Data Validation

REGION 4 QUALITY ASSURANCE TRAINING
SEPTEMBER 2019
ATHENS, GEORGIA
Agenda

• Validation - What, Why, and Who
• Validation Templates
• Data Review Levels and Supporting Documentation
• AQS Codes and Validation
• Examples and Exercises!!!
Part 1: Introduction to Ambient Air Validation
What influences air monitoring data?
Each data point is influenced by numerous people and processes
Data of Known Quality

Data are said to be of **known quality** when:
• The quality needs were defined **in advance**
• The data were **verified**
• The data were **validated**
• The data were **assessed**

All other data are of: **UNKNOWN QUALITY**
Documentation should be available to track the “life” of all valid sample concentrations, as well as justify concentrations which were flagged or invalidated.
Frequent data review is needed at several levels to ensure data integrity. If this does not occur, it is difficult to go back in time and accurately qualify the data.
Data Review

Data review is the in-house examination of data to ensure it has been recorded, transmitted, and processed correctly.

- Data verification and validation are methods in the data review process.
- Include techniques used to accept, reject, or qualify data in an objective and consistent manner.
Definitions

- **Verification**: Evaluation of data for **correctness and completeness**
- **Validation**: Evaluation of data for **compliance** with specified quality control
- **Assessment**: Evaluation of the **aggregated** data set’s ability to **meet the intended objectives**
- **Reconciliation**: Evaluation of the **aggregated** data set’s and the specified objectives’ ability to **meet the users’ needs**
Data Verification

• Is the process for evaluating the completeness, correctness, and conformance of data against method, procedural, and/or contractual specifications

• It can be further defined as the confirmation, through provision of objective evidence, that specified requirements have been fulfilled
Data Verification

Site Operator
Self-review of SMALL data sets
- Data gaps
- Calibration specifications
- QC check specifications
- Datalogger-applied status flags
- Instrument diagnostic / performance specifications
- Concentration values
Data Validation

• Routine process designed to ensure that reported values meet the quality goals of the environmental data operation

• It can be further defined as the confirmation, through provision of objective evidence, that particular requirements for a specified intended use are fulfilled

• Intended Use = Monitoring Objective(s)
Data Validation

Data Reviewer

Verifies the verifier – and more!

Compared data results to:

- QAPP / SOP Requirements
- CFR and Method Requirements
- Instrument FRM/FEM Designation Specifications
- Measurement Quality Objectives (MQOs)
- Actual Events (documentation)
Data Validation, Continued

• Looks for trends
• Uses **professional judgment** to make some decisions on validity (usability, defensibility)
• Ensures **consistency** in data review judgment calls
• Ensures consistent AQS data coding, to provide **comparable** data results for the monitoring organization’s network
Independence is needed in order to minimize personal bias

The data reviewer must judge the validity of data based upon tangible, objective supporting records and documentation.
All staff who review data need to follow the same set of business rules

- Data validation SOPs are needed to ensure a consistent process
- One central/independent figure should be the final decision maker, and should spot check the validation process
DECISION MAKER

DQOs: Big picture
• Aggregate of all QC checks collected at site and across pollutant network
• CV/bias computation
• Indicator of systemic issues
  • If fails, big picture questions & investigation needed.
  • For example, warning limits may need to be tightened or aged monitors replaced
• DATA ASSESSMENTS

DATA COLLECTOR

MQOs: Individual Analyzer
• Single QC checks
• Percent difference (%d) computation
• Assess how well the analyzer compares to the standard against which it was challenged – at that moment in time
  • If fails, investigation needed to determine cause of failure, in order to return the analyzer to an “in control” status
• DATA VALIDATION

Reminder: DQOs vs MQOs

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Part 2: Validation Templates
Templates & Weight of Evidence

40 CFR Part 58, Appendix A, Section 1.2.3

“Each PQAO is required to implement a quality system that provides sufficient information to assess the quality of monitoring data. . . . Accordingly, the EPA and PQAOs shall use a ‘weight of evidence’ approach when determining the suitability of data for regulatory decisions...
Templates & Weight of Evidence

40 CFR Part 58, Appendix A, Section 1.2.3 – Continued

...The EPA reserves the authority to use or not use monitoring data submitted by a monitoring organization when making regulatory decisions based on the EPA's assessment of the quality of the data. **Consensus built validation templates** or validation criteria already approved in QAPPs should be used as the basis for the weight of evidence approach.”
QA Handbook, Appendix D: Data Validation Templates
Data Validation Templates

Data Validation templates are the MQO tables for each pollutant.

Data validation templates are typically ~2-4 pages per pollutant.
The data validation templates were developed by a workgroup consisting of OAQPS, the EPA Regions, and State/Local/Tribal air monitoring organizations!
The main focus of data validation is determining data quality in terms of accomplishment of measurement quality objectives (MQOs).
How to “Read” the Templates

- Pink = Critical Criteria
- Yellow = Operational Criteria
- Blue = Systematic Criteria

Column 1 = Itemized Requirement/Element
Column 2 = Frequency of Requirement
Column 3 = Acceptance Criteria
Column 4 = Additional information, including citations noting where the requirement originated

Use of **Bold Italics** identifies requirements codified in the CFR
**Critical Criteria**

- Requirement, implementation frequency, and/or acceptance criteria are found in CFR
- Critical to maintaining the integrity of a sample or group of samples
- **Invalidate** unless there is compelling evidence for not doing so
- This compelling evidence is needed in order to **prove** the data is valid

