

Lets Go ISO!

ISO Audits and After Actions

What happens next?

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New York State Department of Agriculture and Markets

Ready for the ISO Audit?

- ▶ All deficiencies from gap analysis have been addressed
- ▶ Fill out accrediting bodies paper work to request an audit

American Association for Laboratory Accreditation (A2LA)

- ▶ Fill out checklist
- ▶ Send (upload) necessary documentation (a/k/a your management system)
 - ▶ Quality Manual
 - ▶ Corrective Action SOP
 - ▶ Preventative Action SOP
 - ▶ Organization Chart
 - ▶ SOPs for in-scope methods

		American Association for Laboratory Accreditation	
C204 – Specific Checklist: Combined ISO/IEC 17025 and Food & Pharmaceutical Testing Laboratory Accreditation Program Requirements		Document Revised: December 19, 2011 Page 6 of 87	
		[RESERVED FOR A2LA ASSESSORS ONLY]	
Conf. with Ann. under to the c) It its e rights storag d) It any comp	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;		QM 4.1.5c SOP GP-4-05 WI-712
e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services; There shall be readily available to staff members an organizational chart or charts indicating all reporting relationships and responsibilities. The organizational chart shall include the most responsible position for the unit and all positions in that hierarchy; (AOAC)	QM 4.1.5e Organizational Charts		
f) specify the responsibility, authority and	QM 4.1.5f		

L:\Checklists\C204 – Specific Checklist: Combined ISO/IEC 17025 and Food & Pharmaceutical Testing Laboratory Accreditation Program Requirements

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C204 – Specific Checklist: Combined ISO/IEC 17025 and Food & Pharmaceutical Testing Laboratory Accreditation Program Requirements		Document Revised: December 19, 2011 Page 6 of 87			
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Requirement	Reference	Compliance			Comments
		Y	N	NA	
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;					QM 4.1.5d & 4.1.4 Employee's Handbook NYS Public Officers Law
There shall be readily available to staff members an organizational chart or charts indicating all reporting relationships and responsibilities. The organizational chart shall include the most responsible position for the unit and all positions in that hierarchy; (AOAC)					
f) specify the responsibility, authority and	QM 4.1.5f				

L:\Checklists\C204 – Specific Checklist: Combined ISO/IEC 17025 and Food & Pharmaceutical Testing Laboratory Accreditation Program Requirements

Pre ISO Audit

PUBLIC OFFICERS LAW

§ 74. Code of ethics.

1. **Definition.** As used in this section: The term "state agency" shall mean any state department, or division, board, commission, or bureau of any state department or any public benefit corporation or public authority at least one of whose members is appointed by the governor or corporations closely affiliated with specific state agencies as defined by paragraph (d) of subdivision five of section fifty-three-a of the state finance law or their successors.

The term "legislative employee" shall mean any officer or employee of the legislature but it shall not include members of the legislature.

2. **Rule with respect to conflicts of interest.** No officer or employee of a state agency, member of the legislature or legislative employee should have any interest, financial or otherwise, direct or indirect, or engage in any business or transaction or professional activity or incur any obligation of any nature, which is in substantial conflict with the proper discharge of his duties in the public interest.

3. Standards.

a. No officer or employee of a state agency, member of the legislature or legislative employee should accept other employment which will impair his independence of judgment in the exercise of his official duties.

b. No officer or employee of a state agency, member of the legislature or legislative employee should accept employment or engage in any business or professional activity which will require him to disclose confidential information which he has gained by reason of his official position or authority.

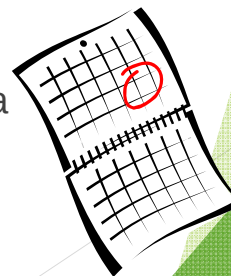
c. No officer or employee of a state agency, member of the legislature or legislative employee should disclose confidential information acquired by him in the course of his official duties nor use such information to further his personal interests.

