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AMERICAN NATIONAL STANDARD

ASQ/ANSI E4:2014

Quality management systems for environmental information and technology programs—Requirements with guidance for use

Prepared as an American National Standard by:
ASQ Energy and Environmental Division and ASQ Standards Committee

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An American National Standard approved February 4, 2014

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Foreword

The American National Standards Institute (ANSI) is the national standards-setting body for the United States of America and is the U.S. member body to the International Organization for Standardization (ISO). In carrying out the development of American National Standards, ANSI often delegates the preparation of standards to accredited technical organizations. The American Society for Quality (ASQ) is recognized and authorized by ANSI for the preparation of quality-related standards.

The ASQ Mission is to facilitate continuous improvement and increase customer satisfaction by identifying, communicating, and promoting the use of quality principles, concepts, and technologies; and thereby be recognized throughout the world as the leading authority on, and champion for, quality.

This 3rd edition of ASQ/ANSI E4 was prepared by the Energy and Environmental Division of ASQ under the auspices of the ASQ Standards Committee.

This Standard replaces ANSI/ASQ E4-2004: Quality systems for environmental data and technology programs-Requirements with guidance for use, in its entirety. Annex A, Annex B, and Annex C of this American National Standard are for information only.

The Energy and Environmental Division thanks the members of the ASQ Standards Committee for their contributions to the consensus process by which this Standard was approved.

Suggestions for improvement of this Standard are welcome. They should be sent to the Standards Administrator, ASQ, P.O. Box 3005, Milwaukee, WI 53201-3005.

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INTRODUCTION

0.1 General

This American National Standard presents requirements for a Quality Management Systems (QMS) for environmental programs.

A national consensus standard for a QMS for programs involving environmental information and technology has been shown to be a valuable instrument to verify and help to improve the suitability and effectiveness of quality control (QC) and quality assurance (QA) practices applied to environmental programs. This American National Standard is intended to provide a minimum set of requirements to enable organizations to plan, implement, and assess the suitability and effectiveness of a QMS for environmental programs involving environmental information and technology.

Recognizing the diversity of scope of environmental programs and the breadth of the field of application, this Standard also provides non-mandatory guidelines in an annex to enable users to extend quality beyond the minimum requirements.

0.2 Compatibility with Other Management Systems

This Standard incorporates relevant criteria from other management systems standards and guidelines, including the ISO 9000 series and ISO Directives on management systems standards, and presents them from an environmental information and technology perspective. Efforts have been made to align this Standard with ISO 9001:2015, Quality management systems – Requirements. There is some deliberate duplication in the Standard in order to preserve the logical flow of the requirements and to provide a self-contained document that would not require references to other standards.

This Standard defines and describes quality control and quality assurance activities for environmental programs involving information generation and use, and technology design, development, and operation. This Standard does not provide specifications or guidelines on environmental management systems rather it may be used to support the quality aspects of environmental management systems and applications. Environmental management is outside the scope and intent of this standard and is addressed in ISO 14001 (Current Edition), Environmental management systems - Specification with guidance for use. This Standard may be used by organizations implementing an environmental management system to provide QC and QA support to the activities supporting the environmental management system.

To the extent practicable, this American National Standard conforms to terminology and definitions adopted by ISO for management systems in order to facilitate the understanding and usefulness of the clauses.

0.3 General Design of the Standard

This Standard is modular in design. Clauses 1, 2, 3, and 4 pertain to all applications of the Standard. Clause 4 describes the quality management elements that are common to an organization's environmental programs regardless of their technical scope. Clauses 5 and 6 contain the QMS elements applicable to technical areas on environmental information and environmental technology, respectively. The specific applicability of these clauses to individual environmental programs is left to the user to determine.

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Clause 3, Terms and Definitions, contains the terminology needed for QMS applied to environmental programs. While efforts have been made to conform to the common terminology now being required for ISO management systems standards (MSS), this terminology does not always fit conventional use and understanding across environmental programs. In situations where the common terminology does not convey the desired intent, this Standard will retain the traditional terminology.

