17025 Simplified Highlights for Laboratory Directors

NEW Section Number (2017)	OLD Section Number (2005) [1]	Simplified 17025 Section Heading	Key Point for Weights and Measures Directors
4.1	---	Impartiality	State Ethics and Conflict of Interest policies and the laboratory Quality Management System normally cover these requirements.
4.2	---	Confidentiality	State Ethics and Conflict of Interest policies and the laboratory Quality Management System normally cover these requirements. FOIA requirements may apply.
6.1	5.1	General	Generic "catch-all" section that highlights ensuring sufficient resources to perform calibrations and references staff, facility, procedures, equipment, and so on.
6.2	5.2	Personnel	Good technical and analytical skills and attention to detail are essential. Math and computer skills required. It takes three to five years to get someone through the training, completing PTs and assigned problems, and competent. No back up is high risk of losing recognition, accreditation, or closing the doors. NIST offers core/required training and plans training calendar but regularly adds classes based on needs of State labs.
6.3	5.3	Facilities and Environment	Facility requirements are published in Handbook 143 and in the Standard Operating Procedures. Monitoring is required. HVAC systems must have regular maintenance and will usually need upgrades/updates in 15 to 20 years. Lab design concepts are covered in training. NIST available to review designs/plans. Security of the laboratory standards and equipment is essential to support traceability.
6.4	5.5	Equipment	Equipment needs regular maintenance (just like your car!) to last longer. NIST regularly gets information from manufacturers and shares it with the laboratories (e.g., parts/service on balances). Laboratory equipment is expensive! A good replacement plan should be in place and followed – or funds available in the event equipment goes down. Equipment must be assessed for suitability based on the laboratory Scope and essential uncertainty required.

[1] International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General Requirements for the Competence of Testing and Calibration Laboratories, 2005(R2010) and 2017 update.

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6.5	5.6	Traceability and Standards	Essential elements include 1) unbroken chain of calibrations; 2) documented uncertainties (see also 5.4.6); 3) documented procedures (see also 5.4); 4) accredited technical competence (see also 5.2 and 5.9); 5) reference to the International System of Units (SI); 6) suitable and documented calibration intervals; and 7) measurement assurance (see also 5.9). Standards and check standards must be available to meet requirements to support calibration and measurement capabilities and must have current calibrations from a suitable (NIST or accredited) supplier. A documented inventory, hierarchy, and schedule of calibrations is required to support evidence of traceability. OWM is evaluating labs on this section in the 2017 Annual Submission process.
6.6	4.6	Purchasing (Supplier Evaluation)	Supplier evaluations must be completed for anything that impacts measurement results to ensure quality. Staff must be able to write and evaluate specifications to be sure that what is ordered meets the needs. Top areas of problems are new HVAC systems during lab design or renovations, purchase of new balances, provers, and mass standards, and obtaining calibrations. Staff might need assistance with procurement interactions.
7.1	4.4	Contract review	Contract review is not “signing a contract” – it is review of customer requests and purchase orders to make sure the lab has everything in place so that you “can” and “should” do the calibrations that are requested.
7.2	5.4	Calibration methods	OWM publishes procedures for > 90 % of the laboratory workload. Procedures incorporate traceability, measurement assurance, uncertainties to meet lab requirements. OWM has a validation webinar and procedure for lab-developed methods (records of validation must be kept if the procedure is still in place!) Field standards must be evaluated for compliance to specifications and tolerances for legal metrology.
7.3	5.7	Sampling	Laboratories perform calibrations of 100 % of the items submitted; no sampling is performed. This section is generally not applicable for weights and measures.