<table>
<thead>
<tr>
<th>CRITICAL CRITERIA-OZONE</th>
<th>Meets requirements listed in FRM/FEM designation</th>
</tr>
</thead>
</table>
| Monitor                 | NA                                            | 1) 40 CFR Part 58 App C Sec. 2.1  
2) NA  
3) 40 CFR Part 53 & FRM/FEM method list |
| One Point QC Check      | Every 14 days                                 | 1 and 2) 40 CFR Part 58 App A Sec. 3.1  
3) Recommendation based on DQO in 40 CFR Part 58  
App A Sec. 2.3.1.2. QC Check Conc range 0.005 - 0.08 ppm and 05/05/2016 Technical Note on AMTIC |
| Single analyzer         |                                              | 1 and 2) QA Handbook Volume 2 Sec. 12.3  
3) Recommendation and related to DQO |
| Zero/span check         | Every 14 days                                 | 1 and 2) 40 CFR Part 58 App A Sec. 3.1  
3) Recommendation based on DQO in 40 CFR Part 58  
App A Sec. 2.3.1.2. QC Check Conc range 0.005 - 0.08 ppm and 05/05/2016 Technical Note on AMTIC |
|                         |                                              | 1 and 2) QA Handbook Volume 2 Sec. 12.3  
3) Recommendation and related to DQO |
Compelling Evidence

• Data that concretely establishes instrument performance or validity of the check

• Includes, but is not limited to, data generated from:
  • Independent audit point(s), multi-point verification, and/or prior zero/span check

• This data establishes whether the analyzer was operating within its acceptance limits

• Indicates whether a QC check itself is considered valid or invalid
Operational Criteria

• Important for maintaining and evaluating the quality of the data collection system

• The sample or group of samples for which one or more of these criteria are not met are suspect unless other quality control information demonstrates otherwise and is documented

• Violation of an operational criterion may result in the application of an AQS QA qualifier flag(s)

• Violation of an operational criterion or a number of operational criteria may also be cause for data invalidation

• The reason for not meeting the criteria must be investigated, mitigated or justified
# Operational Criteria

## Operational Criteria - Ozone

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Requirement</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shelter Temperature Range</strong></td>
<td>Daily (hourly values)</td>
<td>20.0 to 30.0°C (Hourly avg) or per manufacturers specifications if designated to a wider temperature range</td>
</tr>
<tr>
<td><strong>Shelter Temperature Control</strong></td>
<td>Daily (hourly values)</td>
<td>≤ 2.1°C SD over 24 hours</td>
</tr>
<tr>
<td><strong>Shelter Temperature Device Check</strong></td>
<td>Every 182 days and 2/ calendar year</td>
<td>≤ ± 2.1°C of standard</td>
</tr>
<tr>
<td><strong>Annual Performance Evaluation Single analyzer</strong></td>
<td>Every six every 365 days and 1/ calendar year within period of monitor operation.</td>
<td>Percent difference of audit levels: 3-10 ≤ ±15.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Audit levels 1&amp;2 ≤ ± 1.5 ppb difference or ≤ ± 15.1%</td>
</tr>
<tr>
<td><strong>Federal Audits (NFAP)</strong></td>
<td>70% of sites audited in calendar year</td>
<td>Audit levels 1&amp;2 ≤ ± 1.5 ppb difference all other levels percent difference ≤ ± 10.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Verification/Calibration</strong></td>
<td>Upon receipt/adjustment/repair/installation/moving and repair and recalibration of standard of higher level. Every 182 day and 2/ calendar year if manual zero/zero performed biweekly. Every 365 day and 1/ calendar year if continuous zero/zero performed daily</td>
<td>All points ≤ ± 2.1 % or ≤ ± 1.5 ppb difference of best-fit straight line whichever is greater and Slope 1 ± .05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Zero Air/Zero Air Check</strong></td>
<td>Every 365 days and 1/calendar year</td>
<td>Concentrations below LDL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Systematic Criteria

• 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
  • Includes such items as reporting units and quarterly data completeness goals
  • Includes the DQOs

• If the DQOs are not met, it does not invalidate specific samples; rather, it may impact the uncertainty associated with the attainment/non-attainment decision
  • In some cases, violation of a systematic criterion may result in the application of AQS QA qualifier flags
# Systematic Criteria