Clause 4, Management and Organization, describes the quality management elements needed for taking into account the way the organization implements and maintains a QMS for environmental programs. This Clause defines common quality management practices and responsibilities that must be addressed in the QMS to enable project-specific operations to be planned, implemented, and assessed. Clause 4 is used in conjunction with the other parts of the standard to formulate a complete QMS that is consistent with the scope of the organization's environmental programs.

Clause 5, Environmental Information, provides the additional QMS elements needed to plan, implement, and assess environmental information operations, including the collection, handling, analysis, and evaluation of this information. Clause 5 is used in conjunction with the elements in Clause 4 to provide for a complete QMS for collecting, producing, and evaluating environmental information. Such information may include chemical, biological, toxicological, ecological, radiological, and physical parameters. This information may be obtained directly from the environment or from systems representing environmental conditions, such as laboratories, test chambers, or models. The activities described in Clause 5 have traditionally been associated with environmental monitoring. The QMS requirements in Clause 5 also apply to the collection of environmental information that is used directly to design, construct, or operate environmental technology.

Clause 6, Environmental Technology, provides the additional QMS elements needed to plan, implement, and assess the design, construction, and operation of such technologies, and to enable the intended performance of the technologies. In addition, Clause 6 provides the additional QMS elements needed to duplicate environmental conditions for test purposes, remediate environmental contamination, prevent or remove pollutants from process discharges, or dispose of or store hazardous, radioactive, and/or mixed wastes. Environmental process or condition characterization activities that produce information used in support of the design, construction, and operation of environmental technology should be conducted according to the specifications of Clause 5. The QMS elements in Clause 6 should be used in conjunction with Clause 4 to provide for a complete QMS for the design, construction, and operation of environmental technology.

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Quality management systems for environmental information and technology programs - Requirements with guidance for use

1 SCOPE

This American National Standard specifies requirements for a Quality Management System (QMS) to enable an organization to formulate policies and procedures to plan and implement sufficient and adequate quality management practices for environmental programs.

This Standard is applicable to any organization that wishes to:

- implement, maintain, and improve a QMS for environmental programs;
- specify quality requirements when contracting for work;
- assure itself of its conformity with its stated quality policy; and
- demonstrate such conformity to others.

All the requirements in this Standard are intended to be incorporated into QMS supporting environmental programs involving the collection and use of related information and the design, construction, and use of environmental technology. The extent of the application of this Standard will depend on the environmental policy of the organization, the nature of its environmental programs, and the conditions under which it operates.

A QMS is the means by which an organization implements quality management in a systematic, organized manner. It is a management system in much the same manner as an organization manages its financial operations or health and safety programs. A quality system encompasses a variety of technical and administrative elements, including policies and objectives, organizational authority, responsibilities, accountability, and procedures and practices.

A QMS is the “blueprint” or framework by which an organization applies sufficient quality control (QC) and quality assurance (QA) practices to produce results from its environmental programs that meet or exceed the organization’s objectives and expectations. The QMS encompasses both management and technical activities pertaining to the planning, implementation, and assessment of environmental programs within the organization’s mission and scope.

The business plan model used for implementing a QMS based on this Standard encompasses three stages: planning, implementation, and assessment. This model is based on the concept of first planning the work, doing what was planned, and assessing the results against performance criteria, and acting on what was found by such a comparison (e.g., Plan-Do-Check-Act, or PDCA).

QMS for programs and activities subject to this Standard shall include requirements for:

- general or common planning, implementation, and assessment policies, procedures, and management practices applied by the organization,
- collection, generation, compilation, analysis, and use of environmental information, and

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– design, construction/fabrication, testing, and use of environmental technology.

The application of the requirements of this Standard to any environmental programs shall incorporate the principle of graded approach.

NOTE: Guidelines on implementing these and other quality management practices that may exceed the minimum set of requirements given in this Standard are given in Annex B (informative).

2 NORMATIVE REFERENCES

There are no normative references in this Standard.

