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Standard Practice for Generation of Environmental Data Related to Waste Management Activities: Quality Assurance and Quality Control Planning and Implementation[1]

This standard is issued under the fixed designation D5283; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 Environmental data generation efforts are composed of four parts: (*1*) establishment of data quality objectives (DQOs); (*2*) design of field measurement and sampling strategies and specification of laboratory analyses and data acceptance criteria; (*3*) implementation of sampling and analysis strategies; and (*4*) data quality assessment. This practice addresses the planning and implementation of the sampling and analysis aspects of environmental data generation activities (Parts (*1*) and (*2*) above).

1.2 This practice defines the criteria that must be considered to assure the quality of the field and analytical aspects of environmental data generation activities. Environmental data include, but are not limited to, the results from analyses of samples of air, soil, water, biota, waste, or any combinations thereof.

1.3 DQOs should be adopted prior to application of this practice. Data generated in accordance with this practice are subject to a final assessment to determine whether the DQOs were met. For example, many screening activities do not require all of the mandatory quality assurance (QA) and quality control (QC) steps found in this practice to generate data adequate to meet the project DQOs. The extent to which all of the requirements must be met remains a matter of technical judgement as it relates to the established DQOs.

1.4 This practice presents extensive management requirements designed to ensure high-quality environmental data. The words "must,"" shall," "may," and "should" have been selected carefully to reflect the importance placed on many of the statements made in this practice.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

NOTE 1—A complete table of contents of this practice is given in Appendix X1.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1129 Terminology Relating to Water

E1187 Terminology Relating to Conformity Assessment (Withdrawn 2006)[3]

2.2 *U.S. Environmental Protection Agency Documents:*[4]

SW-846, *Test Methods for Evaluating Solid Waste*, Vol 1, Third Edition (NTIS No. PB88239223/LL), November 1986

QAMS-005/80 (NTIS No. PB83170514/LL), *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans*, Office of Monitoring Systems and Quality Assurance, December 29, 1980

EPA/QAMS, *Development of Data Quality Objectives, Description of Stages I and II,* July 16, 1986

QAMS 004/80 (NTIS No. PB83219667/LL), *Guidelines and Specifications for Preparing Quality Assurance Program Plans*, Office of Monitoring Systems and Quality Assurance, September 20, 1980

2.3 *Other documents related to the subject matter of this practice are cited in Appendix X2. This list is not intended to be comprehensive.*

3. Terminology

3.1 *Definitions*—The terms most applicable to this practice have been defined in Terminologies D1129 and E1187.

3.2 *Definitions of Terms Specific to This Standard:*

[1] This practice is under the jurisdiction of ASTM Committee D34 on Waste Management and is the direct responsibility of Subcommittee D34.01.01 on Planning for Sampling.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from Superintendent of Documents, Government Printing Office, Washington, DC 20402.

3.2.1 *background sample*—a sample taken from a location on or proximate to the site of interest and used to document baseline or historical information.

3.2.2 *collocated samples*—independent samples collected as close as possible to the same point in space and time and intended to be identical.

3.2.3 *data quality objectives* (DQOs)—statements on the level of uncertainty that a decision maker is willing to accept in the results derived from environmental data (see EPA/QAMS, July 16, 1986).

3.2.4 *environmental data generation activity*— tasks associated with the production of environmental data, including planning, sampling, and analysis.

3.2.5 *equipment rinsate (equipment blank)*—a sample of analyte-free media that has been used to rinse the sampling equipment. This blank is collected after the completion of decontamination and prior to sampling and is useful for documenting the adequate decontamination of sampling equipment.

3.2.6 *field blank*—a sample of analyte-free media similar to the sample matrix that is transferred from one vessel to another or exposed to the sampling environment at the sampling site. This blank is preserved and processed in the same manner as the associated samples and is used to document contamination in the sampling and analysis process.

3.2.7 *field duplicates*—collocated samples that are analyzed independently and are useful in documenting the precision of the sampling and analytical process.

3.2.8 *laboratory control sample*—a known matrix spiked with compound(s) representative of the target analytes and used to document laboratory performance.

3.2.9 *material blank*—a sample composed of construction materials such as those used in well installation, well development, pump and flow testing, and slurry wall construction. Examples of these materials are bentonite, sand, drilling fluids, and source and purge water. This blank documents the contamination resulting from use of the construction materials.

3.2.10 *matrix duplicate*—an intralaboratory split sample used to document the precision of a procedure in a given sample matrix.

3.2.11 *matrix spike*—an aliquot of sample spiked with a known concentration of target analyte(s) and used to document the bias of an analytical process in a given sample matrix. The spiking occurs prior to sample preparation and analysis.

3.2.12 *matrix spike duplicates*—intralaboratory split samples spiked with identical concentrations of target analyte(s) and used to document the precision and bias of a procedure in a given sample matrix. The spiking occurs prior to sample preparation and analysis.

3.2.13 *method blank*—an analyte-free media, to which all reagents are added in the same volumes or proportions used in sample processing. The method blank must be carried through the complete sample preparation and analytical procedure and is used to document contamination resulting from the analytical process.

3.2.14 *project*—single or multiple data collection activities that are related through the same planning sequence.

3.2.15 *project planning documents*—all documents related to the definition of the environmental data collection activities associated with a project.

3.2.16 *quality assurance program plan (QAPP)*—an orderly assemblage of management policies, objectives, principles, and general procedures by which an organization involved in environmental data generation activities outlines how it intends to produce data of known quality.

3.2.17 *quality assurance project plan (QAPjP)*—an orderly assemblage of detailed procedures designed to produce data of sufficient quality to meet the DQOs for a specific data collection activity.

3.2.18 *reference material*—a material containing known quantities of target analytes in either solution or a homogeneous matrix and used to document the bias of the analytical process.

3.2.19 *split samples*—aliquots of sample taken from the same container and analyzed independently. These are usually taken after mixing or compositing and are used to document intra- or interlaboratory precision.

3.2.20 *standard addition*—the practice of adding a known amount of an analyte to a sample immediately prior to analysis, typically used to evaluate matrix effects.

3.2.21 *standard operating procedures (SOPs)*—the established written procedures of a given organization. Special project plans may require procedures different from the established SOPs.

3.2.22 *surrogate*—an organic compound that is similar to the target analyte(s) in chemical composition and behavior in the analytical process, but is not normally found in environmental samples.

3.2.23 *trip blank*—a sample of analyte-free media taken from the laboratory (or appropriate point of origin) to the sampling site and returned to the laboratory unopened. A trip blank is used to document the contamination attributable to shipping and field handling procedures and is also useful in documenting the contamination of volatile organics samples.

4. Summary of Practice

4.1 This practice describes the criteria and activities for field and laboratory organizations involved in generating environmental data in terms of human and physical resources, QA and QC procedures, and documentation requirements depending on the DQOs.

5. Significance and Use

5.1 Environmental data are often required for making regulatory and programmatic decisions. These data must be of known quality commensurate with their intended use.

5.2 Data generation efforts involve the following: establishment of the DQOs; design of the project plan to meet the DQOs; implementation of the project plan; and assessment of the data to determine whether the DQOs have been met.

5.3 Certain minimal criteria must be met by the field and laboratory organizations generating environmental data. Additional activities may be required based on the DQOs of the data collection effort.

5.4 This practice defines the criteria for field and laboratory organizations generating environmental data and identifies some other activities that may be required based on the DQOs.

5.5 This practice emphasizes the importance of communication among those involved in establishing DQOs, planning and implementing the sampling and analysis aspects of environmental data generation activities, and assessing data quality.

5.6 Environmental field operations are discussed in Section 7, and environmental laboratory operations are discussed in Section 8.

