

Data Integrity

The Harvard Business School defines data integrity as:

“the accuracy, completeness, and quality of data as it’s maintained over time and across formats.”

Data integrity is paramount to any metrology laboratory because the primary output of the laboratory is data. Data on the accuracy of a standard. Data on the uncertainty of a measurement. Data on the suitability of an artifact for specific calibrations or uses in the field.

Clearly documenting and communicating data in the laboratory ensure the measurement results are accurate and useful to customers. Nearly everything done in the laboratory affects the quality of the data given to customers from the procedures used to supplies and supplier evaluations. The adage “shit in-shit out” is extremely relevant whenever considering the integrity of a lab’s data. Below are just a few topics that relate to data integrity that haven’t been covered in any other on-the-job training topics.

Calibration Intervals

A calibration interval is the amount of time between subsequent calibration of a standard. All standards need to be calibrated from time to time, ensuring they are still accurate and suitable for use regardless of whether they are used in a laboratory or in the field.

In a metrology laboratory the standards are directly related to the data generated by the lab, so their link to the integrity and accuracy of that data is relatively straight forward. Stable standards will provide consistence accuracy and precision (increased data integrity), while unstable standards will increase uncertainty and adversely affect the accuracy of measurements (decreased data integrity). If a mass standard drifts (changes mass over time) the accuracy and therefore the integrity of the calibration data generated using that standard will suffer. Conversely, standards that have shown stability from one calibration cycle to the next create increased confidence in the measurement results.

Establishing Calibration Intervals

The duration of the interval should be set to ensure the validity of all measurement results without being wasteful of resources or overly burdensome. [NIST GMP 11](#) tables 2 and 3 provide recommended standard calibration intervals based on the Echelon of work completed by the lab. For metrology laboratories without established historic data on the stability of their artifacts, calibrations need to be completed at these intervals. Once historic data has been established showing the stability or instability of an artifact, these intervals can be adjusted in accordance with that information and [NIST GMP 11](#). In some case, unstable standards may need to be replaced.

Impartiality & Confidentiality

Impartiality is a prerequisite for recognition and accreditation, but it is also important to the integrity of any data. If a measurement result is biased or if a laboratory is more lenient with one customer than another then the over quality of that lab’s data is degraded. While working to remove bias and treating all customers equally serves to add validity to the data.

Confidentiality refers to who has access to data and the tools used to create that data. These are more universally known as “Document Control”. Ensuring only those who need access have access reduces the risk of data leaks, losses, or

manipulations. For instance, if a laboratory's IT department moves information from one server to another without first backing up the information, there is a risk of data corruption or loss.

Errors, Amendments, and Changes

External Documents

Although everyone tries to avoid them, mistakes and errors happen from time to time. To ensure these errors do not affect the data integrity of the laboratory, documentation must acknowledge, correct, communicate, and record mistakes when they occur. Alternatively, customers sometimes ask for calibration certificates to be changed. For example, a customer may want to group their artifacts on one certificate instead of several for ease of record keeping on their end, or they may have moved their office and would like their certificates to reflect that new address.

Whether amending a certificate to correct an oversight or upon request, [ISO/IEC 17025:2017](#) specifically requires that all amendments be trackable to the original document or observation and state that the document was amended with the reason for the change. This requirement stays the same regardless if a laboratory is correcting an error or changing something else based on a customer request.

All laboratories must have a policy and procedure with the steps required each time changes are made to a document that has already been issued to the customer.

Internal Documents

All laboratories have a quality management system. These systems are updated periodically to comply with changing standards, improving workflow, or taking corrective actions. It is good practice to log all updates and improvement to any laboratory document, and in practice incorporating these logs into the documents themselves makes this a smoother process.

To illustrate this process let's think about a spreadsheet used as a calibration aid. If you are just changing the font or adding some wording to the instructions for clarity, the document doesn't need to go through a full software verification and validation process, but the changes should be noted in a revision log. The same thing applies to a quality or standard administrative procedure manual. However, if the changes to any of these documents are more substantial, then not only should the changes be logged but a more comprehensive review should be carried out whether that is verification and validation or an audit to a standard.

The process of logging and reviewing changes reduces the risk that important information (data) will be lost or misrepresented, increasing the overall data integrity of the laboratory.

Units Specified

Recording and reporting the intended unit of measure is crucial to the accuracy and integrity of a laboratory's data.

Recording

Recording data in the correct unit(s) is the basis for all the work that follows. For instance, when calibrating a 5-gallon test measure with SOP 19, the technician needs to record both the reading of the meniscus and the temperatures of the standard and the test measures. Typically, labs use software to calculate the correction of these artifacts, and these job aids

are set up to collect data in specific units. If a technician enters a temperature in Fahrenheit when a spreadsheet is set up for a temperature in Celsius, the resulting calculated correction will be incorrect.

Reporting

Specifying the units of measure for every value on a calibration certificate reduces the risk of that information being misunderstood. Calibration certificates for mass artifacts can be filled with many different units. The nominal mass values can be in pounds, while the tolerances or MPE and uncertainties can be in milligrams. Additionally, some customers may want their 50 lb and 20 kg standards on the same certificate, and serial numbers can look like correction values. All these requirements and requests can add confusion to a document and make the reader more likely to misinterpret the information. Clearly identifying all the information that a lab reports increases the integrity of that data.

Record Retention

Retention of records is required by [ISO/IEC 17025:2017](#) for anything that might influence laboratory activities and other pertinent information. Retained records can serve as evidence of good data integrity and aid when performing a root cause analysis to improve data quality.

Most states have record retention policies for all documents within state government, so all state laboratories must first comply with these requirements before setting policies for the lab itself.

Additional Resources

[NIST Handbook 143](#)

[NIST GMP 11](#)