QUALITY MANAGEMENT PLAN

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Arizona Department of Environmental Quality
Quality Assurance/Quality Control Program

FOREWORD

Arizona Department of Environmental Quality (ADEQ) is committed to the Health and Safety of all of Arizona's citizens. The health of our environment is vital to the life style most Arizonan's enjoy. For this reason, quality environmental data is an invaluable tool for monitoring the wellbeing of our environment.

This commitment to quality is the reason for this revision of the Quality Management Plan (QMP). The QMP is the umbrella, or blueprint, of ADEQ's overall Quality Management System. There are many other components to the quality system and each of these will be discussed in detail in the QMP.

ADEQ has revised its QMP under the direction of agency-wide QA/QC program management (AQPM) (and QA representatives from each of the three Environmental Divisions of ADEQ. This plan decentralizes the role of QA/QC for reasons of efficiency and accuracy. The agency-wide QA/QC program management consists of either an agency-wide QA/QC manager, or designated QA/QC representatives from each division to fulfill the roles and responsibilities stated in this QMP.

The current vision for the role of the AQPM within ADEQ is as a primary resource for all agency disciplines to use and as a coordinator for standardizing protocols. The AQPM will coordinate the activities of division QA/QC specialists who will frequently examine and audit the environmental data collection procedures and use of that data in order to continually improve the Quality Management System.

The AQPM is independent of the Leadership Team who serve as the policy making group for ADEQ. With this separation of groups, Leadership Team, division specialists, and the AQPM autonomy is preserved in fact and appearance. The ultimate responsibility for Quality Assurance for ADEQ lies with the agency Director.

This decentralized approach has been made necessary by the large number of different skill sets required to accomplish all of the environmental data collection activities, and ultimately the use of the environmental data. The degree of specialization would require that the AQPM handle a tremendous volume of work to complete all QA/QC activities, and serve each unit equally and in a timely fashion. The system proposed herein addresses that issue by offering aid to all units when the workload is unusually heavy while making certain that no project or program should suffer from a bottleneck in the system caused by another unit's heavy load.

CHAPTER 1 ORGANIZATION AND MANAGEMENT

1.1. QUALITY ASSURANCE (QA) POLICY

1.1.1. DOCUMENT PURPOSE

The Quality Management Plan (QMP) describes the quality management processes the Arizona Department of Environmental Quality (ADEQ) uses to maintain a Quality Management System consistent with the U.S. Environmental Protection Agency (EPA) requirements. The quality system supporting ADEQ programs involving environmental data or technology shall be covered by this QMP. The QMP is an "umbrella" document which details in broad terms the strategies used to carry out QA/QC functions during environmental data collection activities and proper data use thereafter. The QMP was prepared in accordance with the March 2001 edition of the EPA requirements document numbered EPA QA/R-2, and entitled *Requirements for Quality Management Plans*, and to comply with EPA Order CIO 2105.0CIO 2105.0, entitled Policy and Program Requirements for the Mandatory Agency-Wide Quality System.

1.1.2. DEFINITION OF QUALITY ASSURANCE/QUALITY CONTROL (QA/QC)

Quality Assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed, and expected, by the customer.

Quality Control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer. The QC system includes operational techniques and activities that are used to fulfill requirements for quality.

At ADEQ, the Quality Management System is implemented largely through the following Agency functions:

1. QA/QC training for certain identified job functions;
2. Use of Agency QA Program Plans (QAPrPs);
3. Use of Agency QA Project Plans (QAPjPs);
4. Clearly defined agency-wide QA/QC program management (AQPM) oversight responsibilities (oversight authority may be delegated to the division representatives);
5. Periodic Management Systems Reviews (MSRs) and Technical System Audits (TSAs) coordinated through the AQPM ;
6. Focus on continuous improvement efforts;
7. Appropriate documentation and record keeping for all data related activities.

Each of these systems is discussed in more detail in the appropriate section within this document. This document officially establishes these requirements as components of the ADEQ Quality Management System.

QC is largely implemented at the Program level through Quality Assurance Program Plans (QAPrPs). Each Division has unique requirements, statutory guidelines, rules, and policies that must be followed. QAPrPs should incorporate the unique qualities that are specific to each Division or Program. Consequently, QC is managed first at the Program level, and more specifically on a project-by-project basis through the use of Quality Assurance Project Plans (QAPjPs) and required data assessment activities. Project/Program based division QA/QC specialists, through a review and approval process involving AQPM, are individually responsible for assuring that the QAPjP is capable of producing reliable work, of known quality, which meets stated project needs. As defined in the QAPrP, in many cases a sampling plan and data quality objectives will suffice to assure data integrity.

1.1.3. IMPORTANCE OF QA/QC TO ADEQ

The quality of decisions made by ADEQ depends heavily on the quality of information used to make those decisions. If those data are not of adequate quality to support their intended use, then subsequent decisions will suffer commensurately.

Environmental data are used for setting priorities; strategic direction; targeting inspections; measuring compliance; identifying enforcement actions; measuring progress and trends; certifying laboratories; and for many other uses. Environmental data are critical because they can impact our Programs direction and emphasis, determine whether an enforcement case can be successful, or dictate which of several cleanup options will be implemented at a contaminated waste site.

The consequences of poor data (i.e., do not meet user requirements) are that our individual and collective decisions are not as sound as they could or should be. Poor data can also have extremely negative consequences, such as when an enforcement case has to be withdrawn because our own underlying compliance data are successfully challenged by defendants.

ADEQ is involved in conducting studies that have goals in several broad categories that include but are not limited to:

- Determining baseline conditions for lakes, streams, soil, groundwater, and air quality;
- Identifying and quantifying the presence of environmental contaminants in areas of potential exposure to humans or the environment;
- Verifying the effectiveness of techniques and methods by which data sets are collected;
- Determining the impacts of environmental contaminants on human health and ecosystems;
- Determining whether, how, and by whom such threats to human health and the environment should be remediated;
- Monitoring compliance with environmental regulations.

QA/QC is integral to the functions of this State agency because quality data ensure the scientific credibility of the data on which decisions are based. Proper QA enhances proper planning, reducing the likelihood of duplicative and repetitive sampling, thereby reducing costs to the taxpayers.

1.1.4. GENERAL GOALS AND OBJECTIVES OF THE ADEQ QUALITY MANAGEMENT SYSTEM

ADEQ's Quality Management System is designed to avoid occasions where the environmental data collected falls short of meeting the data quality objectives (DQOs) established by the users of the data. The primary goal of the ADEQ Quality Management System is to ensure that all environmentally related data collection and processing activities, performed by or under the Agency's oversight, will result in the production of data that are both documented and of known quality. This will ensure that the data can be used with a high degree of certainty by the user to support specific decisions or actions that are appropriate for the intended purpose. ADEQ's Quality Management System applies to monitoring and measurement activities that occur within, or for, the Agency. For those programs that are supported by EPA through grants, contracts, or interagency agreements, the mandatory elements for EPA quality systems will be utilized. ADEQ's QMP will be achieved by ensuring that appropriate resources are made available and that the proper procedures are followed throughout the entire process of planning, collecting, analyzing, and interpreting environmental data.

The goals of ADEQ's Quality Management System are to:

- Produce quality data that are acceptable for the intended purpose;
- Encourage the use of QA/QC principles in the management of environmental projects;
- Facilitate the timely identification of problems and implement corrective actions;
- Assist in the identification of training needs for agency personnel;
- Ensure that Division staff and the AQPM work cooperatively to identify and correct systemic weaknesses;
- Provide for continuous improvement in Agency data operations.

It is ADEQ's policy that:

1. Programs generating, using, or requiring the collection of environmental data will be consistent with the intentions outlined in this QMP, ADEQ policies, and standard processes documentation.

2. The DQO's for generating any new environmental data will be determined prior to data collection activities so that appropriate resources and QA/QC methods can be applied to ensure a level of data quality commensurate with the intended use(s) for the data.

3. A comprehensive QAPrP should be used to detail activities under the regulatory Program. Each Program or activity that generates environmental data will develop and

implement a QAPrP and/or QAPjP containing SOPs which specify the detailed procedures required to assure production of quality data. The QAPrPs shall be prepared by the appropriate agency staff, and if needed, with the support of the AQPM. Effective organizational QAPjPs and QA standard processes shall be developed, implemented, and approved as required except as provided for in number six below.

4. All environmental data generated by the Agency should be of known and documented quality, as defined by pre-established DQOs or existing regulatory levels. DQOs need to be clearly stated with each individual project, but are often predetermined by regulatory criteria and action levels within similar Programs. If the DQO formal process is needed, it should be implemented consistent with EPA's *Guidance for the Data Quality Objective Process, August 2004*, EPA QA/G-4 or an equivalent document.

5. ADEQ's AQPM shall act as the liaison for information to and from EPA Region 9 and shall provide necessary research to support the technical authority for any ADEQ data collection activity.

6. QAPjPs shall be prepared by the originating ADEQ Program, and if necessary in coordination with the AQPM, prior to the start of any data collection effort. The originating Program has the option to utilize the services of a private contractor. QAPjPs and QAPrPs shall be approved by AQPM. The AQPM will submit all QAPrPs to EPA Region 9 for approval.

   A separate stand-alone QAPjP or equivalent document may be developed, as appropriate, for site-specific projects undertaken by the organization utilizing non-EPA resources. QAPjPs, or equivalent documents, developed for projects not funded by EPA shall be developed within the guidelines set forth in this plan. The AQPM may assist the independent contractor, or ADEQ Project team with the development of a QAPjP. The AQPM will also make available DQO's, Field Sampling Plans (FSP's), and standard process documentation, or other guidance documents, where such documents can provide sufficient guidance to the project team. The originating Program has the option to either utilize the services of a qualified contractor or other independent ADEQ staff, provided the person has had appropriate training, has demonstrated an understanding of QA principles, and has satisfactory experience in generating QA documents. Short-term projects and one-time events (e.g. emergency response) do not require QAPjPs as long as the sampling protocols and objectives used are addressed in the Program's QAPrP.

7. Regular technical systems audits (TSAs) may be conducted by the AQPM for division program specialists utilizing contractors and ADEQ projects involving environmental data collection to ensure that they comply with ADEQ QMP requirements. The TSA is a process used to measure the conformance of a measurement system to criteria defined by ADEQ. Additionally, ADEQ's QMP may involve periodic Management Systems Reviews (MSRs). Deficiencies highlighted in these assessments will be addressed in a timely manner as defined in Section 9.2.1 of this document.

8. The requirements of the QMP may be waived only under exceptional circumstances.

Each waiver will be reviewed by the AQPM on its own merits upon receipt of a written request. The waiver must address the requirement to be waived, the rationale, and the consequences of non-approval. If found appropriate, the requirement will be waived. For sites which are under the jurisdiction of EPA Region 9 or if the project is supported by EPA funds, the request for a waiver must also be approved by the EPA Region 9 Quality Assurance Manager. When a waiver is granted, the actual procedures for the data management activities will be documented and available for review and assessment during the decision-making process associated with the project.

1.1.5. RESOURCES FOR THE QA SYSTEM

The resources necessary to conduct the various QA and QC activities within ADEQ are provided by ADEQ's Leadership Team, and, in some cases, by Program staff requiring assistance in order to successfully implement their Programs. QA is viewed as an integral part of any Program which deals with environmental measurements and data generation. This includes all monitoring activities. The level of QA resources needed for any given Program or project is determined initially by the relevant Program or division QA/QC specialist.

ADEQ provides in-house and contracted expertise in QA and technical support services to all Programs within ADEQ. These support services include data quality assessments, data validation, and other evaluations provided by chemists, toxicologists, engineers, and others. Personnel that provide these services are located either within ADEQ, or within other State agencies such as the Arizona Department of Health Services (ADHS).

1.2. SCOPE OF THE QUALITY MANAGEMENT PLAN

ADEQ's QMP is intended to establish the foundation for implementing an effective QA Program within ADEQ and cover, at a minimum, internal and external activities which involve the generation of environmental data for Programs funded by EPA or other sources. At a minimum, the QMP applies to ADEQ Programs, activities, grants, contracts, and interagency agreements that generate environmental data which is used to make decisions or support actions related to the Agency's defined mission and responsibilities that are funded by EPA. Environmental data is defined as information or measurements resulting from field data collection activity, laboratory analyses, or models involving the assessment of chemical, physical, or biological factors relating to the environment. Therefore, any Programs, activities, etc., which generate such data are required to comply with the requirements of this QMP.

1.2.1. TYPES OF ACTIVITIES SPECIFICALLY COVERED BY THE ADEQ QMP

The five types of data generation and monitoring activities covered under this QMP include:

1. Data generated by field sampling and laboratory analysis;
2. Data generated and used for design, construction, and operation of engineered remediation/treatment systems;
3. Data acquired from sources outside ADEQ submitted for ADEQ regulatory purposes;
4. Data generated for use in supporting permitting decisions;

5. Data generated in demonstrating compliance with Program requirements.

Activities that fall under any of these categories must be implemented in accordance with the QA requirements of EPA Order CIO 2105.0. Health and Safety monitoring data are specifically not included and are not subject to the requirements herein.

Whenever these activities are performed, either directly by ADEQ or by State contractors under the State's supervision, ADEQ's division QA/QC specialists, with support from the AQPM, have full responsibility for ensuring that all ADEQ QA requirements are met. When such activities are performed using EPA funds through an external funding mechanism such as Inter-Agency Government Agreements, Grants, or Program funds given to the State, the division QA/QC specialists are responsible for ensuring that the State complies with all relevant EPA QA requirements.

Since ADEQ employs a primarily decentralized approach to quality management, each ADEQ Division is responsible for determining the specific environmental Programs and activities to which the ADEQ Quality Management System will apply. The following list includes representative environmental Programs, grants, and activities within each Division which are covered by the ADEQ QMP.

