Five Star Products, Inc.

NUCLEAR QUALITY ASSURANCE MANUAL

Revision History

Rev. #:	Rev. Date:	Reason for Changes & Sections Affected:	Submitted by:	Approved by:	Effective Date:
0	11/17/2010	New Manual, all sections	Bruce Romano/QA Manager	Brian Feidt/CFO	11/15/2010
1	04/05/2012	Improved Org Chart, Clarifications, Editorials	Bruce Romano/QA Manager	Brian Feidt/CFO	04/05/2012
2	10/11/2016	Incorporations of procedural changes, statement of compliance to ASME NQA-1 standards	Sarah Grumman/QA Manager	Chris Piekos/Technical Director	10/11/2016
3	9/8/2020	Update 17025 accreditation requirements to new revision. 17025:2017	Sarah Grumman/QA Manager	Atom Saverse/VP of Operations	9/8/2020
4	05/26/2021	Update to NQA-1 2015 Edition and editor clarifications	Sarah Grumman/QA Manager	Atom Saverse/VP of Operations	5/26/2021

Contents

POLICY STATEMENT

The Five Star Products' Nuclear Quality Assurance Program (NQAP) provides the requirements to be integrated into all aspects of nuclear work performed by Five Star Products personnel and its lower tier suppliers.

Five Star Products' Nuclear Quality Assurance Program was established and implemented to meet the requirements of 10 CFR 50 Appendix B and 10 CFR 21. *This program meets the requirements of ASME NQA-1 1994 Edition, 2008 Edition with 2009 Addenda, and 2015 Edition.*

The NQAP is controlled, documented, and implemented by this Nuclear Quality Assurance Manual (NQAM), written policies, objectives, procedures, and instructions, and is fully sanctioned and supported by the CEO/President of Five Star Products. The responsibility for day-to-day maintenance and execution of the Nuclear Quality Assurance Program (NQAP) is delegated to the Quality Assurance Manager who reports to the CEO/President. However, the CEO/President retains responsibility for the overall program effectiveness.

1. Organization

The Five Star Products organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented and delineated in the Nuclear Quality Assurance Program *and Annex A and in accordance with the NQAM, NQP-02.1, ASME NQA-1 1994ed, 2008ed/2009add, and 2015ed.*

a. *Members of the Five Star Products, Inc. Executive Management Team establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired results. These expectations shall be communicated through company policy, objectives, goals, and/or action items from the Management Assessment Meeting.*
b. Quality is achieved and maintained by those assigned responsibility performing the work.
c. Quality is verified by those not directly responsible for performing the work, such as personnel performing testing and inspection, and auditors conducting internal audits and process reviews.
d. Quality personnel report to senior level management and shall have sufficient independence from production cost and scheduling considerations. Personnel performing activities verifying quality have sufficient authority, direct access to responsible levels of management, organizational freedom to:
    i. Identify quality problems,
    ii. Initiate, recommend, or provide solutions to quality problems through designated channels,
    iii. Verify implementation of solutions, and
    iv. Assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Delegation of Work

Employees of Five Star Products may delegate work to other personnel and or external organizations but shall retain responsibility therefor.

Interface Control

Where more than one organization is involved in the activities covered by the nuclear quality assurance program, the responsibilities, interfaces, and authority of each organization shall be

clearly defined and documented. External interfaces between organizations and the internal interfaces between organizational units, and changes thereto shall be documented when applicable.

2. Quality Assurance Program

2.1. Documented Quality Assurance Program

The Five Star Products Nuclear Quality Assurance Program (NQAP) is planned, implemented, and maintained to the requirements of 10 CFR 50 Appendix B, 10 CFR 21, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed for certain designated cement and epoxy- based grouts.

The Nuclear Quality Assurance Manager has overall responsibility for the implementation of this nuclear quality assurance program including inspection and testing personnel.

- The NQAP includes consideration of the technical aspects of activities affecting quality and provides control over activities to an extent consistent with their importance.
- The NQAP provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, such as adequate cleanness and assurance that prerequisites for the given activity have been satisfied. This program provides for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items for verification of quality by inspection and testing. The program also establishes and implements processes to detect and correct quality problems.
- The NQAP provides for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure suitable proficiency is achieved and maintained.
- *Members of Five Star Products' Executive Management Team actively participates and supports the NQAP and shall regularly assess the adequacy and effective implementation of the NQAP.* The Quality Assurance Manager is responsible for arranging with management to regularly assess the adequacy and effective implementation of the NQAP. *The President/CEO is responsible for endorsing the Management Assessment in accordance with NQP 02.1 and ASME NQA-1-1994ed, 2008ed/09A, 2015ed Requirement 1 by signing the completed Management Assessment Form.*

