Steps to Correctly Validate Data after a Failed Critical Criteria Checks

Due to the issues related to the OIG Management Alert[1] with failing 1-point quality control (QC) checks and data invalidation, it has become evident that the past practice to remove the 1-point QC (i.e., precision) checks that result in invalidation of routine data may not have been the best practice (see QA EYE Issue 13 page 6[2]). In addition, there are cases where there is compelling evidence to consider the routine data valid upon failure of a 1-point QC check. A valid QC check which exceeds acceptance criteria (i.e., "fails") should result in at least some data invalidation, but sometimes there is "compelling evidence" available regarding corrective actions and/or additional analyzer checks that may not be readily viewable in the AQS dataset that helps bracket the data set to be invalidated. A valid QC check is one that is conducted using certified, properly functioning equipment, conducted in a manner that adheres to appropriate procedures (SOP). However, as described below, there may be cases (as described in #2 and #3) where additional information shows that an initially failing QC check was for some reason, invalid. We need to use these checks in a consistent manner.

Compelling evidence is data, such as an independent audit point(s) or a multi-point verification that establishes whether analyzer was in fact operating within precision and bias acceptance criteria and whether the 1-point QC check itself is considered valid or invalid. The following three scenarios may exist for a monitor when a 1-point QC check has exceeded the established acceptance criteria.

1. 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 needs adjustment/calibration. This confirmation provides evidence that the 1-Point QC check was a valid check and, resultantly, routine data should be invalidated. The 1-Point QC check is reported to AQS, and the null code "AS" (poor QA Results) replaces the routine data.
    a. Note: If no additional verification check or other investigative measure is performed on the analyzer or the QC system following the QC exceedance, then the 1-point QC check will be considered valid by default and there will be no compelling evidence to support that the routine data are valid. The data will be replaced with the "AS" null code back to the last passing check; data will also be invalidated forward until the corrective action measure/check is completed.

2. A 1- point QC check exceeds the established acceptance criteria and **there is compelling evidence** to consider the analyzer's data valid. For example, after the failure the monitoring organization reviewed the data, went out to the site and conducted an "as is" QC check, performance evaluation, or multi-point verification (no adjustment to analyzer) at a concentration around the original QC check. This additional check shows the analyzer is operating within the 1-point QC acceptance limits and, therefore, supports that the routine data are valid. This compelling evidence also suggests that corrective action is needed to the QC system that generated the invalid 1-point QC check. It is suggested that corrective action be

[1] Report: Certain State, Local and Tribal Data Processing Practices Could Impact Suitability of Data for 8-Hour Ozone Air Quality Determinations [HYPERLINK "https://www.epa.gov/office-inspector-general/report-certain-state-local-and-tribal-data-processing-practices-could"]

[2] [HYPERLINK "https://www3.epa.gov/ttn/amtic/qanews.html"]

taken on the QC system immediately in order to determine the definitive cause of the invalid check, which serves as further evidence to support the validity of the routine data and a second acceptable 1-point QC check is then run the so that routine data validity is established from the acceptable check to the next 1-point QC check.

3. Similar to case #2 above where there is compelling evidence but a 1-point QC check was not run immediately after verifying that the analyzer is operating within acceptance limits, but was run within a few business days *(Need to distinguish this scenario from the one stated in the NOTE above (scenario #1).*

In case #1, the 1-point QC check will be reported to AQS since it is considered a valid check. It will not be used in aggregated statistics since in scenario #1 the routine data is removed and therefore the imprecision and bias represented by the QC check is no longer reflected in the routine data set.

In the case of scenarios #2 and #3, the precision and bias of the 1-point QC check did not reflect the precision and bias of the monitor and therefore the 1-point QC point does **not** need to be reported[3]. Data will need to be flagged appropriately in order for AQS to "pick up the right signals"

The attached flow chart illustrates these scenarios…

Flagging Process for Scenarios 2 and 3

The following process is for gaseous pollutant data that fail (exceed acceptance criteria) to meet 1-point QC checks (or Zero/Span) but monitoring organizations **have compelling evidence to consider data valid** (scenarios #2 and 3). In other cases, where a monitoring organization responds to a failing QC check with an adjustment/ recalibration, followed by a verification (ideally, followed by another QC check at the same concentration); the data after the multipoint calibration/ verification until the next passing p-check may be considered valid.

1. The invalid, failed 1-point QC check is not reported since the QC check is not considered valid.
2. Routine data within the time frame between the last acceptable check and the next passing check should be flagged with a "1" flag signifying failed critical criteria and a "V" flag signifying the data was reviewed and there is a compelling reason to consider the data valid.
3. During annual certifications monitoring organizations will provide compelling evidence for the "1V" flags. The AMP600 Report will be modified to include ways for the monitoring organizations to provide the compelling evidence. As an option, monitoring organizations can provide free form comments in AQS. This comment can be entered via the web application on the maintain raw data form. EPA will work with monitoring organization and provide additional guidance on this part of the process.
4. EPA Regions during the annual certification/concurrence process will concur with the data flagged "1V".