## Systematic Criteria-Ozone

<table>
<thead>
<tr>
<th>Standard Reporting Units</th>
<th>All data</th>
<th>ppm (final units in AQs)</th>
<th>1, 2 and 3</th>
<th>40 CFR Part 50 App I Sec. 2.1.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bounding convention for design value calculation</td>
<td>All routine concentration data</td>
<td>3 places after decimal with digits to right truncated</td>
<td>1) 40 CFR Part 50 App I</td>
<td></td>
</tr>
<tr>
<td>Completeness (seasonal)</td>
<td>3-Year Comparison</td>
<td>&gt; 90% (avg) daily max available in ozone season with min of 75% in any one year</td>
<td>1) 40 CFR Part 50 App I</td>
<td></td>
</tr>
<tr>
<td>8-hour average</td>
<td>≥75% of hourly averages for the 8-hour (6 of 8 hours)</td>
<td></td>
<td>2) 40 CFR Part 50 App I Sec. 2.3</td>
<td></td>
</tr>
<tr>
<td>Valid Daily Max</td>
<td>&gt; 75% of the 24, valid 8-hour averages (18 of 24 8-hour averages)</td>
<td></td>
<td>3) 40 CFR Part 50 App I Sec. 2.3 (b)</td>
<td></td>
</tr>
<tr>
<td>Sample Residence Time Verification</td>
<td>Every 365 days and 1/calendar year</td>
<td>≤ 20 Seconds</td>
<td>1) 40 CFR Part 58 App E, Sec. 9 (a)</td>
<td></td>
</tr>
<tr>
<td>Sample Probe, Inlets, Sampling train</td>
<td>All sites</td>
<td>Borosilicate glass (e.g., Pyrex® or Teflon®)</td>
<td>2) Recommendation</td>
<td></td>
</tr>
<tr>
<td>String</td>
<td>Every 365 days and 1/calendar year</td>
<td>Meets string criteria or waiver documented</td>
<td>3) 40 CFR Part 58 App E, Sec. 9 (c)</td>
<td></td>
</tr>
<tr>
<td>EPA Standard Ozone Reference Photometer (SRP) Recertification (Level 1)</td>
<td>Every 365 days and 1/calendar year</td>
<td>Regression slope = 1.00 ± 0.01 and intercept &lt; 5 ppb</td>
<td>1) 40 CFR Part 58 App E, Sec. 2-6</td>
<td></td>
</tr>
<tr>
<td>Precision (using 1-point QC checks)</td>
<td>Calculated annually and as appropriate for design value estimates</td>
<td>90% CL CV &lt; 7.1%</td>
<td>2) 40 CFR Part 58 App A 2.3.1.2 &amp; 3.1.1</td>
<td></td>
</tr>
<tr>
<td>Bias (using 1-point QC checks)</td>
<td>Calculated annually and as appropriate for design value estimates</td>
<td>95% CL &lt; ±7.1%</td>
<td>3) 40 CFR Part 58 App A 2.3.1.3 &amp; 3.1.1</td>
<td></td>
</tr>
</tbody>
</table>

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Template Rankings

• Operational or systematic quality control checks need to be performed

• Not performing an operational or systematic quality control check that is required by regulation can be a basis for invalidation of all associated data

• Consistently not meeting an operational or systematic criteria requires a corrective action(s) be implemented
Part 3: Data Review Levels
Tiered Data Review Approach

• Multi-step review process, conducted by several individuals with different perspectives

• May not be fully possible in smaller agencies, but efforts should be made to ensure independence

• Ensures data in AQS tells the complete and correct story
Level 0
- Datalogger / Sampler
- Continuous / Daily
- Distinguish measurements from measurement errors or pre-programmed (automated) QC activities

Level 1
- Site Operator
- Daily / Monthly
- Distinguish measurements from measurement errors or interferences

Level 2
- Independent Reviewer (QA)
- Monthly / Quarterly
- Verify Level 1 Review
- Ensure data meets QA/QC requirements and objectives of its intended use

Level 3
- Independent Review (QAM)
- Monthly / Quarterly / Annually
- Verify Level 1 and 2 Reviews
- Approve data suitability for release to AQS

AQS qualifier flags or null value codes can be applied or suggested at any level.
Level 0 Review

• Continuous / Real-time

• Data loggers can be pre-programmed to flag data during certain events

• Data loggers and samplers will also apply status flags when certain pre-programmed specifications have been exceeded

• Data sets polled / downloaded will display the flags applied by these instruments
Level 1 Review

- Performed by the operator
- Daily / Weekly / Monthly Process
- Goal is to distinguish measurements from measurement errors or interferences
- Operator is the most knowledgeable about the specific site and specific instrument-performance
Level 2 Review

• Independent Reviewer (QA)
• Monthly / Quarterly Process
• Goals include:
  • Verifying the Level 1 Review and supporting documentation
  • Ensure data meets the QA/QC requirements and objectives of its intended use (validation)
Level 3 Review

• Additional Independent Reviewer (QA Manager or equivalent)
• Monthly / Quarterly / Annual Process
• Verifies the Levels 1 and 2 Reviews
• Ensures data is accurate, complete, comparable, representative, and defensible, given the supporting documentation
• Includes data quality assessment (DQA)
• Approves data suitability for release to AQS
• Specific quarterly reporting periods
• Report all data and information gathered during the reporting period to AQS within 90 days after the end of the quarterly reporting period
• For example, the data for the reporting period January 1-March 31 are due on or before June 30 of that year
Validation Timeline

- 40 CFR Part 58.16 establishes the timeline by which data must be edited, validated, and reported to AQS
- The reporting schedule allows approximately 90-180 days for Levels 0 – 3 data review activities to occur
- Data modifications can occur at any time after data has been reported to AQS
- Data certification is due May 1 annually
The process of evaluating data against the Data Quality Objectives (DQOs) – **after** validation has been completed!
Data Quality Assessments

- Monitor-level and network-level (PQAO)
- Annual data assessments should be completed by QAM (or other designated staff)
  - Annual data certification is an assessment
  - Other AQS reports can be run, such as the AMP 256
- 3-year assessments are also helpful when assessing criteria pollutant data
- Longer-term assessments (e.g., 6-year or 10-year) may happen in some programs, like toxics
Continuous Analyzer Data Review
The following slides describe general procedures to review data
Data Verification
Levels 0-1

Level 0
- Datalogger / Sampler
- Continuous / Daily
- Distinguish measurements from measurement errors or pre-programmed (automated) QC activities

Level 1
- Site Operator
- Daily / Monthly
- Distinguish measurements from measurement errors or interferences

Level 2
- Independent Reviewer (QA)
- Monthly / Quarterly
- Verify Level 1 Review
- Ensure data meets QA/QC requirements and objectives of its intended use

Level 3
- Independent Review (QAM)
- Monthly / Quarterly / Annually
- Verify Level 1 and 2 Reviews
- Approve data suitability for release to AQS
Level 0 is performed **automatically** by the site datalogger or the sampler.

