Questions and Answers, Pb-PEP Data Approval Process

In preparation for the Pb-PEP data upload into AQS, OAQPS has made a push for all Pb-PEP data to be reviewed as soon as possible. The Pb-PEP data resides on the AIRQA website that stores and combines the field data and laboratory analysis results for each audit. The website performs automated validation checks for both the ESAT (or equivalent program) conducted collocations and the SLT "extra collocated" runs. There are two sets of validation parameters specific to each type of audit. Each one of these automated validation processes require an "approval" before the data can be uploaded into AQS. As this push for review has moved forward, several inquiries have arisen regarding the data review and approval process. Below is a walkthrough of the process with common questions that a reviewer may ask during the review. This document, by no means, addresses all situations, but intends to provide a consistent approach throughout the program.

1. Where is the Pb-PEP website, and how do I gain access?

The AIRQA website is currently located at https://airqa.rti.org/. To access the website, users must click the link "Log In" in the upper left corner of the page and enter their username and password. If the user does not have a username and password, they must click the "Register" link to the right of the "Log In" link and fill out the form. Shortly after submittal, an email will be sent confirming access.

Note: RTI International currently operates the website; however, Battelle will take over the maintenance of site in July, 2013. The functionality of the site should not be affected, but the web address will change. When this occurs, a notification will be sent to users.

2. Who is responsible for approving the audits?

The regional Pb-PEP contact is responsible for approving ALL Pb-PEP audits which includes the ESAT (or equivalent program) conducted collocations and the SLT "extra collocated" runs.

3. Where do I go on the website to approve the audits?

After logging in, click the "8) Audit Approval" selection on the front page of the website. A page will appear that will include a table containing a summary of all of the audits conducted in your region. This table has several tools to help the user filter, sort, order, group, and export audit data. There is a link to a User Guide on the center right of the page, "UserGuide - AirQA

Reports" which provides direction on how to effectively use these tools. The Audit Approval page has many columns of useful information to help identify audits and check status.

4. How do I know if an audit needs to be approved?

The last column on the Audit Approval page is labeled "Approved By". If an audit has been approved, the reviewers name will appear in the cell. If it has not been approved, the cell will be blank. The column preceding "Approved By" is "Approval Status". All audits that not been approved (reviewer name displayed to the right) will be marked as "QC Checked" or "Not Processed". "Not Processed" means that no analytical data from the laboratory has been received and it cannot be approved until the data is uploaded from the laboratory. "QC Checked" means that the laboratory data has been uploaded and the audit has been subjected to a series of automated validation checks. Audits marked "QC Checked" can be reviewed and approved.

5. What does "Approved" mean to the website?

When approving the Pb-PEP audit data, the reviewer will have the option of marking the audit "Approved" or "Rejected". "Approved" means that the data meets required QA/QC criteria, and the data will be included for submission to AQS. "Rejected" means that the data does not meet QA/QC criteria and will not be submitted to AQS.

6. How do I look at the results of the QC checks?

Before viewing the audit(s) that need approval, the QC checks results may be screened by looking under the "QC Checks Passed" column. This column shows a tally of how many QC checks have passed for an individual audit. After identifying the audits for review, click "View" under the column "QC Checks". A summary page showing the Chain of Custody, Field Data Sheet, automated QC, and QA status will appear. In the validation table, the different criteria and their validation status are displayed.

7. What do I base my validation decision on?

Several appendices in 40 CFR Part 50 describe specific quality control criteria that Pb sampling data must meet to be approved. These "must" or "shall" statements included in CFR have been compiled in the automated validation template and are referred to as "Critical Criteria". These "Critical Criteria" are named as such because these required elements may have a significant bearing on the quality of the data. Other elements which are described in CFR as "should" or "may" are referenced as "Operational Evaluation Criteria" in the automated validation template. As a general rule, any audit that fails a "Critical Criteria" should be rejected. The "Operational Evaluation Criteria" leave more room for interpretation, but at as a minimum

standard, two or more failures may result in a rejected audit. Individual regions have the final word in determining the approval status of their audits, and the general rules above should provide some consistency across all regions. The general rules above are intended to be a guide in determining approval status.

8. Can I trust the automated validation template's assessment?

Yes, the automated template has been tested and is working as designed; however, this is assuming that the auditor has entered the information into the website correctly. For example, if an auditor enters the flow rate into the website as cubic feet per minute instead of cubic meters per minute the audit will automatically fail the flow rate critical criteria and could be marked as rejected. The flow rate may in fact be within the acceptance criteria, but represented in the wrong units.

9. Where is the supporting data located to review the checks?

The AIRQA website is a repository for program documentation which includes quality assurance documents, field data sheets, chain of custodies, analytical data, sampler downloads, and review status. This documentation can be found and reviewed under the eight selections on the Pb-PEP main menu.

10. In audits where pre- and post-verifications were required; the sampler failed the pretemperature check and the post-temperature check. Would this be counted as one or two operational criteria failures?

In the situation described above where the same check is required to be conducted twice (-pre and -post) during an audit, this should be considered all as part of the same check.

11. If I need to make a correction or edit the data on the website, how should the change be documented?

If any changes to the data need to be made during the review, the reviewer should make the change and record what changed, why it changed, who changed it, and when the change was made in the "VALIDATION NOTES" section of the audit summary page. Any other comments or observations made by the reviewer should be recorded in the "VALIDATION NOTES" section of the audit summary page as well. All entries must have the name of the reviewer and the date the entry was made recorded in the section.

12. The "Shipment Integrity OK?" parameter is always marked as "Fail". What effect does this have on my audit?

The "Shipment Integrity OK?" check is an indicator that identifies if there were any issues with the shipment on route to the laboratory. This check is being completed and recorded at the laboratories using a LIMS system. Because the shipment condition is being recorded in the LIMS, the laboratory does not enter the shipment condition on the website. The reviewer should disregard this flag in its entirety.

13. How do I classify an audit that is entered as "Void"?

An audit that is identified as "Void" experienced an issue where the auditor or laboratory made the determination that the quality of the audit was such that they essentially made the decision to invalidate the sample. "Void" samples may exist on the website because the auditor set up the audit on the web prior to going into the field, as directed in the SOP, and then a failure of some kind occurred. Examples of void samples may be: the sampler did not run, the filter was blown onto the ground, the laboratory experienced a critical quality control failure, or the auditor could not reach the site. The reviewer would identify these audits as "Rejected".

14. If field data is missing from the summary page, what is the course of action to recover these data?

If field data is missing from the online forms, the auditor who collected the data is responsible for reviewing notes, hard copies, etc, to complete the forms. If the information needed on the form can be found within the documentation on the website, then the reviewer may fill that information into the proper place on the form. The reviewer may be able to find missing audit information on the AIRQA website in several places. On the main Pb-PEP page, shipping and chain of custody information may be found under the "7) Audit Status" selection, sampler run summary and diagnostic information may be found under "4) EPA Raw Sampler Data Files", and laboratory summary information can be found under "6) EPA Region 9 Analytical Results.