

## Traceability Evaluation Form

Assess whether all of the essential elements of traceability are available for the entire Scope by completing the table below. Specific Analysis: Include specific comments on what was observed and what evidence is available.

QMS Reference	Description	Specific Example or Evidence (replace template verbiage with what is observed)	Complies? Yes/No
	<b>Unbroken Chain of Evidence.</b> Standards (Reference, Working, and Check or Control) demonstrate an unbroken chain to SI references.	Standards and reports are all documented with appropriate identification and test numbers, and available for all parameters and ranges per Scope. E.g., worksheet for GMP 13, hierarchy, Excel tables, flow charts.	
	<b>Documented Uncertainty.</b> Needed for each step in the hierarchy.	Uncertainty of each process is documented and reported appropriately. Uncertainty is suitable (e.g., if class designations are used, uncertainty is sufficiently small to meet conformity assessment guidelines.)	
	<b>Documented Procedures.</b> Suitable, applicable, documented and validated procedures.	Selected procedures are documented and are nationally or internationally accepted. Laboratory developed procedures have been validated to ensure measurement traceability in the outputs (requires validation procedure and evidence to support validation.)	
	<b>Accredited Technical Competency.</b> Demonstration of competency is documented.	Which staff members have demonstrated competency through what type of 1) training 2) successful proficiency testing and 3) observations by assessors.	
	<b>Realization to SI Units.</b>	If non-standard, measurement units, are/should conversions provided.	
	<b>Calibration intervals.</b>	Intervals documented for the laboratory specifically for all standards being used. Calibration dates and suitable intervals are documented for all standards (Reference, Working and Check/Control). Procedure for setting and adjusting calibration intervals is technically sound and used appropriately. Extension of calibration intervals is based on technical decisions (vs costs). E.g., GMP 11, RP 1.	
	<i>No calibration intervals are "past due."</i>	System is in place to flag due dates before standards are used to produce calibration results. E.g, Excel table is color coded with conditional formatting; linked files don't allow calculations if dates are flagged as past due. Access database provides warning emails.	
	<i>Measurement Assurance.</i>	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. There is no evidence of standards or processes that are out of control with no subsequent action taken.	

### Sample Technical Audit for Traceability Evidence

Select 3 calibration reports for the past year, and identify the following specific information to support traceability for each calibration. On each chart, next to each block for your primary and working standards, please list evidence that is available in your laboratory:

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	
Uncertainty analysis components included(s)	
Uncertainty file name where data is stored	
Documented SOP used	
Evidence of competency	
Measurement assurance type	
Measurement Assurance file name where data is stored	
Report contains a Traceability Statement	

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. Note it below.

Question: Does each Essential Element need to be ON the report itself?

Item	Essential Element	On Report? (per Section 5.10 and SOP 1)
1	Unbroken Chain	Yes in the Traceability Statement. Some labs also put List of Standards on their reports, but it's not required.
2	Uncertainty	Required value on the report. Summary of all uncertainties is required for the lab for Scope. (Maintained in ONE place!)
3	Documented Procedure	Yes. Usually reference to SOP (must reference the correct publication!) Handbook 145 is generally not the correct reference.
4	Accredited Competence	NO! Usually, the assessment will reference documented training, completion of LAP problems, and completion of <i>applicable</i> PT. May include an observation by an assessor during a lab assessment or lab visit.
5	Reference to the SI	Yes. Traceability statement may reference it. Units also need to clearly reference link.
6	Calibration Intervals	No. This is intra laboratory documentation in your inventories. Some labs do put this on their reports, but it's not required.
7	Measurement Assurance	No. A statement can be added to the Uncertainty or Traceability statement if you want, but it's not required on the report. Technically, it is required in the lab by section 5.9 of the standard and not a part of the international interpretations of traceability. NIST includes it on the traceability website and in GMP 13. It helps answer the question of "how do you know something is accurate, now?"