In some organizations, the status flags applied during Level 0 verification are programmed to translate into AQS null codes by the data acquisition software.

Types of flags available for this example application:
• **Level 1 = Site operator**

• **Daily** data review (**target = 100%)**
  - Proactive approach to preventive data loss
  - Scrutinize the previous 24 hours of data

• **Monthly** data review also recommended to look for **trends**

• **Goal**: To distinguish measurements from measurement errors or interferences

• Operator will have information and evidence to illustrate whether data anomalies resulted from analyzer issues and/or localized events near the site (e.g., nearby prescribed fire)
Level 1 Verification should include, but is not limited to, the following:

- Look for missing data (gaps)
  - If identified, determine root cause and document it
- Re-poll datalogger or instrument, if possible
- Review all status flags applied by the datalogger/sampler
  - Determine if those flags are expected (i.e., correct)
  - If unexpected, investigate the data points further to determine root cause(s) and document it
Level 1 Verification, Continued:

• Verify data against FRM/FEM specifications. Document any excursions.

• Verify data against other instrument specifications. Document any excursions.

• Review the **maximum and minimum concentrations**
  • Do the values make sense?
  • Are the values real or the results of an automated QC procedure?
  • If errors are found, document them, along with the reasons explaining their cause.
Level 1 Verification, Continued:

• Look for **outliers**. If identified, investigate to determine root cause. Document findings.

• Compare pollutant concentrations to the analyzer’s **strip chart** (analog or digital) to check for DAS accuracy.
Monthly Data Verification Procedures

• Still Level 1 Review – but a larger data set (i.e. one month, instead of 24 hours)
• Use same criteria as previously described for daily review to look for oversights

Trends become more apparent through a monthly review!
Data Verification Best Practice: Review Minute Data

Look for patterns in the minute data

Verify data spikes and anomalies to determine root causes
Benefits of Minute Data Review

• Graphical display of data can illuminate problems that might be harder to catch if only viewing numerical reports

• Can identify faulty or degrading equipment prior to a major malfunction, which minimizes data loss

• Identifies problems with instrument set-up or datalogger programming, which can expedite corrective action & minimize data loss

• More easily identifies trends & patterns in the data set; anticipated behavior of pollutants can be more easily seen and verified

• Provides a higher level of confidence in the quality of data collected & reported to AQS
Expected Ozone Diurnal Pattern

24-hr view of data
Analyzer leak following internal filter change

Minute data illustrates lack of diurnal pattern during heat of day

Failed span check follows

Diurnal pattern?

Site visit & maintenance

24-hr view of ozone data
Solenoid and/or Detector Malfunction

The QC data for this day looked normal, as did the hourly averages. However, you can see from the graph that there is actually a malfunction occurring.
Water in the Sample Lines

The QC data for this day looked normal, but the operator can see from the graph that there is something wrong.
Significantly low concentrations of ozone in July?
Monthly Data Verification Procedures

• Re-review minute data (strip charts) to watch for trends or shifts over time

• Review logbook notations for issues not previously observed
Monthly Data Verification Procedures

- Verify documentation on all spreadsheets, forms, and/or supporting data reports
  - Is documentation complete and accurate?
  - Does it convey everything the data validator needs to know?
• **Document** Level 1 Reviews
  • Daily: Notations on an electronic log, printed Daily Summary Report
  • Monthly summary report
  • Agency-specific written report
• Sign and date the data review report/summary
• Submit report and any required supporting documentation to the designated next-level reviewer
Data Validation
Levels 2-3

Level 0
- Datalogger / Sampler
- Continuous / Daily
- Distinguish measurements from measurement errors or pre-programmed (automated) QC activities

Level 1
- Site Operator
- Daily / Monthly
- Distinguish measurements from measurement errors or interferences

Level 2
- Independent Reviewer (QA)
- Monthly / Quarterly
- Verify Level 1 Review
- Ensure data meets QA/QC requirements and objectives of its intended use

Level 3
- Independent Review (QAM)
- Monthly / Quarterly / Annually
- Verify Level 1 and 2 Reviews
- Approve data suitability for release to AQS
• Level 2 = **Independent** data reviewer/validator

• **Monthly** data review (percentage)

• **Quarterly** data review to look for trends or oversights

• **Goals:**
  
  1) Verify Level 1 Review
  
  2) Ensure data meets QA/QC requirements and intended use

• Use supporting documentation and objective evidence to make data validity judgment calls

• Do **not** make assumptions
Level 2 Goal #1: Verify the Level 1 Review

Should include, but is not limited to, the following:

• Look for any missing data (gaps) not identified by the operator
  • If found, investigate cause and determine method to handle data gap

• Check suggested null codes against supporting documentation

• Review the daily maximum and minimum concentrations for accuracy

• Look for constantly repeating values and/or outliers

• If errors are found, the data validator should scrutinize a larger percentage of the data and/or return the data package to the Level 1 Reviewer for a second review
Level 2 Goal #2: Ensure data meets QA/QC requirements and the objectives of its intended use

What does this generally include?