2.2. Indoctrination and training are commensurate with the scope, complexity, and importance of the activities, and the education, experience, and proficiency of the personnel *and shall be controlled in accordance with this NQAM and NQP-02, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 2, para. 200.*

- **Indoctrination**
  Personnel performing or managing activities affecting quality *shall receive indoctrination in their job responsibilities and authority; general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements in accordance with NQP-02 and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 2, para 202. Indoctrination and training records will be documented on the Five Star Nuclear Training Matrix. Training for QC Testing and Inspection personnel may be documented on a separate section of the matrix due to the complexity of their training requirements.*
- **Training**
  The Quality Assurance Manager along with the Human Resource and/or the departmental manager shall determine the need for a formal training program for personnel performing or managing activities affecting quality in accordance with NQP-02 and Requirement 2. Training will be provided to achieve initial proficiency, if needed, to maintain proficiency, and/or adapt to changes in technology, process, or job responsibilities*. On the job or hands-on training shall be used if direct hand-on applications or experience is needed to achieve and maintain proficiency. Training requirements, and completed training, included on the job training will be documented on the Five Star Nuclear Training Matrix in accordance with this NQAM, NQP-02 and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 2, para 202.*

2.3. Qualification Requirements

Five Star Products has designated those activities that require qualification of personnel and the minimum requirements for such personnel such as QC Inspector and Testing personnel and Lead Auditors. *Written procedures, NQP-19 for Inspection and Test Personnel and NQP-18 for Auditors have been established for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform these activities:*

- **Inspection and Test**
  In accordance with this NQAM, NQP-19, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 2, para. 302 the initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. *The QA Manager or VP of Operations shall evaluate the performance of inspection and test personnel at periodic intervals not to exceed 3 years. The R&D Director may determine additional training requirements for ASTM testing.* Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of standard indoctrination and training section to this NQAP. If during this evaluation or at any other time, it is determined by the evaluators that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has

been demonstrated. Any person who has not performed inspection or testing activities in the qualified area for a period of one year shall be reevaluated. In addition, inspection and test personnel shall be evaluated annually.

- ***Lead Auditors***
  In accordance with this NQAM, NQP-18, ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 2, para 303 the Lead Auditor organizes and direct audits, reports audit findings, and evaluates corrective actions. The individual shall meet the requirements of ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 2, paras. 301-303.4 prior to being designated a Lead Auditor. Lead Auditors shall maintain proficiency in accordance with the requirements of para 303.6 as applicable. The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attesting to in writing by the QA Manager or VP of Operations.

2.4. *Records of Qualification*
Records of qualification will be documented maintained in accordance with this NQAM, NQP-19, NQP-18 and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed, Requirement 2, para. 400, 401, and 402. The QA Manager shall document and maintain qualification records for auditors, inspectors, and testing personnel.

2.5. *Records of indoctrination and training shall include one or more of the following in accordance with NQP-02. NQP-18, and NQP-19 and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 2, para. 500:*

- *Attendance sheets*
- *Training logs*
- *Personnel training records*

The QA Manager shall establish and maintain records for indoctrination and training, Auditor and Lead Auditor qualification and requalification, and inspection and test personnel qualification and requalification. The HR Manager shall maintain job descriptions, qualifications, and training records for personnel performing activities not related to quality activities such as Production personnel and Operations Management.

3. Design Control

The R&D Director has overall responsibility for Design Control. Measures shall be established to assure that applicable regulatory requirements and the design basis for those components are correctly translated into written documents such as specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the components.

Design control measures shall be applied to items such as the following: thermal, hydraulic, compatibility of materials and delineation of acceptance criteria for inspections and tests.

Five Star Products' design activities shall be defined, controlled, and verified in accordance with this NQAM, NQP-03 and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed, Requirement 3. Design inputs shall be specified on a timely basis and translated into design documents. *Design interfaces shall be identified and controlled by the R&D Director in Design Control Binders.* Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

Incoming customer orders for safety-related products must be submitted on a formal purchase order. Purchase orders for safety-related products shall be reviewed and approved by *the Engineering Specialist - Power* and the Quality Assurance Manager to ensure technical and quality requirements are met. Any exception to technical or quality assurance requirements detailed in must be documented in writing and submitted to the customer for review and acceptance.

3.1. Design Input

- Applicable design inputs such as performance requirements, regulatory requirements, codes, and standards shall be identified and documented, and their selection reviewed and approved.
- Design inputs shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

3.2. Design Process

- Design work shall be prescribed and documented to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.

