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Internal Validation

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Goal

- To improve participants understanding of the value of internal validations; how to perform internal validations in an efficient manner; and what needs to be done after the validation has been completed

Purpose

- Internal validations are not uniformed from one lab to the next and in many instances are taking to long due to poor guidance and labs being cautious, which ultimately delays the implementation of a new chemistry or instrument.
- Can contribute to backlogs in laboratory's that are already overburdened
- DNA Forensics methods continue to advance with the introduction of new and better methods, chemistries, and software and thus internal validations will continue to be important for Forensic Laboratory's to perform efficiently and thoroughly.
- There will always be something to "Validate"

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Agenda Slide

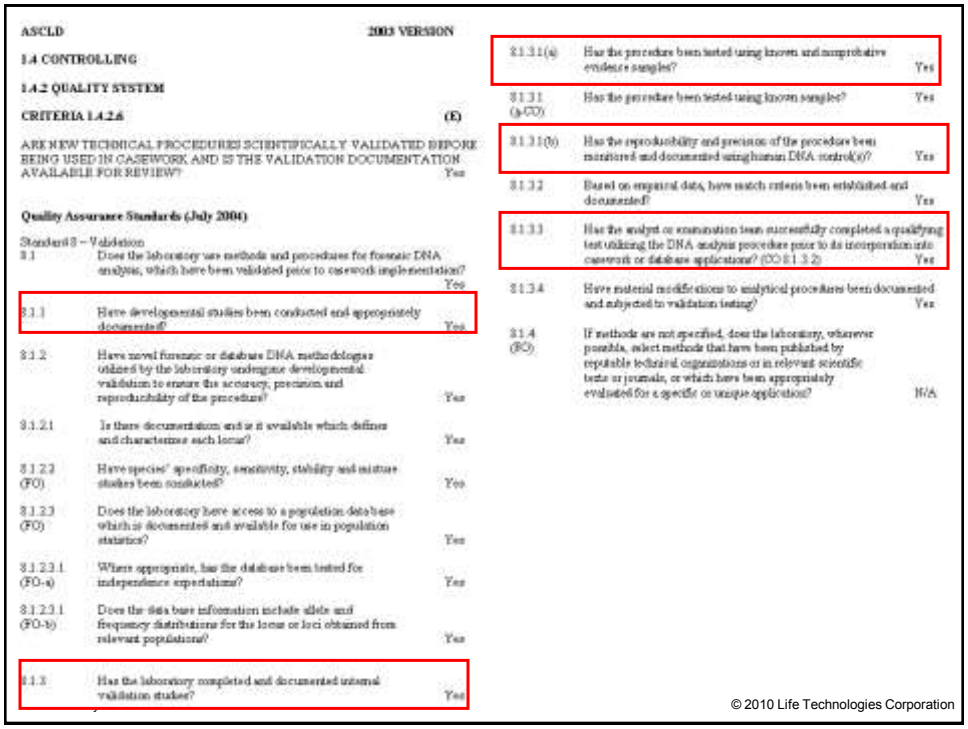
- The importance of Internal Validations
- History of Validation Guidelines
- Examples of Validation experimental designs
- Documentation of internal validation studies
- What needs to occur after internal validation completed

Elements that Guarantee Quality Forensic DNA testing

- Accepted Standards and Guidelines for Operation
- Laboratory Accreditation
- Proficiency Testing of Analysts
- Standard Operating Procedures
- **Validated Methods**
- Calibrated Instrumentation
- Documented Results
- Laboratory Audits
- Trustworthy Individuals

Validation: What is it and why should it be done

- Is part of the overall QA program with in a laboratory



ASCLD 2003 VERSION

1.4 CONTROLLING

1.4.2 QUALITY SYSTEM

CRITERIA 1.4.2.6 (E)

ARE NEW TECHNICAL PROCEDURES SCIENTIFICALLY VALIDATED BEFORE BEING USED IN CASEWORK AND IS THE VALIDATION DOCUMENTATION AVAILABLE FOR REVIEW? Yes

Quality Assurance Standards (July 2004)

Standard 8 – Validation

8.1 Does the laboratory use methods and procedures for forensic DNA analysis, which have been validated prior to casework implementation? Yes

8.1.1 Have developmental studies been conducted and appropriately documented? Yes

8.1.2 Have novel forensic or database DNA methodologies utilized by the laboratory undergone developmental validation to ensure the accuracy, precision and reproducibility of the procedure? Yes

8.1.2.1 Is there documentation and is it available which defines and characterizes each locus? Yes

8.1.2.2 (FO) Have species' specificity, sensitivity, stability and mixture studies been conducted? Yes

8.1.2.3 (FO) Does the laboratory have access to a population database which is documented and available for use in population statistics? Yes

8.1.2.3.1 (FO-a) Where appropriate, has the database been tested for independence expectations? Yes

8.1.2.3.1 (FO-b) Does the data base information include allele and frequency distributions for the locus or loci obtained from relevant populations? Yes

8.1.3 Has the laboratory completed and documented internal validation studies? Yes

8.1.3.1(a) Has the procedure been tested using known and non-probative evidence samples? Yes

8.1.3.1 (a-CO) Has the procedure been tested using known samples? Yes

8.1.3.1(b) Has the reproducibility and precision of the procedure been monitored and documented using human DNA control(s)? Yes

