QMS Quick Learning Activity

# Contracts, Subcontracts, Purchasing and the Laboratory

ISO/IEC 17025 Standard

# What does a laboratory need to do?

Establish procedures for the review of:

- Requests
- Tenders
- Contracts


ISO/IEC 17025 Section 4.4

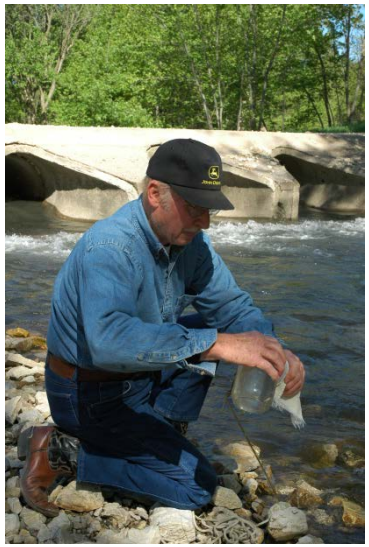
# Reviews

- These reviews leading to a contract shall ensure that:
  - The requirements for the methods are defined, documented, and understood
  - The laboratory has the capability to meet the requirements
  - The appropriate test method is selected and can meet the customers' requirements
- Any differences shall be resolved before the work begins.
- Each contract is agreeable to the laboratory and the customer.

# What is a “Request”?

When the laboratory receives notification from the customer; examples:

- Sample received in the laboratory from a customer with a sample collection form
- An email outlining the request



Customer

Laboratory

# What does ‘Tender’ mean?

- The response (or proposal) that the laboratory makes to the request for service.
- This proposal may include clarifications to the initial request, methods to be used, scheduling information, financial statements, etc.

Laboratory

Customer

# What is a “Contract”?

The actual agreement between the customer and the laboratory.

- This can be a formal contract or can be an implied agreement.
- With no special requests, the laboratory will follow its quality management system for laboratory services

Laboratory

Customer

# Records of Reviews Must be Maintained

- Include significant changes
- Include pertinent discussions with the customer relating to the customer's requirements or results
  - Use the date and identification of the person responsible for carrying out the contract for routine tasks
- Include subcontracted work
- If changes must be made, you MUST inform the customer
- If the contract has been agreed upon and there are changes, the same review process must be repeated and any amendments (changes) communicated to all affected personnel

# Subcontracting

If the laboratory does not do a test and must subcontract (send to another laboratory), the work must be placed with a competent subcontractor.

- A “competent subcontractor” is one that complies to the same accreditation requirements as the submitting laboratory.
- If the subcontracted laboratory is not accredited, then the laboratory should record and maintain the subcontractor’s capability towards meeting those requirements.
- If the customer requests a sample be sent to a specific laboratory for additional testing, this request and the capabilities of the laboratory should be documented.

# Subcontracting

- The laboratory shall advise the customer in writing and, when appropriate, gain the approval of the customer, preferably in writing.
- The laboratory sending out the work is responsible for the subcontractor's work, unless the subcontractor is specified by the customer or regulatory agencies.
- The laboratory should maintain a list of all subcontractors used and record the evidence of their compliance and their capabilities.

# Purchasing

The laboratory should have policies and procedures for the:

- Selection of services and supplies it uses that affect the quality of the tests performed
- Purchasing, reception, and storage of reagents and consumables used
- Testing, inspection, or verification of reagents and consumables before they are used as defined by the method (records shall be maintained)

# Purchasing

- Purchasing documents shall contain data describing the services or supplies ordered and reviewed to ensure they fit the test method or service required.
- The laboratory shall evaluate suppliers of critical consumables, supplies, and services and shall maintain records of these evaluations and list those approved for use.

# Connection

How are purchasing and laboratory testing connected?