- Design documents shall support facility design, fabrication, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.
- Design methods, materials, parts, equipment, and processes that are essential to the function of the item shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

- **The final design shall:**

  3.2.4.1. Be relatable to the design input by documentation in sufficient detail to permit design verification.

  3.2.4.2. Specify required inspections and tests and include or reference appropriate criteria.

  3.2.4.3. Identify components that are part of the item being designed. *When such a component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented per NQP-07 and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed, Requirement 3, and ASME NQA-1 subpart 2.14.* Critical characteristics of the item to be verified are those that provide reasonable assurance that the item will perform its intended function. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to documented definition of the difference.

3.3. Design Analyses

- Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.
- Computer program acceptability shall be pre-verified, or the results verified with the design analysis for each application. Pre-verified computer programs shall be controlled. *At the present time there are no controlled computer programs in use applicable to these requirements. Any methods will be documented at the procedure level along with compliance.*
- Documentation of design analyses shall include:

  3.3..1. Objective of the design analyses

  3.3..2. Design inputs and their sources

  3.3..3. Results of literature searches or other applicable background data

  3.3..4. Assumptions and indication of those that must be verified as the design proceeds.

3.3.3.5 Identification of any computer calculation shall include identification of the computer type, name of computer program, revision identification, inputs, outputs, evidence of reference to computer program verification, and the bases **(or** reference thereto) supporting application of the computer program to the specific physical problem.

3.3..5. *The R&D Director shall prepare, and the VP of Operations shall review and approve.*

3.4. Design Verification

- The responsible design organization shall identify and document the design verification method(s) used. The results of the design verification shall be documented with the identification of the verifier clearly indicated. Design verification must be performed by any competent individual or group other than those who performed the original design but who may be from the same organization. The verifications may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or provided the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews are not adequate to satisfy the standards or interest to Five Star Products.
- Design verification shall be performed prior to releasing the design for procurement, manufacturing, construction, or release to another organization for use in other design activities except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled, and in all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its intended function.
- If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.
- The extent of design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this NQAP, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. The original design and associated verification documentation shall be referenced in records or subsequent application of the design.
- **Acceptable design verification methods** shall be applied to verify the adequacy of the design. Methods include but are not limited to any one or a combination of the following:

  3.4..1. Design reviews

  3.4..2. Use of alternate calculations.

3.4..3. Performance of qualification testing

- **Design reviews** shall provide assurance that the final design is correct and satisfactory. Details shall be at the procedural level.
- **Alternate calculations** shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, the computer program, its associated computer hardware and systems software, or other calculation methods used shall also be reviewed.
- **Qualification testing** shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.
- Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualification testing of a prototype unit under the most adverse design conditions.

3.5. Change Control

- Design changes including field changes shall be justified and subject to design control measures commensurate with those applied to the original design.
- Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any analysis upon which the design is based.
- Changes shall be approved by Five Star Products when originally responsible for approving the design document.
- When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the changes into the documents, where such incorporation is appropriate.
- Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified, as necessary.

3.6. Interface control

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

3.7. Documentation and records

- Design documentation and records shall include not only final documents such as drawings, specifications, and revisions to those documents, but also documentation that identifies the

most important steps in the design process, including sources of design inputs that support the final design.

4. Procurement Document Control

Procurement Document Control is in accordance with this NQAM and NQP-04, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 4. Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services. To the extent necessary, procurement documents shall require suppliers to maintain a quality program consistent with the pertinent provisions of Five Star Products' Nuclear Quality Assurance Program.

The QA Manager or designee prepares procurement documents with the appropriate requirements and the R&D Director reviews and approves the Purchase Order.

Procurement document control procedures also applies to suppliers of laboratory testing services and calibration services with ISO 17025 accreditation.

4.1. Excluded from the NQAP procurement requirements are:

4.1.1. Office supplies, work tools, production supplies, and supplemental labor and administrative services.

4.1.2. Commodity or commercial material procurement

4.1.3. *Commercial products ordered for subsequent commercial grade dedication by Five Star Products will be ordered based on their published product descriptions and in accordance with Five Star's ISO 9001:2015 program. The nuclear requirements below do not apply unless the vendors were commercial grade surveyed.*

4.2. Content of the procurement documents

4.2.1. Procurement documents shall include the following, as applicable to the item or service being procured:

- Scope of Work – A clear, concise statement of the scope of the work to be performed by the supplier.
- Technical Requirements – technical requirements shall be specified and where necessary these requirements must be specified by reference to specific drawings, specifications, codes, standards, procedures, or instructions (including revisions) that describe the items or services to be furnished. The procurement documents also must include the identification of tests, inspections, and acceptance criteria for determining acceptability of the item or service.
- Quality assurance requirements shall be specified in the procurement documents. These requirements shall be consistent with the importance and/or complexity of the item or service being procured.