• Compare data to pollutant’s MQO table

• Verify QA/QC checks were completed & performed in accordance with QAPP/SOPs (strip chart!!)

• Compare data to other QAPP/SOP requirements

• Investigate any areas of concern noted by the site operator

• Compare concentrations to neighboring sites

• Bracket data using QA/QC check results and/or other objective, documented evidence

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Sign and date the data review report/summary to document the completed Level 2 review

Submit report/summary and any required supporting documentation to the designated next-level reviewer
• Level 3 = Another independent data reviewer (QAM)

• Goals:
  • 1) Verify Levels 1 & 2 Reviews
  • 2) Ensure data meets objectives of its intended use
  • 3) Approve data suitability for upload to AQS

• Similar to Level 2 review, except that a smaller percentage of data is examined

• Verify that in-house records and documentation support the data validation decisions

• If issues are found, the QAM should review a larger percentage of the data and/or return the package to the Level 2 reviewer for second review
Intermittent Sampler Data Review
Monitoring Organization

- Level 0 = Sampler
- Level 1 = Site Operator
- Level 2 = Data Reviewer
- Level 3 = QAM

Laboratory

- Level 1 = Lab Analyst
- Level 2 = Lab Supervisor
- Level 3 = Lab QAM

Final Review & Approval by Monitoring Org QAM

AQS
## Example Particulate Data Validation Template

### Field Criteria

<table>
<thead>
<tr>
<th>Field Criteria</th>
<th>Laboratory Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample Monitor</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Filtering Time</strong></td>
<td>8 hours before sampling</td>
</tr>
<tr>
<td><strong>Sample Recovery</strong></td>
<td>8 hours from sample and data</td>
</tr>
<tr>
<td><strong>Sample Period (days multiple of 24)</strong></td>
<td>888/3000 minutes or 14 days</td>
</tr>
<tr>
<td><strong>Sampling Temperature</strong></td>
<td>Temperature between 2°C and 25°C</td>
</tr>
<tr>
<td><strong>Average Flow Rate</strong></td>
<td>5% of flow at 50 LPM</td>
</tr>
<tr>
<td><strong>Flow Rate Variability</strong></td>
<td>&lt;= 1%</td>
</tr>
<tr>
<td><strong>Flow Rate Change</strong></td>
<td>&lt;= 1%</td>
</tr>
<tr>
<td><strong>Flow Sensor</strong></td>
<td>No flow rate changes &gt; 5% for &gt; 5 min, &lt;= 1% for &gt; 10 minutes</td>
</tr>
<tr>
<td><strong>External Leak Check</strong></td>
<td>Pressure drop of &gt; 0.01 mbar/sec (over 2 sec)</td>
</tr>
<tr>
<td><strong>Internal Leak Check</strong></td>
<td>Pressure drop of &gt; 0.01 mbar/sec</td>
</tr>
</tbody>
</table>

### Laboratory Criteria

<table>
<thead>
<tr>
<th>Laboratory Activities</th>
<th>Information / Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-sampling Weighting</strong></td>
<td>all filters</td>
</tr>
<tr>
<td><strong>Temperature</strong></td>
<td>20°C to 25°C</td>
</tr>
<tr>
<td><strong>Humidity Range</strong></td>
<td>50% to 70%</td>
</tr>
<tr>
<td><strong>Humidity Control</strong></td>
<td>60% or 40%</td>
</tr>
<tr>
<td><strong>Relocation</strong></td>
<td>All filters</td>
</tr>
<tr>
<td><strong>Temperature Change</strong></td>
<td>&lt;= 1°C/30min</td>
</tr>
<tr>
<td><strong>Microbial Activity</strong></td>
<td>Manifestation's evaluation</td>
</tr>
</tbody>
</table>

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The monitoring organization is responsible for final validation of data, including data obtained from contract laboratories.
In The Lab

• Each method will have different QA/QC requirements that will need to be reviewed.

• Analyst will be responsible for verifying laboratory batch session results.

• Lab supervisor will ensure the acceptability of the analyses, QC checks, and the completeness of the data.

• Final review and release to client by laboratory QAM.
In The Field – Monitoring Organization

**LEVEL 0 DATA REVIEW**

- Some models of PM samplers contain data loggers that are pre-programmed to identify exceedances of critical performance specifications or other outliers
  - Examples: Flow rate and temperature excursions
- Some samplers will also throw status flags in the event of certain mechanical failures
- Capabilities are model-specific.
- Less sophisticated PM samplers do not have these capabilities.

**LEVEL 1 DATA REVIEW**

- Site operators are responsible for pre- and post-sample collection activities, including verifying specific instrument and atmospheric conditions
- Visual inspection of sample media
- Visual inspection of sampler and station conditions
- Download and review of all data collected by the sampler to look for errors
- Documentation of all activities and observations which impact sample integrity
- Can recommend sample be “void” based on data review or known issues (e.g., damaged sample)
Level 2 Data Review (Field)

Should include, but is not limited to:

- **Verification of all flow rate verifications**
  - Completed on time?
  - Within acceptance criteria (transfer standard and design flow rate)?

- **Verification of performance audit results**
  - Completed on time?
  - NIST-traceable, Independent equipment?
  - Within specification (transfer standard and design flow rate)?

- **Results of field blanks**
  - Within acceptance limits?
  - Any trends? Control charts recommended

- **Sampler Maintenance**
  - Perform when required?
  - Sampler performance specifications checked before & after maintenance?