- Purchasing is one process that can have a significant impact on the final results of any laboratory test
- Ability to obtain needed supplies and services that allow continuity of testing is a critical component of any system

# Connection

- Components of the standard that are discussed in this presentation relate to any purchases that impact the quality of the testing and calibration
- Reviewing the process and working with purchasing department to deal with suppliers of consumables and services that are less than ideal is key

# ISO 17025:2005 Standard

## Section 4.6 Purchasing services and supplies

- Considered an integral component of the quality management system (QMS)
  - *QMS is more than quality assurance and quality control – it also includes all the business processes of a laboratory that are required to ensure quality.*[1]
- There are four main areas that outline the basics of what to consider:
  - Selection and Purchasing
  - Inspection and Verification
  - Purchasing Documents
  - Evaluation

# Selection and Purchasing

Section 4.6.1 requires that a policy and procedure (s) be in place for the selection and purchasing of services and supplies impacting the quality of testing

- If the organization already has policies and procedures in place that meet the needs of the standard these can be used
  - The assessor will review these
- If more is needed, collaborate to create a process that works for everyone

# Selection and Purchasing

The procedures shall also include information related to reagents and laboratory consumable materials relevant to tests and calibration:

- Purchase
- Reception (receiving)
- Storage
  - This component of the standard may be included in individual test procedures or general quality plans

# Inspection and Verification

Section 4.6.2 indicates that no purchased supplies, reagents, or consumable materials should be used until they have been inspected or verified

- Inspection process can be as simple as indicating that packing slips received must be signed off by staff indicating acceptance of items or a note indicating why it is not acceptable
- Verification can be referenced in the test methods as part of the overall testing process
- Important to record what was done and maintain the records

# Purchasing Documents

Section 4.6.3 requires that purchasing documents (e.g. forms) shall contain description about what specifically was requested

- Examples:
  - Not enough information: Gloves
  - More specific: Nitrile gloves, medium; vendor: ThermoFisher Catalog number 12345
- It is a good idea to have vendor, part number, and any other information that will ensure the correct product the first time through

# Approved for Technical Content

Section 4.6.3 also requires that purchase documents must be reviewed and approved for technical content prior to finalizing and sending to the vendor

- Be clear in your process as to what is considered the final version for approval
- Laboratory staff should be the approvers of technical content

# Evaluation of Critical Items

Section 4.6.4 indicates that evaluation of critical suppliers of consumables, supplies and services shall be performed

- Organization can use a process that is already in place and provided as a record to assessor
- Or if current process is not robust enough for standard or needs more, can work together to create process

# Evaluation of Critical Items

- Create a system that reviews all vendors over a period of time
  - Check with your accreditation body for any requirements on frequency
- All vendors can start with same rating and change as the review occurs

# Internal Audits

Internal audits of the purchasing process is required per section 4.14

- *"The internal audit programme shall address all elements of the management system, … [2]"*
- Recommended that this be done annually

- Internal audits would encompass critical supplies and services

# Staff Responsibilities

Laboratory staff responsibilities

- Staff should understand the purchasing process in their particular area
- Knowing the purchasing process is a skill set in the quality management system competencies
  - APHL/CDC Quality Management Systems, 5.00 Purchasing and inventory; ensure that requirements for supplies and services are consistently met[1]

# Staff Responsibilities

QA staff

- Work with laboratory and purchasing staff
- Perform internal audits of the entire purchasing process
  - This includes trace back from purchased supplies to ordering process
  - Also includes ensuring that the procedure is being followed

# Staff Responsibilities

## Purchasing staff

- Depending on how your agency is set up, this may be one group or multiple groups involved in the process
- Understand the importance of critical supplies and services to laboratory testing
- Assist with setting up the procedures and processes
- Available for internal audits

# Staff Responsibilities

Staff from all sections

- Read procedures and sign off
- Follow procedures
- Write corrective actions when procedure and process not followed

# Accreditation Body

- As with any process, be sure that you discuss with your accreditation body and check their website for any additional requirements that they may have specified
- If you are receiving accreditation to another standard (not just ISO), be sure to check any additional requirements they may have for purchasing

# References


1. *MMWR Competency Guidelines for Public Health Laboratory Professionals;*
    I. CDC and the Association of Public Health Laboratories; May 15, 2015
    II. Supplement/Vol. 64/No. 1
2. ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*