AIR QUALITY DIVISION:
Air Quality Assessment Section
- Data Management & Quality Assurance Unit
- Monitoring Unit
- Evaluation and Special Projects Unit

Planning Section
- Planning Unit
- Emission Inventory Unit

Permits Section
- New Source Review Unit

Compliance Section
- Inspections & Field Services Unit
- Technical Services Unit

Vehicle Emissions Section
- Operations Unit
- Inspections and Compliance Unit

WASTE PROGRAMS DIVISION:
Remedial Projects Section
- Voluntary Remediation and Federal Projects Unit
- Remedial Projects Unit
- SRO Superfund Team

Permits Section
- Sustainable Programs Unit
- Permits and Plan Review Unit

Inspections & Compliance Section

LUST Enforcement
Inspection & Compliance Unit
Corrective Action Section
State Lead Unit
Site Investigation and Remediation Unit
Underground Storage Tank (UST) and Division Support Section
Coordination Unit
Information Management Unit
Rules Unit

WATER QUALITY DIVISION:
Emergency Response Unit
Admin Services Team
Compliance Section
Inspections and Compliance Unit
Enforcement Unit
SRO Compliance Programs
Drinking Water Section
Monitoring & Protection Unit
Programs Unit
Surface Water Section
Watershed Protection Unit
Monitoring Unit & Assessment Unit
Stormwater & General Permits Unit
Permits Section
AZDES Individual Permits Unit
APP Unit

1.2.2. DATA GENERATED BY FIELD SAMPLING AND LABORATORY ANALYSIS

Some examples of activities covered under the ADEQ QMP are the generation of environmental data, including field work, where chemical, physical, or biological samples are collected for analysis; the collection of in situ measurements; field work for site characterization and remediation; and compliance inspections.

Environmental samples for chemical, physical, or biological analyses are commonly collected by, or for, ADEQ and analyzed to accomplish the following goals:

- Confirmation of the presence or absence of pollutants or contaminants;
- Determination of contaminant concentration levels of various sample fractions;
- Determination of the sources of contamination;
- Delineation of horizontal and vertical distribution;
- Evaluation of the rate and direction of transport;
- Determination of the eventual fate of identified pollutants;
- Determination of the effectiveness of treatment;
- Establishment of time trends, to monitor changes and evaluate progress;
- Evaluate compliance with environmental statutes, rules, and permit requirements;
- Analyses of geotechnical parameters.

The above sampling activities may be conducted for site characterization, for ongoing monitoring Programs, or during remediation and removal activities. Any data collected for the State may also be potentially used as an input for risk screening and/or assessment calculations incorporating exposure to humans, wildlife, and the environment.

Where appropriate, data collection activities conducted for ADEQ must be adequately addressed in a QAPjP, which should include project specifics for sampling procedures and the analytical process; this portion is commonly called a Sampling and Analysis Plan (SAP). The corresponding QAPrP will specify when these activities are necessary.

Activities covered under this category include collecting media samples in the field, observing and recording field observations, performing analyses in the field and in field (mobile) laboratories, and analyzing samples in fixed laboratory settings. Examples of media include solid or liquid waste, fluid discharges or emissions, groundwater, surface water, soil, sediment, air, and biota. Measurements include physical measurements and observations made in the field such as flow rates, water levels, particle sizes, geological matrices, etc. Biological monitoring and sampling activities such as habitat evaluation, species identification, and diversity assessments are also covered under this category. Portable equipment can be used to make field chemical determinations of such parameters as pH, temperature, and specific conductance. QAPjPs shall describe methods of collection, methods of analyses, methods of transportation, and methods of documentation for each of these activities.

1.2.3. TECHNICAL ACTIVITIES NOT COVERED BY THE ADEQ QMP

Two types of data collection activities that are generally not covered by the QMP are indicated and clarified below:

1. Data collected only for safety or workplace regulations is not covered in the QMP. However, if the same data is used to identify hot spots for subsequent investigation the collection is covered by the QMP.

2. Collection of employee medical monitoring data is generally not covered under the QMP. However, if the data is used to determine risk factors related to work exposure they would generally be covered.

1.3. ADEQ ORGANIZATIONAL STRUCTURE

ADEQ employs a decentralized approach to QA management, whereby each Division is responsible for deciding how it will specifically implement the general policies and procedures of this QMP. The ADEQ Director has delegated day-to-day responsibility for overseeing the QMP to the AQPM which consists of either an agency-wide QA/QC manager, or designated QA/QC representatives from each division.

The Leadership Team is the group of ADEQ Management assembled and under the direction of ADEQ's Director, who are charged with the policy making and operational strategies of the Agency. The Leadership Team consists of the following members: ADEQ Director and Deputy Director; Waste, Water, Air Division Directors, Budget, IT, Personnel and Communications Chief Officers, and the Administrative Counsel.

The AQPM oversees the Quality Assurance Program and has direct access and reporting authority to the ADEQ Administrative Counsel. For matters concerning QA/QC, the AQPM also has direct access and reporting authority to the ADEQ Administrative Counsel. The AQPM maintains independence in both location and function from any offices or Programs which generate environmental data or are involved in environmental data collection.

ADEQ is composed of three Divisions (Air, Waste, and Water) that generate environmental data, as well as an Administrative Services Division. The AQPM provides support to each of the three ADEQ Divisions that generate environmental data, functions as the Agency technical QA expert, and assists with a variety of QA functions.

1.4. ROLES AND RESPONSIBILITIES

Anyone in ADEQ who is either directly or indirectly involved with environmental data collection or laboratory analyses has some responsibility for ensuring data quality. This may include staff level personnel, Program supervisors, unit managers, section managers, Deputy Division Directors, Division Directors, the ADEQ Deputy Director and the ADEQ Director. The following is an overview of the QA responsibilities of some of ADEQ's Agency personnel:

1.4.1. AGENCY-WIDE QA/QC PROGRAM MANAGEMENT AUTHORITY

ADEQ's agency-wide QA/QC program management (AQPM) has the authority and responsibility for managing QA activities within ADEQ's Quality Management System. The AQPM may recommend suspension of environmental data collection projects, and request corrective action, in the event that data quality/environmental technology QA activities do not meet the Agency's QA policy or requirements. If the AQPM and division QA/QC specialists are unable to resolve QA issues at the staff level, those concerns shall be elevated to the appropriate ADEQ Section Manager or Director.
The AQPM has responsibility for oversight of ADEQ's quality systems and the general direction of the QA/QC Program. Other functions of the AQPM are examining and auditing environmental data collection procedures.

The AQPM is specifically responsible for ensuring that:

- All internal and external projects involving the generation of environmental data are performed in accordance with the ADEQ QMP and an approved QAPjP, or other suitable project guidance;
- There is a review of agency quality documents, such as QA standard processes documentation and QAPrPs, to confirm they are prepared in accordance with ADEQ's QMP;
- Industry standard procedures required to implement QA management requirements are identified and provided;
- Laboratory and field audits are performed, and analytical data are validated, as necessary;
- Formal reviews and assessments of QA and QC activities are coordinated and the report of findings is prepared and forwarded to Section Managers. The AQPM will make recommendations for appropriate corrective action as indicated by audit findings;
- Technical assistance to ADEQ Programs and contractors is provided and EPA guidance documents, policies, and procedures are distributed as appropriate;
- ADEQ training needs are assessed; and arranging for, developing, and/or presenting training courses on QA topics;
- An adequate degree of auditing by the AQPM [i.e., management system reviews (MSR) and technical system audits (TSAs)] is performed to assess compliance with ADEQ QA requirements for monitoring and evaluating overall project implementation;
- The QAPjPs specifically address the technical adequacy of DQOs, when such documentation is required;
- There is an annual review of the QMP.

1.4.2. LINE MANAGEMENT AND STAFF AUTHORITY

1.4.2.1. ADEQ DIRECTOR

The ADEQ Director has overall responsibility for ADEQ's QA Program as outlined in EPA Order CIO 2105.0. More specifically, the ADEQ Director is responsible for ensuring that QA is an identifiable activity having adequate resources allocated for the accomplishment of the mission's goals for ADEQ's centralized Programs. These goals include providing the resources for the collection of the right type, quantity, and quality of data for all in-house and external projects.

1.4.2.2. DIVISION QA/QC SPECIALISTS

All Program Divisions: Air, Water, and Waste, shall assign QA/QC specialists that assist with the QA efforts within each Division and have responsibility for specific projects supported through contracts, grants, or interagency service agreements (ISAs). Programs retain the discretion to determine if a single QA/QC specialist or a team of individuals is the best course of action for each program. QA specialists work with the AQPM in writing and implementing QAPrPs within their prospective Divisions. Other duties include identifying projects that require development of QAPjPs, standard processes documentation, and/or audits, and coordinating with Unit and Section Managers in designating personnel for reviewing QA documents and scheduling audits. Responsibility lies with the Division QA/QC specialists to coordinate third party autonomous review and approval of QA documents by the AQPM, qualified appropriate personnel within their Division but removed from the project, or themselves. This review process should not be conducted by Unit Managers for their own projects. With concurrence from the AQPM, Division QA/QC specialists have the ability to halt projects in the event of significant QA deviations. Division QA/QC specialists perform the duties necessary for QA oversight of their divisions and projects, and are trained to approve QA documents in accordance with AQPM guidelines.

ADEQ's QA requirements shall be followed for those internal activities, and external oversight projects, which generate environmental related data. In addition to ADEQ's QMP, the relevant QA requirements for external projects are specified in 40 CFR 30 and 31, and 40 CFR 15. The division QA/QC specialist has the principal responsibility for ensuring that project data quality objectives are met. Paramount among those requirements is that, when indicated, an approved QAPjP is established prior to initiating any data collection efforts.

Division QA/QC specialists have the responsibility of communicating QA/QC activities to their Division Director, as well as staying apprised of QA activities within their Division. These duties are driven by the common goal of continual improvement of the Quality Management System.

Division QA/QC specialists must ensure that:

- All projects needing a QAPjP are identified, and that the QAPjPs are written, and approved, prior to commencing environmental data collection activities as specified in section 2.2;

- DQOs, specifications, and acceptance criteria for the projects have been prepared by the Program, and approved by an appropriate person, prior to commencing data collection activities as specified in section 2.2;

- They are available to participate in conducting QA system/performance audits of projects, as necessary, with the AQPM;

- Appropriate corrective action is taken if indicated in the audit findings;

- Unresolved data quality problems are reported to the AQPM and designated Program staff.

1.4.2.3. ADEQ DIVISION DIRECTORS:

The Division Directors have the overall responsibility for managing the QA Program within their organization in accordance with the ADEQ QMP. The Directors are specifically responsible for ensuring that adequate resources are provided to support ADEQ QA/QC Program responsibilities.

1.4.2.4. ADEQ UNIT AND SECTION MANAGERS:

Unit and Section Managers must ensure that:

- Whenever environmental measurements are to occur, a QA/QC specialist is designated to coordinate and assist the AQPM with the implementation of the ADEQ Quality Management System;
- All ADEQ environmental data collection activities include appropriate planning and documentation regarding DQOs, QAPrPs, and QA standard processes;
- ADEQ site-specific QAPjPs are written by Program personnel, contractors, or other responsible parties, and approved by appropriate Division personnel and by the AQPM , to ensure effective implementation for projects that generate environmental data;
- Deficiencies identified in audits are corrected expeditiously;

- Program-specific QA-related training needs are identified.

- Section Managers may delegate tasks of ensuring appropriate QA/QC procedures to Unit Managers, but review of QA documents shall be completed by an autonomous third party.

1.5. COMMUNICATIONS

To be effectively implemented, the QMP must not only be approved, circulated, and regularly updated, but it must also be understood by those responsible for its implementation. Two strategies will be used to ensure that this occurs. The AQPM will keep Division and Agency

Management apprised of QA issues as new information, policies, or other QA procedures develop. The AQPM will also arrange for training on an ongoing basis in order to ensure that personnel responsible for QA functions and QA plan preparation understand QA requirements and practices related to their responsibilities.

Having an accurate and up-to-date QMP is essential for implementing an effective Quality System. Minor changes to the QMP will be implemented on a yearly basis through an annual internal review process, as detailed in Section 9.1, which in turn will be submitted to EPA Region 9 for record keeping. The life-span of any QMP is five years; therefore at that time a comprehensive review will be conducted, and a revised QMP will be submitted to EPA Region 9 for approval. It is the intent of ADEQ's Quality System to continually document changes in the QMP so when a comprehensive review is required, revision and concurrence should involve minimal effort.

CHAPTER 2 QUALITY MANAGEMENT SYSTEM

2.1. PRINCIPAL COMPONENTS OF THE QUALTY MANAGEMENT SYSTEM

The Quality Management System consists of staff, defined functions, tools, and quality assurance (QA) procedures. These components are used to ensure that environmental data generated by ADEQ, or by contractors/consultants, is of appropriate quality for its intended purpose. The agency-wide QA/QC program management (AQPM) has determined that the following twelve essential elements comprise an effective QA System:

- A statement of the Arizona Department of Environmental Quality (ADEQ) QA Goals and Policy (identified in ADEQ's QMP);
- Adhering to applicable ADEQ QA requirements and criteria (EPA Orders, regulations, and guidelines);
- Defining ADEQ's QA organizational structure;
- Describing ADEQ Programs and activities covered by the QA requirements;
- Outlining the roles and responsibilities of those involved with ADEQ QA functions;
- Utilizing QA tools and procedures;
- Identifying resource allocations;
- Establishing a communications process (internal and external);
- Affording QA training opportunities;
- Dictating documentation and record keeping requirements;
- Implementing review and evaluation procedures to ensure continuous improvement;
- Defining of key QA terminology.

2.2. PRINCIPAL TOOLS OF THE QUALITY MANAGEMENT SYSTEM

ADEQ uses a graded approach to the Quality Management Plan (QMP). The graded approach recognizes that different projects, depending on size or complexity, may require a greater or lesser degree of formal planning. The successful implementation of ADEQ's Quality Management System requires a consistent and graded approach for QA practices to commensurate with the intended uses of the data. ADEQ's QMP requires that a variety of tools and procedures be utilized for planning, implementing, and evaluating the Quality Management System. ADEQ Managers and staff members will be informed of the availability and use of these tools through ADEQ-sponsored training.

This AQPM performs no environmental data collection activities and thereby preserves autonomy and independence. The AQPM is responsible for establishing, implementing, and evaluating the details of the QMP.

The QA planning and implementation tools include a QMP, establishment of Data Quality Objectives (DQOs), Quality Assurance Program Plans (QAPrPs), Quality Assurance Project Plans (QAPjPs), standard processes documentation, and Sampling and Analysis Plans (SAPs) or Field Sampling Plans (FSPs). ADEQ's Program staff, or their contractors, create the previously stated plans with technical assistance, as necessary, from the AQPM.

The QA evaluation and assessment tools comprising ADEQ's Quality Management System include Management System Reviews (MSRs), Technical System Audits (TSAs), Performance Evaluation (PE) Studies, and Data Quality Assessments (DQAs). These are either arranged for, or performed by the AQPM.

