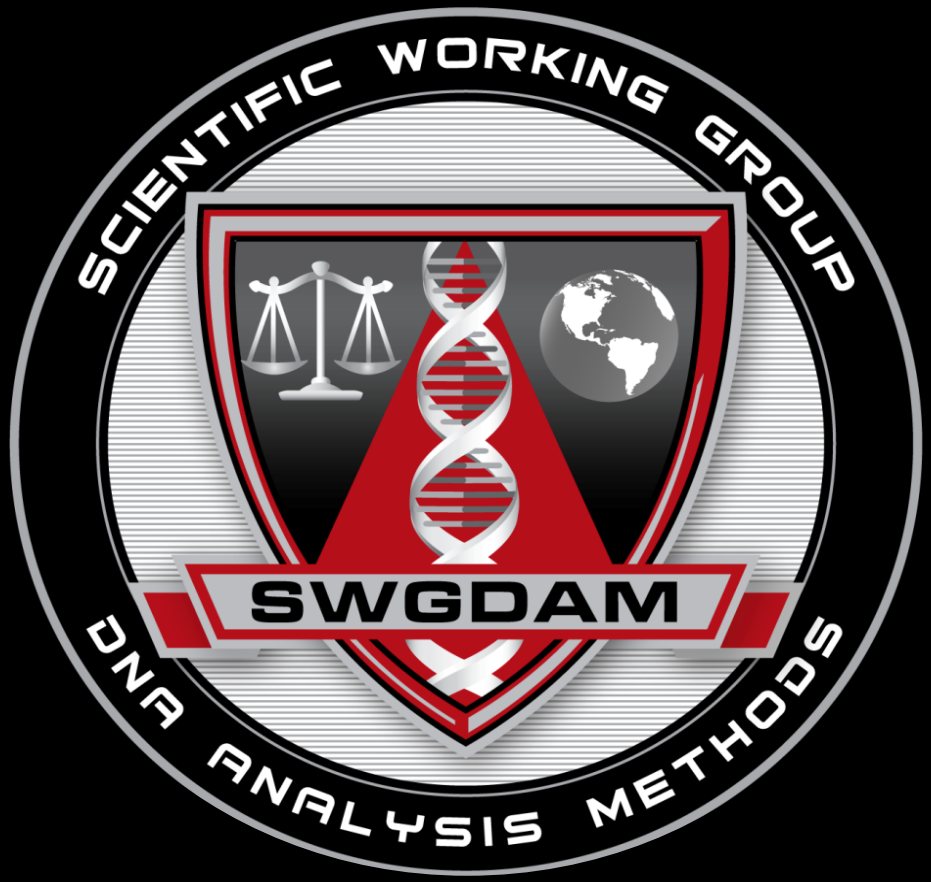
QAS Guidance Document DRAFT Edits



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SWGDAM QA Committee Co-Chair
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More Disclaimers

- It is impossible to think of every possible scenario individual labs will encounter when applying the standards. The QAS Guide is meant to help clarify the intent of the standards and to provide examples of how they might be applied or expectations for compliance.
- Accreditation requirements may be more stringent than QAS requirements.
- These draft edits were based on questions and feedback over the last 2 years and include historic and updated interpretations.
- We know we did not answer every question.
  - Continue to submit questions to QAS@fbi.gov

5.2.5 TL Authority and Responsibility

- Standard 5.2.5 “The technical leader shall have the following authority and minimum responsibilities:”,

- Added wording from 2011 back in requiring laboratories to have documented compliance with the standard.
  - “To successfully satisfy Standard 5.2.5, the laboratory must clearly define and document the technical leader’s duties and authority. Compliance must be demonstrated with all of the substandards of Standard 5.2.5.”

Coursework Preemptive Disclaimers

- Current QAS Guidance was taken from the past SWGDAM Training Guidance Document
  - We did not intend to increase the requirements for the 3 historic courses (genetics, molecular biology, biochemistry) by adding the topic lists.
  - We know evaluating coursework can be complicated and there are no easy answers when courses are questionable.
  - The intention of the standards is for analysts to have the foundational scientific knowledge.
- We are starting discussions for the next revision of the Standards and this is one of the areas in need of review.
- If you have ideas or suggestions, please share them!

