIT): PIT is a valuable tool but should only be used in combination with other acceptance methods. While PIT can verify that the item will perform its design function, it may not verify related key design attributes such as seismic and environmental qualification requirements (SQ/EQ). Verification of SQ/EQ requirements is typically accomplished via direct tests and inspections by the purchaser or verification of processes and controls at the manufacturer's facility resulting in acceptance via a certificate of conformance (CoC).

Key Take-aways:

- Technical and quality design bases documents are required to be incorporated into procurement documents regardless of selected procurement strategy.
- Accurate, complete communication of design bases requirements in procurement documents should not be influenced by who is selected to supply the item or service.
- Additional requirements necessary to ensure adequate quality are selected to ensure that the delivered item meets design requirements. These requirements can vary greatly depending on the selected procurement strategy and supplier.
- Other methods of acceptance, beyond the CoC, are available to the purchaser as methods of acceptance.
- PIT should not be employed as the sole method of acceptance.
- When using a CoC as the method of acceptance with a commercial supplier, the contract should clearly define the requirements for how to generate a CoC.
- Include provisions, milestones, and hold points in the contract to approve and accept the scope of work incrementally.

4. NQA-1 Requirement 7 Control of Purchased Items and Services:

NQA-1: Requirement 7, Para 502, "Control of Purchased Items and Services," provides specific requirements which address the acceptance process for SS/SC/SR items, stating:

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

Additionally for a Certificate of Conformance, Para 503, goes on to state:

> *"The certificate shall identify the specific requirements met by the purchased material or equipment, such as codes standards and other specification… Means shall be provided to verify the validity of Supplier Certificates and the effectiveness of the certification system."*

Control of Purchased Items and Services addresses the entire procurement process including, but not limited to, supplier selection, bid evaluation, methods of acceptance, and commercial grade dedication. Implicit in the standard are two acceptance methods, the first being addressed in Paras 200 through 600, and the second being addressed in Para 700 which addresses the use of the CGD process (in lieu of Paras 200 through 600) and refers users to Subpart 2.14. The CGD process is not discussed herein.

It is important to recognize that formal quality assurance requirements exist in many codes or standards other than NQA-1, for example ANSI B31.1; ASME Paras III, VIII, and XI; UL; Military Standards; etc. The purchaser's engineering organization must be cognizant of these

requirements as they require additional document submittals, inspections, surveillance, tests, and/or documentation.

Discussion:

NQA-1, Requirement 7, contains detailed quality assurance criteria that must be met when procuring SS/SC/SR items and/or services. In the nuclear lexicon, the term “qualified supplier” has come to mean the supplier has a nuclear quality assurance program, which has been evaluated by the purchaser’s desktop review of the quality assurance manual followed by a formal audit of the supplier’s quality assurance program. It is worth noting, the term “Qualified Supplier” does not appear anywhere in NQA-1; additionally, the term “Supplier” has no special connotations relative to quality assurance (See Part 1, Paragraph, “Terms and Definitions”). The following is a detailed review of Requirement 7, which is necessary for understanding how SS/SC/SR items and/or services are accepted. The following discussion will explore the various methods of acceptance including acceptance via a CoC.

4.1 Supplier Selection and Evaluation Para 200

Requirement 7, Para 200:

“Prior to award of a contract, the Purchaser shall evaluate the Supplier’s capability to provide items or services in accordance with the requirements of the procurement documents.

Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:”

Discussion:

The most common means of fulfilling this requirement across the DOE complex today is via a qualification audit where the purchasing organization evaluates the supplier’s NQA-1 quality assurance program in accordance with some variation of an NQA-1 applicability matrix. This method is detailed in Para 200, Option (b), below and will further be discussed there. Given the state of today’s nuclear supply chain, this method may limit the purchaser’s options when selecting suppliers best able to meet the purchaser’s technical/design bases requirements regardless of the supplier’s adopted quality standard. Accordingly, purchaser’s procurement documents must clearly define technical requirements that the supplier’s product must meet and quality requirements that the supplier’s program must meet. These documents then serve as a standard against which the purchaser may evaluate the supplier’s product and program for adequacy. Examples of procurement documents where these requirements can be defined are identified below:

- Procurement Specification
- Inspection plans
- Submittals
- Deliverables
- Witness and hold points
- Quality Clauses.

Development of these procurement documents should be a collaborative effort between engineering, procurement, and quality. Doing so will ensure alignment between those organizations and increase the procurement’s likelihood of success. This process may result in the purchasing organization identifying suppliers who do not possess a nuclear quality

assurance program. Development of the procurement documents should be done with an awareness of supply chain capability to the greatest extent possible. Should items or services required by the purchaser only be available from suppliers without an NQA-1 program, the procurement documents should be fashioned such that prospective suppliers can meet specified technical and quality requirements. The extent of evaluation of the supplier's ability to meet specified technical and quality requirements should be consistent with the importance and/or complexity of the item or service, along with the quality controls the supplier is required to provide. Whether or not the supplier has a quality program, supplier evaluation and selection results shall be documented.

