17.0 Data Review, Verification and Validation

Data review, verification and validation are techniques used to accept, reject or qualify data in an objective and consistent manner. Verification can be defined as confirmation, through provision of objective evidence that *specified requirements* have been fulfilled[1]. Validation can be defined as confirmation through provision of objective evidence that the particular requirements for a specific *intended use* are fulfilled.   It is important to describe the criteria for deciding the degree to which each data item has met its quality specifications as described in an organization's QAPP. This section will describe the techniques used to make these assessments.

In general, these assessment activities are performed by persons implementing the environmental data operations as well as by personnel "independent" of the operation, such as the organization's QA personnel and at some specified frequency. The procedures, personnel and frequency of the assessments should be included in an organization's QAPP. These activities should occur prior to submitting data to AQS and prior to final data quality assessments that will be discussed in Section 18.

Each of the following areas of discussion should be considered during the data review/verification/validation processes. Some of the discussion applies to situations in which a sample is separated from its native environment and transported to a laboratory for analysis and data generation; others are applicable to automated instruments.   The following information is an excerpt from *EPA G-5*[2]:

Sampling Design - How closely a measurement represents the actual environment at a given time and location is a complex issue that is considered during development of the sampling design. Each sample should be checked for conformity to the specifications, including type and location (spatial and temporal). By noting the deviations in sufficient detail, subsequent data users will be able to determine the data's usability under scenarios different from those included in project planning.

Sample Collection Procedures- Details of how a sample is separated from its native time/space location are important for properly interpreting the measurement results. Sampling methods and field SOPs provide these details, which include sampling and ancillary equipment and procedures (including equipment decontamination). Acceptable departures (for example, alternate equipment) from the QAPP, and the action to be taken if the requirements cannot be satisfied, should be specified for each critical aspect. Validation activities should note potentially unacceptable departures from the QAPP. Comments from field surveillance on deviations from written sampling plans also should be noted.

Sample Handling- Details of how a sample is physically treated and handled during relocation from its original site to the actual measurement site are extremely important. Correct interpretation of the subsequent measurement results requires that deviations from the sample handling section of the QAPP and the actions taken to minimize or control the changes, be detailed. Data collection activities should indicate events that occur during sample handling that may affect the integrity of the samples. At a minimum, investigators should evaluate the sample containers and the preservation methods used and ensure that they are appropriate to the nature of the sample and the type of data generated from the sample. Checks on the identity of the sample (e.g., proper labeling and chain of custody records) as well as proper physical/chemical storage conditions (e.g., chain of custody and storage records) should be made to ensure that the sample continues to be representative of its native environment as it moves through the analytical process.

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[1] ISO-9000 http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000.htm
[2] EPA Guidance to Quality Assurance Project Plans http://www.epa.gov/quality1/qs-docs/g5-final.pdf

Analytical Procedures- Each sample should be verified to ensure that the procedures used to generate the data were implemented as specified. Acceptance criteria should be developed for important components of the procedures, along with suitable codes for characterizing each sample's deviation from the procedure. Data validation activities should determine how seriously a sample deviated beyond the acceptable limit so that the potential effects of the deviation can be evaluated during DQA.

Quality Control- The quality control section of the QAPP specifies the QC checks that are to be performed during sample collection, handling and analysis. These include analyses of check standards, blanks and replicates, which provide indications of the quality of data being produced by specified components of the measurement process. For each specified QC check, the procedure, acceptance criteria, and corrective action (and changes) should be specified. Data validation should document the corrective actions that were taken, which samples were affected, and the potential effect of the actions on the validity of the data.

Calibration- Calibration of instruments and equipment and the information that should be presented to ensure that the calibrations:

- were performed within an acceptable time prior to generation of measurement data
- were performed in the proper sequence
- included the proper number of calibration points
- were performed using standards that "bracketed" the range of reported measurement results otherwise, results falling outside the calibration range should be flagged as such
- had acceptable linearity checks and other checks to ensure that the measurement system was stable when the calibration was performed

When calibration problems are identified, any data produced between the suspect calibration event and any subsequent recalibration should be flagged to alert data users.

