Quality Management Plan

State of Idaho
Department of Environmental Quality

January 2021

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Quality Management Plan

January 2021

Idaho Department of Environmental Quality
1410 North Hilton Street
Boise, Idaho 83706

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List of Acronyms

CAP	corrective action plan
CAR	corrective action report
DEQ	Idaho Department of Environmental Quality
DQA	data quality assessment
DQI	data quality indicators
DQO	data quality objectives
EDMS	electronic document management system. Currently DEQ uses the Hewlett-Packard TRIM software application.
EPA	United States Environmental Protection Agency
FSP	field sampling plan
GIS	geographic information system
HAZWOPER	hazardous waste operations and emergency response
IDAPA	refers to citations of Idaho administrative rules
PDF	portable document format
QA	quality assurance
QAO	quality assurance officer
QAPP	quality assurance project plan
QC	quality control
QMP	*Quality Management Plan*
QMS	quality management system
QSR	quality system review
SOP	standard operating procedure

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Quality Management Plan Approval Form

Quality Management Plan

Version 5

Idaho Department of Environmental Quality

1410 North Hilton Steet

Boise, Idaho 83706

Approvals

DEQ Director Date 12/14/2021

DEQ Quality Manager Date 12/13/2021

Concurrences

DEQ Deputy Director Date 12/14/2021

Air Quality Division Administrator Date 12-14-2021

Waste Management and Remediation Division Administrator Date 12/14/2021

Drinking Water Protection and Finance Division Administrator Date 12/14/2021

Surface and Wastewater Division Administrator Date 12/14/2021

Technical Services Division Administrator Date 12/14/2021

Concurrences

Date 12/14/21
Boise Regional Office
Administrator

Date 12/14/2021
Coeur d'Alene
Regional Office
Administrator

Date 12/14/21
Idaho Falls Regional Office
Administrator

Date 12/14/2021
Lewiston Regional Office
Administrator

Date 12/14/21
Twin Falls Regional Office
Administrator

Date 12/14/21
Pocatello Regional Office
Administrator

EPA Acceptance and Approval

State of Idaho Quality Management

Plan Version 5

submitted to

United States Environmental Protection Agency, Region 10
1200 Sixth Avenue
Seattle, Washington 98101

DONALD BROWN Digitally signed by DONALD BROWN Date: 2022.01.11 12:42:14 -08'00' Date _____

EPA Region 10 Quality Manager

MATTHEW SZELAG Digitally signed by MATTHEW SZELAG Date: 2022.01.11 12:01:28 -07'00' Date 1/11/22

EPA Idaho Operations Office Director

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Mission and Quality Management Policy Statements

The mission of the State of Idaho Department of Environmental Quality is to protect human health and preserve the quality of Idaho's air, land, and water for use and enjoyment today and in the future.

DEQ Policy Statement

PS16-01

Quality Management

Purpose

To document the Idaho Department of Environmental Quality's (DEQ's) recognition of the importance of quality in data, processes, products, and services used to support agency environmental decisions.

Background

The United States Environmental Protection Agency requires state departments to provide a policy statement on quality assurance as a component of their quality management plan. This requirement is found in Section 3.1 of the *EPA Requirements for Quality Management Plans—EPA QA/R-2* (EPA/240/B-01/002).

Statement of Policy

DEQ strives to meet strategic goals and fulfill our mission in the most cost-effective and efficient manner possible. Meeting the mission of the agency necessitates environmental decisions achieved through the use of high-quality data and consistent and intelligent management, planning, and implementation. DEQ employees are integral to such high-quality data, processes, products, and services, as well as continual agency improvement.

Responsibility

DEQ's quality manager is responsible for maintaining this policy and quality management system programs, plans, and procedures that comply with this policy. The quality manager is

expected to identify quality management problems, initiate actions that result in solutions, and verify solution implementation.

DEQ division and regional administrators are responsible for implementing established quality management system programs, plans, and procedures. DEQ employees are responsible for achieving agency goals to continuously improve the quality of agency products and performance.

The DEQ director, quality manager, division and regional administrators, project officers, and quality assurance officers are expected to stop any work not meeting DEQ's quality criteria.

Implementation

This policy is effective immediately and will remain in effect for 5 years unless amended, replaced, or rescinded prior to expiration.

Dated this _____ day of _____, 2021

_____

Jess Byrne
Director

Introduction

This *Quality Management Plan* (QMP) describes the Idaho Department of Environmental Quality's (DEQ's) quality management system (QMS) to communicate and implement quality management procedures within DEQ. DEQ has taken the responsibility for defining and implementing an effective QMS for DEQ by establishing this QMP. DEQ fulfills its mission—to protect human health and preserve the quality of Idaho's air, land, and water for use and enjoyment today and in the future—by engaging in a variety of activities, including monitoring and assessing environmental conditions, establishing policies and rules, issuing permits, cleaning up contamination, enforcing environmental laws, and educating businesses and citizens to encourage pollution prevention. Inherent in all of these activities is a commitment to produce quality products, recommendations, and services through quality work. This document supersedes the 2017 version (DEQ 2017) of the QMP.

Purpose of the Quality Management Plan

The primary purpose of the QMS is to provide a framework for DEQ to ensure quality in environmental data and information; the QMP documents that framework. Successful data collection and monitoring activities require DEQ's team of scientists, engineers, technicians, managers, and support staff to collect, manage, and make informed decisions based on a variety of environmental information generated both internally and externally, by citizens, businesses, industries, and others with vested interests in Idaho's environmental quality. Quality data and information constitute the foundation of informed decision-making.

The primary benefits of a well-documented QMS include the following:

- Defensible products and decisions
- Integrity of scientific data
- Effective resource management
- Justifiable resource expenditures
- Continual process improvement
- A healthier, cleaner Idaho

Additionally, a documented QMS meets federal requirements mandated by the United States Environmental Protection Agency (EPA).

This plan has a degree of flexibility to allow DEQ's QMS to meet a region, division, or project's particular needs. Since environmental projects and tasks are very diverse, flexibility in implementing this plan is essential. Project-specific quality assurance project plans (QAPPs) and supporting procedures may incorporate standards beyond the requirements of this QMP to provide management controls applicable to the scope of work to be performed. Conversely, only the appropriate requirements from this QMP need to be incorporated in DEQ programs and projects.

Quality Management Plan Structure and Intended Use

Sections 1 and 2 provide an overview of the DEQ QMS. Section 1, "Management and Organization," specifically focuses on the QMS structure within the department, its scope, and application within the larger framework of environmental monitoring and data collection within the state of Idaho. This section describes the roles, lines of authority, and responsibilities of staff and management who support the QMS. Section 2, regarding QMS and project components, describes the tools or physical documents and products of the QMS and the life cycle of typical projects. Collectively, these tools define quality within DEQ at the policy, organization, division, program, and project levels. Moreover, the QMS tools document quality within DEQ's environmental operations and serve as the collective history and memory of DEQ.

Sections 3 through 6 describes the requirements and policies that directly support the QMS. These sections of the QMP draw together diverse state and DEQ policies—such as personnel qualifications and training (Section 3), procurement of items and services (Section 4), documents and records (Section 5), and computer hardware and software (Section 6)—and highlight how these elements support the QMS. Although generally beyond the scope of the QMS, the policies described in these sections may be successfully employed and adapted to support quality within DEQ's operations.

Sections 7 through 10 focuses on QMS processes and procedures that apply to division or project-specific activities, such as planning (Section 7), implementation of work processes and operations (Section 8), assessment and response (Section 9), and QMS improvement (Section 10).

Following Section 10, the reference section includes cited material and additional resources—all with document-specific web links when available—as well as general website addresses for all websites mentioned in the QMP.

In matters of quality assurance (QA), the QMP shall take precedence over other agency guidelines and policy documents when a conflict exists between the documents. Identified conflicts shall be brought to the attention of the DEQ quality manager.

Implementation

This QMP recognizes that all environmental programs and projects may not necessarily require the same degree of control. Project QAPPs developed as a result of implementing this QMP are intended to provide the necessary level of control over activities to ensure that the performance objectives and technical specifications of each project can be met and will be cost-effective. The controls applied to a project, or to an item or service, may vary with the degree of confidence needed in the results.

The degree of control required is typically determined by the importance of an activity or item to the environment, human health and safety, or the economic impact of failure to achieve stated objectives. Major projects—such as characterizing the nature and extent of contamination at a waste site—or critical items and services may require extensive controls throughout the project. Less critical projects or items may require only limited control.

DEQ projects shall use this QMP as a basis for preparing QAPPs. The QAPP is the most important QMS tool at the project level and is required for all environmental data collection and

generation activities at DEQ. The QAPP summarizes the data quality objectives (DQOs) of the project and integrates all technical and quality aspects—including planning, implementation, and assessment—into a single document.

QAPPs provide direction for specific projects and should make maximum use of and reference established DEQ standard operating procedures (SOPs), as applicable, to avoid re-creating established practices. QAPPs will include those elements of the QMP that apply to the scope of the project. QAPPs shall also include any specific federal or state quality requirements; that is, any additional requirements imposed by the conditions of any grants must be considered in preparing and implementing a QAPP.

A hierarchical QA document approach provides several advantages. It lends itself to personnel development by providing a consistent baseline that can be transferred from project to project. It provides for improvement based on individual direct experience. Moreover, this approach is efficient and cost-effective for DEQ since it will reduce unnecessary duplication of procedures and documentation.

Quality Management Plan Review and Revisions

This QMP should be reviewed annually to reconfirm the suitability and effectiveness of the approved quality management practices. This review shall be conducted and documented by the DEQ quality manager.

The following conditions require modification, and subsequent EPA approval, of the DEQ QMP:

- Expiration of the 5-year life span of the approved QMP
- Major changes in mission and responsibilities, such as changes in the delegation status of a program
- Reorganization of existing functions that affect programs covered by the QMP
- Assessment findings that require QMP revision as a component of the corrective action and response

Minor QMP revisions will be submitted to EPA Region 10 as a report as revisions occur. However, if significant changes have been made to the QMS that affect the performance of work for DEQ, it may be necessary to resubmit the entire QMP to EPA Region 10 for re-approval.

This QMP shall be submitted to EPA Region 10 for approval and is valid for 5 years from the effective version date.

1. Management and Organization

This section documents the overall scope, applicability, and management responsibilities set forth in DEQ's quality management policy, as implemented in the QMS.

1.1 Quality Management Objectives

As part of its goal to work cooperatively with Idahoans for a healthy, sustainable environment, DEQ activities are expected to result in products and decisions of known and acceptable quality. Specifically, within the context of DEQ's environmental monitoring and assessment activities (or any other activities that rely on or produce environmental data for use by DEQ), quality management practices shall be implemented to document and ensure that all environmental data generated, stored, reported, or used by DEQ is of known and adequate quality to fulfill the needs of the primary data user. Moreover, data used by DEQ shall be accurate, precise, complete, representative, comparable, and when required, legally defensible. This applies to data generated internally (within DEQ through the direct efforts of DEQ personnel) and externally from regulated activities, contracts, interagency agreements, grants, and/or cooperative agreements.

Specific objectives of the DEQ QMS include the following:

- Ensure that the intended use of the data and level of data quality needed for any specific purpose is established through a planning process before the start of data collection activities.
- Ensure that environmental data generated and used by DEQ is of known and documented quality through the use of approved QAPPs.
- Ensure that DEQ activities meet or exceed any quality management requirements mandated through state or federal regulations or any other contractual agreements.
- Establish a standard set of quality guidelines that are followed by all divisions and regions.
- Ensure that quality management practices are implemented in external procurements or service agreements that result in environmental data reported to DEQ.
- Define a support system for measuring and rating the quality of DEQ data.
- Provide quality management support to data collection, assessment, and management activities.
- Assess and report to senior management on the adequacy of the DEQ QMS.
- Document the QMS in a QMP.

1.2 DEQ Organizational Structure

The organizational structure established for implementing the QMP is shown in Figure 1.

