The CGB-157 quality assurance (QA) section conducts audits on laboratories involved in analytical activities that support Interior Region 10, California-Great Basin projects. The audit consists of reviewing the laboratory's QA manual and the last three years of approved round-robin performance study results, submitting performance evaluation samples, and conducting an onsite audit. The review process allows the QA section to determine if laboratories are capable of performing quality analyses on Interior Region 10, California-Great Basin samples while following QA/QC practices that meet or exceed Interior Region 10, California-Great Basin standards and protocols.

Background Review

Prior to the audit, the QA section will contact the laboratory QA officer or the laboratory director and request a copy of both the current QA manual and the last three years of approved round-robin performance study results. The performance study results and QA manual are reviewed by the QA section.

Performance Evaluation Samples

Prior to the onsite audit, the QA section conducts a performance audit by submitting performance evaluation samples. The purpose of the performance evaluation samples is to evaluate the laboratory's ability to generate accurate data. If the laboratory performs poorly on the performance evaluation samples, the QA section may consider not conducting the onsite audit. The parameters submitted for the performance evaluation samples will be tailored to reflect those of current Interior Region 10, California-Great Basin projects and the methods the laboratory performs.

If the laboratory does not obtain a result within its acceptance criterion, the laboratory will be directed to reanalyze the sample(s). If the reanalyzed result is within the acceptance criterion, then the performance audit is considered acceptable. If the laboratory still does not meet the acceptance criterion upon reanalysis, a new performance evaluation sample from a different lot or vendor will be submitted. If the laboratory can obtain an acceptable result on the new performance evaluation sample, the performance audit is considered acceptable. If the laboratory does not meet the acceptance on the original, reanalysis, or new performance evaluation sample, the laboratory will not be audited or approved for this method/parameter.

Audit Agenda

Approximately one week prior to the audit, the auditor will send the laboratory contact a proposed audit agenda. The audit agenda details the times allotted for the initial meeting with management, analytical method reviews, document review, and debrief. After laboratory review and approval, the audit agenda will be finalized.

Onsite Audit

An onsite laboratory audit is conducted by the QA section to assess the laboratory's expertise in conducting the analyses, the capability for producing valid data, the ability to effectively support the data, and the integrity of the QA/QC practices.

Meet with Management

The first step of the audit will be to meet with management and key laboratory personnel to discuss the purpose of the audit and give a general overview about the Interior Region 10, California-Great Basin Region and the Environmental Monitoring and Assessment Branch (CGB-157). During this meeting, the audit team will discuss CGB-157's policies and requirements, the performance evaluation sample results (if available), document request, and questions for the QA Officer (QAO).

Analytical Method and Document Review

During the onsite audit, the QA officer, analysts, and other key laboratory personnel are questioned to determine their overall understanding of the methods and laboratory procedures. Documentation practices are also reviewed. In general, the auditors are checking to see if the laboratory procedures follow the laboratory's QA manual guidelines and the EPA method, Standard method, or other method protocols.

Debrief

At the laboratory's discretion, a debrief meeting will be held. The most serious deviations are presented to the laboratory as findings in a debrief meeting at the end of the audit; the debrief is generally conducted the day after the audit. All the deviations are written as findings or observations in the final audit report.

Audit Report

Any deviations from accepted protocols are written in an audit report as findings. The report can also include good practices for any procedures that the auditors would like the laboratory to continue and observations for any procedures that the auditors would like the laboratory to adopt.

Laboratory Audit Response and Final Approval Letter

The laboratory is asked to send a response to each finding detailed in the QA section's audit report. The auditors will review this response and assess if the corrective actions and explanations are acceptable. If any response is questionable, the laboratory is contacted for clarification. Once the review of the laboratory's audit response is complete, the lead auditor will send a final letter addressing whether or not the laboratory is approved for use.