## REVISION RECORD

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<th>Rev.</th>
<th>Revision Description</th>
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<td>0</td>
<td>Initial issue includes pages 1-24 with Exhibits 1-4 to meet NQA-1 criteria and MIL-Q-9858. This Manual was adapted with changes from manual dated 01-05-1996.</td>
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<td>1</td>
<td>Changes to meet requirements of DOE 5700.6C.</td>
<td>01/27/1997</td>
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<td>2</td>
<td>Changes to meet requirements of Battelle PQD-CDT-031</td>
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<td>3</td>
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<td>4</td>
<td>Update Manual Sections 2, 9, 10, 12, 15, 17, &amp; 18</td>
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<td>8</td>
<td>Corrected Organization Chart to reflect positions and level of authority as displayed in manual.</td>
<td>11/15/2006</td>
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<td>9</td>
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<td>06/09/2016</td>
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QUALITY ASSURANCE PROGRAM NOTICE

In late 2013, Springs Fabrication, Inc. (“SFI”) purchased the assets of IP Systems, Inc., the former custom process equipment manufacturer located in Broomfield, CO. Included in that purchase, was the IP Systems’ Quality Assurance (“QA”) Program, an ASME NQA-1-2008 compliant nuclear QA Program which has been adopted and integrated into SFI as the Quality Tier – 2 (“QT-2”) Quality Program. Core personnel from IP Systems, along with additional talent now operate as SFI Advanced Technology Group (ATG) in a new and larger facility located in Westminster, CO. As a result, SFI now consists of two manufacturing facilities across the Colorado Front Range, expanding our capabilities to include nuclear quality products and services in addition to our ISO 9001 (QT-1) and ASME U, S, & R Stamp (QT-3) manufactured products.

SFI remains a project-driven manufacturer of engineered metal products with the same focus, commitment, and understanding of producing the highest quality products. Resources at all three facilities will be utilized to complete our projects on-time and to our customer’s satisfaction. However, projects that require the application of a nuclear quality assurance program will be performed under the direction of SFI – Advanced Technology Group in accordance with the QT-2 Quality Program.

The Advanced Technology Group General Manager retains responsibility for establishing the QT-2 Quality Program and ensuring products manufactured at that location achieve the desired end results. The Advanced Technology Group QA Manager retains responsibility to ensure the effective implementation of the QT-2 Quality Program. SFI accepts responsibility for the previously completed elements of IP Systems’ QA Program that are necessary to maintain QT-2 Quality Program implementation and effectiveness, including but not limited to, test records and data used for the purpose of qualifying and/or certifying personnel, procedures, and approved suppliers.

This Notice shall be considered part of the QT-2 Manual, which establishes and defines the SFI QT-2 Quality Program. All implementing procedures and work instructions previously approved by IP Systems remain in effect as part of the QT-2 Quality Program until revised and reapproved. The transition of implemented elements to identify new ownership and the integration of programs and systems with other Quality Tiers will be completed as necessary and is considered an ongoing process. Until such time those elements are revised, the identification of “IP Systems, Inc.”, “IP Systems”, or “IPS” as used throughout the Quality Program shall mean the same as Springs Fabrication, Inc. – Advanced Technology Group.
QUALITY POLICY

Springs Fabrication, Inc. specializes in fabrication of engineered metal products. Within Springs Fabrication, the Advanced Technology Group offers customers the necessary expertise and skill to manufacture reliable and safe products used in processing radioactive, hazardous, toxic, corrosive, or energetic materials; or when impeccably clean, inert or sterile process environments are required. Ultimately, we understand that the safety and health of personnel, the public, and the environment, depend on Springs Fabrication’s skilled workmanship and commitment to quality.

Springs Fabrication, Inc. is committed to comply with the requirements set forth in this manual.

We will strive to continually improve our products, services, and processes by pursuing four overall goals:

- Safety First – To provide a safe work environment free of known hazards, and to continuously improve the safety inspection process
- On Specification – To provide products and services that meet or exceed customer requirements
- On Budget/On-Time Delivery – To achieve quality objectives within the customer’s expectations for cost and schedule
- Continuous Improvement – To continually improve the quality program, processes, and activities affecting quality for the betterment of our organization and our customers

Springs Fabrication, Inc. understands that by reaching our goals and maintaining a commitment to quality, we ensure a means of providing our expertise and skill to meet the needs of our customers for many years to come.

Approved:

Nicole Coons, General Manager – Advanced Technology Group  
Date: 6/14/2016

Tom Neppl, President/CEO  
Date: 6/14/10

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PURPOSE AND SCOPE

This Quality Manual sets forth the standard quality assurance commitments and expectations of Springs Fabrication, Inc. (“SFI”) for projects and work activities associated with projects that have been assigned the QT-2 Quality Program. Specific SFI Procedures and Work Instructions implement the requirements described in this Manual. This Manual and applicable SFI Procedures and Work Instructions constitute the QT-2 Quality Program (“QT-2 Program”). The SFI Advanced Technology Group is responsible for implementation and maintenance of the QT-2 Quality Program.

The QT-2 Program is specifically designed to meet the requirements delineated in the standard, American Society of Mechanical Engineers (ASME) NQA-1-2008 with the NQA-1a-2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications*, and Nuclear Regulatory Commission (“NRC”) quality assurance program requirements found in 10CFR21, *Reporting of Defects and Noncompliance*. These standards are nuclear industry standards. They are comprehensive and stringent so that compliance to them generally encompasses many other commonly specified quality assurance program requirements, including those found in 10CFR50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*; 10CFR830 *Nuclear Safety Management*, Subpart A, *Quality Assurance Requirements* (1-1-2011) and DOE O 414.1D, *Quality Assurance* (8-2011) and other standards associated with non-nuclear industries. These other nuclear industry standards have been consulted and used in the development of this Manual.

Quality program requirements governing projects and work performed at SFI may vary depending on the contractual agreement imposed by the mutually accepted procurement documents. Application of the QT-2 Program, any portions thereof, or deviations thereof, is identified in the procurement documents.
SECTION 1: ORGANIZATION

1.1 General Requirements

SFI Advanced Technology Group is responsible for the establishment and execution of the QT-2 Program. The SFI Advanced Technology Group organizational structure, functional responsibilities, levels of authority and lines of communication for activities affecting quality is defined below and illustrated in the Advanced Technology Group Organization Chart (ORG-02).

1.2 Structure and Responsibilities

1.2.1 General Manager (GM)

The GM is responsible for establishing the overall expectations for effective implementation of the applicable quality program and obtaining the desired end results.