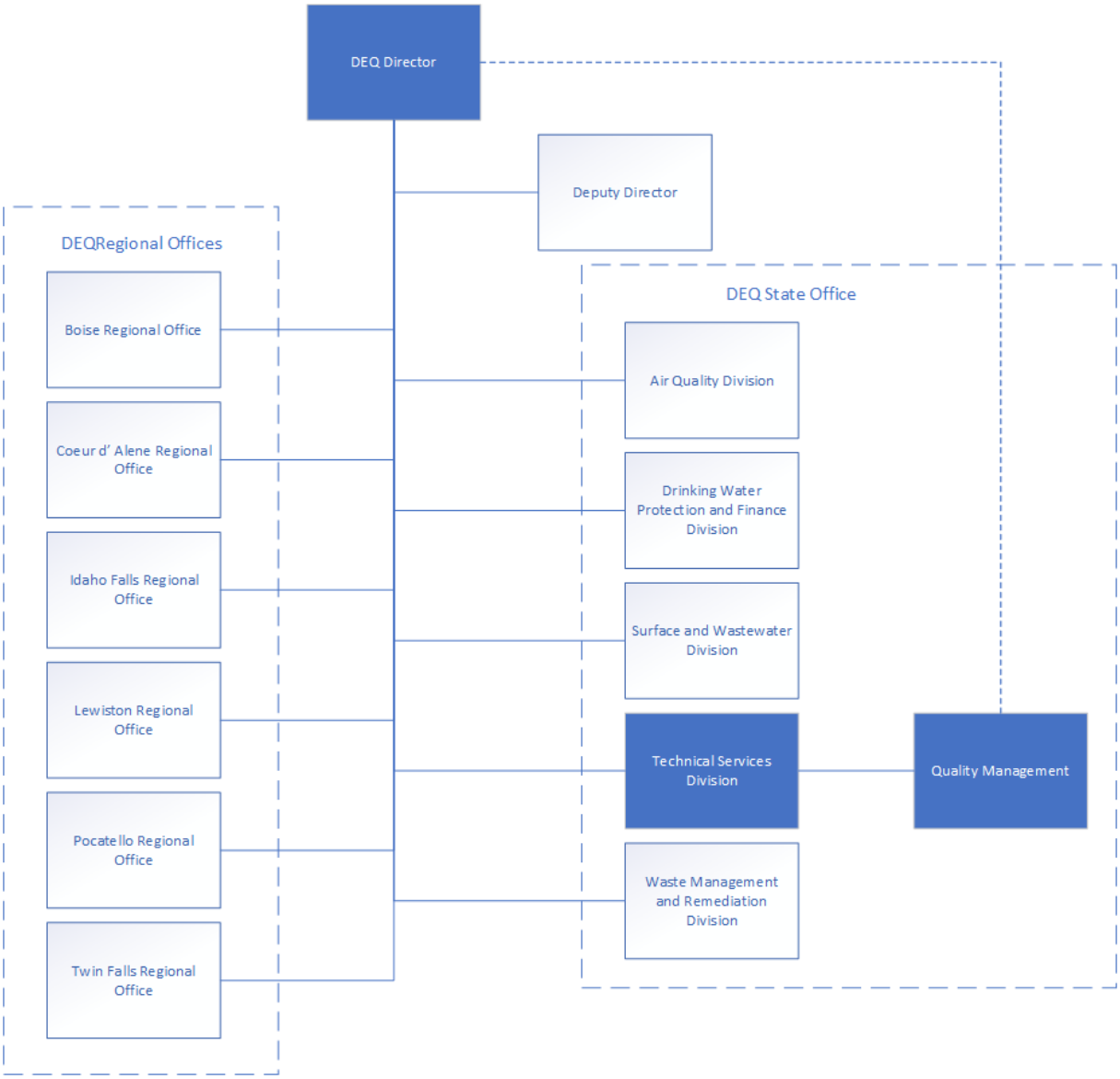

Figure 1. DEQ organizational structure for QMP implementation. Stippled rectangles indicate agency structure for quality management.

1.2.1 Applicability of the Quality Management System to Functional Divisions, Regions, and Management

DEQ is headed by the Director's Office, which is accountable to the governor of Idaho. Under the director, six regional offices are located throughout the state and five divisions are located in the DEQ State Office in Boise. The five divisions include the following individual bureaus and disciplines:

Waste Management and Remediation Division

- Hazardous Waste
- Assessment and Compliance
- Remediation

Air Quality Division

- Planning Bureau
- Data Management Bureau
- Stationary Source Bureau

Technical Services Division

- Engineering
- Environmental Resources
- Environmental Engineering/GIS
- Geosciences
- Modeling/Risk Analysis
- Information Technology
- Quality Management
- Safety

Drinking Water Protection and Finance Division

- Drinking Water
- Ground Water
- Grant/Loan Program

Surface and Wastewater Division

- Surface Water
- Wastewater
- Idaho Pollutant Discharge Elimination System

All functional programs or individuals within the Director's Office, regions, or divisions that produce or use environmental data fall within the scope of the QMS. Division and regional administrators shall ensure that applicable elements of this plan are understood and implemented in all activities under their responsibility involving collecting and evaluating environmental data, oversight activities, compliance, and enforcement activities. Division and regional administrators are responsible for providing adequate resources to implement the requirements of this QMP.

1.2.2 Role of the Quality Management System in Project Management

The DEQ Quality Policy Statement at the beginning of this document requires QMSs to be considered and involved in all aspects of work. Project management shall retain and exercise authority and responsibility for implementing the QMS to include planning and scheduling project and work activities. Planning, scheduling, and cost control activities shall consider appropriate QMS requirements. Initial estimates, used in planning, shall be based on sound data and assumptions relating to personnel, material/service costs, availabilities, and productivity. The extent or applicability of QMS components may be determined using a graded approach. The graded approach must be determined in sufficient time to effectively prepare and implement the appropriate QMS requirements (section 2.2.2).

1.2.3 Authorities Granted to Quality Management Personnel by the DEQ Director

DEQ quality management personnel are given sufficient authority, access to work areas, and organizational freedom to do the following:

- Identify quality management problems.
- Initiate, recommend, or provide solutions to quality management problems through designated channels.
- Verify implementation of solutions.
- Ensure that further processing, delivery, installation, or use of nonconforming items or services is controlled until proper disposition of a nonconforming condition, deficiency, or unsatisfactory condition has occurred.
- Halt or stop work.
- Approve certificates of compliance/conformance, when required, in consultation with the assigned project quality assurance officers (QAO) and the responsible project manager.

1.2.4 Roles, Responsibilities, and Authorities of the DEQ Quality Manager

The DEQ quality manager has direct access to management at a level where appropriate action can be affected. The quality manager has a direct line of communication to the DEQ director. Day- to-day operations are coordinated between the quality manager and the applicable division or regional administrator. The quality manager shall review the selection of DEQ personnel, made by the regional/program manager, as project QAOs for given tasks or projects. Project QAOs have a direct line of communication to the quality manager to ensure required authority and organizational freedom, including sufficient independence from cost and schedule considerations.

The quality manager has the responsibility and authority for the administration and maintenance of this QMP; Policy Statement PS15-09; the instructions for preparing DEQ SOPs, including the administrative and technical templates; and the peer review SOP. The quality manager has the authority and responsibility to ensure that appropriate levels of quality management are established and effectively implemented for each division or region by conducting or participating in regular division or regional reviews. Summary reports of such reviews regarding the effectiveness of quality system implementation will be provided to the applicable DEQ division or regional administrators by the quality manager.

1.2.5 Roles, Responsibilities, and Authorities of Project Quality Assurance Officers

Project QAOs have authority and responsibility for ensuring that suitable QAPPs and field sampling plans (FSPs) are developed and approved according to the QMP and verifying their effective implementation at the project level within the scope of their activities. Project QAPPs shall be developed based on the requirements of this QMP and other applicable and relevant requirements and guidance documents (i.e., the current version of the DEQ QAPP template and EPA requirements and guidance documents). Project QAOs represent their assigned projects as the primary spokespeople on matters relating to QMS implementation. In matters of project QA, this individual will have a direct line of communication to the DEQ quality manager.

The project QAO will assist in developing, reviewing, and approving the project QAPP, and associated FSPs, to which they are assigned. The QAO should not be assigned as the primary author of project documents, such as the QAPP and associated FSPs, to maintain independence from the unit generating environmental data.

After a QAO has been assigned to a project by the program/regional manager, the project QAO has the authority and responsibility to approve QA documents specific to that project, such as the project QAPP and related project FSPs. Before signing a project QAPP or FSP as an approver, the QAO will review all SOPs referenced for use in the project QAPP or FSP to ensure they support the quality objectives of the project. This review does not constitute approval of a DEQ SOP, as these documents are generated and approved according to section 2.2.5 of this QMP. Once the project QAPP or FSP has been signed, the project QAO shall enter the document into the *QAO Project Document Tracker* (record 2012AEB8).

The project QAO will provide data validation per the project QAPP and FSP. The project QAO may also be part of the review team for project final reports.

The project QAO is authorized to stop work if, in the judgment of that individual, the work is performed contrary to or in the absence of prescribed controls, safety requirements, or approved methods and further work would make it difficult or impossible to obtain acceptable results. The project QAO may also stop work if completing the corrective actions is not acceptable.

The project QAO shall periodically review and assess assigned projects to verify effective implementation of the project QAPPs, FSPs, and associated SOPs. This review/assessment shall be performed annually, with the results documented in the project files and presented to the assigned project manager. Project laboratory services will be assessed and evaluated according to 4. If the QAPP, FSP, or SOPs require revision as a result of this review/assessment, the QAO will provide the review comments to the responsible party to consider and incorporate into the document. The revised document must be submitted to the same approval authorities as the original document for approval before implementation.

Project QAOs are responsible for evaluating data and information from instances of nonconformance, inspection reports, surveillance reports, audit and assessment reports, quality system reviews (QSRs), corrective action reports (CARs), corrective action plans (CAPs), stop-work orders, and other sources. These data should be used to identify trends or conditions adverse to quality, which shall be brought to the attention of the quality manager for incorporation into the quality improvement process.

Project QAOs shall review and approve CAPs and provide follow up to ensure effective implementation of the corrective actions according to section 10.5 of the QMP.

To preserve the independence of the project QAO for internal project QAPPs and FSPs, the project QAO shall not be the project manager, regional/program manager, or be otherwise assigned to the project data generation efforts. The project manager and project QAO may not directly report to each other within the DEQ organizational structure, and both of these individuals may not be directly supervised by the same person.

Two exceptions are allowed to the general QAO-independence rule stated above. First, in projects where the QAPP and data are generated by a contractor working under a signed contract

with DEQ, the DEQ project manager and the QAO may be the same person. Second, in projects where only existing third-party data will be used, the DEQ project manager and QAO still need to be separate individuals, but they may work for the same person.

For external third-party QAPPs, refer to section 7.4 for further project QAO duties and responsibilities.

For situations involving the use of existing data, refer to section 7.5 for further project QAO duties and responsibilities.

All assigned project QAOs are encouraged to contact the DEQ quality manager to discuss the project before signing any project QAPP as an approver. Based upon project conditions, the quality manager may elect to review the project QAPP before final approval. At this time, the DEQ quality manager shall also verify that the assigned project QAO has entered the project in the QAO Project Document Tracker spreadsheet.

1.2.6 Quality Assurance Roles, Responsibilities, and Authorities of Project Managers

Project managers have authority and responsibility for ensuring that suitable QAPPs, FSPs, and SOPs are developed and approved according to the QMP and verifying effective implementation of the QAPP, FSPs, SOPs, and QMP requirements at the project level within the scope of their activities. The project manager is generally assigned the role of primary author for project documents, such as the project QAPP and, if applicable, associated FSPs.

