

US EPA ARCHIVE DOCUMENT



Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation

EPA QA/G-11

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed an Agency-wide Quality System, which is authorized by EPA Order 5360.1 A2 (U.S. EPA, 2000a). The Order provides that all environmental programs performed by or directly for EPA are to be supported by individual quality systems that comply fully with the American National Standard *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* [American National Standards Institute/American Society for Quality Control (ANSI/ASQC) E4-1994] (ANSI/ASQC, 1994). While previous guidance and requirements documents published by EPA have focused primarily on quality systems for environmental data collection, this *Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation* describes how to develop a quality system for environmental technology programs.

This document provides guidance to EPA program managers and planning teams as well as to the general public as appropriate. It does not impose legally binding requirements and may not apply to a particular situation based on the circumstances. EPA retains the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may periodically revise this guidance without public notice.

This document is one of the *U.S. Environmental Protection Agency Quality System Series* documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. After five years from the date of publication, EPA plans to review this document and either reissue it without modification, revise it, or remove it from the *U.S. Environmental Protection Agency Quality System Series* documents. Questions regarding this document or other *Quality System Series* documents should be directed to the Quality Staff at:

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PREFACE

Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation provides a technical overview for applying quality assurance (QA) and quality control (QC) practices to engineering projects involving environmental technologies, an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment.

This guidance document is intended for use by technical managers and QA staff responsible for engineering design, construction, and operation, by: (1) providing basic guidance on applicable QA and QC practices; (2) outlining engineering planning, construction, and operation processes that may require QA and QC elements; and (3) identifying resources and references that may be utilized by environmental professionals during the design, construction, and operation of environmental technologies.

The guidance discussed is non-mandatory and is intended to be a technical engineering and QA guide for project managers and QA staff in environmental programs to help them to better understand when and how QA and QC practices should be applied to engineering work. That is, it is a resource for users to help them understand the range and scope of QA and QC practices in support of environmental technologies. This guidance is not written exclusively for engineers even though highly-technical engineering terminology and recognized good engineering principles/practices are used, but may be used by managers with non-engineering backgrounds. As a further aid, the guidance uses and refers to applicable *basic quality principles* when discussing the application of QA and QC during a project.

Accordingly, this guidance should not be regarded as an engineering manual or as a complete reference on basic quality principles.

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CHAPTER 1

INTRODUCTION

1.1 PURPOSE AND OVERVIEW

The purpose of this guidance is to provide users with an understanding of the basic quality assurance (QA) and quality control (QC) procedures that may be used in planning, implementing, and assessing the design, construction, and operation of *environmental technologies*, an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. This guidance is intended to complement the requirements defined in the American National Standard *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4-1994) (ANSI/ASQC, 1994) by (1) providing basic guidance on applicable QA and QC practices; (2) outlining engineering planning, construction, and operation processes that may require QA and QC elements; and (3) identifying resources and references that may be utilized by environmental professionals during the design, construction, and operation of environmental technologies.

This document is not a manual on engineering design, construction, or operation. Rather, it is intended to be a guide for technical project managers and QA staff in environmental programs to help them to better understand when and how QA and QC practices should be applied to engineering work. That is, it is a resource for users to help them understand the range and scope of QA and QC practices in support of environmental technologies. Accordingly, while this guidance is not written exclusively for engineers, it does use highly-technical terminology and may be used by managers with non-engineering backgrounds. As a further aid, the guidance uses and refers to good engineering principles/practices (GEPs) when discussing the application of QA and QC during a project. There are many other texts and manuals in the literature that can provide more details on the subjects discussed in this guidance.

Moreover, this document is non-mandatory guidance and all parts of the document may be used with discretion. It is not intended to imply any requirements for the use of environmental technology. Such requirements are defined by appropriate environmental statute or regulation, or as part of an applicable extramural agreement (e.g., contract, assistance agreement) or enforcement agreement, order, or other enforceable document.

1.2 BACKGROUND

ANSI/ASQC E4-1994 defines a quality system as “. . . a structured and documented management system describing the policies, objectives, principles, organized authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services.” It further explains, “. . . the quality system

provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.” The present guidance document presents the basic quality elements for technology implementation.

The U.S. Environmental Protection Agency (EPA) Quality System conforms to ANSI/ASQC E4-1994 and bases the implementation of its Quality System on the principles and practices found in this American National Standard. Part C of the E4 standard provides the specifications for the design, construction and fabrication, testing, and operation of environmental technology. As noted above, the term “environmental technology” includes devices and systems used in environmental programs to duplicate environmental conditions for test purposes or to control, prevent, treat, or remediate waste in process discharges (e.g., emissions, effluents) or the ambient environment. Usually, this term will apply to hardware-based systems; however, it can also apply to general methods or techniques used for pollution prevention, source reduction, or containment of contamination to prevent further movement of the contaminants.

Quality systems have been developed for a wide range of disciplines and industries. Within the environmental community, most available guidance on the subject has focused primarily on data quality issues. In more recent years, this topic has been broadened to include the full continuum of environmental projects. For purposes of this document, the quality system includes the development and implementation of comprehensive procedures as well as process checks to ensure compliance with all aspects of environmental technology deployment. Included in this scope are planning, design, procurement, fabrication, feasibility study, construction, shakedown, operation, maintenance, and performance evaluation of environmental technologies. Project management activities such as staffing, budget tracking, and organizational communication are also included in this scope to the extent that they relate to the quality system. Because quality assurance related to data generation and management is covered by existing EPA Quality System guidance, that topic is not discussed in this document. However, it is assumed that whenever environmental data are needed to formulate design criteria or equipment specifications or to evaluate technology performance, the appropriate QA and QC for environmental data operations will be applied.

1.3 INTENDED AUDIENCE

This document is intended to provide clear, coherent, and user-friendly guidance for project managers, engineering planning teams, and QA staff. Because it is technical in nature, users should have a general knowledge of the good engineering practices and basic quality principles used. Officials in EPA and other state and federal agencies, as well as non-government organizations, may find it useful for implementing quality systems when deploying environmental technologies. The intended audience for this guidance includes QA officers, site remedial project managers, persons responsible for site clean-ups, and other environmental professionals involved with environmental technology design, construction, and operation. It is designed to assist all those responsible for writing, reviewing, or approving quality management plans or quality assurance project plans for environmental technology projects.

1.4 TERMS AND DEFINITIONS

The following definitions indicate how selected key terms are used in this document. A complete set of terms and definitions will be found in Appendix A.

Constructor – The party assigned by the developer in charge of technology construction. The constructor's role should be specifically defined in the developer/constructor contract.

Design team – The parties responsible for the design of an environmental technology application. Depending on the scope of the project, this may consist of one or more professionals employed by the developer, or it may include representatives of various contractors and subcontractors as well.

Developer – The organization(s) responsible for site development and technology construction/implementation. The developer may be a single organization, as in the case of a site-specific treatability study for which the technology developer is also the site developer. In other cases, additional parties are involved, especially in the case of a large-scale technology implementation.

Good engineering principles/practices (GEPs) – A broad set of QA, conservation, and safety activities, techniques, and approaches that are commonly accepted throughout the engineering profession.

Owner – The company or organization that has the lead role in the development of the project and implementation of the environmental technology in question. The owner can be a private firm that actually owns the property, or it can be a site developer or architectural and engineering design firm that has been hired by the owner to manage the environmental technology installation from beginning to end, or it may be the private- or public-sector organization responsible for clean-up.

Project team – The parties involved in the construction and/or operation of an environmental technology application. Depending on the scope of the project, this may consist of one or more professionals employed by the developer, or it may include representatives of various contractors and subcontractors as well.

Responsible party – An individual or organization that has contributed to contamination problems at a site or has assumed site responsibility and is therefore a participant in the environmental technology application.

1.5 PERIOD OF APPLICABILITY

Consistent with the *EPA Quality Manual for Environmental Programs* (U.S. EPA, 2000b), after five years, EPA plans to review this guidance and either reissue it without

modification, revise it, or remove it from the EPA Quality System series. In addition, this guidance may be revised within five years if EPA determines that such a need exists.

1.6 ORGANIZATION OF THIS GUIDANCE DOCUMENT

The structure of this document is based on the organization used in Part C of the E4 standard:

- General
- Planning
- Design of Systems
- Construction/Fabrication of Systems and Components
- Operation of Environmental Technology
- Assessment and Response
- Verification and Acceptance of Systems

The remainder of the document is organized as follows:

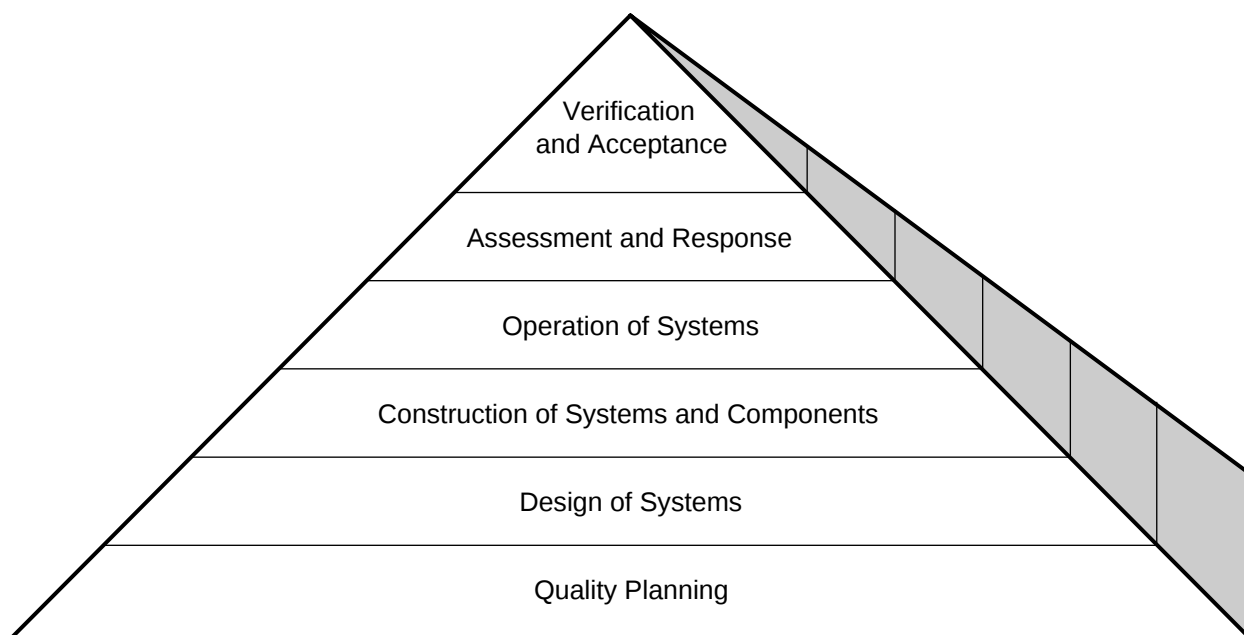
- Chapter 2 presents general quality system principles and elements.
- Chapter 3 describes QA and QC practices that should be considered for project planning and management, including quality systems and policies, organizational structure, project staffing, communication strategies, and document and records control.
- Chapter 4 addresses QA and QC practices and related activities that should be considered during the design of environmental technologies. Topics discussed as they apply to QA and QC include design process planning; organizational and technical interfaces; design inputs; the design process and its outputs; development of operation and maintenance (O&M) procedures; review of design alternatives; design documentation; and design verification, validation, and changes.
- Chapter 5 describes QA and QC practices and related activities that should be considered during construction and fabrication of environmental technology systems and components. Topics discussed as they apply to QA and QC include: site selection; review of resources; contractual arrangements; procurement of supplies, equipment, and services; scheduling and tracking; cost and materials management; inspection, testing, control, and tracking; and construction certification.
- Chapter 6 presents QA and QC practices and related activities that should be considered during the operations and maintenance phase of environmental technology deployment. These include planning and training; O&M

considerations during the design, construction, fabrication, system start-up, and normal operations phases; inspection and testing; and handling issues.

- Chapter 7 describes quality system practices that should be considered for assessment and response during the course of a project as well as during verification and acceptance of systems.

CHAPTER 2

GENERAL QUALITY SYSTEM PRINCIPLES



GENERAL GUIDING PRINCIPLES applicable to environmental technology design, construction, and operation

2.1 INTRODUCTION

This chapter provides an overview of QA principles applicable to process design, construction, and operation. Subsequent chapters will provide QA and QC specifications for specific implementation stages. While these topics can apply to a wide range of operations, they have been tailored to meet the objectives of environmental technology design, construction, and operation.

2.2 GENERAL GUIDING PRINCIPLES

Quality assurance is the system of operations that provides the user with the knowledge and assurance that project activities are likely to meet specific project objectives. In addition, **quality control** activities document the level of quality obtained during process operations. While the general environmental community has been provided with numerous guidance documents that cover specific aspects of quality assurance for environmental data operations, this guidance document breaks new ground by addressing quality assurance and quality control for environmental technology applications.

The following general guiding principles (which are adapted from the E4 standard) underlay the structure and content of this guidance document:

Quality planning – All work involving the design, construction, and operation of environmental technology should be planned, documented, and controlled as needed to achieve conformance with approved quality criteria.

Design of systems – Processes and procedures should be established and implemented to ensure that environmental technologies are designed using sound engineering/scientific principles and appropriate quality standards.

Construction of systems and components – Construction, fabrication, manufacture, and erection of systems and components should be performed under appropriately controlled conditions according to the drawings and specifications of the approved design.

Operation of systems – Environmental technologies should be operated in accordance with approved design documentation and operating instructions and guides.

Assessment and response – Work performed during the design, construction, and operation of environmental technology that affects quality should be assessed regularly to ensure that approved planning and design specifications and operating guides are being implemented as prescribed.

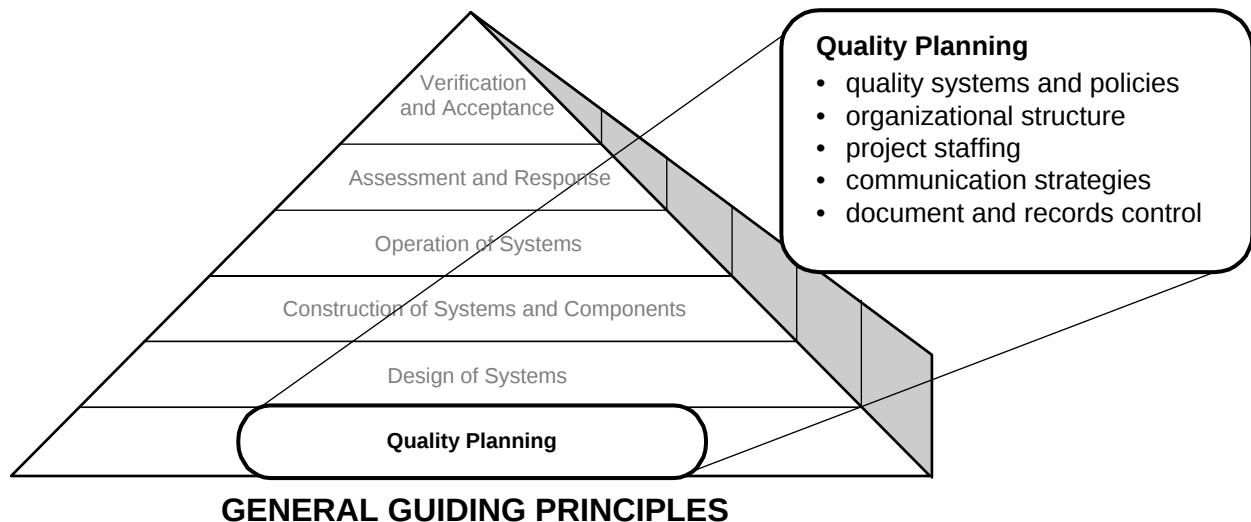
Verification and acceptance – The performance of environmental technology should be verified according to its intended use as documented in approved design specifications. When acceptance criteria are not met, deficiencies should be resolved and reassessments conducted as necessary.