3 TERMS AND DEFINITIONS

For the purposes of this American National Standard, the terms and definitions below apply to the understanding and use of the standard. To the extent possible, this Standard aligns with ISO conventions for standard nomenclature (i.e., Annex SL); however, some deviations from ISO standard nomenclature are necessary to clarify some terms relative to their use in QMS for environmental programs.

This Standard uses accepted definitions of *shall*, *should*, and *may*. The use of shall or should shall have no bearing on the voluntary nature of American National Standards. Inclusion of or reference to an American National Standard in a document, standard, or contract by a company, agency, or regulatory body is a voluntary act. When the standard is cited or invoked as part of or because of a legal agreement, regulation, statute, or policy, the standard shall become a requirement within the limitations set forth by the policy, legal requirement, or agreement.

NOTE 1: Bold type in a definition indicates a cross-reference to another term defined in this clause, and the number reference for the term is given in parentheses.

NOTE 2: Ancillary terms and definitions that may be helpful to users of environmental programs and this Standard are found in Annex A of this Standard.

3.01
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its **objectives** (3.08)

NOTE 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.02
interested party (preferred term)
stakeholder (admitted term)
person or **organization** (3.01) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

3.03
requirement
need or expectation that is stated, generally implied or obligatory

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NOTE 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.
NOTE 2 to entry: A specified requirement is one that is stated, for example, in documented information.

3.04
management system
set of interrelated or interacting elements of an **organization** (3.01) to establish **policies** (3.07) and **objectives** (3.08) and **processes** (3.12) to achieve those objectives

NOTE 1 to entry: A management system can address a single discipline or several disciplines.
NOTE 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning, operation, etc.
NOTE 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.05
top management
person or group of people who directs and controls an **organization** (3.01) at the highest level

NOTE 1 to entry: Top management has the power to delegate authority and provide resources within the organization.
NOTE 2 to entry: If the scope of the **management system** (3.04) covers only part of an organization then top management refers to those who direct and control that part of the organization.

3.06
effectiveness
extent to which planned activities are realized and planned results achieved

3.07
policy
intentions and direction of an **organization** (3.01) as formally expressed by its **top management** (3.05)

3.08
objective
result to be achieved

NOTE 1 to entry: An objective can be strategic, tactical, or operational.
NOTE 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and **process** (3.12)).
NOTE 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality objective or by the use of other words with similar meaning (e.g. aim, goal, or target).
NOTE 4 to entry: In the context of quality management systems, quality objectives are set by the organization, consistent with the quality policy, to achieve specific results.

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3.09
risk
effect of uncertainty

NOTE 1 to entry: An effect is a deviation from the expected — positive or negative.
NOTE 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
NOTE 3 to entry: Risk is often characterized by reference to potential **events** (ISO Guide 73, 3.5.1.3) and **consequences** (ISO Guide 73, 3.6.1.3), or a combination of these.
NOTE 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated **likelihood** (ISO Guide 73, 3.6.1.1) of occurrence.

3.10
competence
ability to apply knowledge and skills to achieve intended results

3.11
documented information
information required to be controlled and retained or maintained by an organization (3.01) and the medium on which it is contained

NOTE 1 to entry: Documented information can be in any format and media and from any source.
NOTE 2 to entry: Documented information can refer to
– the **management system** (3.04), including **related processes** (3.12);
– information created in order for the organization to operate (documentation) and maintained;
– evidence of results achieved (records) and retained.

3.12
process
set of interrelated or interacting activities which transforms inputs into outputs

3.13
performance
measurable result

NOTE 1 to entry: Performance can relate either to quantitative or qualitative findings.
NOTE 2 to entry: Performance can relate to the management of activities, **processes** (3.12), products (including services), systems or **organizations** (3.01).

3.14
outsource (verb)
make an arrangement where an external **organization** (3.01) performs part of an organization's function or process (3.12)

NOTE 1 to entry: An external organization is outside the scope of the **management system** (3.04), although the outsourced function or process is within the scope.

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NOTE 2 to entry: Outsourced organizations include those external entities under contract or other obligation for products and services.