PUBLIC OFFICERS LAW §74
NEW YORK STATE JOINT COMMISSION ON PUBLIC ETHICS



Pre ISO Audit

- ▶ Accreditation body may come back with requests for additional documentation
- ▶ After documentation has been received and reviewed an auditor(s) will be assigned
 - ▶ A2LA gives the opportunity to ask for another auditor
- ▶ Work with auditor(s) to set up date of audit
- ▶ Auditor (lead) will send an proposed agenda



Pre ISO Audit

- ▶ Hold an “all lab” staff (including support staff) meeting
 - ▶ Dates of audit
 - ▶ Who the auditor(s) will be
 - ▶ What is in scope and what is not
 - ▶ How to answer questions



Pre ISO Audit

- ▶ Remind staff that an audit is just an opportunity to
 - ▶ Increase your understanding of the ISO 17025 standard (will be working with an expert)
 - ▶ Improve the management system
 - ▶ Improve the quality of test results



During the ISO Audit

- ▶ Opening meeting(s)
 - ▶ Management, QA staff, and other senior staff
 - ▶ Invite entire staff
- ▶ Lab tour
 - ▶ Meet/talk to analysts
- ▶ Adjust agenda if needed/decide on meeting schedule
- ▶ Decide what kind of findings report will be generated (A2LA)
 - ▶ With Observations
 - ▶ Without Observations

Never let an ISO Auditor roam laboratory unescorted!!

During the ISO Audit

- ▶ Answer questions openly and honestly
- ▶ Don't have something auditors are looking for just say so – worst that could happen is a deficiency
 - ▶ Deficiencies can be corrected
 - ▶ Gained knowledge about what is needed to be accredited
- ▶ Don't try and correct deficiencies while the auditors are at the laboratory
 - ▶ Each deficiency needs a corrective action – including root cause analysis

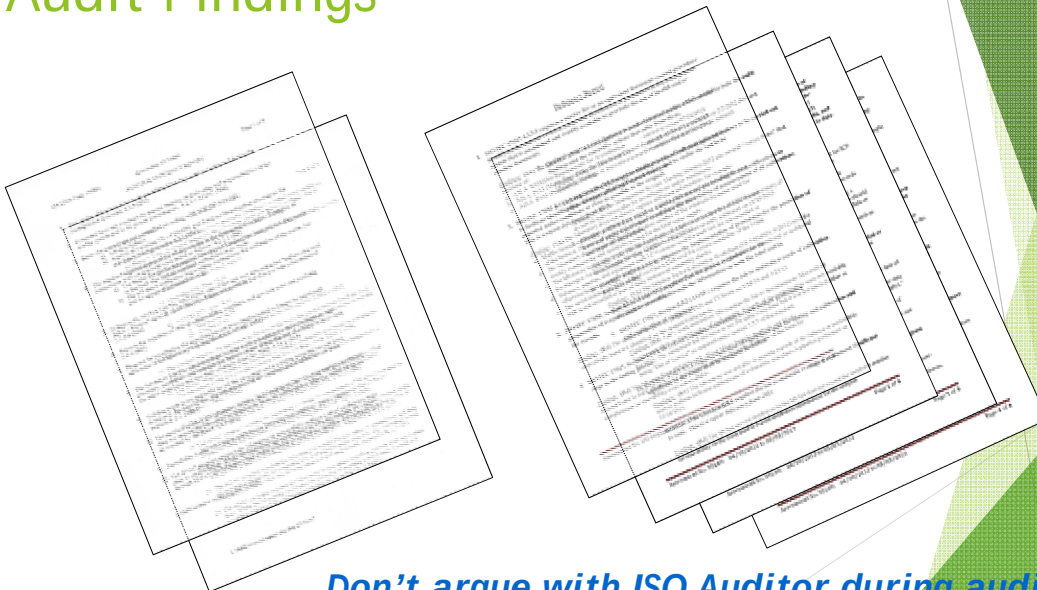


ISO audit

- ▶ Management System Documentation – (our lab ~1 ½ days)
- ▶ Technical Information – (our lab ~1 day)
- ▶ End of day meetings with QA staff and ISO committee
- ▶ End of Audit Closing meeting
 - ▶ Invite all staff (including support staff)
 - ▶ Auditors go over audit findings



Audit Findings



Don't argue with ISO Auditor during audit

After Audit

- ▶ Give laboratory staff time to think about responses
- ▶ A2LA –
 - ▶ Initial Assessment
 - ▶ response not due for 30 days
 - ▶ all deficiencies resolved within 6 months
 - ▶ Renewal Assessments
 - ▶ response not due for 30 days
 - ▶ all deficiencies resolved within 60 days
- ▶ ISO committee meets and decides who is going to handle each deficiency
- ▶ Thank analytical staff – PARTY!