Note that these principles span the three main phases of EPA's Quality System: planning (principles 1–2), implementation (principles 3–4), and assessment (principles 5–6).

Each of these general guiding principles is supported by a set of applicable lower-tier basic quality principles; these lower-tier principles will be detailed in the remainder of this document. In addition, at several points in subsequent chapters, there will be lists of GEPs that are pertinent to a particular topic. GEPs are a broad set of QA, conservation, and safety guidelines that are common to all engineering disciplines and are included in this document as an aid for those with an interest in exploring a broader suite of engineering issues and approaches. However, the primary focus of this document is on engineering QA topics. See Appendix B for a more complete list of several categories of GEPs that are most likely to be applicable to the design, construction, and operation of environmental technologies.

CHAPTER 3

PLANNING AND MANAGEMENT



3.1 PURPOSE AND OVERVIEW

Basic Quality Principle

Adherence to quality principles and practices in project management, not only in the planning stages but throughout the project, is key to the successful implementation of an environmental technology.

Basic to any technology design and implementation are the planning stages. Planning is an organized activity, typically begun and driven by the manager to define how to design the environmental technology; amass qualified personnel; acquire quality components and materials; and construct, install, and ultimately operate and/or evaluate an environmental technology meeting the appropriate quality criteria.

3.2 QUALITY SYSTEM DESCRIPTION

Basic Quality Principle

Every organization implementing an environmental technology should be driven by a policy that defines quality expectations.

Quality policies are usually defined at the highest level of a company, corporation, or government agency. In order to ensure that quality performance is achieved, the organization

quality policy should state the requirement for employee integrity, confirm management's commitment to meet contractual obligations, and place responsibility for quality with those who perform the work. An organizational quality policy should direct the employees to ascend to the highest possible work ethic, and in turn the organization should provide the resources necessary to achieve these expectations.

The corporate or organizational quality policy should be connected to the type of environmental technology to be tested, maintained, or operated through a project-specific quality plan. Identification of the needs and expectations of all involved parties or stakeholders should be included. The project-specific quality plan is therefore used to guide personnel in performing appropriate procedures, using specified equipment, and performing specified operational and maintenance checks. Therefore, the purpose of this plan is to ensure that all work will be performed by qualified personnel, to ensure that project objectives can be achieved, and to document design, construction, and operational quality. This plan should be carefully reviewed and scrutinized prior to project initiation. Subsequent specifications in the plan should be followed by all personnel. Deviations from planned procedures should occur only with permission of the party responsible for technology implementation and should always be documented and approved by QA and technical personnel before being implemented. The project-specific quality plan for a technology evaluation, therefore, should reflect an agreement reached among all parties prior to project initiation as to how a process will be evaluated and how it will be determined to be successful or not successful. The importance of this approved and signed document is that it is an agreed-upon plan, laying down the ground rules of technology implementation and/or evaluation prior to project initiation. This helps define project objectives and defines how to achieve these objectives.

3.3 ORGANIZATIONAL STRUCTURE/CHAIN-OF-COMMAND AND RESPONSIBILITIES

Basic Quality Principle
Organizational structure should be defined at every level in which QA and QC activities are necessary.

The first level of organization for which appropriate QA and QC practices should be defined is the project owner's organization. This may be an individual, a private firm, or a government agency. The organizational structure should clearly indicate that project management and QA responsibilities are separate and independent and should clearly define the lines of communication for all parties. Following this level is the organization of the individual project to which the technology operation is to be applied. Both project management and QA personnel should report to the highest management levels. Each program and/or project should also provide resources designated for QA organizational leaders and QA assessments. Responsibilities and authority of each level should be defined and individual responsibilities should be outlined, including those of subcontractors (if any). This is important for those instances when construction or operation of a technology is stopped because of quality issues

and operations reviewed due to unexpected occurrences. It is also important that these entities understand and commit to the organizational goals and project objectives.

In the example of a hazardous waste site remediation project where a responsible party is known, the site developer is typically the organization responsible for site development and technology construction/implementation. The developer may be a single organization, as in the case of a site-specific treatability study where the technology developer is also the site developer. In other cases, additional parties are involved, especially in the case of a large-scale technology implementation. A site developer may subcontract with firms to perform site grading and material handling; installation of infrastructure, such as sewers, foundations, footers, berms, and lagoons; installation of specialized equipment, such as boilers or water treatment facilities; and a variety of other functions. It is important that the site owner enlist the developer and its subcontractors in following the quality goals and project objectives.

A state or federal oversight agency may be involved in projects including regulatory compliance. For site-specific treatability studies, a third-party evaluator contracted by the site owner or the regulatory agency may be involved. Local community organizations and environmental groups may also be involved in these types of evaluations and in full-scale technology implementations. The needs of all of these organizations, sometimes referred to as “interested parties,” should be addressed in the planning stages of the project.

3.4 PROJECT TEAM STAFFING

Basic Quality Principle
Different phases of a project call for staffing of appropriate and competent personnel for the following activities and organizations: site owner/management, design, construction, and operation.

The project owner/management may fill a variety of staffing roles depending upon the scope of the project and the experience of the available personnel. These roles may be limited to project oversight by using the design firm as the project manager or may include roles in project management, project design, portions of construction, and process operation. Design, construction, and operation are likely to involve several organizations employing different personnel for each of the separate stages. Engineering and design professionals are more likely to be involved in everyday activities during design, while some of these same personnel are likely to be in a supervisory or assessment role during construction and operation. Construction personnel may be involved in the design phase to provide input to limitations on the design posed by the site or by construction activities. They may also provide training for system operation.

The owner functions include project management and, potentially, any of the other functions previously described. Therefore, project managers with sufficient experience in environmental installations are the primary project staff sought by the project owner. This

experience would typically include budgeting, scheduling, design reviews, personnel management, and management of various subcontractors. In addition, other support personnel may be needed, including personnel knowledgeable in legal and regulatory requirements and management controls associated with contracts and management of subcontractors.

The project team involved in the design (e.g., the site owner, the design firm, and the construction contractor) should work together to effectively establish and maintain procedures to complete the definitions of specifications and control and to verify the design of the project to ensure that specifications are met. Often, engineers develop the specifications and the design plans with input from the project owner, regulators, and other team members of interested parties. Portions of the design may be farmed out to specialty design firms as needed. The project manager for the design firm should appoint personnel not directly involved in the design to perform periodic design review, verification, and validation. Ideally, a team of experts should perform design reviews at set intervals.

Construction personnel should be competent and experienced in the types of construction to be performed. Construction firms typically have personnel experienced in areas such as materials handling, metal working, welding and pipe fitting, electrical and plumbing installations, concrete work and masonry, and carpentry. The construction contractor may use its own personnel, subcontract specialty crafts (e.g., electrical and plumbing) or work requiring specialized equipment (e.g., large cranes), or may utilize day labor (typically for manual labor requiring a minimum of skill). It is the responsibility of the construction manager to ensure that the personnel used are qualified and trained to perform the specific planned construction activities.

Operations personnel should be competent and experienced in operating environmental systems similar to the planned project. These personnel may be current employees of the project owner or may be new hires specifically for the project. Typically, either the design firm or the constructor, or both, will assist the owner in training personnel on the operation of the system.

Training programs should include training of management and field personnel to ensure competency in the required knowledge and skills necessary for technology deployment. Subcontractors who are participating in the program should also be trained, including those added to the program or project at a later date. Training should be initiated by the project owner early in the project design phase. Initial training should consist of an overview of the project goals, QA specifications, and overall and project-specific organizational structure and lines of communication. As the project progresses from design to construction, training programs and procedures are constantly updated to cover construction activities, especially any that were not anticipated in the initial procedures and training. This is often a good time to incorporate “lessons learned” during the design and initial construction stages, especially in regard to communication failures or modifications made to improve communication processes. As the project moves to the technology implementation phase, key training elements include technology operational procedures, field responsibilities, and reporting of field operations. How poorly or how well systems are performing in the field is communicated to all appropriate personnel.

3.5 COMMUNICATION STRATEGY/PROCEDURES

Basic Quality Principle

Effective project planning and implementation depend upon good coordination among all parties, which, in turn, depends on effective communication among those same parties.

The project should be viewed as a whole process from conception to completion, and an overall communication strategy should be developed for the entire project. Critical information should be communicated to the correct team members in a timely fashion. Communication strategies and procedures related to technology operation, construction, and design are similar to other areas of environmental management. These include development and implementation of overall program- and project-specific training procedures and implementation of chain-of-command and lines-of-communication procedures built into the organizational hierarchy.

During the development of a strategy for communication, mechanisms for ensuring that communication is occurring throughout the project team should be implemented. This includes communication with oversight agencies, the developer, the operator, the evaluator, local communities, associated organizations, or others that have a vested interest in the project. The key is to ensure design and/or operation expectations are communicated to all personnel. The goal should be an overall balance that ensures adequate dissemination of information while avoiding over-communication.

3.6 DOCUMENT AND RECORDS CONTROL

Basic Quality Principle

Documents should be controlled to ensure that the correct documents are being used.

For the purpose of this guidance document, the term *document control* is defined as the act of ensuring that program/project-specific documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. Documents that should be controlled are, at a minimum, those that specify requirements, prescribe processes, or establish the design of environmental processes. Examples include drawings, specifications, management plans, procedures, technical reports, test reports, and any documents pertaining to legal requirements (e.g., permits, codes).

Applicable GEPs include:

- backup/duplicate copies;
- maintaining/archiving electronic and/or paper copies;
- distribution/delivery/circulation list for control documents;
- document/records authentication and verification;
- document approval procedures; and
- reviews—peer, project level, program level, organizational, and legal.

3.6.1 Document Preparation, Review, Approval, and Issuance

Project management should identify the individuals or organizations responsible for the preparation, review, approval, and issuance of controlled documents. Procedures for controlling documents should be developed. These procedures should specify that the documents requiring control be identified and that the documents then be assigned control numbers (e.g., the document version) and dated. Where applicable, a master list of controlled documents may be specified for a project (e.g., all design drawings and specifications). Regardless of whether a master list is generated, document control numbers should be placed on each page of the document along with the page number, date, and document version. A distribution list for reviewers and/or document users should be incorporated into the document when possible. Document control procedures should be implemented when documents are first prepared.

Documents should be reviewed for adequacy, correctness, and completeness prior to approval and issuance. The organization requesting review should identify the specific review criteria and any pertinent background information. Reviewers should be individuals other than the document originator and should include the applicable technical specialist(s) of each organization affected by the document being reviewed. Other specialists in the fields of QA, environmental compliance, and safety should also review the documents, as needed. The document originator should specify the date that comments are due and, as warranted, the form in which any comments should be transmitted (e.g., document markups, summary memos, or electronic markups or review copies). The document review procedures should also specify the approval process. In some cases, each reviewer may be requested to submit an approval when all comments have been incorporated into the document and the final version is satisfactory to all reviewers. In other cases, the document originator may be responsible for document approval after incorporating review comments.

3.6.2 Document Distribution and Use

The distribution and use of controlled documents and forms that document or prescribe work, including changes and editorial corrections to documents, should be controlled to ensure that current and approved copies are available for use by those persons doing the work. A limited and known number of copies should be distributed. This is important to prevent someone not on the distribution list from getting and using a copy that is later superseded but not distributed to that individual. The effective date should be clearly identified on each controlled document; when appropriate, the duration that the document is in effect should be indicated. Documents should be used only for their intended purpose and any caveats or exclusions should be clearly marked on the document. It is important that appendices, attachments, and footnotes containing such information be included with all copies. As with the distribution and use of controlled documents, the disposition of obsolete documents should be controlled to avoid inadvertent use.

3.6.3 Document Changes

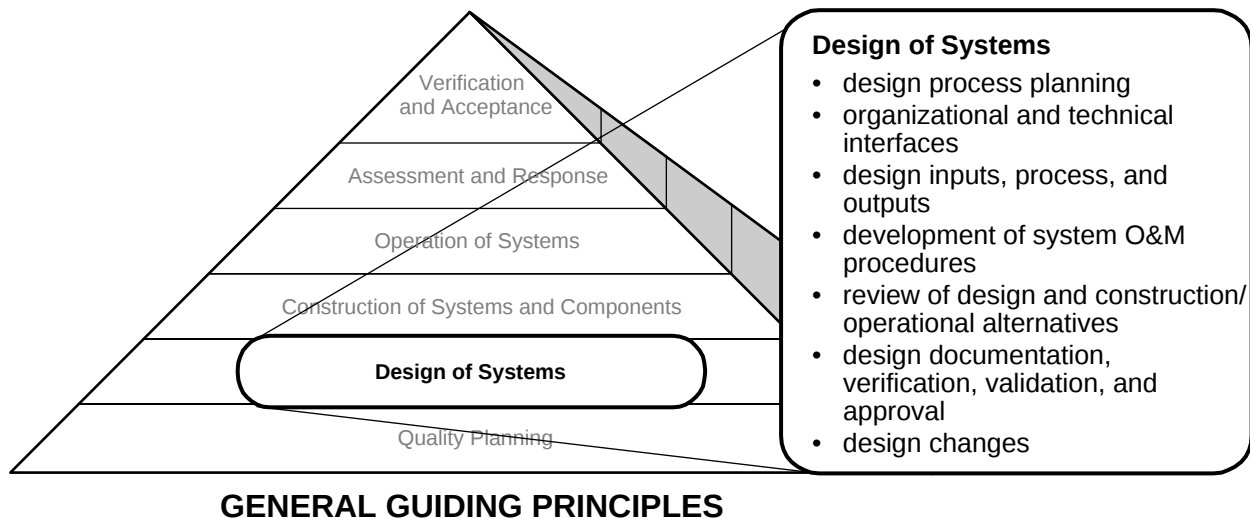
Changes to documents should be reviewed and approved by personnel with similar expertise to those that performed the original review and approval. Changes should be clearly noted in the document, and document dates and subsequent versions should reflect that changes have been made. Procedures for review should normally be the same as those used for the original document. Minor changes, such as grammar, spelling, and minor formatting changes would not normally require review.

