UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF AIR QUALITY PLANNING AND STANDARDS

Steps to Qualify or Validate Data after an Exceedance of Critical Criteria Checks[1]

1/21/2022

In order to address issues related to the February 6, 2017 OIG Management Alert[2] associated with findings of failed gaseous pollutant 1-Point quality control (QC) checks and data invalidation, EPA is providing this guidance to promote national consistency in the data validation of these checks that have been identified as "critical criteria" in the QA-Handbook[3]. These critical criteria checks[4] for criteria pollutants are part of the validation template found in Appendix D of the 2017 QA-Handbook that was developed by EPA and the State, Local, and Tribal (SLT) monitoring organizations. Monitoring organizations, in their organization's specific quality assurance project plans, may identify checks in addition to those specified in the QA-Handbook that they deem critical. The definition of the critical criteria can be found in Appendix D of the QA-Handbook, but the following quote is the driver behind this guidance:

> "Observations that do not meet each and every criterion on the Critical Criteria should beinvalidated unless there are compelling reasons and justification for not doing so."

When an unacceptable lack of agreement (exceedance of critical criteria) exists between a monitor's response to a quality control check, one of the two following cases exist. Compelling evidence is required to supporting either decision below.

1. **Valid QC Check (Failure of monitor):** A valid QC check is one that is conducted using certified, properly functioning equipment, conducted in a manner that adheres to appropriate procedures (SOPs). The test concentration is accepted as accurate and thus represents truth. The lack of agreement between the monitor and the quality control standard is a result of the monitor's failed performance.

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[1] Memo originally posted on AMTIC on 8/30/2017, revised 1/30/2018 to address clarification on qualifier flags, revised 1/21/2022 to address qualifier flags and calculations in AQS.

[2] Report: Certain State, Local and Tribal Data Processing Practices Could Impact Suitability of Data for 8-Hour Ozone Air Quality Determinations

[3] Quality Assurance Handbook for Air Pollution Measurement Systems Volume II Ambient Air Quality Monitoring Program Appendix D Validation Templates

[4] Although the guidance focuses on 1-point QC checks since it is the only check currently reported to AQS. There are other critical criteria that fall within the QA-Handbook guidance.

In this scenario, monitor calibration and/or maintenance is required to bring the monitor's measurements back to true or within the acceptance criteria. Routine ambient measurements made by this monitor must be invalidated back to when compelling evidence is present to support retaining the monitor's measurements. Routine ambient measurements are also invalidated forward until the point in time when measurements are again known to be valid[5]. **The results of quality control checks and any associated routine ambient measurements are invalidated in AQS using appropriate null codes.** OAQPS has developed a new "1F" QC null data code for AQS to qualify these null QC records.

2. **Invalid QC Check (Failure of QC standard):** An invalid QC check is a check in which there were technical issues with the generation of its test concentration, including the use of expired standards[6]. The test concentration is not accepted as accurate and does not represent truth. In this scenario the monitor's valid measurements are reported to AQS. The result of the invalid quality control check result is reported as null in the AQS QA-Transaction file with the "1C" null data code.

NOTE: The "1F" and "1C" null codes are intended to replace QC check results in AQS. These two null codes should not be used to replace invalidated routine ambient concentration data in AQS.

Compelling evidence are the measurements and recordkeeping that when taken together establishes something as true and forms the basis of a quality decision or course of action. In data validation for ambient air monitoring compelling evidence includes, but is not limited to, data generated from independent audit points, multi-point verifications, and/or a prior zero/span checks that establish whether the analyzer was operating within its acceptance limits and whether the QC check itself is considered valid. Because these are critical criteria, timely action (e.g., action taken the next day) on the part of the monitoring organization to determine the cause of this "critical" failure should be the normal course of action.

The following two scenarios provide examples for data validation and qualification for a monitor's measurements when a 1-point QC check has exceeded the established acceptance criteria. A flowchart follows that describes these two scenarios:

Scenario 1

[5] Please reference EPA's Best Practices for Review and Validation of Ambient Air Monitoring Data Section 3.1.1
[6] Please reference EPA's Best Practices for Review and Validation of Ambient Air Monitoring Data Section 3.2.3

A 1-point QC check exceeds the established acceptance criteria. Upon investigation, the operator determines that the 1-point QC check provided a valid concentration, and that the analyzer requires adjustment/calibration. This investigation provides the compelling evidence that the 1-Point QC check was in fact a valid check and, consequently, the routine data should be invalidated.

Flagging Process for Scenario 1

1. The 1-Point QC check is reported to AQS with a "1F" null code. The null code will create a "placeholder"in AQS that will document that a valid QC check occurred within the required 14-day timeframe. The null code "EC" (exceeds critical criteria) qualifies the invalidated routine ambient data back to either the last acceptable 1-point QC check or where additional compelling evidence exists (see #2). The "EC" null code is also used to invalidate routine ambient data forward until the point of time when measurements are again known to be valid. The "EC" null code is the recommended null code for this scenario, but it is not the only null code that can be selected. When qualifying invalidated routine ambient data with null codes monitoring agencies should select the null codes that best describe the reasons for the missing data.

