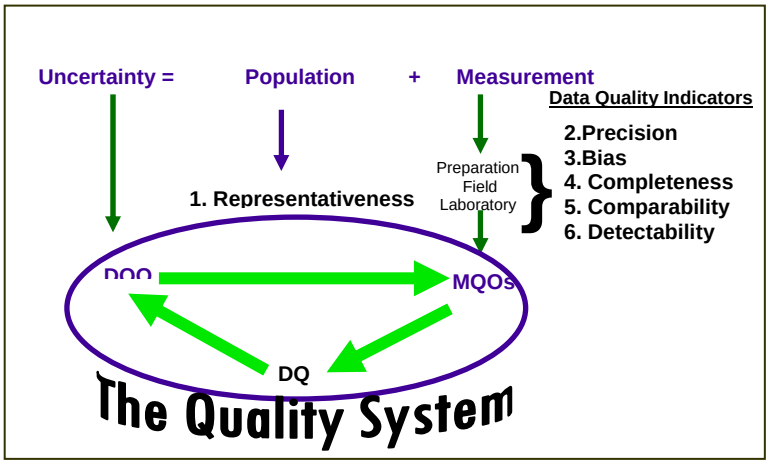
10.0 Quality Control



As described in Section 3, any data collection process that provides an estimate of a concentration contains uncertainties related to spatial/temporal variability (population) and the measurement process. DQOs define the data quality needed to make a correct decision an acceptable percentage of the time. Data quality is defined through quantification of the following **data quality indicators.**

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

Precision - a measure of mutual agreement among individual measurements of the same property usually under prescribed similar conditions. This is the random component of error. Precision is estimated by various statistical techniques using some derivation of the standard deviation.

Bias - the systematic or persistent distortion of a measurement process which causes error in one direction. Bias will be determined by estimating the positive and negative deviation from the true value as a percentage of the true value.

Detectability - The determination of the low range critical value of a characteristic that a method specific procedure can reliably discern.

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. Data completeness requirements are included in the reference methods (40 CFR Pt. 50).

Comparability - a measure of confidence with which one data set can be compared to another.

Measurement quality objectives (MQOs) identify the **quality control samples** and the acceptance criteria for those samples that will allow one to quantify the data quality indicators.

Data quality assessments (DQAs) are the statistical assessments that determine if the DQOs are met and to provide descriptions of data uncertainty. If the DQOs are not met, the DQAs are used to determine whether modifications to the DQOs are necessary or "tighter" **quality control** is required.

Within any phase or step of the data collection process, errors can occur. For example:

- samples and filters can be mislabeled;
- data can be transcribed or reported incorrectly or information management systems can be programmed incorrectly;
- calibration or check standards can be contaminated or certified incorrectly resulting in faulty calibrations;

- instruments can be set up improperly or over time fail to operate within specifications; and
- procedures may not be followed.

Quality Control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer[1]. Quality control includes establishing specifications or acceptance criteria for each quality characteristic of the monitoring/analytical process, assessing procedures used in the monitoring/analytical process to determine conformance to these specifications, and taking any necessary corrective actions to bring them into conformance. The EPA's QAPP guidance document QA/G5[2] suggests that "QC activities are those technical activities routinely performed, not to eliminate or minimize errors, but to measure their effect". Although there is agreement that the measurement or assessment of a QC check or procedure does not itself eliminate errors, the QC data can and should be used to take appropriate corrective actions which can minimize error or control data to an acceptable level of quality in the future. So, QC is both proactive and corrective. It establishes techniques to determine if field and lab procedures are producing acceptable data and identifies actions to correct unacceptable performance.

The goal of quality control is to provide a reasonable level of checking at various stages of the data collection process to ensure that data quality is maintained and if it is found that the quality has not been maintained, that it is discovered with a minimal loss of data (invalidation). Figure 10.1 provides an example of some of the QC samples used in the $PM_{2.5}$ data collection process. The figure also identifies what sources of error are associated with the QC sample. So, in developing a quality control strategy, one must weigh the costs associated with quality control against the risks of data loss.