3.6.4 Document and Record Storage and Archiving Methods/Criteria

Records should be maintained to reflect the achieved level of quality for completed work and/or to fulfill any contract or statutory requirements. Federal records must be maintained in accordance with applicable Federal records schedules. Record-keeping procedures should specify what records are to be prepared, reviewed, authenticated, and maintained. Records should be indexed and classified so that they can be expeditiously identified and retrieved. Maintenance procedures for records should include provisions for retention, protection, preservation, traceability, and retrieval. Retention times for Federal records are determined by applicable Federal records schedules. Other retention times should be determined based on contractual or statutory requirements or management requirements, whichever is longer. Documents should be stored in such a manner and location as to protect and preserve the information contained in the documents. This means that records are to be protected from damage, loss, and deterioration, whether the records are in paper or electronic form or both. Document identification and storage procedures should ensure that documents can be traced to their original source and are easily retrievable; this calls for a systematic approach for document storage. When evidentiary records are involved, chain-of-custody and confidentiality procedures should be prescribed and implemented.

CHAPTER 4

DESIGN OF SYSTEMS



4.1 PLANNING AND THE DESIGN PROCESS

Basic Quality Principle

The engineering/design professional, contractor, or subcontractor (*the design team*) should establish and maintain documented procedures to control and verify the design of the "environmental technology" in order to ensure that QA specifications are met.

In the design phase of a project, the functional specifications stated during the conceptual phase are given form, and documents are prepared to define the project for construction and operation. Planning and managing the design effort involve elements of organization, staff selection, management, control, and coordination aimed at achieving quality in the project. The developer or designee selects a design team, or at a minimum designates an individual, who will serve as the *design team leader* for managing the design. The design team leader should prepare *design criteria* that will outline the specifications of the design. It is important, therefore, to define the design team organization and specify responsibilities required for its implementation.

Crucial to the design criteria are project objectives that are developed for project evaluation and detail the measurements or information suitable to meet developer specifications. It is not adequate to state the objective; there should also be a description of the methods that will be used to determine whether or not the objectives are achieved. Precisely defining these objectives will determine the ultimate ability of measuring project success. The design team should therefore define the ultimate goal of their operation when determining project objectives.

Questions that should be considered as part of project design include the following: (1) Is the operation a long-term technology for clean-up of a particular contaminant or site, or is it for demonstration purposes? (2) Is this technology to be used at other, similar sites also under the purview of the site responsible party? (3) Will design and construction phases be time limited in order to meet operation specifications? (4) Who will operate and maintain the technology? (5) Who is ultimately responsible for ensuring that technology specifications have been achieved and, if the technology is for clean-up efforts, who will be responsible for certifying site clean-up?

Design criteria should clearly state the design staffing specifications and selection criteria and provide the basic guidelines for initiation and coordination of the design process, for example, meeting schedules and budgets while maintaining quality. Activities should then be assigned to qualified personnel equipped with adequate resources. These plans are updated as the design evolves.

Design criteria include the various GEPs that will drive the design processes. Designed procedures, equipment, structures, and facilities should be flexible to the extent possible to accommodate variations when required. When toxic or highly dangerous materials are involved, designs should include sufficient safeguards with adequate engineering controls for safe operation. Interchangeability of resources, such as materials, personnel, equipment, etc., should be considered during the design planning phase as a means to control project cost and improve system reliability and resilience. During the design planning stage, the purchasing and procurement, fabrication and construction, and the operations and maintenance teams should be consulted to avoid compromising financial, logistical, or technical situations, after the fact.

Construction and deployment of an environmental technology entails that specific operations be followed and maintained. Because many environmental technologies may

Planners and managers should strive to incorporate the following GEPs during design planning:

- fail-safe/intrinsically safe design of procedures, processes, equipment, structures, and facilities;
- flexible built-in designed procedures, processes, equipment, structures, and facilities;
- design of self-correcting procedures and processes;
- analysis of availability and interchangeability of all resources, such as materials, personnel, and equipment;
- automatic communication/notification procedures and processes among all team members;
- integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements;
- integration/optimization of human, material, energy, and economic resources and logistical, political, social, environmental, and technical factors;
- modeling and simulation of technical, logistical, economic, social, environmental, and political systems prior to, during, and after installation/implementation;
- sound project management principles/practices; and
- automatic shutdown of systems, equipment, and processes.

be innovative and may have undergone very little field testing, however, the design team is responsible for achieving quality objectives during construction based upon previously set standards and performance criteria and based upon their experience and ability to adjust designs to adapt to new applications and to changing conditions. When the project involves retrofitting or scale-up of an existing environmental technology, the design team should review and analyze all available documentation related to the planning and implementation of the original design, construction, and system operations, and if possible, interview and consult with the previous design team staff. Incident reports and existing documentation should then be carefully reviewed and analyzed to avoid potential pitfalls.

4.1.1 Feasibility Studies and Reviews (FSRs)

In some cases, conceptualizing and planning for construction and deployment of environmental technologies may entail the development and study of various alternatives. This may be particularly true when design decisions involve different choices of technology or engineering approaches. These are often known as *feasibility studies*. Such activities are a joint effort of the technology developer, design team leader, and, if available, the constructor and operator. The resources spent in formulating, investigating, and studying alternative approaches to decisions will vary depending on the size and complexity of the project.

Prior to undertaking the formal design and development activities, the design team may conduct FSRs to gain full understanding and establish a sound working knowledge of the various technical, logistical, and economic factors, challenges, and issues involved with the deployment of the designated environmental technology at the specified site. Controls and measures should be defined, identified, and set in place to allow updating of the various FSRs during the course of design, construction, and operation of the deployed technology.

Technical feasibility studies include life cycle analysis, environmental impact statements, and investigation of alternative solutions. The various alternatives studied will affect project performance and appearance, life-cycle cost, cost/benefit ratio, schedule of completion, and socioeconomic and environmental impacts. The number of alternatives chosen for examination, the extent to which each is subjected to detailed planning evaluation, and whether more than one “preferred” alternative is selected for final design are key decisions best made early in the project planning and scoping process.

In addition to the GEPs listed in Section 4.1, designers should consider the following GEPs when conducting the various FSRs:

- reuse of materials required for technology operation or development;
- reduced use of virgin materials, wastes generated, energy sources, and human resources;
- recycling/recovery of materials, utilities, and energy sources;
- conservation of materials and energy sources;
- substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives; and
- use of interlocks as safety measures.

Logistical feasibility studies include analyses of alternatives for the procurement, distribution, deployment, maintenance, and replacement of materials and personnel. Economic feasibility studies include cost-benefit analyses and analyses of short- and long-term economic impacts on the community and the region. Cost alternatives that should be carefully analyzed and considered include design cost, capital cost of construction, operation and maintenance costs, various life-expectancy or design-life periods, return on investment, cost comparison of deploying the environmental technology on a full-scale basis versus deploying it in stages, value of extra cost for aesthetics, and cost/benefit ratios.

Feasibility studies allow for insight and investigation into all aspects that may impact technology construction and operation. The FSRs, as stated previously, are important in considering alternative solutions and determining whether those alternatives can offer a realistic solution.

4.1.2 Resource Identification and Allocation

Identification and allocation of resources, including personnel, should be performed during design planning in order to ensure adequate resources will be available during construction and operation of a technology. Resource requirements should specify the level of quality needed to accomplish the stated objectives. The design team may include engineers, scientists, and perhaps geologists or others familiar with the workings of the process and of the site being considered for remediation; they should be trained in QA principles and in all standard operating procedures governing their areas of responsibility. Each professional discipline plays a role in offering input into the technology design. Identification and allocation of the correct mix of design team professionals is therefore crucial to achieving the project's technical as well as economic success.

4.2 ORGANIZATIONAL AND TECHNICAL INTERFACES

Basic Quality Principle
Organizational and technical interfaces should be identified during planning stages and controlled appropriately during the design efforts.

Organizational and technical interfaces include organizations and individuals, such as the site owner, regulatory agencies, design professional, construction/fabrication contractor, equipment and materials supplier, and the technology operator. When the project involves retrofitting or scale-up of an existing environmental technology, to the extent possible, interfaces with the previous designers, construction contractors and operators, and suppliers should be identified and incorporated into the prevailing organizational structure. Overall project and technical organizational flowcharts should be used to identify the participating organizations and individuals and their respective roles, responsibilities, and authority.

Typically, the design team leader keeps the developer and design team members informed on the design's status, normally submitting monthly (or more frequent, if necessary) progress reports to the owner. These reports contain information on meetings held and work accomplished in the subject period. Most importantly, design problems and issues should be recognized as early in the process as possible and reported to the appropriate decision makers (e.g., technology developer); those problems that may cause a change in scope, budget, or schedule should be promptly identified, documented, communicated, and resolved among the participating parties.

4.3 DESIGN INPUTS

Basic Quality Principle
Prior to the start of the design phase, the owner and the design, construction, and operations teams, separately as well as collectively, should identify all pertinent design characteristics for the project.

Applicable *design inputs*, such as conceptual design reports, performance specifications, regulatory requirements, codes, and standards should be documented and controlled by those responsible for the design in accordance with the following specifications:

- Design inputs should be identified and documented and their selection reviewed and approved by those responsible for the design.
- Design inputs should be specified and approved on a timely basis and to the level of detail appropriate to permit the design work to be carried out correctly in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.
- Changes from approved design inputs and reasons for the changes should be identified, approved, documented, and controlled.
- Design inputs based on assumptions that call for re-verification should be identified and controlled.

During the design input phase, as part of the technical directives, the developer usually outlines the desired GEPs (see box) that the design professional can incorporate into the design, to the extent possible. In addition, early identification of appropriate codes and standards can prevent reworking plans and specifications and save considerable cost and delay. Codes and standards are developed by governmental units and industry or professional-technical associations to protect the public's health and safety. Because codes and standards typically address particular aspects of design, construction, and operation of a technology, the design team can expect to find a number of codes and standards applicable to a project, including those pertaining to civil, mechanical, electrical, structural, and process engineering, as well as architecture. Applying codes and standards to the design may sometimes be difficult, especially for design professionals working on a project in an unfamiliar geographical area (as in the case

of a remote but hazardous or toxic waste site), but is required in order to comply to specified regulations.

4.4 DESIGN PROCESS

Basic Quality Principle

The responsible design organization(s) should define, manage, and document the design activities on a timely basis and to the level of detail appropriate to permit the design process to be carried out correctly, effectively, and in a timely manner and to permit verification that the design meets specifications.

The following issues should be addressed as part of the design process:

- Design methods, materials, parts, equipment, and processes that are key to the function of the structure, system, or component should be selected and reviewed for suitability of application.
- Changes from all specifications and standards, including the reasons for the changes, should be identified, approved, documented, and controlled.
- Applicable information derived from experience, as set forth in reports or other documentation, should be made available to cognizant design personnel.
- If the design effort is to support an existing technology retrofit or scale-up, the designers should take into account the design inputs, design outputs, and the actual performance of the existing products and processes against their respective design expectations. Such analyses provide a better understanding of the limitations of the technology and the challenges it is likely to face when retrofitted and/or scaled up.

The following GEPs should be considered when establishing/developing the design inputs:

- reuse of materials required for technology operation or development;
- reduced use of virgin materials, wastes generated, energy sources, and human resources;
- recycling/recovery of materials, utilities, and energy sources;
- conservation of materials and energy sources;
- substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives;
- use of commercially available and tested materials, products, processes, equipment, and supplies;
- computerized/remote control of unit operations and processes;
- use of lockout/tagout procedures and equipment during systems fabrication/installation and operations; and
- prevention of calamities through process hazard analysis, hazardous operations analysis, failure mode and effects analysis, fault tree analyses, and incident investigations.

4.5 DESIGN OUTPUTS

Basic Quality Principle

Design output should be documented and expressed in terms that can be verified against design criteria (including specific acceptance criteria) and validated.
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Design output documents should:

- meet the design-input specifications,
- contain or make reference to acceptance criteria, and
- identify those characteristics of the design that are crucial to the safe and proper functioning of the technology and its components (e.g., operating, storage, handling, maintenance, and disposal requirements).

Design output documents are usually reviewed and approved before release. The distribution of the design output documents should be controlled and, where deemed critical, verified.

4.6 DEVELOPMENT OF SYSTEM OPERATION AND MAINTENANCE PROCEDURES

Basic Quality Principle

O&M specifications should be considered in each phase of project planning, design, construction, and start-up.
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In the preliminary design phase, decisions are made relating to site selection and access, process choice, equipment selection, and other elements that impact operation and maintenance of the completed project. Since decisions made here limit flexibility in subsequent phases of the project, O&M coordinators and advisers should be consulted for choices of brands or models of equipment to be selected, arrangements or layout of facilities, access for equipment repair, routine operation and maintenance procedures, and other design features that influence O&M costs and activities.

Effective operation and maintenance entails up-front planning to ensure that products and services will perform according to project specifications. The various stages of the project (planning, design, construction, start-up, and operation) each involve input from O&M staff. Roles of O&M staff are certainly weighted towards process operation, but if input is not provided during planning or design, technology processes may suffer from over-design whereby standard “off the shelf” equipment is not used, or they may suffer from operations that are difficult to maintain. O&M staff input provides a “reality check” for the design and planning stages and provides assistance during construction and start-up.

Environmental technology should be operated in accordance with approved design documentation and operating instructions and guides. Designers should ensure that the technology operating guides and manuals include, but are not limited to:

- appropriate controls for materials (including consumables) and measuring and testing equipment;
- configuration management;
- operating procedures and parameters for specific components and systems configuration, including specified safety limits;
- spill, fire, and other hazard safety procedures;
- process equipment control and maintenance, including specifications during abnormal conditions for inspection and test situations and fault and emergency conditions;
- special environments, time, temperature, or other factors affecting the quality of operation; and
- the skill, capability, and knowledge of operators to meet operational, environmental, and quality goals. This should be accomplished through the use of specific standards, resources, and worker training and certification.

4.7 REVIEW OF DESIGN AND CONSTRUCTION/OPERATIONAL ALTERNATIVES

Basic Quality Principle
At appropriate stages of design (e.g., 30, 60, and 90%), formal documented reviews of the design are planned and conducted.

Design reviews or audits for purposes of validation are cornerstones of the design professional's QA program. Design review can be carried out by members of the design team or an independent review board selected for their expertise. Design audits are performed by individuals other than members of the design team. Design reviews or audits have the purpose of establishing the levels of quality of the design by identifying unsound concepts, analyzing the overall feasibility of the project, eliminating redundancies, and assisting in interdisciplinary coordination. Participants at each design review should include representatives of all pertinent functions/disciplines concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of all such reviews should also be maintained.

4.8 DESIGN DOCUMENTATION

Basic Quality Principle
The design professional should establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of design output documents including drawings, calculations, and results, as well as references, standards, codes, design basis, and assumptions used in the design process.