The procurement documents shall require the supplier to incorporate appropriate quality assurance program requirements in sub tier procurement documents.

- Rights of access – provisions must be made in the procurement documents for access to the suppliers' and sub tier suppliers' facilities and records for surveillance, inspection, or audit by Five Star Products or by others authorized by Five Star, if applicable.
- Documentation – The procurement documents at all tiers must identify the documentation to be submitted e.g., calibration certificate or a certificate of conformance, at the time of submittal, and whether it is for information or review and acceptance. If Five Star requires the supplier to maintain specific quality records, the retention time and disposition requirements shall be prescribed.
- Nonconformances – the procurement documents shall specify the purchaser's requirements for the suppliers reporting of nonconformances.
- *Spare and replacement parts – the procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.*
- 10 CFR 21 – Reporting of significant defects adverse to quality as requirement by 10 CFR 21 shall be imposed on 10 CFR 50 Appendix B, and ASME NQA-1 suppliers.

4.3. Procurement Document Control

4.3.1. A review of the procurement documents and any changes thereto shall be made and documented prior to award to assure that documents transmitted to the supplier include appropriate provisions to assure that items or services will meet the specified requirements. Procurement document reviews shall be performed and documented to provide objective evidence of review prior to contract award.

4.3.2. Technical or quality assurance program changes made because of bid evaluation or pre-contract negotiation shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award.

4.3.3. Procurement document review shall be performed by personnel who have access to pertinent information and have an adequate understanding of the requirements and intent of purchasing documents.

4.4. **Procurement document changes** affecting the technical or quality assurance program requirements shall be subject to the same degree of controls utilized in the preparation of original documents.

5. Instructions, Procedures, and Drawings

5.1. *Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings controlled by this NQAM and NQP-05, ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 5,* of a type appropriate to the contract services Five Star Products is providing. These documents shall include or reference appropriate quantitative and qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

5.2. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

6. Document Control

Measures shall be established to control the issuance of instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality in accordance with this NQAM, NQP-06, and *ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed, Requirement 6*. These measures shall assure that documents including changes are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless otherwise designated.

The QA Manager is responsible for the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. *Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by the VP of Operations or the R&D Director for work instructions for laboratory testing, and procedures for Design and Commercial Grade Dedication.*

6.1. Document Control

6.1.1. Documents that specify quality requirements or prescribe activities affecting quality such as manuals, procedures, and work instructions shall be controlled. The control system should be documented under the Document Control Matrix providing for:

- Identification of controlled documents and their specific distribution at the appropriate location
- Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
- The review of documents for adequacy, completeness, and correctness prior to approval and issuance.
- A method to ensure the correct document is being used.

6.1.2. The Quality Assurance Manager shall be responsible for the distribution of quality documents including the manual, procedures, and work instructions. *Controlled copies are maintained on the internal company network and/or company website. Distribution of the NQAM to customers and subcontractors such as audit personnel will be controlled on the NQAM Distribution Matrix.*

6.2. Document Changes – Major vs. Minor Revisions

The Quality Assurance Manager determines whether a document has undergone a major or minor change.

6.2.1. Major revisions are considered any change that affects the intent of the document and shall be reviewed, approved, and distributed per the Document Control Matrix.

6.2.2. Minor revisions such as inconsequential editorial changes or the correction of grammar or spelling do not need to undergo the same approval and review as major revisions and may be revised by the QA Manager at her discretion.

7. Control of Purchased Material, Equipment, and Services

Measures are established through policies and procedures to assure that purchased material, equipment, and services conform to the procurement documents in accordance with this NQAM, NQP-04, NQP-07, NQP-12 and *ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirements 4 and 12*. These programmatic controls shall include provisions as appropriate, for:

- Source evaluation and selection,
- Objective evidence of quality furnished by the supplier,
- Inspection at the supplier source,
- Examination of items or services upon delivery or completion.

Documentary evidence that material and equipment conform to the procurement requirements shall be available. This documentary evidence shall be retained and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.

The effectiveness of the control of quality by suppliers shall be assessed by Five Star Products, Inc. at intervals consistent with the importance, complexity and quantity of the product or services.

7.1. Supplier Evaluation and Selection

7.1.1. Supplier selection shall be based on evaluation of the suppliers' capability to provide items or services in accordance with the procurement document requirement prior to award of contract.

7.1.2. The R&D Director and/or the QA Manager are responsible for determining supplier capability.

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

- Suppliers' history of providing an identical or similar product that performs satisfactorily in actual use. The supplier history should reflect current capability.
- An evaluation of the suppliers' current quality records, supported by documented qualitative and quantitative information that can be objectively evaluated.
- An evaluation of the suppliers technical and quality capability based on an evaluation of the suppliers' facilities, personnel, and quality program implementation.

