Standard: ISO 17025:2017
Object of Assessment: QM-001:2005 Quality Manual

Date of Assessment: 1-Feb-18
Assessment Completed by: Norton Global, LLC

Clause	Section Heading	Requirement(s)	Conforms?	Analysis	Suggested Improvements	Comments
6.2.	Personnel					
6.2.1	Personnel	All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be supervised and competent, and shall work in accordance with the l...	No	QM-001:2005 does not directly address the scope of personnel who could influence activities or the need for them to act impartially. QM-001:2005 addresses impartiality in Clause 4.2.2. QM-001:2005 addresses competence in Clause 5.2.1.	Add text to QM-001:2017 clause 6.2.1 to reference impartiality from clause 4.1, list out the personnel who could influence laboratory activities. Move QM-001:2005 text from 5.2.1 to QM-001:2017 clause 6.2.1 Move QM-001:2005 text from 4.2.2 to QM-001:2017 clause 6.2.1 Consider adding an activity assessment to identify the personnel who could influence laboratory activities.	Depending the type of testing or calibration activities included in a laboratory's scope, an activity by activity analysis may be required to determine which personnel (internal or external) could influence the laboratories activities. Proving that employees are supervised can be difficult to assess and will likely be assessed through training records, authorization of test and calibration reports, and other normal activities of laboratory management.
6.2.2	Personnel	The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical k...	No	QM-001:2005 does not address documenting competence requirements for each function.		
6.2.3	Personnel	The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.	No	QM-001:2005, Clause 5.2 generally describes the procedure followed by the laboratory but ISO 17025:2017 imposes additional requirements for ensuring competence that are not adequately addressed by QM-001:2005.	Add a new procedure for ensuring competent personnel that describes the how to determine competence requirements, how to assess laboratory personnel, and how to respond to competence gaps. Add a competence requirements list that displays the competence requirements for each activity contained in the scope of laboratory activities recommended in 5.3 of this assessment.	Ensuring personnel have competence implies that there needs to be some competence requirements to serve as a basis for comparison. Understanding the significance of competence deviations and responding to deviations implies that something should be done when the competence requirements are not met. Because of this and due to the requirements if ISO 17025:2017 Clause 6.2.5., it is highly recommended to create a more detailed procedure and a scheme to record competence assessments. Without such a scheme or records, it will be extremely difficult for laboratories to demonstrate conformance to the requirements of ISO 17025:2017 Clause 6.2.
6.2.4	Personnel	The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.	Yes	QM-001:2005, Clause 5.2.4. addresses this requirement.		
6.2.5	Personnel	The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authori...	No	QM-001:2015 does not address this requirement.	Add a new procedure for ensuring competent personnel that addresses each item of this requirement.	This is a new requirement that is very specific about which procedures are needed and the records required. As noted in the commentary from 6.2 of this assessment, it is highly recommended to create a more detailed procedure for ensuring competence and a scheme to record competence assessments.

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6.2.6	Personnel	The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: a) development, modification, verification and validation of methods; b…	Yes	QM-001:2005, Clause 5.2.5. addresses this requirement.	Consider adding a new Activity Authorization Matrix that lists each personnel, the specific activity, the assessment of competence, authorizer's name, and date authorization was granted. This additional list will greatly enhance the laboratory's ability to demonstrate conformance to all requirements of ISO 17025:2017: Clause 6.2.	
6.3.	Facilities and environmental conditions					
6.3.1.	Facilities and environmental conditions	The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.	Yes	QM-001:2005, Clause 5.3.1. addresses this requirement.		
6.3.2.	Facilities and environmental conditions	The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented	Yes	QM-001:2005, Clause 5.3.1. addresses this requirement.		
6.3.3.	Facilities and environmental conditions	The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the validity of the results.	Yes	QM-001:2005, Clause 5.3.2. addresses this requirement.		
6.3.4.	Facilities and environmental conditions	Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: a) access to and use of areas affecting laboratory activities; b) pr…	Yes	QM-001:2005, Clauses 5.3.1., 5.3.2., and 5.3.3. address this requirement.		
6.3.5.	Facilities and environmental conditions	When the laboratory performs activities at facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this International Stan…	No	QM-001:2005 does not address this requirement.	Add a clause to QM-001:2017 to specify this requirement and how it will be met.	
6.4.	Equipment					
6.4.1.	Equipment	The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxi…	No	QM-001:2005 does not completely address this requirement. QM-001:2005, Clause 5.5.1. partially addresses this requirement.	Add a clause to QM-001:2017 to specify this requirement and how it will be met. Merge new clause text with text from QM-001:2005, Clause 5.5.1.	
6.4.2.	Equipment	When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	Yes	QM-001:2005, Clauses 5.5.1.1. and 5.5.1.2. address this requirement.		

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6.4.3.	Equipment	The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and in order to prevent contamination or deterioration.	Yes	QM-001:2005, Clauses 5.5.6. and 5.5.6.1. address this requirement.		
6.4.4.	Equipment	The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.	Yes	QM-001:2005, Clauses 5.5.6. and 5.5.6.1. address this requirement.		
6.4.5.	Equipment	The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.	No	QM-001:2005 does not address this requirement.	Add a clause to QM-001:2017 to specify this requirement and how it will be met.	
6.4.6.	Equipment	Measuring equipment shall be calibrated when: the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or calibration of the equipment is required to estab...	No	QM-001:2005 does not address this requirement.	Add a clause to QM-001:2017 to specify this requirement and how it will be met.	
6.4.7.	Equipment	The laboratory shall establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.	Yes	QM-001:2005, Clause 5.5.2. addresses this requirement.		
6.4.8.	Equipment	All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of cali...	Yes	QM-001:2005, Clause 5.5.8. addresses this requirement.		
6.4.9.	Equipment	Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shal...	Yes	QM-001:2005, Clause 5.5.7. addresses this requirement.		
6.4.10.	Equipment	When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.	Yes	QM-001:2005, Clause 5.5.10. addresses this requirement.		
6.4.11.	Equipment	When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the correction factors and reference values are updated and implemented, as app...	Yes	QM-001:2005, Clause 5.5.11. addresses this requirement.		
6.4.12.	Equipment	The laboratory shall ensure practicable measures are taken to prevent unintended adjustments of equipment which would invalidate results.	Yes	QM-001:2005, Clause 5.5.12. addresses this requirement.		