6. Project Specification

6.1 Project activities should be defined prior to the start of any field or laboratory activities. At a minimum, project specifications should address the following topics:

6.2 *Data Quality Objectives*—DQOs for the data generation activity should be defined prior to the initiation of field and laboratory work. It is desirable that the field and laboratory organizations be aware of the DQOs so that the personnel conducting the work are able to make informed decisions during the course of the project.

6.3 *Project Plan*— The project should be designed to meet the DQOs, and the project plan should define the following:

6.3.1 *Project Objectives*—Project objectives provide background information, state reasons for the data collection effort, identify any regulatory programs governing data collection, define specific objectives for each sampling location, and describe the intended uses for the data.

6.3.2 *Project Management*—A person(s) shall be designated as having responsibility and authority for the following: (*1*) developing project documents that implement the DQOs; (*2*) selecting field and laboratory organizations to conduct the work; (*3*) coordinating communication among the field and laboratory organizations and government agencies, as required; and (*4*) reviewing and assessing the final data.

6.3.3 *Sampling Requirements*—Sampling locations, equipment, and procedures and sample preservation and handling requirements shall be specified.

6.3.4 *Analytical Requirements*—The analytical procedures, analyte list, required detection limits, and required precision and bias values shall be specified. Regulatory requirements and DQOs shall be considered when developing the specifications.

NOTE 2—This does not imply that the specified analytical requirements can be met.

6.3.5 *Quality Assurance and Quality Control Requirements*—The QA and QC requirements shall address both field and laboratory activities. The means for controlling false positives and false negatives shall be specified. Standard practices for field and laboratory operations as described in Sections 7 and 8 of this practice shall be required.

6.3.5.1 *Field Quality Control*—The types and frequency of field QC samples to be collected, including field blanks, trip blanks, equipment rinsates, field duplicates, background samples, reference materials, material blanks, and split samples, shall be specified. Control parameters for field activities shall also be described (see 7.6.4).

6.3.5.2 *Laboratory Quality Control*—The types and frequency of use of laboratory QC samples, such as laboratory control samples, laboratory blanks, matrix spikes, matrix duplicates, and matrix spike duplicates, shall be specified. Any specific performance criteria shall be specified. Data validation criteria shall be defined.

6.4 *Project Documentation*—All documents required for planning, implementing, and evaluating the data collection effort shall be specified. These may include, although not limited to, a statement of work, technical and cost proposals, work plan, sampling and analysis plan, quality assurance project plan (QAPjP), health and safety plan, community relations plan, documents required by regulatory agencies, requirements for raw field and analytical records, technical reports assessing the environmental data, and records retention policy. Planning documents shall specify the required level of document control and identify the personnel having access. Document formats that may be required to ensure that all data needs are satisfied shall be specified. In addition, a project schedule that identifies critical milestones and completion dates should be available.

7. Standard Practices for Environmental Field Operations

7.1 *Purpose*—The field organization must conduct its operations in such a manner as to provide reliable information that meets the DQOs. To achieve this goal, certain minimum policies and procedures must be implemented in order to meet the DQOs.

7.2 *Organization*—The field organization shall be structured such that each member of the organization has a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the total effort. The organizational structure, functional responsibilities, levels of authority, job descriptions, and lines of communication for activities shall be established and documented. One person may cover more than one organizational function.

7.2.1 *Management*—The management of the field organization is responsible for establishing organizational, operational, health and safety, and QA policies. Management shall ensure that the following requirements are met: (*1*) the appropriate methodologies are followed, as documented in the standard operating procedures (SOPs); (*2*) personnel clearly understand their duties and responsibilities; (*3*) each staff member has access to appropriate project documents; (*4*) any deviations from the project plan are communicated to project management; and (*5*) communication occurs between the field, laboratory, and project management, as specified in the project plan. Management shall foster an attitude within the organization that emphasizes the importance of quality and supports implementation of the quality assurance program plan (QAPP).

7.2.2 *Quality Assurance Function*—The organization shall appoint a person or persons to be responsible for monitoring field operations in order to ensure that the site facilities,

equipment, personnel, procedures, practices, and documentation are in conformance with the organization's QAPP and any applicable QAPjP. The QA monitoring function should be entirely separate from, and independent of, personnel engaged in the work being monitored. The QA function shall be responsible for the QA review, as per 7.7.

7.2.3 *Personnel*—It is the responsibility of the organization to establish personnel qualifications and training requirements for all positions. Each member of the organization shall possess the education, training, technical knowledge, and experience, or a combination thereof, to enable that individual to perform his or her assigned functions. Personnel qualifications shall be documented in terms of education, experience, and training. Training shall be provided for all staff members, as necessary, so that they can perform their functions properly.

7.2.4 *Subcontractors*—The use of subcontractors shall not jeopardize data quality. Therefore, subcontractors shall comply with the requirements of Sections 7 and 8, as appropriate to the specific task(s) they are performing.

7.3 *Field Logistics:*

7.3.1 *General*—Sampling site facilities shall be examined prior to the start of work in order to ensure that all required items are available. The actual sampling area shall be examined to ensure that trucks, drilling equipment, and personnel have access to the site. Security, health and safety, and protection of the environment shall be controlled at the site support areas and sampling site.

7.3.2 *Field Measurements*—Project planning documents shall both address the type of field measurements to be performed and plan for the appropriate area to perform the work. Planning documents shall address ventilation, protection from extreme weather and temperatures, access to stable power, and provisions for water and gases of required purity. Plans shall be made to identify and supply applicable safety equipment, as specified in the project health and safety plan.

7.3.3 *Sample Handling, Shipping, and Storage Area*—The determination of whether sample shipping is necessary shall be made during project planning. This need is established by evaluating the analyses required, holding times, and location of the site and laboratory. Shipping or transporting of the samples to a laboratory shall be completed in a timely manner, ensuring that the laboratory is allowed sufficient time to perform its analysis within any required holding times.

7.3.3.1 Samples shall be packaged, labeled, and documented in an area that minimizes sample contamination and provides for safe storage. The level of custody and whether sample storage is required shall be outlined in the planning documents.

7.3.4 *Chemical Storage*—Safe storage areas for solvents, reagents, standards, and reference materials shall be adequate to preserve their identity, concentration, purity, and stability prior to use.

7.3.5 *Decontamination*—Decontamination of sampling equipment may be performed at the location at which sampling occurs, prior to transfer to the sampling site, or in designated areas near the sampling site. Project documentation shall specify where this work will be performed and how it will be accomplished. If decontamination is to be conducted at the site, water and solvents of appropriate purity shall be available. The method of accomplishing decontamination and the materials, solvents, and water purity shall be specified in planning documents or standard operating procedures (SOPs).

7.3.6 *Waste Storage Area*—Waste materials may be generated during both the sampling process and on-site or *in situ* analysis. Planning documents and SOPs shall outline the method for storage and disposal of these waste materials. Adequate facilities shall be provided for the collection and storage of all wastes. These facilities shall be operated so as to minimize environmental contamination. Waste storage and disposal facilities shall comply with applicable federal, state, and local regulations.

7.3.7 *Data Storage Area*—Planning documents shall specify the location of long- and short-term storage for field records. The storage environment shall be maintained to ensure the integrity of the data. Access shall be limited to authorized personnel only.

7.4 *Equipment and Instrumentation:*

7.4.1 *Equipment and Instrumentation*—The equipment, instrumentation, and supplies required at the sampling site shall be appropriate to accomplish the activities planned. The equipment and instrumentation shall meet the requirements of pertinent specifications, methods, and SOPs. Before the field staff arrives at the site, a list of required items shall be prepared and checked to ensure availability at the site.