3.15
monitoring
determining the status of a system, a **process** (3.12) or an activity

NOTE 1 to entry: To determine the status there may be a need to check, supervise or critically observe.
NOTE 2 to entry: In an environmental context, monitoring may refer to the collection of environmental **information** (3.23) through **measurements** (3.16) and other methods.

3.16
measurement
process (3.12) to determine a value

3.17
audit
systematic, independent and documented **process** (3.12) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

NOTE 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).
NOTE 2 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

3.18
conformity
fulfillment of a **requirement** (3.03)

3.19
nonconformity
non-fulfillment of a **requirement** (3.03)

3.20
correction
action to eliminate a detected **nonconformity** (3.19)

3.21
corrective action
action to eliminate the cause of a **nonconformity** (3.19) and to prevent recurrence

3.22
continual improvement
recurring activity to enhance **performance** (3.13)

3.23
environmental information

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any data, measurements, or calculations that describe environmental **processes** (3.25), location, or conditions; ecological or health effects and consequences; or the performance of environmental technology.

NOTE 1 to entry: Environmental information includes data collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

NOTE 2 to entry: Environmental information also includes data derived from samples collected from the environment, the results of other analytical testing (e.g., geophysical, hydrological) of environmental conditions, and process data or physical parameters collected from the operation of environmental technologies.

3.24
activity
specific set of operations or tasks to be performed that result in a product or service

NOTE 1 to entry: Environmental activities may include, but not be limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

3.25
environmental program
set of environmental **activities** (3.24) whose collective **objectives** (3.08) are intended to produce desired outcomes

3.26
environmental processes
manufactured or natural processes that produce discharges to or that impact the ambient environment.

3.27
environmental technology
all-inclusive term used to describe pollution monitoring, measurement and control devices and systems, waste treatment processes and storage facilities, and site remediation processes and their components

NOTE to entry: Examples of discharge controls include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

3.28
management controls
system of management functions to plan, implement, check, and evaluate **activities** (3.24) for **conformity** (3.18) to management and performance objectives

NOTE to entry: Management controls enable managers to determine that the operations of a program or organization satisfy predetermined goals and objectives, that performance is in line with standards and specifications, and that any needed remedial actions are implemented and confirmed to ensure that human and

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other resources are being used in the most effective and efficient way possible in achieving the organization's mission.

3.29
graded approach
process of applying **management controls** (3.28) to an **activity** (3.24) according to the intended use of the results and the degree of confidence needed in the quality of the results.

4 MANAGEMENT AND ORGANIZATION

4.1 CONTEXT OF THE ORGANIZATION

The organization shall specify the way it will define, implement, and retain a quality policy relevant to its purpose and which sustains its ability to achieve the intended outcomes of its mission.

The organization shall determine:

- the interested parties that are relevant to the QMS; and
- the requirements of these interested parties.

NOTE: The term 'interested parties' may include customers of the organization, regulatory authorities, and other stakeholders with which the organization has a relationship either formal or informal.

The knowledge gained shall be considered when designing the organization's environmental management system.

4.2 QUALITY MANAGEMENT SYSTEM

The organization shall specify the way it will implement, maintain, and continually improve a suitable and effective Quality Management System (QMS) for the environmental programs it conducts or directs in accordance with the requirements of this Standard.

The organization shall identify and include in its QMS all elements of this Standard necessary to provide sufficient and effective management controls for quality in its environmental programs. The organization shall include in its QMS sufficient management controls to obtain environmental information and the products and services produced from such information, including environmental technology, that are of the type and quality needed and expected. The organization shall specify the way it will ensure that management elements of the QMS are implemented and confirmed before the initiation of affected environmental programs. These elements shall be used in conjunction with the other applicable clauses of this Standard to formulate a complete QMS.

This QMS and its operation shall be described and retained as documented information in the organization's Quality Management Plan (QMP). The QMP shall be reviewed and approved for implementation in accordance with the organization's approval policy and applicable procedures.

The organization shall maintain a current QMP and revise it as necessary to enable its continuing relevance and conformity with policies and requirements.