8.1.3.2 Based on empirical data, have match criteria been established and documented? Yes

8.1.3.3 Has the analyst or examination team successfully completed a qualifying test utilizing the DNA analysis procedure prior to its incorporation into casework or database applications? (CO 8.1.3.2) Yes

8.1.3.4 Have material modifications to analytical procedures been documented and subjected to validation testing? Yes

8.1.4 (RC) If methods are not specified, does the laboratory, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals, or which have been appropriately evaluated for a specific or unique application? N/A

Validation: What is it and why should it be done

- Is part of the overall QA program with in a laboratory
- Want the correct answer when collecting Data
  - We want analytical measurements made in one location to be consistent with those made elsewhere (guarantees the success of a national DNA database).
- Want no false negatives
  - If a sample does not give a result need to be confident that this is due to no DNA and not an issue with the chemistry or detection method.

Why is it necessary to validate a method

- Important Part of Quality Control
- Helps to provide assurance that the answer obtained is correct
- Provides data which are used as the basis for comparisons between laboratory's
- Allows for the accumulation of data to identify which parts of the method are stable and what parts can cause problems.
- Allows for the generations of suitable QC procedures
- Validation of Methods is good science

Roper, P., *et al.* (2001) *Applications of Reference Materials in Analytical Chemistry*. Royal Society of Chemistry, Cambridge, UK, pp. 107-108.

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Definitions

- **Validation** is confirmation by examination and provision of objective evidence that the particular requirements for a specified intended use are fulfilled.
- **Method validation** is the process of establishing the performance characteristics and limitations of a method and the identification of the influences which may change these characteristics and to what extent. It is also the process of verifying that a method is fit for purpose, i.e., for use for solving a particular analytical problem.

EURACHEM Guide (1998) *The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics*; available at http://www.eurachem.ul.pt/guides/valid.pdf

- **ISO17025**
  - 5.4.5.1 Validation is the **confirmation by examination** and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
- **SWGDAM**
  - 1.1 Validation is the process by which the scientific community acquires the necessary information to
    - (a) Assess the ability of a procedure to obtain reliable results.
    - (b) Determine the conditions under which such results can be obtained.
    - (c) Define the limitations of the procedure.
    - The validation process identifies aspects of a procedure that are critical and must be carefully controlled and monitored.

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Validation Definition

- ***Validation***
  - Process used to show that procedures or kits are robust, reliable and reproducible by different analysts with in the laboratory.
    - Robust method: One that generates successful results a high percentage of time.
    - Reliable method: One where the sample results are accurate for the sample being tested.
    - Reproducible method: One that generates the same quality results when the same sample is used by different people at different times.

J.M. Butler (2005) *Forensic DNA Typing*, 2nd Edition, p. 389, 391

General levels of Validation

- **Developmental Validation** – commonly performed by commercial manufacturer of a novel method or technology (more extensive than internal validation)
- **Internal Validation** – performed by individual lab when new method is introduced
- **Performance Checks** – can be performed with every run (set of samples)

When is Validation Needed

- Before introduction of a new method into routine use
- Whenever the conditions change for which a method has been validated, e.g., instrument with different characteristics
- Whenever the method is changed, and the change is outside the original scope of the method

L. Huber (2001) Validation of Analytical Methods: Review and Strategy. Supplied by www.labcompliance.com

VAM Principles

VAM = Valid Analytical Measurement

- Analytical measurements should be made to satisfy an agreed requirement.
  - SWGDAM
  - Developmental validation
- Analytical measurements should be made using methods and equipment that have been tested to ensure they are fit for their purpose.
  - Developmental validation
- **Staff making analytical measurements should be both qualified and competent to undertake the task**.

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VAM Principles

VAM = Valid Analytical Measurement

- There should be a regular and independent assessment of the technical performance of a laboratory.
  - SRM
  - Proficiency tests
- Analytical measurements made in one location should be consistent with those made elsewhere.
  - Performance Check
- Organizations making analytical measurements should have well defined quality control and quality assurance procedures.
  - SWGDAM January 2010 talks about SOPs

General Steps for Internal Validation

- Review literature and learn the technique
- Obtain equipment/reagents, if necessary
- Determine necessary validation studies
- Collect/obtain samples, if necessary
- Perform validation studies maintaining all documentation
- Summarize the studies and submit for approval to Technical Leader
- Write-up the analytical procedure(s). Include quality assurance (controls, standards, critical reagents and equipment) and data
- interpretation, as applicable
- Determine required training and design training module(s)
- Design qualifying or competency test

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Urban Legends of Validation…

- 1: HUNDREDS OR THOUSANDS OF SAMPLES ARE REQUIRED TO FULLY VALIDATE AN INSTRUMENT OR METHOD
- 2: VALIDATION IS UNIFORMLY PERFORMED THROUGHOUT THE COMMUNITY
- 3: EACH COMPONENT OF A DNA TEST OR PROCESS MUST BE VALIDATED SEPARATELY
- 4: VALIDATION SHOULD SEEK TO UNDERSTAND EVERYTHING THAT COULD POTENTIALLY GO WRONG WITH AN INSTRUMENT OR TECHNIQUE
- 5: LEARNING THE TECHNIQUE AND TRAINING OTHER ANALYSTS ARE PART OF VALIDATION
- 6: VALIDATION IS BORING AND SHOULD BE PERFORMED BY SUMMER INTERNS SINCE IT IS BENEATH THE DIGNITY OF A QUALIFIED ANALYST
- 7: DOCUMENTING VALIDATION IS DIFFICULT AND SHOULD BE EXTENSIVE
- 8: ONCE A VALIDATION STUDY IS COMPLETED YOU NEVER HAVE TO REVISIT IT