Data Reduction and Processing- Checks on data integrity evaluate the accuracy of "raw" data and include the comparison of important events and the duplicate keying of data to identify data entry errors.

Data reduction may be an irreversible process that involves a loss of detail in the data and may involve averaging across time (for example, 5-minute, hourly or daily averages) or space (for example, compositing results from samples thought to be physically equivalent) such as the Pb sample aggregation or $PM_{2.5}$ spatial averaging techniques. Since this summarizing process produces few values to represent a group of many data points, its validity should be well-documented in the QAPP. Potential data anomalies can be investigated by simple statistical analyses.

The information generation step involves the synthesis of the results of previous operations and the construction of tables and charts suitable for use in reports. How information generation is checked, the requirements for the outcome, and how deviations from the requirements will be treated, should be addressed.

17.1 Data Review Methods

The flow of data from the field environmental data operations to the storage in the database requires several distinct and separate steps:

- initial selection of hardware and software for the acquisition, storage, retrieval and transmittal of data
- organization and the control of the data flow from the field sites and the analytical laboratory
- input and validation of the data
- manipulation, analysis and archival of the data
- submittal of the data into the EPA's AQS database.

Both manual and computer-oriented systems require individual reviews of all data tabulations. As an individual scans tabulations, there is no way to determine that all values are valid. The purpose of manual inspection is to spot unusually high (or low) values (outliers) that might indicate a gross error in the data collection system. In order to recognize that the reported concentration of a given pollutant is extreme, the individual must have basic knowledge of the major pollutants and of air quality conditions prevalent at the reporting station. Data values considered questionable should be flagged for verification. This scanning for high/low values is sensitive to spurious extreme values but not to intermediate values that could also be grossly in error.

Manual review of data tabulations also allows detection of uncorrected drift in the zero baseline of a continuous sensor. Zero drift may be indicated when the daily minimum concentration tends to increase or decrease from the norm over a period of several days. For example, at most sampling stations, the early morning (3:00 a.m. to 4:00 a.m.) concentrations of carbon monoxide tend to reach a minimum (e.g., 2 to 4 ppm). If the minimum concentration differs significantly from this, a zero drift may be suspected. Zero drift could be confirmed by review of the original strip chart.

In an automated data processing system, procedures for data validation can easily be incorporated into the basic software. The computer can be programmed to scan data values for extreme values, outliers or ranges. These checks can be further refined to account for time of day, time of week, and other cyclic conditions.   Questionable data values are then flagged on the data tabulation to indicate a possible error. Other types of data review can consist of preliminary evaluations of a set of data, calculating some basic statistical quantiles and examining the data using graphical representations.

17.2 Data Verification Methods

Verification can be defined as confirmation, through provision of objective evidence that *specified requirements* have been fulfilled[3]. The verification requirements for each data operation are included in the organizations' QAPP and in SOPs and should include not only the verification of sampling and analysis processes but also operations like data entry, calculations and data reporting. The data verification process involves the inspection, analysis, and acceptance of the field data or samples. These inspections can take the form of technical systems audits (internal or external) or frequent inspections by

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[3] Guidance on Environmental Data Verification and Data Validation (QA/G-8) http://www.epa.gov/quality1/qa_docs.html throgh proviosion of objective evidence

field operators and lab technicians. Questions that might be asked during the verification process include:

- Were the environmental data operations performed according to the SOPs governing those operations?
- Were the environmental data operations performed on the correct time and date originally specified? Many environmental operations must be performed within a specific time frame; for example, the NAAQS samples for particulates are collected once every six days from midnight to midnight. The monitor timing mechanisms must have operated correctly for the sample to be collected within the time frame specified.
- Did the sampler or monitor perform correctly? Individual checks such as leak checks, flow checks, meteorological influences, and all other assessments, audits, and performance checks must have been acceptably performed and documented.
- Did the environmental sample pass an initial visual inspection? Many environmental samples can be flagged (qualified) during the initial visual inspection.
- Have manual calculations, manual data entry, or human adjustments to software settings been checked? Automated calculations should be verified and accepted prior to use, but at some frequencies these calculations should be reviewed to ensure that they have not changed.
- Were the environmental data operations performed to meet data quality objectives designed for those specific data operations and were the operations performed as specified? The objectives for environmental data operations must be clear and understood by all those involved with the data collection.

