

North Carolina Department of Agriculture & Consumer Services



Scope of ISO Accreditation

International Laboratory Accreditation Cooperation –ILAC

Guideline for the Formulation of Scopes of Accreditation for Laboratories

The scope of accreditation of a laboratory is the formal and precise statement of the activities which the laboratory is accredited for. It is as such the result of a combination of information (scope parameters) concerning the field of activity (e.g. testing, calibration), the product/object tested or calibrated and the methods and procedures used.

ILAC-G18:04/2010

Scope of ISO Accreditation

- test methods
- flexible (technology) scope

What do you consider when determining test method scope?

- Which sections of the lab
- Lab testing capabilities
- Time
- Cost
- Customer needs

Priority ?



Which sections of the lab?

- Lab staff
 - Headcount
 - Experience – technical skills, writing skills
 - Supervision
- Work load
 - Always busy vs. seasonal
- Amount of documentation already in place

Laboratory Capability – equipment

- 5.5.1 *The laboratory shall be furnished with ... test equipment required for the correct performance of the tests.*
- 5.5.2 *Equipment and its software used for testing... shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests...concerned.*

Laboratory Capability – validations

- 5.4.5.2 *The laboratory shall validate... amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application.*

Laboratory Capability – test methods

- 5.4.2 Selection of Methods
 - *The laboratory shall use test methods ... which meet the needs of the customer and which are appropriate for the tests it undertakes. Methods published in international, regional, or national standards shall preferably be used.*
 - *...published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.*

Laboratory Capability- test methods

- *which meet the needs of the customer ?*
 - *Example*

- *which are appropriate for the tests it undertakes?*
 - *Example*

Laboratory Capability- test methods

- *....or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.*
 - *AOAC - Association of Analytical Communities*
 - *ASM - American Society for Microbiology*
 - *AFNOR*
 - *FDA BAM – Bacteriological Analytical Manual*
 - *FDA PAM – Pesticide Analytical Manual*
 - *FDA LIBS – Laboratory Information Bulletins*
 - *USDA/FSIS MLG – Microbiological Laboratory Guide*
 - *Journals [Mass Spectrometry, Chromatography]*
 - *Equipment manuals, kit inserts*

BLJ1

Time

- Documentation
 - test methods, work instructions, equipment instructions, worksheets
- Test method validations, verifications, matrix extensions
- Training
- Auditing

Cost

- PTs
- equipment PM and calibration frequencies
- equipment that meets specifications
- class A glassware
- certified reference materials

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BLJ1 And training - to ISO & QMS requirements
Brenda Jackson, 4/30/2014

Customer needs

- Regulatory authority
 - FDA, USDA/FSIS, State, County, City
 - State laws and regulations
 - ❖ NC Administrative Code adopted, by reference,
AOAC
FDA BAM
FDA PAM
Standard Methods for the Examination of Dairy
Products

BLJ2

Customer needs

- Types of samples
 - Manufactured foods - sandwiches, frozen dinners, bakery, ice cream, bottled water
 - Non-manufactured foods – raw fruits & vegetables, raw milk, seafood, nuts
 - Environmental swabs
- Analytes of interest
- Action levels [detection limits]

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BLJ2 And action levels (detection levels) the customer needs
Brenda Jackson, 4/30/2014

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Benefits of being more inclusive

- NC example
- If the quality management system is required for the entire lab:
 - does not mean every test method is in scope
 - everyone trained on qms
 - everyone held to same qms expectations
 - one set of audit criteria
 - analysts already trained if moves from non-scope test methods to in-scope test methods

Expanding scope

- When
 - During AB audits
 - Between AB audits – remote approval
- Minimize effort
 - test method already in-scope
 - matrix extension or analyte extension,
 - then AB may be willing to remotely review/approve based on revised test method, PT results, verification package & training records
 - new test method
- Minimize cost
 - Avoiding AB auditor travel costs
 - PTs

Flexible (technology) Scope

International Laboratory Accreditation Cooperation (ILAC) https://www.ilac.org/documents/ILAC_G18_04_2010.pdf

- “...laboratory...is allowed to include additional activities in its scope of accreditation on the basis of its own validations without evaluation by the accreditation body prior to operation of the activity.”
- “Flexible scope can be established based on degrees of freedom for flexibility such as:”
 - products, matrices, parameters, components, analytes

Contact your Accrediting Body

- Note your ABs documentation requirements

pros/cons

Test method scope

- If conducting routine testing for pre-determined samples, this scope meets needs
- PTs for each method

Flexible scope

- method development, method modifications, new analytes or matrices without prior approval
- immediate testing of non-routine samples
- react more quickly to customer needs
- reduced amount of PT testing
- lab accountable for supporting documentation [contact you AB]