MASTER Code 129851

Assessment ID 14466

Page 1 of 2

ASSESSOR DEFICIENCY REPORT

1. The quality objectives have been established but they were not reviewed during the management reviewed. 4.2.2 (BM)
2. Personnel have not received the annual training on their roles and responsibilities in the quality system and in its proper maintenance. 4.2.2 e AOAC (BM)
3. Some documents are not controlled according with SOP GP 4-02 / 01:
 - a) Job descriptions
 - b) Analytical variation TB – CHM001 and fertilizer investigation allowances for secondary micronutrients. 4.3.1 (BM)
4. The standard requires approval for all documents in the management system. Examples of instructions with no approval were noted as follows: 4.3.2.1 (BS)
 - a) The binder for media preparation had several handwritten instructional documents in the back that had no approval authorization on them.
 - b) The pH meter calibration log contains instructions for calibration of the meter, but had no approval information on it.
5. In Report FL 293718 Lab No. 08CO2380, one of the test was subcontracted “carbon sira total SIRA – Protein” dated 9-10-08 this report does not mention that this test was subcontracted. 5.1.0.6 (BM)

Audit Response

FR-CAR003; Original, 1/17/08

New York State
Department of Agriculture and Markets
Food Laboratory

Corrective Action Response To Assessor Deficiency Report

Date: 11/17/08
Master Code: 129851
Assessment ID: 14466
Deficiency No.: 1

Deficiency Statement:

The quality objectives have been established but they were not reviewed during the management reviewed. 4.2.2 (BM)

Root Cause:

The quality objectives were reviewed in the management review meeting held in March of 2008. Because the objectives had been recently written, there was not an extensive discussion. All attendees found them to be acceptable as they were. A note was made in the meeting minutes that they were "okay"

Corrective Action:

At the next management review, which will take place in March of 2009, the quality objectives will be discussed in more detail.

Supporting Documentation Attached:

2008 Management review meeting notes pg. 6 with relevant section highlighted.

Audit Response

New York State
Department of Agriculture and Markets
Food Laboratory

Management Review Meeting Notes

FTIR has not arrived in expected time. Dan will follow up to see about this.

Mission Statement

Want to add something to mission statement found in Quality Manual. "To provide expert state of the art analytical testing" (this is what is found on the web site).

Objectives – okay

LIMS System – current plan is not to continue to provide an interpretation of results with the new LIMS. Customers need to be informed that our goal is to provide the best results - not interpret results. Dan will continue to promote this idea with the division directors that will be impacted. May explore using the Counsels office for input on interpretations.

Proposed New Programs

State level pesticide residue testing program – a proposal was provided to the Commissioner but we have not received any direction on this proposed program.

PulseNet – We are now a PulseNet laboratory and receive training and travel

- a. A2LA R101(Gen Requirements for Accreditation) – current revision 07/02/2012
- b. A2LA P113 (Msmt Traceability for Life Sciences) - current revision 11/16/2012
- c. A2LA R103 (Proficiency Testing) - current revision 01/01/2013

2. ISO/IEC 17025 4.13.2.1 requires the laboratory to retain records of sufficient information to facilitate identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original.

This is a repeat deficiency from 2011.

Finding: (SA) The laboratory does not always capture sufficient information, for example:

- a. Muffle furnace calibration performed on 3/6/12 or 4/29/13 does not include (a) identification of the furnace; (b) name of personnel who performed the calibration.
- b. The laboratory does not record the identification number of the conductivity meter used for weekly conductivity and resistivity testing for the DDI water supply.
- c. ~~The laboratory is not able to provide the Certificate of Analysis or lot number of EDTA used for Nitrogen Analysis Sample Number 122022 on 05/25/2011.~~
- d. Balances, pipettes, and equipment such LC Columns used for each test are not recorded or otherwise linked to sample analyses/test reports.
- e. ~~The serial number (#2910) of the Foss Check Cell used for system suitability of the FOSS NIR is not recorded as part of daily instrument suitability checks.~~

3. ISO/IEC 17025, Section 4.13.2.1 (AOAC) requires that the person responsible for the preparation of reagents shall be traceable through the information on both the label and in the records.

Finding: (RJ) The names of the persons preparing TSB and TT Broth on 1/28/13 and 4/23/13

12. ISO/IEC 17025 5.5.1, 5.5.5 b-g requires the laboratory to be furnished with all items of measurement and test equipment required for the correct performance of tests, including preparation of test items, processing and analysis of test data (5.5.1). Records shall be maintained on each item of equipment and shall include (b) unique identification; (c) checks that the equipment complies with the specification; (d) the current location; (f) dates, results and copies of reports and certificates of adjustments, acceptance criteria, and due date of next calibration; (g) the maintenance plan and maintenance carried out to date. This is a repeat deficiency from 2011.