17.3 Data Validation Methods

Data validation is a routine process designed to ensure that reported values meet the quality goals of the environmental data operations. Data validation is further defined as examination and provision of objective evidence that the particular requirements for a specific *intended use* are fulfilled. A progressive, systematic approach to data validation must be used to ensure and assess the quality of data.

The purpose of data validation is to detect and then verify any data values that may not represent actual air quality conditions at the sampling station. Effective data validation procedures usually are handled completely independently from the procedures of initial data collection.

Because the computer can perform computations and make comparisons extremely rapidly, it can also make some determination concerning the validity of data values that are not necessarily high or low. Data validation procedures should be recommended as standard operating procedures. For example, one can evaluate the difference between successive data values, since one would not normally expect very rapid changes in concentrations of a pollutant during a 5-min or 1-h reporting period. When the difference between two successive values exceeds a predetermined value, the tabulation can be flagged, with an appropriate symbol.

Quality control data can support data validation procedures (see section 17.3.3). If data assessment results clearly indicate a serious response problem with the analyzer, the agency should review all pertinent quality control information to determine whether any ambient data, as well as any associated assessment data, should be invalidated. Therefore if ambient data are determined to be invalid, then the associated precision, bias and accuracy readings should also be invalidated. Any data quality calculations

using the invalidated readings should be redone. Also, the precision, bias or accuracy checks should be rescheduled, preferably in the same calendar quarter. The basis or justification for all data invalidations should be permanently documented.

Certain criteria, based upon CFR and field operator and laboratory technician judgment, may be used to invalidate a sample or measurement. These criteria should be explicitly identified in the organization's QAPP. Many organizations use flags or result qualifiers to identify potential problems with data or a sample. A flag is an indicator of the fact and the reason that a data value (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 organization. Flags can be used both in the field and in the laboratory to signify data that may be suspect due to contamination, special events or failure of QC limits. Flags can be used to determine if individual samples (data), or samples from a particular instrument, will be invalidated. In all cases, the sample (data) should be thoroughly reviewed by the organization prior to any invalidation.

Flags may be used alone or in combination to invalidate samples. Since the possible flag combinations can be overwhelming and can not always be anticipated, an organization needs to review these flag combinations and determine if single values or values from a site for a particular time period will be invalidated. The organization should keep a record of the combination of flags that resulted in invalidating a sample or set of samples. These combinations should be reported to the EPA Region and can be used to ensure that the organization evaluates and invalidates data in a consistent manner.

Procedures for screening data for possible errors or anomalies should also be implemented. The data quality assessment document series (EPA QA/G-9R[4], EPA QA/G-9s[5]) provide several statistical screening procedures for ambient air quality data that should be applied to identify gross data anomalies.

> **NOTE:** it is strongly suggested that flags, specifically the appropriate null data code flags, be used in place of any routine values that are invalidated. This provides some indication to data users and data quality assessors to the reasons why data that was expected to be collected was missing.

17.3.1 Automated Methods

When zero, span or one-point QC checks exceed acceptance limits, ambient measurements should be invalidated back to the most recent point in time where such measurements are known to be valid. Usually this point is the previous check, unless some other point in time can be identified and related to the probable cause of the excessive drift or exceedance (such as a power failure or malfunction). Also, data following an analyzer malfunction or period of non-operation should be regarded as invalid until the next subsequent (level 1) acceptable check or calibration. Based on the sophistication of DAS (see Section 14) monitoring organization may have other automated programs for data validation. These programs should be described in the monitoring organization's approved QAPP prior to implementation. Even though the automated technique may be considered acceptable, the raw invalidated data should be archived for statute of limitations discussed in Section 5.

