

Quality Assurance Project Plan for the Federal Lead (Pb) Performance Evaluation Program – Appendices A Through C

U.S. Environmental Protection Agency Office of Air Quality Planning and Standards Research Triangle Park, NC

Quality Assurance Project Plan for the Federal Lead (Pb) Performance Evaluation Program Appendices A Through C

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Appendix A

Glossary

The following glossary contains terms commonly used in the Pb-PEP. All terms listed may not actually be used in this document.

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Glossary

Acceptance criteria—Specified limits that are placed on the characteristics of an item, process, or service defined in requirements documents (American Society of Quality Control definition).

Accuracy—This term refers to a measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; the U.S. Environmental Protection Agency (EPA) recommends using the terms "precision" and "bias," rather than "accuracy," to convey the information usually associated with accuracy.

Activity—This all-inclusive term describes a specific set of operations of 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.

Aerometric Information Retrieval System (AIRS)—See the Air Quality System (AQS).

American National Standards Institute (ANSI)—ANSI is the administrator and coordinator of the U.S. private-sector voluntary standardization system.

American Society for Testing and Materials (ASTM)—The ASTM is a professional organization that develops and distributes protocols for testing and provides reference standards.

Analyst—An analyst is a staff member who weighs the new and used filters and computes the concentration of PM_{2.5} in μ g/m³.

ANSI/ASTM Class 1 and 2 standards—These are the standards for weighing operations with a microbalance that is certified by their manufacturer as being in conformance with ASTM's standard specification for laboratory weights and precision mass standards (E 617-9), particularly the Class 1 and 2 specifications. These standards are traceable to the National Institute of Standards and Technology (NIST).

Air Quality System (**AQS**)—The AQS, which is EPA's repository of ambient air quality data, stores data from more than 10,000 monitors, 5,000 of which are currently active. State, local, and Tribal agencies collect monitoring data and submit it to the AQS periodically. The AQS was formerly the Air Quality Subsystem of the AIRS, which also contained an Air Facility System (AFS) that stored information on pollution sources. After the AFS was separated from AIRS, the terms AIRS and AQS became frequently used as synonyms to refer to the ambient air quality database.

AQS Monitor ID—This is a 10-digit combination of the AIRS Site ID and POC (see each in this glossary) that together uniquely defines a specific air sampling monitor for a given pollutant. Some forms and dialog boxes may refer to this as an AIRS ID or 10-digit AIRS ID.

AQS Site ID—This is a unique identifier for an AQS sampling site. The AQS Site ID is frequently combined with the Parameter Occurrence Code (POC) (see POC in this glossary) to provide a unique 10-digit monitor ID. The first nine digits uniquely identify each air monitoring site (two-digit state code,

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three-digit county code, and four-digit site code). The tenth digit (POC) identifies the monitor at that site. The state and county codes are Federal Information Processing Standard (FIPS) codes. The four-digit site codes are assigned by the local agency, which may allocate them in any way it chooses, as long as there is no duplication in the county. AQS Site IDs are associated with a specific physical location and address. Any significant change in location will typically require a new site ID.

Assessment—This term refers to the evaluation process that was used to measure the performance or effectiveness of a system and its elements. As used here, "assessment" is an all-inclusive term that is used to denote any of the following: an audit, a Performance Evaluation (PE), a management systems review (MSR), peer review, inspection, or surveillance.

Audit of Data Quality (ADQ)—A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

Audit (quality)—A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

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

Bias—The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Blank—A sample that is intended to contain none of the analytes of interest and is subjected to the usual analytical or measurement process to establish a zero baseline or background value. A blank is sometimes used to adjust or correct routine analytical results. A blank is used to detect contamination during sample handling preparation and/or analysis.

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

Calibration drift—The deviation in instrument response from a reference value over a period of time before recalibration.

Cassette—A device that is supplied with PM_{2.5} samplers to allow a weighed Teflon[®] filter to be held in place in the sampler and manipulated before and after sampling without touching the filter and to minimize damage to the filter and/or sample during such activities.

Certification—The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service, usually for a specified time.

Chain of custody—An unbroken trail of accountability that ensures the physical security of samples, data, and records.

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

Check standard—A standard that is prepared independently of the calibration standards and analyzed exactly like the samples. Check standard results are used to estimate analytical precision and to indicate the presence of bias due to the calibration of the analytical system.

Collocated samples—Two or more portions collected at the same point in time and space, so as to be considered identical. These samples are also known as "*field replicates*" and should be identified as such.