- **Field Equipment Repairs Noted? If so, determine:**
  - What was the issue?
  - Were sensors recalibrated?
  - QC check prior to field use?

- **Exceptional Events**
  - Unusually high concentrations?
  - Regional review of data results
  - Supporting documentation?
• Levels 2 and 3 review at the monitoring organization should include a review of the **lab data package** to ensure all method requirements and pollutant-specific critical criteria elements were met.

• Monitoring Organization should establish agreement with the laboratory to provide specific QC data from the analytical batches in data packages, in addition to sample results (e.g., masses or μg/filter concentrations).

• Copies of all chain-of-custody forms should also be maintained by the monitoring organization.
Scenario:
PQAO-operated Gravimetric Laboratory, with a Concentration Query Generated by Lab Analyst from in-house database for QA Review

Query provides site ID, filter type (e.g., sample filter, field blank, trip blank), sample date, concentration, mass difference, and pertinent comments by the site operator and lab analyst

Query contains results from all sites for one calendar month
Example: Monthly PM$_{2.5}$ Data Review

- Highlight the maximum concentration and one random concentration from each site
- Manually calculate concentrations using lab and field data to ensure computations are correct
- Review all field/lab critical criteria and supporting documentation to ensure samples are valid and meets method requirements
- Highlight all field blanks results
  - Verify concentrations on a percentage of blanks & note if any exceed 30 µg
- Review results between all collocated data pairs
  - If pair exceeds acceptance limits, investigate why
- Highlight any sample concentrations less than 2 µg/m$^3$
  - If observed, review operator notes & compare concentrations from site to site
Example: PM$_{2.5}$ Data Review, Continued

Supporting documentation to review to inform this process:

- Documentation from lab analyst that may cause samples to be questionable or void
- Documentation by site operator for pertinent notes/commentary that may cause samples questionable or void. Includes, but is not limited to:
  - Chain-of-custody forms
  - Logbook documentation
  - QC check, calibration, and/or maintenance forms
- Spot-check a percentage of sampler filter and interval data files for anomalies, in order to confirm Level 1 review
- Bracket data using results of QA/QC checks!
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<th>Sample Date &amp; Sample Retrieval Difference (hrs)</th>
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<th>Exposed Mass (mg)</th>
<th>Net Mass (mg)</th>
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Part 4: Data Handling Qualification Concepts
Data Usability

• QAPP/SOPs will not be able to cover every unique situation or circumstance data reviewers may encounter, but should be detailed enough to guide the data reviewer’s decision-making process

• Data Validation SOP should contain specific procedures and criteria to judge data against, as well as rules on coding and flagging
AQS Data Reporting

Null Data Codes
• Invalidated data
• Impact data completeness

Qualifier Codes
• Data does not meet a particular criterion, but has been determined to be valid
• Does not impact completeness

Informational Flags ("I" series)
• Related to external environmental conditions

Request for Exclusion Flags ("r" series)
• Formal request for data exclusion under the Exceptional Events Rule
Applying AQS Null Codes & Flags

Critical Criteria
• Invalidate with AQS null code
• Or apply AQS QA Qualifier Flag “1”, or “1V” if compelling evidence exists

Operational Criteria
• Apply “2” QA Qualifier Flag

Systematic Criteria
• Apply “3” or other more representative QA Qualifier
Data Flagging

✓ Qualifier flags **caution** data users, but do **not** invalidate data
✓ Increases transparency, when needed
✓ AQS allows up to 10 qualifier codes per data point
  ✓ **Warning:** *If a data point requires multiple flags because of multiple deviations, a null value code may be needed!*
✓ Allows for more data to be used to calculate a design value
✓ Helps ensure data is legally defensible
✓ Supports exceptional events demonstrations and modeling
CAUTION!

Are these samples *really* valid?

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Templates are meant to be applied to **small data sets**
(single values or a few weeks of information)

AQS QA qualifier flag of “1” is **not** intended for widespread, common use
Data Bracketing

When QC checks exceed acceptance limits, data should be invalidated back to the last passing QC check.

Similarly, data should be invalidated forward until the next passing QC check or calibration.
The AQS AMP 350 Report Tells a Story

Code change?  What malfunctioned?
Where is maintenance & recalibration?

Data should be coded in a manner that most accurately represents what happened
After AQS Upload – Next Steps

As a best practice, AQS Reports should be generated after AQS upload in order to spot-check that data entry was successful and complete.

AMP 350 – Raw Data Report
AMP 251 – QA Raw Assessment Report

Manually generated data (such as QA/QC data) should be peer-reviewed for typographical errors or any oversights.

Data quality issues can span AQS reporting schedules. Data modifications can occur after data has been uploaded to AQS.

Data assessments can be performed by AQS, through generating various reports. Results of assessments may also reveal issues that require investigation and potential modification of data in AQS.
Part 5: Examples and Exercises
AQS DATA CODING EXERCISE

DESCRIPTION:

Site technician takes an ozone analyzer off-line and performs a one-point QC check

POSSIBLE CODE/FLAGS:

BD: Auto Calibration
AY: QC Control Points (zero/span)
BF: Precision/Zero/Span
AC: QC Audit
AX: Precision Check
AQS DATA FLAGGING EXERCISE

DESCRIPTION:

Audit team performs a semi-annual flow check on a PM$_{2.5}$ FEM BAM1020

POSSIBLE CODE/FLAGS:

<table>
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<th>BC: Multi-Point Calibration</th>
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<tbody>
<tr>
<td>AT: Calibration</td>
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<tr>
<td>BL: QA Audit</td>
</tr>
<tr>
<td>BM: Accuracy Check</td>
</tr>
<tr>
<td>AM: Miscellaneous Void</td>
</tr>
</tbody>
</table>
AQS DATA CODING EXERCISE

DESCRIPTION:

During a filter weighing session, the lab technician discovers that there is a fingerprint on the filter.

