

Preparing for Laboratory Audits: How to Reduce Stress Associated with the Auditing Process.

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Introduction

Stress during the auditing process is usually caused by uncertainty.

- What is the auditor going to find?
- Is it going to be a good audit?
- How is the audit going to affect our certification?

Let's take some of the uncertainty out of the process:

- The Certification Types are:
 - Normal
 - Supplemental
- The Certification Status you may receive is:
 - Full
 - Provisional
 - Interim
 - Not Certified

Know what is happening in the laboratory at the bench or instrumental level.

- Don't be surprised during the audit.
- Read the methods to ensure methods are being followed at the bench or instrument level. A quality control summary sheet for analytical batches simplifies this task.
- Inventory all log books, review at designated intervals.
- Conduct an internal audit.

Internal Audits

- Generally a good time to conduct an internal audit is when you receive your certification renewal package or any time of the year when your laboratory experiences the lightest workload.

Reference Materials for Internal Audit

- Microbiology:
 - The checklist I use for microbiology comes directly from *The Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition*.
 - General laboratory practices and requirements for support equipment are also covered in the manual.
- Chemistry:
 - When using an U.S. EPA Method, follow the written method for each evaluation. My checklists are developed directly from these methods.
 - When using *Standard Methods*, use the criteria from the method you are performing, the criteria specified in the introduction to the part (i.e. Metals Part 3000), the quality assurance/quality control for the part, and the requirements specified in Part 1000.

What Not To Do

- Don't try to recreate data (fill in months of data from memory).
- Don't say what you think I want to hear. Always answer correctly. This does not mean you have to volunteer information.
- Don't wait until the day before the audit to make corrections, change procedures, change forms, rewrite standard operating procedures.
- Don't overstress. Even if the audit uncovers deficiencies, you can correct them with your reply. In many cases, the reply is weighted as much as the audit when determining certification status.
- Don't answer a question you don't fully understand. I will rephrase the question if you ask. Sometimes I will purposely ask questions where the obvious answer is the wrong answer, followed by the question: "then how do you perform the procedure". These types of questions may be confusing because of the way they are asked.

Materials you can expect me to request

- Method detection limit studies
- Initial demonstrations of abilities
- Proficiency test results and raw data
- Standard operating procedures
- A final report or final reports where results were reported for each certified method
- All associated data to support the reported results.

Contact Information

- If you have questions you may contact me by email at lundyg@michigan.gov or by phone at (517) 335-9219.