

Auditing Microbiological Laboratories

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Before You Go

- Know your laboratory
 - What types of testing they perform?
 - What is their main focus (i.e. drinking water, wastewater discharges, sludge or soils, ambient water research)
 - Who are the clients?
 - Obtain a client list to help you decide what reports are compliance or simply for informational purposes only.
 - What federal or state regulations are used to help clients demonstrate compliance?

How to Prepare

- Obtain documentation from the laboratory
 - Demonstration of Capability Information
 - Standard Operating Procedures
 - Example bench sheets or electronic logs

Six Principles of Efficient Auditing

- Correct preparation
- Correct types and frequencies of QC protocols and procedures
- Correct documentation
- Adherence to method requirements
- Adherence to SOP procedures
- Initial and continuing proficiency demonstrations

Correct Preparation

- Has the laboratory reviewed the method requirements?
- Does the laboratory have the proper equipment onsite to perform the testing?
- Have all reagents and media been properly made and checked prior to first use?

Correct Types and Frequencies of QC Protocols and Procedures

- Have the requirements of the method been met?
- Have the requirements of the standards been met?
- Are the frequencies required followed?
- Is the correct acceptance criteria been determined and is this met or is the resulting data qualified accordingly?

Correct Documentation

- Are records available for you to conduct an effective audit?
- Are the records clear and concise?
- If electronic records are used are they managed effectively?
- Are records stored for the correct time frame as required by regulation or laboratory policies?

Adherence to Method Requirements

- Once reviewed, are all requirements followed as prescribed by the method?
- Are steps and procedures followed in the manner detailed in the SOP?
- Is the laboratory performing any calculations required properly?
- Are acceptable QC criteria used to report data without qualifiers?

Adherence to Standard Operating Procedures

- Does the SOP reflect the requirements of the method?
- Are the sections of the SOP divided effectively to allow for ease of use?
- Does the SOP address the elements required by the standards?
- Is the SOP read and understood and made available to all personnel?

Initial and Continuing Proficiency Demonstrations (IDOC and CDOC)

- Are the requirements of the standards met?
- Is the IDOC performed as part of the request for accreditation?
- Thereafter are CDOC's generated by using the correct types of qc samples?
- Does the raw data match the certification statements?
- Was each matrix of interest investigated (i.e. non-potable water vs. solid and chemical matrices when the same method is used for testing)?

Summary

- Know your laboratory before you go.
- Know the sample types and clients that they service.
- Ask for documentation before the onsite whenever possible.
- Utilize copies of methods or checklists as your guide to smooth and effective auditing.
- Keep notes and obtain copies of any data that you may need for evidence or enforcement actions.
- Praise the efforts of the laboratory owners and staff whenever suitable.
- Be prepared to learn something new about our field with each audit. Benefit from the experience of being able to get back into the laboratory and at the bench.