POSSIBLE CODE/FLAGS:

- **AJ**: Filter Damage
- **AQ**: Collection Error
- **AR**: Lab Error
- **BJ**: Operator Error
- **FI**: Filter Inspection Flag
AQS DATA CODING EXERCISE

DESCRIPTION:

A PM$_{10}$ BAM-1020 measures an hourly concentration of 985 µg/m$^3$ for 2 hours. The preceding and following hourly averages were 675 and 700 µg/m$^3$, respectively.

POSSIBLE CODE/FLAGS:

- DA: Aberrant Data
- DL: Detection Limit Analysis
- AV: Power Failure
- EH: Exceeds Upper Limit
- 5: Outlier
AQS DATA CODING EXERCISE

DESCRIPTION:
A data reviewer observes a concentration of 0.168 ppm during the 0700 hour for the NCore ozone monitor. The logbook contains a notation of “site visit, rainy”, with no additional information. The minute data for the monitor shows the ozone trace with level stair-steps at zero and two span concentrations.

POSSIBLE CODE/FLAGS:

AB: Technician Unavailable

BD: Auto Calibration

BF: Precision, Zero, Span

6: QAPP Issue

No codes / flags – Valid concentration
AQS DATA CODING EXERCISE

DESCRIPTION:

An ozone probe is within 10 meters of a tree dripline.

POSSIBLE CODE/FLAGS:

- 3: Field Issue
- SX: Does Not Meet Siting Criteria
- QX: Does Not Meet QC Criteria
- SC: Sampler Contamination
- AM: Miscellaneous void

R4 QA Training September 2019
AQS DATA CODING EXERCISE

DESCRIPTION:
Internal auditor determined that the agency’s QAPP had not been revised in 6 years since its last EPA-approval. Contents within the QAPP did not meet current regulatory requirements or accurately reflect the agency’s processes.

POSSIBLE CODE/FLAGS:

1: Deviation from CFR/Critical Criteria Requirement

2: Operational Deviation

AM: Miscellaneous void

6: QAPP Issue

No codes or flags: Valid data
AQS DATA CODING EXERCISE

DESCRIPTION:
SOP calls for a quarterly ozone calibrations. Site operator performs the multi-point verification and all points pass, so no adjustment is needed.

POSSIBLE CODE/FLAGS:

- **BC:** Multi-point Calibration
- **BD:** Auto-Calibration
- **QV:** Quality Control Multi-Point Verification
- **BL:** QA Audit
- **AZ:** QC Audit
AQS DATA CODING EXERCISE

DESCRIPTION:
Agency begins monitoring for source-oriented lead (Pb). A QAPP is developed, but the agency does not write an SOP for operating the Pb sampler.

POSSIBLE CODE/FLAGS:

1: Deviation for CFR/Critical Requirement

3: Field Issue

6: QAPP Issue

AS: Poor Quality Assurance Results

No codes/flags: Valid Data

R4 QA Training September 2019
AQS DATA CODING EXERCISE

DESCRIPTION:
Agency’s SOP requires PM2.5 filter-based samples to be retrieved within 96 hours of sample end-time. EPA’s data validation templates allow for 177 hours. Documentation on a sample’s chain-of-custody shows the site operator picked the sample up ~148 hours after sample end-time.

POSSIBLE CODE/FLAGS:

1: Deviation for CFR/Critical Requirement

HT: Sample pick-up hold time exceeded

TS: Holding Time

6: QAPP Issue

No codes/flags: Valid Data
AQS DATA CODING EXERCISE

DESCRIPTION:
Agency’s QAPP requires PM2.5 filter-based samples to be retrieved within 177 hours of sample end-time. Documentation on a sample’s chain-of-custody shows the site operator picked the sample up ~180 hours after sample end-time.

POSSIBLE CODE/FLAGS:

1: Deviation for CFR/Critical Requirement

HT: Sample pick-up hold time exceeded

6: QAPP Issue

TS: Holding Time

No codes/flags: Valid Data

R4 QA Training September 2019
A site operator performs maintenance/repair on an analyzer prior to a calibration. The maintenance/repair took ~40 minutes of the hour, with the calibration procedure starting immediately thereafter. The hour should be coded:

POSSIBLE CODE/FLAGS:

- **BA:** Maintenance / Routine Repairs
- **BC:** Multi-point calibration
- **AT:** Calibration
- **AM:** Miscellaneous Void
- **AL:** Voided by Operator
AQS DATA CODING EXERCISE

DESCRIPTION:

A PM2.5 FRM sampler collects 720 minutes of data. The lab analyst weighed the filter from this sample run. The concentration was 52 ug/m³.

POSSIBLE CODE/FLAGS:

AG: Sample Time Out of Limits

AH: Sample Flow Rate Out of Limits

AI: Insufficient Data, Cannot Calculate

1: Critical Criterion Not Met

AM: Miscellaneous void

R4 QA Training September 2019
AQS DATA CODING EXERCISE

DESCRIPTION:
Site operator does not lock the door to the monitoring site and leaves a sandwich on top of an ozone analyzer. A bear enters the site and destroys everything.