7.2. Bid Evaluation

7.2.1. The proposal or bid evaluation process shall include a determination of the extent the supplier can conform to the procurement document requirements.

7.2.2. *Before the contract is awarded, the QA Manager and/or the R&D Director will resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions identified during the proposal or bid evaluation.*

7.3. Control of Supplier Generated Documents – Controls shall be implemented by Five Star Products to assure that submittal and evaluation of supplier generated documents and changes are handled and approved in accordance with the established methods and in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the supplier quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

7.4. Acceptance of Items or Services – Prior to the item or service acceptance, Five Star shall verify that the item or service being furnished by the supplier complies with the procurement requirements. Where provided by code, regulation, or contract requirement, documented evidence that the item or service conforms to the procurement requirements shall be available. Ultimately the o documented evidence will be provided by Five Star or their customer to the nuclear facility prior to installation or use.

7.4.1. Methods for acceptance include:

- Certificate of Conformance
- Source verification
- Receiving inspection
- Testing such as a Raw Material Check / laboratory batch prior to use in production or a combination of these methods.

7.4.2. It may be necessary to post a conditional release of raw materials while waiting material ID test results such as FTIR testing. Condition release of raw materials will be recorded on the receiving and dedication records until the FTIR testing and acceptance is completed.

7.5. Control of Supplier Nonconformances

7.5.1. Methods for control and distribution of supplier nonconformance for items and service that do not meet procurement document requirements shall include the following:

- Evaluation of nonconforming items
- Submittal of nonconformance notice to Five Star Products by supplier as directed by Five Star purchase order requirements. These submittals shall include supplier recommended disposition and technical justification.
- Five Star Products disposition at supplier recommendation

- Verification of the implementation of the disposition
- Maintenance of records of supplier submitted nonconformances.

7.6. Commercial Grade Items or Services

7.6.1. When commercial grade items or services are used, Five Star, in accordance with NQP-07 & NQP-20, and as the dedicating entity, can use the standard regulatory and industry documented practices, methods, and controls for:

- Technical evaluation to determine the items or service perform a safety function.
- Confirmation the item or service meets the commercial grade definition criteria.
- Identification of the critical characteristics, including acceptance criteria.
- Selection, performance, and documentation of the dedication method(s) for determining compliance with acceptance criteria such as Inspection, Test, or Analyses performed after delivery, Commercial Grade Survey of the supplier, Source Verification, and Supplier/Item performance history in conjunction with the others.

7.6.2 The details of commercial grade dedication shall be stated and implemented in accordance with the documented procedure.

7.7. Records

The QA Manager will maintain records in the Nuclear Receiving and Dedication file, the Purchase Order Log, and/or the Approved Supplier List, established and maintained to indicate the performance of the following functions:

7.7.1 Supplier evaluation and selection
7.7.2 Acceptance of items or services
7.7.3 Supplier nonconformance to procurement document requirements, including their evaluation and disposition,
7.7.4 Use and acceptance of commercial grade items.

8. Identification and Control of Materials, Parts, and Components

In accordance with this NQAM, NQP-08, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 8, controls will be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.

8.1. Identification Methods

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

8.2. Physical Identification

Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function of service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment of coatings unless other means of identification are substituted.

When codes, standards, or specifications include specific identification or traceability requirements (such as identification and traceability of the item to applicable specification and grade of material; batch, lot, part, or serial number; or specified inspection, test, or other records), the program provides such identification and traceability controls.

8.3. Limited Life Items

In accordance with this NQAM, NQP-13, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 8, para. 302, items with a limited calendar life, operation life or cycles shall be identified and controlled to preclude use of items whose shelf life, operating life has expired.

8.4. Maintaining Identification of Stored Items

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

8.4.1. Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging.

8.4.2. Protection of identifications on items subject to excessive deterioration due to environmental exposure; and

8.4.3. Provisions for updated existing plant records.

8.4.4 Controls are in place during inspection and testing processes for identifying suspect (including counterfeit/fraudulent) material, items or components that may not be those ordered.

9. Control of Special Processes

Measures shall be established to assure that special processes including welding, heat treating, and nondestructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

At the time of this revision, there are no special processes as part of Five Star Products' Nuclear Quality Assurance Program.

10. Inspections

In accordance with this NQAM, NQP-14, NQP-10.1, NQQI-14.1 and 14.2, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 10, a program for inspection of activities affecting quality is established and executed by or for Five Star Products, Inc. performing the activity to verify conformance with the documented instructions and procedures for accomplishing the activity. Such inspection (or tests) shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection/hold points which require witnessing or inspecting by the customer's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.