Assumptions When Performing Validation

- The equipment on which the work is being done is broadly suited to the application. It is clean, well maintained and within calibration.
- The staff carrying out the validation are competent in the type of work involved.
- There are no unusual fluctuations in laboratory conditions and there is no work being carried out in the immediate vicinity that is likely to cause interferences.
- The samples being used in the validation study are known to be sufficiently stable.

Roper, P., *et al.* (2001) *Applications of Reference Materials in Analytical Chemistry*. Royal Society of Chemistry, Cambridge, UK, pp. 110-111.

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SWGDAM Guidelines

FORENSIC SCIENCE COMMUNICATIONS

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Standards and Guidelines

Revised Validation Guidelines

Scientific Working Group on DNA Analysis Methods (SWGDAM)

Introduction | Validation Considerations | Developmental Validation | Internal Validation | Material Modification | Performance Check | Definitions

Introduction

The validation section of the Guidelines for a Quality Assurance Program for DNA Analysis by the Technical Working Group on DNA Analysis Methods (*Crime Laboratory Digest* 1995:22(2):21-43) has been revised due to increased laboratory experience, the advent of new technologies, and the issuance of the Quality Assurance Standards for Forensic DNA Testing Laboratories by the Director of the FBI (*Forensic Science Communications* available: www.fbi.gov/hq/lab/fsc/backissu/july2000/codis2a.htm).

This document provides validation guidelines and definitions approved by SWGDAM July 10, 2003.

Overview of Internal Validation Studies

- Internal Validation: The internal validation process should include the studies detailed below encompassing **a total of at least 50 samples**. Some studies may not be necessary due to the method itself.
  - 3.1 Known and non-probative evidence samples
  - 3.2 Reproducibility and precision
  - 3.3 Match criteria
  - 3.4 Sensitivity and stochastic studies
  - 3.5 Mixture studies
  - 3.6 Contamination
  - 3.7 Qualifying test
  - Minimum Threshold

SWGDAM Revised Validation Guidelines http://www.fbi.gov/hq/lab/fsc/backissu/july2004/standards/2004_03_standards02.htm

Internal Validation suggestions

- Minimum Threshold Study
  - No defined standard
  - Analyze all negative controls (10-15 negatives)
  - Used to determine the baseline of the instrument
- Contamination
  - Standard 3.6
  - Amplify negative controls (samples containing water instead of DNA) with each batch of amplifications.
  - These will be the same samples used in Minimum Threshold study

Internal Validation suggestions

- Precision Study (20 or 64)
  - Standard 3.2 and 3.3
  - 250 bp precision
    - Temperature variation
  - Allelic ladder precision
    - 4 cap instrument 20 ladders; 16 cap 64 ladders
- Sensitivity Study (30)
  - Standard 3.4
  - Run 2X dilution series in triplicate (5ng – 0.31ng)
  - Use highly heterozygous sample

Internal Validation suggestions

- Mixture Study (12)
  - Standard 3.5
  - 20:1, 10:1, 7:1, 5:1, 3:1, 2:1….1:20
  - May want to use samples that differ at majority of loci
    - Help with peak height ratio etc
- Concordance A NIST samples (10)
  - Standard 3.3 and 3.7
  - Demonstrate match criteria and qualifies the chemistry and instrument using a traceable standard.

Internal Validation suggestions

- Concordance B Non-Probative (30)
  - Standard 3.1
  - 30 Previously type samples
  - Variety of sample types and extractions
- Reproducibility
  - Standard 3.2
    - Use precision study
    - Sensitivity study positive controls
    - Concordance A

Some SWGDAM suggestions for interpretation of validation material

- Sensitivity of instrument and kit
  - Low copy number
- Analysis threshold vs calling threshold
  - Sensitivity study – stochastic affects etc
- Peak height ratio
  - use sensitivity, mixture and non-probative data
- Stutter
- Reporting criteria

What needs to be done after the Internal Validation has been submitted for review

- **9.1.1** The laboratory shall have an ***standard protocol*** for each analytical technique used.
- **9.1.2** The procedures shall include ***reagents, sample preparation, extraction, equipment and controls***, which are standard for DNA analysis and data interpretation.
- Determine required training and design training module(s)
- Design qualifying or competency test.
- Use the Developed SOP's during the training and competency tests.
  - Allows fine tuning of the SOP's before Implementation.

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What else needs to be done after the Internal Validation has been completed

- **9.2.3** The laboratory shall identify ***critical reagents*** (if any) and evaluate them prior to use in casework……
- **9.4** The laboratory shall monitor the analytical procedures using appropriate ***controls and standards***.
- **10.2** The laboratory shall identify ***critical equipment*** and shall have a documented program for calibration of instruments and equipment.
- **10.3** The laboratory shall have a ***documented program*** to ensure that instruments and equipment are properly maintained.