Historically, the most common approach to the supplier evaluation and selection process is by auditing the supplier's formal quality assurance program for compliance with all applicable parts of NQA-1. While NQA-1 is the most common standard used by nuclear suppliers, other codes and standards exist which may be employed as a means of evaluation and selection, for example:

- IAEA 50-C-Q (Nuclear)
- ASME Section III (Nuclear)
- ASME Section VIII (non-Nuclear)
- RCC-M (France) (Nuclear)
- JEAGG4101 (Nuclear)
- ISO-9001 (non-Nuclear)
- ISO-17025 (non-Nuclear)
- ISO-17065 (non-Nuclear)
- AS-9100 (non-Nuclear)
- NAP-401.1 (non-Nuclear).

Note that only one or more of the methods specified in Paragraph 200 is required for the evaluation.

Take-aways:

- An NQA-1 audit of the prospective supplier is not the only means of meeting this requirement.
- Supplier evaluation and selection should be conducted based on the supplier's ability to meet the technical and quality requirements.
- While incorporating design bases requirements, procurement documents should be tailored to prospective supplier(s) item specification and program capabilities.

4.2 Supplier Selection and Evaluation Section 200(a)

In the following sections, we will discuss how to evaluate and select suppliers, in addition to the most commonly employed method which is auditing the supplier's nuclear quality assurance program.

Requirement 7 Para 200(a):

"Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier's history shall reflect current capability."

Discussion:

Current practice often combines implementation of this requirement with qualification of the supplier in preparation to accept the supplier's items or services via a certificate of conformance. The purchaser may employ a method that separates these two processes. In so doing, the purchaser may perform their supplier evaluation solely by evaluation of supplier's performance history as it relates to the scope of work in consideration for award. This method may not result in an onsite survey or direct evaluation of the supplier's processes and controls at their facility. Accomplishment of this may more closely approximate a documented engineering technical evaluation of the supplier's ability to meet the procurement specification's defined technical and quality requirements.

Application of this method is typical for commercial use (non-nuclear) items coupled with a desktop evaluation of the supplier's quality controls and/or certifications. It is less commonly used as the sole means of evaluation and selection for SS/SC/SR items or services. If selected, it can be employed to evaluate and select suppliers with limited to no quality assurance program. Additionally, this could be a means of evaluating and selecting a supplier for a limited scope of work where the cost of performing a qualification audit may be prohibitive.

Take-aways:

- Supplier performance history may be an adequate means of evaluation and selection prior to contract award.
- If supplier performance history is not available to the purchaser, additional criteria should be employed to evaluate supplier capability, including onsite evaluation. This type of evaluation is typically in the form of an audit of the supplier's Quality Program to ensure compliance with specified quality requirements.
- Bid lists can include all suppliers in a product category with the evaluation process designed to down select to the supplier most capable of meeting specified requirements.

4.3 Supplier Selection and Evaluation Para 200(b)

Requirement 7, Para 200(b):

"Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated and may include current third-party certificates that recognize the Supplier's quality assurance program (QAP) or other technical certifications."

Discussion:

Supplier evaluation via Para 200(b) can be accomplished via a "desktop review". Such a review requires the prospective seller to provide their quality assurance program documents and documentary evidence of implementation when the purchaser is evaluating a supplier whose program basis is NQA-1. Such a review would be performed by ensuring that the supplier meets the quality requirements specified in the procurement documents as well as verifying adequate implementation of procurement document required processes and controls.

A lesser employed means of supplier evaluation noted in Para 200(b) is via evaluation and verification of "*third party certificates"* or certificates of accreditation. Such third-party certificates are commonplace across commercial industry. Subpart 2.19, as derived from NEI 14-05, codifies not only supplier selection, but acceptance of items and services via acceptance of such certifications. As commercial industry quality practices continue to improve, supplier evaluation and selection of a commercial supplier of items intended for use in SS/SC/SR

applications via third-party accreditation may be an adequate and efficient means of meeting Para 200(b).

Take-aways:

- Requirement 7, Para 200(b), can be accomplished via a desktop evaluation of a prospective supplier's quality assurance program with accompanying documentary evidence of implementation.
- Verification of supplier accreditation (i.e., ISO-17025, UL, ISO-17065) may be an acceptable means of meeting this requirement.

4.4 Supplier Selection and Evaluation Para 200(c)

Requirement 7 Para 200(c):

"Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's Quality Management System (QMS)."

Discussion:

This requirement is accomplished via direct evaluation of the supplier's quality assurance program and its compliance to applicable portions of NQA-1 via an on-site audit. The audit verifies adequate implementation of the supplier's program. While NQA-1 is the most typical standard against which the supplier is evaluated, other consensus codes and standards have also been employed as a means of evaluation and selection. Examples are ISO-17025 and ASME Section III. So long as those programs bound the scope of supply, they have been found as sufficient as a basis for selection.