10.1. Inspection Requirements

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents *approved by Five Star Products, Inc.*

10.2. Inspection Hold Points

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points will be placed on appropriate documents.

10.3. Inspection Planning

10.3.1. Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.

10.3.2. Sampling procedures when used, shall be based upon standard statistical methods with engineering approval.

10.4. In-Process Inspection

Inspection of items in process shall be performed as necessary to verify quality.

10.5. Final Inspections

10.5.1. Final inspections shall include a records review of the results and resolution of non-conformances identified by prior inspections.

10.5.2. Completed items shall be inspected as required to verify the quality and conformance of the item to specified requirements.

10.5.3. *The acceptance of the item shall be approved by QC Inspection personnel or the QA Manager.*

10.6. Records

The QA Manager maintains responsibility for documenting and maintaining inspection records. Appropriate records shall be established, maintained, and as applicable identify the item inspected, date of inspection, inspector, type of observation, results/acceptability, and reference to information on action taken in connection with non-conformances.

11. Test Control

11.1. *In accordance with this NQAM, NQP-11, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 11 test requirements and acceptance criteria shall be provided or approved by Five Star Products, Inc. unless otherwise designated.* Tests may include computer program tests such as software design verification, prototype qualification tests, production tests; proof tests prior to installation, construction tests, pre-operational test, operational tests, and in-use tests that shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluations and acceptance.

Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements.

11.2. **Test procedures** shall include or refer to test objectives and provisions for ensuring that prerequisites for a test have been met. Test instructions must include provisions and/or prerequisites for the following:

- **11.2.1.** Appropriate tests and equipment used.
- **11.2.2.** Calibrated instruments are available and used.
- **11.2.3.** Test monitoring is established.
- **11.2.4.** Environmental conditions are maintained.
- **11.2.5.** Test personnel are trained on procedures, standards, notes and exceptions when applicable.
- **11.2.6.** Condition of test equipment and item to be tested.
- **11.2.7.** Provisions for data recording or acquisition
- **11.2.8.** Performance requirements and acceptance criteria

Test Procedures – as an alternative to the test requirements above, appropriate sections of related documents such as ASTM test methods, supplier manuals, equipment maintenance instructions, or approved drawings with acceptance criteria can be used.

Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures shall provide for assuring that the computer program produces correct results. *Currently, Five Star Products, Inc. does not use computer program test procedures.*

For those computer programs used for operational control, computer test procedures shall provide for demonstrating required performance over the range of operation of the controlled

function or process. Procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculation, calculations using comparable proven programs, or empirical data and information from technical literature. *Currently, Five Star Products, Inc. does not use computer program test procedures.*

11.3. **In-use test procedures** shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different system, or when there are significant changes in the operating system. *Five Star does not use computer program test procedures.*

11.4. **Test Results** shall be documented and evaluated by designated individuals to ensure completeness and adequacy of the data and that test requirements have been satisfied. Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization. *Five Star does not use computer program test procedures.*

11.5. **Test Records** shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet documented requirements. *The QA Manager is responsible for maintaining quality control test result records in the NQA-1 Testing database.* As a minimum, the following shall be recorded:

11.5.1. Material tested
11.5.2. Test date
11.5.3. Person performing test or recording data
11.5.4. Type of observation
11.5.5. Results and acceptability
11.5.6. Actions taken in connection with any deviations
11.5.7. Person who reviewed or evaluated the test results

12. Control of Measuring and Test Equipment

*In accordance with this NQAM, NQP-12, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 12, m*easures shall be established to assure tools, gages, instruments and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

12.1. **Selection** of measuring and test equipment shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

12.2. **Calibration** – In accordance with NQP-12, measuring and test equipment (M&TE) shall be calibrated, at prescribed times or intervals, and whenever the accuracy of the M&TE is suspect. Calibration shall be against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no such standards exist, the bases for calibration shall be defined. *The R&D Director and/or appropriately trained designee shall review the calibration service providers' accreditation certificate and scope to ensure that it is up to date and an accrediting body recognized by ILAC MRA and encompassing ISO/IEC 17025:2017. The published scope of accreditation shall be verified by the R&D Director or appropriately trained designee to confirm the scope covers the equipment to be serviced.*

12.3. **Control -** Calibration procedures shall identify, or reference required accuracy and shall define methods and frequency of checking accuracy. The calibration method and interval of calibration shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control and performance. M&TE, which is overdue for calibration or found to be out of calibration, should be tagged and/or segregated, or removed from service, and not used until it is recalibrated. M&TE consistently found out to be out of calibration shall be repaired or replaced.

