



QMS Quick Learning Activity

Personnel Requirements, Ethics, and Continuous Improvement

Abbreviations and Acronyms

- **TM** - Technical Manager-oversees technical aspects of laboratory testing
- **QM** - Quality Manager-oversees the quality management system
- **APHL** - Association of Public Health Laboratories
- **LIMS** - Laboratory Information System
- **CFR** - Code of Federal Regulation
- **HIPAA** - Health Insurance Portability Act-covers patient confidentiality
- **PDSA (PDCA)**- Plan, Do, Study (Check), Act. A four-stage problem-solving model used for improving a process or carrying out change
- **Lean** - Customer focused process improvement methodology used to identify and eliminate waste and to standardize work processes
- **Six Sigma** – Problem-focused process improvement methodology with a view that process variation is waste and that utilizes statistics to understand variation



Goal for Module

The goal of the learning activity is to provide an overview of Personnel Requirements, Laboratory Ethics and Continuous Improvement to better meet the ISO/IEC 17025 standard in your laboratory.



PERSONNEL REQUIREMENTS



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ISO/IEC 17025 Personnel Requirements

Personnel requirements can be found in the standard:

- 4.1 Organization
 - 4.1.5
- 4.2 Management System
 - 4.2.6
- 5.2 Personnel



Personnel Requirements 4.1.5

- 4.1.5 covers policy and procedures that include Ethics
 - Confidentiality
 - Organization structure
 - Supervision
 - Technical manager (TM)
 - Quality manager (QM)
 - Duties for key managerial personnel
- The last three are explained in more detail in 4.2.6



Personnel Requirements 4.2.6

- 4.2.6
 - The roles and responsibilities of technical manager and the quality manager, including their responsibilities for ensuring compliance with ISO/IEC 17025, shall be defined in the quality manual.
- Technical Manager (TM)
 - Overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations (4.1.5)
- Quality Manager (QM)
 - Overall responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times. Shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources (4.1.6).



TM and QM Accrediting Body Requirements

- Review accrediting body requirements and any other standards being utilized for the TM and QM
- For example, AIHA has additional requirements for TM
 - Posses a bachelor's degree in an applicable physical or biological science
 - TM shall be present on site at least 20 hours per week or 50 percent of the laboratory operating hours (whichever is less) to address technical issues
 - Authorize and document that all analyses is accredited and completed by personnel with appropriate education and/or technical background



TM and QM Accrediting Body Requirements - continued

- Ensure that adequate supervision is provided for all laboratory technical personnel
- Shall function as the approved signature though can assign designee
 - Designee reflected in Quality Assurance manual
- The TM could be the laboratory director and/or managers already in place prior to the accreditation



TM and QM Accrediting Body Requirements, continued

- AIHA specific requirements for QM
 - Possess a bachelor's degree in an applicable basic or applied science and have at least one year of nonacademic analytical or quality control experience
 - Documented training in statistics
 - May be part time
- Can have one person act as both if qualifications for both are met



Personnel Requirements (5.2)

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

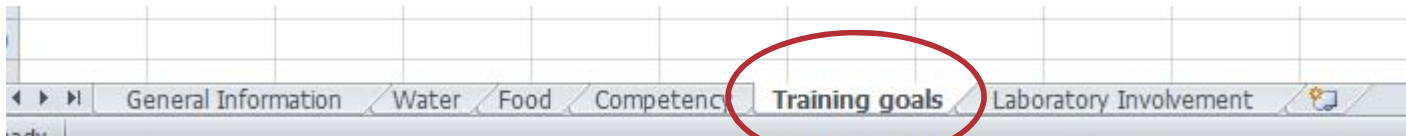
General Information		Water	Food	Competency	Training goals	Laboratory Involvement
Training Goals						
2014 ISO goals	Continue training on 17025 requirements, new policies, procedures as developed and steps taken to implement by the EB unit					
2015 ISO goals	Develop and update all food testing SOP's					

- Electronic Training records
- Training Goals



Personnel Requirements

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated. All staff, including interns, volunteers, and temporary employees should adhere to the personnel requirements.



