

Manual Number: 1Q

Manual Title: *Quality Assurance Manual*

Revision Summary

1.	Document and Revision Numbers: Procedure 2-1, Rev. 10
2.	Document Title: Quality Assurance Program
3.	Effective Date: 12/17/08
4.	Document Changes : Global: Changed “Washington Savannah River Company (WSRC) and /or WSRC” to “Performing Entity” or deleted as applicable. <u>Responsibility</u> Changed “WSRC President” to “Performing Entity” President; Changed “WSRC Site Quality Assurance Manager” to “Performing Entity Senior Quality Assurance Manager”; revised responsibility for same to reflect the removal of 4 burger dots and relocating under new title “SRS M &O Contractor” and deleting burger dot “participating in the selection and performance evaluation of WSRC QA Managers”; Paragraph Performing Entity Senior Quality Assurance Manager burger dot 3 added “, as required” and burger dot 5 added “, when required”; Paragraph Management and Operations (M&O) Quality Services Manager deleted “SRS ...Contractor”, in M&O Contractor deleted “Contractor” and burger dots 1 and 2 deleted “SRS M&O Contractor” Paragraph B.2 added “, when required”. <u>Procedure</u> “A. General Requirements” added new “Note ”; B. Quality Assurance program Documents, paragraph 2, revised to reflect ...The plan is “revised annually,”...; paragraph 7.a. added; “Performing Entity Senior” QA Manger.... <u>Records</u> Burger dot 2. added “SRS M&O Contractor”. <u>References</u> Section revised to reflect changes to Source Documents titles; added “10 CFR 63.142, Quality Assurance Criteria for Disposal; of High Level Radioactive waste

	<p><u>References continued</u></p> <p>in a geologic Repository”; deleted Reference document’s “Revisions”; burger 2 deleted “SRS M&O Contractor”.</p> <p><u>Attachments</u></p> <p>Added new “Attachment B. Special Quality Assurance (QA) Program Requirements”.</p>
5.	<p>Training Requirements:</p> <p>As with any procedure revision, those employees affected by the procedure need to familiarize themselves with the changes. No additional training is required.</p>

Quality Assurance Program

APPROVED
COMPANY-LEVEL
PROCEDURE

Purpose

This procedure provides requirements for the Performing Entity Quality Assurance Program. This documented Quality Assurance (QA) Program includes the Policy, Plans, Manual(s), and implementing procedures or instructions required to define and control activities affecting quality.

This procedure also establishes a mechanism for the Performing Entity to meet the applicable requirements in support of contractual obligations. For a current list of Source Document references, go to the Standards/Requirements Identification Document (S/RID) webpage accessible through ShRINE.

Scope

The provisions of this procedure apply to members of the Performing Entity for management and operations at Savannah River Site (SRS), and to subcontractors performing work for any member of the Performing Entity when required by subcontract or applicable law.

The QA Program applies in a graded manner throughout the life cycle of a facility. The activities which affect quality include experiments, research and development, siting, designing, handling, shipping, receiving, storing, cleaning, procuring, fabricating, erecting, installing, training, inspecting, testing, operating, manufacturing, maintaining, repairing, refueling, modifying, deactivating, decommissioning, and the planning, scheduling, and cost control considerations associated with these activities.

Terms and Definitions

None

Responsibilities

Performing Entity President

The Performing Entity President is responsible for the scoping, planning, implementation, and maintenance of an effective QA Program.

Senior Management Team

The Senior Management team is responsible for:

- implementing the QA Program in their respective organizations,
- ensuring that the QA reporting structure allows for sufficient independence in the organization.

