LIFE

CYCLE

ASSET

MANAGEMENT

Good Practice Guide
GPG-FM-017

Quality Assurance

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John Adachi, Chicago Operations Office
Victor Buzzanca, Brookhaven National Laboratory
Gustav (Bud) Danielson, Environment, Safety and Health, EH-31
Marie Hirzel, Chicago Operations Office
Rudolph Hirzel, Chicago Operations Office
Ronald Lutha, Fermi Group
George Pomeroy, Field Management, FM-20 (Team Leader)
Terry Williams, Superconducting Super Collider Project Office
Robert Wunderlich, Argonne Group
James Yeck, Brookhaven Group

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1. INTRODUCTION

This Guide is designed to help Department of Energy (DOE) project management teams develop and implement quality assurance (QA) programs for their projects. Although the Guide is targeted for use by DOE project managers and their staffs, DOE contractors may also find it useful. To be most useful to the project management professional, the elements of QA are organized by the various phases of project development.

Project quality is the degree to which a project meets or exceeds the customer's requirements and expectations. In turn, quality assurance encompasses all actions and controls necessary to provide confidence that a project meets predetermined requirements and will perform satisfactorily in service. A QA program (or plan) is a documented management system that details the quality objectives and controls to be applied during the various phases of project work. Its purpose is to ensure quality in all work processes, products, and services, and to support continuous quality improvement.

This Guide presents an overview of quality principles as they relate to projects and illustrates how they can be used to develop effective management systems. Project managers can use this Guide to integrate the concepts and practices of project management and quality management to meet good business practices, consistent with DOE O 430.1, LIFE-CYCLE ASSET MANAGEMENT (LCAM). It focuses on the following topics.

- Identification of the goals and principles of QA.
- Description of the framework and process by which QA programs are developed and implemented.
- Identification of the QA program activities associated with the various phases project development.
- Description of the 10 criteria required by DOE O 5700.6C and 10 CFR 830.120 that form the basis of a comprehensive QA program. See Attachment A.

1.1 Applicability

This non-mandatory Guide may be used for all DOE projects subject to the requirements of DOE O 5700.6C, QUALITY ASSURANCE, and 10 CFR 830.120, Quality Assurance (for nuclear facility contractor projects). It can be used to develop, review and approve QA programs for work conducted by DOE, its contractors and their subcontractors.

Examples of work activities for which QA planning is often needed include project design, construction, fabrication, testing, operations, maintenance, decommissioning, and environmental restoration. It should be noted that not every project will require a unique QA program. In many cases, especially for small or low-risk projects, existing sitewide QA programs may be relied upon under a graded approach.

1.2 Graded Approach

Implementation of QA for project management should incorporate a graded approach. The emphasis and detail appropriate for project QA vary with the size and risk of the project. The goal for project managers is to determine the level of detail and resources necessary to provide reasonable assurance that project quality objectives will be met.

Risk analysis can help determine the appropriate application of QA to a project. Risk refers to the probability and consequences of outcomes associated with a project. Risk analysis is performed for the overall project and may be targeted to significant project components. Elements of risk to be considered include: potential impacts to health and safety, compliance with environmental and other applicable regulations, project complexity, schedule uncertainties or constraints, cost uncertainties, ability to demonstrate functional compliance, uniqueness of technology, and stakeholder expectations. Once risks have been identified, they should be classified as low, medium, or high. Management control and risk mitigation strategies should be selected accordingly. (See *Risk Analysis and Management*, GPG-FM-007.)

In addition to project risk, application of QA may be graded for project size. In general, large projects have significant, dedicated infrastructure for project execution and have dedicated project personnel assigned, whereas medium and small projects may rely more on a mix of in-house and contracted activities during project execution, with limited dedicated project staff. General plant projects may have no dedicated project personnel (although one project manager may manage several small projects at the same time), and project execution activities are often contracted out.

A project-specific QA program incorporating all elements of the QA framework would be expected to apply to a Strategic System of several hundred million dollars. For a smaller project (or one with less risk) the project may rely more on an existing QA program covering the overall site, as well as the QA programs of contractors conducting project work. Under a graded approach, a mix of project-specific and site-based QA program elements may be relied upon to ensure quality on projects of smaller scope.

Attachment B is a Decision Tree that project managers can use as a conceptual aid in applying a graded approach to QA for projects of differing size and risk.

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2. PRINCIPLES AND PROCESSES

2.1 Goals, Principles and Framework

2.1.1 Quality Assurance Goals and Principles

The goals of quality assurance are to provide confidence that: project development occurs in a controlled manner; components, systems and processes are designed, developed, constructed, tested, operated, and maintained according to engineering standards and technical specifications; and resulting technical data are valid and retrievable. Quality assurance begins during preconceptual activities and continues through project design, construction, commissioning, and closeout.

The following principles establish the basis for an effective QA program.

- Senior project management defines policies and objectives and provides resources to carry them out. This includes developing and implementing the QA program.
- Senior project management empowers the personnel performing the work to facilitate meeting project goals.
- Each employee takes responsibility for the quality of his/her work.
- Work is assessed to ensure it meets expectations.
- Personnel conducting work activities are properly qualified to perform work and receive appropriate training as determined by project need.
- All personnel are responsible for continuously pursuing quality improvements to products, services, and work practices or processes. This includes prevention of errors and deficiencies as well as identification and correction of those that occur.
- Project planning is consistent with DOE, program and field office strategic planning, to help ensure that the expectations and requirements of customers are met and that the interests of stakeholders are given due consideration.

2.1.2 Quality Assurance Framework

DOE currently has two QA requirements documents: 10 CFR 830.120 (the rule), which applies to nuclear facility contractors; and DOE O 5700.6C, which applies to all DOE

organizations and contractors not covered by the rule. The quality criteria identified in these two documents are essentially the same. When applied, the QA requirements provide a systematic framework for conducting work performed by DOE and its contractors. The 10 quality-related criteria are organized into three functional groups, as follows.

