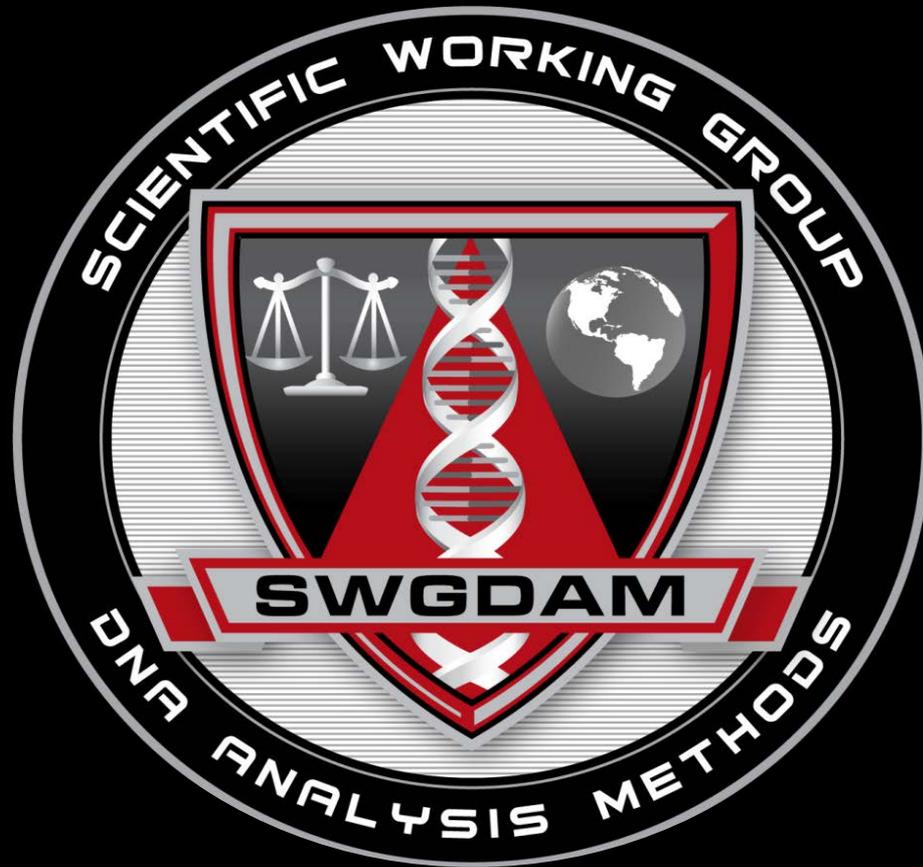


The Next QAS: 2017 Status Update



Jocelyn Carlson
Chair, SWGDAM QA Committee
November 14, 2017



Disclaimer

Contained in this Presentation are

DRAFT PROPOSED

revisions to the Quality Assurance Standards
for Forensic DNA Testing Laboratories.

Until a final document is authorized and issued
by the Director of the FBI the current QAS
Standards, issued September 1, 2011, are to be
adhered to.



SWGDM QA Committee Members & Invited Guests

- Jocelyn Carlson (IG) – Chair
- Beth Ann Marne – Co-Chair
- Clark Jaw (IG)
- Janice Joslin (IG)
- Kristy Kadash (IG)
- Eugene Lien
- Amy McGuckian
- Peg Schwartz (IG)
- Dawn Herkenham – SWGDAM Executive Secretary

Emeritus Committee Participants

- Ken Konzak (IG)
- Elizabeth Morris (IG)



Public Comment Period

- August 16 - October 13, 2017
- SWGDAM QA Committee is working on the “Audit Guide” and making adjustments to the Standards based on public comments.
 - Over 135 comments received
 - At least 1 comment on 15 of the 17 Standards
- That draft is available to view online at swgdam.org

Updates

New!! SWGDM is currently reviewing the public comments submitted about its proposed changes to the FBI National DNA Quality Assurance Standards for Forensic DNA Laboratories. Until a draft is approved by SWGDAM, please use the following link to reference the QAS draft that was subjected to public comment.



The Hot Topics...



Standard 3.3.1

Annual Case File Review

STANDARD 3.3 The quality system as applicable to DNA shall be reviewed annually independent of the audit required by Standard 15....

- 3.3.1 – The laboratory shall annually review case files determined by the laboratory to be a representative sample of the cases worked for that year.

Comments received:

- A valuable addition but...
- What is a representative sample?
- The TL performs technical reviews... does that meet this standard?
- Unnecessary burden on the lab
- Busy work... without much benefit

Why was this added??



Standard 3.3.1

Annual Case File Review

So... Why was it added??

