Quality Management System Updates for ISO/IEC 17025:2017

Suggestion: Insert 17025:2017 crosswalk with/as Table of Contents in Current Quality Manual and update sections before re-organizing. Select applicable version of current manual from the following two tables.

# 1990’s Structure of State Laboratory Quality Manuals

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **17025:2017**  **Crosswalk** | **Manual Section** | **Title** | **17025:2017 Revisions and Updates** | **Page** |
| 1 | **1** | Scope and Parameters |  |  |
| 2, 3 | **2** | References and Definition | Master List Update |  |
| 1 | **3** | Quality Policy | Add: Risk Policy  Add: Confidentiality (to the extent allowed by law) add: notify customer (post policy) |  |
| 5 | **4** | Organization and Management | No TM, QM titled (everyone with responsibility) |  |
| 8.3, 8.5, 8.8, 8.9 | **5** | Management System, Audit and Review (Audit & Assessment) | Management Review  Risk Management  Add Risk Assessment to Audits |  |
| 4.1, 4.2, 5.6  6.2 | **6** | Personnel | Add: impartiality and (employee handbook?) |  |
| 6.3 | **7** | Laboratory Facilities and Environment | Reference SOPs |  |
| 6.4 | **8** | Standards, Equipment and Associate Apparatus | Calibration program |  |
| 6.5, Annex A | **9** | Measurement Traceability and Calibration | GMP 13 – updated  GMP 11 – updated |  |
| 7.2, 7.6, 7.7 | **10** | Calibration Test Methods and Procedures | Master list  Method validation procedure – updated |  |
| 7.4 | **11** | Handling and Storage of Calibration & Test Items |  |  |
| 7.5, 7.11, 8.4 | **12** | Records (Document Control and Record Keeping) | Data Management |  |
| 7.8 | **13** | Calibration Certificates | SOP 1 – updated |  |
| 6.6, 7.1 | **14** | Subcontracting | In general NA |  |
| 6.6 | **15** | Outside Support Services and Supplies | Supplies and Supplier Evaluation procedure – updated |  |
| 7.9, 7.10, 8.5, 8.6, 8.7 | **16** | Complaints, Corrective action and Preventive Action | SAP – merge procedures and use one form Risk Management (vs Preventive Action) |  |
|  | **17** | Site Security | Risk Policy |  |
|  | **18** | Safety | Risk Policy, Safety Manual, Hazard Reviews and SDS |  |
|  |  | Appendices |  |  |

**17025:2005 Structure of Quality Manuals**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **17025:2017**  **Crosswalk** | **Manual Section (17025:2005)** | **Title** | **17025:2017 Revisions and Updates** | **Page** |
| 1 | **1** | Scope and Parameters |  |  |
| 2, 3 | **2** | References and Definition | Master List Update |  |
| 1 | **3** | Quality Policy | Add: Risk Policy  Add: Confidentiality (to the extent allowed by law) add: notify customer (post policy) |  |
| 5, 8.1 | **4.1** | Organization | No TM, QM titled (everyone with responsibility) |  |
| 8.2 | **4.2** | Management System | Management Review  Risk Management  Add Risk Assessment to Audits |  |
| 8.3, 7.11 | **4.3** | Document Control | Data Management (Electronic Docs and Records) |  |
| 7.1 | **4.4** | Contract Review |  |  |
| 6.6, 7.1 | **4.5** | Subcontracting | In general NA |  |
| 6.6 | **4.6** | Purchasing Services and Supplies | Supplies and Supplier Evaluation procedure – updated |  |
| 7.1, 8.6.2 | **4.7** | Customer Service |  |  |
| 7.9 | **4.8** | Complaints |  |  |
| 7.10 | **4.9** | Nonconforming Work |  |  |
| 8.6 | **4.10** | Improvement Action | Add Risk Management |  |
| 8.7 | **4.11** | Corrective Action |  |  |
| 8.5 | **4.12** | Preventive Action | Add Risk Management |  |
| 7.5, 7.11, 8.4 | **4.13** | Control of Records | Data Management (Electronic Docs and Records) |  |
| 8.8 | **4.14** | Internal Audits | Add Risk Assessment |  |
| 8.9 | **4.15** | Management Review |  |  |
| 6.1 | **5.1** | General Technical |  |  |
| 4.1, 4.2, 5.6, 6.2 | **5.2** | Personnel | Add: impartiality and (employee handbook?) |  |
| 6.3 | **5.3** | Facility and Environmental | Reference SOPs |  |
| 7.2 | **5.4** | Methods and Method Validation | Master list  Method validation procedure – updated |  |
| 6.4 | **5.5** | Equipment | Calibration program, includes Standards |  |
| 6.5, Annex A | **5.6** | Measurement Traceability | GMP 11 and GMP 13 updated |  |
| 7.3 | **5.7** | Sampling | Mostly NA |  |
| 7.4 | **5.8** | Handling Test and Calibration Items |  |  |
| 7.7 | **5.9** | Measurement Assurance | Ensuring Validation of Results (GLP 1, SOP 9, 17, 20, 30 updated) |  |
| 7.8 | **5.10** | Calibration Certificates |  |  |
|  |  | Safety and Security | Propose: Safety Manual or Risk Management Policies and Procedures |  |
|  |  | Appendices |  |  |