- Management: program elements, personnel training and qualification, quality improvement, and control of documents and records.
- Performance: control of work processes, design elements, procurement, and inspection and acceptance testing.
- Assessment: management assessment and independent assessment.

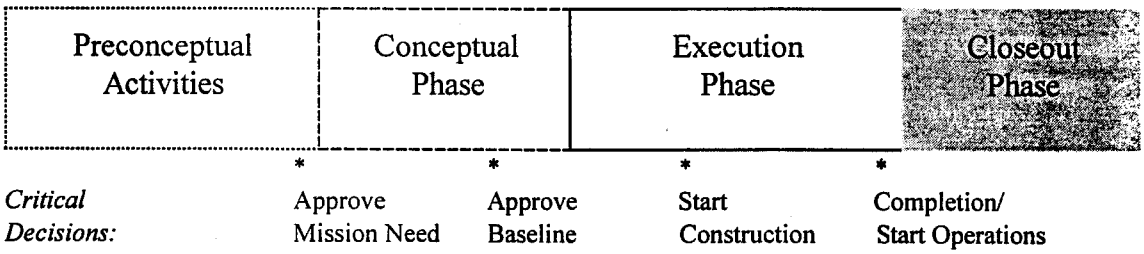
Due to personal experience or convention, project managers may wish to adopt other industry consensus QA standards in developing and implementing the QA program. When using standards such as NQA-1 or Q9001 (identified in section 3, References), the format of the QA program may vary from the 10-criteria format to accommodate different levels of detail. While this variation is acceptable, project managers must still ensure that the requirements of DOE O 5700.6C or the rule are addressed. This can be done through use of a requirements matrix or crosswalk that shows the relationship between the project QA program and the 10 criteria.

Attachment A identifies the 10 criteria and describes how QA activities may be effectively implemented when managing projects.

2.2 Quality Assurance and Project Phases

Quality assurance is an integral part of the DOE project management system. To understand the process of QA program development, it is helpful to review the overall process of project development. DOE uses a phased approach to project management (i.e., preconceptual activities, a conceptual phase, an execution phase, and closeout). See *Project Management Overview*, GPG-FM-001. QA program development is tied to these project phases. Although the discussion of project phases emphasizes large projects, the concepts can also be applied to smaller projects. Figure 1 shows the phases of project development, as delineated by Critical Decision points in the acquisition process for Strategic Systems and Major Systems.

FIGURE 1. Project Phases



2.2.1 Preconceptual Activities

At this initial phase, approval to allocate resources for concept development has not yet been obtained, and there is no assigned project manager. The appropriate program office, in conjunction with the office proposing a project, defines the approach for the project by developing mission need documentation. The documentation typically includes: a clear statement of project goals and a description of how the project will meet these goals; a summary of the anticipated results and benefits to be realized from the project; and a presentation of technical functions, technical performance objectives, and technical interfaces. This initial set of functional requirements forms the basis for subsequent project activities and corresponding QA program elements, which will be used to manage quality during the conceptual and execution project phases. Although a project-specific QA program does not yet exist, work processes conducted in developing the mission need documentation should rely on existing sitewide and contractor QA programs where they exist.

Planning and implementation of QA for projects should be considered within a framework of total quality management and strategic planning. This begins during preconceptual activities. It is important during preconceptual activities that project planning be consistent with DOE program and field strategic planning, including integration with other projects and activities, in keeping with DOE's total quality management objectives. The project should be shown to be an integral part of the program office's mission and objectives and should identify organizational interfaces between the program and field. This helps ensure that the project will conform with the expectations and requirements of its customers, and that the interests of all stakeholders will be given due consideration.

Review of applicable lessons learned from other DOE projects begins during preconceptual activities. These lessons learned may be applied as the project proceeds. Any new lessons learned during the project should be documented during closeout for potential future use by DOE.

Section 3, References, identifies DOE guidance documents on Strategic Planning, Total Quality Management, and Lessons Learned Programs.

2.2.2 Conceptual Phase

At approval of mission need for a large project, the conceptual phase begins. (This is equivalent to the assessment phase for environmental restoration projects.) The emphasis upon project management (i.e., the responsibility for ensuring successful completion of the project) is transferred from the program manager to an assigned project manager. Significant activities include development of the project design concept, trade-off studies, initial environmental assessment documentation, site characterization, safety strategies, baseline development (cost, schedule, scope), and risk analysis. As discussed above, a risk analysis for the project is necessary to implement a risk-based graded approach to quality assurance.

Based on the technical functions, performance objectives, and interfaces defined during preconceptual activities, the qualifications of project personnel and contractors are established. The project team is identified, along with other specific resources that will be required to accomplish project objectives. The project-specific organizational structure, including functional responsibilities, authorities, and lines of communication, are identified. Required project training is established and the document and record control system is planned.

An adequate design basis is established, which defines the project's acceptance criteria and performance capabilities. This information is used to define project-specific criteria for both functional and operational requirements and to develop final design characteristics. Project-specific procedures, work instructions, and specification documents are developed, subject to final design criteria to be established as part of the execution phase.

Performance measures for contracts are developed to assess the physical, technical, schedule, and cost progress of the project. This information is used during the execution phase to define project status in order to identify potential problems, assess their impact, and recommend corrective action. Performance measures are also used as a basis to measure quality improvement.

For a large project, an initial QA program plan or outline is included in the Project Execution Plan, which is part of the baseline to be established or approved upon completing the conceptual phase and entering the execution phase. Although a project-specific QA program document will not generally be approved until early in the execution

phase, project managers rely on preliminary QA program plans for the project as well as existing sitewide or contractor QA programs.

Table 1 presents a crosswalk of the major project activities and the associated QA program activities during the conceptual phase.

Table 1. Conceptual Phase.