All environmental data collection activities conducted by, or on behalf of, EPA Region 9 must be addressed in a QAPjP. These details are discussed in Section 2.2.4. These elements explicitly require clear Data Quality Objectives (DQOs) for each planned data collection activity, and also require that data assessments be conducted to evaluate the validity of the results. Every field investigation should be constructed in accordance with an approved ADEQ QAPjP, or other planning document, suitable for the task. The planning document shall ensure that DQOs will be met. Arizona statute requires that the Arizona Department of Health Services (ADHS) Office of Laboratory Licensure be responsible for licensing all labs generating data for regulatory use by ADEQ. As testing requirements evolve with the introduction of new contaminants of concern, there may be unique cases when an ADHS certified laboratory is not available for the methods required or capable of achieving the required limits. An exception can be made for instances when a method is not certified by ADHS, or no ADHS laboratories are available. All other resources should be exhausted before this option is utilized. These instances should be communicated to the AQPM to track overall regulatory issues and develop solutions in coordination with ADHS.

2.2.1. QUALITY MANAGEMENT PLAN (QMP)

ADEQ's QMP describes the policies, procedures, and systems governing Agency data collection activities. It serves as the umbrella document for all QA/QC operations. Future revisions and updates to this QMP will be reviewed annually, and at any other time that significant changes occur within ADEQ's operational structure. The AQPM will lead this process to gain concurrence from all ADEQ Leadership as well as EPA Region 9 QA/QC representatives. Revisions and/or updates will be completed and prepared for submission to EPA in as expeditious a manner as possible.

2.2.2. QUALITY ASSURANCE PROGRAM PLANS (QAPrP)

A QAPrP is a planning document instituted at the level between the QMP and a QAPjP. This document is used to describe details that are specific to a Program, or Division, when the QMP is too general to encompass the unique circumstances of a Program. It is appropriate to reference Program specific regulations and guidance documents in a QAPrP that are utilized for defining DQOs such as Soil Remediation Levels (SRLs) and Water Quality Standards (WQSs). A QAPrP can encompass an entire Division, or it can be specific for individual sections or Programs. The appropriate level of planning will be determined within the Divisions. For some Programs, a QAPrP may be sufficient to be utilized in lieu of a QAPjP. The Programs will provide a copy of

their QAPrPs to the AQPM for approval, general oversight, and management of the Agency Quality Program. The AQPM will submit all QAPrPs to EPA Region 9 for approval.

2.2.3. DATA QUALITY OBJECTIVES (DQO)

ADEQ is committed to sound science during the generation of environmental data that are technically appropriate for their intended use. Environmental data collected should be of adequate quality and quantity to support intended regulatory decisions, and when necessary be legally defensible. DQOs are used in the planning phase of all Agency data collection activities in the capacity that defined objectives shall be identified before sampling goes forward. *The Guidance for the Data Quality Objectives Process, EPA* QA/G-4 is used, as appropriate, for the development of DQOs by the Agency. In many situations regulatory criteria and action limits are the basis for environmental decisions. In these situations it should be described in the appropriate planning document, (i.e. QAPrP, QAPjP, FSP, or SAP) that regulatory limits are the driving force for DQOs and the formal EPA DQO process is not extensively utilized. Although DQOs are a required element of any QAPjP, these data objectives can be identified with regulatory limits and/or action limits that are already in existence and do not necessarily need to be derived. ADEQ Programs should discuss within their QAPrP circumstances and situations for projects when the DQO process would be utilized.

Each Program within ADEQ is responsible for establishing DQOs for projects where ADEQ takes the lead role in gathering environmental data or for those projects where ADEQ provides oversight. The AQPM will provide technical assistance, if needed, to determine the appropriateness of the DQO process given the intended use of the data.

The development of DQOs is outlined in *EPA's Requirements for Quality Assurance Project Plans* (QA/R-5). For many projects, DQOs may be a simple statement of why data are being collected and what data outputs will be considered significant. For other projects, the complete statistical hypothesis testing approach as described in the EPA's *Guidance for the Data Quality Objectives Process* (QA/G-4) may be appropriate. The AQPM will assist Program staff, as needed, to ensure that each QAPjP specifically addresses the technical adequacy of DQOs for that project. Because systematic planning is not necessary for establishing DQOs for all projects, compliance with QA/G-4 is recommended where appropriate.

Data Quality Objectives are intended to accomplish the following:

- Clarify project objectives;
- Define the most appropriate types of data to collect;
- Determine the most appropriate conditions under which to collect the data;
- Specify the level of uncertainty that is acceptable as the basis for establishing the quantity and quality of data needed.

2.2.4. QUALITY ASSURANCE PROJECT PLANS (QAPjP)

All QAPjP's should be developed as specified in EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*. ADEQ directs that all twenty-four

elements be addressed before programs may submit a QAPjP on ADEQ's behalf. These elements consist of the following:

Group A	Project Management
A1	Title and Approval Sheet
A2	Table of Contents
A3	Distribution List
A4	Project/Task Organization
A5	Problem Definition/Background
A6	Project/Task Description
A7	Quality Objectives and Criteria for Measurement Data
A8	Special Training Requirements/Certification
A9	Documentation and Records
Group B	Measurement/Data Acquisition
B1	Sampling Process Design
B2	Sampling Methods Requirements
B3	Sample Handling and Custody Requirements
B4	Analytical Methods Requirements
B5	Quality Control Requirements
B6	Instrument/Equipment Testing, Inspection, and Maintenance Requirements
B7	Instrument Calibration and Frequency
B8	Inspection/Acceptance Requirements for Supplies and Consumables
B9	Data Acquisition Requirements
B10	Data Management
Group C	Assessment/Oversight
C1	Assessments and Response Actions
C2	Reports to Management
Group D	Data Validation and Usability
D1	Data Review, Validation and Verification Requirements
D2	Validation and Verification Requirements
D3	Reconciliation with User Requirements

The QAPjP dictates the policies and procedures, project organization and objectives, QA requirements, and QC activities designed to achieve the desired type and quality of environmental data necessary to support project objectives. In ADEQ a QAPjP is utilized for collection and analyses of long term and large scale projects.

For those activities funded by EPA, there are additional influences from the federal level on QAPjP preparation. ADEQ Program Plans identify projects requiring QAPjPs and the detail required within that planning document. Some Programs utilize abbreviated QAPjPs in the form of "fill in the blank" documents, although these shortened documents still need to be completed prior to sampling activities. Other Programs within ADEQ, such as Tank Programs, rely heavily

on Guidance Documents for the planning process and do not require formal QAPjPs as such. Short-term projects and one-time events (e.g. emergency response) do not require QAPjPs as long as the sampling protocols and objectives are addressed in the Program QAPrP. Whether or not a project is funded by EPA, planning documents suitable for the task are required. These planning documents, in the form of a QAPjP or an alternative document, are an expected part of the Quality System. The detail within the documents, and the circumstances under which each form is appropriate, will be described in the Program specific documents. A QAPjP, or the equivalent planning document, must be approved by appropriate delegated autonomous Division personnel or by the AQPM. Additionally, all contractors for ADEQ must meet the quality assurance and Program requirements established by the ADEQ QMP.

2.2.5. QUALITY ASSURANCE (QA) STATUS REPORTS

When required by the QAPrP or QAPjP, each plan for environmental data collection should include a section discussing the frequency, content, and format of the required QA status report(s). These factors will be determined by the relevant division QA/QC specialist. Status reports will be placed in the project file by the division QA/QC specialist and will be used to help track project progress. Each status report should address, at a minimum, the following elements:

- Status of the project;
- Changes that occurred in project activities (sampling, QC control measures, analytical methods);
- Results of performance and system audits as they apply;
- Any corrective actions taken;
- Any project organizational changes;
- Results of the assessment of data quality indicators (precision, accuracy, completeness, and comparability), representativeness, and validity.

For some Programs, rules or policies supersede these status reports. The policies or rules establish requirements similar to status reports, and can function as an alternative. The alternative should be referenced in the plan, and may if necessary, discuss elements in addition to those listed above.

2.2.6. STANDARDIZED PROCESSES

The use of standard operating procedures (SOPs) and standard work (SW), collectively called standard processes, serve as mechanisms to ensure comparability across Programs and individual environmental data collection projects. Standard processes documents (SPDs) must be incorporated, either in full or by reference, in the QAPrPs and QAPjPs. SOPs developed by ADEQ must be peer reviewed and the AQPM is available for assistance as appropriate.

2.2.7. TECHNICAL SYSTEMS AUDIT (TSA)

All ADEQ Programs that employ environmental sample collection and analyses are subject to a TSA. TSAs are a principal tool of ADEQ's quality system and are defined more thoroughly in Section 9.2.2.

2.2.8. MANAGEMENT SYSTEM REVIEWS (MSR)

Management System Reviews (MSRs) will be performed periodically within ADEQ for all Programs. Further details on MSRs are provided in Section 9.2.1.

2.2.9. CORRECTIVE ACTIONS

In the normal case, deficiencies are identified, and corrective actions are initiated, as a result of a review or audit. However, there are cases when deficiencies are identified during normal work routines, outside a review or audit. In these cases a corrective action memo is generated to document and communicate the deficiency. The memo, at a minimum, explains the problem and documents procedural changes and actions that will correct the problem and minimize the chance for repeat problems and deficiencies. In some situations, no corrective action is required; however, it is necessary to document the occurrence. For these situations, the corrective actions can be referred to as non-conformances.

2.3. OPTIONAL PRACTICES FOR THE CONTROL OF DATA COLLECTION

2.3.1. FIELD AUDITS

These are "real-time" observations, reviews, and critical appraisals of field sampling activities. Field audits consist of an on-site visit to the sampling location; observation of sampling practices; review of project records and sampling standard processes; and, documentation of findings. The primary intention of such audits is to ascertain whether the QAPjP or QAPrP specified practices are being followed.

When sampling is being performed by ADEQ personnel, or ADEQ contractors, the lead auditor must be an ADEQ employee. In these circumstances, audits may be requested through the AQPM, and are performed by non-project personnel to avoid the appearance of bias.

All field auditing activities will result in the production of a written report. Usually, the draft findings report should be prepared by the lead auditor as soon as reasonably practical after the observation phase of the audit. Whether internal or external, the auditor should send the report to the Division QA/QC Specialist for review. For external audits, the audit report will be passed on to the auditee for comments. Final reports generated by the Audit Team are to be completed within a reasonable and appropriate time. Copies of the Final Report will be stored in the Project file and with the auditor. Additional copies will be distributed as appropriate.

2.3.2. LABORATORY AUDITS

These are audits of laboratory operations. Such audits may be "real-time" (i.e., performed while project samples are under analysis) or performed after analysis is completed. Laboratory audits will consist of an on-site visit to the laboratory, observation of analytical practices when possible, review of project records and laboratory SOPs, and documentation of findings. A

laboratory audit is conducted to determine and document whether laboratory practices and analytical procedures used are consistent with QAPrP and / or QAPjP requirements and laboratory tasking instructions.

When analyses are being performed by ADEQ contractors, the lead auditor must be an ADEQ employee. In these circumstances, audits may be requested through the AQPM, and are performed by non-project personnel to avoid the appearance of bias.

All laboratory auditing activities will result in the production of a written report. A draft of this report is due to the Division QA/QC Specialist as soon as reasonably practical from the completion of the observation phase of the audit, or a mutually agreed upon alternative. The draft will be sent for comments to the Division QA/QC Specialist responsible for the activity observed prior to completion of the report. Written comments must be supplied to the AQPM as soon as reasonably practical from the receipt of the draft, or a mutually agreed upon alternative. Final reports generated by the AQPM are to be completed as soon as reasonably practical from the receipt of comments by the Division QA/QC Specialist. Copies of the Final Report will be stored in the Project's file and also with the AQPM. Additional copies will be distributed as appropriate.

CHAPTER 3 PERSONNEL QUALIFICATIONS AND TRAINING

3.1. POLICY FOR QUALITY ASSURANCE (QA) RELATED TRAINING

The purpose of this Chapter is to explain the processes used by Arizona Department of Environmental Quality (ADEQ) to ensure that staff and managers working in environmental Programs are trained and qualified to perform their required Quality Assurance (QA) responsibilities. This includes Division QA/QC Specialists, field personnel, ADEQ QA/QC staff, data processors, and the individuals who supervise these personnel.

3.1.1. RESPONSIBILITIES

ADEQ's Unit and Section Managers are responsible for ensuring that each staff member involved with collecting or analyzing environmental data has the necessary technical, quality assurance, and project management training required for their assigned tasks and functions. Unit and Section Managers are also responsible for ensuring that technical staff maintains the necessary level of proficiency to effectively meet ADEQ's QA/QC responsibilities. ADEQ's agency-wide QA/QC program management (AQPM) will serve as the Agency resource for arranging for, and assisting in, defining QA/QC training needs on a regular basis to update Program staff with developing QA/QC issues.

Maintaining staff proficiency in critical technical disciplines (e.g., environmental engineers, geologists, hydrologists, hydrogeologists, chemists, biologists, and microbiologists) is assumed to be determined within the hiring process.

3.1.2. IDENTIFICATION OF TRAINING NEEDS

Core training will be coordinated through the AQPM in conjunction with various Division supervisory personnel. Intermediate and advanced skill training will be arranged when the appropriate Agency staff identify the need. The AQPM will identify continuing professional training requirements and address those requirements utilizing external resources for the latest technological advances and evolution in industry standards.

3.1.3. IMPLEMENTATION OF TRAINING REQUIREMENTS

ADEQ staff are encouraged by supervisors to draw upon their educational background, experience, technical training, and on-the-job training to enhance their understanding and performance of QA-related procedures.

ADEQ's AQPM is responsible for developing a training program that will offer, or arrange for through a third-party vendor, the following courses on a schedule and frequency suited to meet the needs of ADEQ's staff with QA responsibilities:

- An Orientation to Quality Assurance Management
- Establishing Data Quality Objectives

- Preparing Quality Assurance Project Plans
- How to Perform a Preliminary Data Review

The goal is to offer no less than three of the four courses during the year. The classes will be open to anyone responsible for QA functions. ADEQ's AQPM will also schedule impromptu QA training designed to address specific QA needs of Program staff.

ADEQ Program staff responsible for QA functions (as identified by Program Management) should strive to complete the above courses within two years from their employment date. In addition, they will be encouraged to attend meetings and seminars, and to take formal training, in accordance with ADEQ's training policy, to enhance their understanding of Program specific QA requirements within the Programs they work.

