QA/QC In Action: Strengthening Data Integrity from a Laboratory Perspective
Webinar Q&A

Accounting for Uncertainties in Methods

Q: How do you account for uncertainties in your methods?

A: Uncertainty is addressed through structured documentation and validation. Measurement uncertainty considers type A sources such as sampling errors, instrument sensitivity, environmental effects and personnel bias.

The uncertainty as defined in CAN-P-1579:2014 “Guidelines for the Accreditation of Mineral Analysis Testing Laboratories” is “a parameter, associated with the results of a measurement that characterizes the dispersion if the values could reasonably be attributed to the measurand.” We also follow guidelines laid out by Eurachem Guide and CAN-P-1623: PALCAN Document: Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing.

Instrument Bias Testing

Q: How do you test new instruments, ICP for example, for bias?

A: Bias is evaluated during method validation. Method validation requires that reference materials go through the same process as samples, ensuring any bias introduced by instruments or procedures is captured. Validation is triggered by new methods, software or changes in application, and includes equivalence testing between instruments or analysts.

SOP Review Frequency

Q: Do you have a set frequency in which SOPs should be updated or reviewed? How do you determine this frequency?

A: SOPs are reviewed based on method changes or quality control trends. SOPs are updated when methods are revised, new software is introduced or performance trends suggest a need for change. Regularly scheduled SOP reviews happen every three years regardless of the previously mentioned reviews. Some SOPs require annual review, and this is determined by our quality team based on the requirements of the information documented in the SOP.

Standard Deviation and Outlier Thresholds

Q: Data sets with more variability will have larger standard deviation, and therefore thresholds of 3SD would be larger. More consistent datasets will have smaller SD values. So more noisy/inconsistent data will have fewer outliers. Does it not punish more consistent data?

A: Control chart thresholds are defined using sigma rules. More consistent datasets with smaller standard deviations will have tighter control limits, potentially flagging more outliers. This does not 'punish' consistency but reflects higher sensitivity to deviations.

NCR Tracking and Risk Ranking

Q: What software do you use to track your NCRs and actions? Do you rank your NCRs by risk to determine the level of response?

A: Non-Conformance Reports (NCRs) are tracked in our Quality Management System (QMS) software. Risk is assessed using a matrix (likelihood × severity), and actions are documented and reviewed for effectiveness, with closure dates and responsible personnel. The priority of NCRs is determined based upon the risk scores.

QQ Blanks and SRM Processing

Q: How often do you run QQ (Quartz) blanks? Does your SRM (standard reference material) material go through exactly the same process (including grinding) as the blanks?

A: At least one blank is run per group. Frequencies can vary based on factors such as method, client request and more.

Trend Analysis for Technician Error

Q: Is it workable to use trend analysis to identify lab tech errors and deviation?

A: While trend analysis of QC data is used to identify deviations, these trends cannot be easily linked to technician performance, but method stability. However, NCRs track specific errors that may arise and can link a technician to an issue triggering further training to alleviate that.

QC Failure Causes

Q: What is the most common cause of QC failure in your experience (e.g., material, human factor, instrument), particularly for the gold fire assay process

A: Failures may stem from material properties, human error or instrument issues. Our lab emphasizes robust method validation and control charting to isolate these causes, and we track the trends from each cause annually to ensure we capture and mitigate the risk of any one factor causing significant failures.

Sorting and Separation Testing Quality

Q: What is SRC's approach for assessing quality of sorting and separation testing results?

A: For questions related to sorting and separation, please email the team.

Duplicate Sample Charges

Q: I like the idea of sending duplicates as a client. The question though is since analyses are charged per sample, will the duplicates be charged as well?

A: Duplicates are treated as separate samples for analysis and billing. This is a common industry practice.

Analytic Process Errors

Q: From your reviews so far, where have you found most errors or deviations occur in your analytic process, from sample preparation to calibration?

A: Errors can occur at any stage: sample prep, weighing, digestion or calibration. Method validation and QC reviews help pinpoint where deviations most often occur. If you are seeing a trend in one area it should trigger a review of the method, training of personnel, environment factors, instrument testing and more.

Q: Which of your analytic process(es) or method(s) have shown to be more susceptible to errors or deviations?

A: Processes involving manual handling or complex instrumentation tend to be more susceptible to errors. Regular audits and validations help mitigate these risks.

ISO Certification Requirements

Q: Do all certified labs have to be ISO … certified? What are the minimum obligations for ensuring quality for certified labs?

A: No, certified labs do not have to be ISO certified. However, obtaining ISO certification, such as ISO 17025, can be highly beneficial because it helps build trust with clients and demonstrates that the lab operates under internationally recognized standards. It also provides a strong framework for establishing a robust QMS and ensures that processes are monitored and improved over time.

That said, whether a lab is ISO certified or not, it is important to review their quality practices and maintain regular communication with their quality team. Staying in conversation with the people responsible for quality helps confirm that procedures are being followed correctly and that data integrity is consistently maintained.

Control Chart Validity

Q: Your control charts use CRM certificate mean and standard deviation for control limits. Some organizations (labs & clients) use the actual mean and standard deviation of the data to define control limits. The premise for doing this is that the original certificate data are not applicable to monitoring an individual lab. Any comments on the 'validity' of this procedure?

A: SRC uses CRM certificate mean and SD for control limits, as well as internally measured limits. We use both to ensure that we maintain consistent results and account for any variation in methods, instrumentation and more.

Turnaround Time and NCR Investigation

Q: What are typical turnaround times for samples arriving at SRC to get the results? If the results failed the QC check, how long does it take to complete the investigation/NCR process and release results back to clients?

A: Turnaround time varies by method and workload. If QC fails, flagged results are reviewed by QA and may trigger reanalysis or NCRs. Timelines depend on severity and method.

Sample Analysis Sequence

Q: Are all samples analyzed in sequential order from the prep stages to analysis?

A: Yes, unless otherwise requested by the client, the samples are run in alpha numeric order as received.