Project quality documents, such as QAPPs and FSPs, shall be developed based on the requirements of this QMP and other applicable and relevant requirements and guidance documents (i.e., the current version of the DEQ QAPP template and EPA requirements and guidance documents).

Project managers are responsible for overall project planning, project QAPP and FSP development and approval, project-related SOP review, sample planning and coordination, laboratory coordination, data review and verification effort coordination, reporting functions, project report/summary development, and documentation of all project activities in DEQ's electronic document management system (EDMS) and elsewhere as required by project documents. Project manager SOP review does not constitute approval of a DEQ SOP, as these documents are generated and approved according to section 2.2.5 of this QMP.

The project manager will provide data review and verification per the project QAPP and associated FSPs. The project manager may also be part of the review team for project final reports.

Following final approval of a project quality document, such as a QAPP or FSP, the project manager is responsible for ensuring that a PDF copy of the approved project quality document (including the signed approval page) is maintained in the EDMS.

The project manager is responsible for ensuring that personnel assigned to the project are appropriately trained and qualified, with the corresponding training records on file in human resources.

Project managers have stop-work authority according to section 1.2.9 and section 10.6.

For external third-party QAPPs, refer to section 7.4 for further project manager duties and responsibilities.

For situations involving the use of existing data, refer to section 7.5 for further project manager duties and responsibilities.

The project manager should periodically review assigned project QAPPs, FSPs, and associated SOPs, at least annually, to determine if revision is necessary and verify that the current project QAPP, FSPs, and SOPs are available in the EDMS. Results of this review should be given to the QAO and documented in the project files. If the QAPP, FSP, or SOPs require revision, the project manager shall coordinate this effort and submit the revised documents for approval before implementation.

Project managers are responsible for evaluating data and information from instances of nonconformance, inspection reports, surveillance reports, audit and assessment reports, QSRs, CARs, CAPs, stop-work orders, and other sources. These data and documents should be used to identify trends or conditions adverse to quality, which shall be brought to the attention of the quality manager for incorporation into the quality improvement process.

Project managers shall ensure that CARs, CAPs, and associated documents are maintained in the project EDMS files.

1.2.7 Quality Assurance Roles, Responsibilities, and Authorities of the Program/Regional Manager

This individual is the state office program manager or regional manager who will assist in developing, reviewing, and approving the project QAPP. This person is responsible for ensuring that the project QAPP is designed to meet the data needs of the program and references currently approved program procedures and policies.

The program/regional manager shall select a person who meets the project QAO requirements of section 1.2.5 and assign this individual as the project QAO.

In addition to signing the QAPP as an approver, the regional/program manager is expected to communicate with regional and state office program counterparts concerning project activities and to facilitate agency-wide coordination efforts and the efficient use of data collection resources.

Program and regional managers are responsible for evaluating data and information from instances of nonconformance, inspection reports, surveillance reports, audit and assessment reports, QSRs, CARs, CAPs, stop-work orders, and other sources. These data should be used to identify trends or conditions adverse to quality, which shall be brought to the attention of the quality manager for incorporation into the quality improvement process.

For external third-party QAPPs, refer to section 7.4 for further regional/program manager duties and responsibilities.

For situations involving the use of existing data, refer to section 7.5 for further regional/program manager duties and responsibilities.

1.2.8 Resolution of Disputes Involving Project Quality Assurance Officers

Disputes involving quality management arising from differences of opinion between the project QAOs and other DEQ project personnel should be resolved at the project level. If the dispute cannot be resolved at the project level, then it may be referred to the regional/division administrator and the quality manager for resolution. Such resolution will not conflict with specified quality requirements.

1.2.9 Authority to Stop Work

All agency personnel are authorized to stop work for situations involving imminent danger to personnel. Safety considerations override planning and scheduling considerations.

Project managers, QAOs, program/regional managers, division/regional administrators, and the quality manager have stop-work authority in circumstances where, if in the judgment of that individual, the work is performed contrary to or in the absence of prescribed controls, safety requirements, or approved methods and further work would make it difficult or impossible to obtain acceptable results. These individuals may also stop work if they determine continued work will not support project objectives or if completing the corrective actions is not acceptable.

Upon notice of stop work, the initiator shall immediately notify the project manager, regional/program manager, project QAO, quality manager, and their immediate supervisor. If external suppliers are affected, DEQ procurement personnel will also be immediately notified.

For additional information about stop-work orders, see section 10.6.

1.2.10 Delegation of Quality Management System Tasks to Third Parties

In cases where DEQ delegates to third parties (e.g., subcontractors, suppliers, and consultants). the task of establishing and executing certain portions of the QMS, overall responsibility for the system remains with DEQ. Such delegation shall be in procurement documents or implementing procedures, or both and shall include, at a minimum, appropriate management controls for the assigned task, including assigning responsibilities and identifying lines of communication. See Section 7.4 for differences between contracted projects and external data projects.

1.2.11 Definition of Organizational Interfaces

Interfaces between internal and external (outside DEQ) organizations, as well as internal DEQ regional and divisional interfaces, shall be described and documented as necessary in project-related quality documents.

2. Quality Management System Components

This section describes DEQ's QMS, including the primary responsibilities for managing and implementing each component of the system.

2.1 Elements of the Quality Management System

The organizational and programmatic elements of the QMS are the foundation of DEQ's day-to-day environmental activities. Although the QMS, as documented in this QMP, largely addresses activities associated with the collection and use of environmental data and information, these tools may be adapted to other DEQ goals, priorities, and activities.

The key programmatic components of the QMS are the QMP, quality systems review, training, and other support elements, as described below.

2.1.1 Quality Management Plan

The QMP is the written documentation of the QMS. It describes the authorities, policies, and tools that are specific to ensuring excellence in DEQ's operations, products, and decisions.

2.1.2 Quality System Reviews

QSRs are management tools used to assess, refine, and improve DEQ's QMS as a whole or within specific DEQ programs, regions, or divisions. QSRs may be performed internally or externally by EPA.

Internal QSRs may be performed on an annual or continuous basis, with continuous meaning that projects and programs are evaluated on a periodic basis, as resources allow, by reviewing and evaluating project and program activities. The results of internal reviews, assessments, and evaluations shall be documented and provided to the affected region or division administrator.

DEQ participates in quadrennial external QSRs initiated by the EPA Region 10 Quality Assurance Management Office (or as requested by division management). Such evaluations provide objective assessments of the resources, commitments to, and implementation of the DEQ QMS. These quadrennial assessments are scheduled through the quality manager and typically conducted according to protocols published in standard reference documents such as EPA's *Guidance on Assessing Quality Systems* (QA/G-3) (EPA 2003).

2.1.3 Training

QMS training is provided to DEQ personnel, as needed, to ensure that staff have the necessary skills, knowledge, and proficiency to meet the quality management requirements of their jobs. QMS training is documented in DEQ training records maintained by human resources.

2.1.4 Miscellaneous Support Elements

Additional organizational support elements to the QMS may include various technical and nontechnical resources. The support elements are designed to strengthen and support DEQ's QMS and may include such items as record management systems, computer/software systems, and data query tools. Some of these miscellaneous support elements are discussed in subsequent sections of this QMP.

2.2 Project Components and the Project Life Cycle

Common components of DEQ projects and the project life cycle are discussed in the following subsections.

2.2.1 Planning

The goal of the QMS at the project level is to provide the appropriate quality management tools to the project manager and project staff so that operations result in data of the appropriate type, quantity, and quality to satisfy the project needs and DEQ's mission to preserve, protect, and enhance the environment for the benefit of all Idaho citizens.

The true structure and shape of the DEQ QMS arises from project-level activities. Projects generate the environmental data that DEQ uses to create products and make decisions. Because project work plays such a prominent role in DEQ's operations, a number of project-level tools are available to ensure excellence in the data and information derived from individual project activities.

Projects typically follow a three-step life cycle: (1) planning, (2) implementation and oversight, and (3) assessment and improvement. The life of the project begins with identifying a specific need.

If resources are available to address that need, a project manager is identified and a systematic planning process is initiated to define how the project needs will be met. The results of the planning process are documented in a QAPP, which describes the project, data collection activities, and assessment activities in detail. The QAPP is agreed upon, approved, and acts as the road map for all activities that occur during the implementation phase of the project. Data and information gathered during the project are verified and validated against the project's objectives for quality. Adjustments to the project may be necessary, and more data acquisition efforts may be required to fulfill the project's objectives. After appropriate data have been collected, the quality of those data is assessed using predefined methods and qualified if necessary. If the assessed data are of sufficient quality, they may be used to test the project's original hypothesis and determine if the initial project need has been satisfied.

2.2.2 Data Quality Objectives

Project planning occurs systematically through the DQO process. A formalized DQO process has been developed by EPA and is DEQ's preferred project planning process. A systematic approach to designing data collection activities results in a series of qualitative and quantitative statements (or performance criteria) that define the project objectives, define types of data, and specify tolerance limits for decision errors. The results of the DQO process are documented in, and form the heart of, the QAPP. Details of the DQO process are addressed in EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process* (QA/G-4) (EPA 2006). The latest version of this document is available on the EPA website and on DEQ's intranet.

Under the *graded approach*, the formal EPA DQO process may not be extensively used for many DEQ projects. Although DQOs themselves are a required element of any QAPP, these data objectives are frequently identified with regulatory limits, action limits, agency policy, consent

order requirements, or similar mechanisms and therefore do not necessarily need to be derived from a formal DQO process. In such cases, as determined by the program generating the data, the DQOs may be a simple statement of why the data are being collected and what data output will be considered significant.

For other DEQ projects, a complete statistical hypothesis testing approach (EPA 2006b) may be necessary and appropriate.

For each DEQ QAPP, the associated program/regional manager is responsible for determining the necessary and appropriate level of DQO process planning to be incorporated into the QAPP. This decision will be based, in part, upon the graded approach and the intended use of the generated/collected data.

2.2.3 Quality Assurance Project Plan

This section describes the requirements for internal DEQ QAPPs. These requirements are modified for third-party QAPPs and for existing data QAPPs as described in sections 7.4 and 7.5.

The QAPP is the most important QMS tool at the project level and is required for all environmental data collection and generation activities at DEQ. The QAPP summarizes the DQOs of the project and integrates all technical and quality aspects—including planning, implementation, and assessment—into a single document.

The primary purpose of a QAPP is to systematically document project activities and provide a road map to the type and quality of environmental data needed for a specific decision or use. The QAPP documents all activities that will take place during the project and specific project needs, including field and laboratory activities; data quality level requirements (e.g., Level I, II, III, IV); data acquisition; data verification and validation; data storage and retrieval; data assessment; project evaluation; and process improvement.

All DEQ work that involves acquiring environmental data generated from direct or indirect measurement activities, collected from other sources, or compiled from computerized databases and information systems must be implemented according to an approved QAPP and, if necessary, associated FSPs. This requirement is in effect regardless of whether data are generated directly by DEQ, already exist, or are submitted to DEQ through the efforts of contractors, third parties, or partners.

Although all environmental data collection and generation activities within DEQ must be covered by an appropriate QAPP, the level of detail and scope of the planning documentation should be scaled to meet individual project requirements (i.e., DEQ encourages using a *graded approach* to project planning and implementing quality requirements). Some projects may require a detailed, project-specific QAPP; other data collection activities may be addressed through the umbrella of a generic statewide QAPP.

A generic statewide QAPP addresses general common activities that are to be conducted at multiple locations or over a long period of time. Generic statewide QAPPs may be useful for large monitoring programs that use the same methodology at several different locations. This QAPP should describe, in a single document, information that applies throughout the applicable monitoring program but is not site- or time-specific. In such cases, a site/time-specific FSP shall

be developed that references the applicable generic statewide QAPP as the parent QAPP. This FSP shall include the site- or time-specific details not contained in the parent QAPP, which were deferred to the FSP for reasons of specificity. Site/time-specific FSPs shall be reviewed and approved by the associated project manager, and QAO, and program/regional manager.

