

### 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<br>0 % NO IMPACT<br>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

| <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<br>0 % NO IMPACT<br>100 % CATASTROPHIC |
| 1<br>PLAN  | <b>Identify</b> Scope, <b>Maintain</b> a Complete Inventory (Equipment and Standards, Calibration Certificates) for your laboratory; <b>update</b> CMC when appropriate (consider “internal scope” needed to support your own traceability) |          |                   |                            |   |
| 2  | <b>Ensure</b> staff are competent through training, proficiency testing, and ongoing monitoring of competency in providing calibrations and <b>document</b> all training and monitoring of staff competency.                                |          |                   |                            |   |
| 3  | <b>Ensure</b> suitable calibration intervals are planned and documented, <b>determine</b> an established baseline (plus DO monitoring); <b>update</b> if/as needed  |          |                   |                            |   |
| 4<br>DO  | <b>Schedule</b> 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  | <b>Document and follow</b> shipping, handling, use, storage, maintenance procedure(s) are defined and followed  |          |                   |                            |   |
| 6  | <b>Schedule</b> Internal Audits (Specifically in this case to assess “traceability” and the “calibration program”. <b>Conduct</b> assessments. <b>Document</b> observations from all steps in the calibration program                       |          |                   |                            |   |
| 7  | <b>Implement</b> procedure for calibration supplier selection and <b>Perform</b> complete Supplier Evaluation (including maintaining history); <b>evaluate and save</b> the supplier CMC prior to use                                       |          |                   |                            |   |

| <i>Iterative steps – review and update if needed during the program.</i> |  | <b>IDENTIFY</b> |                          | <b>ANALYZE</b>                        |  |
|--|--|-----------------|--------------------------|---------------------------------------|--|
| <b>Component</b>   | <b>Component Description</b>   | <b>RISKS</b>    | <b>CONTROLS IN PLACE</b> | <b>PROBABILITY<br/>(0 % to 100 %)</b> | <b>IMPACT<br/>0 % NO IMPACT<br/>100 % CATASTROPHIC</b> |
| 8  | <b>Request</b> budget approvals and process financial requests   |                 |                          |                                       |  |
| 9  | <b>Conduct</b> 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<br>CHECK  | <b>Evaluate</b> Returned Calibrations and Certificates, <b>Evaluate</b> “calibration stickers” or “due dates” if present (request action from suppliers)   |                 |                          |                                       |  |
| 11   | <b>Update</b> Supplier Evaluation history, Provide customer feedback to your supplier  |                 |                          |                                       |  |
| 12   | <b>Document</b> any corrective or preventive action taken based on the evaluation of returning artifacts (and document observations and guidance for future use)   |                 |                          |                                       |  |
| 13<br>ACT  | <b>Update</b> Laboratory Documents and Records (hierarchies, inventories, spreadsheets, uncertainties, observations, corrective actions); <b>File and retain</b> certificates  |                 |                          |                                       |  |
| 14   | <b>Conduct</b> statistical evaluation and <b>adjust</b> 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) |                 |                          |                                       |  |