Elements that Guarantee Quality Forensic DNA testing

- Accepted Standards and Guidelines for Operation
- Laboratory Accreditation
- Proficiency Testing of Analysts
- Standard Operating Procedures
- **Validated Methods**
- Calibrated Instrumentation
- Documented Results
- Laboratory Audits

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Questions?

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Accreditation in Forensics

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Why Accreditation in Forensics?

- Forensic Testing Under Attack
  - Attacks on the reliability of forensic testing
  - Can not attack the science, so go after the laboratory.
  - The forensic community knows that overall a good job is being done by good people
  - But self belief, no matter how well justified, is not going to win the day on its own

Useful Documents

--- International Standard : ISO/IEC 17025
www.http:\webstore.ansi.org (212-642-4900)

---- ILAC G19 : Guidance for Forensic Science Laboratories http://www.ilac.org/guidanceseries.html

---- FBI DNA Quality Assurance Standard

Perception

- No test is infallible, and there are bound to be failures in forensic evidence testing just like there are in tests outside forensics
- Critics will hunt down any actual or perceived errors in cases and use them to support their stance on lack of reliability
- They may also suggest that examiners may be biased

Reality

- Forensic testing meets the criteria of "Objective Test"

A test that has been internally validated and is "Monitored" such that trained examiners using methods that incorporate the right controls will obtain reproducible and accurate results free from bias

- The challenge is to add objective verification that standards are met
- "ISO 17025" accreditation can do that

ACCREDITATION

Process of formal recognition for Competence to perform specific tests Conducted by an independent third party using a defined set of standards

Why Accreditation can help

- Accreditation is an external validation of methods and standards of performance of testing
- It is a tool that is widely used wherever users need assurance about the acceptability of test results

Conformity Assessment

- The process of deciding whether or not a product, service, process, system, person or body conforms to a standard and/or complies with relevant requirements in technical regulations or standards.
  - Sampling, testing, and inspection

Standards

- Documented agreements
- Contain technical specifications or other precise criteria
- Used consistently as rules, guidelines, or definitions of characteristics
- Ensure that materials, products, processes and services are fit for their purpose

Standards

Standards are established by:

- International Bodies
- Regional Bodies
- National Bodies
- State Bodies
- Local Bodies

. . . . to meet a perceived need for minimum levels of performance, quality, safety, etc.

Standards

Standards are adopted to meet needs driven by:

1. Government requirements
2. Expectations of customers
3. Business culture

Adoption of standards is sometimes voluntary, sometimes mandatory

ISO 17025 in More Detail

ISO 17025 is a conformance standard

Conformance → Accreditation

What is ISO-17025

- It's not rocket science--it's just another set of standards
  - Developed by CASCO
  - Council Committee on Conformity Assessment
  - Describe best practices for testing and calibration laboratories
  - Written broadly for general application
  - A conformance standard

ISO 17025 – Development

- **Quality management standard = ISO 9001**
  - Registration
  - Quality management & customer relations
- **Early 1980's—ISO Guide 25**
  - Technical requirements for testing & calibration labs
- **ISO/IEC 17025:1999:** Management elements of ISO 9001 and 9002:1994 and technical requirements of Guide 25
- **Revision in 2005 =** ISO/IEC 17025:2005; aligned with ISO 9001:2000

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ISO 17025

- Philosophy = Preventive, with an emphasis on systems (Total Quality Management)
- **Syste** **Proactive not reactive**
  - Plan: Customer needs; quality standards
  - Do: Good laboratory practices & procedures
  - Check: QC, audits, customer feedback
  - Act: Quality Management
- Flexible
  - Various ways to be compliant with the same standard
  - Laboratory can determine its proposes scope of accreditation

ISO 17025 and DNA QAS Correlations

For Example:

- Most of the DNA QAS can be correlated to an ISO 17025 standard
  - This does not mean that all ISO standards have a correlation with the QAS
- DNA QAS add detail to some of the more general requirements of ISO 17025 Section 5
- ISO 17025 has more specificity in management requirements (Section 4)

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ISO 17025

- Section 1: Scope (explanatory material)
- Section 2: References
- Section 3: Terms & definitions (see ISO 17000)
- Section 4: Management Requirements
  - Requirements contained in 15 clauses numbered 4.1 through 4.15
  - Apply to laboratory mgmt. system, not just technical sections
- Section 5: Technical Requirements
- Appendices and Bibliography

ISO 17025 Terminology

- Shall = must do
- Should = we would expect to see this in a best practice facility
  - Notes = guidance material, not requirements
- "defined", "arrangements", "formulate", "specify", "policy", "procedure" = need something in writing

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ISO 17025 Terminology

- Ensure = "at the end of the day" the objective evidence indicates the goal has been achieved
- "where practicable", "whenever reasonable", "where necessary" = some leeway allowed, but be prepared to explain why not being done
- "appropriate", "sufficient", "as specified", etc. = non-prescriptive terms that will find definition in a laboratory's quality system documents

Very Important Definitions!

- Policy = statement of the overall direction of the organization with regard to the subject activity
- Procedure = document that specifies a way to perform an activity and which must usually contain the purpose and scope of the activity, e.g., what shall be done and by whom, when, where and how it shall be done. A procedure must also address what materials, equipment and documents shall be used and how it shall be controlled and recorded.

