Scientific Working Group on DNA Analysis Methods

SWGDAM Meeting

13th National CODIS Conference

October 30, 2007

Jennifer Luttman, SWGDAM Acting Chair

Outline

- Welcome
- Committee Updates
- Review of Recommended Revisions to Forensic Quality Assurance Standards (QAS)

THANK YOU

- **TO DAVE COFFMAN**
- **FOR HIS MANY YEARS OF DEDICATED SERVICE AND LEADERSHIP SKILLS AS CHAIR OF THE SCIENTIFIC WORKING GROUP ON DNA ANALYSIS METHODS**

Thank You

- To QA Committee for all of their hard work on the revisions
- And a Sincere Thank You to SWGDAM Executive Board Member Christine Tomsey for her many years of dedicated service to the DNA community

Welcome…

- In accordance with SWGDAM Bylaws
- Welcome **Angelo Della Manna** to the SWGDAM Executive Board in January 2008

Scientific Working Group on DNA Analysis Methods

Committee Updates

Scientific Working Group on DNA Analysis Methods

CODIS Committee

CODIS Committee

Tasks/objectives accomplished:

- Submitted Draft Database QAS to SWGDAM Chair for review
- Finalized Hit Counting Procedures, Hit Counting Flowchart and Investigations Aided Flowchart for CODIS Users

CODIS Committee

Tasks/objectives accomplished:

- Discussed topics for the National CODIS Conference in San Francisco

CODIS Committee

What's next:

- Finalize draft of Databasing QAS based upon completed draft of forensic casework QAS for submission to SWGDAM.

- Submit Hit Counting Procedures to NDIS Procedures Board for approval

CODIS Committee

Committee Point of Contact:

Committee Chair:

Douglas Hares

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Scientific Working Group on DNA Analysis Methods

Expert System Committee

Approved Expert Systems

Table 3 – NDIS Approved Expert Systems

Expert System and Version(s)	Manufacturer	Instrument Platform(s)	Kit(s)
i-Cubed™ v.4.0.2 using GeneMapper*ID*v.3.2	Forensic Science Service/Promega and ABI	ABI 3700 (data collection v3.1.1)	Identifiler™
i-Cubed™ v.4.1.3 using GeneMapper*ID*v.3.2	Forensic Science Service/Promega and ABI	ABI 3130xl (data collection v3.0)	Identifiler™
TrueAllele™v.2.7.348	Cybergenetics	ABI 3100 (data collection v1.1)	Profiler Plus™ and COFiler™
TrueAllele™v.2.9	Cybergenetics	ABI 3100 (data collection v1.1)	Profiler Plus™ and COFiler™

Expert Systems Summary

- **NEST (NIJ ES Testbed)**
  - Single Source Program update
  - Mixture analysis project status
  - Committee Marshall Site visit (5/15-16/07)
    - Phase I Marshall training useful for single source ES
    - Phase II Committee & Marshall evaluation Expert Systems for casework useful as **tools** for mixture deconvolution
- Forensic QAS Discussion & NDIS "APPENDIX C" -- On Hold

Expert Systems Committee

- **Marshall Site visit (5/15-16/07)**
  - **Confirmed potential utility of 3 Sole Source ES evaluated**
    - **GM ID & especially FSS I3 (I Stress) & TrueAllele 2**
    - **Hands-on & visual demonstration using same samples**

Specific Expert Systems Identified for Evaluation by NIST

- GeneMapper™ *ID* Software v. 3.2 (GMID); Applied Biosystems
- TrueAllele® System 2 (TA); Cybergenetics
- FSS-i^3; Promega

NEST Sole Source Study Conclusions

- **The Expert Systems produce concordant results.**
- **Each ES has its own features, benefits, and limitations.**
- **Imperative that laboratory evaluate needs prior to purchase.**
- **Expert Systems can assist in assurance of quality data entered into NDIS.**
- **The demonstration sessions at Marshall University are to help labs to assess & compare the 3 expert systems evaluated by the NEST Project Team.**

Phase II of NEST Project

- Evaluate Expert Systems for Mixed Specimens
  - **Performed defined mixture experiments**
  - **Evaluated mixture data on different expert systems**

Expert Systems Committee

- **Marshall Site visit (5/15-16/07)**
  - **Mixture Deconvolution**
    - **Similar comparisons FSS I3 (I Stream) & TrueAllele 3**
    - **Current state of software not suitable for use to independently call components of mixture**
    - **FSS I3, TrueAllele 3 or other software useful as data evaluation tools to assist analyst in mixture interpretation**
    - **Software could assist in making lab's mixture interpretations more standard/follow protocol**

Potential APPENDIX C

- Committee Recommends Development of Appendix C be put on hold:

Guidelines for Submitting Requests for Approval of an Expert Systems for Application to Forensic Casework Samples

- Expert Systems removed from Forensic QAS draft

Scientific Working Group on DNA Analysis Methods

Missing Person / Mass Disaster Committee

MP/MD Committee

Major Accomplishment Since Last Meeting

- SAIC has released the CODIS+Mito v.1.4 for beta testing to the MP Labs
- Changes were based in part on MP/MD Committee recommendations
- Changes include the ability to link STR and Mito data processed by different labs to the same specimen ID
- Implementation of MP Sex filter, STR filer, and mtDNA filter