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[4] Data Quality Assessment: A Reviewer's Guide http://www.epa.gov/quality1/qs-docs/g9r-final.pdf

[5] Data Quality Assessment: Statistical Methods for Practitioners http://www.epa.gov/quality1/qs-docs/g9s-final.pdf

17.3.2 Manual Methods

For manual methods, the first level of data validation should be to accept or reject monitoring data based upon results from operational checks selected to monitor the critical parameters in all three major and distinct phases of manual methods--sampling, analysis, and data reduction. In addition to using operational checks for data validation, the user must observe all limitations, acceptance limits, and warnings described in the reference and equivalent methods per se that may invalidate data. It is further recommended that results from performance audits/evaluations required in 40 CFR 58, Appendix A not be used as the sole criteria for data invalidation because these checks (performance audits) are intended to assess the quality of the data.

17.3.3 Validation Templates

In June 1998, a workgroup was formed to develop a procedure that could be used by monitoring organizations that would provide for a consistent validation of $PM_{2.5}$ mass concentrations across the US. The Workgroup developed three tables of criteria where each table has a different degree of implication about the quality of the data. The criteria included on the tables are from 40 CFR Part 50, Appendices L and N, 40 CFR Part 58, Appendix A, Method 2.12, and a few criteria that are neither in CFR nor Method 2.12.

One of the tables has the criteria that *must* be met to ensure the quality of the data. An example criterion is that the average flow rate for the sampling period must be maintained to within 5% of 16.67 liters per minute. The second table has the criteria that indicate that there *might* be a problem with the quality of the data and further investigation is warranted before making a determination about the validity of the sample or samples. An example criterion is that the field filter blanks should not change weight by more than 30.g between weighings. The third table has criteria that indicate a potentially systematic problem with the environmental data collection activity. Such systematic problems may impact the ability to make decisions with the data. An example criterion is that at least 75% of the scheduled samples for each quarter should be successfully collected and validated.

To determine the appropriate table for each criterion, the members of the workgroup considered how significantly the criteria impact the resulting $PM_{2.5}$ mass. This was based on experience from workgroup members, experience from non-workgroup members, and feasibility of implementing the criterion.

Criteria that were deemed critical to maintaining the integrity of a sample or group of samples were placed on the first table. Observations that do not meet each and every criterion on the **Critical Criteria Table** should be invalidated unless there are compelling reason and justification for not doing so. Basically, the sample or group of samples for which one or more of these criteria are not met is invalid until proven otherwise. The cause of not operating in the acceptable range for each of the violated criteria must be investigated and minimized to reduce the likelihood that additional samples will be invalidated.

Criteria that are important for maintaining and evaluating the quality of the data collection system are included on the second table, the **Operational Criteria Table**. Violation of a criterion or a number of criteria may be cause for invalidation. The decision should consider other quality control information that may or may not indicate the data are acceptable for the parameter being controlled. Therefore, the sample or group of samples for which one or more of these criteria are not met is suspect unless other quality

control information demonstrates otherwise. The reason for not meeting the criteria MUST be investigated, mitigated or justified.

Finally, those criteria which are important for the correct interpretation of the data but do not usually impact the validity of a sample or group of samples are included on the third table, the **Systematic Criteria Table**. For example, the data quality objectives are included in this table. If the data quality objectives are not met, this does not invalidate any of the samples but it may impact the error rate associated with the attainment/non-attainment decision.

Based on the success and use of the $PM_{2.5}$ validation template, the Workgroup embarked on the development of similar templates for the remaining criteria pollutants. Appendix D provides templates for each criteria pollutant. The validation templates are based on the current state of knowledge at the time of development of the Handbook. The template will evolve as new information is discovered about the impact of the various criterion on the error in the resulting concentration estimate. Interactions of the criteria, whether synergistic or antagonistic, should also be incorporated when the impact of these interactions becomes quantified. Due to the potential misuse of invalid data, data that are invalidated will not be uploaded to AQS but should be retained on the monitoring organizations local database. This data will be invaluable to the evolution of the validation template.

> **NOTE:** Strict adherence to the validation templates is not required. They are meant to be a guide based upon the knowledge of the Workgroup who developed them and may be a starting point for monitoring organization specific validation requirement.