Training Goals	
2014 ISO goals	Continue training on 17025 requirements, new policies, procedures as developed and steps taken to implement by the EB unit
2015 ISO goals	Develop and update all food testing SOP's

Electronic
Training
records

Training
Goals



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Personnel Requirements

5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support person are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.



Personnel Requirements

5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations

- Human Resource job descriptions might not be specific enough. In the notes section, ISO/IEC 17025 suggests defining duties and responsibilities in regards to:
 - Performing tests
 - Implementing tests and evaluation of results
 - Reporting and interpretation
 - Method modification and development
 - Expertise and experience
 - Qualification and training programs
 - Managerial duties



Personnel Requirements

5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issues test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of relevant authorization(s), competency, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include date of which authorization and/or competence is confirmed.

- Be careful with wording; do not use the word “certify” unless a certificate is produced

A work authorization form might be used for documentation



Personnel Training and Authorization Requirements

Authorization of analyst Jane Smith for Lead (Pb) Microwave Soil Digestion analyzed by ICPOES						
Prepared by:	XX			Date:	7/12/2010	
Approved by:	XX			Date:	7/12/2010	
Reviewed by:	XX			Date:	3/3/2011	
Results of analyses: Jane Smith is authorized to analyze soil samples for Pb using Environmental Metals by ICPOES method, and is qualified to train others to use this method.						

Material	NIST 2711	CRM 025-50	MRL	Spiked Sample EL10-35 Recovery	Sample EL10-35 860ug/g	Total Within Limits (75% required)
Target Value	1162 ug/g	1450 ug/g	50 ug/g	100% recovery	100% recovery	
Limits (% recovery)	90 to 110 %	90 to 110 %	90 to 110 %	90 to 110 %	90 to 110 %	
Date Digested/Date Analyzed						
6-1-2010/6-2-2010	100.4%	101.2%	98.8%	101.2%	93.5%	100.0%
6-3-2010/6-4-2010	101.8%	88.4%	99.7%	104.8%	95.9%	80.0%
6-9-2010/6-10-2010	100.5%	100.1%	118.8%	100.9%	90.8%	80.0%
6-23-2010/6-24-2010	96.5%	93.2%	109.1%	92.2%	91.7%	100.0%
Number Within Limits	4/4	3/4	3/4	4/4	4/4	90%

Depending on the accrediting body, different authorization requirements are needed. This is for AIHA ELLAP



Personnel Training and Authorization Requirements

Example Training Record for an Analyst who was “Grandfathered”, i.e. an analyst that has been doing the method for a long period of time prior to ISO accreditation. Could also attach an updated copy of a CV for documentation of experience

Training Record									
Purpose: Training is required by regulatory and accreditation agencies prior to performing laboratory functions and reporting results									
Method	Food								
Analyte	Salmonella								
Trainer(s)	XX	XX	XX						
<u>John Doe</u> is authorized to perform <u>ABI 7500 Food PCR, Food Camplyobacter Isolation and Identification, E. coli O157:H7, Salmonella, Listeria, Bacillus Cereus, Staph aureus, Aerobic Plate Count, Coliforms, E. Coli and Yeast and Mold due to the analyst's years of experience, education and acceptable results on proficiency samples in these food testing methods</u>									
Signature of Trainee				<u>John Doe</u>			Date <u>11/4/2013</u>		
Signature of Manager				<u>Bob Smith</u>			Date <u>11/4/2013</u>		



Accrediting Body Personnel Requirements

Review accrediting body-specific requirements for personnel, training, authorization and competence, if applicable. Some examples of specific requirements include but not limited to:

- Personnel must show ability to produce reliable results through accurate analysis of Certified Reference Materials, proficiency testing samples or in-house quality control samples
- Demonstrate competence every 6 months
- Minimum time of hands on experience



Other Personnel Requirements

Review agency requirements and professional requirements

- Personnel may be required to be credentialed, i.e. licensed, professional certification, or other deemed essential for the level of the position
- The laboratory determines the requirements for a position and also the criteria to determine competence



ETHICS REQUIREMENTS



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ISO/IEC 17025 Ethics Requirements

The laboratory shall

- 4.1.5 (a)
 - Have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of the departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate action to prevent or minimize such departures