7.4.2 *Maintenance and Calibration of Equipment and Instrumentation*—An SOP or operation and maintenance manual shall set forth the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of the equipment and instrumentation used in performing geophysical, analytical, or *in situ* measurements. For common malfunctions, procedures or manuals may outline typical problems, methods of trouble-shooting, and possible corrective actions to be taken. Procedures shall designate a person(s) or organizations responsible for maintenance and calibration. Records of all inspections, maintenance, repairs, testing, and calibration shall be maintained.

7.5 *Standard Operating Procedures*—The organization shall have written SOPs for all procedures performed routinely that affect data quality. SOPs shall be available for the following areas and shall contain the information described:

7.5.1 *Sample Management*—These SOPs describe the numbering and labeling system, chain-of-custody procedures, and tracking of samples from collection to shipment or relinquishment to the laboratory. Sample management also includes the specification of holding times, volume of sample required by the laboratory, preservatives, and shipping requirements.

7.5.2 *Reagent and Standard Preparation*—These SOPs describe the procedures used to prepare standards and reagents. Information should be included concerning the specific grades of materials used in reagent and standard preparation, appropriate glassware and containers for preparation and storage, labeling and record keeping for stocks and dilutions, and safety precautions to be taken.

7.5.3 *Decontamination*—These SOPs describe the procedures used to clean field equipment before and during the sample collection process. The SOPs should include the

cleaning materials used, the order of washing and rinsing with the cleaning materials, requirements for protecting or covering cleaned equipment, procedures for disposing of cleaning materials, and safety considerations.

7.5.4 *Sample Collection Procedures*—SOPs for sample collection procedures shall describe how the procedures are actually performed in the field and shall not be a simple reference to standard test methods, unless a procedure is performed exactly as described in the published test method. If possible, industry-recognized test methods from source documents published by the U.S. Environmental Protection Agency, ASTM, U.S. Department of the Interior, National Water Well Association, American Petroleum Institute, or other recognized organizations should be used. The SOP for sample collection procedures should include the following information:

7.5.4.1 Applicability of the procedure,

7.5.4.2 Equipment and reagents required,

7.5.4.3 Detailed description of the procedures to be followed in collecting the samples,

7.5.4.4 Common problems encountered,

7.5.4.5 Precautions to be taken, and

7.5.4.6 Health and safety considerations.

7.5.5 *Equipment Calibration and Maintenance*—These SOPs describe the procedures used to ensure that field equipment and instrumentation are in working order. The SOPs describe calibration and maintenance procedures and schedules, maintenance logs, service contracts or service arrangements for equipment, and spare parts available in-house. The calibration and maintenance of field equipment and instrumentation should generally be in accordance with manufacturers' specifications and shall be documented.

7.5.6 *Field Measurements*—These SOPs describe all methods used in the field to determine a chemical or physical parameter. The SOPs shall address criteria from Section 8, as appropriate.

7.5.7 *Corrective Action*—These SOPs describe procedures used to identify and correct deficiencies in the sample collection process. These should include specific steps to take in correcting deficiencies, such as performing additional decontamination of equipment, resampling, or additional training of field personnel in methods procedures. The SOP shall specify that each corrective action must be documented with a description of the deficiency, the corrective action taken, and the person(s) responsible for implementing the corrective action.

7.5.8 *Data Reduction and Validation*—These SOPs describe procedures used to compute the results from field measurements and to review and validate these data. They should include all formulas used to calculate the results and procedures used to verify independently that the field measurement results are correct.

7.5.9 *Reporting*—These SOPs describe the process for reporting the results of field activities.

7.5.10 *Records Management*—These SOPs describe the procedures for generating, controlling, and archiving field records. The SOPs should describe the responsibilities for record generation and control and the policies for record retention, including type, time, security, and retrieval and disposal authorities. Records should include project-specific and field operations records.

7.5.10.1 Project-specific records relate to field work performed for a group of samples. Project records may include correspondence, chain-of-custody, field notes, all reports issued as a result of the work, project planning documents, and procedural SOPs used.

7.5.10.2 Field operations records document overall field operations. These records may include equipment performance and maintenance logs, personnel files, general field SOPs, and corrective action reports.

7.5.11 *Waste Disposal*— These SOPs describe policies and procedures for the disposal of waste materials resulting from field operations. The disposal of all wastes must conform to federal, state, and local regulations, including those associated with the Resource Conservation and Recovery Act, Superfund Act Reauthorization and Amendments, Department of Transportation, and Occupational Safety and Health Administration.

7.5.12 *Health and Safety*—These SOPs describe policies and procedures designed both to provide a safe and healthy working environment for field personnel and to comply with federal and state regulations.

7.6 *Field Quality Assurance and Quality Control Requirements:*

7.6.1 *Quality Assurance Program Plan*—The field organization shall have a written QAPP that describes the organization's QA policy. The plan shall specify the responsibilities of the field management and field staff and the QA function in the areas of QA and QC, and it shall also describe the QC procedures followed by the organization (see EPA QAMS-004/80 for an example).

7.6.2 *Quality Assurance Project Plan*—Some projects, particularly those that are large or complex, require a QAPjP. The QAPjP details the QA and QC goals and protocol for a specific data collection activity to ensure that the data generated by sampling and analysis activities are of quality commensurate with their intended use. QAPjP elements should include a discussion of the quality objectives of the project, identification of those involved in the data collection and their responsibilities and authorities, enumeration of the QC procedures to be followed, and reference to the specific SOPs that will be followed for all aspects of the project. Elements may be added or removed, as required by the project or the end-user of the data (see EPA QAMS-005/80 for an example).

7.6.3 *Control Samples*— Control samples are QC samples that are introduced into a process to monitor the performance of the system. Control samples, which may include blanks, duplicates, spikes, analytical standards, and reference materials, can be used in different phases of the overall process, beginning with sampling and continuing through transportation, storage, and analysis. The types of control samples used, and the frequency of usage, are dependent on the DQOs of the data collection effort and must be specified for each project.

7.6.4 *Procedures for Establishing Acceptance Criteria*—Procedures shall be in place for establishing acceptance criteria

for field activities, as required in the project planning documents. Acceptance criteria may be qualitative or quantitative. Field events or data that fall outside of the established acceptance criteria may indicate a problem with the sampling process that must be investigated.

7.6.5 *Deviations*—Any activity not performed in accordance with the SOPs or project planning documents is considered a deviation from the plan. Deviations from the plan may or may not affect data quality. All deviations from the plan shall be documented as to the extent of, and reason for, the deviation.

7.6.6 *Corrective Action*—Errors, deficiencies, deviations, or field events or data that fall outside the established acceptance criteria require investigation. Corrective action may be necessary to resolve the problem and restore proper functioning to the system in some instances. Investigation of the problem and any subsequent corrective action taken shall be documented.

7.6.7 *Data Handling Procedures:*

7.6.7.1 *Data Reduction*—All field measurement data are reduced according to protocol described in the appropriate SOP. Computer programs used for data reduction shall be validated before use and verified on a regular basis. All information used in the calculations shall be recorded to enable reconstruction of the final result at a later date.

7.6.7.2 *Data Review*—All data are reviewed according to SOPs to ensure that the calculations are correct and to detect transcription errors. Spot checks are performed on computer calculations to verify program validity.

7.6.7.3 *Data Reporting*—Data are reported in accordance with the requirements of the end-user.

7.7 *Quality Assurance Review:*

7.7.1 *General*—The QA review consists of internal and external assessments to ensure that both QA and QC procedures are in use and field staff conform to these procedures. Planning documents shall specify the requirements for internal, external, and on-site assessment. These documents shall specify the frequency and documentation of these assessments.

7.7.1.1 *Internal Assessment*—Personnel responsible for performing field activities are responsible for continually monitoring individual compliance with the QA and QC programs and planning documents. A QA officer or an appropriate management designee shall review the field results and findings for compliance with the QA and QC programs and planning documents. The results of this internal assessment should be reported to management with requirements for a plan to correct the observed deficiencies.