Findings: (SA) The laboratory does not always meet these requirements, for example:

- a. CEM MarsXpress microwave digesters s/n MD8052 or s/n MD 7990 used for ICP analysis are not on the instrument/equipment inventory and have not been calibrated since 2008.
- b. Thermo Sorvall Legend XT Centrifuge s/n 41425727 used for PDP sample preparation, is not included on the instrument inventory and there are no records to confirm that it complies with specifications.
- c. CEM microwave digester s/n MD7990 (CHM 027) is currently displaying a manufacturer message that states "Preventive maintenance for this system should be scheduled"; the laboratory was not able to provide a maintenance schedule or plan for this equipment.
- d. The laboratory does not include the identification numbers of equipment such as balance, furnace/oven, pipette used for sample preparation in records.

Protest – identify what you are protesting

Deficiency #2d & 12d

2. ISO/IEC 17025 4.13.2.1 requires the laboratory to retain records of sufficient information to facilitate identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original.

This is a repeat deficiency from 2011.

Finding: (SA) The laboratory does not always capture sufficient information, for example:

- d. Balances, pipettes, and equipment such LC Columns used for each test are not recorded or otherwise linked to sample analyses/test reports.

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Findings: (SA) The laboratory does not always meet these requirements, for example:

- d. The laboratory does not include the identification numbers of equipment such as balance, furnace/oven, pipette used for sample preparation in records.

Protest – what the standard says

4.13.2.1 of the standard states: *The laboratory shall retain records of original observations, derived data and sufficient information to establish and audit trail, calibration records, staff records and a copy of each test report or calibration certificated issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for sampling, performance of each test and/or calibration and checking of results.*

Protest – make your case

The laboratory verifies all balances daily (day of use) either by running the internal calibration or by using a standard weight as per Appendix A: Equipment Table 1 Calibration and Verification of Equipment. All balances are considered to be equal therefore individual balances are not traced to samples. Records of internal calibrations or external weight verification are maintained for each balance. If a balance could not be verified it would be marked as being out of service.

Pipettes are either class A or calibrated via a spectrophotometric system every six months as per Appendix A: Equipment Table 1 Calibration and Verification of Equipment. Again because of this, the laboratory considers all pipettes to be equal and therefore not individually linked to samples. Records of calibration are maintained for each pipette.

Protest – make your case

Furnaces are verified annually as per Appendix A: Equipment Table 1 Calibration and Verification of Equipment. If a furnace did not meet the laboratory specification it would be marked out of service. Again the laboratory therefore considered all furnaces to be equal and therefore they are not directly traceable to samples.

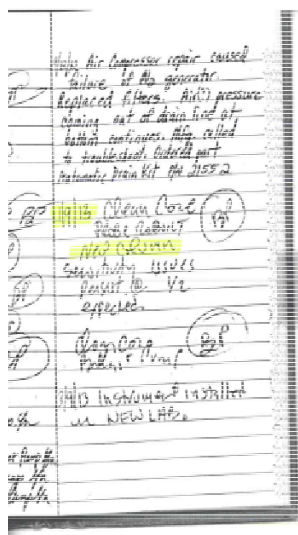
When a chromatographic column is replaced in an instrument the date of replacement is noted in the instrument log book. See attachment 1. There is also a sticker indicating the phase and size of the column and its lot number. This sticker is dated and attached to the instrument when installed. See attachment 2. This makes the column traceable to samples based on their analysis dates.

Protest – make your case

The laboratory feels that records referenced above are sufficient to facilitate the identification of factors affecting uncertainty and to enable the test to be repeated under conditions as close as possible to the original and that no corrective action is necessary.

The laboratory feels that items stated in finding 12d are equivalent as state above, therefore it is not necessary to have their unique identification traced to samples.

Protest – also sent



Protest - Outcomes

- ▶ Balances – won
- ▶ Pipettes – won (or lost in shuffle???)
- ▶ Furnaces – won
- ▶ Chromatographic column
 - ▶ Were indicating what samples were being run on what column (by date of column install)
 - ▶ Column information kept on computers internal log

Updated equipment SOP to clearly state that if calibration/verification not acceptable it will be marked out of service



Accredited – now what?

- ▶ Standard focuses on *continual improvements*
 - ▶ Internal audits
 - ▶ SOP updates
 - ▶ Proficiency Testing (PTs)
 - ▶ Corrective Actions/Preventative Actions
 - ▶ Scope expansions
- ▶ QA staff will always have a full time job!

Attend Accreditation Body's annual meeting

Questions?

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Thank you!