Project Activity	QA Criterion No./QA Activities
Design concept (scope)	6 Identify design basis 6 Control of design input 7 Contractor selection/oversight
Cost estimates	4 Document preparation, review, approval
Schedule estimate	4 Document preparation, review, approval 5 Work control
Trade-off studies/ Constructability studies/ Risk analysis	1,6 Identify hazards/grading 6 Identify design basis 6 Control of design input 7 Contractor selection/oversight
Initial NEPA documentation	4 Document preparation, review, approval
Identify codes/standards	1 Identify hazards/grading 6 Identify design basis
Preliminary safety strategies	1,6 Identify hazards/grading

2.2.3 Execution Phase

The conceptual phase is followed by the project execution phase, with establishment or approval of the project baseline. The two phases are interrelated in that conceptual design documentation leads to project execution planning documentation defined by specific project requirements. The project-specific QA program is approved by DOE early in the project execution phase.

During this phase, QA control processes defined in the QA program are implemented. To ensure that results will satisfy project objectives, periodic design reviews are conducted, as required by good engineering practice, during both preliminary and detailed design stages. Management and independent assessments are performed, significant differences between planned and actual performance are noted and analyzed, nonconformances and potential

quality-related problems are identified, documented, and monitored, and corrective actions implemented as needed.

Planning documentation, including the QA program, guides the project throughout the execution phase: from conceptual design through development of preliminary and final designs, through implementation and construction of the design in accordance with project-specific requirements, to final completion or acceptance of the project. From a quality assurance perspective, it is useful to consider the project execution phase as three process activities: design, procurement, and construction (fabrication or remediation). Tables 2 through 4 present the crosswalks of project activities and associated QA activities.

DESIGN PROCESS: During preliminary and detailed design development, important supporting activities include: establishing the organization (hiring and training staff); developing design specifications and inspection/testing criteria; conducting Constructability studies; developing design control processes; and developing the design acquisition strategy. Designs should incorporate sound engineering standards and scientific principles, while meeting customer requirements. Adequacy of the design is verified before being implemented.

Preliminary project design uses the conceptual design as its basis. Trade-off studies are used to evaluate alternative design approaches, including quality levels for project components and specifications for procuring equipment. The project manager should ensure that processes are adequate so that design inputs are correctly translated into design outputs. Design inputs may include seismic and accident analyses, materials compatibility requirements, maintainability and reliability requirements, and commercial/industrial codes; design outputs may include specifications, drawings, procedures, and instructions.

The project's design control system ensures correct design outputs by: controlling interfaces among engineering disciplines; ensuring that changes resulting from design reviews are sufficiently incorporated and documented; and providing verification by qualified staff independent of the original design work. Controls should be appropriate for the size and risk of the project.

PROCUREMENT PROCESS: Procurement activities occur throughout the project execution phase, and may begin with the selection of a vendor to perform the design. Procurement activities include: developing procurement specifications, selecting vendors, and preparing and issuing bid packages. Related QA program activities include: document

Table 2. Execution Phase - Design Process.

Project Activity	QA Criterion No./QA Activities
Preliminary design (Title I)	6 Design preparation 6 Design review/approval 6 Design verification/validation
Detailed design (Title II)	6 Design preparation 6 Design review/approval 6 Design verification/validation
Detailed cost estimate	4 Document preparation/review/approval
Detailed schedule	4 Document preparation/review/approval 5 Work processes/control
Project plans and documentation Constructability Acquisition strategy	1 Project QAP issued 1 Define organizational structure 2 Develop project training 4 Identify/control project records 5 Procedures developed 6 Design control 7 Contractor selection/oversight

preparation and records retention, identification and tracking of vendor performance criteria and standards, and inspection and testing.

Depending on the complexity of the equipment or service to be procured, information should be obtained to assure the project manager that the vendor can produce the desired result. If the vendor is performing inspections and tests, the personnel qualifications and equipment calibration should be examined. Any manufacturing and assembly activity determined to be critical should have a witness and/or hold point assigned for verification of acceptability. The required documentation (including inspection/testing) should then be provided with the equipment when shipped. Receipt inspection should be performed to check for damage during shipping and to verify that all necessary documentation has been provided.

Information on the vendor's performance should be tracked. For procured equipment and materials, information gathered during receipt inspection should be sufficient. However, for procured services, information must be gathered other ways. Options include inspections, surveillances, standard reports to be generated by the vendor, and assessment results. Incentives or penalties for good or poor performance should be included in the procurement documents.

Table 3. Execution Phase - Procurement Process.

Project Activity	QA Criterion No./QA Activities	
Develop procurement specs	6,7	Manufacturing/performance criteria defined
	6,8	Standards/tests defined
Vendor selection	7	Vendor surveys/source inspections
	3	Track vendor performance
Prepare purchase orders	4	Document preparation/review/approval
Bid packages	4	Document preparation/review/approval
Receipt inspection	7,8	Material inspection and testing
	4	Certs/testing documentation provided

CONSTRUCTION PROCESS: The term "project construction," when used in this Guide, refers to physical construction, environmental remediation, demolition, dismantlement, decommissioning, and associated work processes.

Construction process activities within the project execution phase include: construction management, configuration management, training, records management and documentation, safety management, environmental management, and a host of related work processes. During construction, project turnover activities are ongoing including: documenting all final procedures and configurations, securing all necessary permits and licenses, ensuring that all acceptability criteria are met, and compiling completion/acceptance documentation. QA program activities related to construction include: training, quality improvement (deficiencies identified/tracked/corrected), document control and retention, identifying process procedures, inspection/testing, and assessments.

Depending on project scope, not all of the project activities listed in the construction process table may occur. As a result, only the QA criteria listed with the actual activity being performed need to be addressed.

2.2.4 Closeout Phase

Project closeout includes project transition, physical closeout, and financial closeout. It begins with approval to start operations and acceptance of beneficial occupancy, and ends when financial closeout activities are completed. During closeout, the project manager maintains responsibility for implementing transition planning developed during the execution phase. The office taking beneficial occupancy and operating responsibility for

Table 4. Execution Phase - Construction Process.