Performing Entity Senior Quality Assurance Manager

The Performing Entity Senior Quality Assurance Manager is responsible for:

- providing central leadership and direction for all aspects of the QA Program,

- ensuring that the QA Program is compatible and consistent, with the performing entities Integrated Safety Management System,
- preparing, maintaining, and obtaining Department of Energy (DOE) – Savannah River and National Nuclear Security Administration (NNSA), as required – Savannah River Site Office approval of the QA Management Plan (QAMP),
- defining and ensuring implementation of QA Policy and Program requirements,
- serving as the primary interface with DOE and NNSA, when required on Quality Assurance issues,
- resolving, with organizational managers and appropriate Cognizant Quality Function (CQF)/QA management, those conditions not in compliance with QA Program requirements,
- providing special QA services and support,
- serving as the CQF for assigned organizations,
- providing CQF support for organizations without dedicated CQF resources,
- monitoring the adequacy and effectiveness of the QA Program,
- managing the Software Quality Assurance program and Safety Software Inventory List.

Management and Operations (M&O) Quality Services Manager

The M&O is responsible for:

- developing, approving, and maintaining the QA Manual,
- chairing the Quality Assurance Policy Committee (QAPC),
- serving as the certifying agency for the Quality Control and Audit Programs,
- managing the Management Assessment and Performance Analysis programs.

Cognizant Quality Functions (CQF)

The CQF is responsible for assisting line management in the implementation of the QA Program.

Procedure

This procedure contains the following sections:

- A. General Requirements
- B. Quality Assurance Program Documents
- C. Graded Application of QA Program Requirements
- D. Quality Program Assessments

A. General Requirements

NOTE: See Attachment B for Special QA Program Requirements.

1. The QA Program is planned, implemented, and maintained in accordance with Procedure Manual 1Q, *Quality Assurance Manual*. The Program shall identify the activities and items to which it applies and include consideration of the technical aspects of activities affecting quality, including applicable codes, standards, and practices. Line management retains the responsibility for the scope, planning, implementation, and maintenance of an effective overall QA Program within their organizational areas of responsibility.
2. QA Program requirements shall be planned and documented to ensure that a beneficial, cost-effective and systematic approach is utilized and that the appropriate degree of control and verification is accomplished based upon the application and associated risks. Application of the QA requirements

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- shall consider what is to be accomplished, and by whom, in addition to how and when the activity will be accomplished.
3. The QA Program provides for a graded approach to the application of QA requirements for items and activities; however, the graded approach is not used in the Unreviewed Safety Question (USQ) process or in implementing technical safety requirements. The quality requirements for items and activities is planned, controlled, and verified to an extent consistent with their risk. This graded approach is based on a number of factors, including:
 - Functional Classification as defined in Procedure Manual E7, *Conduct of Engineering*
 - consequence of malfunction or failure
 - design and/or fabrication complexity or uniqueness
 - need for special controls and surveillance over processes and equipment
 - degree to which functional compliance can be demonstrated by inspection or test
 - quality history and degree of standardization
 - difficulty of correction, repair, or replacement.
 4. Implementation of this manual for items and services shall be accomplished by line organizations through direct application of this manual's procedures, detailed organizational procedures which implement the QA Manual procedures or a combination of both. The CQF shall concur with the application specified.
 5. Each individual involved in performance of an activity shall be responsible for the quality of their work and for following requirements of the applicable procedures/instructions with line management having final responsibility for the achievement of quality.
 6. Under certain circumstances, as described in procedures identified below, a further description of the application of this manual's procedures is required as related to specific facilities, projects, and tasks. These descriptions shall be accomplished by line organizations as stated below:
 - a. As required by Procedure Manual 11Q, *Facility Safety Document Manual*, nuclear facilities shall have a QA Program description in the Safety Analysis Report.
 - b. For projects implemented within Project, Design and Construction Services, there shall be a description of the QA Program requirements in a Project Specific Quality Assurance Plan or as an integral part of the Project Execution Plan (PEP) for the project.
 - c. For tasks implemented by the Savannah River National Laboratory (SRNL), there shall be a description of the QA Program requirements specific to each task in accordance with Procedure Manual 1Q, Procedure 2-3, Control of Research and Development Activities.
 - d. Other functions, programs, and projects which desire to define the implementation requirements of the QA Program specific to the activity shall prepare QA Plans describing their programs when requested by the CQF.
 7. QA Program controls shall be implemented, at the earliest time, consistent with the schedule for accomplishing the activities. These controls shall be in place prior to producing an item or performing an activity the program is to control. In those circumstances where new requirements are applied to existing operational activities, line organizations shall prepare a specific implementation plan specifying the details of transition and the schedule for the new controls to be in place.
 8. The QA Program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include having the work performed by appropriately qualified personnel to approved procedures, using appropriate equipment under specified