Don't confuse the two!

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Major Sources of Non-conformity

- Confusing "policy" and "procedure" results in the following non-conformities:
- Lack of required procedures
  - Especially in Section 4
  - Calling policy statements "procedures"
- Incomplete procedures
  - Failure to address all components required by ISO 17025 and the definition of "procedure"

Other terminology bandied about . . .

- Document (noun) = anything that tells your employees how to do their work (policies, procedures, required forms, plans, programs, manuals, instrument operating manuals, etc., etc.)
- Document (verb) = create a record ("if it isn't documented, it didn't happen")
- Record = Evidence of compliance with your quality system (AKA "documentation")

For Those from DNA Labs . . .

- Most of the DNA QAS can be correlated to an ISO 17025 standard
  - This does not mean that all ISO standards have a correlation with the QAS
- DNA QAS add detail to some of the more general requirements of ISO 17025
- Most correlations are with Section 5 technical requirements

Gaps between ISO 17025 and DNA QAS

Major Gaps Between ISO 17025 and the DNA QAS

Some aspects of:

- Organization – ISO 4.1
- Document control – ISO 4.3
- Review of requests – ISO 4.4
- Purchasing – ISO 4.6
- Service to the customer – ISO 4.7
- Complaints – ISO 4.8
- Control of non-conforming testing – ISO 4.9
- Improvement – ISO 4.10
- Corrective action – ISO 4.11
- Preventive action – ISO 4.12
- Internal audit – ISO 4.14
- Management review – ISO 4.15
- Safety – DNA Standard 16

Major Gaps Between ISO 17025 and the DNA QAS

Section 4: Management Requirements

Requirements contained in 15 clauses numbered 4.1 through 4.15 in the International Standard

4.3 Document Control

- One of the major "hot spots" in ISO 17025
  - No equivalent in other standards such as the DNA QAS
- Establish and maintain procedures to control all documents that form part of the quality system, such as regulations, standards, methods, drawings, software
  - ***Not just for internally generated procedures
  - ***Not just for technical procedures
- "inception to retirement"
  - How documents are created, distributed, used, controlled, and destroyed
  - Lack of *procedures*-or incomplete procedures-is a common nonconformity

4.3 Document Control (2)

- Policy and procedures for approval and issue
  - All documents reviewed and approved by authorized personnel prior to release
  - Master list or equivalent **(definitely needed)**
- Procedures to ensure documents are:
  - Available where needed
  - Periodically reviewed
  - Removed if invalid or obsolete
  - Retained for knowledge preservation

4.13 Control of Records

- Procedures for
  - Identification
  - Collection
  - Indexing
  - Access
  - Filing
  - Storage
  - Maintenance
  - Disposal
- Technical AND Quality Records
  - Audit reports, CA, PA, instrument QC, ...
- Shouldn't be much that is "new" to agencies working under other requirements

ISO 17025 TECHNICAL REQUIREMENTS

Requirements contained in 10 clauses numbered 5.1 through 5.10 in the International Standard

Break

Technical requirements

- 5.1 General discussion
- 5.2 Personnel
- 5.3 Accommodation and Environmental Control
- 5.4 Methods and Method Validation
- 5.5 Equipment
- 5.6 Measurement Traceability
- 5.7 Sampling
- 5.8 Handling of Samples
- 5.9 Assuring Quality
- 5.10 Reporting Results

5.4 Methods and Method Validation

- Policy on using appropriate methods and procedures
- Instructions for use and operation of equipment
- Instructions for handling of samples
- Above instructions current and readily accessible
- Policy on deviations

Break

Methods (2)

- Policy on selection of methods
  - Methods appropriate and meet needs of the client
  - Standard methods
  - Published methods
  - Non-standard methods as agreed with client

Break

5.6 Measurement Traceability

- Clause 5.6
  - Programs and procedures for equipment calibrations
  - "Define the relationship between the values of quantities indicated by an instrument and the corresponding values realized by standards"
  - Examples: balances/scales, calipers, pipettes, rulers/tapes, thermometers
- Calibration: the process of comparison
  - Relationship of measurement readings of instrument and units of defined system of measurement
  - Performed under controlled and specified conditions

Break

Calibration is NOT . . .

Preventive maintenance

Corrective maintenance

Break

Calibration Standard

- The calibration standard must be traceable by an unbroken chain of calibrations or comparisons to relevant primary standards, such as national measurement standards
- SI units
- Use of accredited calibration laboratories

Break

Relevant SI units

- Only length, mass, and temperature are relevant in forensic science
  - There is no traceable standard for amount of substance
  - Volume is not one of the basic SI units

5.4. Validation of Methods

- Use appropriate methods and procedures
- Instructions on use and operation of equipment
- Use tests which meet the needs of the customer

5.4.5 Validation of Methods

- Applies to:
  - Non-standard methods
  - Laboratory developed methods
  - Standard methods used outside of their intended scope
  - Amplifications or modifications to standard methods
- Shall be as extensive as is necessary to meet the needs in the given application