7.7.1.2 *External Assessment*—The field staff may be reviewed by personnel external to the organization. The results of the external assessment should be submitted to management with requirements for a plan to correct the observed deficiencies.

7.7.1.3 *On-Site Evaluation*—On-site evaluations may be conducted as part of both internal and external assessments. On-site evaluations may include, but are not limited to, a complete review of the facilities, staff, training, instrumentation, SOPs, methods, field analysis, sample collection, QA and QC policies, and procedures related to the generation of environmental data. Records of each evaluation shall be maintained until superseded or according to policy. These records should include the date of the evaluation, area or site, areas reviewed, person performing the evaluation, findings and problems, actions recommended and taken to resolve the problems, and scheduled date for re-inspection. Any problems identified that are likely to affect data integrity shall be brought to the attention of management immediately.

7.7.2 *Evaluation of Field Records*—The review of field records shall be conducted by one or more persons knowledgeable in the field activities, evaluating the following subjects at a minimum:

7.7.2.1 *Completeness of Field Reports*—This review ensures that all requirements for field activities in the planning documents have been fulfilled, that complete records exist for each field activity, and that the procedures specified in the planning documents have been implemented. The emphasis on field documentation will help assure sample integrity and sufficient technical information to recreate each field event. The results of this completeness check shall be documented, and environmental data affected by incomplete records shall be identified.

7.7.2.2 *Identification of Invalid Samples*—This review involves interpretation and evaluation of the field records to detect problems affecting the representativeness of environmental samples. Examples of items that could indicate invalid samples include improper well development, improperly screened wells, instability of pH or conductivity, and collection of volatiles near combustion engines. The field records shall be evaluated against planning documents and SOPs. The reviewer shall document the sample validity and identify the environmental data associated with poor or incorrect field work.

7.7.2.3 *Correlation of Field Test Data*—The results of field measurements obtained by more than one method shall be compared. For example, surface geophysics may be surveyed using both ground penetrating radar and a resistivity survey.

7.7.2.4 *Identification of Anomalous Field Test Data*—Anomalous field test data should be identified. For example, a water temperature for one well that is five degrees higher than any other well temperature in the same aquifer should be noted. The impact of anomalous field measurement results on the associated environmental data shall be evaluated.

7.7.2.5 *Validation of Field Analysis*—All data from field analysis that are generated *in situ* or from a mobile laboratory shall be validated per 8.7.2. The results of the validation shall be reported. The report shall discuss whether the QC checks meet the acceptance criteria and whether corrective actions were taken for any analysis performed when acceptance criteria were not met.

7.7.3 *Quality Assurance Reports to Management*—The QA program shall provide for the periodic reporting of pertinent QA and QC information to management to allow assessment of the overall effectiveness of the QA program. There are three major types of QA reports to management:

7.7.3.1 *Report on Measurement Quality Indicators*—This report shall include the assessment of QC data (such as that generated per 7.6.3) gathered over the period, the frequency of repeating work due to unacceptable performance, and corrective action taken.

7.7.3.2 *Report on Quality Assurance Assessments*—This report shall be submitted immediately following any internal or external on-site evaluations or upon receipt of the results of any performance evaluation studies. The report shall include the results of the assessment and the plan for correcting identified deficiencies.

7.7.3.3 *Report on Key Quality Assurance Activities During the Period*—A report shall be delivered to management summarizing key QA activities during the period. The report shall stress measures that are being taken to improve data quality and shall include a summary of the significant quality problems observed and corrective actions taken. The report shall also include a summary of involvements in resolution of quality issues with clients or agencies, QA organizational changes, and notice of the distribution of any revised documents controlled by the QA function.

7.8 *Field Records*— Records provide direct evidence and support for the necessary technical interpretations, judgments, and discussions concerning project activities. These records, particularly those that are anticipated for use as evidentiary data, must directly support current or ongoing technical studies and activities and must provide the historical evidence necessary for later reviews and analyses. Records shall be legible, identifiable, and retrievable and protected from damage, deterioration, or loss. Field records generally consist of bound field notebooks with prenumbered pages, sample collection forms, personnel qualification and training forms, sample location maps, equipment maintenance and calibration forms, chain-of-custody forms, sample analysis request forms, and field change request forms. All records shall be completed with black, waterproof ink. Procedures for reviewing, approving, and revising field records must be defined clearly, with the lines of authority included. At a minimum, all documentation errors shall be corrected by drawing a single line through the error and initialing by the responsible individual, along with the date of change. The correction is written adjacent to the error. Deviations from field SOPs shall be documented.

7.8.1 *Personnel Training and Qualification Records*—It is the responsibility of the organization to establish personnel qualifications and training requirements. Each staff member shall possess the education, training, technical knowledge, and experience, or a combination thereof, to enable that individual to perform his or her assigned functions. Personnel qualifications shall be documented in terms of education, experience, and training. Training shall be provided for all staff members so that they can perform their functions properly.

7.8.2 *Standard Operating Procedures*—SOPs shall be available to those performing the task outlined. Any revisions to field SOPs shall be written and distributed to all affected individuals to ensure the implementation of changes. The areas covered by SOPs are given in 7.5.

7.8.3 *Quality Assurance Plans*—The QAPP and all applicable QAPjPs shall be on file.

7.8.4 *Equipment Maintenance*—Maintenance procedures shall be defined clearly and written for each measurement system and required support equipment. When maintenance is necessary, it shall be documented in either standard forms or in logbooks. A history of the maintenance record of each system serves as an indication of the adequacy of maintenance schedules and parts inventory.

7.8.5 *Calibration and Traceability of Standards and Reagents*—Calibration is a reproducible reference base to which all sample measurements can be correlated. A sound calibration program shall include provisions for documentation of the frequency, conditions, standards, and records reflecting the calibration history of a measurement system. The accuracy of calibration standards is an important point to consider because all data will be in reference to the standards used. A program for verifying and documenting the accuracy of all working standards against primary grade standards shall be followed routinely.

7.8.6 *Sample Collection and Tracking Records*—To ensure maximum utility of the sampling effort and resulting data, documentation of the sampling protocol, as performed in the field, is essential. At a minimum, sample collection records shall contain the persons conducting the activity, sample number, sample location, equipment used, climatic conditions, documentation of adherence to protocol, and unusual observations. The actual sample collection record is usually one of the following: a bound field notebook with prenumbered pages, a pre-printed form, or digitized information on a computer tape or disc.

7.8.6.1 Sample tracking records involving the possession of samples from the time at which they are obtained until they are relinquished shall be documented with the following minimum information: (*1*) project name; (*2*) signatures of the samplers; (*3*) sample number, date and time of collection, and grab or composite sample designation; (*4*) signatures of the individuals involved in sample transfer; and (*5*) the air bill or other shipping number, if applicable.

7.8.7 *Maps and Drawings*—Project planning documents and reports often contain maps. The maps are used to document the location of sample collection points and monitoring wells, and as a means of presenting environmental data. Information used to prepare maps and drawings is normally obtained through field surveys, property surveys, surveys of monitoring wells, aerial photography, or photogrammetric mapping. The final, approved maps shall have a revision number and date and shall be subject to the same controls as other project records.

7.8.8 *Results from Control Samples*—Documentation for the collection of QC samples, such as field, trip, and equipment rinsate blanks, duplicate samples, spikes, and reference materials, shall be maintained.

7.8.9 *Correspondence*— Project correspondence can provide evidence supporting technical interpretations. Correspondence pertinent to the project shall be kept and placed in the project files.

7.8.10 *Deviations*—Field changes and deviations from the planning documents shall be reviewed and approved by either the authorized personnel who performed the original technical review or their designees. All deviations from the procedural and planning documents shall be recorded in the site log.