While evaluation and selection based on other standards is not typical, it can be acceptable. In these instances, the purchaser is required to determine quality requirements against which to evaluate the prospective supplier. This has been done by selecting applicable portions of NQA-1 against which the supplier can be evaluated. Alternatively, the purchaser may select another quality standard against which to evaluate the supplier so long as application of that standard results in the purchaser being supplied a product that meets design bases requirements. Examples of alternative quality programs include ASME Section VIII, UL 508A, ISO-9001, AS-9100, and NAP-401.1 Weapons Quality Policy.

It is important to note that supplier evaluation and selection via on-site audit typically results in item acceptance via a CoC. While this is the most typical method of acceptance, the purchaser is not limited solely to this option. The purchaser may elect to accept the item or service via the CoC, "source verification, receiving inspection, or post installation testing," or a combination of the noted methods. Extending the purchaser's methods of acceptance beyond a CoC can enable the purchaser to extend application of their quality assurance program as an adequate means to accept items from non-nuclear suppliers.

Take-aways:

- Employment of this method requires the supplier to have a documented quality assurance program.
- This requirement is accomplished by direct evaluation of the supplier's Quality Assurance program which is typically done in person.
- Nomenclature employed by suppliers to describe their quality program may vary and may be expressed in terms other than "Quality Assurance Program."

4.5 Bid Evaluation Para 300

Requirement 7, Para 300:

"If bids are solicited, the bid evaluation shall include a determination of the Supplier's capability to conform to the technical and quality assurance requirements.

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

Discussion:

The bidding and award process is a successor to the procurement document development (Requirement 4) and supplier evaluation and selection. The focus of this requirement is to ensure that the supplier proposal complies with the requirements specified in the procurement documents. However, by this stage in the procurement process, the suppliers providing proposals should have been evaluated and found to be capable of providing the product or service desired by the purchaser. Depending on the complexity of the item or service, this process can include several clarifications to the defined scope of work via requests for information (RFI) or deviations from the prospective suppliers. This is sometimes referred to as conforming the contract to accommodate the RFIs or deviations ultimately resulting in an award to the most technically acceptable and financially competitive proposal.

Separate from resolution to exceptions to contract requirements evaluated during the bid proposal stage, evaluation of the supplier's quality assurance program may reveal gaps that require remediation in some form. The most typical means is via supplier corrective action to correct the non-compliance via program or procedure update to address.

Take-aways:

- Procurement documents may be conformed to address supplier submitted RFIs and deviation requests.
- Deviation requests may result in a return to design to evaluate the technical adequacy of the supplier's proposal.

4.6 Control of Supplier-Generated Documents Para 400

Requirement 7, Para 400:

"Controls shall be implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements.

These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria."

Discussion:

This requirement applies to the pre-award phase of the contract and on through to delivery and final acceptance. Whether or not the supplier has a quality assurance program, controls shall be implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the supplier submitted documents. This requires review by qualified personnel. If

the supplier does not have a quality assurance program, the evaluation of the supplier-generated documents should be based on the limited scope controls identified in the procurement documentation that the supplier can provide. Acceptance documentation that has not been generated or controlled as part of an approved quality assurance program should be subject to additional controls, testing, and/or inspections identified by the purchaser.

Take-aways:

- Review of supplier documents can require a cross functional review depending on the document submitted. This may include a specialist from engineering such as seismic/structural engineering or nuclear safety.
- Measures should be employed by the purchaser to ensure qualified personnel review submitted documents.
- Review and acceptance of supplier generated documents should be against specified acceptance criteria in purchaser supplied procurement documents.

4.7 Acceptance of Item or Service: General Para 501

Requirement 7, Para 501:

"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.

The extent of the verification activities by the Purchaser shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance.

Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use."

Discussion:

Acceptance of an item or service is an important and somewhat complex process that involves both the supplier and the end user. First and foremost, the supplier must ensure the item or service meets the requirements of the purchase order. Based on an evaluation of the item's end use (safety significance), complexity, importance, lead time, and cost, the end user may perform additional verifications, inspections, and/or tests prior to shipment or at the project site. Additionally, the performance history of both the item and the supplier should be factored into this evaluation.

Additionally, NQA-1 requires, where appropriate, that documentation be provided where required by a code, regulation, or contract (aka purchase order). Examples include:

- ASME Code Data Reports
- Certified Material Inspection Reports
- Heat treatment records
- Calibration records
- Seismic qualification records
- Environmental qualification records
- Product testing records (e.g., UL)

- Inspection records
- Testing records
- Dimensions
- Weights
- Drawings
- Bill of materials.

The paragraph addresses the requirements for the four [4] Methods of Acceptance, which are:

- Certificate of Conformance
- Source Verification
- Receiving Inspection
- Post-installation Test.