Comparability—A measure of the confidence with which one data set or method can be compared to another.

Completeness—A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions.

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 referred to as "software," or it may be stored permanently on computer chips, referred to as "firmware." Computer programs covered in a Quality Assurance Project Plan (QAPP) 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.

Conditioning environment—A specific range of temperature and relative humidity values in which unexposed and exposed filters are to be conditioned for at least 24 hours immediately preceding their gravimetric analysis.

Confidence interval—The numerical interval constructed around a point estimate of a population parameter, combined with a probability statement (the confidence coefficient) linking it to the population's true parameter value. If the same confidence interval construction technique and assumptions are used to calculate future intervals, then they will include the unknown population parameter with the same specified probability.

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

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

Conformance—An affirmative indication or judgment that a product or service has met the requirements of the relevant specification, contract, or regulation; also, the state of meeting the requirements.

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

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Contract Officer's Representative (COR)—The EPA Contract Officer designates this person as the responsible party for managing the work. Depending on the contract, the COR could be the Delivery Order Project Officer (DOPO), the Task Order Project Officer (TOPO), or the Work Assignment Manager (WAM).

Contractor—Any organization or individual contracting to furnish services or items or to perform work.

Control chart—A graphical presentation of quality control (QC) information over a period of time. If a procedure is "in control," the results usually fall within established control limits. The chart is useful in detecting defective performance and abnormal trends or cycles, which can then be corrected promptly.

Corrective action—Any measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

Correlation coefficient—A number between -1 and 1 that indicates the degree of linearity between two variables or sets of numbers. The closer to -1 or +1, the stronger the linear relationship between the two (i.e., the better the correlation). Values close to zero suggest no correlation between the two variables. The most common correlation coefficient is the product—moment, which is a measure of the degree of linear relationship between two variables.

Data of known quality—Data that have the qualitative and quantitative components associated with their derivation documented appropriately for their intended use; documentation is verifiable and defensible.

Data Quality Assessment (DQA)—The scientific and statistical evaluation of data to determine if data obtained from environmental operations are of the right type, quality, and quantity to support their intended use. The five steps of the DQA process include: 1) reviewing the Data Quality Objectives (DQOs) and sampling design, 2) conducting a preliminary data review, 3) selecting the statistical test, 4) verifying the assumptions of the statistical test, and 5) drawing conclusions from the data.

Data Quality Indicators (DQIs)—The quantitative statistics and qualitative 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, and accuracy (bias is preferred); comparability; completeness; and representativeness.

Data Quality Objectives (DQOs)—The qualitative and quantitative statements derived from the DQO process that clarify a study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Quality Objectives (DQO) Process—A systematic planning tool to facilitate the planning of environmental data collection activities. DQOs are the qualitative and quantitative outputs from the DQO process.

Data reduction—The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors and collating them into a more useful form. Data reduction is irreversible and generally results in a reduced data set and an associated loss of detail.

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Data usability—The process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

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

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

Design—The design refers to specifications, drawings, design criteria, and performance requirements, as well as the result of deliberate planning, analysis, mathematical manipulations, and design processes.

Design change—Any revision or alteration of the technical requirements defined by approved and issued design output documents and by approved and issued changes thereto.

Design review—A documented evaluation by a team, including personnel such as the responsible designers, the client for whom the work or product is being designed, and a quality assurance (QA) representative, but excluding the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Detection limit (DL)—A measure of the capability of an analytical method to distinguish samples that do not contain a specific analyte from samples that contain low concentrations of the analyte; the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated level of probability. DLs are analyte and matrix specific and may be laboratory dependent.

Distribution—This term refers to 1) the appointment of an environmental contaminant at a point over time, over an area, or within a volume; and 2) a probability function (density function, mass function, or distribution function) used to describe a set of observations (statistical sample) or a population from which the observations are generated.

Document—Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

Document control—The policies and procedures used by an organization to ensure that its documents and their revisions are proposed, reviewed, approved for release, inventoried, distributed, archived, stored, and retrieved in accordance with the organization's requirements.

Dry-bulb temperature—The actual temperature of the air, which is used for comparison with the wetbulb temperature.

Duplicate samples—Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method, including sampling and analysis (see also *collocated samples*).

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Electrostatic charge buildup—A buildup of static electrical charge on an item, such as the $PM_{2.5}$ filter, which makes it difficult to handle, attracts or repels particles, and can influence its proper weighing.