1.2.2 Quality Assurance Manager (QAM)

The QA Manager is responsible for assuring effective implementation of the applicable quality program, and that activities affecting quality are properly addressed. The QA Manager reports directly to the GM and has sufficient independence and authority to ensure quality is achieved when safety function considerations are opposed to cost and schedule. They are also responsible to ensure that those verifying quality achievement have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform their functions.

1.2.3 Verification Functions

Any personnel assigned the responsibility for verifying quality achievement, as a full-time employee, secondary duty, or subcontractor, is automatically granted authority and access to: identify quality problems; initiate, recommend or provide solutions to quality problems; verify implementation of solutions; and assure that further processing, delivery, installation or use of nonconforming, deficient, or unsatisfactory items are controlled until proper disposition has occurred.

1.2.4 Employees

All employees are expected to achieve and maintain quality in their work and to continuously pursue opportunities to improve product, process, and program quality.

1.3 Delegation of Work

SFI retains the responsibility for establishment and execution of this quality program, even when the responsibility for all or some elements has been assigned to others.
1.4 Interface Control

Where external organizations are involved in the execution of project activities the responsibilities, interfaces, lines of control and authority of each organization are clearly defined and documented as applicable in the procurement documentation.

Internally, the responsibilities, interfaces, and lines of control and authority are as defined and documented at each SFI facility.
SECTION 2: QUALITY ASSURANCE PROGRAM

2.1 General Requirements

SFI’s ATG QA Program addresses activities affecting quality such as designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembly, inspecting, testing, maintaining, repairing, and modifying items for facilities.

The planned, implemented, and maintained activities governed by this quality program are identified by the applicable SFI Procedures and Work Instructions based on the Advanced Technology Group Process Flow Chart (MM-003). Control over activities affecting quality is prescribed by Procedures, Work Instructions, or other documents to the extent consistent with their importance.

Procedures and Work Instructions include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. They identify the planned accomplishment of activities under suitably controlled conditions, and the need for special controls, processes, equipment, tools, skills, and prerequisites. SFI has established processes, such as inspections and audits, to detect and correct quality problems.

Indoctrination, training, and qualification of personnel performing and managing activities affecting quality to ensure suitable proficiency is achieved and maintained is accomplished in accordance with the applicable Procedures.

Regular management assessment regarding the adequacy and effective implementation of this quality program is accomplished in accordance with the applicable Procedures.

2.2 Indoctrination and Training

Indoctrination and training requirements are commensurate with scope, complexity, importance of the activities, and the education, experience and proficiency of the person.

2.2.1 Indoctrination

Employees are instructed in their job responsibilities and level of authority prior to performing work, which includes general information, quality program requirements and objectives, and review or additional actions as required by Procedures applicable to their functions.

2.2.2 Training

SFI employs a formal training program for personnel performing or managing activities affecting quality. Managers are responsible for ensuring that personnel under their supervision are trained, qualified, and if applicable, certified to perform their assigned tasks. On-the-job training is one available method of the program used to achieve and maintain proficiency for hands-on applications.
2.3 Qualification Requirements

The activities identified in this section require performance by qualified and/or certified personnel. SFI Procedures identify the minimum requirements for qualification and/or certification, and for the assurance that only those personnel who meet the specified requirements are permitted to perform these activities.

2.3.1 Nondestructive Examination (NDE)

Personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NR), leak testing (LT), and acoustic emission (AE), NDE methods are qualified and certified to the SFI Written Practice (Procedure G07-Qualification & Certification of NDT Personnel). The SFI Written Practice utilizes the requirements of the American Society of Nondestructive Testing (“ASNT”) Recommended Practice No., SNT-TC-1A.

2.3.2 Inspection and Testing

Personnel performing inspections and tests for the purpose of verifying activities affecting quality are qualified in accordance with SFI Procedure (G08-Qualification & Certification of Inspection Personnel). The initial capabilities of candidates are determined by evaluation of their education, experience, training, and either test results or capability demonstration. Job performance is reevaluated at 3 year intervals unless otherwise stated or required by applicable code or standard; or the individual has not performed the relevant activity for a period of 1 year. Reevaluation is by evidence of continued satisfactory performance. At any time, if it is determined by the QAM and/or the GM that the capabilities of inspection and test personnel are not in accordance with the established requirements, they are removed from performing those activities until such time as the required capability is demonstrated.

Qualification requirements do not apply to self-checking or intradepartmental verification activities that are an expectation of an employee’s responsibility to achieve and maintain quality in their work.

2.3.3 Special Processes

See Section 9 of this Manual

2.3.4 Lead Auditor

Personnel who organize and direct audits, report audit findings, and evaluate corrective action resulting from audit findings are qualified and certified as a Lead Auditor. The SFI Procedure for qualifying and certifying a Lead Auditor includes, at minimum, the following:

2.3.4.1 Communication Skills

Lead Auditors are capable of communicating effectively in writing and orally as attested to by SFI.
2.3.4.2 Training

Lead Auditors shall have completed training to ensure auditing competence. Auditing competence includes: a) knowledge and understanding of ASME NQA-1-2008, Part I, and other nuclear-related codes, standards, regulations, and regulatory guides; b) the general structure of quality assurance programs as a whole; c) auditing techniques; d) audit planning; and e) on-the-job training to include applicable elements of the audit program.

2.3.4.3 Audit Participation

Lead Auditors have participated in a minimum of five audits (one being a nuclear quality audit) within the past three years prior to qualification. Participation in independent assessments may be used to satisfy qualification requirements as prescribed by Procedure.

2.3.4.4 Examination

Lead Auditors have passed an oral, written, and/or practical examination which evaluates comprehension of, and ability to apply, the training knowledge and audit experience noted above.

2.3.4.5 Maintenance of Proficiency

Certified Lead Auditors maintain his or her proficiency through: a) regular and active participation in the audit process; b) review and study of codes, standards, procedures, instructions and/or other quality assurance program and program auditing documents; or c) participation in relevant training programs.

2.3.4.6 Requalification

If a certified Lead Auditor fails to maintain his or her proficiency for more than two years, requalification must include re-training per 2.3.4.2, reexamination per 2.3.4.4, and participation as an Auditor in at least one nuclear quality assurance audit.

2.3.5 Auditors

Personnel who participate in an audit, and are neither designated as Lead Auditor nor Technical Specialist are qualified as Auditors. Qualification as an Auditor may include one or more of the following methods:

2.3.5.1 Orientation

Auditors have been provided a working knowledge and understanding of ASME NQA-1-2008, Part I, and SFI Procedures for implementing audits and reporting results.
2.3.5.2 Training

Auditors have completed general and specialized training in auditing. General training addressed fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training addressed methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

2.3.5.3 On-the-Job Training

Auditors have received on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training included planning, performing, reporting, and follow-up action involved in conducting audits.