7.8.11 *Final Report*— The final report shall summarize the field activities, data, results of deviations from the planning documents, and interpretation of the data. The planning documents shall outline the items to be included in the report, which

may include any special formats required, QC reporting requirements, conclusions, and recommendations.

7.9 *Documentation Storage:*

7.9.1 *Documentation Archive*—Procedures shall be established to ensure that documents required to recreate the sampling, analysis, and reporting of information are stored. These documents may include, but are not limited to, planning documents, SOPs, logbooks, field data records, sample tags and labels, chain-of-custody records, photographs, and any other information noted in 7.8.

7.9.2 *Storage Time*—The length of storage time for field records shall comply with regulatory requirements, organizational policy, or project requirements, whichever is/are more stringent.

7.9.3 *Filing System*—The control of records is essential in providing evidence of technical adequacy and quality for all project activities. These records shall be identified, retrievable, and organized to prevent loss.

7.9.4 *Personnel Authorized to Enter Archive*—Access to project files shall be controlled to restrict unauthorized personnel from having free and open access. An authorized access list shall be prepared for the project files and shall name the personnel who have unrestricted access to the files.

8. Standard Practices for Environmental Laboratory Operations

8.1 *Purpose*—Each laboratory must conduct its operations in such a way as to provide reliable information. To achieve this goal, certain minimum policies and procedures must be implemented.

8.2 *Organization*— The laboratory shall be structured such that each member of the organization has a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the total effort. The organizational structure, functional responsibilities, levels of authority, job descriptions, and lines of communication for activities shall be established and documented. The laboratory shall also maintain a current list of accreditations from government agencies or private associations.

8.2.1 *Management*—The management of the laboratory is responsible for establishing organizational, operational, health and safety, and QA policies. These responsibilities include the following: oversight of personnel selection, development, and training; review, selection, and approval of analysis methods; and development, implementation, and maintenance of a QA program. Management shall foster an attitude within the organization that emphasizes the importance of quality and supports implementation of the QAPP.

8.2.2 *Quality Assurance Function*—The laboratory shall appoint a person or persons to be responsible for monitoring laboratory operations to ensure that the facilities, equipment, personnel, methods, practices, and documentation are in conformance with the laboratory QAPP and any applicable QAPjP(s). The QA monitoring function shall be entirely separate from, and independent of, personnel engaged in direct supervision or performance of the work being monitored. The QA function shall inspect records to ensure that analyses have been performed correctly and within the proper time frame; maintain copies of the QAPP and QAPjPs pertaining to all analyses; perform assessments of the laboratory to ensure adherence to the QAPP; periodically submit written status reports to management, noting any problems and the corrective actions taken; ensure that any deviations from the approved QAPP, QAPjP, or SOPs have been authorized and documented properly; and ensure that the results reported reflect the raw data accurately. The responsibilities of the QA function and procedures used in conducting those responsibilities shall be in writing and shall be maintained.

8.2.3 *Personnel*—It is the responsibility of the organization to establish personnel qualifications and training requirements for all positions. Each member of the organization shall possess the education, training, technical knowledge, and experience, or a combination thereof, which enables that individual to perform his or her assigned functions. Personnel qualifications shall be documented in terms of education, experience, and training. Training shall be provided for all staff members, as necessary, so that they can perform their functions properly.

8.2.4 *Subcontractors*— The use of subcontractors shall not jeopardize data quality. Subcontractors shall therefore comply with the requirements of Sections 7 and 8, as appropriate to the specific task(s) they are performing.

8.3 *Facilities:*

8.3.1 *General*—Each laboratory shall be of a size and construction suitable to facilitate proper conduct of the analyses. Adequate bench space or working area per analyst shall be provided. The space requirement per analyst depends on the equipment or apparatus being used, the number of samples the analyst is expected to handle at any one time, and the number of operations to be performed concurrently by a single analyst. The laboratory shall be well-ventilated, adequately lit, free of dust and drafts, protected from extreme temperatures, and offer access to a stable source of power. Laboratories shall be designed so that there is adequate separation of functions in order to ensure that no laboratory activity has an adverse effect on the analyses. The laboratory may require specialized facilities such as a perchloric acid hood or glovebox.

8.3.2 *Sample Handling, Receiving, and Storage Area*—As necessary to ensure safe and secure storage and prevent contamination or misidentification, there shall be adequate facilities for the receipt and storage of samples. The level of custody required and any special requirements for storage, such as refrigeration and lighting, shall be described in the planning documents.

8.3.3 *Chemical Storage*— Storage areas for reagents, solvents, standards, and reference materials shall be adequately safe to preserve their identity, concentration, purity, and stability.

8.3.4 *Laboratory Operations Area*—Separate spaces for laboratory operations and appropriate ancillary support shall be provided, as necessary, for the performance of routine and specialized procedures.

8.3.5 *Waste Storage Area*—Adequate facilities shall be provided for the collection and storage of all wastes, and these facilities shall be operated so as to minimize environmental

contamination. Waste storage and disposal facilities shall comply with applicable federal, state, and local regulations.

8.3.6 *Data Storage Area*—Space shall be provided for the storage and retrieval of all documents, as specified in 8.8. The storage environment shall be maintained to assure the integrity of the materials stored. Access shall be limited to authorized personnel only.

8.4 *Equipment and Instrumentation:*

8.4.1 *Equipment and Instrumentation*—Equipment and instrumentation shall meet the requirements and specifications of the specific test methods and other SOPs. The laboratory shall maintain an equipment and instrument description list that includes the manufacturer, model number, year of purchase, accessories, and any modifications, updates, or upgrades that have been made.

8.4.2 *Maintenance and Calibration of Equipment and Instrumentation*—Equipment and instrumentation shall be adequately inspected, cleaned, maintained, tested, and calibrated, as required in the SOP or operations manual. SOPs or manuals shall specify the identification and repair of common maintenance problems. Procedures shall designate a person(s) or organizations responsible for maintenance. Records of all inspections, maintenance, repairs, testing, and calibration shall be maintained.

8.5 *Standard Operating Procedures*—The laboratory should have written SOPs for all laboratory functions that affect data quality. Procedures and methods shall be performed in the laboratory as described in the SOPs. Any modification of an SOP made during a data collection activity must be documented. SOPs shall be available for the following areas and shall, at a minimum, contain the information described:

8.5.1 *Sample Management*—These SOPs describe the receipt, handling, and storage of samples.

8.5.1.1 *Sample Receipt and Handling*—These SOPs describe precautions to be used in opening sample shipment containers, as well as procedures used to perform the following tasks: verify that chain-of-custody has been maintained, examine samples for damage, check for proper preservatives and temperature, assign the testing program, and log samples into the laboratory sample streams.

8.5.1.2 *Sample Scheduling*—These SOPs describe procedures and criteria used for scheduling work in the laboratory, including procedures used to ensure that holding time requirements are met.

8.5.1.3 *Sample Storage*— These SOPs describe the storage conditions for all samples and procedures used both to verify and document daily storage temperature, and to ensure that custody of the samples is maintained while in the laboratory.

8.5.2 *Reagent and Standard Preparation*—These SOPs detail procedures used to prepare standards and reagent mixtures. In addition, these SOPs shall specify requirements concerning the following: purity of materials used, including water; appropriate glassware and containers; record keeping and labeling, including dating; procedures used to verify concentration, purity, and stability; and safety precautions necessary to meet the requirements of the DQOs or test methods.

8.5.3 *General Laboratory Techniques*—These SOPs detail all of the essentials of laboratory operations not addressed in other SOPs. These techniques include, but are not limited to, glassware cleaning procedures, operation of analytical balances, pipetting techniques, and use of volumetric glassware.