3.1.4. DOCUMENTATION OF TRAINING

ADEQ's Human Potential Office will aid in maintaining a record of all QA training taken by staff and managers responsible for environmental data generation, through the use of Arizona Department of Administration's training portal, as needed. ADEQ's Leadership Team will provide resources for QA training for ADEQ Program staff as needed. This training will be provided, through internal training and/or external sources, to staff at all levels to ensure that QA requirements and responsibilities are understood and implemented at all stages of projects. Some of the training required to support ADEQ's Quality Management System will come from EPA.

CHAPTER 4 PROCUREMENT OF ITEMS AND SERVICES

Arizona Department of Environmental Quality (ADEQ) procures items such as sampling equipment, instrumentation, field equipment, laboratory services, and consulting services. All items and services relating to environmental data collection and generation are obtained through the procurement process. The ADEQ public procurement process is guided by the Arizona Procurement Code (Arizona Revised Statutes 41-2501 et seq., and administrative rules and regulations A.A.C. R2-7-101 et seq.). This procurement code has modeled itself on the Model Procurement Code as provided by the American Bar Association. The procurement process is also governed by State statutes and rules, and depending on the circumstances of the procurement, may involve the approval of other agencies within the State. Whenever appropriate, requirements for equipment and services specific to individual Programs should be detailed in the Quality Assurance Program Plan (QAPrP) or Quality Assurance Project Plan (QAPjP). Procurement activities may range from general and scientific supplies to highly sophisticated scientific instrumentation and services which directly affect the quality of environmental measurements.

4.1. ITEMS

Within ADEQ, identified equipment needs are submitted to management who prioritize, rank, and approve items for proposed procurement. This process allows ADEQ to identify particular equipment needs, relative to other needs, in order to facilitate quality in measurement processes. Specific monitoring, sampling, and analytical equipment are procured only after quality requirements have been discussed between procurement officials, Program personnel, and when appropriate, agency-wide QA/QC program management (AQPM). The Contracts and Procurement Section requires that items meet the approved specifications. The criteria for selection of the specific items are outlined prior to approval of the equipment.

4.1.1. EQUIPMENT MAINTENANCE

ADEQ field personnel are responsible for maintenance of their own field equipment and instrumentation. ADEQ has either service contracts or in-house capabilities for the repair and maintenance of field equipment and instrumentation. Schedules for preventive and/or corrective maintenance are determined and carried out through service contracts or in-house capabilities.

4.2. SERVICES

Project managers work with the ADEQ Contracts and Procurement Section to incorporate quality control within the specific scope of work for each task assignment. Quality assurance for service contracts is based on contractor performance measures which include but are not limited to: the ability of the contractor to adhere to the contract terms and conditions, and the ability of the contractor to complete the work in accordance with the ADEQ approved QAPjP, Sampling and Analysis Plan (SAP), and/or other work plan. Services (laboratory, consulting, drilling, etc.) that are procured through ADEQ's procurement process are contracted in accordance with the standard terms and conditions of the Uniform Commercial Code as adopted by the State of Arizona. The standard terms and conditions, at a minimum, include the following:

- Contract interpretation;
- Contract administration and operation;
- Costs and payments;
- Contract changes;
- Risk and liability;
- Warranties;
- State's contractual remedies;
- Contract termination.

The division QA/QC specialist from the applicable ADEQ Program can utilize the AQPM in finding services appropriate for their needs. Prior to procurement of services it is important that the data quality objectives (DQOs) of the specific project, as they relate to analytical requirements, can be achieved by the laboratory. The laboratory needs to submit a current Quality Assurance Manual (or similar documentation) for review before the contract is awarded**.**

4.2.1. CONTRACTS WITH EXTERNAL PARTIES

For services procured outside of the general laboratory services contract, and the Monitoring Assistance Program (MAP) contract, the Programs are responsible for ensuring that the contractors meet the quality assurance requirements as outlined in their Program specific Quality Assurance Program Plans (QAPrPs). It is necessary, at a minimum, to obtain a Quality Assurance Manual from the contracting laboratory prior to commencement of work. Other areas where contractors and subcontractors are utilized include: ambient surface water analyses for chemical and microbiological indices, air quality analyses, etc. In addition, ADEQ conducts and oversees assessment (site characterization), remediation, and removal activities at solid and hazardous waste sites in Arizona. For some of these activities, ADEQ may contract directly for environmentally related measurements or data generation.

ADEQ's General Laboratory Services Contract goes out to bid every three to five years. This contract is for General Laboratory Services for a variety of analyses and methodologies and can be awarded to one or more laboratories. This process is a collaboration of ADEQ's Procurement Section and/or the AQPM. All Divisions can utilize this contract for analyses within their Divisions.

The MAP is a Program mandated by Arizona Revised Statutes 49-360, for which ADEQ contracts with vendors to take samples and perform necessary analyses for approximately 900 small drinking water systems within the State of Arizona. This contract goes out to bid through the Drinking Water Section and is awarded on an annual basis.

4.2.2. LABORATORY LICENSURE REQUIREMENTS

In addition to the requirements of the Arizona Procurement Code (A.R.S. 41-2501 et. seq.) and the Arizona Administrative Code (A.A.C. R2-7-101 et. seq.), Arizona Revised Statutes require

that the Arizona Department of Health Services (ADHS) Office of Laboratory Licensure license environmental laboratories engaged in compliance testing.

Compliance testing has been defined by Arizona State Law pursuant to A.R.S. 36-495(1) as any:

> **"Laboratory analysis of any matter, pollutant, contaminant, hazardous substance or other substance subject to regulation pursuant to:**
> **(a) Title 49 or rules adopted or enforced by the department of environmental quality for the purpose of determining compliance with title 49.**
> **(b) Federal environmental statutes or regulations administered or enforced by the United States environmental protection agency relating to the safe drinking water act (42 United States Code sections 300f through 300j), the clean air act (42 United States Code sections 7401 through 7642), the clean water act (33 United States Code sections 1251 through 1376), the resource conservation and recovery act (42 United States Code sections 6921 through 6939B), the comprehensive environmental response, compensation, and liability act (42 United States Code sections 9601 through 9657) and the toxic substance control act (42 United States Code sections 2601 through 2654) as they relate only to the regulation of polychlorinated biphenyls and asbestos."**

Samples analyzed for regulatory or enforcement decisions by non-ADHS licensed laboratories are considered unacceptable for compliance purposes, as statutorily mandated, and should be rejected unless no other options are available. In unique cases, an ADHS certified laboratory might not be available for the methods required or be able to achieve the required detection limits and an exception can be made. These instances should be communicated to the AQPM to track overall regulatory issues and develop solutions.

Upon application for an environmental laboratory license ADHS shall issue the license if, after investigation, ADHS determines that the application conforms with the standards established by ADHS.

The ADHS Director shall prescribe rules providing for minimum standards of proficiency, methodology, quality assurance, operation, and safety for environmental laboratories and may prescribe standards for personnel education, training, and experience to meet Federal environmental statutes or regulation. The ADHS Director may also allow reciprocity with other states, and prescribe the manner and form in which compliance testing results are reported. The rules shall be developed in cooperation with the Director of the Department of Environmental Quality and shall be consistent with Title 49 (Section 49-101 et seq.) and rules administered or enforced by the Director of the Arizona Department of Environmental Quality.

Unless exempted by A.R.S. 36-495.02, no person may operate or maintain an environmental laboratory without a license issued by the ADHS pursuant to A.R.S. 36-495.03 through 36-495.14.

4.3. THE ROLE OF THE AGENCY-WIDE QA/QA MANAGEMENT IN THE PROCUREMENT PROCESS

The agency-wide QA/QC program management (AQPM) will assist the Procurement Section in the development of the Request for Proposal (RFP), or Invitation for Bid (IFB), for the General Laboratory Services Contract which will occur approximately every three to five years. The AQPM will provide input on minimum Quality Control requirements for Contract Laboratories as well as items to be included in submittal for QA/QC evaluation.

The AQPM will advise the Drinking Water section on minimum QA/QC standards for laboratories contracted for the Monitoring Assistance Program.

When appropriate, the AQPM should review an organization's Quality Assurance Manual, or its equivalent, before the formal execution of any agreement or related action with a consultant or contractor. The contractors and subcontractors must also submit a QAPjP to be reviewed by ADEQ before environmental measurements or data collection activities are performed.

The AQPM will confer with ADHS on the good standing of laboratories that are contracted with, or submitting compliance data to, ADEQ.

4.4. THE ROLE OF DIVISION QA/QC SPECIALISTS IN THE PROCUREMENT PROCESS

ADEQ Program Personnel should define the quality of performance and specifications required of services, instruments, and reagents.

The responsibility for monitoring contract performance within ADEQ's Quality Management System lies with the Programs and ADEQ's Procurement Section. All contracts are managed in accordance with the State procurement code.

4.5. AGREEMENTS WITH GOVERNMENTAL ENTITIES

ADEQ also utilizes governmental agreements with EPA and other Federal, State, and local agencies. A.R.S. 41-2501 exempts governmental agreements from the Arizona Procurement Code. Agreements between ADEQ and other state agencies, or universities, to provide or receive a service are authorized under A.R.S. 35-148. Agreements between ADEQ and another State Agency, political sub-division, or other governments to share joint authority (authority possessed by both parties) are authorized by A.R.S. 11-951 through 11-952.

In the event that a governmental agreement scope of work would include environmentally related measurements or data generation, the AQPM role would be substantially the same as it is for the General Laboratory Services Contract. Procurement's role would include coordination with the

AQPM, the division QA/QC specialist, and the outside political subdivision, and then final negotiation of the governmental agreement.

4.5.1. ADHS AND STATE LABORATORY SERVICES

The ADHS provides support for ADEQ as necessary for laboratory services, method development, risk assessments, development of some regulatory limits, and expert testimony.

CHAPTER 5 DOCUMENTATION AND RECORDS MANAGEMENT

Maintaining important quality assurance (QA) documents and records is a continuous process at Arizona Department of Environmental Quality (ADEQ). This process serves as a vehicle for identifying quality-related documents and records requiring management control. Moreover, this process serves to ensure that QA documents and records are accessible, and protected from damage and deterioration during storage. Finally, ADEQ's Records Management Process ensures compliance with all statutory and contractual requirements for records involving environmental Programs. ADEQ Records Management System also provides adequate preservation of key records necessary to support the mission of ADEQ.

5.1. DEFINITION OF PUBLIC RECORDS

"Records" as defined in ARS § 41-1350, "means all books, papers, maps, photographs or other documentary materials, regardless of physical form or characteristics, including prints or copies of such items produced or reproduced on film or electronic media, made or received by any governmental agency in pursuance of law or in connection with the transaction of public business and preserved or appropriate for preservation by the agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the government, or because of the informational and historical value of data contained therein. Library or museum material made or acquired solely for reference or exhibition purposes, extra copies of documents preserved only for convenience of reference and stocks of publications or documents intended for sale or distribution to interested persons are not included within the definition of records as used in this chapter."

Unless specifically exempted in statute, all QA/QC data and documents are expected to be public records and therefore treated as such. In the rare instance QA/QC data or documents are considered confidential the documents will be listed in a "confidential log" as required by Arizona Public Records Law.

5.2. CONFIDENTIAL DOCUMENTS

Some documents collected, received, or generated may, by nature and content, be documents statutorily designated as "confidential" and require special handling procedures. Documents of this category may be, but are not limited to, enforcement sensitive/enforcement confidential, attorney client, or confidential business information (CBI). Confidential documents are handled in accordance with state law and ADEQ policy. Only ADEQ staff and legal counsel are allowed to see documents classified as confidential. Confidential documents shall be maintained separately from other QA documents and logged. Nothing in the requirements put forward in this Quality Management Plan (QMP) shall be construed to supersede any existing requirements for handling enforcement sensitive or confidential documents.

5.3. ROUTINE QUALITY ASSURANCE AND RECORDS MANAGEMENT

ADEQ Records Management Process addresses the system employed by the Agency for handling documents. This plan outlines the roles and responsibilities for management and staff concerning chain of custody procedures and records management.

ADEQ document control procedures require that documents generated, or obtained, by our Agency personnel be accounted for when a project is completed. ADEQ's Records Management System dictates the procedures for checking-in and checking-out files for ADEQ staff, external clients, and the public.

For reasons of file integrity, the files must be reviewed in the presence of the Custodian of Records or their designee. No file can be certified as an original copy if it is reviewed by anyone without a staff member from the Custodian of Records being present. The chain of custody for all Agency files must be carefully guarded in order to have the greatest degree of integrity regarding Agency files.

ADEQ creates and maintains a unique identification code for each investigation or project. ADEQ Records Center is able to use the identification codes, and their cross referencing capabilities, to identify the contents and location of the investigation/project files. All custody tags, custody records, field notes, or analytical records are labeled with ADEQ generated identification codes. Each file is required to have an identification code, date, initials or signature, and where appropriate the ADEQ Index and PCA to indicate the source of the funding for the project. Data packages generated by laboratories which are requested by division QA/QC specialists are submitted to and maintained by the programs.

The AQPM is responsible for maintaining a directory of QA/QC documents within the Agency, this includes the QMP, Quality Assurance Program Plans (QAPrP) and Quality Assurance Project Plan (QAPjP)s. Division QA/QC specialists are responsible for maintaining/tracking QA/QC documents within the division, this includes Field Sampling Plans (FSP), Sampling and Analysis Plans (SAPs), standard processes documentation, and other related QA/QC documents. Duplicates of many of these documents are stored electronically within the particular program unit applicable to the specific QA/QC documents.

Original QA documents are organized by project or site. These documents, along with other records generated, are stored in the applicable Program offices within ADEQ or in the Central Records Management Office. The records will be centrally managed via the records management system, but physically may reside in the Program files, project file, or in the records review area. Regardless of physical location of a file, records and documents associated with a given project are the responsibility of the Division Program that has primary responsibility for that project. Hard copies of site or project specific information such as sample field sheets, chain of custody records, laboratory notes, and instrument/equipment readings shall be maintained in the official project file. The division QA/QC specialist is responsible for assuring that all field and analytical identification codes referencing the project are maintained in the project file. Correspondence that is material to the project and is generated on the network shall be printed and maintained in the applicable project file.