- environmental conditions for accomplishing the activity, assuring that prerequisites for the given activity have been satisfied, and assuring proper in-process reviews and technical support are provided.
9. The QA Program shall provide for any special procedures, work instructions, controls, processes, test equipment, tools, training, and skills to attain and verify the required quality.
 10. The QA Program shall implement Suspect/Counterfeit Item (S/CI) controls to the extent commensurate with the risks posed by the facility and ensure that the controls contribute to a hazard-free workplace. Program elements shall include:
 - a. assurance that all items meet the requirements for their intended use.
 - b. mechanisms to continually update information on S/CIs and associated suppliers.
 - c. maintaining current, accurate information on S/CIs and associated suppliers using all available sources and disseminating relevant information on S/CIs to field organizations and contractors.
 - d. control of the introduction and use of S/CIs through design, procurement, and inspection/maintenance such that no S/CI shall be used or introduced intentionally unless found acceptable through the nonconformance disposition process.
 - e. identification and disposition of S/CIs in safety systems and applications where potential failure could adversely affect the environment, safety, or health of the public, or the health or safety of workers.
 - f. testing of procured, or in-place, S/CIs as necessary (testing methods shall be approved by engineering personnel and done in accordance with applicable procedures).
 - g. training and informing managers, supervisors, and workers of S/CI controls, including prevention, detection and disposition of S/CIs.
 - h. assurance that the standards and methods used in determining the acceptability of items is based on consensus standards and/or commonly accepted industry practices, unless inconsistent with applicable law or otherwise impractical.
 - i. development and implementation of procedures for inspection, identification, evaluation, and disposition of S/CIs in safety systems.
 - j. conducting trend analysis and issuing lessons learned for use in improving all S/CI activities.

S/CIs shall be reported to DOE and the Inspector General in accordance with the following applicable Department of Energy (DOE) Orders: DOE O 231.1A Environment, Safety, and Health Reporting, DOE M 231.1-2, Occurrence Reporting and Processing of Operations Information, and DOE O 414.1C, Quality Assurance. For additional guidance on S/CIs, reference Procedure Manual 1B, *Management Requirements and Procedures*, MRP 5.19, Suspect and Counterfeit Item Program.

B. Quality Assurance Program Documents

The QA Program has been developed to be responsive to the requirements of DOE O 414.1C, Quality Assurance and DOE Safety Rule Title 10 CFR 830 Subpart A, Quality Assurance Requirements. Because of the size and complexity of the Savannah River Site (SRS) and its varied products, services, and missions, the program has been defined in a standard framework of company policy, procedures, and instructions to be used by the implementing organizations to perform quality-related activities. These documents shall, as a minimum, include all of the requirements of WSRC-RP-92-225, Quality Assurance Management Plan (QAMP) criteria for which the implementing organizations have responsibility. These criteria shall be consistent with their importance to reliability, maintainability, operability, and effect on the

environment and safety. The basic documents of the management system which contribute to the definition of the QA Program are shown in Attachment A and are summarized as follows:

1. 1-01, Management Policies, MP 4.2, Quality Assurance

MP 4.2 contains the President's policy statement regarding the Company's commitment to provide products and services which meet or exceed the requirements and expectations of our customers. The Quality Assurance Program is to be implemented in a manner to support implementation of safety, disciplined operations, cost effectiveness, continuous improvement, and teamwork. The Performing Entity has established and implemented an Integrated Safety Management System (ISMS). The QA program is consistent with and an integral part of the ISMS. The policy requires that the program include appropriate procedures to comply with legal, regulatory, contractual, and corporate requirements related to quality. The policy also requires that the QA program comply with DOE O 414.1C, 10 CFR 830, Subpart A and the QA Management Plan. The QA Program applies in a manner which contributes to the safe, reliable, and environmentally sound operation of the SRS. It incorporates a graded approach commensurate with risk in the definition and application of QA/QC requirements. The QA Program provides for the prevention of errors as well as the detection and correction of deficient conditions and incorporates an assessment process for identifying opportunities for continuous improvement. The focus of quality improvement is to reduce the variability of every process that influences the quality and value of products or services.

2. WSRC-RP-92-225, Quality Assurance Management Plan

The QAMP describes the requirements and responsibilities for execution of the QA Program for implementing DOE O 414.1C and 10 CFR 830 Subpart A. American Society of Mechanical Engineers Nuclear Quality Assurance (ASME NQA)-1-2000, Quality Assurance Requirements for Nuclear Facility Applications and other consensus standards are used in the development of the QA Program. The plan is revised annually, jointly approved by the Performing Entity, DOE, and NNSA, when required and serves as the basis for the establishment of the procedures contained in this manual. In case of conflicts, requirements of the QAMP take precedence over requirements in lower-tier documents.

3. Procedure Manual 1Q, Quality Assurance Manual

This manual provides the structure and procedures for achieving and verifying the requirements for quality. The manual consists of a series of Quality Assurance Procedures (QAPs) which describe applicable quality assurance requirements.

4. Procedure Manual 11Q, Facility Safety Document Manual

This manual describes the requirements and guidelines for safety analysis and documentation activities. It also establishes uniform requirements for determining Facility Hazard Categories, managing safety analyses, and implementing 10 Code of Federal Regulations (CFR) 830, Subpart B, Safety Basis Requirements. Safety documents described in this manual include:

- Safety Analysis Reports (SARs)
- Technical Specifications
- Technical Standards (TSs)
- Unreviewed Safety Question Evaluations (USQE)
- Test Authorizations and Test Conclusions (TAs and TCs)
- Operational Safety Requirements (OSRs)
- Documented Safety Analysis (DSA)
- Technical Safety Requirements (TSRs)
- Nuclear Criticality Safety documents, etc.

As required by the Procedure Manual 11Q, descriptions of the QA Program contained in safety documents shall include sufficient detail to enable the reviewer to verify that applicable QA Program requirements are satisfied. The reviews of safety documents shall be performed in accordance with the requirements contained in Procedure Manual 11Q.

5. Integrated Safety Management System (ISMS)

The Performing Entities operate within the framework of the Integrated Safety Management System described in DOE Policy DOE P 450.4, Safety Management System Policy, and the DOE/SRS M&O contract. The overall objective of the policy is to ensure that work is performed safely by adhering to the guiding principles and functions of Integrated Safety Management. Integrated Safety Management has been implemented and verified by DOE at the programmatic and facility level. The cross-linkage between the Integrated Safety Management core functions and the Quality Assurance criteria are identified in the QAMP. The Quality Assurance Program is consistent with, and an integral part of, the Integrated Safety Management System. Integration of Quality, Health, Environment, and Safety requirements into work processes occurs throughout organizations.

6. Procedure Manual 1B, MRP 3.01, Integrated Procedure Management System (IPMS)

The IPMS provides a control system for written management directives in the form of policy, requirements, and procedures. The system applies to the development, approval, release, and maintenance of documents that guide and affect the safety or quality of operations.

7. Project Specific Quality Assurance Plans

- a. QA Program requirements for project type activities including design, modification, procurement, and construction shall be defined and documented by Project Specific Quality Assurance Plans (PSQAP) when not adequately addressed by the existing QA Program. Project type activities include Line Items (LI) and General Plant Projects (GPP); Small Projects, Expense, or Capital Equipment Not Related to Construction (CENRTC). PSQAPs are approved by the CQF unless the PSQAP invoke less controls than normally required by the company's QA program. In these cases, review and approval by the Performing Entity Senior QA Manager is required.
- b. The PSQAPs, developed in conjunction with this manual, define the responsibilities and procedural controls to be implemented by the project organizations to ensure and verify that pre-established requirements have been satisfied. The PSQAP may be provided as an integral part of the Project Execution Plan.
- c. A PSQAP may be written to cover a number of projects having similar activities. This PSQAP will be referenced in the applicable Project Execution Plans.

8. Organizational Procedures

- a. The line organization and the CQFs shall implement the requirements of the QA Program by using the QAPs in this manual directly or through the use of implementing procedures and instructions provided in derivative procedures as described in Procedure Manual 1B.
- b. Organizational procedures implementing this manual shall be approved by the individual assigned responsibility for the organization's QA function.

C. Graded Application of QA Program Requirements

1. The QA Program provides a graded approach to the application of the elements of the QAMP and its implementing administrative controls. The selection of the appropriate controls is dependent on technical, quality and safety requirements.

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2. The organization responsible for establishing the requirements for an item or activity shall determine the classification and, consequently, the technical and quality requirements. Factors to be considered in determining the appropriate elements for control and verifications include:
 - a. The consequence of malfunction or failure.
 - b. The design and fabrication complexity or uniqueness.
 - c. The need for special controls and surveillance over processes and equipment.
 - d. The degree to which functional compliance can be demonstrated by inspection or test.
 - e. The quality history and degree of standardization.
 - f. The difficulty of correction, repair, or replacement.
 3. The responsible Cognizant Technical Function (CTF) determines the applicable technical and quality requirements, including the type and extent of quality verifications (for example, reviews, hold/witness points) to be applied.
 4. The established level and degree of QA administrative controls does not preclude the specification of additional controls.
 5. The proportional application of the levels, types, and intensity of the verification process (for example, design review, inspection, testing, and monitoring) shall be determined by the CTF.
 6. The system or facility shall be assigned the highest functional classification commensurate with the hazards associated with its application or end use. In addition, the functional classification of systems/major components shall also be designated. Applicable quality provisions and extent of control shall be specified consistent with the assigned functional classification for each of the systems/major components.
 7. Implementing procedures shall provide/ensure the assignment of a functional classification down to the individual component or part level, so that the quality provisions can be specified commensurate with the assigned functional classification and be controlled in a cost-effective manner.
 8. When a commercial grade item must be used in a safety-related system or application, the item shall be upgraded/dedicated in accordance with Procedure Manual 1Q, Procedure 7-3, Commercial Grade Item Dedication, to demonstrate its acceptability prior to use.
 9. Provisions shall be made to ensure that subsequent manufacturing, construction, installation, operation, and maintenance actions are taken in a manner consistent with the assigned functional classification for the item/component/facility.

D. Quality Program Assessments

1. Management and Independent Assessment processes are used in a graded approach across programs and projects. The Assessment Program is defined in Procedure Manuals 1Q and 12Q, *Assessment Manual*. Standardized performance objectives and criteria are contained in the WSRC-SCD-4, *Assessment Performance Objectives and Criteria Manual* and can be used in performing assessments.
2. Performance Analysis of the Quality Assurance Program is periodically completed at the company level (Procedure Manual 12Q, PA-1) and the functional program level (Procedure Manual 12Q, PA-2) to identify recurring problems, focus areas for monitoring, and development of corrective actions to prevent recurrence of more serious problems.
3. Operational Readiness Reviews and Readiness Assessments are completed in preparation for startup activities and performed in accordance with Procedure Manual 12Q for the purpose of:
 - a. verifying work prerequisites are detailed and satisfied,

- b. reviewing procedures for adequacy and appropriateness,
- c. ensuring personnel are trained and qualified,
- d. ensuring availability of proper equipment, material, and resources.

Records

Records generated as a result of implementing this procedure are processed in accordance with Procedure Manual 1B, MRP 3.31, "Records Management."