5.4.5 Validation of Methods (2)

- Suggested validation techniques:
  - Calibration using reference standards or materials
  - Comparison with other methods
  - Interlaboratory comparisons
  - Systematic assessment of factors
  - Assessment of the uncertainty of the results
- Range and accuracy relevant to the needs of the client

5.4.6 Uncertainty of Measurement

- "A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measured"
  - For example, standard deviation
- Current application in forensic testing is to quantitative methods
  - Evaluation of uncertainty should be stated in lab's P & P manual

5.4.6 Uncertainty of Measurement

- The laboratory must have and apply a procedure to estimate the uncertainty of measurement for:
  - Calibrations
    - Calibration laboratory
    - In-house
  - Quantitative Testing
- See your AB's policy/guidance document

5.9 Assuring Quality

- QA procedures to monitor the validity of test results
- Trend detection--may include
  - Regular use of reference materials
  - Participation in PT
  - Replicate testing
  - Re-testing
  - Correlation of results
- Standard says "may" for PT but DNA QAS and ABs require a PT program in place

FQS-I Accreditation Programs

- FRA-1: Accreditation to forensic science agencies who conduct forensic testing
- FBI DNA QAS Audit Document : Forensic DNA and Convicted Offender DNA Data basing Laboratories
- FRA-3: Animal racing laboratories involved in drug testing
- FRA-4: Agencies that perform latent print testing
- FRA-5: Agencies that conduct Crime Scene Investigation

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Narrowing the ISO 17025 Focus: Field Specific Criteria or Guidelines

- aka Amplification “Detailed” Documents
- Provide interpretation for the field of testing and the techniques involved

Amplification Documents for Forensic Testing

- International
- National
  - FBI DNA Quality Assurance Standards
- Accrediting Bodies
  - Adoption of International/National standards as a whole or in part
  - AB-specific requirements, guidance, or policies

ILAC G19:2002

- Guidelines for Forensic Science Laboratories

Guide 19

- Available free of charge from ilac.org

ILAC G19

- Developed by an ILAC working group
  - International participation—US, Canada, UK, Australia, other countries
- Guidance, but "may also be used by accreditation bodies to provide appropriate criteria for the assessment and accreditation of laboratories providing forensic services."
  - Adopted by SCC, FQS-I in whole
  - Portions adopted by ASCLD/LAB

ILAC G19—Structure and Content

- 1. Scope
  - Defines “forensic science”
  - Large list of types of activities
- 2. References
- 3. Terms and Definitions
  - “Objective Test”
- 4. Management Requirements amplification
- 5. Technical Requirements amplification

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ILAC G19 - Section 4

- Amplification for 4.13 Control of Records
  - Specific details about case records
  - Record reasons for rejecting test results
  - Checking non-electronic calculations and data transfers
  - Records traceable to case and examiner
  - Pagination
  - P & P for review of case record/report

ILAC G19 - Section 5

- ILAC G19 Guidance for 5.2
  - Emphasis on Competency
  - Training and continuing education to provide, maintain and develop Knowledge, Skills and Abilities
  - Acceptance criteria defined
  - Statement of required competencies
  - Records

ILAC G19 Guidance for 5.3

- Physical separation of low (trace) and high-level work
- Access control
- Evidence storage
  - Security
  - Prevention of loss, deterioration and contamination

ILAC G19 Guidance on 5.5

- Maintenance and calibration program
- Required where settings can significantly affect the test or analytical results
- Performance checks
  - Determined by need, type and performance history of equipment

ILAC G19 Guidance on Traceability (5.6)

- Individual calibration programs
  - In general, intervals not less stringent than manufacturer's recommendation
- "Standard" solutions prepared in laboratory or purchased
- Reference collections must be documented, identified, and controlled
  - For example, gun collections

ILAC G19 - Coming soon

- New ILAC working group forming to work on updated guidance document for forensics
- "The IAF and ILAC Joint General Assembly, acting on the recommendation of the JCCC, endorses a new work item to be undertaken by the Joint Inspection Group (JIG) to draft a single top level document that approaches the forensic process as a whole and provides common guidance for both ISO/IEC 17020 and ISO/IEC 17025 in areas where the activities overlap. The guidance will be based on the guidance document to ISO/IEC 17020 for Crime Scene Investigation, already prepared by EA and ENFSI, and on ILAC G19 for forensic laboratories."

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How can an agency prepare for ISO 17025 accreditation?

Reality Check

The ISO 17025 Standards are not difficult, BUT . . .

- There are "gaps" with the QAS and other non-ISO 17025 accreditation standards
- Areas of correlation are not always an exact match
- It will take time to evaluate and fill the "gaps"
- Management system is a LAB issue, not just an issue for the technical sections

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Getting from here (non-ISO 17025) to there (ISO 17025)

- No different than preparing for any other accreditation
- Critical to have the support of laboratory's senior management
  - Time and money for preparation
  - Management priorities = staff priorities
- Ensure that your operation meets the applicable standards

Quality Manager

- The facility is required to appoint a member of staff as quality manager
- Helpful to do this early in the process because
- Someone has to be responsible for quality or it won't happen
- The language allows considerable flexibility in how this is done ("however named")

THREE KEY STEPS IN PREPARING FOR ISO 17025 ACCREDITATION

- **Know the Standards**
  - Know their interpretation
- **Identify the Gaps**
  -Internal audit
- **Bridge the Gaps**
  -Corrective action program
  -Aim for Best Practice – not for Get By