The project manager and QAO will identify quality management documentation requirements based on a combination of factors, including, but not limited to, project scope, contractual agreement, resource limitations, and statutory requirements.

DEQ's requirements for QAPPs are equivalent to those required by EPA's *Requirements for Quality Assurance Project Plans* (QA/R-5) (EPA 2001).

DEQ personnel shall use the appropriate DEQ QAPP template, available on the DEQ intranet, as a starting point when authoring a new project QAPP or revising a current project QAPP.

A number of specific elements must be present in the QAPP. Each of these elements addresses one of four major aspects of the project: (1) project management; (2) data generation and acquisition; (3) assessment and oversight; and (4) data validation and usability. The specific required QAPP contents for each of the four elements are shown below.

Project Management Elements:

- Title and Approval Sheet
- Table of Contents
- Distribution List
- Project/Task Organization
- Problem Definition/Background
- Project/Task Description
- Quality Objectives and Criteria
- Special Training/Certification
- Documents and Records

Data Generation and Acquisition Elements:

- Sampling Process Design
- Sampling Methods
- Sample Handling and Custody
- Analytical Methods
- Quality Control
- Instrument/Equipment Testing, Inspection, and Maintenance
- Instrument/Equipment Calibration and Frequency
- Inspection/Acceptance of Supplies and Consumables
- Nondirect Measurements and Existing Data Acquisition
- Data Management

Assessment and Oversight Elements:

- Assessment and Response Actions
- Reports to Management

Data Validation and Usability Elements:

- Data Review, Verification, and Validation
- Verification and Validation Methods
- Reconciliation with User Requirements

Additional details on QAPP requirements are found in *EPA Requirements for Quality Assurance Project Plans* (QA/R-5) (EPA 2001). DEQ staff are further encouraged to use the available EPA guidance document that describes each required QAPP element in detail (EPA 2002a). Copies of these EPA guidance documents are available on the EPA website, from the DEQ quality manager, and on the DEQ intranet.

Additional DEQ guidance can be found in the DEQ *Ground Water and Soils QAPP Development Manual* (DEQ 2001), which is also available on the DEQ intranet or by contacting the DEQ quality manager.

In matters of QA, the QMP shall take precedence over all other agency guidelines and policy documents when a conflict exists between the documents.

All DEQ QAPPs must be reviewed and approved by the project manager, regional/program manager, and QAO, at a minimum. The DEQ quality manager may elect to participate in the review and approval process, based on project conditions.

QAPP approvals shall be documented on a signature page that is an integral and permanent page within the QAPP. The approval page shall include the required approver names and positions in typed format adjacent to the approval signatures and the dates of approval. The approval page shall also include the title of the QAPP (i.e., the project the QAPP applies to) and the version/revision number and date of the QAPP that is being approved. All pages of a QAPP, except for the title page, shall also include a header containing the abbreviated QAPP title, QAPP version/revision number, and approval date. An individual project QAPP becomes effective on the date of the last approval signature. If DEQ develops a system for electronic signatures, then the approval signatures may be electronic. However, all other requirements for the approval page, as previously stated, shall remain in effect.

Project managers are responsible for ensuring that QAPPs are approved **before** the start of data collection activities and project operations are implemented as documented. Project managers are also responsible for maintaining copies of the approved QAPP. After the QAPP is approved, the project manager is responsible for ensuring that a PDF copy of the approved QAPP (including the signed approval page) is maintained in the EDMS.

2.2.4 Field Sampling Plans

As discussed in section 2.2.3, generic QAPPs may be written for some projects. For these projects, an FSP may be written to document specific project monitoring activities and requirements. FSPs must reference the parent QAPP and may not make substantial changes to the DQOs established in the parent document.

FSPs are typically developed to document specific sampling design, sampling location, task-specific data quality indicators (DQIs), unique sample handling requirements, and other project-

specific details. If additions or deletions to the FSP sampling requirements are such that the DQOs must be altered, either the parent QAPP shall be revised and reapproved, or a new project-specific QAPP shall be created and approved.

DEQ FSPs shall be approved by the project manager, project QAO, and program/regional manager at a minimum. The individuals responsible for FSP approval must ensure that all parent QAPP requirements have been satisfied in the associated FSP. All approved DEQ FSPs, including a PDF copy of the approved document with signature page, shall be maintained by the assigned project manager in the EDMS.

Environmental data generated from projects led by external parties may have an accompanying QAPP as discussed in sections 7.4 and 7.5. For these projects, any data generated under an FSP must be accompanied by the external source parent QAPP for which the FSP was written.

2.2.5 Standard Operating Procedures

Many projects use standard procedures that do not change from project to project. Such routine tasks are documented in SOPs. SOPs provide a complete and detailed description of routine procedures so that qualified and trained personnel can trace the operation in a reproducible, step-by-step manner through the entire operation, unsupervised. SOPs must be consistent with current EPA and/or state regulations and, in instances where suitable federal or state guidance is lacking, with accepted professional practices and standards.

DEQ SOPs should be prepared for all routine and standard administrative operations (e.g., data entry, data processing, and procurement) and for all routine and standard technical operations (e.g., sampling, analysis, and assessment). Ideally, SOPs should be written even in instances when published reference methods are being used to promote consistency across the agency.

Advantages of using SOPs include the following:

- Establishes an approved and consistent procedure for implementing common recurring tasks within the agency
- Provides step-by-step instruction to employees for a given task, reducing reliance upon specialized training and historical knowledge
- Increases agency efficiency across programs, regions, and divisions as necessary procedures need not be repeatedly authored
- Promotes consistency in acquired data, eliminating several sources of data collection error
- Provides for ease of statewide agency access to the most current document revision through EDMS storage and retrieval
- Allows for procedural improvement over time, through feedback and approved revision
- Provides a record of the methodology employed in the performance of recurring tasks
- Allows for determining causality factors in the event of an inadvertent data gap
- Demonstrates the validation of data at each step of recording, calculation, or transcription

SOPs should ideally be standardized throughout the agency so that all regional and state office staff may use the same SOP for a given standard operation. It is the responsibility of the regional and division administrators, and the applicable regional/program managers, to coordinate the

standardization of agency SOPs over time to the maximum extent practicable. Division administrators (or designees) have the authority to develop, approve, and maintain agency-wide SOPs.

However, differences in operating conditions, equipment, and other factors may often require a procedure unique to a specific region or division. Accordingly, each region or division may establish and authorize region- or division-specific SOPs. Each division and region is responsible for preparing, approving, and maintaining its own administrative, technical, and operational SOPs.

To provide consistency across the agency with respect to SOP format, the DEQ quality manager is responsible for developing, approving, and maintaining (in the EDMS and on the intranet) an SOP for authoring SOPs. The quality manager will periodically revise this SOP based on input from the regional and division administrators. The SOP for writing SOPs can be obtained from the DEQ intranet, EDMS, or DEQ quality manager.

All DEQ SOPs must be submitted to the applicable regional or division administrator (or designee) for approval and signature. If an approved SOP requires revision, based on changing conditions or periodic review, the revised SOP shall be submitted to the same approval authority before adoption.

All DEQ SOPs shall include the following information on the title and approval page: SOP title; applicable SOP region/division; date; version/revision number; EDMS record number; and names and signatures of the author and approving personnel.

To ensure that DEQ staff have access to the most current SOP version/revision, all approved DEQ SOPs, including a PDF copy of the approved document with signature page, shall be maintained in the EDMS.

All SOPs referenced in a DEQ QAPP, FSP, or any other document associated with environmental data collection must be approved according to the QMP. In addition, as part of the approval process for all DEQ QAPPs or FSPs, the assigned project QAO and project manager will review referenced SOPs to ensure the SOP is current, approved, and available in the EDMS.

See section 7.4 for further requirements regarding SOPs referenced in third-party external QAPPs and FSPs.

2.2.6 Assessments

Assessments are systematic and objective examinations of projects or select activities conducted to determine if the following conditions are met:

- Environmental data collection activities and related results comply with the approved project QAPP and other approved project documents, such as FSPs and SOPs.
- Procedures defined by the approved QAPP, FSP, or SOP are implemented effectively.
- Project or other activities are sufficient and adequate to meet the approved QAPP- or FSP-defined data quality goals and objectives.

Assessments of specific DEQ projects or other activities will be conducted according to QMP requirements, when required by project specifications, or as a corrective action to identified

problems. Assessments are not intended to affix blame for poor data or project outcomes. Rather, assessment findings are used to identify practical solutions to complicated issues and to improve future operations and project planning. Additional discussion on assessments is found in 9.

2.2.7 Data Processing, Review, Verification, and Validation

Data processing, review, verification, and validation are quality management tools used to determine if data have been collected as specified in the QAPP with respect to compliance, correctness, consistency, and completeness. In addition, these tools are used to assess the technical usability of the data with respect to the planned objectives or intention of the project. Although these tools are really processes, project-specific measurement criteria for data processing, review, verification, and validation shall be determined during project planning and documented in the QAPP using the checklists provided.

- **Data Processing—**Data processing includes data collection, entry, transfer, storage, and reduction. The QAPP shall describe or reference specific measures used to maintain the integrity of data records and any project-specific data storage/transmittal requirements. Necessary information includes data formats and standards for transferring data to external data users and systems. Specific data processing activities may include the following:
  - *Collection*: For both manual data and computerized data acquisition systems, internal quality control (QC) checks shall be developed and implemented to avoid errors in the data collection process.
  - *Transfer*: Data transfer steps shall be minimized and procedures established to ensure that data are free from errors and are not lost or corrupted during transfer.
  - *Storage*: At each stage of data processing, documentation shall be established to demonstrate that data integrity and security are maintained. QAPPs shall indicate, if applicable, how specified types of data will be stored with respect to format, media, conditions, location, retention time, and access.
  - *Reduction*: Data reduction includes any process that changes either the form of expression, the numeric value of data results, or the quantity of data. This reduction can occur during validation, verification, and statistical or mathematical analysis of the data. Reduction is distinct from data transfer because it entails a change in the dimensionality of the data set. Steps for verifying the validity of the reduction processes shall be described in the project-specific QAPP if the data set is expected to undergo reduction.
- **Review:** Data review is the process used to confirm data have been processed and recorded correctly.
- **Data Verification**—Data verification refers to the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against methodological, procedural, or contractual requirements. Verification focuses on determining that the data have met measurement requirements. Verification evaluates the data for basic elements such as sampling the correct sites, collecting the required number of samples, and analyzing all parameters. Data verification is not concerned with evaluating or assessing the quality of the data set.
- **Data Validation**—Data validation is an analyte- and sample-specific process that extends the data evaluation beyond methodological, procedural, or contractual

compliance (i.e., data verification) to determine the analytical quality of a specific data set. Data validation criteria are typically based on the DQIs developed in the approved QAPP, FSP, or both. For example, data validation compares the analytical imprecision assigned to the obtained results to the allowable error requirements established in the QAPP. Other examples of comparison during validation include spatial and temporal variance of the data with respect to the limitations defined in the approved QAPP. Data validation includes determining, where possible, the reasons for any failure to meet methodological, procedural, or contractual requirements and evaluating the impact of such failure on the overall data set. Data validation applies to activities in the field and the analytical laboratory.

Additional information on data verification and data validation is found in EPA's *Guidance on Environmental Data Verification and Data Validation* (QA/G-8) (EPA 2002b) and the various EPA National Functional Guidelines for Data Review that are available on the EPA Contract Laboratory Program guidance website.

2.2.8 Data Quality Assessment

Data quality assessment (DQA) refers to the scientific and statistical assessment of data to determine if data are of the right type, quality, and quantity to achieve the project objectives. Data at this stage of the project life cycle have been reviewed, verified, validated, and if warranted, assigned a specific data quality qualifier. Although the individual data elements may have been determined to meet specific criteria during validation, the DQA process addresses the fundamental question of the relationship between the quality of the data and its intended use. Although DQA generally occurs toward the middle or end of a project, the groundwork for the process is established during project planning and is documented in the QAPP (e.g., the choice of statistical tests should be made before any data collection has occurred). Documenting the assessment process early means that this quality management tool will be planned and ready for use after the data have been collected, processed, verified, and validated.