Under almost all circumstances, design results and outputs are checked, verified, and certified by a qualified professional belonging to the pertinent discipline. Peer and QA review should be incorporated to ensure it will be understandable and meet specifications. When the project involves technology retrofit or scale-up, the designer should recheck, re-verify and, if determined to be critical for the current design, even re-certify the design results and outputs of the preceding version of the technology. Design documentation and records, which provide evidence that the design and the design verification processes were performed in accordance with project specifications, should be collected, stored, and maintained in accordance with documented procedures. The documentation includes not only final design documents (such as drawings and specifications) and revisions thereto, but also documentation that identifies the important steps, including sources of design inputs that support the final design. Maintaining and ensuring quality during the design process entails that specific documentation standards be followed so that appropriate and relevant information is conveyed to all personnel involved during the design, construction, and operation phases of the environmental technology.

4.9 DESIGN VERIFICATION

Basic Quality Principle
The verification process evaluates the completeness, correctness, and conformance or compliance of the design in terms of meeting contractual, method, or procedural specifications.

At appropriate stages of design, design verification should be performed to ensure that the design output meets the design stage specifications. The design verification measures should be recorded. The following measures can be applied to verify the adequacy of the design:

- (a) Design verification should be performed using one or a combination of the following methods:
 - performing alternative calculations (calculations or analyses that are made using alternate methods to verify correctness of the original calculations or analyses and the appropriateness of any assumptions, input data used, any computer programs, or other calculation methods used);

- comparing with prevailing/proven design (for example, when the project involves retrofitting or scale-up of existing technology);
 - testing under laboratory, field, or simulated conditions (for example, treatability tests and/or mathematical modeling coupled with computer simulation); and
 - reviewing the design stage documents before release.
- (b) The particular design verification method should be identified and its use justified.
- (c) The results of design verification should be documented, including the identification of the verifier.
- (d) Design verification should be performed by competent individuals or groups other than those who performed the original design (but they may be from the same organization). If necessary, this design verification may be performed by the originator's supervisor providing that:
- the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design,
 - the supervisor is the only individual in the organization competent to perform the verification, and
 - the determination to use the supervisor is documented and approved in advance.
- (e) Design verification should be performed at appropriate times during the design process.
- Verification should be performed before release for procurement, manufacture, construction, or release to another organization for use in other design work.
 - Design verification should be completed before relying on the item to perform its function.
- (f) The extent of the design verification should be based on the complexity of design, risk, uniqueness of the design, degree of standardization, technology's state of the art, and similarity with previously proven designs. When the design has been subjected to a verification process in accordance with this standard, the verification process need not be duplicated for identical designs.

(g) Use of a previously proven design should be controlled as follows:

- The applicability of standardized or previously proven designs should be verified with respect to meeting pertinent design inputs for each application.
- Known problems affecting standard or previously proven designs and their effects on other features should be considered.
- The original design and associated verification measures should be adequately documented and referenced in the files of subsequent application of the design.
- Changes in previously verified designs prompt re-verification. Such re-verifications should include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based.

(h) Design verification and approval should be performed in a timely manner.

4.10 DESIGN VALIDATION AND APPROVAL

Basic Quality Principle
Design validation is performed through assessments (see Chapter 7) to ensure that the designed products, processes, and procedures conform to defined user needs.

Validation is confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Typically, design validation follows successful design verification and occurs prior to installation and/or final deployment. When design adequacy is to be validated by qualification tests or pre-operational test runs, the tests are identified and the test configurations are clearly defined and documented. Testing demonstrates adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item should perform satisfactorily should be considered in determining the most adverse conditions. Test results should be documented and evaluated by the responsible design organization to ensure that test specifications have been met. Test results should then be reviewed and validated by an independent individual (outside the organization) technically competent to understand the particular item or product under study.

If validation testing indicates that modifications to the item are called for to obtain acceptable performance, the modification should be documented and the item modified and retested or otherwise validated to ensure satisfactory performance. When tests are performed on models or mockups, applicable scaling laws are normally identified or established and verified. The results of model test work are then subjected to error analysis, when applicable, prior to use in final design work.

4.11 DESIGN CHANGES

Basic Quality Principle

All design changes and modifications should be identified, documented, reviewed, and approved by authorized personnel before their implementation using clearly defined documented procedures.

Design changes should be controlled in accordance with the following instructions:

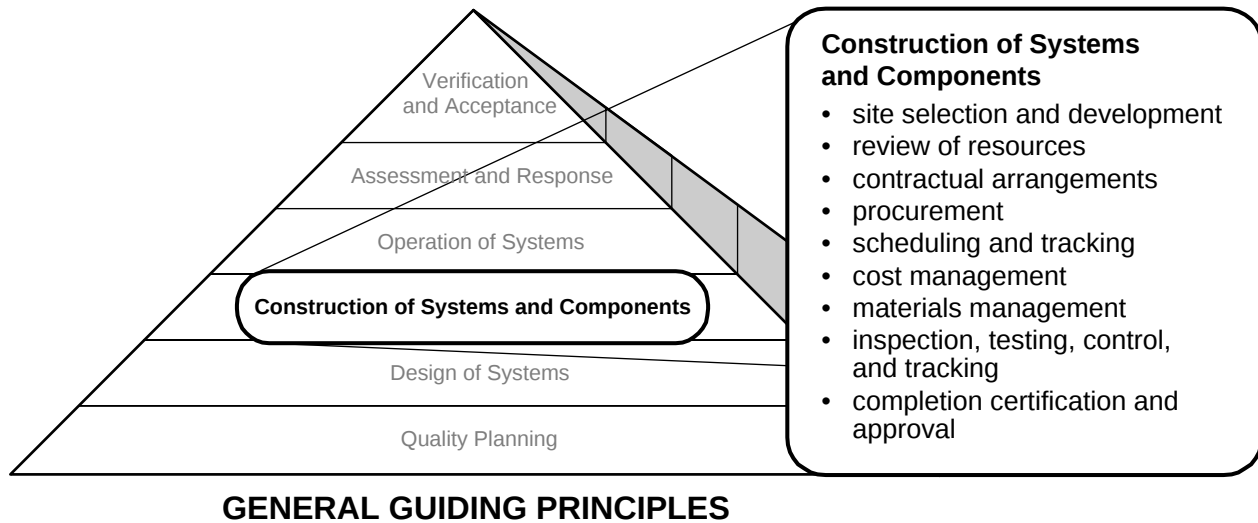
- (a) Changes to final designs, field changes, and nonconforming items dispositioned “use as is” or “repair” should be justified and subject to design control measures commensurate with those applied to the original design.
- (b) Design control measures for changes should include provisions to ensure that the design analyses for the item are still valid.
- (c) Changes should be approved by the same groups or organizations that reviewed and approved the original design documents.
- (d) If a significant design change becomes necessary because of an incorrect original design, the design process and design verification methods and implementing procedures should be reviewed and modified as appropriate. These design deficiencies should also be documented.
- (e) Field changes should be incorporated into the applicable design documents.
- (f) Design changes that affect related implementing procedures or training programs should be communicated to the appropriate organizations.

Designers should consider the following GEPs when addressing design changes:

- worker training/retraining, including hands-on training;
- worker registration/certification;
- certification/permitting of work procedures, processes, equipment, and environment; and
- routine/periodic inspections, testing and compliance audits of systems, procedures, processes, equipment, etc.

CHAPTER 5

CONSTRUCTION/FABRICATION/INSTALLATION OF SYSTEMS AND COMPONENTS



5.1 INTRODUCTION

Basic Quality Principle

Quality in the construction, fabrication, and installation phase of a project is achieved by establishing, implementing, and maintaining documented procedures to control and verify that technical specifications and QA and QC criteria are met.

Project planning for the construction, fabrication, and installation of an environmental technology should be undertaken by the developer or the lead agency. The technology developer may decide to contract with a design professional or the constructor to perform the design and planning activities. Once design and planning activities are completed, the developer may then contract with a construction professional to fabricate the environmental technology. Alternately, the technology developer may perform these assignments “in-house.” Either method involves being responsible for specific compliance with the specifications for the project, including planning and enforcement of site safety programs (designated in a separate health and safety plan); means, methods, and sequencing of construction; management; meeting applicable codes, permit requirements, and other public agency regulations pertaining to his/her operations; and quality control related to construction activities as discussed in this chapter.

5.2 SITE SELECTION AND DEVELOPMENT

Basic Quality Principle

Project site specifications should be established and documented.

Site selection and development activities may take place during the planning and design phases. It should be confirmed, for example, that site selection is appropriate for the specific environmental technology being constructed based upon levels of contamination present at the chosen site. Other aspects of site development typically include, but are not limited to, construction of access roads; extension of utilities to the site; traffic control measures including detour routes; and relocation of utilities, highways, and other facilities. Utility extensions and relocations are frequently performed by the applicable utility, although such activities may be included in the overall project construction contract. Considerations of cost, construction sequencing and scheduling, site congestion, safety, and contractor qualifications will all impact the decision on site selection considerations.

GEPs that are applicable to site selection and development include:

- analysis of availability and interchangeability of resources, such as materials, personnel, and equipment;
- site surveys, including topographical, geological, hydrogeological, hydrological, seismic, wind and weather patterns, as well as social and economical factors;
- automatic communication/notification procedures and processes among all team members;
- integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements;
- modeling and simulation of technical, logistical, economic, social, environmental, and political systems prior to, during, and after installation/implementation;
- use of lockout/tagout procedures and equipment during systems fabrication/installation and operations; and
- prevention of calamities through process hazard analysis, HAZOP, FMEA, fault tree analysis, and incident investigation.

5.3 REVIEW OF RESOURCES

Basic Quality Principle

Management should identify resources available, how they are allocated, and associated responsibilities for resource allocation.

The planning procedures should specify the intended source of required resources and the funding for personnel, materials, and equipment. Resources available to the responsible party, design professional, and constructor for project construction may place constraints on project activities and influence the decisions pertaining to project specifications, planning and design, contracting strategies, and construction operation and quality. It is the responsibility of project management and, ultimately, of senior management to ensure that resources for quality assurance are available. Reporting procedures and delineation of responsibilities for resource reviews should be established. In addition, such reviews should result in the establishment of

procedures and mechanisms for securing the needed resources for construction within the framework of prevailing local, state, and federal regulations.

5.3.1 Financial Resources

The technology developer or responsible party is in charge of securing funds to plan, design, and construct the project. This may be a cooperative effort between several different parties and/or agencies. The availability of these funds, beginning with the onset of the planning phase, will be critical to completion of the project in a timely fashion and to the ultimate quality of the project. Adequate funding of “up front” activities, such as preliminary planning, hydrogeological studies, alternative investigations, and other activities to delineate design criteria and project specifications, is crucial to adequately define the design and reduce the risk of unanticipated events during construction. This can include, for example, additional funding for verification of contaminant levels at the site in order to ensure operational success of the technology. The completion of a project in a manner that ensures the quality of the constructed system entails that the financial interests of all members of the project team (responsible party, design professional, constructor, suppliers, subcontractors, specialty fabricators, etc.) be considered. Financial capabilities should be considered in the planning stages as well as in the contractual and implementation phases of the project.

Applicable GEPs for financial resources include:

- design of self-correcting procedures and processes and
- integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements.

5.3.2 Human Resources

During the initial stages of project planning, the responsible party evaluates the human resource needs of the project. Continuity of key management and professional staff and the availability of a skilled workforce are important factors that contribute to the quality of the project. Project team staffing was discussed in detail in Section 3.4.

GEPs that apply to the management of human resources include:

- analysis of availability and interchangeability of all resources, such as materials, personnel, and equipment;
- integration/optimization of human, material, energy, and economic resources and logistical, political, social, environmental, and technical factors during each critical phase of the project;
- worker training/retraining, including hands-on training; and
- worker registration/certification.

5.3.3 Construction Materials

The availability and cost of materials for construction influence planning, design, and construction operations. In planning construction activities, the responsible party or authorized representative should evaluate the availability and cost of specific materials in the local market, transportation costs for materials not available locally, storage and preparation procedures, and scheduling aspects related to

transportation and specially prepared materials. Material costs can include specialty products requiring fabrication; however, off the shelf availability of such items should be investigated to ensure that material costs are kept to a minimum. All such considerations should be evaluated early in the planning stages to ensure timely completion of the project using quality materials.

5.3.4 Supplier Manufacturing Capabilities

Specialized equipment may call for sophisticated manufacturing capabilities that are available only from a limited number of suppliers. Environmental technologies often involve this type of equipment. This can include, for example, specialized sampling equipment used to monitor technology success or specialty products required for technology construction. In order to ensure completion of the project on time, it is important that such materials and suppliers be identified at the early stages of planning and steps be taken to assess manufacturing and delivery capabilities. In addition, material specifications may be used to document project needs and ensure quality components are manufactured. A review of the manufacturer's implemented quality system, as well as implementation of external quality oversight (audits or inspection of large scale specialty items), are important. (See Chapter 7 for further discussion of assessments.)

Applicable GEPs for construction materials include:

- reuse of materials required for technology operation or development
- reduced use of virgin materials, wastes generated, energy sources, and human resources;
- recycling/recovery of materials, utilities, and energy sources;
- conservation of materials and energy sources;
- substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives.

5.4 CONTRACTUAL ARRANGEMENTS

Basic Quality Principle

The responsible party or technology developer should implement applicable contracting requirements for project design and construction.

Since most contracting issues are not directly related to QA, the details of contracting and procurement activities will not be covered in detail in this document. However, because there are some critical QA elements that should be addressed in contracting and procurement activities, associated roles and responsibilities for technical and QA personnel will be discussed here and in Section 5.5. While contracts are usually negotiated in a different part of the company or organization, technical personnel usually will be required to have some involvement. Generally, and subject to applicable procurement regulations and requirements, technical personnel furnish a statement of work (including detailed construction blueprints) outlining technical tasks that will be required on the part of the contractor and will recommend qualified contractors following technical evaluations of proposals.

Any procurement actions undertaken by EPA or other Federal departments and agencies based on this guidance must comply with applicable procurement regulations (e.g., Federal Acquisition Regulation) and requirements. This guidance is not intended to change or replace any applicable procurement regulations required by the user organization, including Federal and State regulations and statutes. Similarly, use of this guidance by a non-government organization may be subject to contract or other requirements for procurement.

In general, contractual documents usually include four basic elements: (1) solicitation documents, (2) contract forms, (3) contract conditions, and (4) plans and specifications. The types of solicitation documents will depend on the contract mechanism and form selected. Regardless of contract type, documentation related to requests for proposal, technical statement of work and specifications, qualification statements, formal solicitation documents, technical questions and responses, and other correspondence leading up to the selection of the constructor are part of the contract record and should be properly controlled from initiation of the solicitation process through completion of the project. This is likely to be a requirement of the procurement process and is an important practice from a quality stand point. Again, applicable Federal procurement regulations and policies will determine the appropriate contractual arrangement for Federal users.

Also part of the typical contractual record are contract conditions, including milestone and completion dates, general and supplementary conditions, terms and methods of payment, indemnifications, risks and liabilities assumed by each party, warranties and guarantees, and contract termination conditions. Plans and specifications typically include detailed design drawings for facilities to be constructed, materials specifications, specifications for construction or modification of utilities, and any other applicable drawings and specifications, such as field change orders, appropriate sign-offs at various phases of construction, and as-built drawings.