Environmental conditions—The description of a physical medium (e.g., air, water, soil, sediment) or a biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental data—Any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes, conditions, and effects of pollutants on human health and the environment, including results from laboratory analyses or from experimental systems representing such processes and conditions.

Environmental data operations—Any work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental monitoring—The process of measuring or collecting environmental data.

Environmental processes—Any manufactured or natural processes that produce discharges to, or that impact, the ambient environment.

Environmental programs—An all-inclusive term that pertains to any work or activities involving the environment, including but not limited to, the characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

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

Equilibration chamber—A clean chamber that is usually constructed of plastic or glass, held at near constant temperature and relative humidity, and is used to store and condition PM_{2.5} filters until they and their collected particulate sample (if the filters have been exposed) have reached a steady state of moisture equilibration.

Estimate—A characteristic from the sample from which inferences on parameters can be made.

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

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

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Field blank—A blank that provides information about contaminants that may be introduced during sample collection, storage, and transport. A clean sample is carried to the sampling site, exposed to sampling conditions, returned to the laboratory, and treated as an environmental sample.

Field blank filter—New, randomly selected filters that are weighed at the same time that presampling weights are determined for a set of PM_{2.5} filters and used for QA purposes. These field blank filters are transported to the sampling site in the same manner as the filter(s) intended for sampling, installed in the sampler, removed from the sampler without sampling, stored in their protective containers inside the sampler's case at the sampling site until the corresponding exposed filter(s) is (are) retrieved, and returned for postsampling weighing in the laboratory, where they are handled in the same way as an actual sample filter and reweighed as a QC check to detect weight changes due to filter handling.

Field (matrix) spike—A sample prepared at the sampling point (i.e., in the field) by adding a known mass of the target analyte to a specified amount of the sample. Field matrix spikes are used, for example, to determine the effect of the sample preservation, shipment, storage, and preparation on analyte recovery efficiency (the analytical bias).

Field split samples—Two or more representative portions taken from the same sample and submitted for analysis to different laboratories to estimate inter-laboratory precision.

File plan—A file plan lists the records in your office, and describes how they are organized and maintained. For more information about EPA's File Plan Guide, see http://www.epa.gov/records/tools/toolkits/filecode (see also *records schedule*).

Filter chamber assembly—As shown in Figures 5.6 and 5.7 in this Performance Evaluation Program (PEP) Field Standard Operating Procedure (SOP), this is referencing the mechanism in the interior of the BGI main unit. This assembly contains the WINS impactor assembly in the upper half and the filter cassette or holder assembly in the lower half.

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

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

Global Positioning System (GPS)—A space-based global navigation satellite system that provides location and time information in all weather, anywhere on or near the Earth, where there is an unobstructed line of sight to four or more GPS satellites. It is maintained by the United States government and is freely accessible by anyone with a GPS receiver.

Goodness-of-fit test—The application of the chi square distribution in comparing the frequency distribution of a statistic observed in a sample with the expected frequency distribution based on some theoretical model.

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

Graded approach—The process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results (see also *Data Quality Objectives (DQO) Process*).

Guidance—A suggested practice that is not mandatory; it is intended to be an aid or example in complying with a standard or requirement.

Guideline—A suggested practice that is not mandatory in programs intended to comply with a standard.

Hazardous waste—Any waste material that satisfies the definition of hazardous waste given in 40 CFR 261, *Identification and Listing of Hazardous Waste*.

High-efficiency particulate air (HEPA) filter—A HEPA filter is an extended-media, dry-type filter with a minimum collection efficiency of 99.97% when tested with an aerosol of essentially monodisperse 0.3- μ m particles.

Holding time—The period of time a sample may be stored prior to its required analysis. Although exceeding the holding time does not necessarily negate the veracity of analytical results, it causes the qualifying or "flagging" of any data not meeting all of the specified acceptance criteria.

Hygrothermograph—An instrument that results from the combination of a thermograph and a hygrograph and furnishing, on the same chart, simultaneous time recording of ambient temperature and relative humidity.

Identification error—The misidentification of an analyte. In this error type, the contaminant of concern is unidentified and the measured concentration is incorrectly assigned to another contaminant.

Independent assessment—An assessment that is 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—The examination or measurement of an item or activity to verify conformance to specific requirements.

Internal standard—A standard added to a test portion of a sample in a known amount and carried through the entire determination procedure as a reference for calibrating and controlling the precision and bias of the applied analytical method.