Project Activity	QA Criterion No./QA Activities	
Construction support	2	Provide training
	2	Personnel qualification
	3	Track/trend deficiencies
	4	Document control
	4	Records control
Facility/site work and Equipment manufacturing/ installation	3	Identify deficiencies
	4	Results documented
	5	Procedures used
	5	Tools/equipment calibrated
	6	Field changes
	6	Configuration control
	7	Receipt inspection performed
	7	Certs/testing documentation supplied
	8	M&TE calibrated
	9,10	Assessment results are documented
Equipment inspection and testing	4	Results documented
	5	Procedures used
	6	Equipment performs as designed
	8	Hold/witness points used
	8	Acceptance criteria defined
	8	M&TE is calibrated
	8,9	Deficiencies are corrected
Systems testing	4	Results documented
	5	Procedures used
	6	Equipment performs as designed
	8	Acceptance criteria defined
	9	M&TE is calibrated
	8,9,10	Deficiencies are corrected
	9,10	Assessment results are documented
Systems turnover	3	Deficiencies are corrected
	4	Records assembled in turnover packages
	5	System status identified
	6	Drawings as-built
	9	Acceptability of work determined

the project receives documentation transferred from project management. This documentation commonly includes: environmental and safety reports, design basis documents, as-built drawings and specifications, configuration management documents, equipment manuals, and permits and licenses. Upon acceptance of the project, the field organization authorizes the project manager to complete closeout activities. These include: development of lessons learned, contract closeout, and organization transition.

Upon project acceptance and during project closeout, most QA program activities have already been completed. Remaining QA program activities include: document and records control, record retention and maintenance, and lessons learned development. The QA program criteria are more fully described in Attachment A. Table 5 summarizes the crosswalk of project activities and associated QA program activities for closeout.

Lessons learned has more to do with quality improvement for subsequent projects, and is part of DOE's total quality management (see section 3, References, for DOE guidance documents on Total Quality Management and Lessons Learned Programs). As discussed earlier, during preconceptual activities, mission need should be consistent with DOE program and field strategic plans, and any applicable lessons learned should be reviewed for use on the project. Correspondingly, during closeout, any lessons learned should be made available for planning subsequent DOE projects. Lessons learned bring the project full circle, supporting DOE's strategic planning objectives for efficiency and effectiveness.

2.2.5 Project Phase Summary Tables

QA activities and associated quality criteria commonly included in the various project phases are summarized in Attachment C.

2.3 Tools

A Decision Tree for QA application is included as Attachment B. It provides a conceptual guide to assist the project manager in determining how the 10 QA Criteria should apply to projects of different size and risk. (See section 1.2, Graded Approach.)

Table 5. Closeout Phase.

Project Activity	QA Criterion No./QA Activities	
Lessons learned	3	Quality Improvement
	TQM	See Appendix C
Records turnover	4	Records control/retention
Readiness review	10	Independent assessment
	3	Deficiency resolution/closure
Contract closeout	4	Control of project records
	7,9	Work/services completed
Organization transition	1	Total quality management
	TQM	See Appendix C

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3. REFERENCES

Department of Energy

- DOE O 5700.6C, QUALITY ASSURANCE, 1991.
- DOE-ER-STD-6001, "Implementation Guide for QA Programs for Basic & Applied Research," 1994.
- U. S. Code of Federal Regulations, 10 CFR 830.120, "Quality Assurance."
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Q9001, "Quality Systems--Model for Quality Assurance in Design, Development, Production, Installation, and Servicing," 1994.

E4-1994, "Quality Systems Requirements for Environmental Programs."

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4. DEFINITIONS

For definition of major terms used in this Guide, see the Consolidated Glossary.

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5. ASSISTANCE

Questions concerning this guidance document may be referred to the Office of Field Management in Washington, D.C. at (202) 586-4041.

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QUALITY ASSURANCE CRITERIA

The Department of Energy (DOE) currently has two quality assurance (QA) requirements documents: 10 CFR 830.120 (the QA rule), which applies to nuclear facility contractors, and DOE O 5700.6C, which applies to all DOE organizations and contractors not covered by the rule. The criteria of these two documents are essentially the same. For each of the 10 criteria, text from the QA rule is provided below in italics. Following the rule text is a description of how QA activities may be implemented to effectively manage projects. Project managers can use this guidance in developing a QA program appropriate to the size and risk of specific projects.

1. **Criterion 1 - Program.** *A written Quality Assurance Program (QAP) shall be developed, implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe the management processes, including planning, scheduling, and resource considerations.*

1.1 **Project Description**. Prior to establishing an organizational structure, or developing management systems, an understanding of the scope and characteristics of the project is necessary. During preconceptual activities, a detailed project description should be prepared.

Content of the project description depends on the nature of the project, but usually contains a general overview of the project, and may also include:

- purpose of the project, study, design, or work;
- design, process, operating, facility, or site parameters;
- schedule and cost projections;
- project-specific risk analysis factors (including failure consequences, failure probability, complexity or uniqueness of design or fabrication/construction, safety and health impact, special controls, degree of standardization, quality history, ability to demonstrate functional compliance, data generation function, environmental impacts, programmatic impact, and stakeholder expectations);
- description of the design process.

1.2 Project Organization. The project organization, responsibilities/authorities of key project participants, internal and external interfaces, and line of communication should be established during the conceptual project phase.

The following should be considered, depending on project characteristics.

- Work assigned to each project participant should be identified.
- A detailed project organizational structure, including the QA coordinator and participants outside the primary project organization, should be established and delineated on a project organization chart.
- Relevant experience, qualification/certification, and specialized training requirements of key project positions should be established.
- Key participants, in charge of major project activities, should be identified.
- Individuals' responsibilities/authorities should be defined, including authority to stop unsatisfactory work, and communications established.

1.3 Management Systems. The management systems of each project participant should be established and documented.

Descriptions of the project's technical and managerial functions should be developed, which may include the following.