Applicable GEPs for constructual contracts include:

- design of self-correcting procedures and processes;
- analysis and interchangeability of all resources, such as materials, personnel, and equipment;
- automatic communication/notification procedures and processes among all team members;
- integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements;
- integration/optimization of human, material, energy, and economic resources and logistical, political, social, environmental, and technical factors during each critical phase of the project;
- sound project management principles/practices;
- worker training/retraining, including hands-on training;
- worker registration/certification;
- certification/permitting of work procedures, processes, equipment, and environment;
- use of automatic safety/corrective action triggers in technical, logistical, political, social, environmental, and economic situations; and
- routine/periodic inspections, testing and compliance audits of systems, procedures, processes, and equipment, etc.

Applicable legal requirements and specific administrative requirements of the site owner will dictate how long and in what form these and other contractual documents should be retained. The control of contract documents has been addressed in the publication, *The Uniform Locations of Subject Matter and Information in Construction Documents* (ASCE, 1981).

Standardization of construction contracts, in particular, is desirable in order to simplify the solicitation process and reduce the cost of soliciting bids and responding to such inquiries. Additionally, the use of standardized contract forms and language reduces the chance of errors and misunderstandings among the various parties. Many professional organizations and various industry associations have worked individually and jointly to develop standard forms, contracts, general conditions, and other contractual documents with this goal in mind. Examples of “standardized” contracts may be obtained from the Engineers Joint Contract Document Committee, the American Institute of Architects, and the Attorney General’s Chamber. In addition, a standardized form of contractual conditions has been prepared and is widely recognized for international work. The form was prepared by the International Federation of Consulting Engineers (FIDIC) in consultation with lending institutions and constructor associations. The form can be found in *Conditions of Contract for Works of Civil Engineering Construction* (FIDIC, 1992). A guide to the use of FIDIC conditions was published in 1989 and is available through the American Consulting Engineers Council (ACEC) (ACEC, 1989).

It is important that organizational and technical interfaces be established in the contractual process and clearly defined in the contractual documents. The construction team leader establishes the project specifications and communicates them to the team members, provides commensurate funding, encourages cooperation and communication among all team members, ensures adherence to project specifications, and establishes a schedule that is adequate to complete the project in a quality fashion. As part of project definition, it is critical that quality expectations be translated into clear, concise written specifications. In many cases, the design professional will assist in defining project specifications based upon agency expectations and QA and QC objectives. This process of defining project requirements may be iterative. However, it is important that they be fully defined as early as possible in the pre-design stage of the project. Ideally, the constructor’s project supervisor or operations manager should be involved in these discussions so as to better document quality expectations for implementation by procurement personnel in the appropriate contract documents.

In negotiated contract selection, qualifications statements may be solicited and evaluated (usually by technical staff), in accordance with applicable procurement regulations and requirements, to determine the constructor best qualified to perform the desired work. The responsible organization solicits proposals from potential offerors; the award is made on the basis of satisfying proposal elements defined by the organization or contracting entity. Such elements typically include:

- understanding of the project demonstrated by the constructor (based on the supplied scope of work);

- approach to the project, including utilization of unique and cost-effective approaches;
- proposed unit or lump-sum cost of the work, including fees;
- key management and supervisory personnel to be assigned to the project, including the role specified and the availability or commitment of these personnel; and
- plans and staffing to ensure compliance with safety, quality control, environmental, and other regulatory issues.

Additional elements that may be included are:

- proposed schedule with milestones and completion date(s);
- organization of project activities;
- use of local resources (materials, labor, etc.);
- availability of crafts, use of subcontractors, and minority and small business involvement;
- business information, such as labor and overhead costs, insurance, and contracting policies; and
- design of temporary structures, utilities, and transportation services.

The interfaces between the technical personnel and the procurement/contracting personnel should be clearly defined and implemented to ensure that all technical needs are communicated to the procurement/contracting personnel for implementation in accordance with applicable regulations and requirements. As shown in the following section, it may be necessary for the technical and QA personnel to interact with the procurement/contracting personnel to address quality requirements during various steps in the procurement process to ensure the acquisition of satisfactory items or services from the final contractual arrangements.

5.5 QUALITY PRACTICES IN PROCUREMENT ACTIVITIES

Basic Quality Principle
The responsible party and participating organizations, including the design professional, construction contractor, and facility operators should ensure that procured products and services meet established technical and QA objectives and that they perform as specified.

Quality should be an integral element of every procurement activity in the life cycle of an engineering project involving environmental technology. The following general discussions indicate points in a general procurement process where important quality control and quality assurance practices should be defined by technical and QA personnel for implementation by procurement/contracting personnel in accordance with applicable procurement regulations and requirements. These discussions are intended to provide guidance to technical personnel regarding their roles and responsibilities on quality-related actions that may need to be applied

during the procurement phases in engineering projects so that accurate and effective technical advice can be given to the procurement/contracts personnel.

5.5.1 Quality Practices in Procurement Planning

Early planning of and a systematic approach to procurement activities are important to ensure project quality, particularly for items and services that are integral to fabrication or construction of equipment necessary to the engineering project. It is important that organizational responsibility be identified and documented for applicable QA and QC activities such as specification of QA and QC requirements in the contract documents, pre-award audits and inspections to determine contractor capabilities, and technical and quality reviews of submitted bids or proposals. Typically, these activities will be performed by technical or QA personnel working with the procurement or contracting personnel. In addition, it is important that the sequence of actions (e.g., completion of a purchase requisition will occur before supplier bids are requested or a purchase order is awarded) and applicable milestones (e.g., signatures, award date, delivery of supplies or services, etc.) be documented and comply with any applicable procurement regulations or contract requirements. Standard elements of the procurement process typically include preparation, review, and change control of procurement documents; identification and selection of procurement sources; preparation of statement of work or specifications; evaluation and award of bid or proposal; verification of receipt and acceptance of the item or service; evaluation of supplier performance; and quality assurance records.

5.5.2 Quality Practices in the Evaluation of Suppliers

Supplier selection is based partly upon the purchaser's technical evaluation of the supplier's capability to provide the items or services in accordance with the specifications established in the procurement documents and subject to applicable procurement regulations and requirements. Identification of those within the organizations responsible for supplier source evaluation, including the appropriate QA organization, is important to ensure that quality supplies and services are procured. In most cases, these technical personnel will be responsible for determining whether or not the engineering design specifications have been satisfied in the supplier's proposal. Development and implementation of standardized evaluation and award procedures is also important to maintain the integrity of the selection process and ensure that supplier selection results in quality supplies and services. Supplier evaluation should ideally include a review of the supplier's history for satisfactorily providing similar products and services. Alternatively, an evaluation of the supplier's QA program, including quantitative or qualitative documentation of past performance, may be performed (usually by technical personnel) when permitted or authorized by applicable procurement regulations and requirements. In the case of suppliers that are new and do not have documentation of past performance, the supplier's technical and QA capabilities can be assessed based on an evaluation of the supplier's facilities, personnel, and quality program.

5.5.3 Quality Practices in Proposal Technical Evaluation

The solicitation proposal evaluation process determines the extent to which the supplier conformed to the specifications of the procurement document (e.g., request for proposal). This evaluation is typically performed by a team of contract specialists, technical experts, and QA personnel, subject to applicable procurement regulations and requirements. This process evaluates the skill and experience of the supplier's technical personnel; other technical considerations, such as the technical approach identified by the supplier; supplier past performance and production capability; QA program organization, procedures, and personnel; and any exceptions noted or changes in technical approach and specifications recommended by the supplier. Any such exceptions, recommended changes, or deficiencies identified during the evaluation should be resolved (or a commitment obtained from the supplier to resolve the issue), in accordance with applicable procurement regulations and requirements, before the contract is awarded. It is advisable that the purchaser's technical and QA personnel conduct a QA management review and confirm the acceptability of the supplier's QA provisions before the contract is awarded and/or work is started.

5.5.4 Quality Practices in Work Plans and Other Documents

Work plans and similar documents are often part of the quality assurance plan, and, in such cases, should include the following technical elements consistent with applicable procurement regulations and requirements:

- A scope of work detailing the technical and administrative (e.g., progress reports) specifications.
- Other technical specifications, such as design bases (identified and referenced); design drawings and other documents (e.g., codes regulations, procedures, etc.); and tests, inspections, hold points, or acceptance criteria used to monitor and evaluate supplier performance.
- QA provisions, including (1) QA specifications and documentation, (2) pass-down specifications that the supplier is required to incorporate into any sub-tier procurement documents, and (3) applicable QA documents from the purchaser if those are to be implemented in lieu of supplier QA procedures.
- Documentation of QA and QC procedures that may be outside normal industry standards such as usually would be specified in a standard operating procedure. This is especially important for suppliers of services. For example, a supplier may be using a standard operating procedure that is industry-accepted but may not satisfy specific project specifications. This type of situation would benefit from additional monitoring to ensure project specifications are achieved.

5.5.5 Quality Practices in Document Review and Approval

Procurement documents should be reviewed by trained personnel with access to and understanding of the procurement scope and requirements, and in accordance with applicable procurement regulations and requirements. Typically, the contractual aspects of these documents are reviewed by procurement/contracting personnel and the technical (and QA) aspects are reviewed by technical and QA personnel. Comprehensive review against the document requirements may help to ensure full compliance with procurement procedures. This review should help the responsible organization select the best-qualified supplier. This, in turn, increases the likelihood that appropriate and sufficient-quality supplies will be procured, thus helping to ensure that project quality is maintained. Reviews should be performed and documented, along with any changes, in accordance with applicable procurement regulations and requirements prior to the procurement document being issued to the supplier.

5.5.6 Considerations in Evaluating Supplier Quality Management Capability

In some circumstances in the engineering project process, it may be appropriate to require a supplier to have a quality system that conforms to a recognized consensus standard like ISO 9001:2000, *Quality Management Systems - Requirements* (ISO, 2000), as permitted in the Federal Acquisition Regulations in 48 CFR Part 46. In order to confirm that its quality system conforms to such standards, the supplier may demonstrate its conformity through a certification process. Such certificates are widely recognized and accepted, and may provide the customer with increased assurance that the supplier is capable of performing at a level that meets the needs of the customer. However, certification alone may not be sufficient to ensure that the supplier can perform to expectations in providing specific products and services. It may be necessary to assess or audit the supplier's performance directly. These audits are generally allowed under Federal procurement regulations and are typically conducted by customer's technical and QA personnel. The specifications for the audits are derived from the approved procurement documents and specifications.

5.5.7 Quality Conditions in Acceptance of Items or Services

Typically, acceptance by the purchaser of items or services received from the supplier will involve four parts, subject to applicable procurement regulations and requirements:

- source verification,
- receiving inspection,
- post-installation testing, and
- supplier certification of conformance.

Source verification involves acceptance of any goods or services by the purchaser based on monitoring, auditing, or other surveillance activities performed by the supplier. The extent of monitoring and the inspection intervals should be determined based upon the complexity and/or importance of the purchased item or service and previous experience with the supplier and in

accordance with applicable procurement regulations and requirements. Documented evidence of acceptance of the item or service is then furnished to the receiving party. Typically, such inspections are performed by technical personnel and/or QA personnel.

Receiving inspection is used by the purchaser to accept an item in accordance with established inspection procedures, which, in turn, are driven by the established product specifications and applicable procurement regulations and requirements. The inspection verifies, as applicable, product identification and configuration, dimensions, physical characteristics, cleanliness, and lack of damage. Inspections also include a review of the adequacy and completeness of supplier documentation. Accordingly, it is expected that the technical personnel conducting the inspections should have the necessary knowledge of the specifications and skills to evaluate the received items.

Post-installation testing is used frequently in engineering projects to verify that an item meets the specifications of the purchaser. It is critical that the purchaser's specifications be fully documented in advance of the project and that acceptance criteria be mutually agreed upon by the purchaser and supplier. This testing can be in the form of an onsite audit of the equipment supplied. A flow meter, for example, may be tested by calibration after installation to ensure that accuracy and precision specifications meet supplier and purchaser QC specifications. Again, such testing typically performed by technical personnel who will advise the procurement/contracting personnel regarding the acceptability of the items.

In lieu of or in addition to the above acceptance methods, the purchaser may require that the supplier provide a certificate of conformance with applicable technical standards or criteria (such as ISO 9001 mentioned earlier). The certificate identifies the purchased material or equipment along with the purchase order or other identification number traceable to the procurement document. This certificate should identify the codes, standards, specifications, or other procurement requirements met by the item. It is important that this certificate be signed or otherwise authenticated by a responsible official. For example, this certificate of conformance may be an American Society for Testing and Materials certification or other similar authentication that the product performs as specified. Verification of such certificates of conformity is typically performed by technical personnel who will advise the procurement/contracting personnel regarding the acceptability of the items.

5.5.8 Quality Considerations in Control of Supplier Nonconformance

The purchaser and supplier should document an agreed-upon process for handling items that do not conform with procurement document specifications and in accordance with applicable procurement regulations and requirements. At a minimum, the supplier should report nonconforming items to the purchaser within the allotted time frame and utilize the mechanism set up for nonconformance procedures. It is important, therefore, that such procedures establish specific guidelines for handling nonconforming items. In any case, the purchaser ultimately verifies the disposition of the nonconforming items. The technical guidelines should be provided

by the technical personnel to the procurement/contracting personnel, who will conduct discussions with the supplier in accordance with applicable regulations and requirements.

5.5.9 Quality Considerations in the Use of Commercial-Grade Items

The design may specify commercial-grade items. The items should be clearly identified in the design drawing or specifications by the technical personnel and conveyed to the procurement personnel. Any source selection specifications should also be identified in the procurement document from the manufacturer's published product description in accordance with applicable procurement regulations and requirements. Alternative suppliers, product grades, or products typically may be utilized only if the purchaser approves the change or replacement. Acceptance by the purchaser will be based on verification by technical personnel in the design organization that the alternative commercial product performs the intended function and meets design specifications in accordance with applicable procurement regulations and requirements. Acceptance of commercial grade items should be based upon (1) inspection or testing by the purchaser to ensure that the item meets manufacturer's specifications, (2) verification that the item received was the item ordered, (3) confirmation that no damage was sustained during shipment, and (4) confirmation that appropriate documentation was received and is acceptable. Technical personnel are responsible for advising the procurement/contracts personnel regarding the technical acceptability of commercial grade items.

5.6 SCHEDULING AND TRACKING

Basic Quality Principle
Early construction planning by the responsible party, design professional, and constructor enables schedule milestones to be included in the construction contract.

Significant issue dates for design elements and key delivery dates for supplies, materials, and factory-fabricated items should be included in the construction schedule to integrate design, procurement, and construction before construction begins. Other relevant schedule dates, such as utility hookups or changeovers, should be included. It is important that the schedules be based upon labor workforce availability and realistic production rates and quantities. Equally important is that the responsible party recognizes the necessity for preparing, coordinating, reviewing, and approving shop drawings and other submittals and allows sufficient time for such reviews.

