



# LABORATORY ACCREDITATION: *Process & Methods Development*

Presented by

Roger M. Brauninger M.S.

American Association for Laboratory Accreditation

**4<sup>th</sup> Annual Florida Pesticide Residue Workshop**

**July 18, 2005**

## *Topics*



- What is A2LA
- What is Accreditation?
- Accreditation process
- ISO 17025: Method selection, development and validation



## Facts about A2LA

### American Association for Laboratory Accreditation:

- Established in 1978
- Largest *multi-discipline* laboratory accreditation system in the U.S.
  - Major focus: Accredit testing and calibration laboratories for specific tests/calibrations
  - **More than 1600 labs currently accredited**
  - Over 180 currently seeking accreditation
  - **Includes more than 100 laboratories outside the US**
- Non-profit, public service, non-governmental membership organization



## A2LA Assessors

- Minimum 10 years of technical experience
- **Must attend A2LA's 3-day training course.**
- **Many also attend 5-day lead auditor course.**
- **Observed by staff on first two assessments for training and evaluation.**
- **Follow-up evaluation after one year and every 3 years thereafter.**
- **Assessors also evaluated by labs and Accreditation Council members.**

## Accreditation



Defined as a procedure by which an **authoritative body\*** gives formal recognition that a **Conformity assessment Body** fulfills specified requirements and is competent to carry out specific tasks.

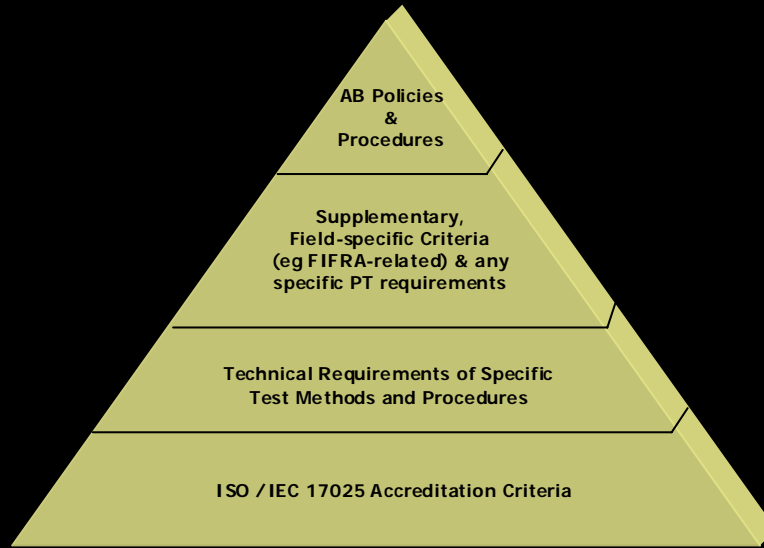
– **Usually using ISO/IEC 17025 as a basis**

*\* (e.g. A2LA, NVLAP, AIHA, UKAS etc).*

## Benefits of Accreditation

- **International recognition of technical competence**
  - Leads to comparable outcomes worldwide
  - Recognition validated via peer evaluation process
- **Legally defensible system**
  - Competent staff
  - Valid and appropriate methods
  - Suitable quality assurance to demonstrate control
  - Traceability of measurements

# Accreditation Requirements



## Accreditation Ten Second Tutorial

*Doing what you Say you are doing*

*And being able to Prove it!*



## Accreditation Ten Second Tutorial (cont)

- **Say**
  - Define your Policy on Quality
  - Create/modify procedures to address policy requirements
    - (Are there written documents (policies, procedures, arrangements) that meet the requirements of the standard)?
- **Do (what you say)**
  - Follow your documentation.
    - (Are you in compliance with your own quality system, test methods and standard?)
- **Prove**
  - Document actions through records.
    - (e.g. training records, standards preparation, work books, client reports, audit reports *(and everything in between!)*)

