

Traceability RISK Assessment Form

Objective: Identify and analyze potential events and risks in the Calibration Laboratory related to the essential elements of Traceability.

		IDENTIFY		ANALYZE	
Essential Element	Element Description	RISKS	CONTROLS IN PLACE	PROBABILITY (0 % to 100 %)	IMPACT 0 % NO IMPACT 100 % CATASTROPHIC
1	Realization of SI Units				
2	Unbroken Chain of Comparisons				
3	Calibration Program				
4	Documented Measurement Uncertainty				
5	Documented Procedures				
6	Accredited Technical Competence				
7	Measurement [Validity] Assurance				

Note: Modified tables from those presented in “Managing the Metrology System” by C. Robert Pennella, ASQC Press, 1997.

Calibration Program Components

<i>Iterative steps – review and update if needed during the program.</i>		IDENTIFY		ANALYZE	
Component	Component Description	RISKS	CONTROLS IN PLACE	PROBABILITY (0 % to 100 %)	IMPACT 0 % NO IMPACT 100 % CATASTROPHIC
1 PLAN	Identify Scope, Maintain a Complete Inventory (Equipment and Standards, Calibration Certificates) for your laboratory; update CMC when appropriate (consider “internal scope” needed to support your own traceability)				
2	Ensure staff are competent through training, proficiency testing, and ongoing monitoring of competency in providing calibrations and document all training and monitoring of staff competency.				
3	Ensure suitable calibration intervals are planned and documented, determine an established baseline (plus DO monitoring); update if/as needed				
4 DO	Schedule Calibrations (on your calendar, with supplier(s) – even if that is your own lab; will likely require evaluating your own workload and availability of standards)				
5	Document and follow shipping, handling, use, storage, maintenance procedure(s) are defined and followed				
6	Schedule Internal Audits (Specifically in this case to assess “traceability” and the “calibration program”. Conduct assessments. Document observations from all steps in the calibration program				
7	Implement procedure for calibration supplier selection and Perform complete Supplier Evaluation (including maintaining history); evaluate and save the supplier CMC prior to use				

<i>Iterative steps – review and update if needed during the program.</i>		IDENTIFY		ANALYZE	
Component	Component Description	RISKS	CONTROLS IN PLACE	PROBABILITY (0 % to 100 %)	IMPACT 0 % NO IMPACT 100 % CATASTROPHIC
8	Request budget approvals and process financial requests				
9	Conduct Contract Review discussions with Supplier (include discussion and agreement of decision rules and specification evaluations) – expect and plan for this step; they are required to do this with you as the customer				
10 CHECK	Evaluate Returned Calibrations and Certificates, Evaluate “calibration stickers” or “due dates” if present (request action from suppliers)				
11	Update Supplier Evaluation history, Provide customer feedback to your supplier				
12	Document any corrective or preventive action taken based on the evaluation of returning artifacts (and document observations and guidance for future use)				
13 ACT	Update Laboratory Documents and Records (hierarchies, inventories, spreadsheets, uncertainties, observations, corrective actions); File and retain certificates				
14	Conduct statistical evaluation and adjust Intervals (if needed) <i>using data</i> following documented procedures and using data from control charts, uncertainties, PTs, calibration history (i.e., adjustment is a defensible and documented technical assessment, not a financial decision)				