POSSIBLE CODE/FLAGS:

- AW: Wildlife Damage
- AP: Vandalism
- BJ: Operator Error
- BK: Site Computer/Data Logger Down
- 6: QAPP Issue
Code / Flag Recommendations

- Always code missing data
- Apply null codes for scheduled, but missed, filter-based samples
- Use **descriptive** qualifier codes or informational flags that best fit the scenario
- Limit use of Miscellaneous Void (AM) null data code – or, define specific applications of the code in your Data Validation SOP
- **Apply codes / flags CONSISTENTLY**
- Rationale for data code/flags should be supported by the appropriate **DOCUMENTATION**
Compelling Evidence - Example

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**REPORT FOR:** NOVEMBER 2017

**Met One BAM - 1020 Mass N**

<table>
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</table>

R4 QA Training September 2019
Compelling Evidence - Example

1. Flow check failed 11/13/17 at 6.8%
2. Instrument installed June 17, 2017
3. Flow audit passed August 13, 2017
4. Flow checks passed June – October
5. Intermittent temperature issue found during failed flow check

How should the data be qualified?
Compelling Evidence - Example

More Information:

1. Intermittent temperature issue apparent in the meta data since instrument installation
2. Temperature inaccuracy variable but could be up to 10°C, when malfunctioning
3. Multiple malfunctions in most hours

Does the Meta Data Change the Validation Decision?
Weight of Evidence – Example 1

• Auditor reviews certification record for agency’s local primary flow standard
  • Vendor certificate show’s low flow cell arrived “out of tolerance” at -7% difference
  • This cell is used to calibrate the dilution mass flow controllers (MFCs) in agency’s gas dilution calibrators
  • The agency had not performed any pre/post checks prior to shipment to the vendor

• A review of in-house certification records shows a dilution MFC in a site calibrator was biased -7%

• Records review also shows an SO₂ analyzer was calibrated (adjusted) using this calibrator with the negative bias

• An NPAP audit of this SO₂ analyzer fails
Weight of Evidence – Example 1A

• Auditor reviews certification record for agency’s local primary flow standard
  • Vendor certificate shows low flow cell arrived “out of tolerance” at -7% difference
  • This cell is used to calibrate the dilution mass flow controllers (MFCs) in agency’s gas dilution calibrators
  • The agency had not performed any pre/post checks prior to shipment to the vendor

• A review of in-house verification records during this time period shows the dilution MFC in an audit calibrator was biased -7%
Weight of Evidence – Example 2

- Agency brings its Level 2 bench standard to EPA for annual certification at the end of the ozone season
  - The standard was not adjusted or modified in any manner prior to arrival at the EPA lab
  - The agency’s Level 2 is used to certify both field and audit standards
- The Level 2 standard does not pass its certification against the SRP
  - The standard is ~6% off
- Recent NPAP ozone audits at several of the agency’s ozone sites have yielded poor to failing audits
Weight of Evidence – Example 2A

• Agency brings its Level 2 bench standard to EPA for annual certification at the beginning of ozone season
  • The standard was not adjusted or modified in any manner prior to arrival at the EPA lab
  • The agency’s Level 2 is used to certify both field and audit standards
• The Level 2 standard does not pass its certification against the SRP
  • The standard is ~6% off
Weight of Evidence – Example 3

• Internal auditor observes a PM2.5 flow check reported to AQS on November 18 at 4.5% difference (d)

• Site operator uses no QA/QC forms in the field, but records all data in a ledger logbook by hand

• Site operator’s manual calculation of the flow check results was 2%d

• Flow rate verifications checks are performed once per month
  • Previous passing check was October 23 at 3.7%d
  • Next passing check is December 30 at 1.6%d

• Semi-annual flow audit performed on December 21 with results of 3.9%

• Logbook shows a flow rate calibration following the December 21 audit
Weight of Evidence – Example 4

• Critical, operational, and systematic criteria met for organization’s PM$_{2.5}$ samples for all field parameters
• TSA conducted on organization’s recently relocated in-house PM2.5 gravimetric laboratory
• Audit occurs within 2 months of start-up, in order to ensure the new set-up is in good order
• TSA finds multiple non-conformances, all of which are considered “operational criteria”

Findings include:
• Aged microbalance has no known calibration or certification (traceability) documentation
• Balance is found to not be properly grounded
• Laboratory blanks (QC samples) are out of specification (acceptance criterion = 15µg; blank results range from 98µg to -477 µg)
• Field blanks (QC samples) are also significantly out of specification
• Newly purchased RH/temperature datalogger doesn’t meet accuracy specifications
Weight of Evidence – Example 5

For toxics, NATTS, and upcoming PAMS....

Audit conducted identified the following issues:

• The laboratory was operating without a QAPP
• Each lab analyst was implementing a different version of a draft SOP
• Laboratory calibration standards were expired
• Laboratory calibration procedures did not adhere to the requirements of TO-15
• Analytical data did not undergo independent review before release to the client
• There no documentation to verify completion of required QA/QC checks of the toxics field sampling equipment
Summary

Site operators and QA staff are both intimately involved in the data review process
  • Good documentation is vital!

Data handling should involve multiple levels of review
There is a significant difference between data verification and validation procedures
Know your QAPP and SOP requirements!
Utilize the Data Validation Templates in the QA Handbook
Questions?