12.4. **Application -** M&TE shall be traceable to its application and use. Five Star Products will maintain a master list of M&TE at Chardon, Ohio and Harahan, Louisiana listing the name, model, serial #, calibration frequency, calibration date, and next due date.

12.5. **Corrective Action -** When M&TE is lost, damaged, or found to be out of calibration, the validity of previous measurements, inspections, or test results, and the acceptability of items previously inspected or tested shall be evaluated. This evaluation shall be from at least the last acceptable calibration of the M&TE. The evaluation and resulting actions shall be commensurate with the significance of the condition.

12.6. **Handling & Storage -** M&TE shall be properly handled and stored to maintain accuracy.

12.7. **Environmental Controls -** M&TE shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

12.8. **Precalibration Checks -** M&TE and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

12.9. **Status Indication -** M&TE shall be suitably marked, labeled, tagged, or otherwise identified to indicate its calibration status and establish traceability to calibration records.

12.10. **Commercial Devices -** Calibration and control measures are not required for commercial equipment such as rulers, tape measures, and levels if such equipment provides the required accuracy.

12.11. **Records** shall be established and maintained to indicate the calibration status and the capability of M&TE to satisfactorily perform its intended function.

Calibration reports and certificates reporting the results of calibration shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements. Five Star will maintain a commercial grade item dedication record for each M&TE listing the tech who performed the calibration, the calibration date, as found/as left data, and acceptance criteria.

13. Handling, Storage, and Shipping

13.1. *In accordance with this NQAM, NQP-10, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 13, m*easures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary, special protective environments shall be specified and provided.

13.2. The QA Manager is responsible for the review of shelf life during the receipt inspection and shall verify that raw material lots listed on Production Work Orders (PWOs) are within shelf life prior to manufacture of safety-related orders in accordance with NQP-13.

13.3. Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

13.4. When required, special equipment and special protective environments shall be specified and provided, and their existence verified.

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

13.6. Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use.

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

13.8. Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

14. Inspection, Test, and Operating Status

*In accordance with this NQAM, NQP-14, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 14, t*he status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location and tags, markings, stamps, inspection records, or other suitable means. The Quality Assurance Manager shall be responsible to ensure that inspection and test results are planned, executed, documented, and evaluated, and status maintained*. Designated employees such as QC Inspectors involved in receipt inspection activities in Chardon, Ohio and Harahan, Louisiana have the authority to apply and remove status indicators such as tags, markings, and labels. The QA Manager may designate employees to apply or remove specific labels as needed.*

Controls shall be in place as part of raw material commercial grade item dedication to ensure detection of counterfeit and/or fraudulent material as part of raw material receipt inspection. These controls may include visual inspection, packaging identification, FTIR analysis, and raw material checks. (RMCs) *in accordance with NQWI 14.1 and 14.2.*

15. Nonconforming Materials Parts and Components

*In accordance with this NQAM, NQP-16, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 15 m*easures shall be established to control materials, parts, or components which do not conform to requirements to prevent their inadvertent use or installation. These measures include as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be identified by legible marking, tag**,** or other methods not detrimental to the item, and placed on either the item, the container, or the package containing the item.

15.1. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

15.2. Nonconforming items shall be evaluated, and recommended dispositions shall be proposed. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

15.3. *The QA Manager has the responsibility and authority for the evaluation and disposition of nonconforming items*. *Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing by the QA Manager.*

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

15.5. *A disposition, such as use-as-is, reject, repair or rework of nonconforming items shall be made and documented on a Nonconformance Report in accordance with NQP-16*. Technical justification for the acceptability of nonconforming items dispositioned repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. The as-built records, when required, shall reflect the accepted deviation, use-as-is or repair condition.

15.6. Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

16. Corrective Actions and 10 CFR 21

*In accordance with this NQAM, NQP-16, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 16, c*onditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined, and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to the appropriate levels of management. Completion of corrective action shall be verified. Control of nonconforming conditions, corrective actions, 10 CFR 50.55(e) and 10 CFR 21 reporting and reportable conditions shall be documented at a procedural level and posted in all locations where nuclear quality related activities are being performed including the Shelton, Connecticut corporate headquarters. *Corrective Action Reports and Nonconformance Reports shall be screened for Part 21 reportability in accordance with NQP-16.*

16.1. 10 CFR 21 Reporting

Each Nonconformance and Corrective Action Report will be evaluated for 10 CFR 50.55(e) and 10 CFR 21 applicability by the QA Manager and documented on a screening and evaluation form (NQF-P21SE.) If the potential for a significant defect exists as described by 10 CFR 50.55(e) and/or 10 CFR 21, the Five Star Products procedure for evaluation, notification, and reporting under 10 CFR 21 of significant defects shall be implemented. Five Star Products shall also post current copies for the regulations of 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974, and the Five Star Products 10 CFR 21 procedure.