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4.3 LEADERSHIP AND MANAGEMENT RESPONSIBILITIES

4.3.1 Leadership

Top management of the organization shall demonstrate leadership and commitment with respect to the QMS by:

- ensuring that the quality policy and quality objectives are implemented and are compatible with the strategic direction of the organization and intended outcomes of its environmental programs,
- ensuring the integration of QMS requirements into the organization's business processes,
- ensuring that the resources needed for the QMS are available,
- communicating the importance of effective quality management and of conformance to the QMS requirements,
- ensuring that the QMS achieves its intended outcome(s),
- directing and supporting persons who contribute to the effectiveness of the QMS,
- promoting continual improvement, and
- supporting other relevant management to demonstrate its leadership as applied to its areas of responsibility.

NOTE: Top management may not perform all of these actions themselves (e.g., they may delegate responsibility to others), but they are accountable for making sure that they are performed.

Relative to assessments, top management shall regularly assess and determine the adequacy of the QMS by:

- defining the objectives of the assessment process;
- specifying the way it has implemented the measures for confirming that the QMS has been established, affirmed in the QMP, and applied effectively;
- determining that appropriate response (e.g., corrective) actions are identified as a result of assessments (both independent and self-assessments);
- implementing response actions and confirming their effectiveness in a timely manner; and
- defining and describing in the QMP a dispute resolution process to address issues pertaining to quality.

Relative to sub-organizations, top management shall define and approve:

- the relevant sub-organizations' functional responsibilities,
- levels of accountability and authority,
- lines of communication, and
- management controls relative to quality in the QMS and describe them in the QMP.

Relative to independence and authority, top management shall provide organizations and individuals responsible for planning, implementing, and assessing the QMS and its application to environmental programs with sufficient authority, organizational freedom, and access to management at all levels for resolution of any disputes.

NOTE: Such access will enable personnel to identify noteworthy practices and quality problems, initiate recommendations or provide solutions to quality problems through appropriate channels, and verify their successful implementation.

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Management at all levels shall:

- implement quality policies and procedures necessary to enable environmental programs covered by this Standard to produce the type and quality of results needed and expected,
- implement and communicate to relevant sub-organizations functional responsibilities, levels of accountability and authority, and lines of communication relative to quality,
- ensure that sub-organizations and individuals responsible for planning, implementing, and assessing quality in environmental activities have sufficient authority, organizational freedom, and access to top management to identify noteworthy practices and quality problems; initiate recommendations, or provide solutions to quality problems through appropriate channels; and verify their successful implementation,
- confirm that personnel are competent to perform the work needed, have sufficient resources, apply the appropriate quality practices, and produce the expected products or services,
- provide sufficient resources to achieve and maintain adequate competence of personnel, proficiency, and performance,
- identify the customers (both internal and external) for the work to be performed and the suppliers of products and services,
- determine the needs and expectations for the products or services to be provided,
- determine appropriate performance objectives for environmental information collection, production, and use that will satisfy these needs, and
- negotiate acceptable measures of quality and success when time, costs, or other constraints may affect the organization's capability to fully satisfy the defined needs and expectations.

NOTE: In small organizations, it may not always be possible to separate the quality oversight operations from line operations.

Management at all levels shall determine that applicable elements of this Standard are understood by the organization's personnel and that they are implemented in the activities under its responsibility.

Management at all levels is responsible for stopping work that may result in inadequate quality, or shall delegate the authority to do so to others.

NOTE: While it may not directly affect quality, unsafe work should be stopped when detected.

Management at all levels shall regularly assess and determine the adequacy of the QMS.

Management at all levels shall comply with all reporting requirements set forth in the QMS.

4.3.2 Management Representative for Quality

The organization's top management shall designate or appoint one or more management representatives for quality with defined authority that includes:

- determining that the approved QMS is implemented for environmental information collection, production, and use, and is retained or maintained in accordance with the requirements of this standard;
- having sufficient authority, organizational freedom, and access to all levels of management and staff to identify noteworthy practices and quality problems; initiate recommendations, or provide solutions to quality problems through appropriate channels, and verify their successful implementation,

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- reporting to top management on the performance effectiveness of the QMS, including needs for improvement; and
- being organizationally independent of operations that directly implement the collection, production, and use of environmental information.