This requirement represents a natural hand-off between procurement and acceptance processes. The supplier, by contract, is required to comply with requirements specified in the procurement documents prior to offering the item or service to the purchaser. Once the supplier has completed the required verification, it is incumbent on the purchaser to ensure that the supplier has complied with the requirements of the purchasing document and delivered what was required including associated documentation. Verification of compliance by the purchaser can range from source verification prior to delivery at the supplier, review of required documentation, receipt inspection activities, and up to post-installation testing to verify compliance to design bases requirements. As stated in the requirement, the level of verification required by the purchaser is dependent on the "*relative importance, complexity, and quantity.*"

Additional verification may be performed by the purchaser as an effective means of acceptance when a CoC does not provide adequate confidence. See discussion below for more detail on item acceptance via a CoC as well as the other methods of acceptance. Additional discussion on each of the acceptance methods will be discussed further in the sections below.

As stated in this requirement, the extent of verification activities performed by the Purchaser is a function of the Supplier's quality program and verification of effective implementation. If the supplier has limited quality controls, or has no quality assurance program, purchaser methods of acceptance are limited to source verification and special tests and inspections.

Take-aways:

- The supplier is responsible for ensuring items or services provided meet purchaser requirements.
- Objective evidence of item or service adequacy is dependent upon the purchaser-chosen method of acceptance. Additional discussion regarding this bullet will be noted in the following sections.

4.8 Methods of Acceptance Para 502

Requirement 7, Para 502:

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

Discussion:

It bears mentioning that the above noted acceptance methods are very similar to CGD Methods 1 through 3. As stated in the introduction, Subpart 2.14 is an amplification of these requirements providing additional depth and detail on how to meet the requirements. Prior to the acceptance of commercial grade dedication, 10CFR50 Appendix B manufacturers often employed these methods to procure from suppliers with commercial quality programs. It continues to be a common practice today with manufacturers of items supplied to the nuclear industry. These practices are documented in EPRI 3002002982 (EPRI NP-5652 Rev. 1), Appendix F, where procurement of safety related items from commercial suppliers without CGD is discussed.

As stated above, acceptable methods of acceptance from the supplier are "*Supplier Certificate of Conformance, source verification, receiving inspection, or post installation test at the nuclear facility site, or a combination of these methods."* The following sections discuss the application and implementation of these acceptance methods.

Take-aways:

- Applying the acceptance methods noted in Para 502 to suppliers who implement non-nuclear quality assurance programs may require additional oversight including submittals, surveillances, and inspections for acceptance. Determination of additional oversight is dependent on the complexity and importance of the item being purchased.
- Decisions on these measures and documentation of their bases may be documented in a quality plan for commercial suppliers in lieu of a CGD plan.
- Noted acceptance methods may be used individually or in combination for item/service acceptance.

4.9 Certificate of Conformance Para 503

Requirement 7, Para 503:

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

Discussion:

Before proceeding, it is important to understand two important definitions:

NQA-1, Requirement 1, Para 400, defines a COC as follows:

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

NQA-1, Requirement 1, Para 400, defines Certification as follows:

> *"Certification: the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements."*

Typically, a CoC is the most common acceptance method to accept items or services from suppliers whose nuclear (aka NQA-1) quality assurance programs have been audited and approved by the purchaser. Although not universally recognized, there are other approaches for accepting a CoC, for example:

- Performance of an audit on a supplier's non-NQA-1 quality assurance program
- Use of documented supplier performance history
- Use of detailed source verification
- Use of pre/post installation testing
- Tests and inspections
- Combination of the above methods.

While evaluation and selection based on other standards is not typical, it is an acceptable practice. In such instances, the end user is required to determine specific quality requirements (e.g., calibration, material control) against which to evaluate the prospective supplier. See Subsection 4.1 for a listing of various quality assurance standards.

Take-aways:

- The most commonly employed means to "*verify the validity"* of a CoC is via an onsite audit of the suppliers documented quality assurance program.
- Acceptance via a CoC may be achieved with non-NQA-1 suppliers.
- A CoC should only be accepted from a supplier with a documented quality assurance program.
- The purchaser should consider employing acceptance via a method other than CoC if they choose not to perform a direct evaluation of the supplier.

4.10 Certificate of Conformance Para 503(a)

Requirement 7, Para 503(a):

> *"The certificate shall identify the purchased material or equipment, such as by the purchase order number."*

Discussion:

It is essential when using this method, regardless of the extent of the supplier's quality controls, that the certificate identifies the purchased material or equipment including identification of the purchase order. If the supplier does not have this in their quality program, it must be a requirement of the purchase order. This can be accomplished by specifying the requirements from this section for the CoC in the procurement documents.

Take-aways:

- The CoC must reference the purchaser's purchase order or contract number as well as identify the item or service provided.

- Traceability via the CoC between the item, purchasing documents, and the supplier is accomplished via this requirement.

4.11 Certificate of Conformance Para 503(b)

Requirement 7, Para 503(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."

Discussion:

It is essential when using this method, regardless of the extent the supplier's quality controls, that the specific procurement requirements met by the supplier (including any changes, waivers, or deviations applicable) and used for acceptance are identified on the certificate. If the supplier does not have this in their quality program, it must be a requirement of the purchase order.

