

Traceability Evaluation Form

Assess whether all of the essential elements of uncertainty are available for the entire Scope by completing the table below.

Reference	Description	Yes/No	Specific Example or Evidence (replace template verbiage with what is observed)
	Standards (Reference, Working, and Check/Control) demonstrate unbroken chain to SI		E.g., worksheet for GMP 13, hierarchy, Excel tables Standards are all documented with appropriate identification and test numbers, and available for all parameters and ranges per Scope
	Calibration intervals		GMP 11, tailored for the laboratory Calibration dates and suitable intervals are documented for all standards (Reference, Working and Check/Control)
	No calibration intervals are “past due”		Excel table is color coded with conditional formatting; linked files don’t allow calculations if dates are flagged as past due
	Suitable, documented procedures		Selected procedures are documented and are nationally or internationally accepted or have been validated to ensure measurement traceability in the outputs
	Uncertainty documented for each process		Uncertainty of each process is documented and reported appropriately
	Demonstration of competency		Which staff members have demonstrated competency through what type of training and successful proficiency testing
	Appropriate measurement assurance		Suitable check standards or repeated measurements are used that reflect the same type of measurement process and standards; control charts or pass/fail systems are integrated into the measurement process, documented, and regularly evaluated No evidence of standards or processes that are out of control with no action taken

Specific Analysis (Include specific comments on what was observed and what evidence is available):

- 1.
- 2.
- 3.
- 4.
- 5.

Sample Technical Audit

Select 3 calibration reports for the past year, and identify the following specific information to support traceability for each test.

On each chart, next to each block for your primary and working standards, please list:

Item Evaluated	Evidence
Calibration selected (Measurement Type, Lab Test Number)	
Test Number(s) for all standards used	
Calibration Date(s) for the standards	
Calibration Interval selected	
Documented SOP used	
Uncertainty analysis components included(s)	
Uncertainty file name where data is stored	
Evidence of competency	
Measurement assurance type	
Measurement Assurance file name where data is stored	

You should be able to identify any gaps and corrective action needed in your laboratory in the area of traceability, uncertainty analysis, and measurement assurance.