



IML Air Science

a division of Inter-Mountain Laboratories, Inc.

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March 27, 2015

Subject: Technical Systems Audit of Inter-Mountain Laboratories (IML) Gravimetric Laboratory-November 19-20, 2014

From: Tim Mendenhall (IML Air Science), Mary Hininger (IML Air Science), and Michelle LaGory (IML)

To: Gregory W. Noah (USEPA, OAQPS), Stephanie McCarthy (USEPA, Region 4), Joshua Rickard (USEPA, Region 8)

SENT VIA EMAIL

Dear auditors,

Inter-Mountain Labs is dedicated to improvement by addressing each finding and recommendation described in the report mentioned in the subject of this letter. IML Gravimetric Laboratory responses to audit findings and recommendations are included with this cover letter. Corrective action has begun based on the finding and recommendations and will continue until completed. Modifications are moving forward in our DMS. The revisions to the SOPs and QAPP will be completed after all the changes in the DMS are completed. The estimated date for completion of QAPP revision 14 is December 31, 2015.

Thanks for your valuable input.

A handwritten signature in black ink that reads 'Mary Hininger' in a cursive script.

Mary Hininger
Gravimetric Laboratory Supervisor

EPA – Audit Findings and Recommendations

1. Neither the analyst nor the DMS calculates a difference between pre- and post- weighing sessions to ensure the filters meet the $\pm 5\%$ difference stated in 40 CFR Part 50, Appendix L, Section 8.3.3. This is a critical criteria due to its inclusion in the CFR and its reference in the QA Handbook. However, an on-site assessment of the climate control percent relative humidity averages over the three-year period showed strict laboratory control at the room's set point from session to session with minimal variability. Also, standard deviations were well within the control criteria stated in 40 CFR Part 50, Appendix L, Section 8.2.4. Nevertheless, this is a critical element that must be tracked in the DMS and communicate to the weighing analyst through the DMS.

EPA Requires that IML develop a calculation in the DMS that documents this criteria and informs the analyst of the result at time of post- weighing.

Corrective Action: IML is working to make the necessary changes to the DMS to calculate the difference between pre- and post- weighing sessions for relative humidity. The comparison will be displayed on the computer interface screen during exposed weigh sessions. The calculation and related information will be added to the QAPP. Estimated implementation date of July 2015 has been set for the changes and the QAPP revision will follow.

EPA – Audit Findings and Recommendations

2. IML uses two methods to show the laboratory is meeting the control requirements specified in 40 CFR Part 50, Appendix L, Section 8: a SD calculation, and a simple $\pm 2^{\circ}$ C limit from the prior 24-hour temperature mean and a $\pm 5\%$ RH limit from the prior 24-hour RH mean. While both are suitable for demonstrating control, one or the other should be chosen as the acceptance criteria to avoid confusion and to ensure the data is treated consistently.

EPA recommends that IML determine which control method should be consistently used, revise the Quality Assurance Project Plan, and implement the change.

Corrective Action: IML will continue to track both methods, but will use the simple $\pm 2^{\circ}$ C limit from the prior 24-hour temperature mean and a $\pm 5\%$ RH limit from the prior 24-hour RH mean to comply with the requirement. The DMS has always used this method for determining if the laboratory is meeting the control limits. The standard deviation is currently tracked for internal purposes only. A statement for clarity will be added to the next QAPP revision.

EPA – Audit Findings and Recommendations

3. IML creates several quality control charts that help in assessing their laboratory's operation. Two of these charts are quarterly plots showing a trace of the weighing room temperature and relative humidity conditions and control statistics. The chart is created using hourly averages plotted across the quarter. Hourly averages mask variability and transient spikes in the dataset that can indicate potential issues and create a false sense of security.

EPA recommends that IML plot five-minute averages to better display variability in the laboratory.

Corrective Action: IML will collect and plot five-minute averages of weighing room temperature and relative humidity conditions. The QAPP will be updated to reflect the change. IML has an estimated implementation date of July 2015.