5.7 COST MANAGEMENT

Basic Quality Principle
During the construction and fabrication of system components, the constructor's (and all subcontractors') estimates should be tracked, refined, and updated.

Documented procedures should be established that will allow control and tracking of construction costs for each phase/area/activity of the construction as well as for the overall project. Work productivity should also be tracked to identify problem areas. Identifying and, if necessary, correcting cost trends early in the process should help prevent overruns, quality problems, and disputes.

5.8 MATERIALS MANAGEMENT

Basic Quality Principle

The constructor should establish a documented plan to control and track purchasing, receiving, special storage, and in-storage maintenance of materials for the project and the time frame.

A documented plan may include a system that will key material deliveries to the project schedules. The availability of materials should be a prime consideration any time the project schedule is revised. Productivity and quality often suffer when crews are started and stopped repeatedly due to material shortages. Construction materials will generally fall into one of two major classes: *in situ* materials and manufactured items.

In situ materials include soils and rocks used for backfill, construction bases (e.g., gravel bases for roads and foundations), or components of site structures (e.g., clay used in landfill and lagoon liners and berms, limestone in cement, or gravel in concrete). Depending upon the material requirements, these materials may be excavated at the site or may be shipped from local, regional, or national suppliers. Transportation of these materials should be considered in construction scheduling, especially during severe weather. Stockpiles onsite may be used to provide a steady supply of materials; the location and footprint of such stockpiles should be considered during site planning.

Manufactured items include a wide variety of materials. Examples include metal or plastic piping; paints and sealers; liners or other plastic products; structural steel; electrical conduit, wiring, circuit breaker, switches, and other electrical components; motors, pumps, and other mechanical installations; plywood, particle board, and other wood and timber products; brick and other masonry products; and asphalt. As with *in situ* materials, identification of suppliers, establishment of contractual relationships, development of quality specifications, and consideration of schedule are all important elements of materials management. Materials quality specifications may be established by broadly-accepted standards developed by organizations, such as the American Society for Testing and Materials, the American Concrete Institute, Institute of Electrical and Electronic Engineers, and so forth. Alternatively, site-specific standards may be developed by the design firm. A good list of acceptance standards for a variety of materials is presented in the American Society of Civil Engineers guide, *Quality in the Constructed Project: A Guide for Owners, Designers and Constructors* (ASCE, 2000).

5.9 INSPECTION, TESTING, CONTROL, AND TRACKING

Basic Quality Principle
An important part of the work planning process is to identify the items and processes to be inspected or tested, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, any hold points, and the organization responsible for performing the tests and inspections.

Inspection and testing of specified items and processes are conducted using established acceptance and performance criteria. The acceptance of items and processes is made by and documented by qualified and authorized personnel. It is important that equipment used for inspections and tests be calibrated. An inspection and testing program for the construction/fabrication/installation of environmental technology should be in accordance with the following key specifications.

First, it is important that a planning program be implemented for the inspection, testing, and monitoring of materials. Several objectives should be considered:

- the quality of supplies should be verified in accordance with specified procedures,
- the inventory of supplies and materials should also be monitored to ensure the continuity of construction activities, and
- the workmanship and adherence to technical specifications should be verified for specially-fabricated materials and equipment.

Second, a thorough and comprehensive inspection, testing, and monitoring program should be implemented. This may involve the inspection of supplies and materials in process at the supplier location. Alternatively, inspections may be made of goods ready for shipment from the supplier or as received by the constructor or the contractor.

Third, the performance of inspections and testing, as well as the results, should be fully documented. This is critical in cases where problems and defects occur and there is a disagreement between the receiver and the supplier as to the quality of the product or material or as to who is responsible. Since such problems cannot be predicted, it is important that thorough documentation be an integral part of the inspection and testing process.

Finally, a quality assurance program is vital to the inspection and testing program. It is important that any monitoring, measuring, testing, and data collection equipment be properly selected and utilized. Equipment selection entails that the equipment measure the parameter within the established acceptance range. Therefore, the testing equipment should be properly sized such that its measurement range and accuracy meets those standards established for the product or material. In addition, the testing equipment should have a precision range that encompasses the agreed-upon tolerance limits for the product. As has been discussed previously, the acceptance range and tolerance limits should be established in advance, agreed

upon with the supplier, and fully documented in the appropriate contractual documents. Not only should the measurement instrument be properly selected, it should be properly used and controlled to ensure the reliability of testing results. The equipment should be used according to the manufacturer's instructions for that equipment. Frequent performance and documentation of equipment calibration is important, especially under harsh operating conditions. Zero checks and calibration with known standards are typically the minimum calibration specifications. Additional calibration procedures may include measurement of internal standards (standard incorporated into the matrix to be measured) or other more sophisticated QA procedures. Equally important to the selection and calibration of testing equipment are the qualifications of inspection and test personnel. Training in inspection and testing procedures, equipment use and calibration, and proper procedures to document inspections and tests is critical to the success of any quality assurance program.

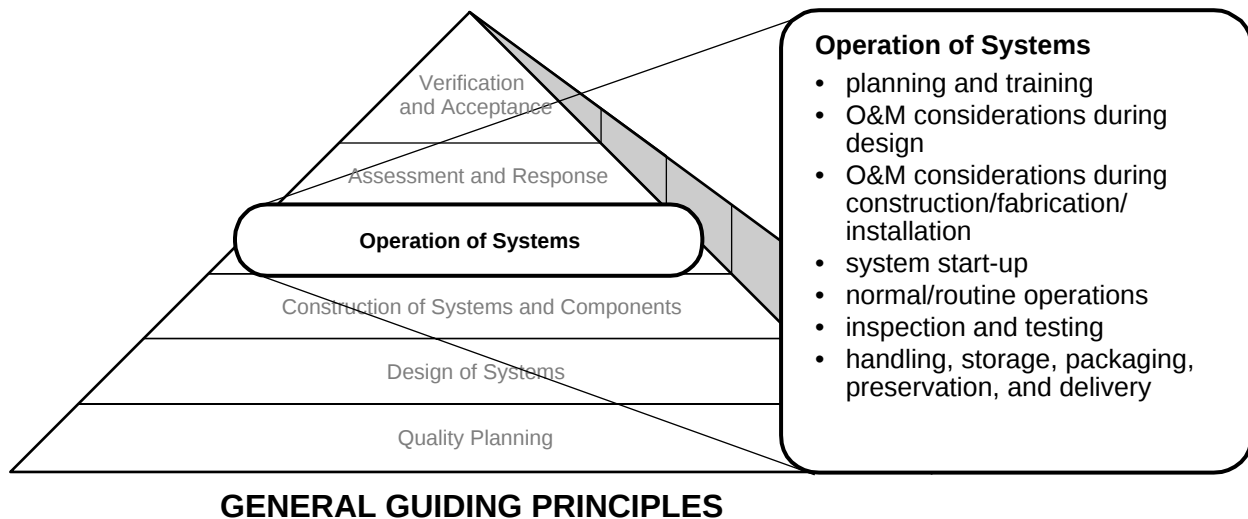
5.10 COMPLETION APPROVALS

Basic Quality Principle
During the planning phase of the project, specifications for construction completion certification and approvals of external agencies and other groups should be established, documented, and communicated with appropriate individuals.

Environmental technology construction projects may have two levels of approvals: (1) internal and (2) external/independent/regulatory. Internal certifications and approvals consist of the design professional verifying/authenticating and certifying for the responsible party the completion of part or all of the construction/fabrication/installation. When a project is completed (or critical portions thereof), many agencies require some sort of release or affidavit, or both, certifying that work has been done substantially in accordance with the appropriate contract documents. Furthermore, information on the location or completeness of record drawings and certain project-specific design/construction documents may be required. In addition to formal regulatory review, environmental projects involving other stakeholders (e.g., local communities, environmental groups, etc.) may require approval by these stakeholders or their technical representatives.

CHAPTER 6

SYSTEM OPERATION AND MAINTENANCE



6.1 INTRODUCTION

Basic Quality Principle

O&M factors influence life-cycle costs, continuity of service, durability, public health and safety, environmental impact, and other features of the completed environmental technology project/program/facility.

The operational characteristics and maintenance of the project after completion determine the success in meeting project objectives. Consideration of O&M specifications in each phase of project planning, design, construction, and start-up is therefore desirable. For all projects, active participation of the developer from an O&M viewpoint adds to the developer's understanding of the design criteria and the effort to translate the design specifications into an operating facility meeting project specifications. In the planning and design of the project, the O&M concern is with input to and review of design-phase activities; in the construction phase, the concern is with construction observation and inspection; in the start-up phase, the concern is with verification, testing, and acceptance; and in the operational phase, the concern is with the operation and maintenance of the constructed project. O&M procedures are normally established and documented to ensure control and compliance for each of the various stages of the project as discussed below.

6.2 PLANNING FOR O&M INPUT AND TRAINING

Basic Quality Principle

The developer may select from a number of options providing for consideration of the various O&M issues as they influence design, construction, and operation of the environmental technology.
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The following issues should be addressed while planning for O&M:

- The developer may appoint a member of the O&M staff as project coordinator to advise the design professional and the constructor from the O&M standpoint. For this assignment the developer should find an experienced individual, preferably a candidate to head up the operations team for the completed facility.
- The developer may contract with the design professional to have an experienced professional member of the design team or a qualified consultant provide the appropriate O&M advice and review.
- The developer may delegate members of the O&M staff to work under the design professional in observation and/or inspection of construction activity during the construction phase. This assignment provides an opportunity for O&M personnel to become familiar with the project while performing construction phase duties.
- The developer may delegate members of the O&M staff to work with the design professional and constructor during the start-up phase of the project.
- The developer may contract with the design professional and/or constructor to provide review of and advice for operation and maintenance programs for some defined time after the project has been taken over by the operating staff.

6.3 O&M CONSIDERATIONS DURING DESIGN PHASE

Basic Quality Principle

Decisions made during the design phase relating to site selection and access, process choice, equipment selection, and other elements of the project will impact O&M of the completed project and limit flexibility in subsequent phases of the project.
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Reviews stressing the operability and maintainability of various features of the project are scheduled at appropriate points in the design phase and at final design. The frequency and depth of these reviews vary with the size and complexity of the technology to be deployed. Reviews from an O&M perspective normally include the following:

Physical plant considerations – Size and layout of working space to be provided; suitability of equipment types, including efficiency in operation, maintenance schedule, and costs for the equipment; provisions for bypassing and isolation equipment for maintenance; specialized services, such as laboratory and chemicals; staff amenities; efficient land utilization; specific layout of equipment, process, and control systems to provide O&M accessibility; lay-down space and removal paths; appropriate flexibility and redundancy in equipment and controls; and provisions for adequate manufacturer-supplied materials, and spare parts information should be considered.

Control strategies – Alternative strategies on efficiency of operations and staffing.

Life-cycle cost considerations – Building materials and equipment.

Environmental considerations – Provisions to mitigate odors, noise, and undesirable aesthetic effects, as well as the possible need for a public-relations program.

Safety considerations – Equipment, protective devices, etc.

Personnel – Budget planning and O&M staffing.

During the design phase, the developer is responsible for communicating needs, constraints, expectations, and requirements regarding performance, operation, and maintenance of the proposed facility and for providing timely reviews. The developer is also responsible for providing adequate O&M input and determining (with the help of the design professional and the O&M coordinator) O&M budget and staffing requirements. The design professional is then responsible for preparing the plans and specifications incorporating O&M considerations.

6.4 O&M CONSIDERATIONS DURING CONSTRUCTION/FABRICATION/INSTALLATION PHASE

Basic Quality Principle
The construction phase of the project provides an opportunity for the developer's O&M coordinator to make the transition from the advisory and reviewer roles of the design phase to more active roles.

Activities contributing to project construction that can provide valuable information for O&M personnel include:

- inspection and testing of materials and equipment;
- observation of installation and testing of equipment by the constructor;
- observations of construction activities pertaining to utility routing and locations, installation problems affecting O&M, and arrangements of project elements as they affect operational safety and maintenance; and

- assistance to the design professional in preparation and review of the O&M manuals and procedures.

6.5 SYSTEM START-UP

Basic Quality Principle

The O&M staff are key players in the start-up of any project.

The purpose of start-up phase activities is to demonstrate that project elements constructed or installed by the constructor are in working order, and that the facility performs as planned by the developer and the design professional. This activity gives the O&M staff the opportunity to become familiar with the project under the guidance of the constructor and design professional. Start-up of an environmental technology may require the organization and training of a start-up group composed of representatives from the developer, design professional, constructor and O&M staff.

6.5.1 Planning the Start-Up Program

Responsibility for organizing and leading the start-up program is generally part of the developer agreement with the constructor. With responsibility for start-up established, the start-up team is assembled with representation from the design professional, constructor, and developer, with particular emphasis on representation from the O&M staff. Activities of the team in planning for start-up include:

- preparing and reviewing start-up programs and procedures,
- determining construction completion status,
- planning for supervision of system testing and correlation of deficiencies, and
- reviewing final inspection reports and project closeout submittals.

Planning for an environmental technology/treatment system/facility start-up calls for a well-defined approach and documented procedures and methods for:

- hazardous operations review/analysis,
- safety checking/testing,
- operator training,
- system start-up (start-up procedures),
- standard operating procedures, and
- emergency shutdown procedures.

The interaction and exchange of information among the principal parties involved in the project may be outlined in a start-up manual along with planning, scheduling, testing, and other activities planned by the start-up team. Start-up manuals should be structured to fit the project.

Simple, direct, and brief language is preferred. Aids such as forms, checklists, and tabulations are useful.

6.5.2 Start-Up Activities

Project start-up activities demonstrate the integration of various constructed systems into a unified facility. Start-up activities are generally based on the premise that project elements completed by the constructor have met the material, workmanship, and performance specifications. Start-up activities are structured to:

- determine that each component of the project is in working order;
- determine that these components can be integrated to operate as a facility, which performs as planned by the developer and design professional;
- provide a means of training O&M personnel in the operation of each of the components and of the completed facility (O&M during the start-up of the project provides opportunity for the O&M staff to view technology operations with guidance from the design professional and the constructor);
- validate O&M instructions and manuals prepared by the design professional or others;
- check the file of record documents (plans, specifications, manufacturers' operating instructions, maintenance instruction, etc.) for appropriate scope and detail; and
- serve as a vehicle for acceptance of the constructor's completed contract and turnover of the facility to the O&M staff for operation.

6.6 NORMAL/ROUTINE OPERATIONS

Basic Quality Principle
Documented procedures should be established prior to the start of the operating phase and refined, fine-tuned, and updated, as needed, for all substantial activities that constitute the system operation.

The post-construction, post-start-up operating phase of the project is generally the sole responsibility of the developer and the O&M staff. The O&M staff works with and/or through the constructor in seeking enforcement of all applicable warranties (and performance standards) and correction of any defects found in the constructor's work. The O&M staff may also wish to consult with the design professional to request clarification and amplification of operating and maintenance manuals, to seek advice in fine-tuning project operations, and to ask for assistance in testing and evaluating performance for conformance to design criteria and project specifications. Established documented procedure should include the following:

Process control and monitoring – To ensure that process output (the product or discharge stream) complies with reference standards/codes, quality plans, and/or documented procedures, and stays within the permissible tolerance criteria.