This section identifies the requirements, codes, standards, etc. that were requested in the purchasing documents. This section includes any issues and special documents that are to be furnished with the purchase. When these documents and the certificate are put together, they should provide the objective evidence of quality.

Take-aways:

- Purchasers often include explicit certificate of conformance instructions, including a CoC form or template, in the purchasing documents.
- Sole reliance on a CoC for acceptance may necessitate a rigorous CoC acceptance process by the purchaser.

4.12 Certificate of Conformance Para 503(c)

Requirement 7, Para 503(c):

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

Discussion:

When auditing a prospective supplier to accept their products via a CoC, the qualification should include a determination of adequacy of the supplier's program for addressing non-conformances. If the purchaser's evaluation verifies the adequacy of the supplier's non-conformance program, the purchaser's procurement documents should require the supplier to submit deviations from design requirements for approval. Should the purchaser's engineering organization approve such non-conformances, they should be noted on the CoC.

If the supplier does not have a nonconformance process in their quality program, it will be the responsibility of the purchaser to identify any procurement requirements that have not been met together with an explanation and means that was used to resolve the nonconformances. This should be documented along with the acceptance of the item.

Any requirements that were specified in the purchase documents that were not met, or not fully met, should be called out in the section. This also should identify why they have not been met and the steps taken to resolve them. If they are not resolved, they will need to be evaluated as potential nonconformances. Any nonconformances should be properly documented, including disposition and determination of acceptability.

Take-aways:

- The CoC's purpose is to provide the purchaser a means of gaining assurance of adequacy of supplier-provided items or services.
- Deviations from stated purchaser requirements documented in the CoC allow the purchaser to determine item or service adequacy for use.

4.13 Certificate of Conformance Para 503(d)

Requirement 7, Para 503(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."

Discussion:

If the supplier does not have an approved quality assurance program that identifies the person who is responsible for the quality assurance function, a CoC may not be employed as the sole means of acceptance.

Take-aways:

- Validity of a supplier CoC is dependent on the signatory being identified as responsible for the quality assurance function as described in the supplier's quality assurance program.
- The CoC needs to be signed by a person with authority for quality for the supplier organization.

4.14 Certificate of Conformance Para 503(e)

Requirement 7, Para 503(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."

Discussion:

If the supplier does not have a quality assurance program that identifies the certification system and the administrative method for review and approval of the certificate, the purchaser may provide the requirements, processes, and procedures necessary to complete a CoC to the supplier. Incorporation of the CoC processes and procedures would then be required by the purchaser. The purchaser shall also have a defined process for how the CoC is specified in procurement documents as well as a process for acceptance of the CoC once provided by the supplier.

Take-aways:

- The supplier is required to employ a documented process for completion of the CoC described in the above sections.
- The purchaser may assist the supplier by providing a CoC process that the supplier may incorporate for the specified scope of work.
- Note that (e) states that the certification system shall be described in the "Purchaser's or Supplier's quality assurance program." This would indicate that the purchaser may provide the supplier with an adequate certification process.

4.15 Certificate of Conformance Para 503(f)

Requirement 7, Para 503(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."

Discussion:

When selected as the primary method of acceptance, this paragraph identifies options the purchaser has to verify the validity of the CoC. This is most typically accomplished via direct evaluation of the supplier's quality assurance program including the supplier's certification system. However, the purchaser may elect to perform independent inspections or tests to verify the validity of the supplier generated CoC. This is less common but may be appropriate when accepting items from suppliers with commercial quality programs.

Take-aways:

- Commercial suppliers may not have an adequate CoC certification program. In such cases, providing the process requirements via contract documents may be appropriate.
- Independent tests and inspections are an acceptable alternative to direct evaluation of the supplier with regards to verification of CoC validity.
- Acceptance of the CoC is not dependent on the complexity and sophistication of the supplier's quality assurance program.
- Whether accepted via direct evaluation or independent tests and inspections, Para 503 (a) through (f) are required when the primary method of acceptance is a CoC.
- Purchaser may elect to require the supplier to satisfy the requirements of Para 503 (a) through (f) via separate submittals to be assembled by the purchaser upon receipt.

4.16 Source Verification Para 504

Requirement 7, Para 504:

"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 shall include monitoring, witnessing, or observing selected 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."

Discussion:

The purchaser may elect to accept items and services solely based on the source verification process. When doing so, auditing the supplier's program, as would typically be done, is not required. Application of this process is well suited to single procurements where item conformance to specified design requirements may be accomplished via one or more verifications at the supplier's facility of the item's or service's compliance to design requirements. Additional submittals, including the procedures documenting the processes to be witnessed, may be required to provide additional assurance.