1. Learn about quality systems

- Obtain copies of standards
- Get ideas for applying/understanding the standards
  - Colleagues in "ISO Labs"
  - Training
  - NFSTC Quality Documents program
  - Guidebooks, e.g., **"Introduction to Accreditation for Forensic Labs" by Murray Malcolm and Harold Peel**
  - **Remember that there are different ways to meet the standards—do what works for your laboratory**

2. IDENTIFY THE GAPS

- Internal or External audit
- If Internal Audit
  - Step 1: Obtain training for internal auditing to ISO 17025
    - Just QM or additional staff?
    - More staff trained = more "buy-in"
  - Step 2: Do a self-assessment against ISO 17025/Supplemental requirements

As well as letting you see where you are, this qualifies as an internal audit and so will provide proof of conformance to a major requirement

Data collection for GAP Analysis

- Methods to gather evidence of conformance
  - Verify the existence of documents and records
  - Examine and evaluate documents and records
  - Interviews
  - Examine physical environment
  - Observe testing
- Use checklists to record findings
  - Describe how laboratory meets the standards rated “yes”
  - Explain why something rated “N/A”
  - Explain why something rated “no”

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Developing a Conformance File

- Use findings from Internal Audit as initial basis
- Complete as non-conformities are corrected
- Electronic format with hyperlinks very effective

3. BRIDGE THE GAPS

- Specific description of nonconformities identified in GAP analysis
- Create a project plan for remediation and follow up audit
  - Concentrate on the ISO "hot spots" if time is short
  - What, who
  - Training required?
  - Time lines
  - Estimated costs
  - Quality system documents
    - Define management system in a Quality Manual
    - Write policies and procedures

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One Likely "GAP": Documenting Your Management System

- What policies and procedures do ISO 17025 and the supplements require?
  - What do you already have that's conformant?
  - What do you have that needs revision?
  - What do you need to create from scratch?
- Establish your document control system

Hints for Management System Document Structure

- Caveat: Not “one size fits all”
  - Different agencies have different needs
- ISO 10013 can be used as a guide to structure of documents
  - Hierarchy of Documents
  - Formatting
  - Document and record control

Quality Manual

- The testing facility is required to have a quality manual
- The “Big Picture” of the Management system
- The manual must “document (the Unit’s) policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the test results”
- The manual can be a single document or can be made up of cross references to parts of existing departmental or Unit policies and procedures

Quality Manual

- Remember the Quality Manual is a living document
- Organize the manual in a helpful way
- Involve operation staff in writing and reviewing
  - Promotes understanding and “buy-in”
- Be wary of too much outside involvement in the preparation of the Quality Manual

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Quality Manual

- It is best to begin by capturing what actually happens in the organization, then making sure that it is followed
  - “If you do it, write it”
  - “If you write it, do it”
  - “Is it effective”

Procedures

- Detailed work process description
  - administrative and technical processes
- Purpose of Procedures:
  - Ensure consistency of operation
  - Provide a basis for employee training
  - Describe management system
  - Provide basis for audit process

More on Procedures

- Must cover all topics required by ISO 17025
- Make each as “stand-alone” as possible
- Specific to the agency
- Use a consistent format
  - Title, scope, authorizations, rev. numbers
  - Section headings

Other Documents

- Work instructions
  - Very detailed
  - No specified format
- Forms
  - If contain instructions, must be part of document control system

Writing the Documents

- Don't use non-prescriptive terms in procedures, e.g., "appropriate", "adequate"
  - Could result in non-conformities
- Don't use future tense "the laboratory will . . ."
- One option: Make gradual changes
  - For example, as current documents need revision, incorporate ISO 17025 elements
- Common non-conformity—procedures that don't address all elements required by the Standard

Additional Steps

- Communication with, and involvement of, staff
  - Training on quality policies, standards, accreditation process, changes to policies/procedures
- Follow-up audits
  - To measure progress of implementation

These are ongoing activities, even after accreditation has been obtained

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You Can Do It!

- ISO is not complicated
  - Extension of quality systems already in place in laboratories
- Based on three points
  - Good management system
  - Competency of personnel
  - Objective proof of quality of testing
- ISO is flexible
  - Scopes
  - Field specific criteria

The Bottom Line: Creating an ISO 17025 Conforming Management System

- Say what you do
  - Capture current processes in writing
  - Create new processes
- Do what you say
- Check to be sure your processes are effective

Accreditation Process

Accreditation Process

- Application to Accreditation Body
  - Requested scope of accreditation
    - One discipline, all disciplines?
- Dates set for on-site assessment
  - Lead assessor selected
    - Trained and experienced in ISO assessments in forensic science
    - Authoritative on ISO accreditations
  - Technical assessors and technical experts selected
    - Technical assessors have knowledge of technical practices and procedures in their area of expertise

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Accreditation Process (2)

- Assessment process, costs, etc. agreed upon with accreditation body
- Assessment team goal is to determine whether:
  - The laboratory's policies and procedures conform to requirements
  - The laboratory does what its procedures say it does
  - The laboratory can provide objective evidence that it is technically competent

Accreditation Process (3)

- Laboratory is provided a report that lists areas of nonconformity
- Nonconformities are remediated
- Accreditation body makes a decision on accreditation
  - Accreditation is for a period of time set by AB policy
  - Accreditation is for a specific “scope” of activities
  - Surveillance activities (to assure continuing conformance to standards) per AB policy
- On-site assessment to renew accreditation

The top ten deficiencies

Number 10

- **Measurement Traceability.**

- What?
- It is the ISO 17025 equivalent of chain of custody. Its intent is to be sure that equipment such as balances and thermometers, the performance of which is critical to producing valid test results, is set correctly

- Why?
- A lack of understanding of what is meant by traceability and how to implement it For example in calibration of pipettes and balances

Number 9

- **Purchasing Services and Supplies.**

- What?