Equipment control and maintenance – To ensure that each piece of equipment within a process, process train, or system performs its intended task with the appropriate degree of accuracy and reliability.

Technology operating guides also provide helpful information about systems and processes. They normally include, but are not limited to:

- appropriate controls for measuring and testing equipment;
- operating procedures and parameters for specific components and system configurations, including specified safety limits;
- process equipment control and maintenance;
- special environments, time, temperature, or other factors affecting the quality of operation; and
- the skill, capability, and knowledge of operators to meet operational, environmental, and quality objectives.

6.6.1 Process Control

Process control activities may be documented by instructions, procedures, drawings, checklists, or other appropriate means. These means ensure that process parameters are monitored and controlled and that specified environmental conditions are maintained.

6.6.2 Control of Auxiliaries and Services

When the quality of systems operation is directly affected, auxiliary materials, utilities, and consumables (e.g., water, compressed air, electric power, and chemical feed stocks) should be controlled and verified periodically to ensure uniformity of their effect on the systems involved in accordance with established procedures. Only qualified and accepted services or items and consumables should be used during the operation of systems.

6.6.3 Control of Operational Status

The status of the operating system is controlled to ensure conformance with the approved operating procedures and specifications. Status indicators with tolerance limitations should be provided to display the operating status of systems and components of systems as described in the design and operating instructions and guides. The use of status indicators will help to prevent inadvertent operation or removal from operation of systems or components when such actions would adversely affect performance of the systems, constitute an operational safety or environmental hazard, or violate statutory/regulatory compliance requirements. (Note: Such

situations include the loss of data that are difficult or impossible to reproduce and may result in the unplanned release of pollutants in excess of established limits.)

6.7 INSPECTION AND TESTING

Basic Quality Principle

The O&M organization should establish and maintain documented procedures for receiving, in-process, and final inspection and testing in order to verify that specifications are achieved. Provided in this section are inspection and testing specifications for engineering applications.
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Areas of inspection include:

- equipment, parts, spare parts, system components, hardware, software, and supplies;
- process feed/inputs;
- other processing materials; and
- treated materials and products/by-products.

6.7.1 Qualifications of Inspection and Test Personnel

Each person who verifies conformance of O&M activities for the purpose of acceptance should be qualified to perform the assigned inspection task. Inspections by persons during on-the-job training for qualification should be performed under the direct observation and supervision of qualified personnel.

6.7.2 Inspection and Testing Specifications

A. Planning for Inspection and Testing

Inspection is not a separate QA function. It is a line implementation function and test planning should be performed and documented. This includes:

- identification of the item to be tested or the treatment processes/operations where inspections are necessary;
- identification of the test specifications or the characteristics to be inspected and the identification of when, during the treatment process, inspections are to be performed;
- identification of the testing, inspection, or process monitoring methods to be employed;
- identification of acceptance criteria, including the desired levels of precision and accuracy (when statistical sampling is to be used to verify the acceptability of the subject items or materials, the statistical sampling method should be based upon recognized standard practices);

- identification of sampling activities;
- methods to record inspection or test results;
- selection and identification of the measuring and testing equipment to be used to perform the test or inspection;
- the process used to ensure that the equipment being utilized for inspection or testing is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function;
- provisions for ensuring that prerequisites for the given test or inspection have been met, including hardware and software needs, personnel training and qualification, and suitably controlled environmental conditions; and
- any mandatory hold points.

B. Receiving or Hold Point Inspection and Testing

The O&M staff should ensure that incoming materials or products are not used or processed until they have been inspected or otherwise verified as conforming to specifications. Verification of the specifications should be performed in accordance with the project-specific quality plan and/or documented procedures. When incoming material or product is released for urgent treatment/processing purposes prior to verification, it should be positively identified and recorded in order to permit immediate recall and re-treatment in the event of nonconformity to specifications.

Hold points are used to control work or activities that are not to proceed without the specific consent of the designated representative or organization placing the hold point. The specific hold points should be specified in appropriate documents. Only the organization or representative responsible for the hold point may waive the hold point inspection requirement. Consent to waive specified hold points is recorded prior to continuation of work beyond the designated hold point.

C. In-Process Inspection and Testing

Items or materials in process are inspected and/or tested as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing/treatment methods, equipment, and personnel should be provided. When a combination of inspection and process monitoring methods is used, monitoring should be performed systematically to ensure that the specifications for control of the process and the quality of items are met throughout the duration of the treatment process.

D. Final Inspection and Testing

Final inspections include a review of the results and verification of the resolution of all non-conformities identified by earlier inspections. Treated materials are inspected and tested for completeness or other characteristics as required to verify the quality and conformance of the materials to the applicable specifications. Reprocessing or further treatment of the treated

materials subsequent to final inspection normally entails reinspection or retesting, as appropriate, to verify acceptability.

E. In-Service Inspection and Testing

In-service inspection or surveillance of structures, systems, or components of the environmental technology should be planned and executed by or for the organization responsible for their operation. Inspection and testing methods should be established and executed to verify that the characteristics of the subject material continue to remain within specified limits. Inspection and testing methods include evaluations of performance capability of key equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

F. Inspection and Test Documentation

The O&M staff should establish and maintain records that provide evidence that the components and processes of the environmental technology and the materials involved, including the feed matrices, treatment chemicals and supplies, and the treated residuals, have been inspected and/or tested. These records should clearly indicate whether the subject item has passed or failed the inspections and/or tests according to defined acceptance criteria. Inspection and test results are then evaluated by qualified individuals within the O&M organization to ensure that all test and inspection specifications have been satisfied. When the item fails to pass any inspection and/or test, the procedure for control and replacement of the nonconforming item would apply. Inspection and test documentation should identify:

- items or materials inspected and/or tested;
- the date of inspection and/or test;
- the name or unique identifier of the inspector/tester who documented, evaluated, and determined acceptability;
- the method of inspection and/or the applicable test specifications, plans, and procedures, including revisions;
- the inspection and/or test criteria, sampling plan, or reference documents (including revision designation) used to determine acceptance;
- the results;
- the identification of the measurement and testing equipment used during the inspection and/or test, including the identification number and the calibration due date; and
- reference to any information on actions taken in connection with nonconformities, as applicable.

6.7.3 Inspection and Test Status

The inspection and test status of an item should be identified by suitable means, which indicates the conformance of the item with regard to inspection and tests performed. The

identification of inspection and test status should also be maintained, as defined in the project-specific quality plan and/or documented procedures, throughout the O&M of the treatment process in order to ensure that only items and materials that have passed the inspections are used, installed, or dispatched.

6.8 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

Basic Quality Principle
Documented procedures should be established and maintained for handling, storage, packaging, preservation, and delivery of product.

Additional QA-related O&M aspects include the following:

Handling – The O&M organization should provide safe and proven methods for handling products in order to prevent damage or deterioration.

Storage – Designated storage areas or stock rooms are used to prevent damage or deterioration of product, pending use or delivery.

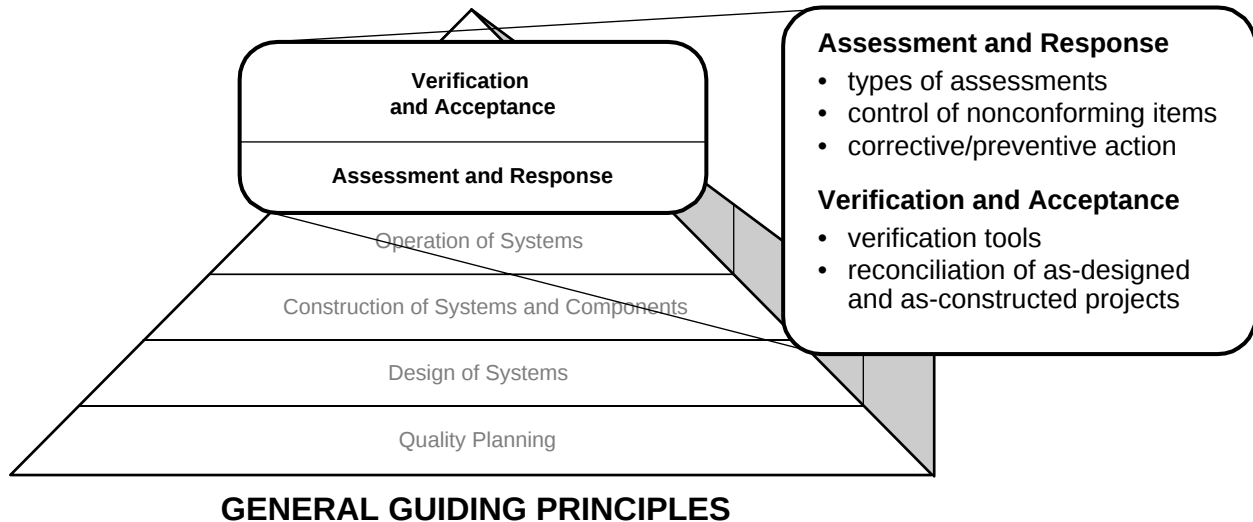
Packaging – Packing, packaging, and marking processes (including material use) should be controlled to the extent necessary to ensure conformance to specifications.

Preservation – Appropriate methods for preservation of products should be applied.

Delivery – The O&M staff should be responsible for the protection of the quality of product after final inspection and testing.

CHAPTER 7

ASSESSMENT AND VERIFICATION



7.1 MANAGEMENT/TECHNICAL ASSESSMENT AND RESPONSE

Basic Quality Principle

Assessment provides the basic program structure to ensure that quality specifications are maintained.

This section summarizes the role of assessments in environmental technology projects and how the results of assessments are used. For more information on how to conduct technical audits and assessments, see *Guidance on Technical Audits and Related Assessments (EPA QA/G-7)* (U.S. EPA, 2000c).

7.1.1 Types of Assessments

Work performed during the design, construction, and operation of environmental technology that affects quality should be assessed regularly to ensure that approved planning steps, design specifications, and operating guides are being implemented as prescribed. When acceptance criteria are not met, deficiencies are normally resolved and reassessments conducted as necessary. Appropriate corrective actions are taken and their adequacy confirmed and documented in response to deficiencies or nonconformities. Under most circumstances the organization performing assessments has sufficient authority and freedom from the activities being assessed to carry out its responsibilities. Persons conducting external or third-party assessments should also be technically qualified and knowledgeable of the items and activities being assessed. In addition, the owner/developer may have a need to conduct internal or first-party assessments.

The types and frequencies of independent assessments are usually based upon the relevant control levels assigned to the items and activities under the cognizance of the organization. In addition, the participant organizations responsible for the performance of activities important to compliance application, waste characterization, or the isolation of waste within the disposal/treatment system should implement a program of surveillance and audits. The program is then planned and documented and should include both routine surveillance of those activities and audits to establish compliance with all aspects of the project-specific QA plan to determine its adequacy and effectiveness.

Periodic assessments or audits may also be desirable throughout the process life cycle. Audit timing should be addressed. Is a process audited only once at the beginning, periodically throughout its life cycle, or perhaps when changes in operation or personnel occur? Selecting qualified personnel for audits is important to the success of the audit. Personnel should be chosen based on two primary factors: (1) the expertise appropriate to review the process or operation being audited and (2) experience in performing audits. Often a team approach is appropriate to provide these qualifications. In many instances a technical expert and QA auditor can work together to provide the combined expertise suitable for the audit. This is particularly useful during technology operation or evaluation. This approach would usually be applied as part of a technical systems audit conducted early in the operation life cycle. Technical experts can provide invaluable expertise in evaluating design, construction, and operation of environmental technologies. The technical expert provides the knowledge and experience adequate to address all parts of the process audited, while the QA auditor provides the understanding of the audit process, helping to focus the audit on those activities that are most critical. The QA auditor can also provide leadership in terms of how to frame questions, what type of follow-up questions might be appropriate, and how to couch audit findings so as to maximize management support.

Audit procedures and checklists should be developed and reviewed by the team before beginning the audit. Thought should be put into the process flow (beginning with receipt, testing, and acceptance of materials, through operational aspects, and ultimately ending with the finished product or completed project). Audit questions should be clear, concise, and nonjudgmental. Potential follow-up questions should be anticipated and, where appropriate, decision trees applied. Another important aspect of audit planning is addressing the issue of responsibility or authority to suspend work if audit findings show that the process is out of compliance with regulatory or QA criteria. Should the process be halted or operational changes evaluated if deficiencies are noted during the course of an audit? Serious findings may be identified. How are they reported? How are they brought to the attention of appropriate personnel? When should work be suspended for reassessment?

Basic assessments include quality control or technical assessments and management audits. These assessments are designed to provide a review of project performance that is unbiased by the pressures of meeting construction schedules and budgets. An example of a quality control assessment is the **technical systems audit**. This is an audit of design, construction, or operational systems to ensure that procedures defined in planning documents are

being carried out properly. The project planning document should be used as a guide when performing these assessments.

Management audits and assessments, on the other hand, are evaluations of program or project management quality. These are performed by managers, or designated internal or external experts, to periodically assess the performance of their organizations. The results of these audits should be used to implement corrective measures, where necessary, and as input into the organization's continuous improvement process. In many cases, such assessments are an integral part of management review.

Surveillances are observations of a specific technical activity on an extended basis. The surveillance process consists of monitoring or observing to determine whether an item, activity, system, or process conforms to specifications. Surveillances are intended to accomplish the following:

- monitor work in process,
- document compliance or noncompliance with established specifications and procedures,
- identify actual and potential conditions adverse to quality,
- obtain timely corrective action commitment from cognizant managers for identified conditions adverse to quality,
- provide notification to responsible managers of the status and performance of work under surveillance, and
- confirm timely implementation of corrective action.

Assessments should be performed using the written procedures related to the activity being assessed. Elements that have been selected for assessment are then evaluated against specifications. Objective evidence is obtained to determine if those elements are being implemented effectively. Conditions requiring prompt corrective action should be reported immediately to management of the monitored organization. Conditions adverse to quality should also be documented and corrected according to the discussion in Section 7.1.3 below.

7.1.2 Control of Nonconforming Items

Documented procedures should be established and maintained in order to ensure that items and materials that do not conform to specifications are prevented from unintended use, installation, or release. This control should provide for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming products, and notification to the functions concerned.

Identification of nonconforming items by marking, tagging, or other methods should not adversely affect the end use of the item. The identification should be legible and easily recognizable. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, is then identified.

Nonconforming items should be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations, other precautions should be employed to preclude inadvertent use of a nonconforming item.

Nonconforming item characteristics are to be reviewed, and recommended dispositions of nonconforming items should be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item is then controlled pending an evaluation and an approved disposition by authorized personnel.

The responsibility for review and authority for the disposition of nonconforming product should be defined. Personnel performing evaluations to determine a disposition should have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the specifications, and have access to pertinent background information.

Disposition of nonconforming product and the technical justification for the disposition should be identified and documented. Nonconformity of an item may be disposed through:

- reworking or retreating to meet the specifications,
- accepting with or without repair or remedy by concession,
- regrading for alternative treatment or applications, or
- rejecting or scrapping.