The ADEQ Director represents the final custodian of that information. Projects involving the generation of environmental data shall include, at a minimum, Quality Assurance Project Plans (QAPjPs) and final laboratory reports. For projects not funded by EPA, some project planning documents other than a QAPjP may be acceptable providing that the objectives are clear and the documentation is likely to produce data of known quality and appropriate for its intended use. QAPjPs submitted to ADEQ are peer reviewed by the respective division QA/QC specialist, and approved by designated Program staff. The approval process will be based upon guidelines set forth by the AQPM. The process for QAPjP review is spelled out in corresponding QA Program Plans. Approved copies, with the approving signatures, are retained by the division QA/QC specialist and the ADEQ AQPM, or their designee. The QAPjP and the final analytical reports will be stored together, thereby allowing a subsequent analyzer or investigator, to understand the full context of the data produced and the conclusions reached.

The AQPM, in conjunction with EPA Region 9 where appropriate, ensures that all QMPs and QAPrP are current. The AQPM will also ensure that any other QAPjPs are current. Should one of these documents become outdated, the AQPM and EPA Region 9, in conjunction with the division QA/QC specialist, shall determine the status of the plan and initiate appropriate action. The Division Program and the AQPM shall be responsible for maintaining copies of ADEQ revised/approved QAPjPs for five years after completion of the project.

ADEQ Office of Administrative Counsel will assure that the objectives of the Records Management Process are achieved. These objectives include the following:

- Prevent the creation of unnecessary records in any media;
- Promote the continuous development of filing systems and structures that allow for the efficient organization, maintenance, and retrieval of records;
- Ensure that records of continuing value are preserved, but that valueless or non-current information is disposed of or transferred to storage in a timely manner in accordance with ADEQ and/or Arizona Department of Health Services (ADHS) records retention requirements;
- Ensure that the acquisition and use of all direct paper to microform systems and equipment, or electronic digital imaging, are technically feasible, cost-effective, and most importantly, satisfy Program needs;
- Preserve and protect information that is vital to the essential functions or mission of the organization. Preserve and protect information that is essential to the legal rights and interests of individual citizens and the government.

5.4. IN-HOUSE QUALITY ASSURANCE GUIDANCE DOCUMENTS

Quality guidance documents developed in-house are peer reviewed by the AQPM and the appropriate Divisional Program. Most of the in-house quality guidance documents are formatted as SOPs covering specific environmental monitoring activities such as field inspection, sample collection/handling, analytical protocols, and data review/validation.

Other in-house quality assurance guidance documents include policies. The AQPM drafts quality assurance and analytical policies to express the Agency's position when interpreting analytical data generated by laboratories using EPA methods which may have multiple procedural interpretations. One such Agency wide policy is ADEQ Policy # 0154.000 "Addressing Spikes and Matrix Effects."

5.4.1. REQUIREMENTS FOR FIELD DOCUMENTATION

Documentation of field activities establishes procedures, identifies written records, enhances and facilitates sample tracking, standardizes data entries, and identifies and establishes authenticity of the sample data collected. Proper documentation helps to ensure that all essential and required information is consistently acquired and preserved. Timely, correct, and complete documentation establishes the chain-of-custody, a requirement for data intended to provide evidence in court proceedings. Exact procedures vary from Program to Program and are detailed within individual Program documents.

Field records shall be generated and stored as specified in project specific QAPrP, QAPjPs, SPDs, or guidance for handling field records.

5.5. MAINTAINING DOCUMENT INTEGRITY

Following all required ADEQ documented policies and actions regarding Records Management, the file clerk, and all other ADEQ staff, with access to potentially sensitive documents and records (i.e., audit reports and performance evaluation reports) will take special care to preserve the integrity of these documents. If sensitive documents are to be used at a work station, due care will be used in order to maintain the integrity of the data.

CHAPTER 6 INFORMATION TECHNOLOGY (IT) AND DATA MANAGEMENT

Data management serves a critical function in both preserving information and making that information available. Data management necessarily encompasses a variety of activities related to planning environmental monitoring, collecting samples from different media, laboratory and in-situ analysis of samples, organizing and storing resulting data, analyzing and interpreting data, disseminating data, and communicating the monitoring results and knowledge gained.

The way we manage data has evolved substantially in the past decade primarily due to Internet availability (e.g., opportunities in electronic government), increased emphasis on enterprise architecture, and the need for better security of environmental data. Also, ADEQ strives to comply with all EPA standards and regulations, as appropriate, pertaining to hardware, software, database system development, and data reporting.

This section summarizes Arizona Department of Environmental Quality's (ADEQ) information management practices and related information technology topics. Additional aspects of project management, such as planning, data gathering, and evaluation by ADEQ Programs, are addressed in Quality Assurance Program Plans (QAPrPs) or other project planning documents as appropriate.

6.1. MANAGEMENT PRACTICES FOR ENVIRONMENTAL DATA

An important Agency goal is to continue to improve the way data are generated, compiled, stored, and disseminated across each of the ADEQ Divisions (Air, Waste, Water, and Director's Office). The manner data is managed is governed by the Agency mission, Program business needs (e.g., permitting, compliance, assessments), and specific data collection project/Program objectives. Additional activities that influence data management approaches include EPA reporting requirements, quality assurance, cost control, and security.

Information management systems are typically evaluated for return on investment, risk management, and total cost of ownership. This has led ADEQ to adopt an Oracle-based enterprise architecture that offers common services and consolidated purchases as a foundation for all our major database applications that include but are not limited to: AZURITE (the Agency's enterprise database application for managing data related to the functions of licensing/permitting, inspections, compliance, and remediation), AirVision Database, Water Quality Database, Safe Drinking Water Information System (SDWIS), Surface Water Quality System, Groundwater Quality System, Drywell System, and Engineering Review System.

6.1.1. DATABASE DEVELOPMENT:

Data models are employed when developing database systems to serve as a bridge between those collecting the data and the information processing systems that support those using the data. Data models are basically conceptual schemas that map data relationships, focusing on those relations that matter most to the business. ADEQ utilizes a standard System Development Lifecycle Methodology for information projects, and a rapid application development method, as

appropriate. Generally, the methods used include an analysis and documentation of user requirements, followed by system design specifications. ADEQ uses the Oracle Designer tool to document requirements and system design. ADEQ coding standards are published and implemented, ensuring consistency and maintainability of source code. A project team approach is utilized, which includes end user involvement throughout the project lifecycle. User documentation, including on-line help, is provided with each database system as resources permit.

6.1.1.1. SYSTEMS DEVELOPMENT PLANNING

The State of Arizona utilizes a standard Information Technology (IT) project planning and justification process. The Arizona Department of Administration – Arizona Strategic Enterprise Technology (ADOA-ASET) reviews and approves Project Investment Justifications (PIJs) for IT projects with a combined developmental and infrastructure cost greater than $25,000. PIJ approval must be received before budget monies can be allocated to an IT project. ADOA-ASET also provides oversight to all Agency IT Projects greater than $25,000.

6.1.2. DATA QUALITY AND DATA INTEGRITY:

Data integrity and data quality are related in the fact that both are needed to ensure that the data are sufficient for their intended use. For the purpose of this document data quality relates to the process used to collect, analyze, verify, and validate environmental results. Data integrity relates to the input, storage, maintenance, and retrieval of those results.

6.1.2.1. DATA QUALITY:

Before any change is made to any of the environmental databases, and released for production, such change shall use a standard Quality Assurance procedure to verify that it meets the requirements of its intended use. QAPrPs will describe the level of QA/QC necessary for their Programs and should include references to how data quality is determined with regards to precision, accuracy, representativeness, comparability, completeness and sensitivity.

Regardless of the data entry method, data entry personnel should verify that the data meet the above criteria prior to input into the database. Questionable data may be entered and maintained in a database if it is appropriately documented, qualified, or flagged.

6.1.2.2. DATA INTEGRITY:

The data integrity process begins once the data are ready for input into the databases. Data integrity addresses the vulnerability of the system to unauthorized access, data manipulation, theft, and environmental damage.

These threats are mitigated by implementing a strong internal database QA/QC process. This includes a security process, further detailed in Section 6.8 that recognizes database users through logons and assigned database roles. The process begins through ADEQ's AZURITE database that maintains ADEQ's centralized core data such as:

- PERSON (Individual users of the database, including tracking information);

- PLACE (The sites and facilities that ADEQ regulates or tracks);
- CUSTOMER (individuals, organizations, and businesses that ADEQ regulates or interacts with);
- LTF (Licensing Time Frames).

Daily verification is performed on PLACE, core data to assure that data entry standards are followed, that location information is provided, and that a duplicate record does not exist before validating a new record as part of ADEQ core data. Any record that is not complete, or does not meet data entry standards, will be returned to the originating Program for correction, and the use of that data will be restricted until corrected.

Presenting data in an understandable and useful format is a key component in ensuring data integrity. Agency projects will be presented in a way that is suitable for the intended audience. The following guidelines are implemented by ADEQ, to the extent applicable, useful, and possible in designing effective approaches to Agency projects:

1. Establish a context for presenting data using one or many of the following techniques: displaying data in a geographic context, combining the new data source with existing collections of monitored data, or aggregating the data collected to demonstrate a trend or ongoing view of the environmental conditions. ADEQ will present the data in ways that make that data relevant and useful;

2. Format data for easy interpretation so data are portrayed with the intended message and not misused. ADEQ will make every effort to ensure that data will always be presented in a format that is easy to understand and not subject to misinterpretation. This includes not separating data from corresponding documentation, qualifiers, or flags that may indicate the usability of the data;

3. Be responsive to the users of the data by staying abreast of changing user needs, Agency IT projects are designed to include ways for users to provide feedback on the projects.

Metadata are additional information related to the primary results that are being presented, commonly known as data about the data. This supporting information can significantly impact the usability of the primary data and should always be considered. Specifically metadata includes positional/location data, field measurements, temperatures, quality control data, data qualifiers, meteorological data, facility information, and site conditions. The storage of metadata is specific to each of the databases maintained at ADEQ. Each database, and the Programs associated with the database, are delineated in relevant Program documents and detailed in the Program's QAPrP. It is important to note that metadata often provide substantial information relating to environmental results and should not be separated from those results if it changes the meaning, or usability, of the data in any way.

Audits and Testing are required for all databases and systems. All IT projects involving development of systems for tracking of environmental data will be thoroughly tested to ensure

that they meet the requirements in the written functional specifications. Independent audits of these systems will be conducted within ISDU. The central IT organization has a test server environment that is in place, and is utilized regularly, to test Agency applications prior to being released into production.

6.1.3. ESTABLISHING BACK UP AND ARCHIVING PROCEDURES*:*

Department Programs will coordinate with the Office of Information and Technology to establish standard procedures for data backup and archiving, system failure, and recovery. Data sets will be archived to provide a historical record of data over the lifetime of the project. Current procedures involve daily full or incremental backups of all critical Agency data that are stored on site at ADEQ. Weekly and monthly back up of all critical data are kept in perpetuity and stored off site at ADEQ's Disaster Recovery location in Tucson. Should a catastrophic event occur that renders our Phoenix computer equipment unusable; ADEQ will be able to operate using the equipment and data located in Tucson.

6.2. INFORMATION MANAGEMENT PLAN

ADEQ is developing an updated information management plan that documents our approach to data collection, storage, retrieval, delivery, and communication. ADEQ also has procedures for data quality control and security, which may be incorporated, as appropriate, into QAPrPs. The information management plan will include the following elements:

- **Data Owners**
- **Description of the Data Flow Process**
- **Data Standards (Content)**
- **Description of Data Collection Methods**;
- **Description of the Data Storage and Retrieval System**
- **Data Retention (Public Records)**.

6.3. ELECTRONIC DATA INTERCHANGE (EDI) AND NODE

ADEQ collects and manages compliance, measurement, and statistical data for a number of environmental Programs within the State of Arizona. The data are managed and reported both internally and externally to other state and federal agencies. Typically, the electronic data interchange (EDI) is performed using rigid data formats that are difficult to maintain and managed using proprietary methods. The rigidity and closed nature of the interchange make it very difficult to add new data formats, communicate with new data partners, or improve the overall process. The purpose of ADEQ's Node is to eliminate proprietary exchange formats and more easily facilitate the exchange of information between the Environmental Protection Agency (EPA), and other participating organizations, by developing a Web Service based gateway that supports the EPA XML message formats. ADEQ currently has a fully compliant production Node, and has successfully exchanged data with EPA's Facility Registry System. Additional data flows are planned to exchange data with EPA's RCRA Info and AQS systems. In addition, the Node can be used internally and for non-EPA partner exchanges.

6.4. LEVELS OF DOCUMENTATION FOR ENVIRONMENTAL PROJECTS

Documentation is important because it helps users make informed decisions regarding the use of environmental data, provides consistency and IT project memory over time, and allows the data to be shared and used for a variety of purposes and in a variety of computing environments. ADEQ has developed the following four kinds of documentation requirements for environmental IT project data systems:

1. **Data System Documentation**: Documenting critical information about the IT project, including the project purpose and scope, the user requirements, the IT PIJ, and the IT project plan;

2. **Data Set Documentation**: Clear information about what data are collected and how to access and use them;

3. **Data Element Documentation**: Full definitions and specifications for each element collected and maintained in a data set;

4. **Database System Documentation**: Electronic and hard copy documentation of system design and implementation.

6.5. COMPUTER HARDWARE/SOFTWARE REQUIREMENTS

ADEQ managers and staff will comply with all ADEQ hardware and software standards, which are maintained by the Office of Information and Technology. These standards address compatibility, hardware, operating systems, communication, database management, user and printer interface, application development, and applications.

ADEQ will procure hardware and software that conforms to ADEQ and EPA information management architecture. In some cases, ADEQ will procure and configure hardware, or develop application software, through vendors that are not on the statewide contract. All such purchases will be evaluated to ensure that they comply with ADEQ standards as outlined in the Agency's software and hardware standards. Prior to any purchases, ADEQ's Chief Information Officer, or designee, will evaluate software and hardware to determine its performance capabilities, impact of implementation upon ADEQ, and its reporting requirements to EPA.

6.6. SYSTEM DEVELOPMENT

All ADEQ system development, enhancement, and modernization efforts will comply with Agency standards. The standards include a systematic and comprehensive dialogue between the data providers, data/system users, and system developers. The majority of the dialogue occurs prior to the design of the system in order to ensure extensive and successful user participation, and a systematic approach to the design. Systems will be designed and built to integrate with core Agency data in such a manner that re-use of code, and its associated cost savings, is maximized.

All software systems shall be operated and maintained in accordance with written specifications and/or the owner's manual. All software systems will be subjected to acceptance testing by end users prior to being placed into a production environment.

For the proper implementation and maintenance of technology infrastructure, ADEQ's Office of Information and Technology:

- Maintains an inventory of the computer system(s) hardware and written operating procedures for routine maintenance operations;
- Documents data management systems in use, including functional and design specifications and requirements;
- Maintains standard processes documentation (SOPs, SW) which describe routine operation, maintenance, and testing to ensure that both the hardware and software in use are accurately performing their intended functions.