DQA poses and answers two fundamental questions:

- Is the quality of the data appropriate to support making a decision (or estimate) with the desired level of confidence?
- If the same data collection strategy was applied to similar projects in the future, would the resulting data support the same intended use of data with the desired level of confidence?

The data user's immediate need is generally to answer a question or decide a course of action. The reliability of and confidence in decisions can be increased by following the DQA process. Assessing these immediate needs using the DQA process will result in one of two determinations: (1) the data satisfies the objectives of the QAPP and can be confidently used to make an informed decision or (2) the uncertainty of the data is such that it does not satisfy the intended use of the data and a reliable decision cannot be made.

DQA can also help determine the applicability of methods used in the current project to future projects. Through DQA, the results of one study are used to improve future projects by improving the type, quality, and quantity of the collected data, resulting in more reliable and

better quality data. Essentially, the lessons learned from the DQA process for each project can lead directly to the refinement and increased efficiency of related future projects.

Fundamentally, DQA is often a statistical process. Since all measurement processes are subject to error, environmental data measurements provide *estimates* of some true value. Consequently, confidence in any given data set must be determined through a rigorous evaluation of the data using statistical methods.

Although a number of methods may be applied to the DQA process, a five-step process outlined by EPA in *Data Quality Assessment: A Reviewer's Guide* (QA/G-9R) (EPA 2006a) provides a good starting point and includes the following steps:

1. Review the DQOs and sampling design
2. Conduct a preliminary data review
3. Select the statistical method
4. Verify the assumptions of the statistical method
5. Draw conclusions from the data

Strict adherence to this DQA process is not always practical; DQA should be iterative in nature so that the process is constantly improved and adapted to meet project and data needs. The underlying goal of the DQA process is to understand and instill confidence in the data set, leading to informed decision making.

A detailed discussion of the DQA process is beyond the scope of this document. Investigators are encouraged to familiarize themselves with the EPA process and apply sound statistical principles to their own DQA.

3. Personnel Qualification and Training

This section documents the procedures for ensuring that all DEQ personnel performing project-related work have the necessary skills to effectively accomplish their work.

3.1 Requirement for Hiring Qualified Staff

Although personnel qualifications and training are not directly managed by the QMS, they are major support elements of the QMS. Staff hired within DEQ generally must meet minimum qualification standards that are established at the time of recruitment. These qualification standards are incorporated into position requirements to ensure that personnel have the appropriate experience, skills, and education to fulfill the necessary job functions. DEQ encourages employees to continue their education, especially in job-related fields.

3.2 Management Responsibilities

DEQ managers shall ensure that personnel performing work activities under their direction have the required education, training, and experience. Management shall determine the level of competence, experience, and training necessary to ensure capable performance of the assigned work. The need to require formal qualification or certification of personnel performing certain specialized activities should be evaluated and implemented where necessary.

Management shall encourage participation in continuing education and peer reviews to ensure that all personnel (including managers) demonstrate and maintain proficiency in performing their assigned work.

3.3 Technical and Administrative Training

Personnel performing, verifying, or managing work activities shall receive training to the extent necessary. The extent of training shall be commensurate with the scope, complexity, and nature of the activity to be performed and the education, experience, and proficiency of the person. Training shall be provided, as needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

Training includes education in theories and principles and education to enhance an employee's skills and practices. This training shall ensure that personnel understand the processes and resources (tools) they are using, the extent and sources of variability in those processes and resources, and the degree to which they do and do not have control over that variability.

Training shall emphasize the correct performance of work and provide an understanding of why quality management requirements exist. Training shall provide an understanding of the fundamentals of the work and its context. Training shall address potential consequences of improper work and focus on doing it right the first time.

3.3.1 Qualification for Specialized Work

Personnel performing work that requires special skills or abilities shall be qualified before performing work. Qualification requirements shall be established and documented before initiating work activities. Qualification shall include the demonstrated proficiency of each candidate before initiating work and periodically thereafter to maintain skills to meet current practices.

3.3.2 Training and Qualification Review and Records

Training and qualification shall be subject to ongoing review to determine if training efforts meet agency needs. Training and qualifications shall be upgraded when needed improvements or other enhancements are identified.

Records of completed training qualifications shall be established and maintained by DEQ human resources. These records shall include the following, as appropriate:

- Attendance sheets
- Records of course content, including date of training and name of instructor
- Personnel training records, including certificates of completion
- Personnel qualification records, including certifications
- Evidence of previous project training or qualification/certification that may qualify as a substitute for additional training

These training records serve multiple purposes, including the following:

- Tracking required training for staff (e.g., Hazardous Waste Operations and Emergency Response [HAZWOPER], first aid, refresher courses)
- Monitoring how much training is provided to staff
- Enabling employees to track training they have received. Such records can be useful for completing applications for advanced positions, supporting qualifications during an interview, or documenting professional development for inclusion in performance evaluations.

3.4 Quality Management System Training

In addition to technical training, QMS training must be considered when it will provide managers with a working understanding of the QMS along with the tools and techniques (i.e., managerial, communication, and interpersonal skills) necessary to enable their full participation in planning, implementing, and assessing quality system aspects. QMS training should be provided to management and project personnel, as needed, to ensure that personnel have the necessary skills, knowledge, and proficiency to meet the project quality requirements and can effectively implement QAPP requirements. Training pertaining to the DEQ QMS is always available to all staff on the Quality Management page of the agency intranet site at *http://deq.intranet/quality-management/training.aspx*. QMS training shall emphasize the requirements of this QMP and the specific requirement to ensure that project QAPPs are approved according to this QMP **before** data collection and QAPP implementation. QMS training shall be documented in training records maintained by DEQ human resources

Management should also understand the criteria and tools available to assess the effectiveness of the QMS. Similarly, QMS training should be provided to technical personnel and other staff to enhance their understanding of and contribution to the QMS.

All DEQ employees are, at a minimum, expected to read and become familiar with the requirements set forth in this QMP. Regional/program management personnel are encouraged to ensure all assigned staff are given the necessary resources to accomplish this task.

4. Procurement of Items and Services

This section documents the procedures for purchasing items and services that directly affect the quality of environmental decisions.

The procurement practices of all State of Idaho agencies are governed by laws, rules, and policies. Idaho Statute Title 67 Chapter 57 is devoted to public purchasing, governs all public procurements in the state, and requires the Idaho Department of Administration to adopt rules related to public procurement. The statutes and rules governing State of Idaho purchasing practices are found at the following websites:

- *http://legislature.idaho.gov/idstat/Title67/T67CH57.htm*
- *http://purchasing.idaho.gov*
- *http://adminrules.idaho.gov/rules/current/38/0501.pdf*

4.1 DEQ Procurement Policies

DEQ purchasing policies and procedures follow the state's laws and rules. DEQ's Fiscal Office oversees procurement activities to all DEQ divisions and regions to ensure compliance with the appropriate statutes, rules, and policies.

The Fiscal Office works collaboratively with division and regional staff to ensure procurement documents are accurate and complete and clearly describe the item or service needed and the technical requirements, including quality requirements and documentation, of the product or service.

The Fiscal Office reviews and approves all applicable responses to solicitations for goods and trade services to ensure the documents satisfy solicitation requirements. The division or regional staff who generated the original procurement request reviews the response to solicitation to ensure the documents satisfy the technical and quality requirements.

4.2 Quality of Procured Items and Services

Although procurement rules are established independently from the QMS by the State of Idaho and DEQ, ensuring the quality of items and services is an important element in the QMS. Procurement policies are established by the Idaho Department of Administration's Division of Purchasing, but DEQ personnel bear the responsibility of verifying that products, services, and contracts meet the quality requirements specified in this QMP and the project QAPP.

Upon receipt of procured goods or services, division, regional, and project staff are responsible for ensuring that any procured items and services received are of acceptable quality and satisfy project requirements or contractual obligations. This evaluation includes ensuring that all required quality documentation (e.g., QMP, QAPPs, SOPs, and QA/QC data) are received with the product or service and that the documentation satisfies all procurement quality-related specifications.

Laboratory services in support of DEQ environmental data projects shall be assessed and evaluated on an annual basis by DEQ project QAOs using the graded approach, and as resources allow. Laboratory-specific documents and services upon which the DEQ assessment will be based may include on-site audit/assessment activities; review of laboratory QMPs, analytical methods, and SOPs; protocols; certifications; quality control procedures; sample identification and tracking systems; data verification and validation reports; contract documents; available EPA assessment and audit documentation; equipment maintenance and calibration logs and procedures; and any other pertinent data or information necessary to evaluate the laboratory quality process. Project laboratory assessments and evaluations will be documented by the assigned project QAO in the associated project EDMS file. Additional laboratory assessment requirements may be established by regional or division administrators based on specific project or program needs.

5. Documents and Records

This section documents appropriate controls for quality management-related documents and records important to the mission of DEQ. TRIM is the EDMS used at DEQ. It facilitates the exchange of information by providing a central repository of electronic documents and records that can be accessed by agency staff.

5.1 Document Control

Specifics for controlling quality management related documents, records, and appropriate forms shall be described in standards, procedures, or templates, which shall identify the following:

- Types of documents to be controlled
- The responsible party for preparing, receiving, reviewing, approving, issuing, using, and revising documents
- Timeliness guidelines for distributing new or revised controlled documents
- Measures to ensure that only correct documents are in use. Outdated copies of documents should be marked *superseded* or *canceled* or in some other manner to indicate that a more current revision exists and should be kept for a specified retention period.

The document control process covers, at a minimum, the following documents:

- DEQ QMP, current version
- QAPPs
- FSPs
- SOPs
- Standards, procedures, plans, and instructions used by any region or division to support QMS project work associated with environmental data gathering efforts
- Design data, including drawings, specifications, and calculations

5.2 Document Changes and Approval

Changes to the documents defined in section 5.1 shall be reviewed and approved by the same approval authorities within the division or region that performed the original review and approval according to the QMP.

5.3 Work Records

Standards or procedures shall be established and implemented under the direction of the appropriate division or regional administrators to ensure sufficient records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed project work.

Records may include, but are not limited to, records of design; environmental conditions, such as soil, water, or geotechnical samples and data; applied research and development; procurement; construction; audits and assessments; inspections; tests; material analyses; work performance monitoring; qualification of personnel, procedures, and equipment; calibration procedures and

reports; technical and peer review reports; nonconformance reports; CARs; and CAPs. Documents and records must be legible, accurate, complete, and reflect the completed work.

5.4 Record Maintenance

Records shall be legible, identifiable, traceable, and retrievable. Records shall be protected against damage, deterioration, or loss. Methods and responsibilities for record protection, preservation, accountability, transmittal, distribution, retention, maintenance, and disposition shall be identified in standards or procedures.

5.5 Record System Documentation

A records system shall be established. The scope of the records system shall be defined and described in standards or procedures. In addition, the records system shall be implemented and enforced.

5.6 Chain of Custody, Confidentiality, and Evidentiary Records

Chain-of-custody records and procedures shall be established and implemented as required in project-quality documents. Confidentiality considerations and control of evidentiary records shall be in accordance with the "Rules Governing the Protection and Disclosure of Public Records" (IDAPA 16.01.21) and Idaho Code sections concerning public records requests (§§9-337 through 9-347). Issues that arise and are not addressed in these documents shall be brought to the attention of the Idaho Attorney General's Office for resolution.

5.7 Record Changes

Corrections to records shall be controlled. Controls shall provide for appropriate review and approval by the originating group. All corrections shall include the date and the person authorized to issue the correction.

5.8 Record Disposition

Record disposition shall be as prescribed by the DEQ *Records Retention Schedule* (DEQ no date).

6. Computer Hardware and Software

This section documents how DEQ will ensure that computer hardware and software satisfies agency requirements.