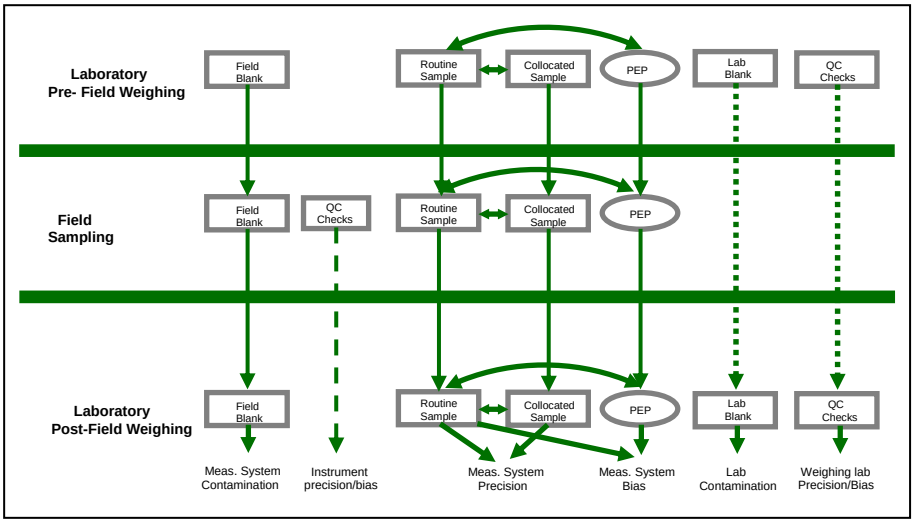


Figure 10.1 QC samples for $PM_{2.5}$ placed at various stages of measurement process

With the objective to minimize data loss, quality control data is most beneficial when it is assessed as soon as it is collected. Therefore, information management systems can play a very important role in reviewing QC data and flagging or identifying spurious data for further review. These information management procedures can help the technical staff review these QC checks coming from a number of monitoring sites in a consistent and time efficient manner. There are many graphical techniques (e.g., control charts and outlier checks) that can be employed to quickly identify suspect data. More details of information management systems are discussed later in this section.

[1] American Nation Standard ANSI/ASQ E4-2000 http://www.asq.org/
[2] http://www.epa.gov/quality/qa_docs.html

It is the responsibility of the monitoring organization, through the development of its QAPP, policies and procedures, to develop and document the:

- QC techniques;
- frequency of the QC checks and the point in the measurement process that the check is introduced;
- traceability of QC standards;
- matrix of the check sample;
- appropriate test concentrations;
- actions to be taken in the event that a QC check identifies a failed or changed measurement system;
- formulae for estimating data quality indicators;
- QC results, including control charts; and
- the means by which the QC data will be used to determine that the measurement performance is acceptable.

10.1 QC Activity Areas

For air monitoring projects the following three areas must have established QC activities, procedures and criteria:

1. Data Collection.
2. Data management and the verification and validation process.
3. Reference materials.

Data collection includes any process involved in acquiring a concentration or value, including but not limited to: sample preparation, field sampling, sample transportation, field analytical (continuous) methods, and laboratory preparation/analytical processes. Depending on the importance of the data and resources available, monitoring programs can implement QC samples, as illustrated in Figure 10.1, to identify the errors occurring at various phases of monitoring process. Many of the QC samples can identify errors from more than one phase. Table 10-1 provides a list of the majority of the QC samples utilized in the ambient air program and include both their primary and secondary uses in error identification. Many of these checks are required in CFR; others are strongly suggested in the method guidance. The MQO/validation templates provided in Appendix D provide the minimum requirements for the frequency that these checks be implemented but many monitoring organization choose more frequent checking in order to reduce the risk of data invalidation. A good example of this is the zero/span and one-point precision checks for the gaseous criteria pollutants. Although CFR requires the check to be performed once every two weeks, due to the advent of more sophisticated automated monitoring systems, many monitoring organization perform these checks every 24-hours (11:45 PM – 12:15 AM). In addition, once the QC checks are developed for a particular monitoring method, it is important to identify the acceptance criteria and what corrective action will be taken once a QC check fails. The MQO/Validation template in Appendix D can be used to list the QC samples with a column added to include corrective action. Table 10-2 provides an example of a QC Sample Table for $PM_{2.5}$. Although the validation templates provide guidance for when data should be invalidated, it is up to the monitoring organization to provide the specific corrective actions for the failure of a specific QC check and therefore, Table 10-2 does not identify specific corrective actions.