2.4 Records of Qualification

Qualifications for inspection, test, and Lead Auditor personnel are certified in writing and include:

- Identification of SFI as the employer
- Identification of the individual
- Activities the individual is qualified to perform
- Basis of qualification through; education, experience, indoctrination, and training; test results; and capability demonstration results, as applicable
- Results of periodic evaluation
- Results of physical examinations, when required
- Signature of the QA Manager who is responsible for personnel qualification and certification
- Dates of certification, recertification, and expiration

SFI retains the responsibility for conformance of qualification exams to SFI Procedure requirements when exam activities have been subcontracted to independent certifying agencies. Integrity of the examinations is maintained by SFI or the certifying agency, and objective evidence regarding the type(s) and content of examination(s) are retained by SFI in accordance with the requirements below.

2.5 Records

Records for indoctrination and training, and Auditor, Lead Auditor, inspection, and test personnel are established and maintained by SFI. Indoctrination and training records must be one of the following forms: attendance sheets; training logs; or personnel training records.
SECTION 3: DESIGN CONTROL

The sections below identify the requirements associated with design control consistent with those defined in the NQA-1-2008, Part I Standard, such that SFI may perform the necessary design activities to assist customers in meeting the product design objectives and expectations (design basis) as specified in customer procurement documents. SFI may not have the authority or access to information necessary to fulfill these requirements in their entirety, but recognizes that our knowledge, expertise, and implemented Quality Program can be necessary to satisfy the overall product goals.

As a result, the requirements below are implemented and carried out to the extent possible and as deemed necessary to satisfy customer contract requirements and expectations. Ultimately, the responsibility for the establishing the design basis resides with the customer.

3.1 General Requirements

Product design is defined, controlled, and verified in accordance with SFI Procedures and Work Instructions, including identification and control of design interfaces necessary to complete the design beyond the customer/supplier relationship. Design Inputs are specified and translated into design documents. Design adequacy is verified by individuals other than those who designed the item or computer program. Design changes are governed by control measures commensurate with those applied to the original design.

3.2 Design Input

Design Inputs are specified by customer procurement documents. Elements of the design created or established by SFI are based on satisfying specific design inputs or the overall design basis, and are specified to a level of detail necessary to permit the design activities be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

3.3 Design Process

Design activities are prescribed and documented to the level of detail necessary to carry out the design process in the correct manner and to permit verification that the design meets the specified requirements. Appropriate quality standards are identified and documented, and their selection reviewed and approved.

Design methods, materials, parts, equipment, and processes essential to the function of items are selected and reviewed for suitability of application. Applicable information derived from experience as found in reports or other documents are available to design personnel.

Final designs:

- Are relatable to design inputs/design basis by documentation sufficient in detail to permit design verification.
- Specify required inspections and tests and include or reference appropriate acceptance criteria.
• Identify assemblies and/or components that are part of the item design. When an assembly or component is a commercial grade item, the critical characteristics to be verified for acceptance and the acceptance criteria for each characteristic are documented.

Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended safety function. A commercial grade item that is modified or selected by special inspection or testing to requirements that are more restrictive than the Supplier’s published product data, the item will be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.4 Design Analyses

Design analyses are documented in sufficient detail such that a person technically qualified in the subject can review and understand the analyses and verify adequacy of the results without requiring additional information from the originator.

3.4.1 Use of Computer Programs

Computer programs used for design analysis are verified for acceptability either before use or by verifying the results for each application. Verification must show that:

• The computer program produces correct solutions for the encoded mathematical model within defined limits for each parameter employed, and

• The encoded mathematical model produces a valid solution to the physical problem associated with the particular application.

Computer programs verified before use are controlled by applicable procedures or work instructions.

3.4.2 Documentation of Design Analyses

Documentation of design analyses includes; 1) objective of the analysis; 2) design inputs and their sources; 3) applicable background data; 4) assumptions and indication of which assumptions require verification as design proceeds; 5) identification of computer calculations including computer type, program name and revision, inputs, outputs, evidence of or reference to program verification, bases for using the particular program; and 6) review and approval.

3.5 Design Verification

The responsible design organization identifies and documents the method(s) used to verify the design. The results of design verification are documented, and include identification of the verifier(s). Design verification is performed by competent individuals or groups other than those who performed the original design, but who may be from the same organization. Verification by the originator’s supervisor is permitted, provided: the supervisor did not specify a singular design approach or rule out certain design considerations, and did not establish the design inputs; or, the supervisor is the only individual in the organization competent to perform the verification.
Design verifications are performed before releasing the design for procurement, manufacturing, construction or use by another organization, except where such timing cannot be met and the unverified portions are identified and controlled. This does not preclude release of a design in staged sub-packages so long as each sub-package is verified before its release. In all cases, design verification must be completed before relying on the item or computer program to perform its intended function.

Design changes to resolve verification findings require re-verification of the modified design prior to its release or use.

The extent of design verification is a function of the importance to safety, the complexity of the design, and the state of the art. Each SFI project is considered a new design. As a result, uses of previously performed design verifications are prohibited.

3.5.1 Methods

Acceptable verification methods include, but are not limited to, any one or combination of the following:

3.5.1.1 Design Reviews

Reviews provide assurance that the final design is correct and satisfactory by addressing, where applicable, that:

- Design inputs / design bases were correctly identified
- Assumptions were adequately described and reasonable, and where necessary, assumptions were identified for re-verification of completed design
- Appropriate design methods and computer programs were used
- Design inputs / design bases were correctly incorporated into the design
- Design outputs are reasonable when compared to design inputs / design bases
- The necessary design inputs / design bases are specified in design documents for interfacing organizations
- Suitable materials, parts, processes, and inspection and test criteria have been specified

3.5.1.2 Alternate Calculations

Alternate calculations verify correctness of the original calculations or analyses by using methods different from that used to produce the original. Performance of alternate calculations include review of the appropriateness of assumptions, input data, and computer program (including associated hardware and software) used in the original calculation or analyses.
3.5.1.3 Qualification Tests

Testing demonstrates adequate performance under conditions that simulate the most adverse design conditions, with consideration given to operating modes and environmental conditions for determining the most adverse design conditions. When testing verifies only specific design features, other features are verified by other means. Tests performed on models or mock-ups must incorporate verification of applied scaling laws, and the results are subject to error analysis, where applicable, prior to use in the final design.

3.6 Change Control

Changes to design inputs/design bases, final design, and field changes are justified and subject to the control measures applied to the original design. These measures include evaluation of the effects on the overall design and any analysis upon which the design is based. Changes are reviewed and approved by the same organization(s) that approved the original design. When the organization(s) responsible for review and approval of the original design is no longer responsible, the owner or their designee is responsible for review and approval, and assuring the new organization is competent in the specific design area of interest and has adequate understanding of the original design requirements and intent.

Approved design changes made other than as revisions to the design documents are incorporated into these documents, where appropriate, in accordance with defined control measures.

3.7 Configuration Management of Operating Facilities

This element does not apply to SFI Advanced Technology Group.

3.8 Interface Control

Interface control measures include assignment of responsibility and establishment of the procedures to be used among participating design organizations, which address review, approval, release, distribution, and revision of design documents.

Design documents transmitted across interfaces identify the status of the document and any incomplete items that require further evaluation, review, or approval.

3.9 Software Design Control

This element does not apply to SFI Advanced Technology Group (refer to Section 11.4).

3.10 Design Documentation and Records

Design documents and records include final design documents and their revisions, and other documentation that identifies the important steps in the design process.
SECTION 4: PROCUREMENT DOCUMENT CONTROL

4.1 General Requirements

Procurement documents issued to Approved Suppliers include applicable design bases and other requirements necessary to assure adequate quality. Where appropriate, procurement documents require Approved Suppliers to have a quality assurance program consistent with the applicable elements of NQA-1-2008, Part I.

4.2 Content of the procurement documents

As deemed necessary, and in accordance with SFI Procedures, procurement documents include provisions for the following:

- Scope of work statement or document
- Technical requirements by reference to drawings, specifications, codes, standards, regulations, procedures or instructions; and appropriate tests and inspections with defined acceptance criteria
- Quality assurance program requirements, including flow-down of those requirements to sub-tier suppliers
- Right of access to supplier’s and sub-tier supplier’s facilities and records for the purpose of conducting quality assurance activities
- Documentation requirements including how and when documents are to be submitted, and for what purpose; and record retention requirements with defined retention times and means of disposal
- Nonconformance reporting requirements to the purchaser (SFI)
- Requirements to identify spare and replacement parts and/or related data for ordering such parts
- 10CFR21 defect and nonconformance reporting requirements including notification that such requirements have no defined end date

4.3 Procurement Document Review

Procurement documents and changes thereto, are reviewed prior to issuance to Approved Suppliers to assure that appropriate provisions are included. Review of procurement documents is performed by personnel who have access to pertinent information and adequate understanding of the requirements and intent of the procurement. Changes as a result of bid evaluations or negotiations are incorporated prior to issuance.

4.4 Procurement Document Changes

Revisions to the procurement documents affecting the technical or QA program requirements are controlled in the same manner as preparation of the original documents.
SECTION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 General Requirements

Activities affecting quality are prescribed by and performed in accordance with the applicable documented SFI Procedures, Work Instructions, or drawings. Procedures, Work Instructions and drawings include or reference appropriate quantitative and qualitative acceptance criteria to determine that requirements have been satisfactorily fulfilled. The need for, and level of detail written in, Procedures and Work Instructions is determined based upon complexity of the task, the need to assure consistent and acceptable results, significance of the activity, typical work environment, and expected worker proficiency, education, training and experience.

Procedures are written in a manner intended to establish and define quality systems and prescribe standard work processes for the purpose of providing instructions as to how the requirements of this Manual are satisfied. They are written in general terms with an expectation that they be used in combination with applicable customer requirements.

Work Instructions are written in a manner intended to prescribe specific work activities for the purpose of providing more detailed instructions not otherwise found in Procedures, or when deemed necessary to achieve project specific quality requirements.

Guides, postings, and other documents are also used to provide instruction when deemed necessary, for the purpose of providing recommended best practice, but are not considered controlled elements of this Quality Program as they typically do not define quantitative or qualitative acceptance criteria.
SECTION 6: DOCUMENT CONTROL

6.1 General Requirements

The preparation, issue, and change of SFI Procedures, Work Instructions, and drawings are controlled to ensure that correct documents are being employed. These documents are reviewed for adequacy and approved by appropriate personnel before being issued for use.

6.2 Document Control

Controls applied to Procedures, Work Instructions, and drawings include:

- Identification
- Specified distribution and location
- Identification of individuals responsible for the preparation, review, approval and distribution
- Review for adequacy, completeness, and approval
- Methods of verification for correct use

6.3 Document Changes

Major changes to Procedures, Work Instructions, and drawings are reviewed and approved by the same organization that performed the original review and approval unless otherwise stated. The reviewing organization is responsible to obtain the necessary pertinent background data or information upon which to base their approval.

Minor changes to Procedures, Work Instructions, and drawings (i.e. editorial corrections) do not require the same review and approval as the original document. SFI Quality Managers are authorized to determine the classification of a change as minor or major.
SECTION 7: CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 General Requirements

Procurement of items and services is controlled to assure conformance with specified requirements. Control methods and requirements as described below are applied to an extent relative to the importance, complexity, safety, and quantity of the items or services procured based on the defined or expected level of importance, complexity, and safety established by customer procurement documents.

Suspect / Counterfeit Items (S/CI) are controlled and reported in accordance with SFI Procedure Q16. Personnel are trained to identify S/CI per DOE Suspect/Counterfeit Items Awareness Training Guide.

7.2 Supplier Evaluation and Selection

SFI issues procurement documents to Approved Suppliers. Approved Suppliers have been qualified by an evaluation of their capabilities to provide items or services in accordance with defined or expected requirements. Documented qualification (evaluation and results) of Approved Suppliers includes one or more of the following:

- Supplier’s history of providing similar items or services that perform satisfactorily and reflect current capability
- Supplier’s current quality records and supporting qualitative or quantitative information
- Supplier’s technical and quality capabilities as determined by a direct evaluation of their facilities, personnel, and quality assurance program
- Supplier’s designation as the required source by customer procurement documents

7.3 Bid Evaluation

Bids may be solicited by SFI for the procurement of complex items, items of very-high importance such as safety-significant items, or quality services and are not to mean the same as a request for quote of raw materials, catalog parts, common services or similar items and services. If unacceptable technical or quality assurance conditions are discovered during bid evaluation, resolution or commitments to resolve those conditions are to be obtained prior to issuance of procurement documents, unless those conditions do not negatively affect the intended procurement or are otherwise mutually agreed to be resolved through the terms and conditions of the procurement.

7.4 Control of Supplier-Generated Documents

Supplier-generated documents are acquired, processed, and evaluated in accordance with SFI Procedure.
7.5 Acceptance of Item or Service

7.5.1 General

The extent of the verification activities are relative to the importance, complexity and quantity of the item or service procured and the Supplier's quality performance.

7.5.2 Methods of Acceptance

Methods used to accept an item or service includes Certificates of Conformance, source verification, receiving inspection, post-installation testing or any combination of these methods.

7.5.3 Certificate of Conformance

When a Certificate of Conformance is solely used for acceptance, the certificate must:

- Identify the purchased material or equipment, such as by order number
- Identify specific requirements met by the purchased material or equipment such as codes, standards, and other specifications, including any approved changes, waivers, or deviations
- Identify requirements that have not been met, together with an explanation and means for resolving the nonconformance
- Be signed or otherwise authenticated by the person responsible for that function as defined in the Supplier’s quality assurance program
- Provided in accordance with the Supplier's established procedures that have been evaluated for acceptability during audits, independent inspection or test, or qualification

7.5.4 Source Verification

Source verification is performed in accordance with documented plans that specify the required evaluations at predetermined points. Documented evidence of source verification acceptance is provided to the receiving destination, and the Supplier.

7.5.5 Receiving Inspection

Receiving inspection verifies conformance to the procurement requirements, taking into account source verification, audit activities, and the demonstrated quality performance of the Supplier. Receiving inspection verifies features such as, but not limited to: configuration; identification; physical characteristics; freedom from shipping damage; cleanliness; and supplier-generated documentation.

7.5.6 Post-installation Testing

When post-installation tests are used for acceptance, the parameters, requirements, and acceptance criteria are mutually agreed upon by SFI and the supplier.
7.5.7 Acceptance of Services Only

Acceptance of procured services may be by any of the following methods: technical verification of data produced; surveillance or audit of the activity; review of objective evidence to the procurement requirements.

7.6 Control of Supplier Nonconformance

Supplier submitted nonconformance documentation is evaluated against the applicable SFI customer procurement documentation to determine disposition, approve the recommended disposition, or notify the customer for disposition determination and approval.

Supplier nonconformance identified at receipt of items or services is addressed by Section 15 of this Manual.

7.7 Commercial Grade Items

7.7.1 General

The requirements of this section may be utilized as acceptable alternatives to 7.2 through 7.6 when SFI is required to perform commercial grade dedication activities. Commercial grade dedication activities are required when the procurement of customer identified safety-significant items, or otherwise identified as safety-significant by SFI based on evidence in customer procurement documents, is issued to Approved Suppliers that do not have an accepted nuclear quality assurance program.

The sections below identify the requirements associated with commercial grade dedication activities consistent with those defined in the NQA-1-2008, Part I Standard, such that SFI may perform the necessary activities as a service to assist customers in meeting commercial grade dedication requirements. SFI does not have the authority or access to information necessary to fulfill these requirements in their entirety, but recognizes that our knowledge, expertise, and implemented Quality Program can be factors in the dedication process.

As a result, SFI may implement any or all portions of the requirements below as deemed necessary to satisfy customer contract requirements and expectations. Ultimately, the responsibility for commercial grade item or service utilization and ensuring the complete and adequate performance of dedication activities resides with the end user.

7.7.2 Utilization

The need and use of commercial grade items or services is based on the following:

- Technical evaluation to determine that the item or service performs a safety function
- Confirmation that the item or service meets the commercial grade definition criteria
- Identification of critical characteristics, including acceptance criteria
- Selection, performance, and documentation of the dedication method(s) for determining compliance with acceptance criteria

When one or more critical characteristics cannot be verified by the dedication methods, the requirements of this section cannot be utilized to procure and accept the item or service.
7.7.3 Critical Characteristics

Critical characteristics are identifiable and measurable attributes or variables as they relate to the safety function or the item or service, and are related to the location of the item in a facility, unless controls are in place to prevent usage in undesignated locations.

7.7.4 Dedication

Dedication includes providing reasonable assurance that the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by inspections, test, or analyses performed after delivery, supplemented as necessary by one or more of the following:

7.7.4.1 Commercial Grade Survey

Survey of the supplier performed in accordance with a checklist or plan that includes or addresses: 1) identification of the item(s) or service(s) within the scope of survey; 2) identification of the critical characteristics to be controlled by the supplier; 3) verification of effective implementation of the supplier’s processes and quality program controls; 4) identification of survey methods or verification activities performed with results; and 5) documentation of the adequacy of supplier processes and controls.

This supplemental method cannot be employed for suppliers that have an undocumented quality program or those that do not effectively implement the required processes and controls.

After the survey and accepted use of the supplier, the verified processes and controls must be invoked or referenced on the purchase order, and the supplier required to submit a Certificate of Conformance attesting to the implementation of those processes and controls.

7.7.4.2 Source Verification

Verification, inspection, or test activities performed in accordance with a checklist or plan applicable to actual item(s) or service(s) at the supplier’s facility or other appropriate location. The checklist or plan includes or addresses the same five provisions as required in the commercial grade survey appropriate to source verification.

7.7.4.3 Acceptable Supplier / Item / Service Performance Record

Documented evaluation of the supplier, item, or service performance history that includes or addresses: 1) identification of the supplier/item/service being evaluated; 2) identification of previously established critical characteristics specific to the supplier/item/service; 3) identification of industry data examined; 4) identification of basis for determining that industry data substantiates acceptability; 5) documentation of the adequacy and acceptance if the supplier/item/service performance record.
This supplemental method cannot be used, unless:

- The historical record is based on industry-wide performance data directly applicable to the established critical characteristics and the intended facility application (i.e. single source information is not adequate).
- The manufacturer/supplier’s measures for the control of design, process, and material change have been accepted by the dedicating entity.

Continued application of an acceptable supplier/item/service performance record must include periodic update and review.

### 7.7.5 Supplier Deficiency Correction

Deficiencies identified in the supplier’s process and controls must be corrected and verified by the dedicating entity, if those processes or controls are used for acceptance of critical characteristics.

### 7.8 Records

SFI utilizes and maintains records for documenting the performance of:

- Supplier Evaluation and Selection
- Acceptance of items and services
- Supplier nonconformance
- Utilization and acceptance of commercial grade items, as appropriate to the scope of dedication activities
SECTION 8: IDENTIFICATION AND CONTROL OF ITEMS

8.1 General Requirements
Identification and traceability of items and materials are controlled to assure that only correct and accepted items and materials are used or installed. Identification is maintained on the items/materials or in documents traceable to the items/materials, or in a manner that assures identification is established and maintained.

8.2 Identification Methods

8.2.1 Item Identification
Item and material identification and traceability is maintained from initial receipt acceptance through fabrication up to shipment. Identification information is sufficient to relate the item to an applicable design or other product specifying document.

8.2.2 Physical Identification
Physical identification is employed to the maximum extent possible. Where physical identification is either impractical or insufficient, physical separation, procedure, or other appropriate controls are utilized. Markings materials and methods are used to provide clear and legible information and that does not degrade the function or service life. Markings are transferred to individual parts when subdivided, and are not removed or obscured unless other means of identification have been substituted.

8.3 Specific Requirements

8.3.1 Identification and Traceability of Items
Identification information includes requirements of applicable codes, standards, or specifications (such as applicable specification and grade of material; heat, batch, lot, part, or serial number).

8.3.2 Limited Life Items
Items having limited calendar life, operating life or number of cycles are identified and controlled to preclude use after expiration.

8.3.3 Maintaining Identification of Stored Items
Stored items are periodically examined to assure identification information is maintained consistent with the planned duration and conditions of storage, including consideration of excessive deterioration due to environmental exposure. Identification markings and records are replaced or updated as needed.
SECTION 9: CONTROL OF SPECIAL PROCESSES

9.1 General Requirements

Special Processes performed at SFI include welding and nondestructive testing (or nondestructive examination). When the performance of other Special Processes (i.e. heat treating) are required, the applicable customer and Quality Program requirements are specified in purchase orders to the subcontractor and may include any or all of the requirements described in this section.

Welding is performed by qualified personnel using qualified procedures in accordance with the applicable customer procurement documents. Nondestructive testing is performed by qualified personnel using approved procedures compliant with industry codes and standards in accordance with the applicable customer procurement documents.

9.2 Process Control

9.2.1 Special Processes

Special Processes are performed in accordance with documented instructions (Procedures, Work Instructions, or welding documentation) and may require supporting documents such as drawings, specifications, checklists, Work Orders, or other appropriate means. Documented instructions include or reference qualification requirements, prerequisites, and conditions necessary to successfully accomplish the process.

9.2.2 Acceptance Criteria

Documented instructions include default acceptance criteria when no specific criteria are provided by the customer, however, supporting documents may identify the acceptance criteria where appropriate.

9.2.3 Special Requirements

For Special Processes not covered by existing codes or standards or where quality requirements exceed the criteria in existing codes and standards, the necessary requirements for qualification of personnel, procedures, or equipment are specified in the documented instructions.

9.3 Responsibility

The organization performing Special Processes is responsible for adherence to the approved documented instructions.

9.4 Records

Records are maintained for qualified personnel, processes, and related equipment for each Special Process performed at SFI.
SECTION 10: INSPECTION

10.1 General Requirements
Inspections are planned and executed to verify conformance of items or activities to specified requirements. Characteristics and methods of inspection are specified where appropriate and to the extent consistent with customer procurement requirements and quality expectations. Inspections are conducted by qualified personnel who did not perform or directly supervise the work being inspected, and the results documented.

10.2 Inspection Requirements
Inspection requirements and acceptance criteria are in accordance with the design documents or other pertinent technical documents applied by customer procurement documentation.

SFI generated design documents include specific inspection requirements or acceptance criteria where necessary to satisfy the customer procurement requirements and quality expectations; or default inspection requirements and acceptance criteria are provided in the applicable Procedure or Work Instruction when no specific criteria are provided by the customer.

10.3 Inspection Hold Points
Customer specified mandatory hold points are identified in SFI Work Orders to ensure work does not proceed without the required consent. Documented waiver of hold points is required prior to continuation of work.

10.4 Inspection Planning
Characteristics to be inspected, methods of inspection, and acceptance criteria consistent with the customer procurement requirements and quality expectations are identified in the development and generation of SFI Work Orders.

Sampling, when used, is based on standard statistical methods with engineering approval.

10.5 In-Process Inspection
SFI utilizes planned inspections during fabrication as necessary to verify conformance which cannot otherwise be accomplished later, or as required by applicable codes and standards that include in-process inspection requirements. Planned inspections take into account conditions where it is impossible or disadvantageous to inspect completed items according to the applicable requirements.

When quality requirements cannot be verified by inspection alone, both inspection and process monitoring will be used. Process monitoring is performed by qualified personnel or qualified automated means.

10.6 Final Inspection
10.6.1 Resolution of Nonconformance
Final inspection includes review of documented nonconformance identified by prior inspections to assure proper resolution.
10.6.2 Inspection Requirements

Final inspection includes verification of product and record completeness, and assessment of cleanliness, workmanship, and other characteristics necessary to assure conformance to the applicable quality requirements.

10.6.3 Modifications, Repairs or Replacements

Final inspection includes verification that modified, repaired, or replaced items have been re-inspected or re-tested for determination of acceptability in accordance with the applicable requirements.

10.6.4 Acceptance

Final inspection includes acceptance of items by authorized personnel.

10.7 Inspections during Operations

This element does not apply to SFI Advanced Technology Group.

10.8 Records

Inspection Records, or other documents used to record completed inspections, include the following information:

- Item inspected
- Date of inspection
- Inspector
- Type of observation
- Results or acceptability
- Reference to information on action taken in connection with nonconformance
SECTION 11: TEST CONTROL

11.1 General Requirements
Tests are planned and executed to verify conformance of items or to demonstrate satisfactory performance prior to installation and service (Factory Acceptance Tests). Characteristics and methods of testing are specified where appropriate and to the extent consistent with customer procurement requirements and quality expectations. Test results are documented and evaluated for conformance to the test requirements and acceptance criteria.

Test control requirements as described in this section do not apply to nondestructive testing which is addressed in Section 9.

11.2 Test Requirements
Factory Acceptance Tests and other tests applicable to this section (qualification tests, production tests, proof tests, etc.) are performed in accordance with SFI Procedures, Work Instructions, test plans, or other applicable documented instructions. Documented instructions are developed with consideration to the test objectives, configuration, suitable environmental conditions, and means of recording the necessary data, including accuracy, to assure evaluation and determination of acceptance.

Documented instructions are approved prior to use and include test requirements and acceptance criteria based upon customer procurement documentation, or industry codes and standards or other pertinent technical documents that provide approved requirements.

11.3 Test Procedures (Excluding Computer Programs)
Documented instructions include or reference test configurations and objectives, and include provisions for:

- Assuring prerequisites and environmental conditions have been met
- Adequate instrumentation is available and used
- The appropriate tests, test methods or techniques, and equipment are used
- Any necessary monitoring is performed

Prerequisites include: calibrated instrumentation, appropriate equipment; personnel training or qualification requirements; conditions of the equipment or items to be tested; environmental conditions; and data acquisition requirements.