17. Quality Assurance Records

*In accordance with this NQAM, NQP-17, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 17, q*uality assurance record controls are in place at the procedural level, furnishing documentary evidence that items or activities meet specified quality requirements. The QA Manager is responsible for the overall management of the NQAP record system, receipt control, and status of records.

The records shall be specified, prepared, authenticated, and maintained. The records shall include at a minimum, operating logs, results of reviews, inspections, tests, audits, monitoring of work performance, material analysis, and related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall identify the inspector or data recorder, the observation, results, acceptability, and the action taken in connection with any deficiency. Individuals handling documents intended to become quality assurance records, shall provide reasonable protection for the records from damage or loss until the records are submitted to the records system.

17.1. Generation of Records

Records shall be legible and traceable to associated items and activities and accurately reflect the work accomplished or information required.

17.2. Authentication of Records

17.2.1. Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

17.2.2. Electronic documents shall be authenticated with comparable information as stated above (17.2.1):

- With identification on the media; or
- With authentication information contained within or linked to the document itself

17.3. Classification

Records are classified as either Lifetime or Nonpermanent and maintained accordingly.

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

- Those that would be of significant value in demonstrating capability of safe operation.
- Those that would be of signification value in maintaining, reworking, repairing, replacing, or modifying an item.

- Those that would be of significant value in determining the cause of an accident or malfunction of an item.
- Those that required baseline data for in-service inspections.

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

17.4. Storage

Five Star Products shall utilize a typical minimum two-hour fire rated container or computer based electronic media and one-hour fire rated container if in an appropriate building structure.

Records storage arrangements should provide adequate protection of records that maintained will minimize the risk of loss, damage, or destruction from natural disasters such as winds, floods, or fires. The storage method will also minimize the impact of other environment conditions such as high and low temperatures and humidity. The container location will also serve to minimize or eliminate the chance for infestation of insects, mold or rodent, dust, or airborne particles. Such provisions will also prevent damage from harmful conditions such as excessive light, stacking, and electromagnetic fields.

Five Star Products uses multiple server and cloud-based data backup systems, backing up to redundant servers located at the Shelton, Connecticut headquarters, and hourly redundant cloud-based servers located in two separate physical locations in Connecticut.

Records shall remain retrievable, preferably as a PDF, regardless of hardware, software, or technology changes. When records are duplicated or transferred to the same media or a different media for storage, the duplication or transfer must be authorized and the record content, legibility, and retrievability maintained. Computer-based records will have the same offsite back-up method as listed above.

17.5. Retention

The retention period of records shall be documented in the Quality Assurance Records and Indexing Procedure and retained for their retention period as stated.

18. Audits

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program i*n accordance with this NQAM, NQP-18, and ASME NQA-1-1994ed, 2008ed with 09A, and 2015ed Requirement 18*. The audits shall be performed in accordance with the written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient area, shall be taken where indicated.

18.1. Scheduling

The Quality Assurance Manager shall schedule audits in a manner to provide coverage and coordination based on ongoing activities, status, and importance. Scheduled audits may be supplemented by additional audits of specific subjects when deemed necessary.

18.2. Audit Plan

Five Star Products shall develop an audit plan for each audit identifying the scope, requirements, audit personnel, and activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

18.3. Personnel

Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. The VP of Operations with the QA Manager is responsible for training, evaluating, testing, and certifying Lead Auditors. The VP of Operations is responsible for performing annual evaluations as required of all Five Star auditors.

The audit team shall be identified prior to the beginning of each audit. The team shall contain one or more auditors, one being designated Lead Auditor who organizes and directs the audit. The audit team shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

18.4. Performance

Criteria and processes selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these are being implemented effectively. Conditions requiring prompt corrective action shall be reported immediately to the management of the audited area.

18.5. Reporting

18.5.1. The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The contents of the report shall:

18.5.2. Describe of the audit scope.

18.5.3. Identify auditors and persons contacted.

18.5.4. Summarize audit results, including a statement on the effectiveness of the criteria and processes audited.

18.5.5. Describe each reported adverse audit finding.

18.6. Response

Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned. Audit responses shall be evaluated.

18.7. Follow-up Action

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled. The Audit Team Leader or QA Manager is responsible for evaluating finding responses and acceptance. The QA Manager may also request a follow up audit to verify corrective action for the identified deficiencies.

18.8. Records

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

Annex A

Organization Chart for the Nuclear Quality Assurance Program