These documents will be readily available in the areas where these procedures will be performed. Changes in any part of the operating procedures shall be properly authorized, reviewed, and accepted in writing by the designated responsible person.

6.7. DATA STANDARDS

To take full advantage of both ADEQ's and EPA's growing technology, data standards, and resources there must be an increased emphasis on improving the compatibility of data among computer systems. In addition to the policies and standards contained in the CFR, federal data policies and standards that are currently followed, including those which ADEQ is attempting to implement, include:

- Chemical Abstract Service Registry Number Data Standard, EPA Order 2180.1, June 26, 1987;
- Data Standards for the Electronic Transmission of Laboratory Measurement Results, EPA Order 2180.2, December 10, 1987;
- The Minimum Set of Data Elements for Ground Water Quality, Policy Order 74500.IA, September 11, 1989;
- Facility Identification Data Standard, U.S. EPA Office of Administration and Resources Management, Information Management and Services Division, April 9, 1990.
- Policy on Electronic Reporting, U.S. EPA Office of Administration and Resources Management, July 30, 1990;
- Site Location Identification Policy and Responsibilities, Region III, Order 5361.5, September 14, 1988;
- ADEQ Locational Data Policy, 0034.001 (see Appendix J);
- Locational Data Policy, IRM Policy Manual, Chapter 13, April 1991; and

- Locational Data Policy Implementation Guidance- Guide to the Policy, U.S. EPA Office of Information and Resources Management, March, 1992.
- Cross Media Electronic Reporting, Final Rule, October 13, 2005.

6.8. INFORMATION SECURITY

It is important that ADEQ information resources are protected from potential loss and misuse from a variety of accidental and deliberate causes. Failure to adequately protect database systems can affect the integrity of data, privacy of data sources, availability of data for use (e.g., for legal and enforcement purposes), and the very existence of data. ADEQ utilizes the following security procedures and protocols:

- Network Operating Systems use log in and password controls;
- Internal rights to Agency data are granted by local management for their employees;
- Maintaining a "chain-of-custody" for any data value created or changed in a database;
- A firewall security system for Internet usage;
- Remote access controls for employees and third parties include the use of log in and password protection;
- All UNIX, NetWare, and Remote Access Operating Systems comply with DOD C2 security standards;
- The main computer room is physically secured to limit access to only critical IT personnel.
- Enterprise class antivirus software
- Encrypted mobile devices

CHAPTER 7 PLANNING

A primary goal of Arizona Department of Environmental Quality's (ADEQ) Quality Management System is to promote effective planning for the collection, analyses, and processing of environmental data. Quality planning must occur at three levels to ensure that such data meet ADEQ's programmatic quality goals. The three levels are:

- Agency wide Requirements;
- Program Specific Requirements;
- Project Level Requirements.

7.1. AGENCYWIDE PLANNING

7.1.1. INTERNAL STRATEGIC PLANNING

The ADEQ Strategic Plan is the foundation upon which all Programmatic priorities, and corresponding environmentally related data collection and use activities, are based. Using the projected annual budget for ADEQ from the various funding sources including EPA and the State of Arizona, ADEQ's Director and senior managers meet each fiscal year to discuss and set ADEQ priorities. These priorities are then reflected in ADEQ's Strategic Planning process, which establishes overall goals, direction, resource utilization, policies, and budget allocations. Yearly action plans, developed by each ADEQ Division, are tied to ADEQ's Strategic Plan and budget allocation process. Action plans further specify the types of environmentally-related data generation activities that will occur. The yearly action plans also delineate what decisions they are designed to support and the corresponding requirements for quality assurance and quality control procedures.

7.1.2. EXTERNAL DATA COORDINATION

ADEQ must also coordinate the collection and use of environmentally related data across numerous government agencies, and academic and private organizations. Close coordination and planning is essential to ensure that data are of sufficient quality to support decision-makers, or otherwise meet their intended use. Data Quality Objectives (DQOs) and other pertinent data can be shared across programs, sites, and governmental agencies, where appropriate. ADEQ encourages data sharing whenever possible. However, data sharing is only done when adequate data quality indicators (DQIs) are available so that the quality of data is sufficiently known to support the applicable decision(s).

7.2. PROGRAM-SPECIFIC PLANNING

The ADEQ Programs are functional areas of work authorized by statutory reference (e.g., Air Toxics Program or Drinking Water Program) or by Agency direction (e.g., the Voluntary Remediation Program). Any of ADEQ's environmental Programs which generate environmental data are covered by the Quality Management Plan (QMP), though it is acknowledged that not every Program or project requires the same level of quality assurance. Generally, Program managers (their grades and titles vary by Division) are responsible for Program level planning,

which includes the responsibility to ensure that there is agreement between the customer and the data supplier as to expected data quality.

Establishing DQOs when initiating a new project, or incorporating major statutory changes, is a mandatory component of the ADEQ Quality Management System. The EPA Quality Staff guidance document, *Guidance for the Data Quality Objectives Process*, EPA QA/G-4 is available to assist users in developing these objectives, as are other resources available through the agency-wide QA/QC program management (AQPM) when the formal DQO process is necessary. Predetermined DQOs based on regulatory criteria and action levels within similar Programs are often available, and thus a formal DQO process may not be necessary. DQOs at the project level address all sources of error (i.e., design, sampling, measurement, and indicator error) that will accumulate and affect the interpretation of data for status and trends. Program-level DQOs have the ability to meet Division Program objectives. DQOs are also used as performance criteria for assessments of data quality for their adequacy in determining status and trends.

It is critical to consider the QMP during the planning process when modifying existing or designing new Programs. Although the QMP outlines the minimum QA requirements for ADEQ, it is likely that most of the Programs covered by the QMP will need more QA specificity when implementing their Programs. In these cases, supplemental QA components and procedures are developed and described by the Program. If requested, the AQPM will serve as a technical advisor in the development of these components and procedures. Division QA/QC specialists are also available to serve as technical advisors in the formulation of QA components and procedures. All Programs covered by the QMP should review their programmatic requirements each year to determine if the QMP adequately covers their QA needs, and if not, incorporate supplemental procedures into their Program Plans.

7.3. PROJECT-LEVEL PLANNING

A project is an organized set of activities within a Program. The Quality Assurance Project Plan (QAPjP) is the primary vehicle for ensuring that there is adequate data quality at the project level (see Chapter 2, Section 2.2 for a more complete discussion of the QAPjP development and review process.) The ADEQ QMP refers to QA activities as a well-defined component of any project plan involving the collection or use of environmental data.

The key to good quality planning at this level is to link the data collection or analyses to be performed directly to the environmental decision to be made. This is essential so that ADEQ does not collect excess data for which there is no purpose. Achieving this key component requires dialogue between the decision maker, contractor, and the data supplier. Again, the EPA Quality Assurance Division document EPA QA/G-4, *Guidance for the Data Quality Objective Process March, 2006*, as well as resources within the ADEQ QA/QC Program, can be invaluable in establishing the desired data certainty requirements based on the decision to be made. The use of statistical methods to quantify data acceptability measures is highly recommended. Members of the QA Team in EPA Region 9 can provide assistance with statistical applications. The AQPM can assist specific ADEQ Programs by providing appropriate references.

Planning documentation identifies ADEQ personnel responsible for ensuring that all components of a QAPjP are addressed appropriately. Division QA/QC specialists will normally be responsible for the development of these QA components, which will adhere to the requirements of EPA QA/R-5, *EPA Requirements for QA Project Plans. March, 2001*. In some cases, QA planning may be integrated with Sample and Analysis Plans (SAPs) developed for specific projects. Formal QAPjPs are reviewed to ensure that all the required EPA and ADEQ elements are appropriately addressed. The review process is conducted by the AQPM. Where QA planning is addressed in a SAP, a review is conducted and an approval granted by the Unit manager overseeing the project or an appropriate designee.

When initiating a site-specific project, a preliminary plan is developed for accomplishing the required work. Through this process, specific individuals are made accountable for different aspects of the investigation.

ADEQ planning process considerations include:

- Identifying the regulations involved;
- Defining the requirements of the regulations;
- Structuring communication between all the parties involved in the project;
- Defining the scope of the project to meet enforcement objectives;
- Identifying and scheduling activities;
- Identifying resources needed;
- Identifying health and safety issues;
- Questioning the validity of scientific models and methods proposed for use.

7.3.1. ON-SITE MONITORING

The determination to use on-site monitoring, and the specific type of monitoring to be conducted, is based upon the project objectives as defined by the QAPjP or the EPA. Field screening information, combined with statistics, can be used to define the number and type of samples needed to meet project objectives.

Monitoring for personal protection may include using a specific instrument to screen the work area to determine the appropriate level of personal protection needed. These instruments can also be used for continuous monitoring while work is being performed.

Quality control indicators used in on-site monitoring depend on the applicable regulations, the type of equipment, the nature of the materials monitored, and monitoring objectives. Quality control parameters such as blanks, blank spikes, matrix spikes, field duplicates, surrogates, and applicable QC-related calibration curve data shall be documented.

7.3.2. SAMPLING EVENTS

Sampling activity shall be focused toward meeting regulatory, technical, and analytical requirements defined during the planning phase. ADEQ sample collection activities are designed to answer questions such as:

- How do the media compare to a regulatory threshold?
- How do the media compare to other site media?
- Is a specific component or condition present?
- Are there trends or hot spots?

The sampling activity requires:

- Coordinating field activities with laboratory activities;
- Maintaining sample integrity;
- Focusing on regulatory and Agency-defined data quality requirements.

7.3.2.1. SAMPLE SCHEDULING

Communication with the laboratory prior to sampling is critical in achieving the stated DQOs. Some sample events are unique one-time events, while others are routine and ongoing. For non-routine samples, communication, scheduling, and coordination with the lab is advisable several days before sample submission; routine sampling as a part of an ongoing project or larger program may have standing instructions or submission criteria communicated to the labs at the beginning of a contract period or fiscal year. Coordination and scheduling with labs in the latter case may be more informal, occurring at the time of sample submission. Ongoing communication as necessary at any time to achieve project objectives is advisable. Communications should include time frames, methods, matrix types, required detection limits, and where appropriate, the purpose for testing to ensure the requirements of Federal or State statutes under which ADEQ intends to regulate are fulfilled. The AQPM can facilitate finding appropriate laboratories, ensuring that the DQOs can be met, and that the laboratory meets the minimum ADEQ Quality Control requirements.

7.4. ANALYTICAL REQUIREMENTS

Analysis involves the characterization of samples based on chemical and/or physical properties. Analysis results in generating raw data from either instrumental analysis, chemical analysis, or physical testing. The analytical methods used will be specific, sensitive enough to answer the question posed by Program objectives, and meet the data quality goals associated with those objectives.

Division QA/QC specialists may consult with the AQPM, or research a variety of published or written materials, to aid them in selecting or developing measurement technologies. The AQPM shall maintain a file of in-house procedures and practices used in the measurement process. Data Quality Indicators (DQIs), and the AQPM's professional knowledge, are used to identify instances that require particular analytical procedures.

DQIs as defined by EPA involve precision, accuracy, representativeness, completeness, comparability, and sensitivity, also known as "PARCC" parameters. It is expected that these indicators be used in data evaluation, but in general, the criteria by which DQIs are evaluated are based on project data quality needs. The extent to which these indicators will be utilized should be provided in a Program's QAPrP.

7.5. DATA TRANSLATION

Data translation involves translating raw data into useable information which can include qualitative identifications, quantitative determinations, and/or narrative statements of condition. This process can include arithmetic calculations and/or statistical evaluations of results from a sample or collection of samples.

7.6. DATA INTERPRETATION

The division QA/QC specialists or their designees will use sample data to form an opinion about the QA characteristics of a data set. The division QA/QC specialist will use the quality control indicators incorporated into sampling and analyses to support conclusions or to identify limitations of the data. The AQPM will be available to assist the division QA/QC specialist in assessing data quality indicators when actions have regulatory implications. For compliance testing, the characteristics of the data set will also be compared to regulatory requirements to determine compliance.

7.7. HEALTH AND SAFETY

Health and safety are an integral part of the ADEQ Quality Management System, because the management philosophy is that a safe workplace is essential for the long term success of the Quality Management System. ADEQ Management, with the assistance of the ADEQ Health and Safety Officer, is responsible for developing policies and procedures focused toward a safe working environment, and a Program that is sufficient to protect the health and safety of ADEQ staff. The ADEQ Health and Safety procedures implement applicable EPA and Office of Safety and Health Administration regulations. The ADEQ Safety Officer conducts or contracts for specialized training programs to meet the safety needs of ADEQ measurement activities.

The ADEQ Health and Safety Environmental Management Program is the mechanism which ensures that appropriate issues are considered prior to the initiation of measurement activities. The ADEQ Health and Safety Environmental Management Program includes the following three key elements:

1. Training - Includes field and laboratory safety, first aid and CPR, supervisory safety, hazardous waste, OSHA, and other pertinent training, such as MSHA where applicable;

2. Audits, Inspections, Investigations, and Hazard Control - Includes planning reviews, associated reporting, and record-keeping to identify, prevent, and/or abate health and safety problems;

3. Occupational Medical Monitoring - Includes medical monitoring of staff who may be exposed to chemical, biological, radiological, or other agents, or who may experience physical stress during their work.

CHAPTER 8 IMPLEMENTATION OF QUALITY ASSURANCE WORK PROCESSES

This Chapter of the Quality Management Plan (QMP) describes the processes used at Arizona Department of Environmental Quality (ADEQ) for facilitating the effective implementation of the quality assurance (QA) plans and procedures which comprise ADEQ's Quality System. Any changes to the QMP will be documented in revisions and will receive as a minimum Agency Director-level approval. As with the QA planning described in Chapter 7, implementation of QA procedures takes place at the Agency, Program, and project levels.

8.1. AGENCY-WIDE IMPLEMENTATION

ADEQ utilizes a tiered approach to ensure that environmental data are of sufficient quantity and quality for its intended purpose. Any revisions to the QMP will be processed in the same manner as was the original document. QMP revisions will be drafted by the agency-wide QA/QC program management (AQPM) or appointed designees, with final approval by ADEQ's Leadership Team. The AQPM will provide general oversight of implementation of the ADEQ Quality Management System and identify needs for revisions to the QMP. ADEQ Programs will provide technical oversight for implementing environmental data operations through the development of Quality Assurance Program Plans (QAPrPs).

8.1.1. DIVISIONAL QUALITY ASSURANCE PROGRAM PLANS

QAPrPs will be developed within the individual Programs. When requested, the AQPM will assist in development and implementation of environmental data operations according to approved planning documents. Each QAPrP needs to identify those specific activities that will ensure the generation of quality data by:

- Defining commonalities in operations, methods, and procedures used throughout the Program;
- Covering elements of Program management, data generation and acquisition, assessment and oversight, and data validation and usability;
- Describing the different types of QA documents used by the Program, focusing on those elements that are not time- or site-specific;
- Identifying those responsible for implementation of Program QAPrPs and describing the procedures for Program QA document preparation, review, and approval;
- Discussing data quality objectives (DQOs) including the identification of Program-wide technical or regulatory criteria;
- Attaching reference and supporting documents used throughout the Program, such as SPDs and regulatory lists.

Each ADEQ QAPrP should be reviewed and revised at a minimum of every five years or when significant changes in the business operation occur to ensure that the plans accurately reflect how

business within the Program is conducted. It is essential that the workflow outlined in the QAPrP be consistent with actual business conducted. The Programs will provide a copy of their QAPrP to the AQPM for approval, general oversight, and management of the Agency-wide Quality System. The AQPM will submit all QAPrPs to EPA Region 9 for approval.

8.2. PROGRAM LEVEL IMPLEMENTATION

8.2.1. OPERATING POLICIES AND PROCEDURES

Any ADEQ Program which generates or uses environmental data will document its QA policies and procedures. Programs will also develop and/or use appropriate policy and procedure manuals for QA purposes. The AQPM will provide support and oversight in the generation of such documents. The EPA Quality Assurance Staff issues documents to provide information on satisfying Federal Regulations, for example, *Guidance for Preparing Standard Operating Procedures, March, 2001* (QA-G6); this document should be referenced by ADEQ Programs when developing procedure manuals for administrative and technical QA operations. Implementation of these procedures will enable Program personnel to gain and document procedural knowledge about their operations and will also serve as a training guide for new staff members.

The AQPM will work with the ADEQ Programs to ensure that operational QA policies and procedures developed by the Programs are consistent with the ADEQ QMP. This responsibility includes defining procedures for appropriate routine, standardized, special, or critical operations, including the policies and procedures that address, but are not limited to:

- The identification of operations needing standardized procedures;
- The process for preparation of procedures, including form, content, and applicability;
- Determination of standard processes adequacy, and consequent review and approval.

Any QA procedure manuals developed by the AQPM will be made available to all personnel involved in Program implementation. If implementation of the Program is delegated or outsourced, these QA procedural manuals will be referenced in the Task/Work Assignment, Task/Delivery Order, or similar document consistent with the ADEQ Procurement process. A Program using data generated by external sources must develop criteria and a process by which to evaluate the acceptability of the data supplied. The data quality assessment process described in Chapter 9.4, of this document, can be useful here.

8.3. PROJECT LEVEL IMPLEMENTATION

8.3.1. QUALITY ASSURANCE PROJECT PLAN IMPLEMENTATION

All environmental data operations will be implemented in accordance with an approved Quality Assurance Project Plan (QAPjP) or QAPrP. The division QA/QC specialist should include identifiable QA milestones and target dates where appropriate in the project timeline so that

progress and completion of QA and QC activities can be effectively tracked. Any changes to the QAPjP will be documented as soon as possible in writing with an amendment to the QAPjP. Amendments will be reviewed and approved by the division QA/QC specialist. It is critical to have a quick and efficient system for any QAPjP changes so the plan can be accurately used for its intended purpose, as a reference and guide throughout the project.

8.3.2. STANDARDIZED PROCESSES

Many repetitive procedures that are routinely used can be standardized and documented in writing as Standard Operating Procedures (SOPs) or Standard Work Instructions (SW). SOPs are generally used for more complex processes and SW for simpler processes. SOPs and SW can be prepared for routinely conducted sampling, analytical, and quality control procedures. Once established, the SOPs and SW can be cited in the QAPrPs, QAPjPs, contract proposals, grant agreements, and other similar documents, thus saving time and paper by avoiding the need to write out the specific procedures in each document. ADEQ SOPs and SW relating to QA/QC shall be maintained by the appropriate Program office with technical support provided by the AQPM, as appropriate. Tasks or functions that may be effectively addressed within a SOP or SW include:

- Sampling network design;
- Sampling site selection;
- Sampling and analytical procedures;
- Sample collection methods and devices, containers, preservatives, holding times, handling and transportation methods;
- Documentation and chain-of-custody procedures;
- Calibration and maintenance of instruments and equipment;
- Quality control procedures;
- Data review, reduction, and validation;
- Data Certification and submittal;
- Database management;
- Data summaries and reports;
- Safety procedures;
- Inspection and audit procedures.

ADEQ has established the following policies, procedures, and/or guidance for sample collection and analytical techniques. These procedures, where relevant, apply to all analytical data being generated for use by ADEQ. These procedures should be followed unless special exceptions have been requested and approved, and/or deviations are outlined in a Program's QAPrP.

- ADEQ Temperature/Preservation Guidance Policy;
- Substantive Policy *0154 Addressing Spike And Surrogate Recovery As They*

Relate To Matrix Effects In Water, Air, Sludge And Soil Matrices Policy;

- Substantive Policy 0170 *Implementation Of EPA Method 5035 - Soil Preparation For EPA Method 8015B, 8021B and 8260B*;
- Arizona Data Qualifiers.

The Arizona Data Qualifiers are revised periodically with the consensus of the Arizona Environmental Laboratory Advisory Committee (ELAC). The most recent version should be used when applying qualifiers to data and can be found on the Arizona Department of Health Services (ADHS) and ADEQ websites.

CHAPTER 9 QUALITY ASSESSMENT AND RESPONSE

This Chapter of the Quality Management Plan (QMP) describes how Arizona Department of Environmental Quality (ADEQ) will assess the effectiveness of its Quality Management System. ADEQ will use a variety of internal management and technical reviews, performance evaluations, and QA audits to ensure that the procedures in this QMP are implemented successfully. ADEQ will also utilize, as needed, independent reviews of the systems and procedures described in ADEQ's QMP by personnel from the EPA Region 9 Quality Assurance Section. This chapter will also describe ADEQ's commitment to using the results of these evaluations to make any necessary operational adjustments to ADEQ's data collection and analytical procedures, as well as to other aspects of the Quality Management System.

9.1. ANNUAL REVIEW OF THE QUALITY MANAGEMENT PLAN

The Quality Assurance (QA) practices and procedures described in the QMP will be assessed annually by the agency-wide QA/QC program management (AQPM). As an integral part of the process, ADEQ's AQPM is responsible for coordinating this assessment, arranging division QA/QC specialists to assist with the review, and for incorporating any recommended changes into the QMP. Minor changes in the QMP proposed by the ADEQ Programs should be submitted in writing to the AQPM. After approval by the AQPM, the QMP will be turned over to the Leadership Team for updated signatures. A copy, for record keeping, will be sent to EPA Region 9. A major rewrite will take place every five years with approvals needed by ADEQ's Leadership Team and final approval by EPA Region 9.

9.2. QUALITY AUDITS

ADEQ employs several QA assessment tools designed to provide a better understanding of the components of, and basis for improving, the ADEQ Quality Management System. Internal (programmatic) and External QA audits are one of the principal tools for determining the effectiveness of the ADEQ QA/QC components. QA audit frequency and scheduling will vary with the type of review conducted. Specifics of frequency and type of review will be outlined in the individual Program Quality Assessment Program Plans (QAPrPs). The following is a description of some of the evaluation tools:

9.2.1. MANAGEMENT SYSTEM REVIEWS (MSRS)

An MSR is an independent assessment of a Program's QA management practices and data collection procedures, and is generally performed by the AQPM. The MSR will qualitatively assess a Program to determine if the ADEQ Quality Management System is adequate to ensure the quality of the Program's data. MSRs address the effectiveness of management controls in achieving and assuring data quality, the adequacy of resources and personnel devoted to QA functions, the effectiveness of training and assessments, and the applicability of data quality requirements. While MSRs can identify significant QA concerns and areas of needed improvement, they also point out noteworthy accomplishments.

ADEQ Program MSRs are generally conducted by an external party (typically the AQPM) and focus on the Program's adherence to the approved Agency QMP, its QAPrP, as well as the

implementation of QA practices within a single Program area. The AQPM will attempt to conduct an MSR for every major Agency Program once every four years. The AQPM's MSRs focus on the overall structure and procedures for accomplishing the QA Program.

Most MSRs will examine the following elements:

- An assessment of the overall effectiveness of the QA management system, as measured by its adherence to the approved QMP;
- Procedures for developing Data Quality Objectives (DQOs);
- Procedures for developing and approving QAPrPs and Quality Assurance Project Plans (QAPjPs);
- The effectiveness of existing QAPrP guidance and QAPjPs;
- Procedures for developing and approving standard processes;
- Procedures, criteria, and schedules for conducting QA audits;
- Tracking systems for assuring that the QA Program is operating effectively, and that corrective actions disclosed by QA audits have been taken;
- Responsibilities and authorities of various unit managers, and QA personnel, for implementing the QA Program;
- The degree of management support;
- The level of financial and other resources committed to implementing the QA Program.

MSRs performed or arranged by the AQPM will be conducted in accordance with the *Guidance on Assessing Quality Systems, March, 2003*, EPA QA/G-3. ADEQ may also make occasional use of independent, outside reviews of its quality assurance practices. When electing to use an outside source, the AQPM, in consultation with the Division Director will make arrangements for such a review by selecting an appropriate team of qualified reviewers (e.g., EPA Region 9). The goals and objectives of this type of review will be the same as if the assessment were conducted internally.

EPA Region 9's QA Section has the authority and may, from time to time, audit ADEQ's Quality System as part of its oversight responsibilities.

All MSRs will result in the production of a written report. A draft of this report is due as soon as reasonably practical from the completion of the observation phase of the audit. The draft will be sent for comments to the Program's senior management. Comments must be supplied by the Program's senior management as soon as reasonably practical from the receipt of the draft. Final reports are to be completed as soon as reasonably practical from the receipt of comments by the Program's senior management

9.2.1.1. REVIEW ADEQ QUALITY ASSURANCE PROGRAMS

ADEQ's AQPM will conduct internal assessments of the individual ADEQ Quality Assurance Programs as described in the Agency QMP. All major data generating Programs within ADEQ will be reviewed every four years. These Programs include those listed in Chapter 1 of this document. These reviews will be authorized by the ADEQ Director and the results of the evaluations will be transmitted to the ADEQ Division Director, in a written memorandum. The reviews are intended to accomplish the following objectives:

- Identify any data quality problems;
- Identify benchmark practices that could be used in other Agency Programs;
- Propose recommendations for resolving quality problems;
- Confirm implementation and effectiveness of any recommended corrective actions.

The reviewed Program prepare a written response to the reviewer's memorandum as soon as reasonably practical. If the evaluation report recommended corrective actions, the reviewed Program should address those recommendations and include a schedule for making any appropriate changes in its quality assurance procedures. These reviews will be used by the ADEQ Leadership team to gauge the effectiveness of the Agency QMP and of the Programs' approaches to data quality management.

9.2.2. TECHNICAL SYSTEMS AUDITS (TSAs)

A Technical Systems Audit is conducted to assess the sampling and analytical quality control procedures used to generate environmental data. The AQPM will use TSAs to evaluate laboratory and field procedures used by EPA, state personnel, and contractors. TSAs entail a comprehensive on-site evaluation of the field equipment, sampling and analyses procedures, documentation, data validation, and training procedures for collecting or processing environmental data.

TSAs may be routinely planned by AQPM, specifically requested by the division QA/QC specialist, or result from the findings of another audit or review. ADEQ's AQPM-is responsible for assembling the audit team. Results will be reported to the audited organization in the form of a written report as soon as reasonably practical from the completion of the audit. Written comments by the division QA/QC specialist must be supplied to the AQPM as soon as reasonably practical from the audit findings. Copies of the TSA Audit Final Report will be stored in the project file and also with the AQPM. Additional copies will be distributed as appropriate. Internal TSAs may also be performed within the Divisions by Program QA personnel in order to meet QA practice requirements and recommendations.

9.2.2.1. LABORATORY TSAs

TSAs will be conducted on the Arizona Department of Health Services (ADHS) State Laboratory, ADEQ contract laboratories, and the contract laboratories of those consultants and contractors who submit analytical data to ADEQ. TSAs will also be conducted on other Federal agency laboratories that perform sample analysis under Interagency Agreements with ADEQ. The primary goals of TSAs will be to review the laboratory organization, operation, and

capabilities; determine the reliability of data; and note corrective action for any apparent deficiencies. Auditors for TSAs will be selected by the AQPM based on their technical proficiency in the subject area. The designated auditors will be responsible for planning and conducting the audit, and reporting the findings to the laboratory manager and to the AQPM.

9.2.2.2. FIELD TSAs

Oversight of field operations is an important part of the quality assurance process, and the AQPM, will conduct QA audits of field sampling activities, both for its own field operations, and on those contractors and other federal agencies that collect samples for Programs sponsored by EPA. ADEQ will specify frequency and procedures for conducting field TSAs within specific Program areas. When QAPjPs are reviewed and during any MSRs or other QA audits, the AQPM will determine the necessity of field TSAs.

9.3. PERFORMANCE EVALUATIONS

Performance Evaluations (PEs) are conducted to assess the ability of a laboratory, or field measurement system, to provide reliable data. PEs will normally be accomplished at laboratories providing analytical services, directly or indirectly, for ADEQ and will be traceable, whenever possible, through the National Institute of Standards and Technology (NIST). The evaluation consists of providing a reference "blind" or “double blind” sample to the laboratory for analysis. This PE sample contains known concentrations of chemical constituents, or pollutants, of interest and will normally be in the appropriate media (e.g., soil, water, air). The analytical results obtained by the laboratory are compared to the known concentrations of the chemical constituents contained in the PE sample(s), as a means of determining if the laboratory demonstrated its ability to properly identify, and quantify, pollutants within established, or calculated, control limits.

PE samples will be scheduled at a frequency specified by Program requirements, or on an as-needed basis depending on the laboratory and Program involved. Some national Programs, such as the Public Water Supply Supervision (PWSS) and National Pollutant Discharge Elimination System (NPDES) Programs, have regularly-scheduled PE studies in which participation is mandatory for designated laboratories. For the PWSS Program, PE evaluations are required twice a year for all laboratories who wish to be certified for drinking water analysis. In addition, PE samples of specific parameters may be obtained from the appropriate EPA Office of Research and Development laboratory or prepared commercially.