Data management quality control is discussed in more detail in Section 14 and the verification/validation process in Section 17. However, both processes require some frequency of checks to ensure that they are performed consistently and without error. This is especially true for data management since errors in programming can cause consistent errors for long periods of time if not checked.

Reference materials are the standards by which many of the QC checks are performed. Reference material can be gaseous standards as well as devices (e.g., flow rate standards). If these standards are not checked and verified as to their certified values, then the quality of data becomes suspect. Reference materials need to be certified and recertified at acceptable frequencies in order to maintain the integrity of the reference material. It is suggested that standards be certified annually. More discussion on standards is included in Section 12.

10.2 Internal vs. External Quality Control

Quality control can be separated into 2 major categories: internal QC and external QC. Most of the quality control activities take place internally, meaning the monitoring organization responsible for collecting the data also develops and implements the quality control activities, evaluates the data, and takes corrective action when necessary. The internal activities can be used to take immediate action if data appear to be out of acceptance. External quality control samples are usually of two types: "double-blind" meaning the QC sample is not known (looks like a routine sample) and therefore its concentration in unknown, or "single-blind" meaning they are known to be a QC sample but its concentration is unknown. These samples are also called performance evaluation or proficiency test samples and are explained in Section 15. Because these checks are performed by external organizations, the results are not always immediately available and therefore have a diminished capacity to control data quality in "real-time." However they are useful as an objective test of the internal QC procedures and may identify errors (i.e., biased or contaminated standards) that might go unnoticed in an internal QC system. Both types of quality control are important in a well implemented quality system. Other elements of an organization's QAPP that may contain related sampling and analytical QC requirements include:

- **Sampling Design** which identifies the planned field QC samples as well as procedures for QC sample preparation and handling;
- **Sampling Methods Requirements** which includes requirements for determining if the collected samples accurately represent the population of interest;
- **Sample Handling and Custody Requirements** which discusses any QC devices employed to ensure samples are not tampered with (e.g., custody seals) or subjected to other unacceptable conditions during transport;
- **Analytical Methods Requirements** which includes information on the subsampling methods and information on the preparation of QC samples (e.g., blanks and replicates); and
- **Instrument Calibration and Frequency** which defines prescribed criteria for triggering recalibration (e.g., failed calibration checks).