Source verification is a tool that may be used to verify aspects and critical steps in a manufacturing process. Observations should be well documented in a manner that is repeatable and verifiable. As part of the procurement planning process, a quality plan may be developed to identify submittals, deliverables, and witness and hold points with the bases for the level of rigor applied. The quality plan should consider supplier capabilities and critical points in the manufacturing process where the purchaser may verify key design bases attributes. This quality plan should either be included or have the necessary elements incorporated in procurement documents.

Take-aways:

- Right of access to perform the source verification must be incorporated into the procurement documents.
- Witness and hold points must be incorporated into the procurement documents.
- The supplier is not required to have a documented quality assurance program to employ source verification as an acceptance method.
- It is recommended that the supplier submits the procedure documenting the processes to be witnessed for review and acceptance prior to performance of the source verification(s).

4.17 Receiving Inspection Para 505

Requirement 7, Para 505:

"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 verify by objective evidence such features as:

(a) configuration

(b) identification

(c) dimensional, physical, and other characteristics

(d) freedom from shipping damage

(e) cleanliness

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

Discussion:

Whether or not the supplier has a quality program, receiving inspection may be used as the primary method of acceptance. This section provides adequate requirements for receiving inspection for items from a supplier that does not have an approved quality assurance program. Receiving inspection may need to include independent testing and inspection of the items being accepted. Verification of supplier documents (e.g., CoC, MTR) and confirmation of required purchaser activities (e.g., source verification, audits) can be incorporated into the receipt inspection process.

Receipt inspection activities (e.g., dimensional inspection, functional testing) can be incorporated as a result of observed supplier deficiencies. Receipt inspection activities should not be limited to a simple "kick and count" as this does little to assure design requirements are met. Receipt inspectors must be trained and qualified in accordance with the purchasers program requirements.

Take-aways:

- Receipt inspection can be employed as the sole method of acceptance.
- Limiting receipt inspection to a "kick and count" may not provide adequate confidence.
- Review of supplier documents and verification of required purchaser activities may be incorporated into the receipt inspection process.

4.18 Post-installation Testing Para 506

Requirement 7, Para 506:

"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."

Discussion:

Unlike other acceptance methods, post installation testing (PIT) usually is a direct verification of the item's safety function. It is not usually used for simple, non-complex items, but is used for components such as pumps, valves, fire protection and electrical items. When used, it is commonly used in conjunction with receipt inspection. It should be noted that PIT is not used or applicable to the equipment qualification process.

PIT can be employed as a sole method of acceptance. When applied, evaluation of the supplier's program is not required. Care should be taken when employing this method to ensure that PIT adequately addresses identified credible failure mechanisms sufficient to provide adequate confidence that the item will perform its safety function. In cases where PIT does not address all identified credible failures, additional acceptance methods are required to provide adequate confidence.

Take-aways:

- Post installation testing may be employed as the sole method of acceptance.
- Post installation testing should not be employed as the sole method of acceptance if PIT does not address identified credible failure mechanisms.

4.19 Acceptance of Services Para 507

Requirement 7, Para 507:

"Acceptance of Services Only: In cases involving procurement of services only, such as third-party inspection; engineering and consulting

services; auditing; 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"

Discussion:

Acceptance of services may not follow the path typically taken to accept items. While the acceptance methods defined in Requirement 7, Para 502, may be employed, the standard defines alternate methods for acceptance of certain services. Subpart 2.14, Para 700, contains additional information on acceptance of services that should be reviewed when defining acceptance strategies for services.

Take-aways:

- Acceptance methods employed when procuring services may differ from those employed for acceptance of items.
- Subpart 2.14, Para 700, contains additional information on acceptance of services.

4.20 Commercial Grade Items and Services Para 700

Requirement 7, Para 700:

"Commercial Grade Items and Services

When dedication is used for accepting commercial grade items or services, the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall apply."

Discussion:

The CGD acceptance process is an acceptable alternative to NQA-1, Requirement 7, Paras 200 through 600. The basic CGD process described in Subpart 2.14 largely evolved from the approach promulgated by the Electric Power Research Institute (EPRI) in the late 1980s (EPRI Report NP-5652). Over time, NQA-1 began to address this process culminating in 2008 edition publishing Subpart 2.14. EPRI also has continued addressing this process, publishing revisions and new documents over the past 30 years. The complexity of the CGD process is beyond the scope of this document.

Only suppliers with an approved quality assurance program should be allowed to perform commercial grade dedication. Requirements for the commercial grade dedication process are found in Subpart 2.14.

4.21 Acceptance Methods Key Points

- It is incumbent on the end user to provide procurement documents (e.g., purchase order, specification, data sheets, drawings) which define technical and quality requirements (e.g., safety functions, design functions, design attributes, environment, materials, quality assurance, inspection, and testing).
- An NQA-1 audit of a prospective supplier is not the only means of placing a supplier on the end user's Qualified Supplier List (QSL).
- A CoC is only valid when supplied and certified by a company whose quality assurance program has been reviewed and approved by audit, regardless of if the quality assurance program meets a nuclear standard (e.g., ASME Section III, NCA3800 or NQA-1) or a nonnuclear standard (e.g., ISO 9001 and NAP 401.1)
- By definition, a quality assurance program must be documented, controlled, and approved by the supplier for use.
- A CoC must reference the end user's purchase order as well as the item being supplied (e.g., part number, serial number, and model number).
- Traceability between the CoC and the item being supplied must be provided and auditable.
- The CoC must be signed and dated by a person at the appropriate management level, which is described in the quality assurance program.
- The quality assurance program must encompass the products being procured.