6.1 Use of Hardware and Software

Computer, computer-controlled hardware, and hardware/software configurations used by DEQ shall be installed, tested, used, and maintained as necessary. Hardware/software configurations shall be tested before use, and the results shall be documented and maintained. Changes to hardware/software configurations shall be assessed to determine the impact of the change on the technical and quality objectives of the division or region, and appropriate actions shall be taken as necessary.

6.2 Software Requirements and Criteria

Computer software used by DEQ shall meet the requirements of the project, division, or region and shall conform to applicable data management criteria. Documentation, such as reference manuals and user guides, shall be maintained and easily accessible to users.

DEQ user-developed software/applications shall be independently validated by the end user or, where validation is not possible or practical, the end user shall ensure the software/application is independently verified by others. The software/application end user shall retain the validation and verification documentation. This requirement does not apply to software/programs for hand-held calculators and data management programs such as Excel (i.e., software/programs that do not model).

7. Planning

The purpose of this section is to document how individual environmental data operations will be planned within DEQ to ensure that data and information collected are of the type and quality necessary for their intended use. Requirements for projects involving the generation, acquisition, and use of environmental data shall comply with the following requirements.

7.1 Project Management and Roles and Responsibilities

Communication, commitment, and involvement are all critical elements to creating a successful project planning team. All key players should be involved with designing and scoping the project from the start of the process.

The project manager takes the leadership role in the project planning process. The project manager should identify the key team members, encourage fair and honest dialogue, and ensure that all team members are well informed throughout the project life cycle. Moreover, the project manager should see that team members understand their roles within the scope of the project.

Individual team members have an obligation to actively participate in the planning process. They should understand what role they will play in the planning and life of the project and be committed to the project's success. Team members should make a firm commitment to fair and honest communication and encourage cooperation and respect among team members.

7.2 Planning and Documentation

Projects involving the generation, acquisition, and use of environmental data shall be planned and documented. Ensuring that quality data results from a project begins with early planning. Project planning at DEQ uses a team-based approach that draws together diverse interests and participants (internal and external, when necessary) to define the project framework before actual work begins. Although the exact planning details will vary from project to project, a standard process should be followed to ensure that all planning requirements have been fulfilled before any project work has begun.

One of the primary objectives of the project planning team is to define the project's DQOs. DEQ does not mandate that any specific planning method be followed, giving the project manager flexibility to address unique project requirements or considerations; however, the planning method should be scientifically based and use approaches that are widely accepted within the professional environmental community.

When developing project DQOs, DEQ staff are strongly encouraged to use EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process* (QA/G-4) (EPA 2006b), which is available from the EPA website or the DEQ intranet.

Using a systematic approach to designing data collection activities should result in a series of qualitative and quantitative statements (or performance criteria) that define project objectives, define types of data and the required level of data quality, and specify tolerance limits for decision errors. The products of this process—the DQOs—are the fundamental project measurement criteria.

All DEQ projects that generate environmental data must be defined and documented in a QAPP following the guidelines and formats defined for DEQ QAPPs (section 2.2.3). The DEQ QAPP template and guidance can be obtained from the DEQ quality manager or from the DEQ intranet.

The QAPP represents the culmination of the project planning process and will help ensure that data collection activities proceed in a systematic and defined manner such that resulting data are of known quality and integrity, meet the needs of data users, and are generated and processed in an efficient and cost-effective manner. The QAPP developed by the project team must then be submitted for approval before implementation. Requirements for QAPP approvals are described in section 2.2.3.

The type and quality of environmental data needed should be defined and documented using the approach outlined in section 2.2.2. Project-specific planning must involve the key users of the data and the technical staff responsible for obtaining, analyzing, evaluating, and overseeing the data. Project managers are responsible for guiding and ensuring that planning activities are documented and that participants are informed of and understand completely the requirements of the project.

7.3 Coordination of Project Planning

Project planning shall be coordinated among participating divisions and regions and forms the basis for developing the project QAPP. At a minimum, the project planning shall be documented in the QAPP and should include the following tasks:

- Define the project/task scope, the project objectives, and the desired action or result from the work. (When appropriate, this includes the definition of the precise problem and the associated action to be taken.)
- Identify the divisions and regions that need to participate in the project and their role in planning, implementing, and assessing the project.
- Identify the project schedule and the agency resources necessary to successfully conduct and complete the project.
- Identify the required type and quantity of environmental data to achieve the desired action or result.
- Identify QA and QC requirements and performance criteria necessary to establish the quality of the data collected or produced, including the following elements:
  - Goals for DQIs (e.g., precision and accuracy)
  - Minimum requirements for data completeness, precision, and accuracy, if applicable to the project
  - Acceptable level of confidence (or statistical uncertainty)
  - Level of required data validation and verification, how the data validation and verification will be accomplished, and who shall be responsible for it
- Identify required personnel skills and types of equipment.
- Identify the extent of documentation needed to adequately describe the quality of the results.
- Identify special applicable regulatory requirements and other constraints (e.g., time and budget).
- Determine and identify project assessments and evaluations (i.e., technical reviews, peer reviews, surveillances, and project audits, including how audits and assessments will be documented and recorded).
- Identify methods/procedures for gathering, storing, analyzing, and reporting the data based on its intended use.
- Identify possible methods/procedures (including waste minimization objectives) for testing and disposing contaminated sample material that may accumulate during the project.

7.4 External QAPPs, FSPs, and SOPs

DEQ routinely receives and makes decisions based on data collected or submitted to DEQ by contractors or external organizations (e.g., permittees, consultants, private laboratories, industry, and volunteer-monitoring groups). Although DEQ personnel may not have direct responsibility for collecting and analyzing environmental samples and data in these situations, DEQ is responsible for assessing the quality of the data before using it in decision-making processes.

Consequently, both contractors and external entities/organizations play an important role in Idaho's environmental quality. As is appropriate with their level of

involvement, contractors and external organizations should be involved in project planning and understand the role they will play in the project. Contracted third parties or those under an EPA grant subaward are required to submit a QAPP, FSP, QMP, or other quality-related documentation for DEQ approval before conducting project work.

7.4.1 DEQ Contracted Projects

DEQ-contracted projects that gather environmental data for use by DEQ, or under an EPA grant subaward regardless of DEQ use of the data gathered, shall conduct such work according to a DEQ-approved QAPP, in addition to all requirements as set forth in the contract/request-for-proposal process. Project quality documents, including project-related QAPPs and FSPs, must be approved before conducting work. DEQ shall assign a project manager and QAO to these contracted projects who will provide review and approval of the QAPP and associated FSPs. Project quality documents must meet the quality requirements of the DEQ QMP, such as the QAPP/FSP elements defined in sections 2.2.3 and 2.2.4. The required level of data quality necessary to meet the project DQOs shall be clearly specified and documented within the QAPP. Contract project FSPs must be accompanied by, and clearly reference, the parent QAPP and may not make substantial changes to the DQOs established in the parent document. For these projects, the assigned DEQ project manager may also act as the DEQ QAO since the contracted third party is considered responsible for generating project data. In these circumstances, the DEQ project manager remains independent and objective with respect to data generation activities. However, in such cases, the project QAPP and associated FSPs shall also be signed for approval by a DEQ regional/program manager.

Specific quality requirements for contracted project data must be conveyed to the contractor through appropriate guidance documents or by individual project managers. Because DEQ's data collection and generation activities are diverse across the department, the scope for each external QAPP within individual divisions and regions is evaluated by staff on an ongoing basis.

SOPs referenced in a contracted project QAPP that have the potential to affect data quality must be submitted to DEQ with the associated QAPP and FSP for review. While DEQ does not approve such documents, their effect on the quality of the project must be understood and addressed to the satisfaction of DEQ project personnel before approving the QAPP and associated FSPs.

7.4.2 Other External Data Projects

External data not generated or gathered under a DEQ-approved QAPP (internal or contracted projects) before conducting work shall be considered existing data and shall be addressed per section 7.5.

7.4.3 Additional Requirements

In addition to the requirements noted in this section, QMS requirements found elsewhere in the QMP also apply to DEQ staff assigned to externally generated project quality documents, such as QAPPs and FSPs. For example, sections 1.2.5, 1.2.6, and 1.2.7 describe the duties and responsibilities applicable to all DEQ staff assigned to any project as the project QAO, project manager, or regional/program manager, respectively.

7.5 Existing Data

Existing data, also referred to as *secondary data* or *non-direct measurements*, require a different approach before use. Prior to accepting or using any existing data from external sources for project-related purposes, DEQ will develop an internal QAPP according to section 2.2.3 with a clearly defined problem statement, data quality needs, and criteria that will be used to assess the quality of that data. The project-specific QAPP shall clearly specify the methods that will be used to perform data review, verification, validation, and assessment, including any relevant statistical methods, required QC elements, and contractor certifications that must be satisfied to accept data from the external source.

In the DEQ-generated QAPP, the externally generated data shall be thoroughly researched, reviewed, verified, assessed, and validated using all available information to determine if the data are of sufficient quantity, type, and quality for use by DEQ. Efforts shall be made to collect any useful information or metadata that may provide information concerning the validity and quality of the existing data. The results of this data assessment shall be fully documented in the DEQ-generated QAPP, including, at a minimum, all sources of information used; the format of the data; a description of the data; how the data will be accessed, acquired, and managed by the project; a description of the QA procedures used when the data were originally obtained; the intended use of the data; a description of the specific criteria used for acceptance or rejection of the data before use; the methods used for data verification, validation, and assessment; the specific criteria used to determine data-use limitations; and any limitations placed upon on the use of the data to support environmental decisions as a result of the assessment.

DEQ staff are highly encouraged to follow the guidance for use of existing data found in chapter 3 of EPA's *Guidance for Quality Assurance Project Plans* (QA/G-5) (EPA 2002a) in conjunction with these activities. This EPA guidance document is available on the EPA website, from the DEQ quality manager, or on the DEQ intranet. These requirements apply to all external data sources (e.g., federal databases and published data) and existing data collected by contractors or external organizations, unless specifically excluded by state or federal rules.

8. Implementation of Work Processes and Operations

The purpose of section 8 is to document how work processes will be implemented within DEQ to ensure that environmental data and information collected are of the needed and expected quality for their desired use.

8.1 Work Processes

Work processes shall be conducted according to established QA requirements and associated SOPs. Performance monitoring will measure work progress against project requirements.

8.1.1 Quality Assurance Requirement

Work or task activities associated with the collection of environmental data shall be conducted according to approved QAPPs, procedures, standards, and technical documents. Procedures shall be established to ensure that work is performed according to plan, including providing a level of QA oversight and inspection commensurate with the importance of the project or work activities.

8.1.2 Procedures

Procedures shall be developed and implemented in accordance with Section 2 of this QMP.

Procedures that specify technical requirements shall be reviewed for adequacy by qualified technical personnel before use.

8.1.3 Performance Monitoring

Performance shall be routinely measured against established technical and quality requirements. Work processes shall be monitored to ensure continued satisfactory performance. The independence of personnel monitoring work performance shall be commensurate with the nature and importance of the activity. Inspection, use of analytical QC samples, and nondestructive examination are examples of work performance measurements.

8.2 Implementation of Planned Operations Related to Environmental Data

To effectively implement planned operations, qualified personnel must carry out the operation as documented, with any deviations noted to project management. Successful operations depend on quality supplies, accurate and reliable equipment, and proper treatment of samples and data.

8.2.1 Qualified Personnel and Documentation

Environmental data activities shall be implemented according to approved applicable planning documentation. Such operations shall be implemented by qualified personnel in a manner that ensures that the type and quality of environmental data required and expected are obtained. Deviations from the planning documentation shall be documented and reported to project management. The impact and significance of the deviation on planned operations shall be determined, and appropriate adjustments to such operations shall be made as needed. Changes to planning documents and operating guides and manuals shall be made and distributed to project personnel and holders of previous documents.