- Managerial functions, such as: planning; cost control and estimating; purchasing; training and personnel development; preparing, reviewing, approving, and issuing instructions, procedures, manuals, schedules, and procurement documents; controlling and maintaining records.
- Technical functions, such as: preparing, reviewing, approving, and verifying designs; qualifying and selecting suppliers; verifying work by suppliers; controlling and identifying hardware and software; manufacturing, fabrication, and construction; facility operation; calibrating and controlling measuring and test equipment; maintenance, repairs, and improvements; conducting investigations, inspections, testing, and data acquisition; performing assessments; and controlling and maintaining records.

2. Criterion 2 - Personnel Training and Qualification. *Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.*

2.1 Determining Qualification/Training Needs. During the planning for each project phase, management should determine the qualification and training needs of project personnel. Qualification requirements such as level of experience, education, and specialized training should be established for critical technical, quality, and management job categories of the project.

Training should provide for the maintenance of proficiency in technical, managerial, and supervisory skills, as well as for progressive enhancement beyond initial qualifications.

Tasks that require such specialized skills/abilities to demonstrate proficiency should be identified. The skills/abilities of personnel performing such tasks should be verified prior to performing the work, and demonstrated periodically thereafter to verify continued proficiency. Examples of such tasks may include welding, heat treatment, and nondestructive testing.

2.2 Implementation of Training/Qualification Program. Management ensures that all project personnel are capable of performing assigned tasks effectively, safely, and efficiently. Efforts start with selecting personnel who satisfy position qualification requirements and extend to requiring participation in ongoing training to maintain and enhance skills. The extent and level of formality of a training program should be commensurate with the scope and complexity of the project.

Training programs should ensure that:

- training curricula address specific project needs;
- training emphasizes an understanding of quality and technical requirements and the consequences of improper work;
- personnel are adequately trained before performing work;
- personnel understand the processes involved in their tasks;
- personnel are made aware of the extent and sources of variability affecting performance and the degree to which they have control over the variables.

Training programs should be periodically reviewed to evaluate their effectiveness and upgraded if necessary.

3. Criterion 3 - Quality Improvement. *Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services and processes needing improvement.*

3.1 Controlling Nonconformances. An important aspect of quality improvement, especially in the project execution phase, is control of nonconforming items and processes. A nonconformance is a deficiency in the characteristics, documentation, or procedure that renders a material, component, assembly, or process unacceptable.

The project should establish a system to identify, evaluate, control, and correct nonconformances. The level of rigor and formality of the evaluations, actions, and documentation of a nonconformance system should be commensurate with the project's scope, complexity, and risk.

A project's nonconformance system should address the following.

- All project personnel should have authority to identify nonconformances and stop work when the nonconformance creates an imminent life-threatening hazard.

- Nonconforming items and processes should be controlled and/or segregated to prevent their inadvertent use.

- Nonconformances should be evaluated by appropriate technical personnel. The cause of nonconformances should be determined to enable measures to be instituted to prevent recurrence. The extent and formality of the root cause analysis should be commensurate with the significance of the deficient condition.

- Nonconformances, their disposition (e.g., use as is, rework, scrap, repair, return to vendor) and associated corrective action should be appropriately documented. The status of nonconformance reports should be tracked

through completion of the resulting corrective action(s). The implementation and effectiveness of corrective actions should be verified.

3.2 Improving Quality. The project should establish and implement other processes to promote continuous improvement in areas such as reduction of process variability and increasing component/system reliability.

The project should implement activities that allow potential problems and opportunities for improvement to be identified. Examples of such processes include:

- identifying performance standards and establishing associated performance measures;
- analyzing applicable performance data and trends, including costs related to failures and downtime due to unscheduled maintenance;
- design reviews and configuration control;
- peer reviews;
- risk and safety analysis;
- value-engineering;
- constructability, reliability, availability, and maintenance reviews; and
- management and independent assessments.

4. Criterion 4 - Documents and Records. *Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.*

4.1 Documents. Documents establish policies, prescribe work and processes, specify requirements, and establish design.

The number and type of document varies with the size, scope, characteristics and complexity of the project. Examples include:

- statements of work;
- system descriptions;
- safety analysis reports;
- specifications;
- design, manufacturing, fabrication, and construction drawings;
- design engineering calculations;
- vendor equipment manuals;
- contract, subcontract and procurement documents, purchase orders;
- project plans, QA programs, manuals, procedures, and instructions;
- data files; and
- software code.

The project should establish a system to control the preparation, review, approval, issuance, use, and revision of documents. The level of rigor and formality of a document control system should be commensurate with the risk the control of the document has on the project.

- Responsibility/authority for the preparation, review, approval, and revision of documents should be established.
- Controls should be instituted that ensure that document revisions are distributed, and that only the current version of documents are used by persons performing work impacted by those documents.

4.2 Records. Records document the quality of items, services, processes, and design.

The number and variety of records will vary with the size, scope, characteristics, and complexity of the project. The records that must be generated and maintained for a project should be determined and specified during the planning stages of each project phase. Examples include:

- design records;
- records of environmental conditions;
- applied research and development records;
- data acquisition records;
- procurement records;
- manufacturing, fabrication, and construction/installation records;
- inspection and testing records;
- maintenance and repair records;
- modification and as-built configuration records; and
- measuring and test equipment calibration records.

The project should establish the responsibilities/authorities regarding the preparation, review, approval, and revision/correction of records. The formality of a records system should be commensurate with the size and risk of the project.

Systems for records storage/maintenance/retrieval should be established. Record retention periods should be established. The protection afforded to records, and their length of retention, should be commensurate with the relative importance of the record.

5. Criterion 5 - Work Processes. *Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.*

5.1 Work. Work includes the tasks/activities that comprise management, administration, procurement, research, engineering, design, manufacturing, fabrication, installation, construction, operations, maintenance and repair/modification, software development and use, inspection and testing, investigation and assessment, data acquisition, and analysis.

- Personnel performing work are responsible for the work's quality. They should be knowledgeable of the requirements and processes of the work they perform. Management should ensure personnel have the necessary training, resources, and controls/systems to accomplish assigned tasks.