- CoCs are usually used in conjunction with other methods (i.e., receipt inspection)
- Receipt inspections must be performed in accordance with specific directions that include inspection attributes, specific acceptance criteria, and where applicable, tolerances (e.g., product chemistry element tolerances).
- Receipt inspectors must be trained and qualified in accordance with the purchaser's program requirements.
- Like receipt inspection, source verification must be performed in accordance with specific directions that include specific attributes and acceptance criteria, as well has supplier procedures for practices such as heat treatment, welding, and factory acceptance testing.
- Source verification must be performed by qualified, trained, and certified personnel.
- Source verification witness and hold points along with the notification process, should be clearly addressed in the purchase order.
- The supplier is not required to have a formal (aka documented) quality assurance program when the end user employs source verification as an acceptance.
- PIT should only be used for complex items with high safety significance.
- PIT should normally be combined with other acceptance methods.
- PIT should always be performed in accordance with a controlled document (e.g., work order, test procedure) by trained and qualified personnel (e.g., maintenance and operations).
- The supplier's ability to meet the technical requirements may require that the purchaser employs additional quality oversight methods to accept the service from a non-NQA-1 supplier or a supplier with no documented quality assurance program.

Examples of all four acceptance methods, including combinations thereof, can be found in Appendix A. Additional appendices will be included over time.

5. CONCLUSION

NQA-1 provides multiple success paths for the acceptance of SS/SC/SR items and services. Regardless of the acceptance method utilized, the end user must have reasonable assurance / adequate confidence that the SS/SC/SR item or service will perform its intended safety function.

While the previously described acceptance methods, (including procurement items from a non-NQA-1 supplier, [sans CGD]) may be employed at any level of the supply chain, it will most commonly be observed at a manufacturer. While the CGD process is well suited to acceptance for small lots or replacement parts, manufacturers may leverage the advantages of embedding the required quality acceptance requirements into existing processes.

Conversely, end users may default to acceptance via CoC from an NQA-1 qualified supplier or commercial grade dedication as those methods may be more effectively implemented by the end user. Application of CGD or procurement from an NQA-1 approved supplier is typically better suited for DOE M&O or construction contractors as item or commodity specific quality acceptance plans are required to support continuing operations or construction. Given the wide variety of items and services procured, it may not be feasible to embed acceptance requirements into enterprise-wide processes, especially for large complex items. Development of "one-off" acceptance plans via CGD or procurement specifications to NQA-1 qualified suppliers may be more efficient.

The final take-away of this paper is that the is that application of the NQA-1 standard provides multiples paths to success in the procurement and acceptance process. Regardless of the method selected, the purchaser is required to achieve adequate confidence / reasonable assurance that the item or service will perform its safety function.

While the described methods of acceptance (i.e., procurement from a non-NQA-1 supplier sans CGD) can be employed at any level of the supply chain, it will most commonly be observed at a manufacturer. While the CGD process is well suited to design an acceptance plan for small lots for construction or replacement parts, manufacturers may be better served to embed the required quality acceptance requirements into their enterprise processes using a wholistic approach. The required quality verification steps in these instances are incorporated into the manufacturers processes and procedures while achieving the required adequate confidence.

Conversely, end users (utilities, DOE M&O contractors) will most typically default to acceptance via CoC from an NQA-1 qualified supplier or commercial grade dedication as those methods may be more effectively implemented by the end user. Application of CGD or procurement from an NQA-1 qualified supplier is typically better suited for DOE M&O or construction contractors as item or commodity specific quality acceptance plans are required to support continuing operations or construction. Given the wide variety of items and services procured, it may not be feasible to embed acceptance requirements into enterprise-wide processes. Development of “one-off” acceptance plans via CGD or procurement specifications to NQA-1 qualified suppliers may be more efficient.

As previously noted, effective implementation of each of the chosen methods is dependent on a robust training program, clear written direction, and experienced SMEs to guide the process.