8.5.4 *Analytical Methods*—SOPs for analytical methods for sample analysis shall be a description of how the analysis is actually performed in the laboratory and not a simple reference to standard test methods, unless the analysis is performed exactly as described in the published test method. If possible, industry-recognized test methods from source documents published by the U.S. Environmental Protection Agency, American Public Health Association, ASTM, the National Institute for Occupational Safety and Health, or other recognized organizations should be used. The SOP for analytical methods should include the following:

8.5.4.1 Sample preparation and analysis procedures, including the applicable holding time, extraction, digestion, or preparation steps, as appropriate to the method; procedures for determining the appropriate dilution to analyze; and any other information required to perform the analysis accurately and consistently.

8.5.4.2 Instrument standardization, including the concentration and frequency of analysis of calibration standards, linear range of the method, and calibration acceptance criteria.

8.5.4.3 Raw data recording requirements and documentation, including the sample identification number, analyst, data verification analyst, date of analysis and verification, and computational method(s).

8.5.4.4 Detection and reporting limits for all analytes in the method.

8.5.4.5 Reference to the applicable QC SOPs and any specific exceptions or additions.

8.5.5 *Equipment Calibration and Maintenance*—These SOPs describe procedures used to assure or verify that the laboratory equipment and instrumentation are in working order. The SOPs describe calibration and maintenance procedures and schedules, maintenance logs, service contracts or service arrangements for all equipment, and spare parts available in-house. Calibration and maintenance of the laboratory equipment and instrumentation shall be in accordance with manufacturers' specifications and shall be documented.

8.5.6 *Quality Control Data*—These SOPs detail the type, purpose, and frequency of QC samples analyzed in the laboratory and establish acceptance criteria. They should include information on applicability of the QC sample to the analytical process, statistical treatment of the data, and responsibility of laboratory staff and management in generating and using the data.

8.5.7 *Corrective Action*—These SOPs describe procedures used to identify and correct deficiencies in the analytical process. These include specific steps to take in correcting deficiencies, such as the preparation of new standards and reagents, recalibration and restandardization of equipment, reanalysis of samples, or additional training of laboratory personnel in methods and procedures. The SOP shall specify

that each corrective action must be documented with a description of the deficiency, corrective action taken, and person(s) responsible for implementing the corrective action.

8.5.8 *Data Reduction and Validation*—These SOPs describe the procedures used to review and validate the data. They should include procedures for computing and interpreting the results from QC samples and procedures used to verify independently that the analytical results are correct. In addition, routine procedures used to monitor precision and bias, including evaluations of reagent, field, and trip blanks, calibration standards, control samples, duplicate and matrix spike samples, and surrogate recovery should be detailed in an SOP.

8.5.9 *Reporting*—These SOPs describe the process for reporting the analytical results.

8.5.10 *Records Management*—These SOPs describe the procedures for generating, controlling, and archiving laboratory records. The SOPs should detail the responsibilities for record generation and control and the policies for record retention, including type, time, security, and retrieval and disposal authorities. Records shall include project-specific and laboratory operations records.

8.5.10.1 Project-specific records related to analyses performed for a group of samples shall be maintained. These records may include an index of documents, correspondence, chain-of-custody records, request for analysis, calibration records, raw and finished analytical and QC data, data reports, and project planning documents.

8.5.10.2 Laboratory operations records, which document the overall laboratory operation, shall be maintained. These records may include the following: laboratory notebooks, instrument performance and maintenance logs in bound notebooks with prenumbered pages; laboratory benchsheets; software documentation; control charts; reference material certification; personnel files; laboratory SOPs; and corrective action reports.

8.5.11 *Waste Disposal*—These SOPs describe policies and procedures for the disposal of chemicals, including standard and reagent solutions, process waste, and samples. The disposal of these materials shall conform to federal, state, and local regulations, including those associated with the Resource Conservation and Recovery Act, Superfund Act Reauthorization and Amendments, Department of Transportation, and Occupational Safety and Health Administration.

8.5.12 *Health and Safety*—These SOPs describe policies and procedures designed both to provide a safe and healthy working environment for laboratory staff and to comply with federal and state regulations.

8.6 *Laboratory Quality Assurance and Quality Control Procedures:*

8.6.1 *Quality Assurance Program Plan*—The laboratory shall have a written QAPP that describes the organization's QA policy. The plan shall specify the responsibilities of the laboratory staff and management and the QA function in the areas of QA and QC and describe the QC procedures followed by the laboratory, including the following: (*1*) use of control samples; (*2*) statistical and mathematical basis for assigning warning and rejection limits; (*3*) detection of shifts, trends, or biases; (*4*) how an out-of-control condition is detected; (*5*) how control is re-established; (*6*) how out-of-control events and corrective actions are documented; (*7*) how reporting limits are established, including their dependence on serial dilutions and sample size; (*8*) how instrument calibration and maintenance logs, corrective action reports, and routine QC data summaries are maintained; and (*9*) QA assessment procedures used (see EPA QAMS-004/80 for an example).

8.6.2 *Quality Assurance Project Plan*—Some projects, particularly those that are large or complex, require a QAPjP. The QAPjP details the QA and QC goals and protocol for a specific data collection activity in order to ensure that the data generated by sampling and analysis activities are of quality commensurate with their intended use. QAPjP elements should include a discussion of the quality objectives of the project, identification of those involved in data collection and their responsibilities and authorities, enumeration of QC procedures to be followed, and reference to the specific SOPs that will be followed for all aspects of the project. Elements may be added or removed, as required by the project or the end-user of the data (see EPA QAMS-005/80 for an example).

8.6.3 *Method Proficiency*—The laboratory shall have procedures for demonstrating proficiency with each analytical method used in the laboratory. These shall include procedures for demonstrating the precision and bias of the method as performed by the laboratory and procedures for determining the method detection limit (MDL). All terminology, procedures, and frequency of determinations associated with the laboratory's establishment of one MDL and the reporting limit shall be well-defined and well-documented. Documented precision, bias, and MDL information shall be maintained for all methods performed in the laboratory.

8.6.4 *Laboratory Control Procedures*—The laboratory shall have procedures for demonstrating that it is in control within laboratory established limits or project specified limits during each data collection activity.

8.6.4.1 *Laboratory Control Samples*—The laboratory shall analyze control samples for each analytical method. A laboratory control sample consists of a control matrix spiked with analytes representative of the target analytes. Laboratory control sample(s) shall be analyzed with each batch of samples processed in order to verify the precision and bias of the analytical process. The results of the laboratory control sample(s) are compared to the control limits established for both precision and bias to determine the usability of the data (see 8.6.6). Analytical data generated with laboratory control samples that fall within the prescribed limits are judged to be generated while the laboratory was in control. Data generated with laboratory control samples that fall outside of the established control limits are judged to be generated during an "out of control" situation. These data are considered suspect and must be repeated or reported with qualifiers.

8.6.4.2 *Method Blank*—To assess contamination levels in the laboratory, a method blank shall be run with each batch of samples processed, unless it is not appropriate for the method. The laboratory shall have guidelines in place for accepting or rejecting data based on the level of blank contamination.

8.6.5 *Determination of Matrix Effects*—The laboratory shall have procedures for documenting the effect of the matrix on method performance. The type of matrix-specific information required for a specific data collection activity is dependent on the DQOs of the activity.

8.6.5.1 *Matrix Spikes*—Procedures shall be in place for determining the bias of the method in the matrix unless not appropriate for the method. These procedures should include the analysis of matrix spikes, use of surrogates for organic methods, and method of standard additions for metal and inorganic methods. The frequency of use of these techniques shall be based on the DQOs of the data collection activity.