- Work processes and output should be reviewed by management to ensure the desired quality is achieved and to identify areas in need of improvement.

- Commensurate with the work's complexity and risk, work should be planned, authorized, and accomplished under controlled conditions using technical standards, instructions, and/or procedures.

5.2 Identification, Control, Storage and Handling of Items. During the conceptual phase of the project, items critical to project quality should be identified. Processes for the identification, control, maintenance, storage, handling, shipping, cleaning, and preservation should be established. These processes should ensure appropriate traceability; control consumables and items of limited shelf life; prevent use of defective items; control samples; prevent damage, loss, deterioration, or contamination; and provide for special protective measures, such as containers, shock absorbers, inert gas atmospheres, or specific temperature and humidity levels.

5.3 Calibration and Maintenance of Monitoring and Data Collection Equipment. Depending on the characteristics of the project, measuring and testing equipment (M&TE) used for monitoring and data collection should be appropriately maintained, controlled, and calibrated to ensure the accuracy of the measurements/data.

Monitoring and data collection activities that merit such controlled and calibrated M&TE should be identified. The accuracy requirements should be established. The type of M&TE should be specified. Calibration of M&TE should be traceable to national standards, where possible.

6. Criterion 6 - Design. *Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.*

6.1 Design Inputs. Design inputs may include seismic, stress, hydraulic, radiation, magnetic, and accident analyses; design bases; fire protection requirements; compatibility of materials; cost comparisons; access, repair, maintenance, and reliability requirements; and requirements from Code of Federal Regulations and appropriate commercial and industrial codes.

Preliminary project design uses the conceptual design as its design basis. Preliminary design generally entails trade-off studies, including evaluation of alternative design approaches, definition of project design criteria and establishment of quality levels for project components and systems, and development of specifications for equipment procurement.

6.2 Design Outputs. Design inputs should be correctly translated into design outputs, such as specifications, drawings, procedures, and instructions. The project's design control system ensures correct design outputs by providing for the following, as appropriate to the complexity and risk of the project.

Design control procedures provide for the control of design requirements, processes, outputs, reviews, revisions, records, and interfaces among engineering disciplines within the design organization as well as with other project participants whose work affects design.

Documented review of each design ensures that design inputs are appropriately translated into the design and that any design revisions resulting from the review are sufficiently incorporated.

Design records should include not only the final design and any revisions, but also evidence of sources of input and important design steps, such as calculations, analyses, and computer programs that support the final design.

Changes to final designs resulting from field changes, modifications, and nonconforming items dispositioned as use-as-is or repair should be justified and subjected to design control measures consistent with the original design.

6.3 Design Verification. The acceptability of design work and documents, including design inputs, processes, outputs, and changes, should be verified before approving and implementing the design.

- The extent of verification should be commensurate with the complexity, risk, and uniqueness of the design. Verification methods include design reviews, alternate calculations, and qualification testing.

- Design verification should be performed by qualified individuals or groups independent of the original design work; however, the individuals may be from the same organization.

7. Criterion 7 - Procurement. *Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.*

7.1 Requirements for Procured Items/Services. During the design phase, the project identifies and develops the appropriate specifications, drawings, scope of work, and other documentation necessary to enable procurement of the desired items or services. Project technical and quality requirements, including acceptance criteria, should be included in procurement documents. To ensure compatible quality, consideration should be given to procurement of spare parts along with the original equipment using the same technical requirements.

7.2 Supplier Selection. Procurement processes should be established for evaluating prospective suppliers to determine if they can satisfy project needs. Prospective suppliers may be evaluated through assessment/inspection of the supplier's operation and/or products and evaluation of their quality history. The prospective supplier's financial stability, order backlog, and production capability should be evaluated to determine if they can support the project's schedule needs. Sub-tier suppliers of the prospective supplier should also be considered in these evaluations.

7.3 Monitoring and Acceptance of Procured Items/Services. The project organization should implement activities to ensure that procured items and services meet their established requirements and will perform as specified. The level of rigor of these activities should be commensurate with the complexity and risk associated with the procured item/service.

Depending on the importance of the procured item/component/system, suppliers, and as appropriate sub-tier suppliers, may be monitored periodically to verify continued acceptability.

Procured items and services should be accepted using approved methods, including review of manufacturing/fabrication process control data, source verification, receipt inspection, pre- and post-installation testing, certificates of conformance, or a combination of these methods.

Procedures and controls should be instituted to prevent acceptance of substandard, suspect, or counterfeit parts in procured items/components.

Prior to placing a procured item into service, procurement specification inspection and test requirements should be satisfied. Nonconformances should be properly dispositioned before the item is used.

8. Criterion 8 - Inspection and Acceptance Testing. *Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.*

8.1 Inspection and Acceptance Testing. Work products to be inspected and/or tested should be identified, and the appropriate type of inspection or testing and corresponding acceptance criteria should be defined. The rigor of inspections and acceptance testing, and the extent of documentation of the inspection or test procedure and resulting data, should be commensurate with the complexity and risk of the item/process. The project should institute administrative controls to ensure that required inspections and tests are performed.

Types of inspection may include source, in-process, final, receipt, maintenance, and in-service. Examples of testing include: bench tests and proof tests prior to installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests.

Procedures that document the inspection or test process may describe: prerequisites and instructions to perform the inspection/test; requirements for data, accuracy, and M&TE; test configuration; and acceptance criteria.

Records that document the results of inspections or tests may include: identification of item or process; measurements taken; the acceptance criteria; the M&TE used; description of any deficiencies identified by the inspection/test; an acceptance/rejection statement; and identification of the individual who performed the inspection/test.

Inspections and acceptance tests may be performed by the organization responsible for the work being inspected/tested; however, persons should not inspect or test their own work.

8.2 Measuring and Testing Equipment. M&TE used for performing inspections and acceptance testing should be selected and controlled to ensure they are of the proper type and provide appropriate range, accuracy, and tolerance for the purpose. The project should establish an M&TE calibration and control system to accomplish this, commensurate with the complexity and risk associated with the project.