- External Proficiency Tests can only do so much
 - What else can be done?
- Experience from SWGDAM attendees
 - Good Quality measure
 - Can catch issues that PTs can't
 - Some labs already do Case File Audits for Accreditation
- Can look for specific elements across a range of cases vs a range of elements on a specific case (Std 12)
- Identify inconsistencies or procedural drift



Annual Case File Review

Audit Guide Content

- The scope of the review must ... address both the time period and the representative sample.
- The technical leader will determine the representative sample ... may vary from year to year. Sampling may be based on...
 - corrective actions, perceived analytical gaps, and/or at random.
 - a percentage or a specified number of cases.
 - the forensic samples tested, technology, conclusions reported, complexity of the typing results, or cases where testimony has occurred and transcripts were available for review.

As examples, a representative sample may be a percentage of all sexual assault cases, a percentage of all Y-STR cases, a specific number of random cases from each analyst, or a specific number of complex mixture cases.
- This annual review may not be replaced by technical reviews as a part of Standard 12.
- The annual QAS audit required by Standard 15 cannot be used to replace the annual review of casefiles; however, the annual case file review may be conducted concurrently with an internal QAS audit.



Standard 3.4

Annual Case File Review

- Decided to “Un-parent” and Reword to...

STANDARD 3.4 The laboratory shall annually review case files determined by the technical leader to be a representative sample of the cases worked and shall be independent of an external audit conducted under Standard 15. The scope of the review shall be defined prior to each annual review and shall be approved by the technical leader.



Standard 13.1

Proficiency Testing

Why did we keep it semiannual??

- Originally required by the Federal DNA Identification Act [42 U.S.C. §14132(b)(2)]* which was enacted in 1994 and stated --
 - "prepared by laboratories, and DNA analysts, that undergo, at regular intervals of not to exceed 180 days, external proficiency testing by a DNA proficiency testing program meeting the standards issued under section 14131 of this title; "
- Amended in 2000 [Public Law 106-546] to replace "at regular intervals of not to exceed 180 days" with "semiannual"
- Replaced in 2004 [Public Law 108-405] with the following provisions:
 - "(A) not later than 2 years after October 30, 2004, have been accredited by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community; and
 - "(B) undergo external audits, not less than once every 2 years, that demonstrate compliance with standards established by the Director of the Federal Bureau of Investigation; and".

*42 U.S.C. §14132 reclassified as 34 U.S.C. §12592



Standard 13.1

Proficiency Testing

Current QAS:

- 13.1 ... shall undergo semi-annual external proficiency testing in each technology performed to the full extent in which they participate in casework.
- 13.1.1 Individuals routinely utilizing both manual and automated methods shall be proficiency tested in each at least once per year to the full extent in which they participate in casework.
- 13.1.5 Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology performed.

DRAFT QAS:

- 13.1 ... shall undergo semi-annual external proficiency testing.
- 13.1.1 ...



Standard 13.1.#

Proficiency Testing

... specific requirements shall be proficiency tested at least once per year:

- 1. Analysts ... in each technology...
 - all CODIS core loci or CODIS core sequence ranges shall be attempted ...
- 2. Analysts ... in each typing test kit...
 - Analysts qualified to perform modified Rapid DNA analysis ...
- 3. Individuals that perform analytical procedures ... shall perform at least one method in each methodology...
- 4. Except as in Standard 13.1.4.1, each external proficiency test shall be assigned to and completed by one analyst.
 - 13.1.4.1 Laboratories that employ technicians and/or use team approach to casework examination may do so ... each analyst shall be assigned a proficiency test to complete the interpretation and report the results.
- 5. Individuals whose sole responsibility is technical review* ... in the technical review of each technology and typing test kit...

* A qualified analyst proficiency-tested in the specific technology is qualified to serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.



Standard 13.1.3

Proficiency Testing

Current QAS:

- **Methodology** is used to describe the analytical processes and procedures used to support a DNA typing technology—for example, extraction methods (manual vs. automated), quantitation methods (slot blot, fluorometry, real time), typing test kit, and platform (capillary electrophoresis, real-time gel, and end-point gel systems).

DRAFT QAS:

- **Methodology** refers to the categories of methods used to perform a step of a DNA typing technology or technologies. For example, methodologies for STR technology can include extraction, quantitation, amplification, and detection
- **Method** is a combination of procedural steps used to perform a specific technical process. The method includes the validated steps, reagents, and critical instruments needed to perform the process or portion of a process. The same method may be conducted using different equipment (automated vs. manual) when appropriately validated.
- **Typing Test Kit and Platform** – Separated from methodology



NEW Standard 6.1 Training Program

- 6.1.3.1 – Analysts training needs to cover Technical Review.
 - *Audit Guide:* The training program for an analyst will cover the elements of technical review even if laboratory does not authorize analysts to perform technical review without an additional qualification. The laboratory can determine when and how analysts are authorized to perform technical reviews and if the analyst will be required to have additional experience or training. Refer to Standard 6.10 for authorizations.
- 6.1.4 – Training program for analysts and technicians needs to include an assessment of oral communication skills and/or a mock court exercise
 - *Audit Guide:* Individuals who process forensic samples may be required to testify in court even if they do not generate a report; therefore, the requirement for an assessment of oral communication skills and/or a mock court exercise applies to analysts and technicians.