EPA – Audit Findings and Recommendations

4. While reviewing balance check control charts, unusual shifts in the data were identified. IML uses a double substitution calculation quarterly to re-determine the mass of the working standards, which is not the correct use of this calculation. The double substitution method is a method that weighs a set of primary standards against a set of working standards to generate a reference point. Whenever the double substitution is computed, the new calculation is compared to the previous to determine if there has been a shift in mass. This method is not intended to calculate a “new mass” for a standard, which resultantly caused the shift in balance check data observed in the control charts.

EPA recommends that IML cease using the double substitution method for creating a new mass, and instead use the calculation as a quarterly verification against the primary standards.

Corrective Action: IML will change from using the double substitution method for re-certifying working standards to a verification of working standards. The SOP will be rewritten to make the change. The procedure change has an estimated implementation date of July 2015. The revised SOP will be included in the next QAPP revision.

EPA – Audit Findings and Recommendations

5. 40 CFR Part 50, Appendix L, Section 10.10 states that filters shall be removed from the samplers within 177 hours from the end of the sampling run. This time period is not being tracked in the IML DMS. While not a laboratory validation element, this is an important CFR field element for data validation, and it should be reviewed for any clients who contract for data management and analytical services.

EPA Requires that IML track this criteria and use it in their data management services. This change would require an update in the QAPP.

Corrective Action: A space will be provided for Sampler removal time and date on the filter cassette Bag Label. The information will then be input into DMS if provided by the operator and compared to the sample date in the DMS. The client's report will have the data flagged when the 177 hours is exceeded. The changes will be added to the SOP and QAPP. IML has an estimated implementation date of July 2015 with the SOP and QAPP revision to follow.

EPA – Audit Findings and Recommendations

6. The IML QAPP was revised by IML staff on January 31, 2013, and was reviewed by the EPA auditors prior to the audit. Some areas for improvement were identified and are listed below:

- Add pre- and post- $\pm 5\%$ RH comparison check
- Track 177-hour sample pick-up time criteria
- Review data verification tables, current ranges are too wide to be useful
- Provide detail on data review procedure or develop data review SOP
- Correct record retention time contradictions
- Update the NAAQS standard references to the new standard (12 $\mu\text{g}/\text{m}^3$ annual mean)
- Update SOPs
- Add sliding scale weighing formula and how it is implemented at IML.

Corrective Action: IML is currently modifying DMS and adding new features. IML QAPP and SOPs will be revised to correct errors and update newly implemented procedures in detail. The estimated implementation date of July 2015 has been set for the changes in the DMS. The QAPP revision will follow.

EPA – Audit Findings and Recommendations

7. The analysts do not wear gloves or use a laboratory coat to protect against particulate contaminating the filters. The weighing room is maintained as a “semi-clean room” to minimize the chance of particulate contaminating the filters. The practice of wearing gloves and a coat is considered “best laboratory practice” in reducing the chance of contamination from the analysts themselves. EPA questioned the gravimetric lab supervisor regarding the lack of gloves and a lab coat. She responded that gloves reduced the dexterity of the analysts, increasing the chance of a dropped filter, and that quality control blanks were very low. EPA examined the quality control data and acknowledges that the levels are consistent or lower than other laboratories which require the use of gloves and coats.

However, EPA maintains that IML should use anti-static gloves and lab coats when handling filters in keeping with “best laboratory practices”.

Corrective Action: IML has ordered and received anti-static gloves and lab coats. A pilot study is being conducted to assess the impacts of using lab coats and gloves. Laboratory QC results will be compared to assess the impact, if any, of using coats and gloves. Implementation of lab coats and anti-static gloves will be dependent upon the outcome of the pilot study.