NOTE 1: A management representative may be referred to as Quality Director, Quality Assurance Manager, etc.

NOTE 2: Other management representatives (e.g., Quality Assurance Officer, Quality Assurance Coordinator) may be defined for appropriate levels in the organization as needed

The roles and responsibilities of all management representatives for quality shall be described in the organization's QMP.

4.3.3 Management Review and Reporting

Top management and management at all levels shall, at regular intervals, but at least annually, evaluate the QMS to confirm its ongoing effectiveness and its adherence to the organization's policies and procedures. The QMS shall be revised to reflect organizational, operational, and policy changes identified during this review or as otherwise determined by top management. The changes shall be described in a revised QMP and shall be reviewed and approved in accordance with the organization's review procedures.

4.4 SUPPORT

4.4.1 Resources

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS.

The organization shall provide the resources needed to plan, implement operations, and evaluate the performance of activities supporting environmental program objectives.

4.4.2 Competence of Personnel

The organization shall:

- determine the necessary competence (i.e., technical skills, demonstrated knowledge, and documented experience) of personnel doing work under its control that affects its quality performance;
- confirm that these persons are competent on the basis of appropriate knowledge, skills, education, training, or experience;
- when needed and applicable, provide actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and
- retain appropriate documented information as objective evidence of competence or proficiency.

NOTE 1: Personnel needing additional skills to perform work should be trained and qualified or certified (as needed) based on project-specific requirements prior to the start of the work or activity. The need for formal qualification or certification of personnel performing certain specialized activities should be evaluated and implemented where necessary.

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NOTE 2: Objective evidence of personnel job proficiency or competence should be maintained for the duration of the environmental program or activity affected, or longer if required by statute or organization policy.

4.4.3 Awareness

Persons doing work under the organization's control shall be aware of:

- the organization's quality policy,
- their contribution to the effectiveness of the QMS, including the benefits of improved quality performance, and
- the implications of not conforming to QMS requirements.

4.4.4 Communication

The organization shall take into account the need for internal and external communications relevant to the QMS including:

- what it will communicate,
- when to communicate, and
- with whom to communicate.

NOTE 1: Internal communications may include the dissemination of policies, procedures, references and guidelines to persons within the organization.

NOTE 2: External communications may include interested parties, stakeholders, and other organizations under obligation to the organization (e.g., sub-contractor).

4.5 DOCUMENTED INFORMATION

4.5.1 General Requirements

The organization's QMS shall include:

- documented information required by this Standard;
- documented information determined by the organization as being necessary for the effectiveness of the QMS; and
- description of the main elements of the QMS in the QMP and the relationships among them and with other business processes.

NOTE: The extent of documented information for a QMS can differ from one organization to another due to:

- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their inter-relationships;
- obligations to other organizations (e.g., statutory, contractual), and
- the competence of personnel to perform needed actions.

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4.5.2 Creating and Updating

When creating and updating documented information, the organization shall take into account that the information is supported by appropriate:

- identification and description (e.g., title, date, author, reference number),
- format (e.g., language software version) and media (e.g., paper, electronic),
- reviews for suitability and adequacy, and
- approvals by authorized personnel.

4.5.3 Control of Documented Information

The organization shall determine documented information requiring control and shall describe the controls in its QMP.

The organization shall specify the way it will implement, retain, and maintain appropriate management controls for documented information including tracking, chain of custody, and confidentiality procedures (including the handling of information identified as sensitive or confidential).

Documented information required by the QMS and by this Standard shall be controlled to affirm that the information is:

- available and suitable for use where and when it is needed,
- reviewed by competent personnel for conformity with technical requirements and QMS requirements and approved for release by authorized personnel, and
- adequately protected (e.g., from loss of confidentiality improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

- distribution, access, retrieval, and use;
- storage and preservation, including preservation of legibility;
- control of changes (e.g., version control); and
- retention and disposition.