Appendix A

Benchmark Example of Design and Manufacture Under a QA Program Meeting the Requirements of 10CFR50, Appendix B (or NQA-1)

The following example will show the full life cycle process of a typical nuclear purchaser from receipt of a contract through delivery of the final Q component. In this example, the Licensee is ordering Basic/Q component whose design has been verified as suitable for end use application. The resultant process employed to fulfill that order will be detailed in the example below. Key portions of that process are numbered in the associated flow chart as follows:

1.0 Order Entry

2.0 Contract Review

- 2.0 Engineering: Create Bill of Material (BOM)
- 2.1 Engineering: Create Drawings
- 2.2 Engineering: Procurement Requisition
- 2.3 Engineering: Create Shop Traveler
- 2.4 Engineering: Create Factory Acceptance Test (FAT)

3.0 Procurement: Create Purchase Order

4.0 Manufacturing: Perform Assembly and Test

5.0 Supplier Qualification: Survey, Audit, Source Verification

- 5.0 Quality Assurance: Receipt Inspection
- 5.1 Quality Assurance: Final Inspection
- 5.2 Item Packaging and Shipping

In this example, the process is being employed to procure material and parts for a nuclear qualified actuator.

1.0: Order Entry:

In 1.0 through 1.2, the contract is processed into the manufacturer's business management system, typically an Enterprise Resource Planning (ERP) or Manufacturing Resource Planning (MRP) based system. Tasks are then initiated for engineering to begin work on fulfillment of the order.

The requirement basis for this activity is Requirement 1, Paragraph 300, from NQA-1.

2.0: Contract Review:

A contract review by engineering is accomplished next to evaluate the contract requirements for items ordered. As the Licensee is ordering a basic component, contract review consists of confirming that the requested item, configuration, version, and additional quality requirements align with Basic/Q component offered.

This step is performed by engineering, typically a Responsible Engineer.

The requirement basis for this activity is Requirement 3, Paragraph 601, from NQA-1.

Output document types: Engineering Task Orders with applicable customer requirements.

2.1: through 2.5: Engineering (Design):

Upon completion of contract review and requirements, engineering generates the documents necessary to fulfill the order. Those documents can include:

- Bill of Material
- Project specific drawings
- Material Requisitions including:
  - Acceptance Criteria
  - Required submittals
  - Required deliverables
- Shop traveler/routing
- Assembly instructions
- Factory Acceptance Test Procedure including:
  - Required Tests
  - Required Inspections.

Customer specific requirements are incorporated into the order specific documents noted above for use in procurement, production, assembly and required tests and inspections.

As these output documents are a result of a qualified design, the governing NQA-1 requirements are Requirements 4 and 5.

3.0: Create PO:

In the above step, Engineering has generated various requisitions for fulfillment by procurement. Procurement includes the necessary technical information including codes, standards, drawings, and specifications included in the engineering generated material requisition.

Output documents:

- Purchase Orders

The requirement basis for this activity is Requirements 4 and 7.

4.0: Assembly and Test:

The Assembly and Test plan includes the assembly router as well as the required tests for acceptance including functional and material testing.

The Factory Acceptance Test Plan identifies the "Design Characteristic," "Sample Size," and “Acceptance Criteria and method of testing." These additional tests include visual verifications, dimensional inspections, functional and pressure testing, X-Ray Fluorescence Testing, Optical Emission Spectroscopy Testing (OES), and Infra-Red Spectroscopy Testing (FTIR) testing.

The testing required by the FAT coupled with the supplier qualification activities provide adequate assurance that the material will perform its Q function.

Output documents:

- Inspection and test reports
- Completed assembly and test router.

The NQA-1 requirement basis for this activity is Requirement 7, Paragraph 505, and Requirement 5.

5.0: Supplier Evaluation:

Supplier evaluation is performed as requested by engineering against specified quality requirements. Suppliers are placed on the QSL based on evaluation and verification that suppliers meet specified requirements. When supplier is unable to complete certain scopes of work, such as material testing, the purchaser performs the required testing upon receipt of the item to achieve adequate assurance of item acceptability.

Output documents:

- Audit Reports (Purchaser)
- Certificate of Conformance (Supplier).

The NQA-1 requirement basis for this activity is Requirement 2, Paragraph 303, and Requirement 7, Paragraphs 200 through 600.

5.1: Receipt Inspection:

Purchaser receipt inspection includes standard document review and visual inspection of items as noted below. Receipt inspection activities identified in purchaser receipt inspection reports focus on visual inspection and document review. Acceptance testing specified by engineering can be accomplished during receipt inspection. However, in this example, acceptance testing is defined in the Factory Acceptance Test discussed below.

Output documents:

- Inspection and test reports

The NQA-1 requirement basis for this activity is Requirement 7, Paragraph 505.

5.2 Quality Assurance: Final Inspection

Item is subject to final inspection to ensure all required tests and inspections have been completed acceptably.

5.3 Item packing and shipping:

This is the point in the process when the item is considered a basic component (10-CFR-50 Appendix B end user) or a safety SSC (DOE end user) and is shipped to the Licensee or end user.

Final Conclusion:

The design bases requirements are adequately defined by the procurement documents. Other requirements necessary to assure adequate quality have also been incorporated into the procurement documents including the requirement to implement their quality assurance program along with a number of quality assurance requirements. The supplier qualification oversight activities coupled with the additional tests and inspections performed at the purchaser's facility provide adequate assurance that the items delivered to the end user will perform their safety function.

Manufacturer FlowChart: