

PROGRAM QUALITY PLAN

DOCUMENT NO. PQP – NUCLEAR

Revision 3

NUCLEAR SERVICES

**Prepared by
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Institute Quality Systems

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Revision 3:
QSM references updated in line with ISO 9001:2008 and SwRI QSM Revision 3.

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1.0 INTRODUCTION

This program quality plan (PQP) defines the Quality Assurance (QA) program requirements for personnel providing engineering, analytical, testing, or other services to the nuclear and radiation related industries. The QA requirements shall be implemented through the use of this plan in conjunction with the Southwest Research Institute® (SwRI®) *Quality System Manual (QSM)*. Project activities controlled by this program shall be accomplished through the application of the appropriate operating procedures and work instructions found within each of the divisions/departments/sections conducting work in support of the nuclear industry. Upon notification of the initiation of project activities, Institute Quality Systems (IQS) or the appropriate management representative shall determine if this PQP shall be applied. If, due to complexity, duration, or other factors, it is determined that a unique, project-specific project quality plan is required, a plan shall be generated in accordance with the applicable document control procedures.

2.0 SCOPE

Unless otherwise determined or specified, this PQP shall be applied to any services performed by SwRI where required by contract to meet 10CFR50 Appendix B, ASME NQA-1, or other related quality standard(s). This document supplements the requirements of the SwRI QSM written to the requirements of ISO 9001. SwRI maintains a quality management system meeting the requirements of ISO 9001 and supplements additional requirements through the use of program- or project-specific quality plans. Other standards related to the nuclear or radiation industries may also be addressed by incorporating the applicable requirements within a project-specific quality plan.

3.0 APPLICABLE SECTIONS OF THE QSM

The QSM contains elements or clauses that correspond to the 18-point criteria of 10CFR50 Appendix B and NQA-1 as shown in Appendix A. In general, the elements of ISO 9001, apply to this system as supplemented in this quality plan.

4.0 SUPPLEMENTAL REQUIREMENTS

The following requirements are in addition to those of the SwRI QSM. In the event of a conflict between these requirements and those of the QSM, these requirements supersede those of the QSM. References to NQA-1 requirements apply to the 1997 edition.

4.1 Indoctrination and Training (Ref. NQA-1, Requirement 2)

Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority. The indoctrination and

training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

4.1.1 Indoctrination

Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards; regulatory commitments; company procedures; and QA program requirements.

4.1.2 Training

The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

4.2 Qualification of Personnel (Ref. NQA-1, Requirement 2)

4.2.1 Inspection and Test Personnel

When inspection and/or test personnel are required to be formally qualified and certified, they shall be qualified and certified in accordance with the division or department procedures which shall address, as a minimum:

- 1) qualification requirements;
- 2) personnel selection and experience;
- 3) training requirements;
- 4) determination of initial capability;
- 5) evaluation of performance;
- 6) physical requirements; and
- 7) certification record.

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 job performance of inspection and test personnel shall be re-evaluated at periodic intervals not to exceed three years. Re-evaluation shall be by evidence of continued satisfactory performance or re-determination of capability in accordance with the requirements in Paragraph 4.1 of this document. If, during this evaluation

or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person would 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.

4.2.2 Quality Assurance Audit Personnel

The qualification of QA audit personnel shall be accomplished in accordance with written procedures. This procedure shall establish the personnel qualifications for the certification of QA auditors and lead auditors, and the requirements for use of technical personnel to accomplish the internal or external auditing of the SwRI nuclear QA program.

4.2.3 Records

Records of the implementation of indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. Records of qualification, including re-qualification, for auditors and lead auditors, and for inspection and test personnel shall be established and maintained by IQS for indoctrination and training.

4.3 Design Control (Ref. NQA-1, Requirement 3)

Design adequacy shall be verified by individuals other than those who designed the item.

4.3.1 Change Control

- a) Changes to design inputs, final designs, field changes, and temporary and permanent modifications shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analyses upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. The design organization approving the change shall have demonstrated competence in the specific design area of interest, and have an adequate understanding of the requirements and intent of the original design.
- b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

- c) 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.

4.3.2 Control of Software

Software design controls (NQA-1, Requirement 3, Paragraph 800) are not implemented in this program. SwRI does not design software for its nuclear industry customers. Software controls are implemented by SwRI, but are limited to the software used for testing purposes as described in the QSM, Section 7.6, and the applicable division procedures.

4.4 Right of Access (Ref. NQA-1, Requirement 4)

The procurement documents shall provide for access to the suppliers' and sub-tier suppliers' facilities and records for surveillance, inspection, or audit by SwRI, its designated representative, and others authorized by SwRI.

4.5 Control of Supplier–Generated Documents (Ref. NQA-1, Requirement 7)

Controls shall be implemented to assure that the submittal and evaluation of supplier-generated documents are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

4.6 Acceptance of Services Only (Ref. NQA-1, Requirement 7)

In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any or all of the following methods:

- a) technical verification of data produced;
- b) surveillance and/or audit of activity; or
- c) review of objective evidence for conformance to the procurement document requirements.

4.6.1 Certificate of Conformance

When a Certificate of Conformance is used, the following shall apply:

- a) The certificate shall identify the purchased materials or equipment, such as by the purchase order number.
- b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the material or equipment.
- c) The certificate shall identify any procurement requirements that have not been met together with an explanation and the means for resolving the nonconformances.
- d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.
- e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.
- f) Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

4.7 Commercial Grade Items (Ref. NQA-1, Requirement 7)

An item shall be considered "commercial grade" where it is to be incorporated into a deliverable to a customer and that item is:

- 1) not subject to design or specification requirements that are unique to nuclear facilities;
- 2) used in applications other than nuclear facilities; and
- 3) to be ordered from the manufacturer/supplier on the basis or specifications set forth in the manufacturers' published product and description.

The following requirements may be used as an acceptable alternative for procuring and accepting commercial grade items:

- a) The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.
- b) Source evaluation and selection, where determined necessary by SwRI based on complexity and importance to safety, shall be in accordance with Section 200 of NQA-1, Requirement 7.
- c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (for example, catalog number.)
- d) One, or a combination, of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance:
 - 1) special test(s) or inspection(s), or both;
 - 2) commercial grade survey of the supplier;
 - 3) source verification; and/or
 - 4) acceptable supplier/item performance records.
- e) Prior to acceptance of a commercial grade item, the purchaser shall determine that:
 - 1) damage was not sustained during shipment;
 - 2) the item has satisfied the specified acceptance criteria; and
 - 3) specified documentation, as applicable to the item, was received and is acceptable.

4.8 Identification and Control of Items (Ref. NQA-1, Requirement 8)

Items having limited calendar or operating lifecycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

4.9 Control of Special Processes (Ref. NQA-1, Requirement 9)

For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

4.10 Inspection (Ref. NQA-1, Requirement 10)

Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected. Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections.

Sampling procedures, when used, shall be based upon valid statistical methods.

4.11 Inspection and Testing (Ref. NQA-1, Requirement 11)

Required tests shall be conducted under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test.

Test procedures shall include or reference:

- 1) Configuration and objectives;
- 2) Prerequisites and environmental conditions; and
- 3) Adequate and calibrated instrumentation, equipment, and monitoring and data acquisition devices.

As an alternative to the test procedures specified above, appropriate sections of related documents, such as ASTM methods, supplier manuals, equipment maintenance instructions, or approved drawings for travelers with acceptance criteria, can be used.

4.12 Control of Measuring and Test Equipment (Ref. NQA-1, Requirement 12)

Measuring and test equipment shall be properly handled and stored to maintain accuracy.

Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

4.13 Handling, Storage, Packaging, Preservation, and Delivery (Ref. NQA-1, Requirement 13)

Where appropriate to the item or material, controls shall be included for cleaning and any special protective environments. Special handling tools and equipment shall be utilized and controlled where necessary. Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

4.14 Inspection, Test, and Operating Status (Ref. NQA-1, Requirement 14)

The authority for application and removal of tags, markings, labels, and stamps shall be specified.

4.15 Control of Nonconforming Items (Ref. NQA-1, Requirement 15)

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

A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptance of a nonconforming item dispositioned repair or use-as-is shall be documented.

4.16 Quality Assurance Records (Ref. NQA-1, Requirement 17)

Quality Assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. QA records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Requirements and responsibilities for these activities shall be documented. The term *records* used throughout this section is to be interpreted as *quality assurance records*.

4.16.1 Generation of Records

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

4.16.2 Authentication of Records

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

4.16.3 Classification

Records shall be classified as *lifetime* or *nonpermanent* by the owner, or his agent when authorized, in accordance with the criteria given in the paragraphs below.

Lifetime Records

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

- a) those that would be of significant value in demonstrating capability for safe operation;
- b) those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;
- c) those that would be of significant value in determining the cause of an accident or malfunction of an item; and/or
- d) those that provide required baseline data for in-service inspections

Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.

Nonpermanent Records

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.

4.16.4 Receipt of Control and Retention of Records

Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing. Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.

4.16.5 Storage

Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of damage or destruction from the following:

- 1) natural disasters such as winds, floods, or fires;
- 2) environmental conditions such as high and low temperatures and humidity; and
- 3) infestation of insects, mold, or rodents.

Dual facilities, containers, or combination thereof, shall be provided for records storage if a single facility, container, or combination thereof, is not capable of providing adequate protection.

4.16.6 Disposition

- 1) Custodian shall inventory submittals, acknowledge receipts, and process the records.
- 2) Records retention periods shall be documented.
- 3) Records shall be maintained for their retention periods.

4.16.7 Maintenance of Records

The methods for record changes shall be documented.

Provisions shall be made for specially processed records (such as radiographs, photographs, negatives, microform, and magnetic and optical media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

4.17 Audits (Ref. NQA-1, Requirement 18)

The contents of the audit report shall:

- 1) Describe the audit scope;
- 2) Identify auditors and persons contacted;
- 3) Summarize audit results, including a statement on the effectiveness of the elements audited; and
- 4) Describe each reported adverse audit finding.