Procedures should be implemented that identify the M&TE to be calibrated, describe the method and frequency of calibration, establish accuracy requirements, and describe proper M&TE maintenance.

M&TE should be uniquely identified to enable traceability to test data.

M&TE should be properly maintained and recalibrated at specified intervals. Recalibration frequency should be based on the required degree of accuracy, purpose, frequency of use, and stability characteristics. Calibration should be traceable to nationally recognized standards, when such standards exist.

If M&TE is found to be out of calibration, the validity of previous inspections/tests performed using that M&TE should be evaluated.

9. Criterion 9 - Management Assessment. *Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.*

9.1 Scope of Assessment Activities. All levels of management should periodically assess the performance of the project to determine if leadership is being provided to continuously meet customer requirements and expectations. The rigor, level of formality, and frequency of management assessments should be commensurate with the size, scope, complexity, and risk associated with the project. Participation of senior management in planning and performing management assessments is important.

Management assessments should evaluate how well the integrated management system focuses on meeting project goals, rather than on strict compliance with a myriad of detailed requirements. Such assessments should identify management systems that impede, as well as those that encourage, the success of environmental, safety, and quality efforts. Management assessments should also determine the

adequacy of management controls, resources, personnel, and project planning documents for achieving project goals.

Project information systems can provide valuable inputs for management assessments. Such information systems may include management walkthroughs, periodic project review meetings, action tracking systems, performance measures, occurrence reports, nonconformance reports, failure reports, repair/maintenance reports, trend analyses, surveillance and assessment reports from internal and external organizations, and corrective action status reports.

9.2 Reporting. Management assessments should be sufficiently documented to facilitate dissemination of the information gained from conducting the assessment. Recommendations resulting from a management assessment should receive prompt response and act as drivers for the quality improvement process.

10. Criterion 10 - Independent Assessment. *Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.*

10.1 Scope of Assessment Activities. Independent assessments should be periodically conducted or sponsored to evaluate the performance of work processes with regard to customer requirements and project goals. Assessments should also address management processes that affect work performance, such as planning and training. The scope, rigor, level of formality, and frequency of assessments should be commensurate with the size, scope, complexity, and risk associated with the project. Independent assessments should be conducted using established criteria for acceptable work performance. The assessments should focus on process results and finding opportunities to enhance overall project quality.

10.2 Reporting. Results of independent assessments should be documented and reported to a level of management sufficient to take action to correct any cited problems. Responses to independent assessments should address remedial corrective measures, analysis of the root cause of the problem, and any actions taken to preclude recurrence of the problem. Actions should be tracked to completion, and the effectiveness of the corrective actions should be verified.

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SUMMARY SHEET: QA Activities within Project Phases

QA Criteria	Preconceptual Activities	Conceptual Phase	Execution Phase			Closeout Phase
			Design Process	Procurement Process	Construction Process	
1. Program		○ Responsibilities/ interfaces identified ♦ Risks/grading/ standards identified	♦ QA program established ○ Org. structure defined			♦ Organization transition
2. Training		○ Project training developed	○ Project training provided		♦ Project training provided	
3. Quality Improvement	♦ Lessons learned reviewed/ used	○ System developed	○ Establish system	○ Vendor performance tracked	♦ Deficiencies identified/ tracked/ trended	
4. Documents and Records		○ Document prep./ review/ approval	○ Document prep./ review/ approval ○ Project records identified/ controlled	○ Document prep./ review/approval ○ Project records controlled	♦ Project records controlled ♦ Document preparation/ revision control	♦ Records turnover/ retention
5. Work Processes		○ Project plans & procedures developed	○ Project plans & procedures established		♦ Procedures used ♦ Tools/equip. calibrated ♦ Personnel qualified	
6. Design		♦ Basis identified ♦ Design inputs controlled	♦ Preparation ♦ Review/approval ♦ Verification/ validation	♦ Procurement specs developed	♦ Field changes controlled ♦ Configuration controlled	
7. Procurement		♦ Contractor selected/ oversight	♦ Contractor selected/ oversight	♦Vendor surveys/ source inspections ♦ Receipt inspection		

♦ Key Activities

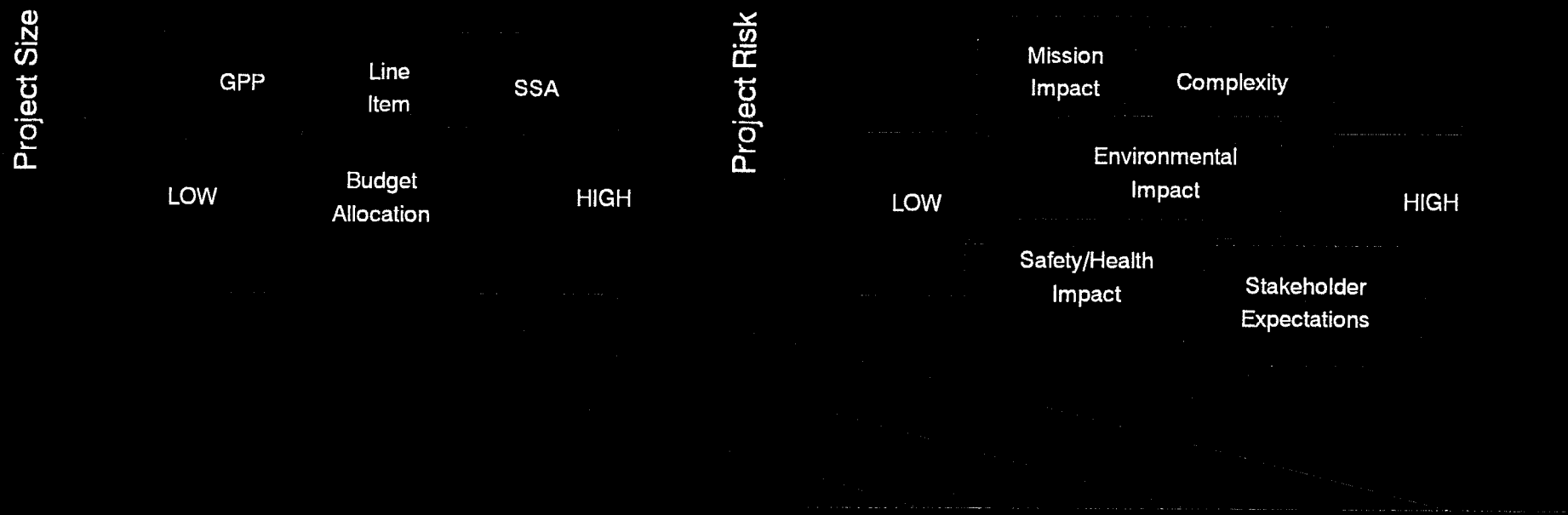
SUMMARY SHEET: QA Activities within Project Phases (continued)