Item—An all-inclusive term that is 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.

Laboratory analyst—The generic term used to describe the Environmental Sampling and Assistance Team (ESAT) contractor(s) responsible for the activities described in the SOPs.

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Laboratory blank filters—New filters that are weighed at the time of determination of the presampling (tare) weight of each set of $PM_{2.5}$ filters intended for field use. These laboratory blank filters remain in the laboratory in protective containers during the field sampling and are reweighed in each weighing session as a QC check.

Laboratory split samples—Two or more representative portions taken from the same sample and analyzed by different laboratories to estimate the inter-laboratory precision or variability and the data comparability.

Limit of quantitation—The minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit and within specified limits of precision and bias during routine analytical operating conditions.

Local Standard Time—The time used in the geographic location of the sample site that is set to standard time. Standard time is used in the Federal Reference Method (FRM) program to match continuous instruments to filter-based instruments. During the winter months, all areas of the country use standard time; however, in the summer months, some areas may go to Daylight Saving Time (1 hour ahead of standard time).

Management—Those individuals who are directly responsible and accountable for planning, implementing, and assessing work.

Management system—A structured, nontechnical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management Systems 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.

Mass reference standard—The NIST-traceable weighing standards, generally in the range of weights expected for the filters.

Matrix spike—A sample that is prepared by adding a known mass of a target analyte to a specified amount of matrix sample for which an independent estimate of the target analyte concentration is available. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

May—When used in a sentence, this term denotes permission but not a necessity.

Mean squared error—A statistical term for variance added to the square of the bias.

Mean (arithmetic)—The sum of all the values of a set of measurements divided by the number of values in the set; a measure of central tendency.

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Measurement and Testing Equipment (M&TE)—Tools, gauges, instruments, sampling devices, or systems used to calibrate, measure, test, or inspect to control or acquire data to verify conformance to specified requirements.

Memory effects error—The effect that a relatively high concentration sample has on the measurement of a lower concentration sample of the same analyte when the higher concentration sample precedes the lower concentration sample in the same analytical instrument.

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.

Method blank—A blank that is prepared to represent the sample matrix as closely as possible and analyzed exactly like the calibration standards, samples, and QC samples. Results of method blanks provide an estimate of the within-batch variability of the blank response and an indication of bias introduced by the analytical procedure.

Microbalance—A type of analytical balance that can weigh to the nearest 0.001 μ g (i.e., one microgram, or one-millionth of a gram).

Mid-range check—A standard used to establish whether the middle of a measurement method's calibrated range is still within specifications.

Mixed waste—A hazardous waste material as defined by 40 CFR 261 and the Resource Conservation and Recovery Act (RCRA) and mixed with radioactive waste subject to the requirements of the Atomic Energy Act.

Must—When used in a sentence, this term denotes a requirement that has to be met.

Nonconformance—A deficiency in a characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

Objective evidence—Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

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

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

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

Outlier—An extreme observation that is shown to have a low probability of belonging to a specified data population.

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Parameter—A quantity, usually unknown, such as a mean or a standard deviation characterizing a population. Commonly misused for "variable," "characteristic," or "property."

Pb-PM₁₀—Low-volume PM₁₀ sampling using a 46.2-mm Teflon filter for determining lead (Pb) concentration.

Pb-TSP—High-volume sampling of total suspended particles (TSP) using a 8x10-inch glass fiber filter for determining lead (Pb) concentration.

Peer review—A documented, critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. Conducted by qualified individuals (or an organization) who are independent of those who performed the work but collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. Peer reviews are conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. 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 (PE)—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.

PM_{2.5}—Particulate matter (suspended in the atmosphere) having an aerodynamic diameter less than or equal to a nominal 2.5 μ m, as measured by a reference method based on 40 CFR Part 50, Appendix L, and designated in accordance with 40 CFR Part 53.

PM_{2.5} **sampler**—A sampler that is used for monitoring PM_{2.5} in the atmosphere that collects a sample of particulate matter from the air based on principles of inertial separation and filtration. The sampler also maintains a constant sample flow rate and may record the actual flow rate and the total volume sampled. PM_{2.5} mass concentration is calculated as the weight of the filter catch divided by the sampled volume. A sampler cannot calculate PM_{2.5} concentration directly.