Table 10-1 QC Samples Used in Various Ambient Air Monitoring Programs

Data Quality Indicator	QC Check and QC Sample	Sources of Measurement Error										Purpose
		Sample Collection				Sample Transport	Field (continuous)/ Laboratory Analytical Method					To evaluate or determine the source of measurement error arising from:
		Sampling Equipment	Conditions During Sampling	Preservation Technique	Sampling Matrix	Shipment Process	Sample Storage	Sample Preparation Reagents	Sample Preparation	Analytical Methods Reagents/ Standards	Analytical Equipment	
Accuracy/Bias Positive or negative bias primarily due to contamination. (could also be due to operator error)	Lot Blank								✓✓			Filters that have not equilibrated
	Exposure Lot Blanks								✓✓	✓	✓	A batch of filters that have not equilibrated
	Laboratory Blanks						✓✓	✓✓	✓✓	✓✓	✓✓	Ambient contamination arising within laboratory or balance not operating
	Trip Blanks					✓✓	✓	✓	✓	✓	✓	Contamination from shipping and/or lab
	Field Blanks	✓✓	✓✓	✓✓		✓	✓	✓	✓	✓	✓	Ambient contamination from field activities sampling equipment, shipping and/or lab
	Reagent Blank			✓✓				✓	✓	✓	✓	Contamination introduced by reagents used in sample preparation/preservation.
	Equipment Blank (Rinsate Blank)	✓✓		✓		✓	✓	✓✓	✓✓	✓✓	✓✓	Carryover contamination resulting from successive use of sampling equipment.
Accuracy/Bias Due to sample matrix or sample preparation/ Analytical methodology	Matrix Spike				✓✓			✓	✓	✓	✓	Preparation/analytical bias for specific compounds in sample matrices
	Surrogate Spike				✓✓			✓	✓	✓	✓	Preparation/analytical bias for specific sample matrices
	Lab Control Samples							✓✓	✓✓	✓✓	✓✓	Labs ability to accurately identify and quantitate target compounds
Accuracy/Bias due to inadequate temp. control	Cooler Temp Check			✓✓		✓✓	✓✓					High temperatures causing volitilization affecting mass concentration
	Temp Verifications	✓✓					✓✓				✓✓	Sampler, sample storage, or laboratory prep facilityproblems
Accuracy/Bias Primarily due to equipment malfunction or not properly calibrated and/or operator error	Balance Check										✓✓	Analytical balance precision and stability
	Flow Rate Verifications/ Audits	✓✓									✓✓	Equipment not operating within specified parameters
	Humidity Verifications	✓✓							✓✓		✓✓	Laboratories inability to have an adequate measurement environment
	Pressure Verifications	✓✓										Sampler malfunction
	Leak Checks	✓✓										Sampler malfunction
	Timer Verifications	✓✓										Sampler malfunction
	Zero/Span								✓	✓	✓✓	Analyzer out of calibration or bad standards
Precision/ Bias	One-Point QC Check								✓	✓	✓✓	Analyzer out of calibration or bad standards
Precision	Collocated Samples	✓✓	✓	✓	✓✓	✓	✓	✓	✓	✓	✓	Cumulative effects of both field & lab precision to measure overall precision
	Field Duplicates	✓	✓	✓	✓✓	✓	✓	✓	✓	✓	✓	Cumulative effects of both field & lab precision to measure overall precision
	Sample /Analytical Replicate										✓✓	Filters not equilibrating, incorrect weighing procedure or balance problems
	Standard Certifications	✓✓								✓✓	✓✓	Contaminated Reagents/Standards
	Calibrations	✓✓								✓✓	✓✓	Sampling analytical equipment bias or drift
Accuracy/Bias	Round Robins								✓✓	✓✓	✓✓	Overall sampling/analysis process
	Proficiency Tests								✓✓	✓✓	✓✓	Overall sampling/analysis process
Bias	PEP	✓✓		✓		✓	✓		✓✓	✓✓	✓✓	Overall sampling/analysis process
	NPAP									✓✓	✓✓	Overall sampling/analysis process
Sensitivity	MDL Studies							✓✓	✓✓	✓✓	✓✓	