ISO/IEC 17025 Ethics Requirements

- 4.1.5 (b)
 - Have arrangements to ensure that management and personnel are free from any undue internal and external commercial, financial, and other pressures and influences that may adversely affect the quality of their work
- 4.1.5 (c)
 - Have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results



ISO/IEC 17025 Ethics Requirements

- 4.1.5 (d)
 - Have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity
- 4.1.5 (f)
 - Specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations



Ethical Considerations in the Laboratory

- The laboratory should have a policy in place addressing the laboratory's position on ethics, integrity, and code of conduct. Procedures based on this policy should be put in place that define exactly how the policy will be implemented and ensured.
- Detecting and deterring testing or actions which are improper, unethical, or even illegal must be the culture established by management.
- Ensure all employees and non-paid staff are informed!



Ethical Considerations in the Laboratory, continued

- An ethics program should include written ethics agreements, examples of improper practices, examples of improper data manipulations, requirements for an ethics program training, and any resources available to employees.
- Employees must understand the consequences of unethical behavior
- APHL is a source of webinars on Ethics and Ethical Practices; internal sources such as Offices of the Inspector General of an agency, for example, may also be a good resource for provision of training.



Ethical Considerations in the Laboratory, continues

- Improper actions include unauthorized intentional or unintentional deviations from analytical practices which are contract-specified or method-specified.
- Unethical or illegal actions are the deliberate falsification of analytical or quality control results, where failed method or contractual requirements are made to appear acceptable.



Ethical Considerations in the Laboratory, continued

- Have in place a “whistle-blower” reporting policy that encourages all personnel to report suspected improper, unethical, or illegal activities without fear of retribution.
- Investigate any allegations promptly and thoroughly.
- Require initial and annual ethics training
- Ensure changes to data (policies and procedures) is reviewed as part of the internal audit program
- Require an explanation and sign-off on all manual changes to data
- Where available, in instrument software or LIMS, all electronic tracking and audit functions must be enabled



Consider Contract Requirements and Laws When Developing Ethics Policies and Procedures-Examples

- National Institutes of Health
 - Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, “Responsibilities of Institutions”
 - Recipient responsibilities are required to have written policies and procedures for addressing allegations of research misconduct and take all reasonable and practical steps to foster research integrity.
 - Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- HIPAA Privacy Rule
 - [Health Insurance Portability and Accountability Act of 1996](#)
 - A set of federal standards to protect the privacy of patients’ medical records and other health information maintained by covered health plans
 - The HIPAA Security Rule establishes national standards for the security of electronic protected health information.



Codes of Ethics

An Example Outline of a Professional Code of Ethics: American Chemical Society (www.acs.org)

– Chemical Professionals acknowledge their responsibilities to:

- The Public
- To the Science of Chemistry
- To Their Profession

Chemical professionals should strive to remain current with developments in their field, share ideas and information, keep accurate and complete laboratory records, maintain integrity in all conduct and publications, and give due credit to the contributions of others. Conflicts of interest and scientific misconduct, such as fabrication, falsification, and plagiarism, are incompatible with this Code.

- To Their Employer
- To Their Employees or Subordinates
- To Students
- To Colleagues
- To Their Clients
- To the Environment
- To Temporary Employees



CONTINUOUS IMPROVEMENT



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ISO/IEC 17025 Continuous Improvement