Coursework (5.2.1.2/5.4.1)

Big changes in the interpretation of coursework standards. Some of this new guidance is distinctly different to training and guidance that has been provided in the past.

- Courses CAN count for 2 topics (e.g., a course titled Molecular Genetics)
- 3 distinct (genetics, molecular biology, biochemistry) courses are not required if the credit hours and subject areas are met. (e.g., Molecular Genetics I and II, and Biochemistry)
- Semester hours = quarter hours for this standard, conversion math not required.
- General BIO (i.e., BIO-101) cannot be used for credits or courses.
- Additional guidance for what should be in a letter from a professor.
- The integral component topic list is not intended to be all inclusive or require that everything in the lists be covered. Lists are provided as examples of the variety/range of topics that meet the subject area.
- Integral component still applies and is STILL subjective. Labs need to document justification for accepting courses.

Coursework (5.2.1.2/5.4.1)

- This does not mean TLs can accept courses that DO NOT meet the QAS requirements.
  - Example: “Cell and Molecular Biology” is often NOT enough Molecular Biology to be counted
- Labs should be prepared to defend an evaluation with documented justification if questioned by an auditor.
  - “For example, the specific topics, the textbook, course description, or description of the portion of the course that covered the subject area to demonstrate that the subject area constitutes an integral component of the course.”

Education Outreach

- SWGDAM has reached out to FEPAC and AAFS to help notify colleges, universities, and student members of the QAS requirements.
  - See SWGDAM Notice on QAS Educational Requirements
    (swgdam.org → Publications → SWGDAM communications)

- If you have connections with colleges and universities (i.e., internship connections), please make sure they are aware of the QAS course requirements, so their students take appropriate classes and retain justification materials while still in school.

8.3 Internal Validation and Software

- If Internal Validation includes testing software, auditors should check both 8.3 and For 8.8/DB 8.9
  - Studies may be the same.
- New Text:
  - When an internal validation includes new or modified software used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, the laboratory must also demonstrate compliance with the applicable substandards of **Forensic Standard 8.8/Database Standard 8.9**. The studies performed under **Standard 8.3** or evaluations performed under **Standard 8.5** may be concurrently used as the software testing.

8.4 - SRM

- A certified reference material (aka SRM) is not required for Rapid DNA.

- New Text:
  - The check against an appropriate and available certified reference material prior to the implementation is not required for an NDIS approved Rapid DNA System for use on database, known or casework reference samples that has been performance checked in accordance with Forensic Standard 8.7/Database Standard 8.8 or for a Rapid DNA instrument used for modified Rapid DNA analysis on database, known or casework reference samples that has been internally validated in accordance with Standard 8.

8.5 vs 10.3.1 for New Equipment

- What is enough for a modification evaluation (8.5) is dependent upon what is being modified and what impact the change has on the efficacy and reliability.
- The evaluation performed under Standard 8.5 may be used to fulfill the requirement of a performance check for new critical equipment or instruments under Standard 10.3.1.
  - STANDARD 8.5 The performance of a modified procedure shall be evaluated by comparison to the original procedure using similar DNA samples and the evaluation documented. The evaluation shall be reviewed and approved by the technical leader prior to the implementation of the modified procedure into casework applications.
  - 10.3.1 New critical equipment or instruments, not requiring validation, shall undergo a performance check before use in casework analysis. Each additional critical instrument, of the same instrument model validated for use in the laboratory, shall require a performance check prior to use in casework analysis.

8.5 vs 10.3.1 for New Equipment

- Caution: Make sure YOUR procedures for performance check allow for alternate evaluation methods (i.e., 8.5 studies) or you risk a finding under 10.3.
  - STANDARD 10.3 The laboratory shall have procedures for conducting performance checks and evaluating results of critical equipment or instruments.
- New examples in Guide of when 8.5 and 10.3.1 can be used together and when more internal validation (8.3) might be needed.
- An 8.5 evaluation is NOT required if you get another instrument of the same model that is already validated:
  - STANDARD 10.3.1 … Each additional critical instrument, of the same instrument model validated for use in the laboratory, shall require a performance check prior to use in casework analysis.