Table 10-2 $PM_{2.5}$ Field and Lab QC Checks

Requirement	Frequency	Acceptance Criteria	Corrective Action
Field QC Checks			
Calibration Standards			
Flow Rate Transfer Std.	1/yr	±2% of NIST-traceable Std.	
Field Thermometer	1/yr	± 0.1° C resolution ± 0.5° C accuracy	
Field Barometer	1/yr	± 1 mm Hg resolution ± 5 mm Hg accuracy	
Calibration/Verification			
Flow Rate (FR) Calibration	If multi-point failure	± 2% of transfer standard	
FR multi-point verification	1/yr	± 2% of transfer standard	
One point FR verification	1/4 weeks	± 4% of transfer standard	
External Leak Check	every 5 sampling events	80 mL/min	
Internal Leak Check	every 5 sampling events	80 mL/min	
Temperature Calibration	If multi-point failure	± 2% of standard	
Temp multi-point verification	on installation, then 1/yr	± 2EC of standard	
One- point temp Verification	1/4 weeks	± 4EC of standard	
Pressure Calibration	on installation, then 1/yr	∀10 mm Hg	
Pressure Verification	1/4 weeks	∀10 mm Hg	
Clock/timer Verification	1/ 4 weeks	1 min/mo	
Blanks			
Field Blanks	See 2.12 reference	±30 Φg	
Precision Checks			
Collocated samples	every 6 days	CV ≤ 10%	
Audits (*external assessments*)			
FRM PEP	5 or 8 sites/year	± 10%	
Flow rate audit	1/6mo	± 4% of audit standard	
External Leak Check	1/6mo	< 80 mL/min	
Internal Leak Check	1/6mo	< 80 mL/min	
Temperature Audit	1/6mo	± 2EC	
Pressure Audit	1/6mo	∀10 mm Hg	
Laboratory QC Checks			
Blanks			
Lot Blanks	3-lot	±15 Φg difference	
Lab Blanks	3 per batch	±15 Φg difference	
Calibration/Verification			
Balance Calibration	1/yr	Manufacturers spec.	
Lab Temp. Calibration	3 mo	± 2EC	
Lab Humidity Calibration	3 mo	∀2%	
Bias			
Balance Audit	1/year	±15 Φg for unexposed filters	
Balance Check	beginning, every 10th samples, end	≤ ±3 Φg	
Calibration standards			
Working Mass Stds.	3-6 mo.	25 Φg	
Primary Mass Stds.	1/yr	25 Φg	
Precision			
Duplicate filter weighings	1 per weighing session	±15 Φg difference	

10.3 CFR Related Quality Control Samples

40 CFR Part 58, Appendix A identifies a number of quality control samples that must be implemented for the SLAMS (and NCore) SPM and PSD networks. By 2009, any special purpose monitors that use FRMs or FEMs will be required to follow these requirements unless granted a waiver by the Regional Administrator. Table 10-3 provides a summary of the QC checks for the criteria pollutants and the CFR reference where an explanation of each check is described. The reader should distinguish the requirements that are related to automated and manual methods since there are some differences.

Table 10-3 Ambient Air Monitoring Measurement Quality Samples

Method	CFR Reference	Coverage (annual)	Minimum frequency	MQOs*
Automated Methods				
One-Point QC: for SO_2, NO_2, O_3, CO	Section 3.2.1	Each analyzer	Once per 2 weeks	**O_3** Precision 7%, Bias ± 7%. **SO_2, NO_2, CO** Precision 10% , Bias ± 10%
Annual performance evaluation for SO_2, NO_2, O_3, CO	Section 3.2.2	Each analyzer	Once per year	≤ 15 % for each audit concentration
Flow rate verification PM_{10},$PM_{2.5}$, $PM_{10-2.5}$, TSP	Section 3.2.3	Each sampler	Once every month	≤ 4% of standard and 5% of design value
Semi-annual flow rate audit PM_{10}, $PM_{2.5}$, $PM_{10-2.5,}$ TSP	Section 3.2.4	Each sampler	Once every 6 months	≤ 4% of standard and 5% of design value
Collocated sampling $PM_{2.5}$, $PM_{10-2.5,}$ TSP	Section 3.2.5	15% within PQAO	Every twelve days	$PM_{2.5}$, - 10% precision $PM_{10-2.5-}$ - 15% precision TSP – 10% precision
PM Performance evaluation program $PM_{2.5}$,$PM_{10-2.5}$	Section 3.2.7	1. 5 valid audits for primary QA orgs, with ≤ 5 sites 2. 8 valid audits for primary QA orgs, with > 5 sites 3. All samplers in 6 years	over all 4 quarters	$PM_{2.5}$, - ± 10% bias $PM_{10-2.5-}$ - ±15% bias
Manual Methods				
Collocated sampling PM_{10}, TSP, $PM_{10-2.5,}$ $PM_{2.5}$	3.3.1 and 3.3.5	15% within PQAO	Every 12 days PSD every 6 days	PM_{10}, TSP, $PM_{2.5}$, - 10% precision $PM_{10-2.5-}$ - 15% precision
Flow rate verification PM_{10} (low Vol),$PM_{10-2.5}$, $PM_{2.5,}$, TSP	3.3.2	Each sampler	Once every month	≤ 4% of standard and 5% of design value
Flow rate verification PM_{10} (High-Vol), TSP	3.3.2	Each sampler	Once every quarter	≤ 10% of standard and design value
Semi-annual flow rate audit PM_{10} (low Vol), $PM_{10-2.5}$, $PM_{2.5}$, TSP	3.3.3	Each sampler, all locations	Once every 6 months	≤ 4% of standard and 5% of design value
Semi-annual flow rate audit PM_{10} (High-Vol), TSP	3.3.3	Each sampler, all locations	Once every 6 months	≤ 10% of standard and design value
Manual Methods Lead	3.3.4	1. Each sampler 2. Analytical (lead strips)	1. Include with TSP 2. Each quarter	1. Same as for TSP. 2. - ± 10% bias
Performance evaluation program $PM_{2.5,}$ $PM_{10-2.5}$	3.3.7 and 3.3.8	1. 5 valid audits for primary QA orgs, with ≤ 5 sites 2. 8 valid audits for primary QA orgs, with ≥ 5 sites 3. All samplers in 6 years	Over all 4 quarters	$PM_{2.5}$, ± 10% bias $PM_{10-2.5-,}$ ±15% bias