Electronic information shall be retained and maintained in an electronic recordkeeping system. If an organization does not have an electronic recordkeeping system, it shall print such information and retain the information in a paper recordkeeping system.

NOTE: In some cases, printing may cause loss of context (e.g., databases, complicated spreadsheets or geospatial data). In those cases, the documented information may be maintained electronically, but must be readable, accessible, and usable for its lifespan, and disposed according to its applicable schedule.

Documented information of external origin that is determined by the organization as being necessary for the planning and operation of the QMS shall be identified, as appropriate, and controlled.

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NOTE: Access to documented information implies having permission for read-only access to the documented information, or having permission and authority to read and change the documented information.

Documented information used to perform work (e.g., technical manuals and operating procedures) shall be identified and maintained current for the use of personnel performing the work. The organization shall instruct users as to the information to be used.

Obsolete or superseded documented information shall be identified. The organization shall take actions as needed to prevent its inadvertent use, including removal from the immediate workplace and from the possession of, or access by, users when practical. Obsolete or superseded information shall be retained in accordance with applicable statutes, the organization's policies, and other relevant specifications for retention and disposal.

The processes for maintenance of documented information shall be described in the QMP and shall include provisions for retention, protection, preservation, traceability, and retrieval.

Documented information involving legal requirements or agreed obligations shall be maintained in accordance with organizational and legal retention policies.

4.5.4 Required Documented Information

Two types of documented information are required by this Standard as a minimum:

- Quality Management Plan (QMP)
- Quality Assurance Project Plan (QAPP)

The QMP and QAPP shall be controlled, retained, and maintained.

4.5.4.1 Quality Management Plan

The organization's QMS and its operation shall be described in a quality management plan (QMP) or equivalent document. The QMP shall be reviewed and approved for implementation as policy or as a directive authorized by top management.

NOTE: Other documents, such as quality manuals, may be equivalent to the quality management plan.

The QMP shall define when and how management controls are to be applied to specific technical or project efforts and shall outline how these efforts are planned, implemented, and assessed. The QMP shall address all applicable and relevant clauses of this Standard. The QMP shall address the following as a minimum:

- context of the organization and quality policy,
- quality management system elements and their description,
- leadership and management responsibilities,
- support to QMS,
- documented information
- information technology,
- acquisition of items and services,
- planning,

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- operations,
- performance evaluation, and
- quality improvement.

The QMP shall also identify in general terms those items, programs, or activities to which it applies. The QMP shall identify and describe activities which directly or indirectly affect quality and shall include as a minimum:

- general and specific responsibilities for management and staff,
- responsibilities and authorities for technical activities, and
- description of all necessary interfaces.

The QMP shall reflect the current practices of the organization for its QMS primarily. Planned or expected practices may be included if their effective implementation dates are also given.

4.5.4.2 Quality Assurance Project Plan

All work performed by or on behalf of the organization involving the collection, production, or use of environmental information shall be described in documented information (e.g., a Quality Assurance Project Plan [QAPP] or approved equivalent planning document. The QAPP defines how specific activities shall be planned, implemented, and assessed during a particular project.

NOTE: The QAPP is a critical planning document for any environmental program since it describes how environmental information activities are planned, implemented, documented, and assessed during the life cycle of a program, project, or task. The ultimate success of an environmental program or project depends on the adequacy and sufficiency of the quality of the environmental information obtained and used.

The QAPP shall provide sufficient detail to conform to the Plan-Do-Check-Act steps of the project life cycle; that is, the QAPP shall include:

- project technical and quality objectives (Plan);
- intended measurements and information collection or acquisition methods appropriate for achieving project objectives (Do);
- performance evaluation procedures sufficient to confirm that information of the type and quality needed and expected is obtained (Check); and
- limitations or restrictions on the use of the information (Act).

The QAPP shall recognize that there are different types of activities that may involve environmental information collection, production, and use including:

- monitoring and use of direct measurements and laboratory results;
- collecting or using environmental information from other sources (e.g., obtained from data bases, Internet, social media, literature);
- sampling or analytical methods development; and
- generating or producing environmental information from the use of mathematical or probabilistic models and computer software.

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