POC (**Parameter Occurrence Code**)—A one-digit identifier used in AIRS/AQS (see both defined in this glossary) to distinguish between multiple monitors at the same site that are measuring the same parameter (e.g., pollutant). For example, if two different samplers both measure PM_{2.5}, then one may be assigned a POC of 1 and the other a POC of 2. Note that replacement samplers are typically given the POC of the sampler that they replaced, even if the replacement is of a different model or type.

Pollution prevention—An organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge into the environment.

Polonium-210 (210 Po) antistatic strip—A device that contains a small amount of 210 Po that emits α particles (He²⁺) that neutralize the static charge on filters, making them easier to handle and their weights more accurate.

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Polytetrafluoroethylene (**PTFE**)—Also known as Teflon, this is a polymer that is used to manufacture the 46.2-mm diameter filters for PM_{2.5} FRM and Federal Equivalent Method (FEM) samplers.

Population—The totality of items or units of material under consideration or study.

Precision—A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions expressed generally in terms of the standard deviation.

Procedure—A specified way to perform an activity.

Process—A set of interrelated resources and activities that transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Project—An organized set of activities within a program.

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

Qualified data—Any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Quality—The totality of features and characteristics of a product or service that bears on its ability to meet the stated or implied needs and expectations of the user.

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

Quality Assurance Program Description/Plan—See Quality Management Plan.

Quality Assurance Project Plan (QAPP)—A formal document that describes in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QAPP components are divided into the following four classes: 1) Project Management, 2) Measurement/Data Acquisition, 3) Assessment/Oversight, and 4) Data Validation and Usability. Guidance and requirements on preparation of QAPPs can be found in *EPA*, *Requirements for Quality Assurance Project Plans, EPA QA/R-5* and *Guidance for Quality Assurance Project Plans, EPA QA/G-5*.

Quality Assurance (**QA**) **Supervisor or Coordinator**—A staff member who assists in preparation of the reporting organization's quality plan, makes recommendations to management on quality issues (including training), oversees the quality system's control and audit components, and reports the results.

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; operational techniques and activities that are used to fulfill requirements for quality. The system of activities and checks used to ensure that measurement systems

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are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring the results are of acceptable quality.

Quality control (QC) sample—An uncontaminated sample matrix that is spiked with known amounts of analytes from a source independent of the calibration standards. This type of sample is generally used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of all or a portion of the measurement system.

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 organization's structure, the functional responsibilities of management and staff, the lines of authority, and the required interfaces for those planning, implementing, and assessing all activities conducted.

Quality system—A structured and documented management system that describes 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 OA and OC.

Radioactive waste—This refers to waste material that contains or is contaminated by radionuclides and is subject to the requirements of the Atomic Energy Act.

Readability—The smallest difference between two measured values that can be read on the microbalance display. The term "*resolution*" is a commonly used synonym.

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.

Record (quality)—A document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

Records schedule—This schedule constitutes EPA's official policy on how long to keep Agency records (retention) and what to do with them afterwards (disposition). For more information, refer to http://www.epa.gov/records/policy/schedule on EPA's Web site or see *file plan*.

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Recovery—The act of determining whether the methodology measures all of the analyte contained in a sample.

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.

Repeatability—This refers to a measure of the ability of a microbalance to display the same result in repetitive weighings of the same mass under the same measurement conditions. The term "*precision*" is sometimes used as a synonym. Repeatability also refers to the degree of agreement between independent test results produced by the same analyst, using the same test method and equipment on random aliquots of the same sample within a short time period.

Reporting limit—The lowest concentration or amount of the target analyte required to be reported from a data collection project. Reporting limits are generally greater than detection limits and are usually not associated with a probability level.

Representativeness—A measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition.

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

Requirement—A formal statement of a need and the expected manner in which it is to be met.

Research (basic)—A process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

Research (applied)—A process, the objective of which is to gain the knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

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

Round-robin study—A method validation study involving a predetermined number of laboratories or analysts, all analyzing the same sample(s) by the same method. In a round-robin study, all results are compared and used to develop summary statistics such as inter-laboratory precision and method bias or recovery efficiency.

Ruggedness study—The carefully ordered testing of an analytical method while making slight variations in test conditions (as might be expected in routine use) to determine how such variations affect test results. If a variation affects the results significantly, the method restrictions are tightened to minimize this variability.

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Scientific method—The principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

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

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

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

Shall—A term that denotes a requirement is mandatory whenever the criterion for conformance with the specification permits no deviation. This term does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

Should—A term that denotes a guideline or recommendation whenever noncompliance with the specification is permissible.