The description of the nonconformity that has been accepted and the description of the repair or remedy is then recorded to denote the actual condition. Repaired, reworked, and/or retreated product should be reinspected, retested, and/or reassessed in accordance with the project-specific quality plan and/or documented procedures.

7.1.3 Corrective and Preventive Action

The participant organization should establish and maintain documented procedures for implementing a corrective and preventive action program. Any corrective or preventive actions taken to eliminate the causes of actual or potential nonconformities are to be appropriate to the magnitude of the problems and commensurate with the risks encountered. The responsible organization should implement and record any changes to the documented procedures resulting from corrective and preventive action.

The procedures for corrective action should include:

- effective handling of client, customer or regulatory complaints, and reports of product nonconformities;
- investigation of the cause of nonconformities relating to product, process, and quality system, and recording the results of the investigation;

- determination of corrective action that will eliminate the cause of nonconformities; and
- application of controls to ensure that corrective action is taken and that it is effective.

The procedures for preventive action should include:

- the use of appropriate sources of information, such as processes and work operations that affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities;
- determination of the steps to be taken to deal with any problems requiring preventive action;
- initiation of preventive action and application of controls to ensure that it is effective; and
- confirmation that relevant information on actions taken is submitted for management review.

Refer to U.S. EPA, 2000c for more information on corrective and preventive actions.

7.2 VERIFICATION AND ACCEPTANCE

Basic Quality Principle
Verification is confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. Though it is related to the concept of assessment, verification is usually considered an ongoing line management responsibility, rather than as independent oversight.

7.2.1 Verification Tools

Verification involves identifying what goals should be met at various stages of operation or evaluation and whether these goals are still achievable. In some instances, for example, re-evaluation of the process being used or evaluated may merit consideration. Updating of QC specifications during the course of operation, changes in operation or construction activities, or re-evaluation of set standards may be called for if operation does not proceed as planned. If re-evaluation shows that initial QC specifications are not adequate, then the implementation plan should identify a process for ensuring that appropriate changes can be incorporated and that appropriate procedures for approval are followed. Who reviews the process? Who approves changes? How many steps of review are involved? Review processes are included at different stages of design, construction, and operation. These can be conducted prior to initiation of operational start-up, subsequently as periodic reviews, or after major events, such as operational maintenance.

Verification reviews provide a basic means of assessing the conformance to specifications of any process or operation. Appropriate **technical reviews** conducted within the project ensure that project objectives are being or have been met. The key to conducting successful reviews is to incorporate personnel who have the appropriate expertise to review the portion of the project in question. Qualifications of those being solicited should be assessed by line management before dedicating the resources for the review.

Peer reviews can be similar to technical reviews. They are conducted by someone who was not involved previously in the planning process, but who has suitable qualifications to provide valuable, previously unsolicited information.

Document/records reviews should be performed to assess whether appropriate and complete records are being maintained. Records to be reviewed should include draft and final reports, plans, procedures, and specifications; technical and peer review comments; steps taken to incorporate comments; technical drawings and specifications; and any inspection or audit reports.

Management oversight typically involves informal inspections and observation of processes. Project managers may perform such oversight as a way of observing day-to-day activities and ensuring that the system is operating as called for in specified procedures. The observer may not use any formal checklist, but rather may use his/her experience with similar operations and knowledge of operating procedures to identify any obvious problems or failures to operate the system as planned

Results of the verification review process are recommendations reported to project management, whose responsibility is to determine if review recommendations should be implemented. Contentious issues may be discussed with all personnel, but ultimate responsibility to make organizational or project improvements resides with project management.

7.2.2 Reconciliation of As-Designed and As-Constructed Projects

In constructed projects, discrepancies may develop between the contract documents and the as-constructed project. Such discrepancies are a consequence of field conditions that are different from those envisioned during design or construction problems whose resolutions result in a contract change. Reconciliation of as-designed and as-constructed conditions may involve the development and implementation of a procedure to determine compliance with design documents by the material supplier, fabricator, erector, constructor, etc., and the review and approval of any necessary changes.

7.2.3 Validation

Depending on the scale and sensitivity of the project, there may be a separate validation step in addition to verification. Validation is normally performed under defined operating conditions and on the final product, but may be appropriate in earlier stages prior to product

completion. Validation activities are used to demonstrate that the designed product is an acceptable representation of the process or the system for which it is intended, and that the product performs within defined limits for each applicable parameter.

In contrast to verification, validation is typically performed by an independent third party. Project methods, test data (including any software-generated results), and conclusions should be documented in a form that can be understood by an independent individual technically competent to understand the particular item under study. The documentation is then reviewed to assess the correctness of the documentation in meeting the validation test specifications.

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APPENDIX A

TERMS AND DEFINITIONS

Activity – An all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

Assessment – The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

Audit – The systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled **[ISO 9000]**.

Auditee – The organization being audited.

Auditor – A person qualified to perform audits.

Authenticate – The act of establishing an item as genuine, valid, or authoritative.

Calibration – Comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

Characteristic – Any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

Confidentiality procedure – A procedure used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.

Configuration – The functional, physical, and procedural characteristics of an item, experiment, or document.

Conformity – The fulfillment of requirements **[ISO 9000]**.

Consensus standard – A standard established by a group representing a cross section of a particular industry or trade, or a part thereof.

Constructor – The party assigned by the developer in charge of technology construction. The constructor's role should be specifically defined in the developer/constructor contract.

Contractor – Any organization or individual that contracts to furnish services or items or perform work.

Corrective action – Action to eliminate the causes of a detected nonconformity or other undesirable situation [ISO 9000].

Client – Any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations. See also Participant and User.

Deficiency – An unauthorized deviation from acceptable procedures or practices, or a defect in an item.

Demonstrated capability – The capability to meet procurement technical and quality specifications through evidence presented by the supplier to substantiate its claims and in a manner defined by the customer.

Design – Specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

Design change – Any revision or alteration of an approved and issued design.

Design review – A documented evaluation by a team, including personnel such as the responsible designers, the client for the work or product being designed, and a QA representative, but other than the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Design team – The parties responsible for the design of an environmental technology application. Depending on the scope of the project, this may consist of one or more professionals employed by the developer, or it may include representatives of various contractors and subcontractors as well.

Developer – The organization(s) responsible for site development and technology construction/implementation. The developer may be a single organization, as in the case of a site-specific treatability study for which the technology developer is also the site developer. In other cases, additional parties are involved, especially in the case of a large-scale technology implementation.

Document – Information and its supporting medium [ISO 9000].

NOTE: A document may be any written, electronic, or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Entity – That which can be individually described and considered, such as a process, product, item, organization, or combination thereof.

Environmental data – Any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

Environmental data operations – Work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental programs – Activities involving the environment, including but not limited to characterization of environmental processes and conditions; environmental monitoring; environmental research and development; laboratory operations on environmental samples; and the design, construction, and operation of environmental technologies.

Evidentiary records – Records identified as part of litigation and subject to restricted access, custody, use, and disposal.

Expedited change – An abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary or intolerable delay in the work.

Extramural agreement – A legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements.

Financial assistance – The process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

Finding – An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative and is normally accompanied by specific examples of the observed condition.

Good engineering principles/practices – A broad set of QA, conservation, and safety activities, techniques, and approaches that are commonly accepted throughout the engineering profession.

Grade – The category or rank given to entities having the same functional use but different requirements for quality.

Graded approach – The process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

Guideline – Conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing, or gauging **[ISO 9000]**.

Independent assessment – An assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Inspection – Examination or measurement of an item or activity to verify conformance to specific requirements.

NOTE: Inspection may include activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic.

Item – An all-inclusive term used in place of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Management – Those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management system – A system to establish policy and objectives and to achieve those objectives **[ISO 9000]**.

May – Denotes permission but not a requirement.

Measurement and testing equipment – Measuring instrument, software, measurement standard, referenced material or auxiliary equipment or combination thereof to realize a measurement process **[ISO 9000]**.

NOTE: Such equipment may include tools, gauges, instruments, sampling devices or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformity with specified requirements.

Method – A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

Must – Denotes a requirement that has to be met.

Nonconformity – Non-fulfillment of a requirement [ISO 9000].

NOTE: A nonconformity may include a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Objective evidence – Data supporting the existence or variety of something [ISO 9000].

NOTE: Objective evidence may include any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

Observation – An assessment conclusion that identifies a condition (either positive or negative) which does not represent a significant impact on an item or activity. An observation may identify a condition which does not yet cause a degradation of quality.

Organization – A company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

Organizational structure – The responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

Owner – The company or organization that has the lead role in the development of the project and implementation of the environmental technology in question. The owner can be a private firm that actually owns the property, or it can be a site developer or architectural and engineering design firm that has been hired by the owner to manage the environmental technology installation from beginning to end, or it may be the private- or public-sector organization responsible for clean-up.

Participant – When used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.

Peer review – A documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions

pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance evaluation – A type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Pollution prevention (P2) – An organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge to the environment.

Procedure – A specified way to carry out an activity or process [ISO 9000].

Process – A set of interrelated or interacting activities which transforms inputs into outputs [ISO 9000].

NOTE: Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Project – unique process consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements including constraints of time, cost, and resources [ISO 9000].

Project team – The parties involved in the construction and/or operation of an environmental technology application. Depending on the scope of the project, this may consist of one or more professionals employed by the developer, or it may include representatives of various contractors and subcontractors as well.

Responsible party – An individual or organization that has contributed to contamination problems at a site or has assumed site responsibility and is therefore a participant in the environmental technology application.

Qualified services – An indication that suppliers providing services have been evaluated and determined to meet the technical and quality requirements of the client as provided by approved procurement documents and demonstrated by the supplier to the client's satisfaction.

Quality – The degree to which a set of inherent characteristics fulfills requirements [ISO 9000].

NOTE: Quality may relate to a product or service regarding its ability to meet the stated or implied needs and expectations of the user.

Quality assurance – Part of quality management focused on providing confidence that quality requirements will be fulfilled [ISO 9000].

NOTE: Quality assurance may include management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

Quality assurance manager – The individual designated as the principal manager within the organization having management oversight and responsibilities for planning, coordinating, and assessing the effectiveness of the quality system for the organization.

Quality assurance project plan – A formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Quality control – Part of quality management focused on fulfilling quality requirements [ISO 9000].

NOTE: Quality control includes technical activities that measure the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer.

Quality improvement – Coordinated activities to direct and control an organization with regard to quality [ISO 9000].

NOTE: Quality improvement is a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality indicators – Measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence.

Quality management – That aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality management plan – A formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

Quality system – A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and

implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

Readiness review – A systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Record (quality) – document stating results achieved or providing evidence of activities performed [ISO 9000].

NOTE: A record is a document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

Reproducibility – The precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

Research development/demonstration – Systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

Self-assessment – An assessment of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Service – The result generated by activities at the interface between the supplier and the customer, and by supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and /or field analysis, repair, and installation.

Should – Denotes a guideline or recommendation whenever noncompliance with the specification is permissible.

Significant condition – Any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

Specification – A document stating requirements [ISO 9000].

NOTE: A specification is a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformity.

Source reduction – Any practice that reduces the quantity of hazardous substances, contaminants, or pollutants.

Standard operating procedure (SOP) – A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

Supplier – An organization or person that provides a product [ISO 9000].

NOTE: A supplier includes any individual or organization furnishing items or services or performing work according to an agreement between two parties, such as a contract or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surveillance (quality) – Continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

Technical review – A documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical systems audit – A thorough, systematic, onsite, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

Traceability – The ability to trace the history, application, or location of that which is under consideration [ISO 9000].

NOTE: In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials.

User – When used in the context of environmental programs, an organization, group, or individual that utilizes the results or products from environmental programs. A user may also be the client for whom the results or products were collected or created.

Validation – Confirmation, through provision of objective evidence that the requirements for a specific intended use or application have been fulfilled [ISO 9000].

NOTE: For example, environmental data may be validated as having satisfied specific precision and bias objectives.

Verification – Confirmation, through provision of objective evidence that specified requirements have been fulfilled [ISO 9000].

NOTE: For example, environmental data claiming to satisfy specific precision and bias objectives may be verified if the claim is true.

Work – the process of performing a defined task or activity

NOTE: Work may include, but not be limited to, research and development, field sampling, analytical operations, and equipment fabrication.

APPENDIX B

GOOD ENGINEERING PRINCIPLES/PRACTICES APPLICABLE TO ENVIRONMENTAL TECHNOLOGY

DESIGN

- Fail-safe/intrinsically safe design of procedures, processes, equipment, structures, and facilities (e.g. alarms, gauges, relief valves, cut-off switches)
- Flexible built-in designed procedures, processes, equipment, structures, and facilities
- Design of self-correcting procedures and processes

RESOURCE UTILIZATION

- Reuse of materials required for technology operation or development
- Reduced use of virgin materials, wastes generated, energy sources, and human resources
- Recycling/recovery of materials, utilities, and energy sources
- Conservation of materials and energy sources
- Analysis of availability and interchangeability of all resources, such as materials, personnel, and equipment
- Substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives

PROCESS OPERATIONS

- Use of commercially available and tested materials, products, processes, equipment, and supplies
- Computerized/remote control of unit operations and processes
- Site surveys, including topographical, geological, hydrogeological, hydrological, seismic, wind and weather patterns, as well as social and economic factors

PROCESS INTEGRATION

- Automatic communication/notification procedures and processes among all team members involved in technology implementation
- Integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and operation and maintenance procedures and requirements
- Integration/optimization of human, material, energy, and economic resources as well as logistical, political, social, environmental, and technical factors during each critical phase of the project
- Modeling and simulation of technical, logistical, economic, social, environmental and political systems prior to, during, and after installation/implementation

PROJECT MANAGEMENT

- Sound project management principles/practices—for example, those outlined by the Project Management Institute (PMI) in *A Guide to the Project Management Body of Knowledge* (PMI, 2000)

WORKER TRAINING

- Worker training/retraining, including hands-on training during technology construction and operation
- Worker registration/certification
- Certification/permitting of work procedures, processes, equipment, and environment

SAFETY CONTROL MEASURES

- Automatic shutdown of systems, equipment, and processes
- Use of automatic safety/corrective action triggers in technical, logistical, political, social, environmental, and economic situations
- Use of interlocks as safety measures
- Use of lockout/tagout procedures and equipment during systems fabrication/installation and operations
- Prevention of calamities, such as spills, leaks, runaway reactions, and explosions/implosions through process hazard analysis, hazardous operations analysis, failure mode and effects analysis, fault tree analysis, and incident investigations

DOCUMENTATION CONTROL

- Backup/duplicate copies of documentation
- Maintaining/archiving electronic and/or paper copies
- Distribution/delivery/circulation list for control documents
- Document/records authentication and verification

VERIFICATION PROCEDURES

- Document approval procedures
- Reviews—peer, project level, program level, organization, and legal
- Routine/periodic inspections, testing, and compliance audits of systems, procedures, processes, equipment, etc.