## 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 | Ensuring Validity (Measurement Assurance) |  |  |  |  |

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

## Calibration Program Components

| *Iterative steps – review and update if needed during the program.* | | **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 forcalibration supplier selection and **Perform** complete Supplier Evaluation (including maintaining history); **evaluate and save** the supplier CMC prior to use |  |  |  |  |
| 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) *using data* following documented procedures and using data from control charts, uncertainties, PTs, calibration history (i.e., adjustment is a defendable and documented technical assessment, not a financial decision) |  |  |  |  |