The following quality assurance program documents are to be maintained as quality assurance records in accordance with Procedure Manual 1Q, Procedure 17-1, Quality Assurance Record Management:

- Quality Assurance Management Plan
- Quality Assurance Manual
- Quality Assurance Program Plans
- Safety Analysis Reports
- Management Assessment Reports of the QA Program
- Independent Audits/Surveillances/Assessments
- Organizational Procedures which implement the requirements of this manual

References

- For a current list of Source Document references, go to the Standards/Requirements Identification Document (S/RID) webpage accessible through ShRINE
- Title 10 CFR 71, "Packaging and Transportation of Radioactive Material"
- 10 CFR 63.142, "Quality Assurance Criteria for Disposal of High Level Radioactive Waste in a Geologic Repository"
- 10 CFR 830, "Nuclear Safety Management"
 - Subpart A, "Quality Assurance Requirements"
 - Subpart B, "Safety Basis Requirements"
- 10 CFR 851, "Worker Safety and Health Programs"
- American National Standards Institute/American Society of Quality Control (ANSI/ASQC) E4, "Quality Systems for Environmental Data and Technology Programs - Requirements with guidance for use"
- American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-2000, "Quality Assurance Requirements for Nuclear Facility Applications"
- Department of Energy (DOE) Acquisition Regulations (DEAR) Clauses 970.5204-2
- DOE Acquisition Regulations (DEAR) 970.5204-78, "Laws, Regulations, and DOE Directives"
- Department of Energy/National Nuclear Security Administration (DOE/NNSA) QC-1, "Weapon Quality Policy QC-1"
- DOE M 231.1-2, "Occurrence Reporting and Processing of Operations Information"
- DOE/RW-0333P, "Quality Assurance Requirements and Description (QARD) for the Civilian Radioactive Waste Management Program"
- DOE O 413.3A, "Program and Project Management for the Acquisition of Capital Assets"
- DOE O 414.1C, "Quality Assurance"
- DOE O 221.1, "Reporting Fraud, Waste, and Abuse to the Office of Inspector General"
- DOE O 226.1A, "Implementation of Department of Energy Oversight Policy"
- DOE O 231.1A, "Environment, Safety and Health Reporting"
- DOE Policy 450.4, "Safety Management System Policy"
- ISO 9002, "Quality System – Model for Quality Assurance Production and Installation"
- Policy Manual [1-01](#), *Management Policies*, MP 4.2, "Quality Assurance"
- Procedure Manual [1B](#), *Management Requirements and Procedures*,

- MRP 3.01, “Integrated Procedure Management System (IPMS)”
- MRP 3.31, “Records Management”
- MRP 5.19, “Suspect and Counterfeit Item Program”
- Procedure Manual [1Q](#), *Quality Assurance Manual*,
 - Procedure 2-3, “Control of Research and Development Activities”
 - Procedure 7-3, “Commercial Grade Item Dedication”
 - Procedure 17-1, “Quality Assurance Records Management”
 - Appendix A, Glossary of Terms
- Procedure Manual [11Q](#), *Facility Safety Document Manual*
- Procedure Manual [12Q](#), *Assessment Manual*
 - Procedure PA-1, “Performance Analysis”
 - Procedure PA-2, “Functional Area Program Performance Analysis”
- Procedure Manual [E7](#), *Conduct of Engineering*
- WSRC-RP-92-225, *Quality Assurance Management Plan*
- WSRC [SCD-4](#), *Assessment Performance Objectives and Criteria Manual*