EPA – Audit Findings and Recommendations

8. The analysts use custom software to track weighing session data. The data recorded is comprehensive, and includes parameters such as filter weights, filter identification, dates, times, and filter flags. However, the temperature and humidity averages are not displayed on the user interface of the software. The software performs the weighing room prior 24-hour temperature and RH means and SDs in the background, and will alert the analyst if conditions are not acceptable to weigh. If conditions are not suitable for weighing, the software will lock out the analyst to prohibit work. The analyst checks present conditions through a different system, but the analyst cannot see the actual background calculations for the prior 24 hours. This observation has been noted in prior audits and should be a priority to ensure filters are weighed under required conditions.

As a quality assurance control check, EPA recommends that IML modify the software to show temperature and humidity so the analyst can verify prior 24-hour conditions.

Corrective Action: The DMS will be modified to display the 24 hour conditions on the computer screen interface for analyst to view. Along with other DMS changes the estimated implementation date of July 2015 has been set with QAPP revision to follow.

EPA – Audit Findings and Recommendations

9. While reviewing training records and interviewing the laboratory analysts, the analysts demonstrated a thorough understanding of the procedures and methodology. However, knowledge regarding why the QC checks are important and what they represent was lacking. Training should include rationale on why a check is completed, what it represents, and the effects that failing a check has on the data. Understanding these elements ensures the quality of a program and diminishes the risk that a problem exists and is not identified. There also appeared to be a gap in understanding the “big picture” of why the PM_{2.5} data produced by the gravimetric laboratory is important and the ramifications of deviating from the method.

EPA recommends that IML add “big picture” information and QC data to the training regimen to strengthen its program.

Corrective Action: IML will add more of the “big picture” as well as the significance of QC checks and the ramifications of deviation from the method to the training program described in the QAPP.

EPA – Audit Findings and Recommendations

10. A refrigerator is present in the shipping and receiving area that is used to store incoming samples at 0° to 4° C as required by 40 CFR Part 50, Appendix L, Section 8.3.6. A logger is used to track the temperature of this refrigerator, but the logger is not verified for accuracy.

EPA recommends that IML use a traceable thermometer to quarterly verify this logger.

Corrective Action: IML has implemented performing quarterly verification of the refrigerator temperature and recording the verification in the laboratory maintenance log book. The verification procedure will be added to SOP ML-AppLO202-1 and included in QAPP revision 14.

EPA – Audit Findings and Recommendations

11. At a client's request, IML may be contracted to conduct data validation and create files for upload to EPA's Air Quality System (AQS) database. IML's data validation is limited by the information the client provides. For example, along with gravimetric laboratory QC, field observations and checks such as sampler flow checks, calibrations, audits, maintenance records, and logbooks would be necessary to validate a dataset with confidence. Without this data and documentation, there are limitations as to what can be validated. Furthermore, 40 CFR Part 58.15 states that each agency is responsible for certifying its own data according to the QA findings. In short, air monitoring agencies hold the final responsibility for data review and validation before upload to AQS.

EPA recommends that IML inform the clients requesting data validation of the limitations of this service and refer them to the language in 40 CFR Part 58.15.

Corrective Action: IML will add a statement to reports to advise clients that the final validation of data is their responsibility. (Each monitoring agency is responsible for certifying its own data according to 40 CFR Part 58.15 utilizing QA findings including field records.) The disclaimer statement will be added in the QAPP and SOP for reporting clarifying the limitations of IML performing the final data validation.

EPA – Audit Findings and Recommendations

12. IML uses an IR thermometer to measure incoming shipment temperature. The IR thermometer has been certified annually against a traceable standard; however, the certification sticker on the thermometer indicated that the unit had exceeded its annual certification. After reviewing certification records, a current certificate for the IR thermometer was found along with a current certification sticker.

EPA recommends that IML remove the expired IR thermometer certification sticker and replace it with the current sticker.

Corrective Action: The current certification sticker was placed on the thermometer at the time of the audit. In the future, IML's Gravimetric Supervisor will place the new certification sticker on the IR thermometer immediately following each new calibration.