- Procedures to make sure that you know and define the specifications for purchase of goods and services that can affect the quality of your test results

- Why?

- The standard is often overlooked as “just another pointless bureaucratic requirement”

-

Number 8

- **Management Review**

- What?
- An annual stocktake of all relevant factors that could affect the operation of the laboratory, conducted to be sure that management is proactive and comprehensive in implementation of the laboratory quality system

- Why?
- Lack of understanding of the requirements - for example often confused with the annual audit

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Number 7

- **Internal Audits.**

- What?
- An annual survey of the whole management system for conformity with its requirements - confirmation of “If you write it, do it”

- Why?
- Lack of awareness that the audit covers **everything**, not just technical elements. DNA labs sometimes think the QAS audit meets this - it does not.

Number 6

- **Personnel.**

- What?
- An extensive list of requirements to ensure that personnel are competent in regard to the testing and interpretations that they conduct.

- Why?
- Requirements are extensive and include some things that are not familiar - such as a requirements to authorize analysts to perform specific tests. Inadequate records and lack of training plans.

Number 5

- **Equipment.**

- What?
- An extensive list of factors needed to make sure all equipment that is in use is working properly

- Why?
- Details missed, for example out of service equipment to be marked as such or removed from the laboratory

Number 4

- **Control of Records.**

- What?
- Procedures to ensure the integrity of records

- Why?
- Procedures did not cover all the specified requirements, or were not followed. Corrections to data were not made properly, with numerous instances of obliterations and/or lack of identification of the person who made the correction(s).

Number 3

- **Organization and Management.**

- What?
- An extensive list of requirements for the way that the laboratory is organized and managed.

- Why?
- Lack of required policies/procedures, policies/procedures not followed, and failure to adequately document the responsibilities and position of the Quality Manager and/or designate a deputy for that key managerial position.

Number 2

- **Document Control.**

- What?
- A process to ensure that all instructions throughout the laboratory are up to date, correct, available and followed.

- Why?
- Failure to control all management system documents, most notably some forms or external manuals or standards; master lists of documents that were incomplete; lack of objective evidence for review of documents; and revision identifiers that were either obsolete or completely lacking.

Number 1

- **Method validation.**

- What?
- Requirements to make sure that methods used are all validated

- Why?
- A major problem for agencies seeking initial accreditation, in that they lacked procedures or had incomplete procedures, or simply were not in conformance with the procedures that they had. Lack of validation records for some tests that were being conducted, or when required aspects of validation were not addressed.

Scared?

- Do not be…..
- Is there help out there?
- Yes
- Who is that?

Forensic Quality Services, Inc. is:

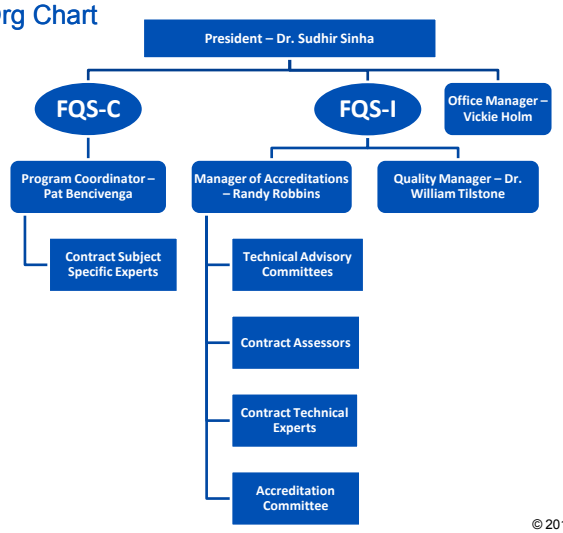
FQS-C

- Provides a range of organizational assistance and training/education services to support forensic science delivery

FQS-I

- The country's longest established provider of ISO 17025 accreditation to forensic testing agencies in the U.S. (First ISO lab 2001)

FQS, Inc. Org Chart



FQS-I Accreditation Programs

- FRA-1: Accreditation to forensic science agencies who conduct forensic testing
- FBI DNA QAS Audit Document : Forensic DNA and Convicted Offender DNA Data basing Laboratories
- FRA-3: Animal racing laboratories involved in drug testing
- FRA-4: Agencies that perform latent print testing
- FRA-5: Agencies that conduct Crime Scene Investigation

FQS-I Accreditation Program

- All ISO 17025 accreditations
  - ILAC G19 accredited – International Audits
- 52 Accredited Laboratories
  - Active applications in process from laboratories new to ISO 17025 accreditation

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Questions?

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