Documents such as ASTM methods, supplier manuals, equipment maintenance instructions, and approved drawings or Work Orders, are used as supplemental information to support documented instructions unless otherwise directed by customer procurement documentation.

11.4 Computer Program Test Procedures
Testing of instrumentation and equipment controlled by computer program is integrated into the documented instructions applicable to non-computer program testing for the purposes of verifying proper connectivity and entry of data inputs to an already developed computer program.
When testing the programming of a computer program is required, the applicable customer procurements requirements are specified in purchase orders to the subcontractor and controlled in accordance with the requirements of Section 7.

11.5 Test Results

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

Test results for design qualification tests and software verification are submitted for evaluation in accordance with the applicable customer procurement requirements.

11.6 Test Records

Test Records include the following information:

- Item tested
- Date of test
- Tester or data recorder
- Type of observation
- Results and acceptability
- Action taken in connection with any deviations
- Person evaluating test results
SECTION 12: CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 General Requirements

Tools, gages, instruments and other measuring and test equipment ("M&TE") used for activities affecting quality are controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.

12.2 Selection

Specific M&TE are specified in the applicable procedure or work instruction, or are selected based on type, range, accuracy, and tolerance required to accomplish the measurement and determine conformance.

12.3 Calibration and Control

12.3.1 Calibration

M&TE is calibrated within defined times or intervals and whenever the accuracy is suspect. Calibration is performed against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards or international standards known to be equivalent to and verified against nationally recognized standards. A basis for calibration is defined when such standards do not exist.

12.3.2 Reference Standards

Reference standards used for calibration have a minimum accuracy four times greater than the M&TE device, or have technical justification for their use.

12.3.3 Control

Calibration is performed in accordance with procedures, work instructions, or other documented instructions that identify or reference the required accuracy and define methods and frequency of checking accuracy. Calibration methods and intervals are established based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance.

M&TE that is overdue or found to be out-of-calibration are tagged and/or segregated, or removed from service until they are re-calibrated. M&TE that is consistently found to be out-of-calibration is repaired or replaced.

12.3.3.1 Application

M&TE is traceable to its application and use.

12.3.3.2 Corrective Action

When M&TE is lost, damaged, or found to be out-of-calibration, the validity of previous measurements and the acceptability of items previously inspected or tested are evaluated. The evaluation includes the time from last calibration to the date the issue was identified. The evaluation and resulting actions are commensurate with the significance of the condition.
12.3.3.3 Handling and Storage

M&TE are properly handled and stored to maintain accuracy in accordance with SFI Procedure, Work Instruction, or manufacturer recommendations.

12.3.3.4 Environmental Controls

M&TE is calibrated and used in environmental conditions that are controlled to the extent necessary to ensure the required accuracy and precision are maintained.

12.3.3.5 Pre-calibration Checks

M&TE and reference standards submitted for calibration are checked and the results recorded prior to any repairs or adjustments.

12.3.3.6 Status Indication

M&TE is marked, tagged, labeled, or otherwise identified to indicate status and establish traceability to calibration records.

12.3.4 Commercial Devices

The calibration and control requirements of this section are not required for commercial devices such as rulers, tape measures, levels, etc., when such equipment provides the required accuracy.

12.4 Records

Calibration reports and certificates reporting the results of calibrations include the necessary information and data for interpreting the calibration results and verifying conformance to the applicable requirements; and identify the calibration status and capability of the M&TE.
SECTION 13: HANDLING, STORAGE, AND SHIPPING

13.1 General Requirements
Handling, storage, cleaning for shipment, packaging, shipping, and preservation of items are controlled to prevent damage, loss, and minimize deterioration, and are performed in accordance with the applicable SFI Procedure, Work Instruction, or other pertinent documented instructions.

13.2 Special Requirements
The use and verification of special equipment and special protective environments are performed in accordance with the applicable documented instructions.

13.3 Procedures
The handling, storage, and preservation of types of items or materials known to be critical, sensitive, perishable, or high-value are performed in accordance with SFI Procedures or Work Instructions.

Specific procedures or work instructions for handling, storage, packaging, shipping, and preservation of fabricated items are implemented when required by customer procurement documentation.

13.4 Tools and Equipment
Handling tools and equipment are utilized when necessary to ensure safe and adequate handling of items. Handling tools and equipment are inspected and tested at regular intervals in accordance with manufacturer instructions and recommendations.

13.5 Operators
Operators of handling and lifting equipment are experienced or trained in the use of the equipment.

13.6 Marking and Labeling
Items and materials are marked, tagged, or labeled to adequately maintain preservation including the identification of special environments or controls.
SECTION 14: INSPECTION, TEST, AND OPERATION STATUS

14.1 General Requirements

The status of inspection and test activities are identified either on items or in documents traceable to the items, where it is necessary to ensure the required inspections and tests were performed and to ensure that nonconforming items are not inadvertently installed, used, or operated. Status is identified by tags, markings, physical location, relatable documentation, or other appropriate means.

The authority for application and removal of tags, markings, labels, and stamps is specified in the applicable SFI Procedure or Work Instruction.
SECTION 15: CONTROL OF NONCONFORMING ITEMS

15.1 General Requirements

Items determined to be nonconforming are controlled to prevent inadvertent installation and use in accordance with SFI Procedure. Procedure instructions include provisions for identification, documentation, evaluation, segregation when practical, disposition, and notification to affected organizations.

Suspect / Counterfeit Items (S/CI) are controlled and reported in accordance with SFI Procedure Q16. Personnel are trained to identify S/CI per DOE Suspect/Counterfeit Items Awareness Training Guide.

15.2 Identification

Nonconforming items are identified by markings, tags, or other methods not detrimental to the items, and placed on the items, their containers, or packaging.

15.3 Segregation

Nonconforming items are segregated, when practical, in a clearly designated hold area until disposition has been completed.

When segregation is not practical or possible other precautions are taken to clearly identify the item and to prevent inadvertent use.

15.4 Disposition

15.4.1 Control

Further processing, delivery, installation, and use of nonconforming items are controlled until the evaluation and approved disposition by authorized personnel has been completed. When required, evaluation and the recommended disposition are submitted to the customer for approval.

15.4.2 Responsibility and Authority

The responsibility and authority for evaluation and disposition of nonconforming items is defined. The responsibility for control of nonconforming items to prevent inadvertent use is designated in writing.

15.4.3 Personnel

Personnel performing evaluations to determine a disposition have: 1) demonstrated competence in the area they are evaluating; 2) adequate understanding of the requirements; and 3) access to pertinent background information.
15.4.4 Disposition

Disposition of nonconforming items are use-as-is, repair, rework, and scrap. Use-as-is and repair dispositions include technical justification for acceptability, and are subject to design control measures commensurate with those of the original design as appropriate to the nonconformance.