QA Criteria	Preconceptual Activities	Conceptual Phase	Execution Phase			Closeout Phase
			Design Process	Procurement Process	Construction Process	
8. Inspection and Testing				♦ Criteria defined	♦ qualified ♦ Tools calibrated ♦ Results documented	
9. Management Assessment			○ Scheduled/ performed		♦ Results documented ♦ Deficiencies corrected	
10. Independent Assessment			○ Scheduled/ performed		♦ Personnel qualified ♦ Results documented ♦ Deficiencies corrected	
11. Total Quality Management	♦ Strategic Plan integrat. ♦ Customer/ stakeholder needs identified					♦ Lessons learned documented

♦ Key Activities

Attachment B

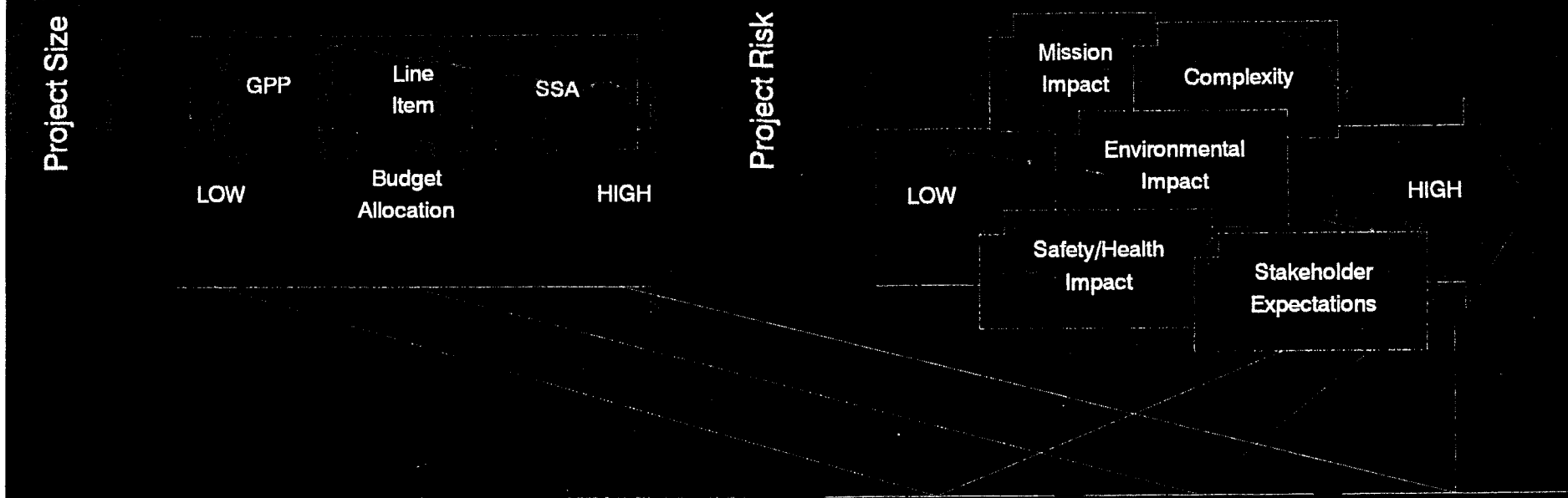
QA Application Decision Tree



Low $/Low Risk	Med $/Low Risk	High $/Low Risk	Low $/High Risk	Med $/High Risk	High $/High Risk
Use site-wide QAP with primary emphasis on procurement, and records management.	Develop and use project specific QAP which addresses design, work processes, and inspection/ test; and refers to site-wide programs for training, records management, quality improvement, procurement, and assessment.	Develop and use project specific QAP which addresses all 10 criteria. Consider using site-wide programs for training, quality improvement, records management, and assessment.	Use site-wide QAP with primary emphasis on procurement and records management. Consider using design control and inspection/test for identified risk areas.	Develop and use project specific QAP which addresses records manage-ment, design, work processes, procurement,and inspection/test; and refers to site-wide programs for training, quality improvement, and assessment.	Develop and use project QAP which addresses all 10 criteria including project specific programs for training, design, records management, procurement, work processes, inspection/test, and assessment.

Attachment B

QA Application Decision Tree



Low $/Low Risk	Med $/Low Risk	High $/Low Risk	Low $/High Risk	Med $/High Risk	High $/High Risk
Use site-wide QAP with primary emphasis on procurement, and records management.	Develop and use project specific QAP which addresses design, work processes, and inspection/ test; and refers to site-wide programs for training, records management, quality improvement, procurement, and assessment.	Develop and use project specific QAP which addresses all 10 criteria. Consider using site-wide programs for training, quality improvement, records management, and assessment.	Use site-wide QAP with primary emphasis on procurement and records management. Consider using design control and inspection/test for identified risk areas.	Develop and use project specific QAP which addresses records manage-ment, design, work processes, procurement,and inspection/test; and refers to site-wide programs for training, quality improvement, and assessment.	Develop and use project QAP which addresses all 10 criteria including project specific programs for training, design, records management, procurement, work processes, inspection/test, and assessment.