All PEs performed for ADEQ, whether required on a regular basis or performed on a one time basis, will be coordinated through or requested from the AQPM or designee. For external projects requiring PEs, the Task/Work Assignment, Task/Delivery Order, or similar document needs to outline the specific details of the Proficiency Evaluation so the associated costs can be included in the contractor proposal. The results of PEs provide a means for assessing overall data integrity, and may be used as the criteria for selecting candidates for on-site evaluations.

9.4. DATA QUALITY EVALUATIONS

Data quality requirements and evaluation methods are addressed in the ADEQ QMP and also in specific QAPrPs and QAPjPs. The QMP describes the methods by which data quality evaluations will be conducted and utilized, and how these evaluations relate to the Data Quality Objectives.

9.4.1. DATA QUALITY ASSESSMENTS (DQAs)

A Data Quality Assessment (DQA) refers to the process used to determine whether the quality of a given data set is adequate for its intended use, using appropriate statistical tools. DQAs can be performed on all, or selected, projects involving data collection. The purpose of this type of evaluation is to determine whether the data collected are acceptable to the decision-maker or end user for their intended use, since the data are ultimately meaningful only in this context. A DQA involves a statistical comparison of the collected data with the Data Quality Objectives (DQOs) for the project. The intended use of the data is established by the project's Data Quality Objectives (see Chapter 7). This evaluation and comparison will result in the determination that the data are of known quality and that they are either useable, or not useable, for their intended purposes. Guidance for this procedure is provided in EPA QA/G-9R, *Guidance for Data Quality Assessment: A Reviewers Guide, July, 2006.*

If necessary, the AQPM can review data generated by the ADHS State Laboratory, and by contract laboratories, for the various ADEQ Programs. These data review activities use checklists, standard processes, and standardized qualification codes to indicate data quality. The use of checklists and standard processes helps standardize the data review process. The extent and level of verification for individual data sets should clearly be defined in the Program's QAPrP and/or QAPjP.

9.4.2. AUDITS OF DATA QUALITY

A related evaluation tool involving data review and assessment is the data quality audit which is used to evaluate the documentation of the quality of data generated for a given project. This assessment primarily involves an evaluation of the completeness of the documentation of field and analytical procedures and quality control results, and usually involves tracing the paper trail accompanying the data from sample collection and custody to analytical results and entry into a database. This technique is commonly used to verify the process involved in entering data residing in large regulatory databases.

Results of both DQAs and audits of data quality can be used in a number of ways. First, they can be used in making recommendations for changes in the design and performance of data collection efforts, and in the use and documentation of QC procedures. Secondly, they can be used as a guide for the planning and acquisition of supplemental data for the project and potentially for other related projects. Problems identified through DQAs may trigger the need for an MSR to determine management deficiencies, or a TSA to identify technical problems.

CHAPTER 10 QUALITY IMPROVEMENT

The Arizona Department of Environmental Quality (ADEQ) Leadership Team actively supports quality improvement by encouraging the ADEQ staff to:

- Continually evaluate the effectiveness of current policies, procedures, and practices;

- Apply innovative approaches while maintaining integrity and accuracy. Conduct regular management reviews to define and celebrate success while recognizing and eliminating undesirable processes or results.

The above goals are achieved by continually committing resources to the Agency's quality management efforts. Peer review and performance audits will enable the constant evaluation of ADEQ Programs, projects, and individual staff performance. The ADEQ Quality Management System is designed to identify opportunities for improving the measurement process. Improvement can take the form of preventing quality problems from occurring by adjusting current work processes, or by seeking out better ways to do the work. The ADEQ Integrated Quality Management process seeks to prevent quality problems from occurring, recognize challenges early, and celebrate success.

Continual improvement is achieved through consistent evaluations of Program, project, and individual performances through the continuous improvement office. Regular oversight allows ADEQ to reshape Program protocol to reflect changing methods or procedures.

10.1. PROGRAM REVIEWS

It is the responsibility of unit management to assure staff participation in all Program reviews and to review annually all QA activities of their staff. This is accomplished by determining that standard processes (SOPs, SW) are in place with revisions as necessary and that Quality Assurance Program Plans (QAPrPs) and/or Quality Assurance Project Plans (QAPjP) are written, approved in advance of project start-up, and that data quality assessments are made. All deviations and discrepancies noted during any independent or self-assessment review will be corrected promptly. Recommendations for modifications to the Quality Management Plan (QMP) will be forwarded in writing to the agency-wide QA/QC program management (AQPM) for implementation and inclusion during regular review sessions, as described in section 9.2.1.

10.2. PROJECT REVIEWS

It is the responsibility of division QA/QC specialists to request project reviews and/or QA audits and to identify where improvements can be made. This process is started during the determination of data quality objectives and is finalized during the assessment of data quality. All corrective actions required during the life cycle of the project are to be filed in the official project file or with the project's final report. Project team debriefing is a regular component of project closeout. All data collection and testing procedures are to be scrutinized for consistency within industry best practices.

The evaluation can include the findings resulting from scientific scrutiny (new technologies) or analytical measurements. The team will prepare a written report of their findings for Division Management and the Agency Leadership Team, along with recommendations for improvement. The Leadership Team may choose to solicit other recommendations for improvement from persons not directly involved with the project. The ADEQ Leadership Team will decide which recommendations to implement in future projects.

TERMS AND DEFINITIONS

Acceptable Quality Level - a limit above which quality is considered satisfactory and below which it is not. In sampling inspection, the maximum percentage of defects or failures that can be considered satisfactory as an average.

Accuracy - the degree of agreement between an observed value and an accepted reference value; a data quality indicator**.**

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

Agency-wide Quality Assurance /Quality Control Program Management (AQPM) – the independent ADEQ program responsible for agency-wide implementation and oversight of the Quality System as approved and directed by the agency Leadership Team. May consist of a single official / manager administering the system, or in the absence of a single manager, designated individuals from each agency division fulfilling the same role on an as-needed basis.

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

Audit - a planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness, as well as compliance with established procedures, instructions, drawings, quality assurance project plans, and other applicable documents.

Audit of Data Quality - a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Bias - the systematic or persistent distortion of a measurement process which causes errors in one direction; a data quality indicator.

Characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and measurable.

Comparability - the degree to which different methods, data sets and/or decisions agree or can be represented as similar; a data quality indicator

Completeness - the amount of valid data obtained compared to the planned amount, and usually expressed as a percentage; a data quality indicator.

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. A computer program may be stored on magnetic media, and be referred to as "software," or may be stored permanently on computer chips, and be referred to as "firmware." Computer programs covered by this document are those used for design analysis, data acquisition, data reduction, data storage (databases), operation or control, and database or document control registers when used as the controlled source of quality information.

Contractor - any organization or individual that contracts to furnish services or items or perform work.

Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to preclude their recurrence.

Criteria - standards on which judgment are based.

Customer - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.

Data - facts or figures from which conclusions can be inferred.

Data Base - a collection of integrated data that can be used for a variety of applications.

Data of Known Quality - data are of known quality when the qualitative and quantitative components associated with their derivation are documented appropriately for their intended use and such documentation is verifiable and defensible.

Data Quality Assessment (DQA) - a process for performing statistical analysis to determine whether the quality of a data set is adequate for its intended use.

Data Quality Indicators - qualitative statistics and quantitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal data quality indicators are bias, precision, accuracy, comparability, completeness, representativeness, and sensitivity.

Data Quality Objectives (DQOs) - qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs are based on EPA regulatory standards or other internal action levels that have been determined to be harmful to public health and the environment. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Data Usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Defensible - the ability to withstand any reasonable challenge related to the veracity of integrity of laboratory documents and derived data.

Design Review - a documented evaluation by a team, including personnel other than the original designers, the responsible designers, the customer for the work or product being designed, and a quality assurance representative to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Division QA/QC Specialists – assigned QA/QC program or project individuals or teams that assist with the QA efforts within each Division. QA specialists work with the agency-wide QA/QC program management in writing and implementing quality assurance documents within their prospective Divisions and serve as technical advisors on QA matters as necessary.

Electronic Data Deliverable (EDD) – an electronic file containing data sorted into specific fields for different data constituents. Designed to be uploaded into databases for overall data management without additional manual input of data.

Engineered Environmental Systems - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollutant reduction or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Environmental Conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, or biological characteristics.

Environmental Data - any information or measurements resulting from field data collection activity, laboratory analyses or modeling involving the assessment of chemical, physical, or biological factors related to the environment, and that describe environmental processes or conditions, or the performance of engineered environmental systems.

Environmental Data Operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmentally Measurements - any measurement or information that describes environmental processes or conditions, or the performance of engineered environmental systems. Thus, environmental data include all chemical, physical, or biological measurements relating to the environment; however, it does not include demographic or financial data. In addition, environmental data includes both direct measurements of environmental conditions and data collected from other sources such as literature, industry surveys, computerized databases, historical data, and mathematical models. Data from such sources are often called secondary data.

Environmental Monitoring - the process of measuring or collecting environmental data over time.

Environmental Processes - manufactured or natural processes that produce discharges to or impact the ambient environment.

Environmental Programs - generally considered a regulatory activity that results from the implementation of an act of Congress or other legislative body (e.g., a state). The duration of a Program is usually legally seven years, (subject to renewal by the legislative body at various intervals), and is effectively continuous. Measurements are usually the same from year to year and take place on a recurring basis, e.g., quarterly monitoring for water or air pollutants, site assessments for Superfund, etc. Although the locations, parameters, and nature of measurements may change, the overall goal, which is to compare data to a regulatory standard, is generally constant. The Clean Water Act, Resource Conservation and Recovery Act, Clean Air Act, etc. are examples of Programs, although not all data generation activities funded under these laws would necessarily be considered Program data if they fall into the project category (see below). A Program requires a QMP, describing its QA System, and usually a Program QAPP (QA Program Plan) to describe in detail the process by which Program data are obtained. In this document, an environmental Program also refers to functional areas of work performed by groups or teams of people within the ADEQ organization.

Environmental Project - is defined as a data gathering activity that usually is of a finite length. Project data quality objectives are established during the planning phase and an assessment is made at the completion to determine whether the data quality objectives were met. Projects may include monitoring, but the data collected are frequently not intended for the use in enforcement of a regulatory standard. A trial burn, testing a new technology, a one-time ecosystem assessment and a habitat inventory are but a few examples of environmental projects. An environmental project requires a Quality Assurance Project Plan (QAPjP).

External Oversight - a term used to convey related activities performed for EPA by ADEQ; usually performed under contracts, grants, or cooperative agreements. Used in reference to Quality Assurance Project Plans and the Quality Management Plan.

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

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

Hazardous Waste - any waste material that satisfies the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste".

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

Inspection - an examination or measurement of an item or activity to verify conformance to specific requirements.

Internal Activities - a term used to describe the activities performed by ADEQ employees; usually used in relationship to Quality Assurance Project Plans, the QMP, contracts, or grants.

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

Leadership Team - that group of ADEQ Management assembled and under the direction of the ADEQ Director. The Leadership Team consists of the following members: ADEQ Director; ADEQ Deputy Director; Waste, Water, Air and Administrative Directors; Communications Officer; and ADEQ Administrative Council.

Management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management System - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management System Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

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

Mixed Waste - hazardous waste material, as defined by 40 CFR part 261 (RCRA), mixed with radioactive constituents.

Peer Review - a documented critical review of work characterized by the existence of potential uncertainty. A peer review is conducted by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

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

Performance Evaluation Sample - (PE) a sample, the composition of which is unknown to the analyst, is provided to test whether the analyst/laboratory can produce analytical results within the specified performance limits.

Procedure - a documented set of steps or actions that systematically specifies or describes how an activity is to be performed.

Process - an orderly system of actions that is intended to achieve a desired end or result. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Qualified Data - any data that have been reviewed, assessed, and labeled as part of data validation or data verification operations.

Quality - the sum of features and properties/characteristics of a process, item, or service that bears on its ability to meet the stated needs and expectations of the user.

Quality Assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

Quality Staff - the EPA Headquarters office within the Office of Environmental Information that establishes and promulgates Quality Assurance Policy for the Agency. Formerly the Quality Assurance Management Staff (QAMS).

Quality Assurance Project Plan (QAPjP) - a formal document at the project level describing in comprehensive detail the necessary QA, QC, and other managerial and technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance (data quality) objectives.

Quality Assurance Program Plan (QAPrP) – a formal document that describes the QA system for environmental Programs such as the Clean Water Act or Clean Air Act that is usually based on environmental regulations. It contains details like a QA Project Plan, but at an organization wide or Program level and can function as a QA Project Plan or it may contain broader spectrum procedures that require additional QA Project Plans with more specific details.

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 that they meet the stated requirements established by the customer.

Quality Improvement - a management Program for improving the quality of operations. Such management Programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation

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

Quality Management Plan (QMP) - a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all QA activities conducted.

Quality System - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC procedures.

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

Remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health or the environment.

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

Sensitivity - The capability of a method instrument to discriminate between measurement responses representing different levels of the variable of interest.

Service - the category of economic activity that does not produce manufactured items. In environmental data operations or engineering projects, such activities include design, inspection, laboratory and/or field analysis, repair, and installation.

Significant Condition - any state, status, incident, or situation of an environmental process or condition of an engineered environmental system in which the work being performed will be adversely affected in a manner sufficiently serious to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software Life Cycle - the period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle

typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

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

Standard Processes – In this document, QA-oriented SOPs or Standard Work (SW) procedures.

Standard Processes Documents/Documentation (SPDs) – the collective documents detailing methods for the execution of repetitive tasks. Consists of both documented SOPs and Standard Work (SW) Instructions.

Supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surveillance - the act of monitoring or observing a process or activity to verify conformance to specified requirements.

Standard Work Instructions (SW) – step by step instructions on how to perform a repetitive process. Generally, standard work is a less complex procedure than an SOP.

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

Technical Systems Audit (TSA) - a thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training procedures, record keeping, data validation, data management, and reporting aspects of a system.

Validation - an activity that demonstrates or confirms that a process, item, data set, or service satisfies the requirements defined by the user.

Verification - the act of authenticating or formally asserting the truth that a process, item, data set, or service is, in fact, that which is claimed. The confirmation that a product or data conform to the specifications defined for the product or data.