Software (For 8.8/DB 8.9)

- Software testing doesn't need to be exhaustive of every feature.
  - New text: "…and may include a risk based approach to determining the extent of the testing to be conducted."
- The standard does not require that the initial software evaluation is reviewed or approved by the TL. Nor does the evaluation have to be separately documented before the testing is completed.
  - STANDARD 8.8 New software or new modules of existing software and modifications to software shall be evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing. This evaluation shall include the determination of which studies will and will not be conducted and shall be documented.
- The TL must review and approve the testing documentation prior to implementation for DNA use.

Software Validation

- Addition similar to “regular” developmental validation:
  - A DNA laboratory may rely upon the software developer or another laboratory’s developmental validation studies.
- New text:
  - Documentation of software testing may include tools as simple as a checklist or a summary of the features that were tested.
- New Text:
  - A functional test is intended to verify that the software is functioning as expected for its use but does not require exhaustive testing of every feature the software can perform. The testing may focus on the pertinent functions of the software.

Software Modification

- Modifications (For 8.8.3/DB 8.9.3) only apply to the “big 3”.
  - See **FBI Notice on Additional Guidance for QAS Standard 8 Effective August 1, 2022**
- New text:
  - Operating system or security patches that are compatible with the system requirements of the software do not fall into the scope of these standards.

9.5 Controls and Standards

- Use of controls requires procedures and evaluation criteria:
  - STANDARD 9.6 The laboratory shall have and follow written guidelines for the interpretation of data that are based on and supported by internal validation studies. The laboratory shall:
    - 9.6.1 Have criteria to evaluate quantification standards, internal size standards, allelic ladders and analytical controls.
- Evaluation criteria needs to define pass and fail.
- Edited Guide Text:
  - Laboratory procedures must define criteria to evaluate quantification standards, internal size standards, allelic ladders and analytical controls as required by Forensic Standard 9.6.1/Database Standard 9.5.1. The criteria for evaluation must include the acceptable results and procedures for addressing sample data processed in parallel if the standards, ladders, or controls fail.

Extracted Concurrently

- The set or batch of samples is defined by the laboratory.
- Text edit:
  - Initiating a run on a robot that processes the set or batch of samples simultaneously or sequentially* would be considered concurrent
    - *Note: Sequentially in this context is referring to robots that process samples that were loaded together one or multiple at a time. (Example: QIAsymphony)
  - If using more than one extraction robot, each must be of the same model and using the same program (e.g., protocol card) for the run to be considered a concurrent set.
- Historically, when using robots:
  - "daisy chaining" simultaneous runs on multiple robots is OK
  - "back-to-back" runs on a robot is not concurrent.

DB 9.4.1.1 Reagent Blanks

- New Text:
  - If a database laboratory is only performing direct amplification without pre-processing steps, **Database Standard 9.4.1.1** is not applicable.
- DB 9.4.1.2 Guidance allows the reagent blank to be concurrently used as the negative amplification control (e.g., direct amplification), but pre-processing reagents must be included to meet 9.4.1.1.

Virtual Standard Curve

- Quant calibrator for virtual/external standard curve is not expected to be a metrological calibration standard.
  - Forensic 9.5.2 Where quantification is used, quantification standards shall be used. If a virtual or external standard curve is utilized, a calibrator must be run concurrently with the samples.
- Edited text:
  - the calibrator sample(s) does not need to be a certified reference material but must be run concurrently with the samples to demonstrate that the data on the plate is performing within expectations.

9.10 Procedures for Stats and Reporting

- The standard does not imply that the lab must have combined procedures for statistical calculations and reporting. Requirements in substandards may be in the lab's procedures for stats and/or reporting
  - STANDARD 9.10 The laboratory shall have and follow procedures for statistical calculations and the reporting of results and conclusions that address the following:
- For 9.10.5.3, added an exception to the guidance not recommending combining technologies:
  - "If independence cannot be demonstrated between the autosomal STR, YSTR, XSTR, SNP, and/or mtDNA results, combining these systems is not recommended unless the approach for combining is supported through peer-reviewed publications."