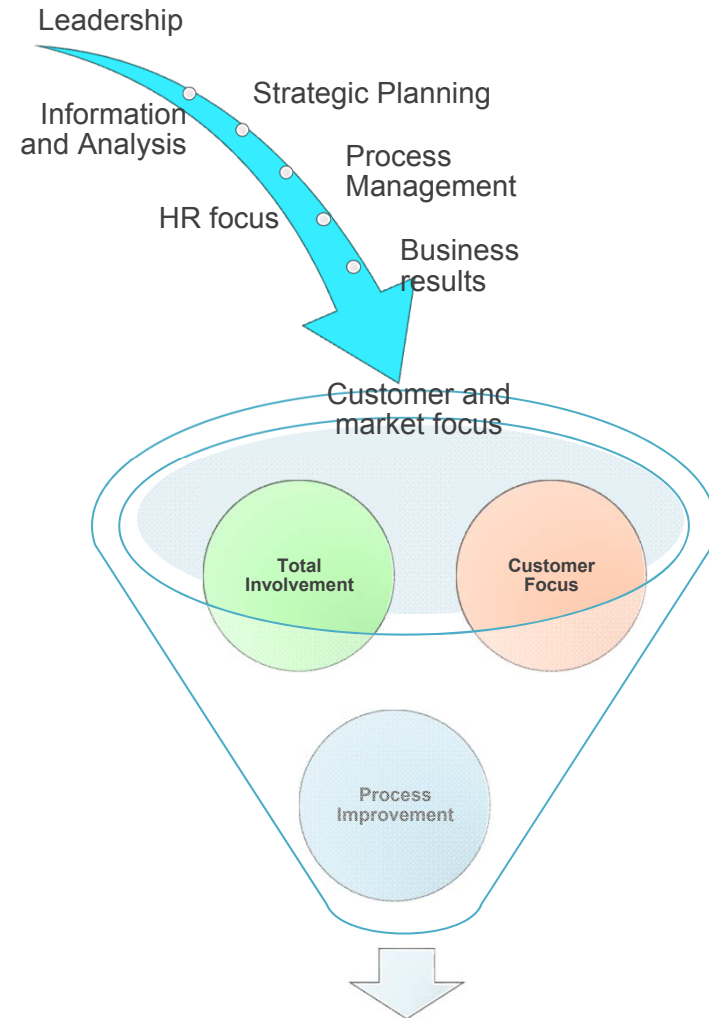
4.10 Improvement

- The laboratory shall continually improve the effectiveness of its management system through policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review



Contributions to a Quality Culture

- A Quality Culture can only be accomplished when all staff are involved in the following:
 - Focusing on the Customer
 - Leading by example
 - Continually Improving
 - Using information and analysis when making decisions (Project Planning)
 - Strategically Planning for the future
 - Knowing that cost effective quality measures can improve laboratory performance and decrease costs



ISO/IEC 17025 Continuous Improvement

- Sources for continuous Improvement
 - 4.15 Management Review
 - The Management Review does a good job covering the overall ISO management system
 - Use the management review for a source to trend corrective action, customer complaints, etc. to identify and implement continuous improvement opportunities
 - Staff input
 - Quality Improvement tools such as PDSA (PDCA), Lean, Six Sigma, etc



Management must ensure that



- The QMS is reviewed and monitored and is implemented and followed by all staff
- Staff are trained and follow a corrective action procedure
- There is a mechanism to identify possible problems and ways to take action to prevent them (preventive action)
- Opportunities are identified to improve the effectiveness of the quality system and are implemented

This module was a:

- Review of personnel requirements and understanding that accrediting bodies have additional requirements
- Review of laboratory ethics and how it is incorporated into ISO/IEC 17025
- Continuous improvement was discussed as it related to ISO/IEC 17025 and beyond



References

- ISO/IEC 17025:2005-<https://www.iso.org/standard/39883.html>
- Stine, J. August 30, 2010. ISO/IEC 17025: Data Integrity Begins with Employee Integrity, Quality Digest <http://www.qualitydigest.com/inside/metrology-article/isoiec-17025-data-integrity-begins-employee-integrity.html#>
- APHL Training site <https://www.aphl.org/training/Pages/default.aspx>
- National Institutes of Health Research Misconduct-
https://grants.nih.gov/grants/research_integrity/research_misconduct.htm
- HIPAA-<https://www.hhs.gov/hipaa/index.html/>
- Environmental Protection Agency-OEI Quality Systems-<https://www.epa.gov/quality>
- American Chemical Society-www.acs.org
- American Society of Quality- www.asq.org
- Minnesota Department of Health Public Health and Quality Improvement Resources & Tools <http://www.health.state.mn.us/divs/opi/qi/toolbox/>
- LEAN- Roos, Daniel, Ph.D.; Womack, James P., Ph.D.; Jones, Daniel T.: The Machine That Changed the World : The Story of Lean Production, Harper Perennial (November 1991) ; One Pager FAQ, Minnesota Department of Health <http://www.health.state.mn.us/divs/opi/qi/toolbox/docs/leanessentials.pdf>
- Six Sigma
- PSDA [The ABCs of PDCA](#) and [PDCA Flowchart \(PDF\)](#) Public Health Foundation