8.2.2 Quality Acceptance for Services and Items

Only qualified and accepted services and items shall be used in the environmental data operations. Acceptance shall be identified on the items themselves and/or in documents traceable to the items. Acceptability shall be established, maintained, and understood by those who use the items.

8.2.3 Equipment Inspections and Acceptance Testing

Inspections and acceptance testing of sampling, measurement, and analytical instrumentation (or other measurement systems) and their components shall be performed as required to confirm the intended use of the items as specified by the QAPP. When acceptance criteria are not met, deficiencies shall be resolved and the equipment shall be re-inspected as necessary.

8.2.4 Equipment Calibration

Tools, gauges, instruments, and other sampling, measuring, and testing equipment used for

activities affecting data quality shall be controlled and, at specified periods, calibrated according to the manufacturer's recommendation to maintain accuracy within specified limits. Calibration shall be conducted using certified equipment and standards with known valid relationships to nationally recognized performance standards. If no such standards exist, the alternative basis for the calibration shall be documented. Instrument calibration status shall be verified as current before use. Calibration shall be documented by the region or division to which the instrument is assigned and be traceable to the instrument.

8.2.5 Equipment Maintenance

Periodic preventive and corrective maintenance of measurement and testing equipment shall be performed according to the manufacturer's recommendation to ensure availability and satisfactory performance of the systems. All equipment subject to maintenance or repair shall be calibrated before the equipment is returned to service.

8.2.6 Sample Treatment

Handling, storing, cleaning, packaging, shipping, and preserving field and laboratory samples shall be performed according to required specifications, protocols, or procedures to prevent damage, loss, deterioration, artifacts, interference, or contamination by hazardous materials and in a manner that prevents harm to the handler. Sample chain of custody shall be tracked and documented.

8.2.7 Data Management

Data or information management—including transmittal, storage, validation, assessment, processing, and retrieval—shall be performed according to the approved instructions, methods, and procedures. These instructions, methods, and procedures shall be documented in the associated project EDMS file.

9. Assessment and Response

This section documents how DEQ will determine the suitability and effectiveness of the implemented QMS and the quality management performance of the environmental divisions and regions to which the system applies.

9.1 Independent Quality Management Assessment and Response

Quality management activities must be periodically assessed for effectiveness and opportunities for improvement. When necessary, corrective action should be taken to address quality management problems.

9.1.1 Assessment Procedures

Planned and periodic independent assessments shall be performed according to documented procedures for performing audits and surveillance. All assessments shall be documented in the associated project EDMS files.

9.1.2 Assessment Personnel

Personnel performing assessments shall be independent of the work activity being assessed and not part of the unit generating the project data.

9.1.3 Assessment Scope

Independent assessments should evaluate the aspects of DEQ's execution of project activities, such as administration, planning, scheduling, construction, safety, health, procurement, engineering, remedial design, remedial action, QA, and QC.

9.1.4 Assessment Responsibilities

The DEQ quality manager has the authority and responsibility to verify that appropriate levels of quality and applicable QA programs are established and effectively implemented for each division and region by conducting periodic assessments. Assessment reports regarding the effectiveness of QA program implementation will be provided to the applicable DEQ division or regional administrator.

Regional and division administrators have the authority and responsibility to implement the QMP in their respective region or division. As such, the administrators (or designees) have the authority to conduct regular assessments of QMP implementation within their respective region or division to evaluate performance.

Project QAOs have the authority and responsibility to annually assess the projects to which they are assigned to evaluate project adherence to the requirements of the QAPP. Results should be documented in the project files and presented to the assigned project manager.

Project managers have the authority and responsibility to routinely review (at least annually) conditions for projects to which they are assigned and to verify that the associated QAPP remains consistent with the existing project conditions and available resources.

Section 10.3 discusses actions required upon discovery of nonconforming quality management conditions.

9.1.5 Work Monitoring

Independent assessors shall monitor work performance to identify abnormal performance, precursors of potential problems, and opportunities for improvement. Assessment shall be documented and reported to project managers to identify quality management problems and cite noteworthy practices that may be shared with others to improve the quality of their operations and activities.

9.1.6 Corrective Action

Where quality management problems are identified, assessment reports shall require effective corrective actions to be taken by project staff, with follow-up conducted by the assessor to ensure that corrective actions are satisfactorily implemented and continued.

9.2 Assessment of Data Usability

Data, both internal and external, must be assessed for their usability in DEQ projects involving environmental data.

9.2.1 Data and Information Qualification

Data and information from environmental data gathering operations shall be qualified according to intended use. The usability of data and information shall be assessed relative to the needs and expectations of the data user. Data qualification shall be based on the DQOs specified in the QAPP or other planning documents. Any limitations on data use should be expressed quantitatively to the extent practicable and documented in any data reporting, either in print or electronic media.

9.2.2 Assessment of Externally Generated Data

Externally generated data obtained from sources that did not generate or gather the data under a DEQ-approved QAPP shall be considered existing data, and the data will be evaluated and assessed before DEQ use by developing an approved DEQ project QAPP (section 7.5).

2 and 7.45 further details about DEQ QAPP development and use of existing data.

9.2.3 Independent Review of Scientific and Technical Work Products

Major scientific and technical work products related to agency decisions should be peer reviewed internally. Agency managers within programs and regions determine and are accountable for the decision whether to employ internal peer review and, if so, its character, scope, and timing. These decisions are made in conformance with Idaho statute, program goals and priorities, resource constraints, and statutory or court-ordered deadlines. Peer review is not restricted to the final version of work products. Peer review at the planning, sampling, data analysis, and engineering/scientific calculation stages of a project is often extremely beneficial.

9.2.4 Evaluation of Previous Data Obtained from Nonconforming Methods or Instruments

Data obtained previously from a method or instrument found to be nonconforming to specifications must be evaluated to determine the impact of the nonconformance on the quality of the data, and appropriate action must be taken. The evaluation should be inclusive of data obtained since the last acceptable use of the method or instrument.

10. Quality Management System Improvement

This section documents how DEQ will improve the products and processes of its QMS.

10.1 Problem Prevention

As procedures, plans, and other work instructions are established and implemented, they should be developed with the objective of preventing problems and improving quality. Examples of planning and problem prevention include, but are not limited to, peer reviews; design review; constructability reviews; risk assessments; safety analysis reports; reliability, availability, and maintainability analyses; trend analyses; lessons learned; and root-cause analyses.

10.2 Trend Analysis

Project managers, QAOs, regional/program managers, regional/division administrators, and the quality manager are responsible for continuously evaluating data and information from instances of nonconformance, inspection reports, surveillance reports, audit and assessment reports, QSRs, CARs, CAPs, stop-work orders, and other sources. These data will be used to identify trends or conditions adverse to quality, which shall then be brought to the attention of the quality manager. During the QMP annual review process, the quality manager will consider all such recommendations for inclusion into the QMS as part of the overall quality system improvement process.

10.3 Identification of Nonconforming Items

DEQ personnel and management at all levels are encouraged to assist in identifying nonconforming items and processes. These efforts should focus on discovering root causes for nonconformance and the potential underlying systematic issues that may exist and not necessarily on affixing blame for the condition. Management shall be involved in the quality improvement process to ensure that proper focus is given, adequate resources are allocated, and difficult issues are resolved.

Nonconforming items shall be identified, documented, segregated where practical, reviewed, evaluated, and controlled to prevent their inadvertent test, installation, or use according to documented procedures and this QMP.

All DEQ and supplier personnel shall identify nonconforming items by tagging or otherwise marking them in a manner that does not adversely affect the end use of the items. The identification shall be legible, easily recognizable, and firmly affixed to the item. If identifying each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.

Nonconforming items will be segregated, when practical, by placing them in a clearly identified and designated holding area until proper disposition is accomplished. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use.

10.3.1 Role and Responsibilities of Regional/Program Managers

DEQ regional/program managers are responsible for the following tasks related to nonconforming items:

- Coordinate disposition of nonconforming items. (Dispositions shall be provided by personnel that are qualified and knowledgeable in the area identified.)
- Ensure that nonconforming characteristics are reviewed, and recommended dispositions are proposed and approved. (Work shall not proceed on nonconforming items before receiving an approved disposition or conditional release from the responsible design organization.)
- Document as-built records, if such records are required, which reflect the accepted deviation, where applicable.
- Identify and document the final disposition (e.g., use-as-is, reject, repair, or rework) of nonconforming items.
- Document technical justification for the acceptability of nonconforming items that have received a disposition of *repair* or *use-as-is*.
- Oversee the generation of a nonconformance report summarizing the issues, to be reviewed by all project personnel and documented in the project file.

10.3.2 Role and Responsibilities of the Project Quality Assurance Officer

The project QAO is responsible for the following tasks related to nonconforming items:

- Monitor activities related to the control of nonconforming items through periodic observation, audits, or both.
- Provide verification that nonconformance dispositions have been properly accomplished. Items with nonconformance disposition classifications of *rework* or *repair* shall be reexamined according to the original acceptance criteria unless the nonconformance disposition has established alternate acceptance criteria.
- Review nonconformance reports to determine if a cause analysis or an action to prevent recurrence is required. If actions are deemed to be insufficient or inappropriate by the QAO, the QAO will generate a CAR to initiate the process.

10.4 Review of Recurrent or Significant Conditions Adverse to Quality

Recurrent or significant conditions adverse to quality shall be identified and controlled according to documented procedures, which include methods for prompt identification and correction. Recurrent and significant conditions adverse to quality shall be reported in a CAR. CARs shall be generated by the entity that discovered the adverse condition, and the report shall clearly identify the party responsible for taking corrective action. The CAR will be distributed to the responsible party, the associated project manager, regional/program manager, QAO, and, if applicable, to the appropriate DEQ supplier. All CARs shall specify the date by which the responsible party must submit the associated CAP.

Subcontract documents shall require subcontractors to promptly identify, correct, and report (to DEQ management) any conditions adverse to quality.

10.5 Response to Corrective Action Reports

Responses to CARs shall be in the form of a CAP and will include a description of the cause of the condition, the action taken or to be taken to correct the condition, actions taken or to be taken

to preclude recurrence, and a scheduled date for implementing the corrective actions. The CAP shall be developed by the responsible party identified in the CAR and submitted to the initiator of the CAR, the associated project manager, regional/program manager, QAO, and, if applicable, to the appropriate DEQ supplier within the time period specified in the CAR.

CAPs shall be reviewed for acceptance by the initiator of the CAR and the associated project QAO. Final approval of the proposed CAP shall be in written format, signed for approval by the initiator of the CAR and associated project QAO, and transmitted to the originator of the CAP. The responsible party identified in the CAR shall then implement the CAP within the time frame described in the approved CAP.

Follow-up shall be conducted by the project QAO to ensure that the corrective actions, as set forth in the approved CAP, have been satisfactorily implemented and have achieved the desired results. This follow-up should occur within 30 days following the scheduled CAP completion date, with results documented in project files.

The responsible project manager shall file the CAR, CAP, and related documentation pertinent to the issue in the associated project EDMS files.

10.6 Stop-Work Orders

Any condition adverse to quality that does not meet the project objectives or indicates unacceptable impacts to the environment, safety, health, or quality may be cause for issuance of a stop-work order. A stop-work order may be issued following a stop-work condition described in section 1.2.9.

10.6.1 Stop-Work Order Process

As described in section 1.2.9, all DEQ and supplier personnel have the responsibility and authority to stop work until an effective corrective action is taken when, in their judgment, the continuation of such work will not meet the project objectives or will have unacceptable impacts to the environment, safety, health, or quality.

Following the stop-work condition, a stop-work order may be issued by the responsible regional/program manager, division/regional administrator, or the DEQ quality manager (issuing officials) if additional measures are deemed necessary to control further processing and to remedy the condition.

Project management—including the project manager, regional/program manager, QAO, and, if applicable, the associated DEQ supplier—may elect to continue stoppage of the work voluntarily and take necessary corrective actions. When voluntary corrective actions are taken, and complied with to the satisfaction of the reporting individual, project QAO, and the issuing official, a stop-work order need not be initiated.