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

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 requirement 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.

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

Span check—A standard used to establish that a measurement method is not deviating from its calibrated range.

Specification—A document that states requirements and refers to or includes drawings or other relevant documents. Specifications should indicate the means and criteria for determining conformance.

Spike—A substance that is added to an environmental sample to increase the concentration of target analytes by known amounts. Spikes are used to assess measurement accuracy (spike recovery), whereas spike duplicates are used to assess measurement precision.

Split samples—Two or more representative portions taken from one sample in the field or in the laboratory and analyzed by different analysts or laboratories. Split samples are QC samples that are used to assess analytical variability and comparability.

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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 deviation—A measure of the dispersion or imprecision of a sample or population distribution expressed as the positive square root of the variance and having the same unit of measurement as the mean.

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

Surrogate spike or analyte—A pure substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them to establish that the analytical method has been performed properly.

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

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

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

Traceability—This term refers to the ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. This term also refers to the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties. Many QA programs demand traceability of standards to a national standard. In most cases this can be achieved through a standard traceable to NIST.

Trip blank—A clean sample of a matrix that is taken to the sampling site and transported to the laboratory for analysis without having been exposed to sampling procedures.

Validation—Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. In design and development, validation refers to the process of examining a product or result to determine conformance to user needs.

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Variance (statistical)—A measure or dispersion of a sample or population distribution. Population variance is the sum of squares of deviation from the mean divided by the population size (number of elements). Sample variance is the sum of squares of deviations from the mean divided by the degrees of freedom (number of observations minus one).

Verification—Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification refers to the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

Wet-bulb thermometer—A thermometer with a muslin-covered bulb, which is moistened and used to measure the wet-bulb temperature.

Wet-bulb temperature—The temperature of the wet-bulb thermometer at equilibrium with a constant flow of ambient air at a rate of from 2.5 meters to 10.0 meters per second.

Wide Area Augmentation System (WAAS)—An air navigation aid developed by the Federal Aviation Administration to augment the Global Positioning System (GPS), with the goal of improving its accuracy, integrity, and availability.

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Appendix B

Training Certification Evaluation Forms

The following forms will be used by the PEP to certify the PM_{2.5} field and laboratory personnel have performed environmental data operations at a satisfactory level.

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| Trainee's Name | Date |
|----------------|-------------|
| | |

Field Performance Examination Checklist

| STANDARD OPERATING PROCEDURE | ACCEPT | RETEST |
|--|--------|--------|
| PEPF 2.1 Equipment Inventory | | |
| 1. General knowledge of the requirement for inventorying and procuring equipment | | |
| Notes: | | |
| | | |
| PEPF 2.2 Communications | | |
| General knowledge of the communication requirements | | |
| 2. Knowledge of the use of the phone communication form | | |
| 3. Knowledge of when, and how often to talk with the Reporting Organizations | | |
| 4. Knowledge of the monthly progress report and the expected information | | |
| Notes: | | |
| | | |
| | | |
| DEDE 2.2 Decrease 4 are for DED Courselling Franch | | |
| PEPF 2.3 Preparation for PEP Sampling Events | | |
| 1. Understanding of the requirements for the Site Data Sheet | | |
| 2. Knowledge of the appropriate days to sample and when it is possible to sample at a different schedule | | |
| 3. Procedure for site visit equipment preparation | | |
| 4. Knowledge of critical filter holding time requirements | | |
| Notes: | | |
| | | |
| | | |
| | | |

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| PEPF 3.1 Filer Receipt, Storage and Handling | |
|---|--|
| 1. Understands process required in receiving filters from OAQPS | |
| 2. Knowledge of procedure for storing filters at the field office during transport to the field and if samples must come back to the field office | |
| 3. Good knowledge of procedure for handling pre-exposed and exposed filters | |
| Notes: | |
| PEPF 4.1 Sampler Transport and Placement | |
| Field Scientist safely transports the transport boxes or sampler to the sampling location | |
| Notes: | |
| | |
| PEPF 5.1 Sampler Assembly/Disassembly | |
| Field Scientist properly assembles the unit [Overall] | |
| Field Scientist properly powers the unit | |
| Field Scientist properly set date/time | |
| Field scientist properly disassembled unit by storing components in correct transport cases | |
| Notes: | |
| | |
| | |
| | |

| PEPF 5.2 Leak Check Procedures | | |
|----------------------------------|--|--|
| 1. Sampler set up properly. | | |
| 2. Correct "screen." | | |
| 3. Conducts leak check properly. | | |
| 5. Data entry to form. | | |
| 6. Troubleshooting explanation. | | |
| Notes: | | |
| | | |