8.6.5.2 *Matrix Duplicates and Matrix Spike Duplicates*—Procedures shall be in place for determining the precision of the method in the matrix. These procedures should include the analysis of matrix duplicates or matrix spike duplicates, or both. The frequency of use of these techniques shall be based on the DQOs of the data collection activity.

8.6.5.3 *Sample-Specific Detection Limit*—Procedures shall be in place for determining the MDL in a specific sample or group of samples. The frequency of use of these procedures shall be based on the DQOs of the data collection activity.

8.6.6 *Procedures for Establishing Control Limits:*

8.6.6.1 Procedures shall be in place for establishing and updating the control limits for analysis control. Control limits shall be established in order to evaluate laboratory precision and bias based on the analysis of control samples (see 8.6.4.1). Control limits for bias are typically based on the historical mean recovery plus or minus three standard deviation units, and control limits for precision range from zero (no difference between duplicate control samples) to the historical mean relative percent difference plus three standard deviation units.

8.6.6.2 Procedures shall be in place for monitoring historical performance, and they should include graphical (control charts) or tabular presentations of the data.

8.6.7 *Deviations*—Any activity not performed in accordance with laboratory SOPs or project planning documents is considered a deviation from the plan. Deviations from the plan may or may not affect data quality. All deviations from the plan shall be documented as to the extent of, and reason for, the deviation.

8.6.8 *Corrective Action*—Errors, deficiencies, deviations, or laboratory events or data that fall outside of the established acceptance criteria require investigation. Corrective action may be necessary in some instances to resolve the problem and to restore proper functioning to the analytical system. Investigation of the problem and any subsequent corrective action taken shall be documented.

8.6.9 *Data Handling Procedures:*

8.6.9.1 *Data Reduction*— Data resulting from the analyses of samples are reduced according to protocol described in the laboratory SOPs. Computer programs used for data reduction shall be validated before use and verified on a regular basis. All information used in the calculations shall be recorded in order to enable reconstruction of the final result at a later date. This information may include the weight or volume of sample used, percent dry weight for solids, extract volume, dilution factor used, and blank- or background-correction protocol followed.

8.6.9.2 *Data Review*— All data are reviewed by a second analyst or supervisor according to laboratory SOPs in order to ensure that calculations are correct and to detect transcription errors. Spot checks are performed on computer calculations to verify program validity. Errors detected in the review process are referred back to the analyst(s) for corrective action.

8.6.9.3 *Data Reporting*— Data are reported in accordance with the requirements of the end-user. The data report may include the following:

(1) Laboratory name and address;

(2) Sample information (including unique sample identification, sample collection date and time, date of sample receipt, and date(s) of sample preparation and analysis);

(3) Analytical results reported with appropriate significant figures;

(4) Detection limits that reflect dilutions, interferences, or correction for equivalent dry weight;

(5) Method reference;

(6) Appropriate QC results as described in 8.6.4 and 8.6.5; and

(7) Data qualifiers with appropriate references and narrative on the quality of the results.

8.7 *Quality Assurance Review:*

8.7.1 *General*—The QA program shall provide for routine evaluations of the effectiveness of laboratory QA and QC procedures and conformance of the laboratory to these procedures. These evaluations can be performed by persons internal or external to the organization and can involve on-site evaluations or performance evaluation studies, or both.

8.7.1.1 *Internal Assessment*—The analyst is responsible for continually monitoring individual compliance with the QA and QC programs. In addition, on some frequent basis, the QA officer, or an appropriate management designee, must review the laboratory data and operations for compliance with the QA and QC programs. The results of the internal assessment should be reported to management with requirements for a plan to correct observed deficiencies.

8.7.1.2 *External Assessment*—The laboratory should periodically be subject to evaluation by an assessor who is independent of the laboratory. This may be a representative of a government agency or other independent organization. The results of the external assessment should be submitted to management with requirements for a plan to correct the observed deficiencies.

8.7.1.3 *On-Site Evaluation*—On-site evaluations should be conducted as part of both internal and external assessments. An on-site evaluation includes a complete evaluation of the facilities, staff, instrumentation, SOPs, analytical methods, sample management procedures, and QA and QC policies and procedures as they relate to the generation of data for specific analytical and regulatory applications. Records of each evaluation shall be maintained by the laboratory. These records should include the date of the evaluation, area(s) or analyses inspected, person performing the evaluation, findings and problems, actions recommended and taken to resolve existing problems, and scheduled date for re-inspection. Any problems identified during the course of an on-site evaluation that are

likely to affect data integrity shall be brought to the attention of management immediately.

8.7.1.4 *Performance Evaluation Studies*—Performance evaluation (PE) studies are used to measure the performance of the laboratory on unknown samples. PE samples are typically submitted to the laboratory as blind samples by an independent, outside source. The results are compared to predetermined acceptance limits set by the submitting agency. PE samples can also be submitted to the laboratory by the laboratory QA officer or an appropriate management designee as part of an internal assessment of laboratory performance. Records of all PE studies shall be maintained by the laboratory. Problems identified as a result of participation in PE studies shall immediately be investigated and corrected.

8.7.2 *Evaluation of Laboratory Data*—The evaluation of laboratory data shall be conducted by one or more persons knowledgeable in laboratory activities. Such evaluations often occur in the QA section of the laboratory. Data evaluation should include the following subjects:

8.7.2.1 *Completeness of Laboratory Data*—This ensures that (*1*) all samples and analyses required by the project planning documents have been processed, (*2*) complete records exist for each analysis and the associated QC samples, and (*3*) the procedures specified in project planning documents and SOPs have been implemented. The results of the completeness check should be documented.

8.7.2.2 *Evaluation of Data with Respect to Detection Limits*—Analytical results should be compared to required detection limits. Any detection limits that exceed regulatory limits or action levels, as specified in the project planning documents, should be identified.

8.7.2.3 *Evaluation of Data with Respect to Control Limits*—The results of QC and calibration check samples should be compared to control criteria. Data not within the control limits require corrective action, and reviewers should check that both corrective action reports and the results of reanalysis are available. Samples associated with out-of-control QC data should be identified in a written record or the data review, and an assessment of the utility of such analytical results should be recorded.

8.7.2.4 *Review of Holding Time Data*—Sample holding times should be compared to those required by the project planning documents, and all deviations should be noted.

8.7.2.5 *Evaluation of Performance Evaluation Results*—PE study results can be helpful in evaluating the impact of out-of-control conditions. Recurring trends or problems evident in PE studies should be documented in the review, and their effect on environmental data should be evaluated.

8.7.2.6 *Correlation of Laboratory Data*—The results of data obtained from related laboratory tests, such as purgeable organic hallides (POX) and volatile organics, shall be documented and the significance of differences discussed in the review reports.

8.7.3 *Quality Assurance Reports to Management*—The QA program shall provide for the periodic reporting of pertinent QA and MQC information to management in order to allow management to assess the overall effectiveness of the QA program. Three examples of QA reports to management are as follows:

8.7.3.1 *Report on Measurement Quality Indicators*—This report should include the assessment of QC data gathered over the period, the frequency of analyses repeated due to unacceptable QC performance, and, if possible, the reason for the unacceptable performance and corrective action taken.

8.7.3.2 *Report on Quality Assurance Assessments*—This report should be submitted immediately following any internal or external on-site evaluation or upon receipt of the results of any PE studies. The report should include the results of the assessments and the plan for correcting the identified deficiencies.

8.7.3.3 *Report on Key Quality Assurance Activities During the Period*—A report summarizing key QA activities during the period should be delivered to management. The report should stress measures that are being taken to improve data quality and include a summary of the significant quality problems observed and corrective actions taken. The report should also include a summary of any changes in certification and accreditation status; involvements in the resolution of quality issues with clients or agencies; QA organizational changes; and notice of the distribution of revised documents controlled by the QA organization (that is, SOPs, QAPP).