4.18 10CFR, Part 21

4.18.1 Reporting of Defects and Noncompliance

SwRI procurement documents shall include SwRI requirements for reporting and approving disposition of supplier nonconformances and, when required, compliance to 10CFR, Part 21.

The manager of Institute QA or director of IQS shall determine if a nonconforming condition is reportable under 10CFR, Part 21, and shall initiate reporting and condition in accordance with SwRI Operating Policies and Procedures, OPP 9.1.5. Safety hazards or defects that could create a substantial safety hazard shall be reported. Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety.

Appendix A
10CFR50B/NQA-1 to SwRI QSM Correspondence Table

18-Point Criteria	Title	Subject Area(s) or Quality Element	Corresponding QSM Section
1	Organization	Responsibility for QA program	5.5
		Senior management responsibility	5.1
		Responsibility for ensuring quality	5.3
		Verification of quality	5.5
		Delegation	5.5
		Interface control	5.3, 4.1, Appendix A
2	Quality Assurance Program	QA Program planning, implementation and maintenance	PQP-N, 4.1, 5.3, 5.4.2, 8.1
		Detection and correction of quality problems	8.2
		Management Review	5.6
		Indoctrination, Training and Qualification	PQP-N, 6.2, 5.3
		Competence, training and awareness	PQP-N
		Job performance	PQP-N
		Qualification requirements	PQP-N, 6.2
3	Design Control	Design control	PQP-N, 7.3
		Design inputs	7.3
		Design changes	7.3
		Design process	7.3
		Design analysis	7.3
		Design verification	7.3
		Design change control	PQP-N, 7.3
		Interface control	7.3
		Design documentation and records	7.5.3, 4.2.4
4	Procurement Document Control	Procurement document requirements	PQP-N, 7.4.2
		Procurement document review	7.4.2
5	Instructions, Procedures, and Drawings	Instructions, Procedures, and Drawings	4.2.3
6	Document Control	Preparation, issue and change of documents	4.2.3
7	Control of Purchased Items and Services	Supplier evaluation	7.4
		Bid evaluation	7.4
		Supplier generated documents	PQP-N
		Methods of acceptance	7.4
		Certificate of conformance	PQP-N
		Source verification	7.4
		Receiving inspection	7.4
		Post-installation testing	7.4
		Acceptance of items or services	PQP-N
		Nonconformance control	8.3
8	Identification and Control of Items	Establishing and maintaining identification	7.5.3
		Item identification	7.5.3
		Physical identification	7.5.3
		Identification and traceability of items	7.5.3
		Limited life items	PQP-N
		Maintaining identification of stored items	7.5.3
9	Control of Special Processes	Personnel qualification	7.5.3
		Process control	PQP-N, 7.5.3
		Responsibility	7.5.3
		Records	4.2.4

18-Point Criteria	Title	Subject Area(s) or Quality Element	Corresponding QSM Section
10	Inspection	Requirements	PQP-N, 7.1, 7.4.3, 8.2.4
		Inspection hold points	7.1
		Planning	7.1
		Sampling	PQP-N
		In-process inspection	8.2.4
		Final inspection, nonconformance resolution, modifications, repairs, or replacements	PQP-N, 8.2.4
		Inspection records	8.2.4
11	Test Control	Test requirements	PQP-N, 7.0
		Test procedures	PQP-N
		Computer program test procedures	PQP-N
		Test records	7.2, 4.2.4
12	Control of Measuring and Test Equipment	Control	7.6
		Selection	7.6
		Calibration	7.6
		Corrective action	8.5.2
		Handling and storage	PQP-N
		Status indication	7.6
		Commercial devices	PQP-N
		Records	7.6
13	Handling, Storage, and Shipping	Procedures	7.5.5
		Special requirements	7.5.5
		Handling and lifting equipment	PQP-N, 7.5.5
		Marking or labeling	7.5.5
14	Inspection, Test, and Operation Status	Inspection and test status	PQP-N, 7.5.3, 8.3
		Operating status	Not applicable
15	Control of Nonconforming Items	Nonconforming item control	8.3
		Identification	8.3
		Segregation	8.3
		Disposition control	8.3
		Disposition responsibility and authority	PQP-N, 8.3
		Disposition	PQP-N, 8.3
		Reexamination	8.3
16	Corrective Action	Corrective action	8.5.2
17	Quality Assurance Records	Quality assurance records	PQP-N, 4.2.4
		Record authentication	PQP-N
		Classification of records	PQP-N
		Record retention	PQP-N
		Record storage	PQP-N, 4.2.4
18	Audits	Audit program	8.2.2
		Schedule	8.2.2
		Audit plan	8.2.2
		Audit team	8.2.2
		Audit performance	8.2.2
		Audit reporting	PQP-N, 8.2.2
		Audit response	8.2.2
		Audit follow-up	8.2.2