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| PEPF 5.3 Flow Rate Verification | |
|---|--|
| 1. Flow transfer standard correctly installed, zeroed and equilibrated. | |
| 2. Flow rate filter not used. | |
| 3. Correct sampler "screen." | |
| 4. Data entry to form. | |
| 5. Proper data review | |
| 6. Comparison of standard with sampler flow rate. | |
| 7. Comparison of standard with design flow rate. | |
| 8. Return to normal operation. | |
| 9. Troubleshooting explanation. | |
| Notes: | |
| | |
| | |
| | |
| | |
| DEDE 5 4 Recompeting Procesure Varification Check | |

| PEPF 5.4 Barometric Pressure Verification Check | | |
|---|--|--|
| 1. BP transfer standard equilibrated. | | |
| 2. Correct sampler "screen." | | |
| | | |
| 3. Data entry to form. | | |
| 4. Troubleshooting explanation. | | |
| Notes: | | |
| | | |
| | | |
| | | |

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| PEPF 5.5 Temperature Verification | | |
|--|--|--|
| 1. Temp. transfer standard equilibrated. | | |
| 2. Correct sampler "screen." | | |
| 3. Ambient T check done properly. | | |
| 4. Data entry to form. | | |
| 5. Troubleshooting explanation. | | |
| Notes: | | |
| PEPF 6.1 Conducting the Filter Exposure | | |
| 1. Install filter in sampler. Include inspection, documentation of filter ID, filter ID face down. | | |
| 2. Program to run sampler for the next day | | |
| Notes | | |
| PEPF 6.2 Sample Recovery and Data Download | | |
| 1. Record Information on Chain of Custody/Field Data Sheet from Run | | |
| 2. Remove from sampler and recover. Include inspection, any needed documentation, | | |
| 3. Download raw sampler data to flash media and save on laptop computer. Ensure files are named using standard conventions described in the SOP. | | |
| 4. Submit data files to EPA via Pb-PEP data receiving website (AIRQA). | | |
| Notes | | |

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| PEPF 6.3 Filter Packing and Shipment | | | |
|--|--|--|--|
| 1. Packing procedu | | | |
| 2. All items in ship | ping container | | |
| 3. Time requirement | nts for shipment known | | |
| 4. Appropriate doc | umentation/data shipped | | |
| Notes: | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| PEPF 6.5 Sampler | r Maintenance and Cleaning | | |
| Field scientist prop | perly identifies and performs maintenance areas to be checked each | | |
| | Temperature probe | | |
| Gaskets | | | |
| | Motor inspection | | |
| | Overall cleanliness of instrument | | |
| | All vital probe connections checked | | |
| | | | |
| Notes: | | | |
| | | | |
| | | | |
| PEPF 7.1 Chain o | f Custody and Field Data Sheet | | |
| 1. COC/FDS form | 1. COC/FDS form appropriately and completely filled out | | |
| 2. COC/FDS data correctly submitted using web-enabled form on Pb-PEP data receiving website. | | | |
| Notes | | | |

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| PEPF 8.1 Quality Assurance/Quality Control | | | |
|--|----------------|-----|--|
| 1.General knowledge of the required QA activities for program | | | |
| 2. Is aware of the frequencies of the QA/QC activities | | | |
| Notes | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| PEPF 9.1 Information Retention | | | |
| 1. General knowledge of the information retention requirements | | | |
| Notes: | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | Instructor's N | ame | |
| | | | |

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Appendix C

Data Qualifiers/Flags

A sample qualifier or a result qualifier consists of 3 alphanumeric characters which act as an indicator of the fact and the reason that the subject analysis (a) did not produce a numeric result, (b) produced a numeric result but it is qualified in some respect relating to the type or validity of the result or (c) produced a numeric result but for administrative reasons is not to be reported outside the laboratory.