8.8 *Laboratory Records:*

8.8.1 All information relevant to environmental QA and QC activities relating to laboratory facilities, equipment, personnel, methods, and practices shall be documented. Copies of the SOPs, and the equipment manuals provided by the manufacturer, shall be accessible in the workplace.

8.8.2 Handwritten test data shall be recorded legibly in ink in laboratory notebooks or on designated benchsheets. Each page shall be signed and dated by the person who performed the analysis and entered the data. Corrections shall be made by drawing a single line through the information to be changed and initialling and dating the change. The reason for the change shall be indicated.

8.8.3 Strip-chart recorder printouts shall be signed by the person who performed the instrumental analysis. If corrections need to be made in computerized data, a system parallel to the corrections for handwritten data shall be in place.

8.8.4 Records of sample management shall be available to permit the re-creation of an analytical event for review in the case of an audit or investigation of a dubious result.

8.8.5 *Personnel Training and Qualification Records*—It is the responsibility of the organization to establish personnel qualifications and training requirements. Each staff member shall possess the education, training, technical knowledge, and experience, or a combination thereof, to enable that individual to perform his or her assigned functions. Personnel qualifications shall be documented in terms of education, experience, and training. Training shall be provided for all staff members so that they can perform their functions properly.

8.8.6 *Standard Operating Procedures*—SOPs shall be written and available for all methods and practices.

8.8.7 *Quality Assurance Plans*—The QAPP and all applicable QAPjPs shall be on file.

8.8.8 *Equipment Maintenance*—Maintenance and performance logs shall be kept on all equipment and instrumentation and must include the following: (*1*) name of the equipment and manufacturer; (*2*) model and serial number of the equipment; (*3*) date the equipment was placed in service; (*4*) instructions for proper maintenance procedures; (*5*) dates of the maintenance and performance checks and the names of personnel performing them; and (*6*) if nonroutine repairs were performed as a result of a malfunction, nature and cause of the malfunction, and name of the person performing the repair.

8.8.9 *Proficiency*— Proficiency information on all parameters reported shall be maintained and shall include the following: (*1*) precision; (*2*) bias; (*3*) method detection limits; (*4*) spike recovery, where applicable; (*5*) surrogate recovery, where applicable; (*6*) checks on reagent purity, where applicable; and (*7*) checks on glassware cleanliness, where applicable.

8.8.10 *Traceability*— Traceability of standards, reagents, and weights shall be documented, with the traceability to national or international sources indicated.

8.8.11 *Calibration*— Calibration and standardization data records for each instrument and method shall include the following: (*1*) data of the last calibration; (*2*) calibration history; (*3*) frequency of calibration; (*4*) outside sources of calibration, if used, for example, the manufacturer; (*5*) date of preparation, expiration date, and name of the person performing the preparation of standards; and (*6*) written procedures for instrument calibration.

8.8.12 *Sample Management*—All required records pertaining to sample management shall be maintained and updated regularly. These include chain-of-custody forms, sample receipt forms, and sample disposition records.

8.8.13 *Original Data*—The raw data and calculated results for all samples shall be maintained in laboratory notebooks and logs, benchsheets, files, and other sample tracking or data entry forms. Instrumental output shall be stored in a computer file or a hardcopy report.

8.8.14 *Quality Control Data*—The raw data and calculated results for all QC and field samples and standards shall be maintained in the manner described in 8.8.13. QC samples include, but are not limited to, control samples, method blanks, matrix spikes, and matrix spike duplicates.

8.8.15 *Correspondence*—Project correspondence can provide evidence supporting technical interpretations. Correspondence pertinent to the project shall be kept and placed in the project files.

8.8.16 *Final Report*—A copy of the final report submitted to the sponsor of the work, or other designated individual, shall be retained.

8.9 *Document Storage:*

8.9.1 A written policy concerning the minimum length of time that documentation is to be retained shall be in place and understood by the appropriate personnel, including the sponsor of the work. Deviations from this policy shall be documented and readily available to those individuals responsible for the deletion or destruction of expired documentation.

8.9.2 Documentation shall be stored securely in a facility that adequately addresses or minimizes its deterioration for the length of time it is to be retained. A system allowing for the expedient retrieval of information shall exist.

8.9.3 Access to archived information shall be controlled to restrict unauthorized personnel from having free and open access. An authorized access list shall be prepared and shall name the personnel who have unrestricted access to the archived information.

8.9.4 All accesses to archived information shall be documented. This documentation shall include the name of the individual, date, reason for accessing the data, and all changes, deletions, or withdrawals that may have occurred.

8.9.5 If a facility conducting testing or an archive contract facility goes out of business before the time period specified in the policy (8.9.1), all documentation shall be transferred in whole to the archives of the sponsor of the work.

9. Data Quality Assessment

9.1 The assessment of environmental data occurs in two phases. Field records and analytical data are reviewed during the first phase to identify whether the data are accurate and defensible. The data are interpreted in the second phase with respect to meeting DQOs.

9.2 Technical reports of environmental data collection efforts should summarize the information contained in the field records and the results of the laboratory data review, as described in 7.7.2 and 8.7.2. This information should be used to identify clearly the data that are not representative of environmental conditions or that have been generated using poor field or laboratory practices.

9.3 The combined field and laboratory data are then subject to a final assessment to determine whether the DQOs have been met. Although the data quality assessment process is beyond the scope of this practice, a general description of the items that should be considered in the assessment process is given below.

9.4 Data quality assessment typically includes, but is not limited to the following:

9.4.1 Evaluation of field duplicate results;

9.4.2 Comparison of the results of all field blanks, trip blanks, and equipment rinsates, with the full data set to provide information concerning contaminants that may have been introduced during sampling or shipping;

9.4.3 Evaluation of matrix effects to assess performance of the analytical method with respect to the sample matrix and determine whether the data have been biased high or low due to matrix effects;

9.4.4 Integration of the field and laboratory data with geological, hydrogeological and meteorological data to provide information on the extent of contamination; and

9.4.5 Comparison of precision, bias, completeness, representativeness, and defensibility of the data generated with that required to meet the DQOs.

APPENDIXES

(Nonmandatory Information)

X1. TABLE OF CONTENTS

X2. REFERENCE LIST

X2.1 *ASTM Standards*: [2]

D1192 Specification for Equipment for Sampling Water and Steam in Closed Conduits

D1357 Practice for Planning the Sampling of the Ambient Atmosphere

D2777 Practice for Determination of Precision and Bias of Applicable Methods of Committee D19 on Water

D3370 Practices for Sampling Water from Closed Conduits

D3614 Guide for Laboratories Engaged in Sampling and Analysis of Atmospheres and Emissions

D3670 Guide for Determination of Precision and Accuracy of Methods of Committee D22

D3694 Practices for Preparation of Sample Containers and for Preservation of Organic Constituents

D3856 Guide for Evaluating Good Laboratory Practices in Laboratories Engaged in Sampling and Analysis of Water

D4210 Practice for Interlaboratory Quality Control Procedures and a Discussion on Reporting Low-Level Data[5]

D4411 Guide for Sampling Fluvial Sediment in Motion

D4447 Guide for Disposal of Laboratory Chemicals and Samples

D4448 Guide for Sampling Groundwater Monitoring Wells

D4489 Practice for Sampling of Waterborne Oils

D4687 Guide for General Planning of Waste Sampling

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E122 Practice for Calculating Sample Size to Estimate, With a Specified Tolerable Error, the Average for Characteristic of a Lot or Process

E178 Practice for Dealing with Outlying Observations

X2.2 *U.S. Environmental Protection Agency Documents*:[4] *A Compendium of Superfund Field Operations Methods*, EPA/540/P-87/001 (NTIS No. PB88181557/LL), December 1987.

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[5] Withdrawn.

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