*Goal: Laboratory practice reflected in procedure and vice-versa*

## Assessment Preparation Options

- Consultants
  - **PRO:** Helps write documentation, identify missing elements, aid interpretation of requirements
  - **CON:** May not know organizational culture/operations
- Pre-assessment
  - Uses agreed-upon A2LA assessor
    - **PRO:** Helps identify missing elements, aid interpretation of requirements
    - **COM:** Cannot write documentation
- Go for it!
  - Use internal & A2LA staff expertise for help

## Issues Requiring Early Consideration

- Proficiency Testing data needed for:
  - Each major matrix of concern
  - For as many analytes/methods as possible
- Estimates of Measurement Uncertainty
  - Develop Procedures, ID contributing factors
  - Training on performing calculations (*e.g. LCS data*)
- Measurement Traceability (*internal & external*)
  - Through an unbroken chain of comparisons, with each step having stated uncertainties
  - Demonstrable competence performing calibration

## What is needed to begin?

- Application
- Quality Manual
- Completed ISO 17025 Assessor Checklist
- Scope: Test names w/corresponding method Ids
- Measurement traceability activities
- Proficiency Testing activities:
  - (General): Enrollment & Successful PT
- Equipment List & Technical Staff Matrix
- Payment of applicable fees



## Quality Manual

- Lays out Quality System roadmap
  - No set format required
  - Level of detail based on structure/ function of the laboratory and its' needs
    - Laboratory's policies must be included or referenced



## Scope of Accreditation

- Identifies precisely what the laboratory is accredited for:
  - *Includes a listing of test methods or test technologies, products or materials on which the testing is done, the anniversary date and location of testing facility.*
- Laboratories are *generally* accredited for specific tests or measurements and for a particular products and test specifications.
  - *Less commonly, a flexible scope allows laboratories accredited to technologies, as a part of method development.*

## Pre-Assessment Review

- Staff reviews application, checklist, drafts scope
- Asr reviews Quality Manual, Lab procedures
  - Do they contain required polices and procedures
  - Review test methods
- Asr review of past PT Results
  - Scope Coverage
  - Look for outliers, evidence of “concern”
- Dates set and agenda provided
- Report on potential areas of noncompliance
  - Allows labs to make “minor” fixes in advance
  - Warning if “major” problems exist

## On-site Assessment

- Review of Quality Requirements
  - Generally requires 1-1.5 days
  - Looks for documents/documentation supporting processes where procedures are required
  - Evaluates “shall ensures” clause implementations
  - Review of PT Results
  - Review additional Specific Program requirements



## On-site Assessment

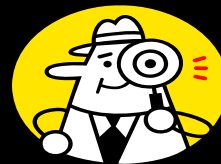


- **Review of Quality Requirements (cont)**
  - Evaluate the lab's management of required administrative activities, including:
    - Organization, Training, Control of records
    - Purchasing, Contract review
    - Client communication, Complaints
    - Internal audits, Management review,
    - CAR/PAR process
  - Looking for adherence to requirements of applicable standards and own policies/ procedures

## On-site Assessment (cont)

- **Review Technical Requirements**
  - Generally requires 1-1.5 days
  - Review of Specific Program requirements
  - Evaluation of MU calculations, calibration traceability, test item handling and sampling procedures, quality control procedures, reporting of results

\*Where applicable



## On-site Assessment (cont)

- Review Technical Performance
  - Documents, Records, Interviews, Demonstrations
  - Evaluation of Laboratory/Analyst Competency
    - Interviews technical staff
    - Observes testing,
    - Suitability of facility for task
    - Sampling activities
  - Reviews equipment maintenance records



## Deficiency (nonconformity)



- A departure from or an instance of noncompliance with a condition or criterion for accreditation
  - ISO/IEC 17025:1999
  - Method
  - Specific Program requirement
  - Policies & procedures