Any routine data represented by a failed 1-point QC check without completing steps 2 and 4 will be identified in EPA quarterly evaluation reports (currently in design phase) and will not be considered

[3] 40 CFR Part 58 Appendix A Section 5.1.1 require the results of all **valid** measurement quality checks to be reported to AQS.

valid for regulatory use. EPA Regions will work with monitoring organizations on this data until a resolution of the validity of this data is reached prior to annual certification.

In addition, 1-point QC checks will be evaluated for completeness in the quarterly reports described above to ensure minimally a check is performed and reported (if valid) every 14 days. It is strongly suggested that these checks be automated to be performed every 24-hours or at least more frequently than every 14 days to minimize loss of data due to invalidation.

For now, steps 1-2 are available for use. We will be working with the National Air Data Group to get the certification/concurrence part of the process implemented before May 2018 concurrence as well as ensuring the correct calculations of precision and bias.

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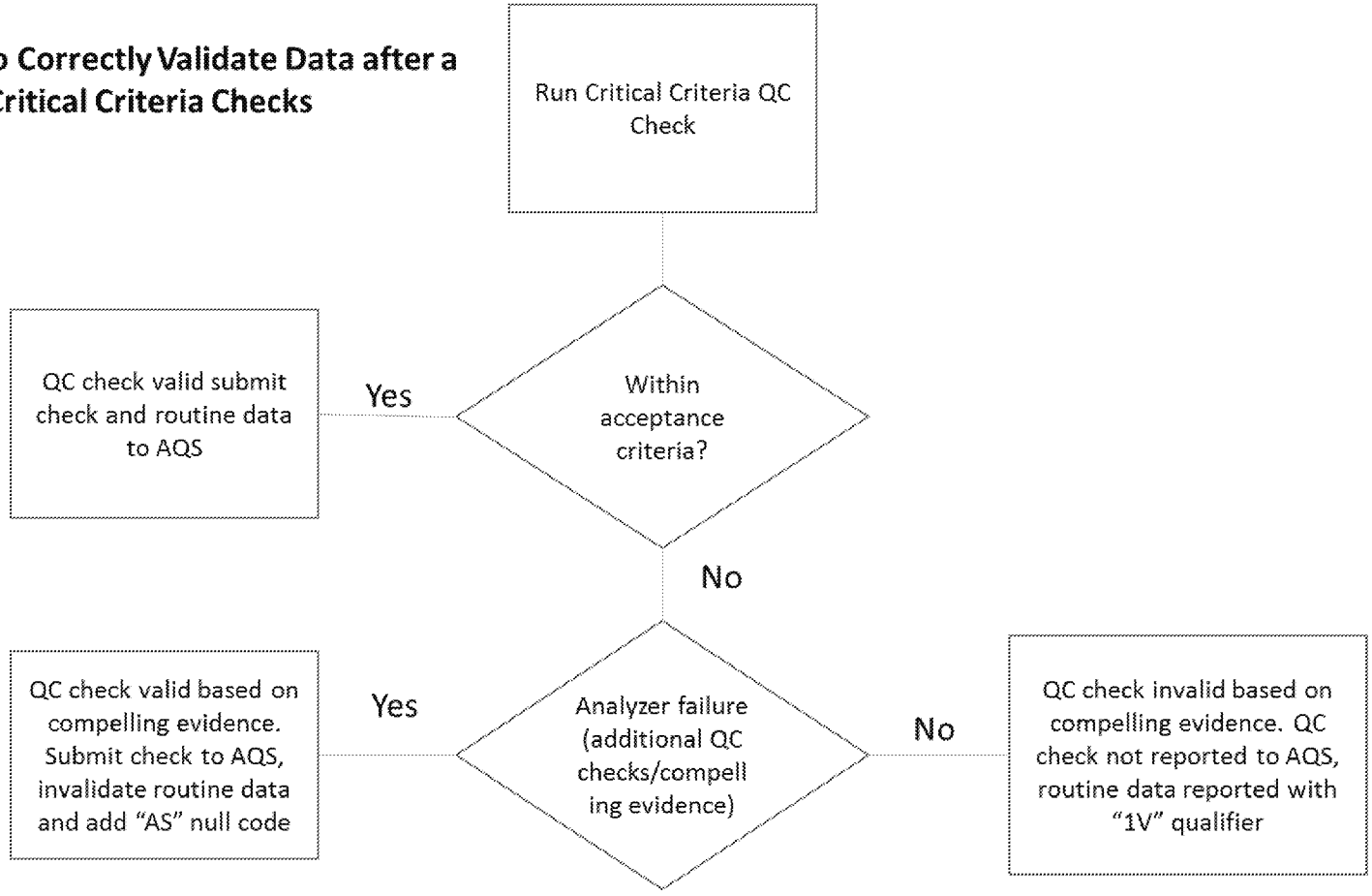

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