Use-as-is and repair conditions are reflected in as-built records that are required for delivery.

15.4.5 Reexamination

Reworked items are reexamined in accordance with the applicable procedures using the original acceptance criteria.

Repaired items are reexamined in accordance with the applicable procedures using the original acceptance criteria, unless the disposition has established other acceptance criteria.

15.5 Defect Reporting Per 10CFR21

Defects and nonconformance of safety-significant items discovered during fabrication are controlled in accordance with the requirements of this section.

Defects and nonconformance of safety-significant items discovered after delivery or when discovered as a result of notifications from suppliers are controlled in accordance with SFI Procedure that addresses the requirements of 10CFR21. SFI Procedure includes notification, reporting, corrective action, and responsibility and authority requirements. The required regulations, procedures, and information are posted in the SFI Advanced Technology Group facility.
SECTION 16: CORRECTIVE ACTION

16.1 General Requirements

Conditions adverse to quality are promptly identified and corrected as soon as practicable.

Conditions adverse to quality identified as significant conditions adverse to quality are documented and include an evaluation of cause of the condition and actions taken to preclude recurrence. Documented corrective actions are verified for completion.
SECTION 17: QUALITY ASSURANCE RECORDS

17.1 General Requirements
Quality assurance records are established to provide documentary evidence that items and activities satisfy the applicable customer procurement or Quality Program requirements. Control requirements and responsibilities for identification, generation, authentication, maintenance, and final disposition of quality records are prescribed by the applicable SFI Procedure or Work Instruction.

17.2 Generation of Records
The requirements to generate, supply, or maintain quality assurance records are in accordance with the applicable customer procurement or Quality Program documents. Completed records are legible and traceable to associated items or activities and accurately reflect the work accomplished or information required.

17.3 Authentication of Records
Quality assurance records are considered complete and valid once stamped, initialed or signed and dated, or otherwise authenticated by authorized personnel.

Electronic documents are authenticated with comparable information as stated above and with identification on the media or contained within or linked to the document itself.

17.4 Classification
Quality assurance records are classified as either lifetime or nonpermanent. These records are maintained in accordance with customer procurement requirements or by SFI according to the following:

17.4.1 Lifetime Records
Lifetime Records are those that would be of significant value in:

- demonstrating capability for safe operations,
- maintaining, reworking, repairing, replacing, or modifying an item,
- determining the cause of an accident or malfunction of an item,

Or, those that provide required baseline data for in-service inspection.

Lifetime Records are maintained for the life of an item while it is in use or stored for future use.

17.4.2 Nonpermanent Records
Nonpermanent Records are those that demonstrate that an activity was performed in accordance with the applicable requirements but do not meet the criteria for Lifetime Records. Nonpermanent Records are retained for an identified period of time.
17.5 Receipt Control of Records
Personnel responsible for the receipt of quality assurance records are identified. Controls for permanent and temporary storage of records, and the identification and inspection of received records are in accordance with the applicable SFI Procedure or Work Instruction.

17.6 Storage

17.6.1 General
Quality assurance records are stored in a manner which minimizes the risk of loss, damage, or destruction due to natural disasters, environmental conditions, infestation, and dust or airborne particles. Access to storage and retrieval of records is limited to authorized personnel.

17.6.2 Facility Types
Quality assurance records are stored using a dual-facility storage method. The locations of each storage facility are sufficiently remote from each other to eliminate chance exposure to a simultaneous hazard.

17.6.3 Temporary Storage
Completed quality assurance records for in-process items are stored in accordance with the dual-facility method.

17.7 Retention
Quality assurance records are maintained for their documented retention periods.

17.8 Maintenance of Records
Quality assurance records are maintained as follows:

- Protected from damage or loss
- Retrieval within planned times based on record type and content
- Through documented methods for record changes
- No unacceptable degradation of electronic media during the retention period
- Remain retrievable after hardware, software, or technology changes
- Duplication or transfer of records to the same or different media for the purpose of maintenance is authorized, and record content, legibility, and retrieval are maintained
SECTION 18: QUALITY ASSURANCE AUDITS

18.1 General Requirements
Audits are performed to verify compliance with quality assurance program requirements, that performance criteria are met, and determine the effectiveness of the program. Audits are performed according to SFI Procedures by personnel who do not have direct responsibility for performing the work being audited. Audit results are documented and provided to management for review. Follow-up audit actions are taken when specified.

18.2 Scheduling
Audits are scheduled in coordination with ongoing activities and to assure adequate coverage, based on the importance of the activity.

18.3 Preparation

18.3.1 Audit Plan
Audit Plans are developed for each audit and include or reference: audit scope; requirements; audit personnel; activities to be audited; organizations to be notified; applicable documents; schedule; and written procedures or checklists.

18.3.2 Personnel
During the audit, audit personnel are given sufficient authority and organizational freedom to ensure the process and outcomes are meaningful and effective.

18.3.3 Selection of Audit Team
Audit team members are identified prior to the start of each audit. At least one member is a Lead Auditor, who organizes and directs the audit. Members are selected to ensure the team as a whole has experience and training commensurate with the scope, complexity, or special nature of the activities being audited.

18.4 Performance
Elements identified for audit are evaluated against specified requirements and objective evidence is examined to the depth necessary to determine effective implementation. Conditions requiring immediate corrective action are immediately reported to management.

18.5 Reporting
Copies of audit reports are signed or otherwise endorsed by the lead auditor and issued to the audited organization. Audit reports include:

- Description of the audit scope
- Identification of the audit team and persons contacted
- Summarized audit results, including a statement of the effectiveness of the elements audited
- Any adverse audit findings
- Signature or endorsement by the Lead Auditor

18.6 Response
Management investigates adverse audit findings and coordinates with the appropriate personnel to complete any required corrective actions.

18.7 Follow-up Action
Follow-up actions are identified and performed to ensure that corrective actions are completed.

18.8 Records
Audit records include audit plans, audit reports and supporting documents, written replies, and records of completion of corrective action.
SECTION 19: EXHIBITS

Exhibits shown are for reference only and may change periodically without requiring approvals from interested parties. Changes that are material to the operations of the business will be reviewed and approved by interested parties as required.

Exhibit 1: Organization Chart
## Exhibit 2 – Procedure Listing

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Exhibit 3 – ATG Process Flow Chart (MM-003) – Next Page
This Flow Chart may not include all activities necessary to fabricate products but is intended to provide the basic relationship of activities to one another and the general fabrication process.