* Some of the MQOs are found in CFR and others in Appendix D of this guidance document.

10.4 Use of Computers for Quality Control

With the wide range of economical computers now available, and the advancements in data acquisition system (DAS) technologies, consideration should be given to a computer system that can process and output the information in a timely fashion. Such a computer system should be able to:

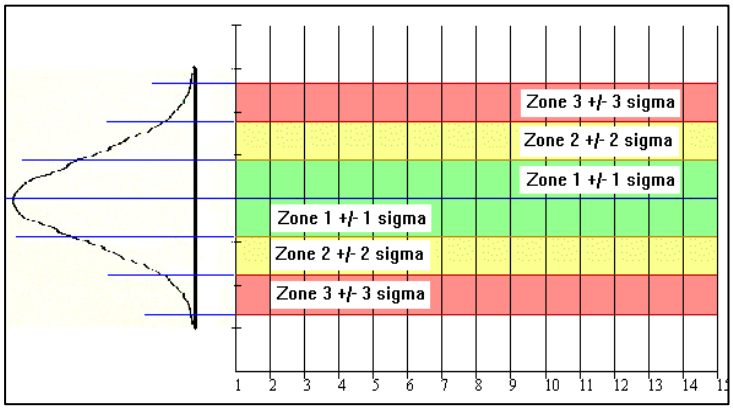


Figure 10.2 Example Control Chart (courtesy of Six Sigma SPC see footnote)

- compute calibration equations
- compute measures of linearity of calibrations (e.g., standard error or correlation coefficient)
- plot calibration curves
- compute zero/span drift results
- plot zero/span drift data
- compute precision and bias results
- compute control chart limits
- plot control charts[3]
- automatically flag out-of-control results
- maintain and retrieve calibration and performance records

Some of these checks (e.g., calibrations) only need to be reviewed as needed or when the actual check is performed. Other checks, like zero/span/one point QC checks or programmed routine data range or outlier checks that may occur every day are much more easily performed automatically by properly programmed computer systems. Earlier versions of this Handbook provided examples of quality control charts for zero and span drifts but with the advanced data acquisition system technologies available, the development of these charts is fairly straight forward.

Many vendors offering newer generation data loggers and ambient air information management systems provide programming of some of the QC checking capabilities listed above. EPA has also provided guidance and a Data Assessment Statistical Calculator (DASC) tool for the precision and bias calculations of the quality control checks required in CFR Part 58, Appendix A. In addition, the AMP 255 Report in AQS also provides these statistics for many of the QC samples described in Table 10-3 but use of these reports requires data reporting to AQS which does not usually occur in time frames needed for quality control.

[3] http://www.sixsigmaspc.com/