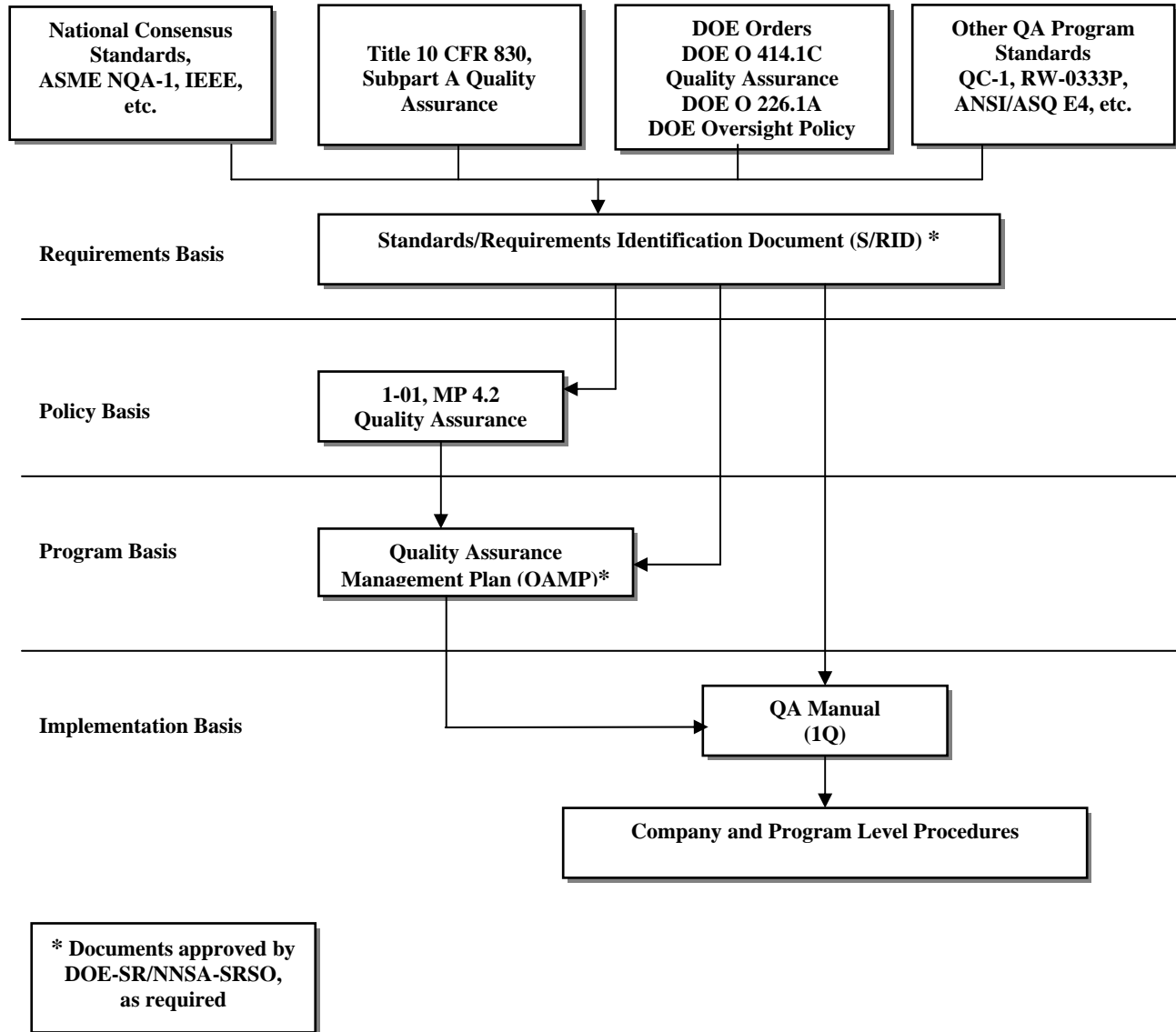
Forms

None

Attachments

Attachment A.	QA Program Description Documents
Attachment B.	Special Quality Assurance (QA) Program Requirements

Attachment A. QA Program Description Documents (page 1 of 1)



Attachment B. Special Quality Assurance (QA) Program Requirements

NOTE: Special QA program requirements apply only to organizations that operate under the specified program.

Special Quality Assurance (QA) Program Requirements to meet DOE/RW-0333P

Procedure Section A, General

Activities addressed in the Quality Assurance Requirements Document (QARD) that specify a frequency schedule for the performance of an activity may be extended by 25% at the discretion of the manager responsible for performing the activity. This flexibility shall not be used to circumvent the next scheduled performance.