10.3.1 New Equipment "…not requiring validation…"

- Attempted to clarify when validation is not required.
  - 10.3.1 New critical equipment or instruments, not requiring validation, shall undergo a performance check before use in casework analysis.
- May be determined by a successful modified procedure evaluation.
  - New Text: "When it is not clear that validation is required, a modified procedure evaluation (Standard 8.5) may be used to determine if internal validation of a new model of equipment or instrument is required."
- Examples similar to 8.5.

11.2 Reporting

- Edited to reflect Standard 11.2.2 wording.
  - "…description of the evidence examined and identification of samples collected…"
- Reminder that evidence includes forensic samples and reference samples.
  - Std 2: Evidence is an item submitted for DNA testing and/or a derivative of an item as defined by the laboratory that is subject to a chain of custody.

12.1 “Batch Reviews”

- Added guidance for batch reviews.
  - For laboratories that use multiple technical reviewers, each review shall be documented.
  - In laboratories that use a team approach, the procedure must preclude an individual from technically reviewing their own work.
  - The author of the report cannot be the technical reviewer.
  - The laboratory must ensure the work is assessed by 2 individuals (i.e., one analyst and one technical reviewer).

12.1.1 TR Qualifications

Summary of New Guidance:

- If a reviewer wasn't qualified as an analyst in the "method, technology, typing test kit, platform, and interpretation software", they must be trained as a TR if they will do TRs (See 5.5.2 and 6.6).
- To continue to TR when something new comes online the TR needs training (See 6.6)
- If a modified procedure doesn't require a new qualification/authorization for an analyst, then it doesn't require a new qualification/ authorization for TR.

13.1 Semi-annual PT interval

- The semi-annual interval between two events applies to events within and between calendar years.
  - Semi-annual requires testing to take place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year, and where the interval between events is at least four months and not more than eight months.

Y Screening PTs

- 13.1.3: Tried to clarify PT req for Y screening.
  - If you only do the quant procedure for Y screening, then do that on a PT.
  - If the same quant is used for Y screening and quant of DNA before amp, then quanting before amp can cover the Y screening use.
- 13.1.4: Team approach
  - Tried to clarify the difference between Y screening analysts (those who write reports with the results of the Y screening) vs Y screening technicians (those who might make decisions on what to continue DNA testing on based on Y screening results) when it comes to “sharing” tests.
  - As in Standard 2, technicians “do not interpret data to reach conclusions on typing results or prepare final reports.”

15 Audits

- Added expectation for audit teams to have relevant casework experience or database experience.
- Clarified that NGS is a platform.
- Added historic link between 15.1 and 15.2
  - For the external audit every 2 years to “count” it must comply with timing requirement in 15.1 (occur at least 6 months but no more than 18 months from the laboratory’s previous annual audit)

15 Audits

- 15.2.2 Added reference to new sections of Appendix E
  - For modified procedure evaluations and software validation and testing
- 15.5 Added email addresses for NDIS custodian and QAS helpdesk
  - Extensions must be requested via email to NDIS@fbi.gov and QAS@fbi.gov
  - Audit documentation must be electronically submitted to the FBI via QAS@fbi.gov

15 Audits

- Reminder from the NDIS Procedures:
  - Any finding(s) challenged by the NDIS participating laboratory shall be clearly indicated as such and appropriate explanation and documentation shall be provided with the audit report.
  - Failure to identify a challenged/contested finding and/or the submission of corrective action(s) for a challenged/contested finding may result in the closure of the audit without consideration of whether the finding was warranted.

17 Outsourcing

- Deleted NDIS participating qualifier for sharing reference samples.
- Attempted to clarify sharing extracts:
  - If you are sending to another lab bc its something you don't do it is not outsourcing.
  - If you are receiving an extract, it is your responsibility to ensure the extraction was created in accordance with the standards.
  - The receiving lab must ensure the creating lab is accredited and audited, approve technical specifications, and verify integrity but an NDIS lab does not have to do a site visit of another NDIS lab.

Release and Effective Date

- Draft Guidance Edits are under final review for approval by SWGDAM.
- Goal is to have the revised Guidance Doc released to be effective by January 1, 2023.

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- Kristy Kadash
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Questions