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7.4	5.8	Handling	Laboratories need a secure area for Incoming and Outgoing work that is not accessible by unauthorized personnel to ensure a good chain of custody and to avoid mixing standards for field staff and various customers. No one should be assigned to "help" without being trained and qualified on the laboratory procedure for handling incoming/outgoing work. Use of a laboratory LOG and Work Order forms are needed and will help track items through the laboratory to avoid mix-ups.
7.5 7.11 8.4	4.13	Control of records	Implement consistent file naming practices. Be familiar with record organizational structure, find and access stored records. Record retention exemptions are needed for validated procedures and software that must be maintained if procedures and software are in use.
7.6	5.4.6	Measurement uncertainty	All NIST SOPs include uncertainty budget tables and guidance on what/how to perform calculations. This is part of the definition of traceability and is reviewed every year or more often if the laboratory updates uncertainties.
7.7	5.9	Measurement Assurance (Validity)	Covers control charts and proficiency tests. Control charting and check standards are an integrated part of the calibration process, not an add-on. Inadequate data might mean invalid uncertainties. PTs are required and coordinated through Regional Measurement Assurance Program (R-MAPs). OWM will be evaluating this section in the 2018 Annual Submission process and it is being covered in training at the 2017 RMAPs.
7.8	4.5	Subcontracting	Typically, not performed in State laboratories. This is not related to supplier evaluations. Subcontracting would be sending customer standards out to someone else to do part of the calibration for you to put on your certificate.
7.8	5.10	Reporting (Calibration Certificates)	This is the laboratory's primary product. Ensure high quality – avoid "the black dots" and corrective actions. (Black dots refer to mistakes on certificates.)
7.9	4.8	Complaints	The laboratory needs a system to collect, review, evaluate, and respond to complaint. Identifying them as insignificant still requires a system to be in place. Must communicate process to customers (e.g., post on website).

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7.10	4.9	Non-conforming control	Deviations must be technically acceptable and approved by management and customer. Process requires compliance, corrective action, or evaluation of impact, communications with and approval by customer, and monitoring. Top 2 problem areas are HVAC limits that are not in control and performance of calibrations outside of laboratory Scope.
7.11	---	Information Technology (Data and Information Management)	Covered in at least five sections in 2005 version. Risks are loss of data and/or records. Need to prevent tampering and ensure protection of data integrity (like a crime laboratory). Significant time required for verification and validation of laboratory spreadsheets that must be re-done if/when systems and software are upgraded. No known laboratory "solutions." Staff might need assistance with IT interactions. IT staff must be aware of laboratory requirements.
8 8.1	4.1	Organization	Define overall organization, critical roles and responsibilities, identify and mitigate conflicts of interest. Best practices – organizational chart, authorized signatory matrix aligned to measurement Scope.
8.1	4.7	Customer Service	Communications with customers are completed to ensure expected services can be met and supported. Good quality "customer service" is an expectation.
8.2	4.2	Management system	Limited ISO/IEC 17025 changes for new standard. Don't reorganize Quality Management System (QMS). Labs need to: 1) Develop Table of Contents with new ISO/IEC 17025 section cross-references. 2) Add Risk Policy.
8.3	4.3	Document control	Maintenance is an ongoing process. Review and update on a quarterly frequency. Takes dedicated time to accomplish, but it's not a fulltime job (QMS < 20 %). Schedule projects on calendar just like calibration work.
8.4	4.13	Record Control	See 7.5 too. Records and record retention. Take care to ensure that verification and validation records of software and procedures are retained as long as used.
8.5	4.12	Preventive action (Addressing RISK)	Process followed when findings require action (e.g., CA, PA, IA, and Risk Management). Identify Issue (e.g., sources: mgmt. review, internal audit, external
8.6	4.10	Improvement	

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8.7	4.11	Corrective action	audit, customer feedback, etc.), evaluate (Root Cause Analysis, determine risk), fix issue (implement solution), then evaluate and monitor effectiveness. Document the process (report), including all findings, actions, monitoring (create record or it didn't happen).
8.8	4.14	Internal audits	Maintain an ongoing process of quality and technical internal assessments. Annual frequency minimum, quarterly projects and tasks, scheduled throughout the year. Takes dedicated time to accomplish, but it's not a fulltime job (QMS < 20 %). Schedule projects on calendar just like calibration work. Document the process (report), including all findings, actions, monitoring (create record or it didn't happen).
8.9	4.15	Management reviews	Communication tool used during normal operations, as well as to manage crisis or change situations. High level overview of lab operational status and needed resources. Opportunity to share (receive & provide) information and updates; share up management chain. Annual frequency minimum (< 4 h) cover all required topics, quarterly meetings ideal (~ 1 h). Document the process (report), including all findings, actions, monitoring (create record or it didn't happen). Schedule meetings, resulting action tasks, and monitoring on calendar just like calibration work. OWM resources – template report form (adding Risk with new ISO/IEC 17025) and training webinar. (Good documents are typically are 8 to 12 pages and definitely less than 20 or 25!)