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Field Qualifiers

| Code | Definition | Description |
|-------------------|--|---|
| CON | Contamination | Contamination including observations of insects or other debris |
| DAM | Filter Damage | Filter appeared damaged |
| EST 1/ | Elapsed Sample Time | Elapsed sample time out of specification |
| EVT | Event | exceptional event expected to have effected sample (dust, fire , spraying etc) |
| FAC | field accident | There was an accident in the field that either destroyed the sample or rendered it not suitable for analysis. |
| FAT | Failed Temperature Check Ambient | Ambient temperature check out of specification |
| FIT | Failed Temperature Check Internal | Internal temperature check out of specification |
| FLR 1/ | Flow Rate | Flow rate 5 min avg out of specification |
| FLT ^{1/} | Filter Temperature | Filter temperature differential, 30 minute interval out of specification |
| FMC | Failed Multi point Calibration Verification | Failed the initial Multi point calibration verification |
| FPC | Failed Pressure Check | Barometric pressure check out of specification |
| FSC | Failed Single Point Calibration Verification | Failed the initial single point calibration verification |
| FVL | Flow volume | Flow volume suspect |
| GFI | Good Filter Integrity | Filter integrity, upon post sampling field inspection looks good |
| LEK | Leak suspected | internal/external leak suspected |
| SDM | Sampler Damaged | Sampler appears to be damaged which may have effected filter |

^{1/-} Flag generated by sampling equipment

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Laboratory Qualifiers

| Code | Definition | Description |
|------|--------------------------------|--|
| ALT | alternate measurement | The subject parameter was determined using an alternate measurement method. Value is believed to be accurate but could be suspect. |
| AVG | average value | Average value - used to report a range of values |
| BDL | below detectable limits | There was not a sufficient concentration of the parameter in the sample to exceed the lower detection limit in force at the time the analysis was performed. Numeric results field, if present is at best, an approximate value. |
| BLQ | below limit of quantitation | The sample was considered above the detection limit but there was not a sufficient concentration of the parameter in the sample to exceed the lower quantitation limit in force at the time the analysis was performed |
| CAN | canceled | The analysis of this parameter was canceled and not preformed. |
| CBC | cannot be calculated | The calculated analysis result cannot be calculated because an operand value is qualified |
| EER | entry error | The recorded value is known to be incorrect but the correct value cannot be determined to enter a correction. |
| FBK | found in blank | The subject parameter had a measurable value above the established QC limit when a blank was analyzed using the same equipment and analytical method. Therefore, the reported value may be erroneous. |
| FCS | failed collocated sample | Collocated sample exceeded acceptance criteria limits |
| FFB | failed field blank | Field blank samples exceeded acceptance criteria limits. |
| FIS | failed internal standard | Internal standards exceeded acceptance criteria limits. |
| FLB | failed laboratory blank | Laboratory blank samples exceeded acceptance criteria limits. |
| FLD | failed laboratory duplicate | Laboratory duplicate samples exceeded acceptance criteria limits. |
| FQC | failed quality control | The analysis result is not reliable because quality control criteria were exceeded when the analysis was conducted. Numeric field, if present, is estimated value. |
| FTB | failed trip blank | Trip blank sample exceeded acceptance criteria limits |
| GSI | Good Shipping Integrity | Integrity of filter upon receipt by shipping/receiving looked good |
| HTE | holding time exceeded | Filter holding time exceeded acceptance criteria limits |
| ISP | improper sample preservation | Due to improper preservation of the sample, it was rendered not suitable for analysis. |
| INV | invalid sample | due to single or a number or flags or events, the sample was determined to be invalid. |

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| Code | Definition | Description |
|------|---------------------------------|---|
| LAC | laboratory accident | There was an accident in the laboratory that either destroyed the sample or rendered it not suitable for analysis. |
| LLS | less than lower standard | The analysis value is less than the lower quality control standard. |
| LTC | less than criteria of detection | Value reported is less than the criteria of detection |
| NAR | no analysis result | There is no analysis result required for this subject parameter |
| REJ | rejected | The analysis results have been rejected for an unspecified reason by the laboratory. For any results where a mean is being determined, this data was not utilized in the calculation of the mean. |
| REQ | reque for re-analysis | The analysis is not approved and must be re-analyzed using a different method. |
| RET | return(ed) for re- analysis | The analysis result is not approved by laboratory management and reanalysis is required by the bench analyst with no change in the method. |
| RIN | re-analyzed | The indicated analysis results were generated from a reanalysis |
| STD | internal standard | The subject parameter is being utilized as an internal standard for other subject parameters in the sample. There is no analysis result report, although the theoretical and/or limit value(s) may be present |
| UND | analyzed but undetected | Indicates material was analyzed for but not detect |

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