## *Causes of Deficiencies*

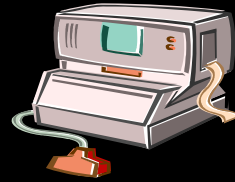
- Lack of top management support
- Lack of system
- Lack of training of staff
- Lack of time
- Lack of resources
- Lack of motivation



## *Typical Deficiencies*

- Equipment
- Accommodation
- Personnel
- Quality System
- Methods

## Equipment



- Calibration and supporting documentation is lacking
- Equipment is substandard, out-of-tolerance, and/or as not been calibrated or verified at suitable intervals
- Substitute equipment is used without acceptable evidence that it performs as specified for the standard involved

## Accommodation\*

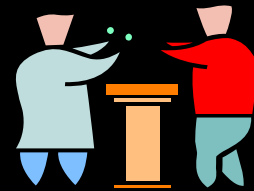
- Temperature and humidity requirements are not being satisfied
- Incompatible activities are not separated



*\*Std. does not address S&H issues*

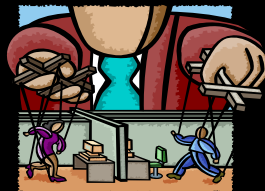
## Personnel

- Objective evidence is not available attesting to the competence of the personnel
- On the job practice has become careless and has departed from prescribed procedures



## Quality System

- Lack of complaints procedure
- Lack of procedure for review of new work
- Lack of purchasing procedures
- Not following through on corrective actions
- Incomplete internal audits





## Methods

- Out-of-date (superseded) methods in use
- Not following methods as written
  - Doing more = OK
  - Doing less = Not OK
- Estimates of measurement uncertainty not calculated

## Granting of Accreditation

- Assessor Reports on On-Site Assessment
- Lab supplies evidence of Corrective Action
- Review CAR by Staff
- Submit Assessment Information to AC
- Decision on Accreditation\*

→ \*Appeal is possible



## Accreditation Timeline

- Initial accreditation effort takes ~ 6-8 months
- 2 year period of accreditation
- 1<sup>st</sup> year On-site Surveillance visit
- Annual documentation review by A2LA staff after the first reassessment, with focus on:
  - Internal Audits
  - Management Reviews
  - Results from relevant proficiency testing

## Flexible Scopes

-or-

*Allowing The Use of Developed Methods*



## EURACHEM/CITAC Guide CG2:

*"Quality Assurance for Research and Development and Non-routine Analysis"*

### Guidelines intended to cover situations where:

- **Methods already exists;**

- But not previously been applied to the particular type of sample now encountered.
- Existing methods need to be evaluated / extended or adapted as necessary;

- **Analytical problem is entirely new;**

- May be tackled by applying existing methods / techniques;
- There is no established method, and something has to be developed from the beginning.

## Flexible Scope - ILAC G18

- **Laboratories applying for a scope of accreditation which allows the possibility for a continuous development of services covered by accreditation must demonstrate their technical capability to validate new developed or modified methods in accordance to § 5.4 of ISO/IEC 17025.**
- **When shown in the past able to implement new methods or modify laboratory-developed methods properly so that the ABs can have confidence in that ability also in future, formulation of accreditation scopes on a more general basis should be considered.**

## Flexible Scope - ILAC G18

- In all cases the laboratory has to keep an updated list of accredited test methods including newly modified, introduced or developed methods available for the accreditation body.
- It must be made clear that the possibility of introducing new, modified or developed methods does not include introduction of new principles of measurement.