2. If there is compelling evidence (i.e., acceptable more frequent zeroes and spans, or other verifications) to accept data between the failing QC check and the prior passing QC check, the routine ambient data that was determined to be valid based on this compelling evidence is reported to AQS and qualified with the "1V" flag (data was reviewed and validated). All compelling evidence must be documented.

    a. If no additional verification checks or other investigative measure to find compelling evidence is performed on the analyzer or the QC system following a QC exceedance, then the 1-point QC check will be considered valid. EPA will consider the routine data suspect and the data should be replaced with the "EC" null code back to the last passing check and forward to the next passing check.

    b. EPA Regions, during the annual certification process and/or technical systems audit (TSA), will be able to evaluate the information and flags used in this process and may request the compelling evidence. Ambient Air Monitoring Assessments or dashboards[7] are available on AMTIC. These dashboards allow for the easy and frequent review and evaluation of 1-point QCs on a PQAO or monitor basis.

[7] Dashboards can be found on the AMTIC – Ambient Air Monitoring Assessments page.

NOTE: If routine data is invalidated in AQS, the valid QC check associated with these routine ambient measurements is also invalidated in AQS and reported to AQS using the "1F" null code. This null code creates a "placeholder" in AQS that will document that a QC check occurred within the required 14-day timeframe for data completeness purposes. All QC check results reported to AQS, except for nulled QC checks, will be used in aggregate statistics of precision and bias. Reporting the results of QC checks that are associated with nulled routine ambient measurements will result in the aggregate measurement quality objective (MQO) statistics being unrepresentative of the remaining routine ambient data.

Scenario 2

A 1-point QC check exceeds the established acceptance criteria but there is compelling evidence that demonstrates that the QC check is not valid. For example, following a QC check where the monitor's response was not within the required acceptance criteria, the monitoring organization determined that the QC instrumentation was not valid after a review of the data. They went out to the site and conducted an "as is" (no adjustment to analyzer) QC check, performance evaluation, or multi-point verification at a concentration around the original QC check. These additional checks (not limited to the examples described above) demonstrate that the analyzer is operating within the 1-point QC acceptance limits and, therefore, supports the validity of the routine data. This compelling evidence also suggests that corrective action is needed to the QC system that generated the invalid 1-point QC check. Corrective action should be taken on the QC system immediately to determine the definitive cause of the invalid check, which serves as further compelling evidence to support the validity of the routine data. A second 1-point QC check should be run immediately with properly functioning equipment so that routine data validity is established from the acceptable second check to the next scheduled 1-point QC check. It is EPA's expectation that consecutive 14-day QC checks will not exceed the acceptance criteria. Timely corrective action should be taken to determine whether the QC system or the monitor is the cause for exceeded QC acceptance criteria.

Flagging Process for Scenario 2

The following process is for gaseous pollutant data that exceed acceptance criteria of 1-point QC checks(or Zero/Span) but monitoring organizations **have compelling evidence to consider the QC check invalid and the routine data valid**.

1. Since the 1-point QC check is not considered valid, it is reported to AQS using a "1C" null code. The null code creates a "placeholder"in AQS that will document that a QC check was attempted within the required 14-day timeframe. To meet

the required 14-day timeframe for 1-point QC checks, a valid check is needed. A QC check will need to be re-run immediately with certified, properly functioning equipment that produces a valid QC check.

2. Document the evidence related to the invalid QC check. See compelling evidence documentation described below.
3. EPA Regions, during the annual certification process and/or TSA, will be able to evaluate the information and flags used in this process.

Compelling Evidence Documentation

Data flagged "1V" after a valid QC check exceedance or a null coded QC check ("1C") should be documented in AQS. In addition to the monitoring agencies internal record keeping practices for documenting this compelling evidence, AQS has two methods available for this documentation:

1. **Comment field added to QA-Transaction file for 1-Point Assessment Type**. This comment can be entered on the QA-Transaction record used for uploading QC results or QC null code qualifiers. EPA is not expecting a complete description of the issue and resolution. Monitoring organizations should utilize instrument logbooks, site logbooks, or other agency forms to provide the details of the flags used in this guidance. Comments on the QA-Transaction record can be a simple as "Operator Error: mm/dd/yyyy" which can refer to a logbook entry date that could then be discussed with the EPA Regions during data certification and reviewed during the next technical systems audit. This is the preferred approach.
2. **Part of AMP600 certification process**. The AMP600 can be indicative of issues related to the QC exceedances and whether they have been handled as described in scenarios 1 and 2. If not, the data will be flagged and require some compelling information so Regions can then review and evaluate the compelling evidence. Similar to #1 above, this information can be a short description and refer to a logbook entry.

Particulate Matter (PM)

The 1-point QC null codes mentioned in this memo ("1F" and "1C") are not available for use on PM QC, including flow rate checks and verifications. Until similar null codes can be made available for PM, the following actions are recommended:

- If a QC check, a flow check or verification, is deemed invalid due to issues with the QC equipment or expired standards, it should not be reported to AQS. This QC check should be immediately re-conducted using correctly functioning

equipment and certified standards in order to count towards the required QC check frequency.

- If a QC check is valid but exceeds the criteria (i.e. a valid but failed QC check), and it is determined the monitor is the issue, requires calibration or repairs for example, routine ambient measurements made by this monitor must be invalidated back to when compelling evidence is present to support retaining the monitor's measurements. Routine ambient measurements are also invalidated forward until the point in time when measurements are again known to be valid. When qualifying invalidated routine ambient data with null codes monitoring agencies should select the null codes that best describe the reasons for the missing data.

NOTE: In the future, OAQPS plans to add null codes in AQS for PM QC checks similar to the ones mentioned in this memo for the gaseous pollutant QC checks.

Steps to Correctly Validate and Qualify Data after Critical Criteria Checks