Standard 6.3

Competency Testing

Current QAS

- 5.1.2.2.3 All analyst/technician(s), regardless of previous experience, shall successfully complete a competency test(s) covering the routine DNA methodologies to be used prior to participating in independent casework analysis.

- **Competency test(s)** is a written, oral, and/or practical test or series of tests, designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform forensic DNA analysis.

- **Audit Guide:** The competency testing must be sufficient for the trainee to demonstrate that he/she has achieved the technical skills and met minimum standards of knowledge necessary to perform the forensic DNA analysis for which the trainee will be authorized to perform on casework.

Draft QAS

- 6.3 All analyst/technician(s), regardless of previous experience, shall successfully complete competency testing covering the routine DNA methods, interpretation, and/or statistical procedures that the analyst/technician will perform prior to participating in independent casework.

- **Competency testing** is a test or series of tests (practical, written, and/or oral) designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform forensic DNA analysis.



Standard 6

Competency Testing

- 6.3.1 For a new analyst shall include a practical component, and written and/or oral components.
- 6.3.2 For a new technician shall include practical components.
- 6.4 For an analyst or technician... to be qualified in a new or additional method & 6.5 For an analyst... to be qualified to interpret data and generate reports for a new or additional technology, typing test kit, platform, or interpretation software...
 - The competency testing shall include practical components.
- *Audit Guide:* The practical component of competency testing should be relevant to the task(s) that the analyst or technician will be authorized to perform on casework samples.



Standards 6.8

Reinterpretation

Current Draft:

- STANDARD 6.8 For a laboratory that performs reinterpretation of legacy data, the laboratory shall have and follow procedures for analysts and technical reviewers whose external proficiency testing does not include a legacy technology, typing test kit or platform for which they are qualified or previously qualified.
- 6.8.1 An analyst or technical reviewer who has not successfully completed a proficiency test or a competency test in the interpretation of legacy data within a two year period shall successfully complete a competency test before reinterpreting legacy data.



Standards 6.8 & 9.11

Reinterpretation

STANDARD 6.8 The laboratory shall have and follow procedures for maintaining or reestablishing the technical skills and knowledge of analysts and technical reviewers who reinterpret legacy data for which they are qualified or previously qualified and whose external proficiency testing does not include a legacy technology, typing test kit or platform.

- 6.8.1 The technical leader shall review the documentation ... and authorize the analyst or technical reviewer to reinterpret legacy data every two years.

Audit Guide: Examples from current SWGDAM Clarification for Legacy Amp Kits.

- For lab's that do not reinterpret (Refer to 9.11)... This is NA.
 - If the lab's procedure for 9.11 says they do not reinterpret legacy data, there does not need to be a procedure to cover 6.8.

STANDARD 9.11 The laboratory shall have and follow a procedure to address the reinterpretation of legacy data.

- Similar to Outsourcing, the lab will need a procedure to say reinterpretation of legacy data is not done.



Standards 5.5 & 6.6

Technical Reviewer

STANDARD 5.5 The technical reviewer shall be an employee or contract employee of the laboratory. The technical reviewer shall meet the education and experience requirements in Standard 5.4 and shall meet the following:

- 5.5.1 A current or previously qualified analyst.
- 5.5.2 Successful completion of documented training.

Audit Guide: Individuals whose sole responsibility is technical review will be evaluated under these standards. For currently qualified analysts that are authorized to conduct technical reviews, Standards 5.5 through 5.5.2 will be marked “Yes”.

STANDARD 6.6 A technical reviewer, who is not currently qualified as an analyst in the laboratory, shall receive training on the case notes, data analysis, interpretation, and reporting criteria for any ... on which they are not qualified as an analyst in the laboratory and will conduct technical reviews of data and/or reports.

- 6.6.1 The technical reviewer shall successfully complete competency testing...

Audit Guide: This standard applies to individuals who will be trained and authorized to conduct technical reviews but are not or will not be authorized as an analyst...



Standard 5.2

Personnel

- 5.2 Consensus of SWGDAM membership that TL minimum Education requirement will remain a Masters Degree.

Point of clarification:

- 5.2.5 The technical leader shall have the following authority and minimum responsibilities
 - Actions to go with TL responsibilities throughout Standards.
 - Example:
 - 5.2.5.5 Approve the technical specifications for outsourcing agreements.
 - 17.2 ... technical leader shall document and maintain the approval of the technical specifications of the outsourcing agreement



What's next?!?

- SWGDAM QA Committee
 - Ongoing weekly teleconferences to update Audit Guide
 - Reviewing Public Comments
- SWGDAM “CDA”
 - Incorporating draft revisions into Database Standards
 - Making additional DB specific revisions
- January SWGDAM Meeting
 - Reviewing remaining Public Comments
 - Finalizing revisions to Standards
 - Preparing to vote for approval to recommend the Forensic Standards to the FBI Director for issuance
- TBD (Goal: Summer/Fall 2018) – FBI approval
- TBD (Goal: January 1, 2019) – Effective Date



Questions?



Comments/Questions

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