### SCOPE OF ACCREDITATION TO ISO/IEC 17025-1999

#### CUSTOMS & BORDER PROTECTION - SPRINGFIELD LABORATORY

7501 Boston Boulevard, #113

Springfield, VA 22153

John L. Sullivan Phone: 703 921 7200

#### CHEMICAL

Valid To: January 31, 2006

Certificate Number: 1706.15

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform method development for the U.S. Customs Laboratory System using the test technologies listed below:

##### Spectroscopy

ICP/MS

FTIR (Fourier Transform Infrared)

##### Microscopy

Light microscopy (PLM)

SEM (Scanning electron microscopy)

##### Chromatography

Gas chromatography

Gas chromatography/Mass spectrometry

##### Wet Chemistry

Gravimetric

SCOPE OF ACCREDITATION TO ISO/IEC 17025-1999

MONARCH ANALYTICAL LABORATORIES  
349 Tomahawk Dr.  
Maumee, OH 43537  
James P. Hojnicky Phone: 419 897 9000

CHEMICAL

Valid To: November 30, 2004

Certificate Number: 1656-01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this

Research and Development laboratory to perform the following types of tests and method development:

Spectroscopy

Optical Emission

Chromatography

High Performance Liquid  
Ion Chromatography

Chromatography

Inductively coupled plasma  
Fourier Transform Infrared  
X-ray Fluorescence

Electrochemical

Polarography

Miscellaneous

Specific ion electrode analysis  
Leco Sulfur Analysis

On glass, ceramics, and related products and raw materials, plastics, polymers, organic and inorganic additives and coatings, elastomers and packaging materials; using product specific methods.

## ISO 17025

### 5.4.2 Method Selection

- Use methods which meet needs of client
- Published, standardized methods are preferred
- Non-standard methods may be used if
  - appropriate for intended use
  - validated
- Laboratory must verify competence in using method

## ISO 17025

### 5.4.3 Laboratory Developed Methods

- Introduction of methods *planned* activity
- Activity assigned to *qualified* personnel with adequate resources
- Plans updated as development proceeds and communicated



## ISO 17025

### 5.4.4 Non-standard Methods

- Subject to agreement with client
- Requires clear client specification
- Requires ***validation*** before use (i.e. confirmation that the particular requirement for a specified end use are fulfilled)
- Method information requirements:



## ISO 17025

### 5.4.4 Method Requirements<sub>(cont.)</sub>

- identification
- scope
- items to be tested
- parameters to be measured
- reference standards
- environmental conditions
- description of procedure
- criteria for approval
- data to be recorded
- uncertainty of measurement estimate

## ISO 17025

### 5.4.5 Validation of Methods

- Laboratory shall validate
  - non-standard methods
  - laboratory developed methods
  - standard methods used outside scope
  - modifications of standard methods
- Validation as extensive as necessary
- New validation required if changes made

## ISO 17025

### 5.4.5.3 Validation of Methods<sub>(cont)</sub>

Performance shall be relevant to clients needs with respect to:

- accuracy
- range
- detection limit
- selectivity
- linearity
- reproducibility
- robustness against external influences and/or cross sensitivity against interference from the matrix of the sample/ test object

## ISO 17025

### 5.4.6 Estimation of Uncertainty

- Laboratory shall have procedure for making a estimation of uncertainty of measurement
- All components considered
- In certain cases , the nature of the method may preclude a rigorous calculation
  - attempt to ID all contributors
  - make reasonable estimate based on *for example:* knowledge of method performance, measurement scope and shall make use of previous experience & use validation data
    - Note: Degree of rigor in estimate depends on factors such as: requirements of method, requirements of client or existence of narrow limits on which decisions on conformance to a specification are based

## *In Summary*



- Accreditation = International recognition of technical competence.
- Ten Second Tutorial: Do, Say, Prove.
- Flexible (technology based) scopes are acceptable, but require more.
- Non standard methods require validation and estimation of uncertainty of measurement.

## *Questions / Comments*



*For Further Information...*

Contact: Roger M. Brauningner

Phone: 301 644 3233

Email: [rbrauningner@a2la.org](mailto:rbrauningner@a2la.org)

American Association for Laboratory Accreditation  
5301 Buckeystown Pike, Suite 350  
Frederick, MD 21704

[www.a2la.org](http://www.a2la.org)