10.6.2 Stop-Work Order Notification Requirements

When the issuing official determines that issuance of a stop-work order is necessary to control further processing of the work, the issuing official will immediately notify the responsible

regional/program manager, project manager, QAO, DEQ quality manager, and, if applicable, the associated DEQ supplier and DEQ procurement manager that a stop-work order is in effect.

When DEQ suppliers are involved in or affected by the issuance of a stop-work order, notification of the stop-work order condition shall include the DEQ procurement manager.

10.6.3 Role of the Project Manager and Project Quality Assurance Officer Following a Stop-Work Order

The associated project manager is responsible for coordinating efforts to implement corrective actions necessary to resolve the cause of the stop-work order. Upon completion of these efforts, the project manager shall inform the QAO and the stop-work order issuing official.

The associated project QAO shall verify corrective action implementation for all conditions leading to the issuance of a stop-work order. The QAO will also determine if conditions adverse to quality have resulted from the stop-work condition/order, and, if so, inform the project manager, regional/program manager, and, if applicable, the associated DEQ supplier for immediate resolution.

Stop-work orders shall only be lifted by the issuing official after corrective actions and actions to preclude recurrence have been completed to the satisfaction of both the project QAO and the issuing official. When the stop-work order is lifted by the issuing official, notification shall be given immediately to the responsible regional/program manager, project manager, QAO, DEQ quality manager, and, if applicable, the associated DEQ supplier and DEQ procurement manager.

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Glossary

Acceptance Criteria	Specified limits placed on characteristics of an item, process, or service defined in the design, codes, standards, or other requirement documents. Commonly, acceptance criteria address the adequacy of existing (secondary) data or information proposed for inclusion into a project.
Activities that Affect Quality	Activities that could compromise the validity of information or data reported and result in an unacceptable risk to the environmental health or safety of the public or the workers or could have a detrimental effect on achieving mission objectives.
Activity	An all-inclusive term describing a specific set of operations or related tasks to be performed, either in series or in parallel, that in total result in a product or service.
Assessment	The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, systems, elements, or services meet specified requirements.
Audit	A systematic, independent, and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the extent to which quality management activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. Audits can be internal examinations of divisions or activities under an organization's control and within its organizational structure or external examinations of divisions, projects, or activities of another organization.
Audit or Assessment Finding	For the purposes of an audit or assessment, findings are defined as instances or conditions of nonconformance or noncompliance with specified requirements. Audit findings require a written response describing the corrective action necessary to correct the nonconforming or noncompliant condition. The written response, in the form of a corrective action plan (CAP), must include the cause that led to the identified condition, actions that will be taken to correct the condition and prevent recurrence, and the date when necessary corrective action measures will be complete.
Audit or Assessment Observation	For the purposes of an audit or assessment, an observation is defined as an item of concern that could lead to a future finding, an item identified as an opportunity for operational improvement, or an observed item/condition considered to be a noteworthy practice and of benefit to the organization. Observations do not require a written response, although observations having the potential to lead to audit or assessment findings will be thoroughly explored in the course of future audits or assessments.
Audit or Assessment Recommendations	For the purposes of an audit or assessment, recommendations are made by the auditor or assessor following review of project plans, documents, or observed activities. Recommendations are based on the auditor or assessor's previous experience relative to projects having similar quality requirements. Recommendations are an opinion expressed by the audit or assessment team, do not require a response, and are offered to help an organization address a corrective action. All findings, and some observations, should be accompanied by a recommendation.

Background	The concentration of a substance in an environmental medium (such as air, water, or soil) in a defined control area during a fixed period of time that occurs naturally and is not the result of human activities.
Blank	A sample subjected to the usual analytical or measurement process to establish a zero baseline or background value. Sometimes used to adjust or correct routine analytical results. A sample that is normally intended to contain none of the analytes of interest. A blank is used to detect contamination during sample handling preparation and/or analysis.
Blank—Field	A field blank is an analyte-free sample that is carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample. This blank is used to provide information about contaminants that may be introduced during sample collection, storage, and transport.
Blank—Method	A method blank is prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and quality control (QC) samples. Results of method blanks provide an estimate of the within-batch variability of the blank response and an indication of bias introduced by the analytical procedure.
Blank—Trip	A trip blank is an analyte free sample, free of measurable contaminants, that is taken to the sampling site and transported to the laboratory for analysis without having been exposed to sampling processes or procedures. Trip blanks are analyzed to assess whether contamination has been introduced during sample shipment.
Certificate of Conformance	A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.
Chain of Custody	An unbroken trail of accountability that ensures the physical security of samples, data, and records.
Characteristic	Any property or attribute of data, items, processes, or services that is distinct, describable, and measurable.
Collocated Samples	Two or more portions collected at the same point in time and space so as to be considered identical. These samples are also known as field replicates.
Computer Program	A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution and to execute it.
Condition Adverse to Quality	An all-inclusive term that includes the following: failure to meet performance objectives, malfunctions, deficiencies, defective items, and conditions of nonconformance, which if left uncorrected could have adverse effects on the environment, health, safety, or operability.
Controlled Process	A process that affects the quality of data, design, procurement, fabrication, construction, inspection, testing, operation, or maintenance and that requires applying either administrative or engineering controls to ensure successful performance.
Corrective Action	Actions taken to rectify conditions adverse to quality and eliminate the causes of an existing nonconformance, deficiency, or other undesirable situation in order to prevent recurrence.

Data	Information generated or acquired from literature reviews, sampling, testing, analyses, measurement, inspection, or observation (including photographs and videos) that relates to engineering or scientific matters from which conclusions can be inferred.
Data Accuracy	A measure of the overall agreement of a measurement to a known value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations. Accuracy is assessed by means of reference samples and percent recoveries. Data accuracy is a data quality indicator.
Data Bias	The systematic or persistent distortion of a measurement process that causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value). Data bias is a data quality indicator.
Data Comparability	A measure of the confidence with which one data set (or method) can be compared to another. Data comparability is a data quality indicator.
Data Completeness	A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained to meet the project data quality objectives. Data completeness is typically expressed as a percentage and is a data quality indicator.
Data Precision	The measure of agreement among individual repeated measurements of the same property under identical or substantially similar conditions. Precision is most desirably expressed in terms of the standard deviation. Various measures of precision exist depending upon the "substantially similar conditions." Precision is assessed by means of duplicate/replicate sample analysis and is a data quality indicator.
Data Quality	The totality of features and characteristics of data that bear on their ability to satisfy the stated or implied needs and expectations of the user. The characteristics of major importance are legibility, accuracy, precision, bias, completeness, representativeness, and comparability.
Data Quality Assessment (DQA)	A statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test and to determine if the data obtained from operations are of the right type, quality, and quantity to support their intended use.
Data Quality Indicator (DQI)	Quantitative statistics and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principle data quality indicators are bias, precision, accuracy, comparability, completeness, and representativeness.
Data Quality Objectives (DQOs)	The qualitative and quantitative statements derived from the DQO process (see below) that clarify a study's technical and quality objectives, define the appropriate type of data, and specify the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support the decisions.
Data Quality Objectives Process	A systematic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a special use. DQOs are the qualitative and quantitative outputs of the DQO process.

Data Reduction	The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors and collating them into a more useful form. Data reduction may be irreversible and generally results in a reduced data set and an associated loss of detail.
Data Representativeness	The degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, or an environmental condition. Data representativeness is a data quality indicator.
Data Validation	An analyte- and sample-specific process that extends the evaluation of data beyond methodological, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of the specific data set.
Data Verification	The process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the methodological, procedural, or contractual specifications.
Deviation	A departure from the specified requirements.
Environmental Conditions	The description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.
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 the US Environmental Protection Agency, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or the literature.
Environmental Technology	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 used to remove pollutants or contaminants from or prevent them from entering the environment.
Examination	An element of an inspection that consists of investigating materials, components, supplies, and services to determine conformance to specified requirements. Examination is usually nondestructive and includes simple physical manipulation, inspection, and measurement.
External Audit	An audit of another organization's quality assurance structure not under the direct control or within the organizational structure of the auditing organization.
Finding	A statement of fact relating to compliance or noncompliance with previously agreed upon codes, standards, specifications, or other forms of contractual or legal obligation.
Graded Approach	The process of basing the level of managerial controls applied to an item or work task according to the intended use of the results and the degree of confidence needed in the quality of the results.

Individual Titles	When individual titles are used in this *Quality Management Plan*, the named position may delegate in writing another qualified individual within the organization to perform the required function, but the named individual retains responsibility for the requirement. This delegation may not be re-delegated, is intended to be temporary, and requires consent from the DEQ quality manager.
Item	An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part structure, subassembly, subsystem, system, unit documented concepts, or data.
Item of Concern	A condition or item that currently meets the established requirements; however, if left without management attention, the item may lead to a departure from established requirements.
Management System	A structured, nontechnical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.
Measuring and Testing Equipment	Devices or systems used to calibrate, measure, gauge, test, or inspect; to control or acquire data to verify compliance to specified requirements; to establish characteristics or values; or to gather data for use in decision-making or facility or process design.
Nonconformance	A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.
Observation	A conclusion that presents the results of a generally subjective evaluation of implementation practices or management systems related to the area, process, or system under review.
Peer Review	A documented critical review of work that is an in-depth analysis and evaluation of documents, assumptions, calculations, activities, materials, extrapolations, acceptance criteria, methodology, conclusions, or data for applicability, correctness, technical adequacy, completeness, appropriateness of interpretation, and assurance that established requirements are satisfied.
Procedure	A set of systematic instructions that specifies or describes how an activity is to be performed.
Process	An orderly system of actions intended to achieve a desired outcome or result by using a set of interrelated resources and activities that transform inputs into outputs.
Quality	The totality of features and characteristics of a product that bear on its ability to meet the stated or implied needs and expectations of the user.
Quality Assurance (QA)	An integrated system of management activities involving planning, implementation, assessment, quality control, reporting, and quality improvement to ensure that a product, process, item, or service is of the type and quality, within a stated level of confidence, needed and expected by the user.

Quality Assurance Project Plan (QAPP)	A formal document describing in comprehensive detail the necessary quality assurance procedures, quality control activities, and other technical activities needed to ensure the results of the work performed will satisfy the stated performance or acceptance criteria.
Quality Control (QC)	The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill the need for quality.
Quality Management Plan (QMP)	A document that describes the quality management system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for planning, implementing, and assessing all activities conducted.
Quality Management System (QMS)	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 management system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control activities.
Record	A completed document that provides objective evidence of the quality of items, activities, or processes. Records may include photographs, drawings, magnetic tape, compact discs, digital versatile discs (DVDs), and other data recording media.
Replicate Sample	Two or more portions collected at the same point in time and space so as to be considered identical. A sample prepared by dividing a sample into two or more separate aliquots. Duplicate samples are considered to be two replicates. Commonly used to determine or provide a measure of precision.
Rework	An action taken on a nonconforming product so that it will fulfill the specified requirements.
Sample	A part of a larger whole or a single item of a group; a finite part or subset of a statistical population; or a representative portion of any material collected from any source for which determination of composition or contamination is requested or required.
Service	The performance of work, such as laboratory or field analyses, design, inspection, nondestructive examination, repair, or installation.
Software Validation	A process that demonstrates that a mathematical model as embodied in computer software is an acceptable representation of the process or system for which it is intended to describe. The test and evaluation of the completed software is conducted to ensure compliance with software requirements.
Specification	A document stating requirements and referring to or including drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.
Standard Operating Procedure	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	Any individual or organization that furnishes items or services in accordance with a procurement document. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub tier levels.
Surveillance	Continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specifications are being fulfilled.
Testing	An element of verification for determining the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions or a combination thereof.
Use-As-Is	A disposition permitted for a nonconforming item when it can be established and documented that the item is satisfactory for its intended use.