MP/MD Committee

Discussion - CODIS 6.0

- Committee was shown how its recommendations have been implemented into the software
- Discussed potential modifications that can be incorporated into future builds
- Software has the flexibility to meet policy requirements provided by NDIS for future use

MP/MD Committee

Discussion - Future NDIS Policies

- Based on the development of CODIS v.6.0, Committee discussed and outlined potential suggestions for the NDIS Procedures Board

MP/MD Committee

Discussion - Minifiler Validation

- UNT CHI, Cal DOJ, FBI, OCME, AFDIL, and MN BCA are participating in this validation
- Most labs are nearing completion of validation work and conducting non-probative sample testing
- Each lab will run 100 profiles from different population groups
- Desired completion of this validation is by the CODIS Conference in Oct. ’07
- Present to the NDIS Procedures Board for kit approval

MP/MD Committee

Discussion – Standardize Dispositions

- Get away from the use of the word ‘match’ when a pedigree comparison is made to UHRs
- Create appropriate dispositions based on the new CODIS 6.0 and standardize their use between MP labs
- Additional work and discussion to follow

MP/MD Committee

Discussion – Future Meetings

- Teleconference scheduled for August and will continue on a monthly basis
- Potential Committee meeting to be held at the CODIS Conference in October ’07

MP/MD Committee

- Committee Point of Contact: John Planz
  - 817-735-2397
  - Jplanz@hsc.unt.edu

Scientific Working Group on DNA Analysis Methods

mtDNA Committee

mtDNA Committee

- Pending tasks/objectives
  - Update on last meeting's tasks
    - HL60
    - SWGMAT position paper
    - CODIS nomenclature proposal
      - MitoTech FBI contract
  - Discuss mito issues
  - Review results on bone exchange study
    - Prepare abstract for August 1 deadline AAFS

mtDNA Committee

- Update on last meeting's tasks
  - HL60
    - New supplier identified
    - Stability study in progress
  - SWGMAT position paper
    - Revisions made
  - CODIS nomenclature proposal
    - OK for exact matches, but not for looking at 1 or 2 bases away (due to known issues with current nomenclature)

History – mtDNA nomenclature issue

- FBI contracts w/ MitoTech for expert system
  - Discovers inconsistencies w/ nomenclature vs. historical data
    - Main problem is with rule 2A/B (indels vs. substitutions)
- Nomenclature debate in Europe
  - Phylogenetics vs. Wilson rules-like approach
  - ISFG meeting in Copenhagen August 2007

MitoTech Software Tool Data

- Used published SWGDAM data
  - 4839 mtDNA haplotypes
- Identified 91,720 regions for alignment
  - 41,025 out of 91,720 contained polymorphisms
- Rule 1 (minimum # differences) resolved all but 7420
- Rules reordered for historical/practitioner preference
- 99.9% of regions resolved with new rules
  - 2 had multiple alignments
- Additional rule handles last two ambiguities

mtDNA Committee

Bone exchange study

- 19 labs fully participating (2 unable to finish)
- all but 1 obtained mtDNA results and sequences were concordant (limited range from one lab).
  - Some also typed for nDNA and Ys – all results concordant
- forwarded spreadsheet to each lab to verify own entries

– Committee reviewed compiled spreadsheet

- Prepared abstract for poster presentation at AAFS meeting
  - Approved by SWGDAM Executive Board

– Discussed version 2 study with challenged sample

mtDNA Committee

Committee Point of Contact:

Connie Fisher

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Scientific Working Group on DNA Analysis Methods

Mixture Interpretation Committee

Mixture Interpretation Committee

Accomplished this meeting (1):

- Reviewed spreadsheets of mixture summary case data collected by CFS Toronto and MN BCA
- Refined spreadsheet for dissemination to general SWGDAM members and beyond
- Outlined topics for AAFS 2008 mixture workshop proposal

CFS Toronto Case Summary Data

Case type		# contributors				
N = 276		1	2	3	4	>4
Sexual Assault	N = 152	**42%**	52%	7%	1%	--
High Volume	N = 56	**69%**	16%	16%	--	--
Major Crime	N = 68	**59%**	34%	7%	--	--

Single source

Mixtures

MN BCA Case Summary Data

Case type	N = 273	1	# contributors 2	3	4	>4
Sexual Assault	N = 117	**60%**	37%	3%	--	--
High Volume	N = 82	**70%**	20%	9%	1%	--
Major Crime	N = 74	**50%**	39%	10%	1%	--

Single source

Mixtures

Spreadsheet Information Requested

Labs requested to also provide info on kit, PCR volume used, etc.

- **Case#**
- **Item#**

This information retained by lab and not returned…

- **Type of sample (biological material if ID'd)**
- **Type of substrate**
- **Quantity amp'd**
- **Minimum # of contributors (1, 2, 3, 4, or >4)**
- **Predominant type (major profile) determined?**
- **Stats reported**
- **Comments**

Will send out spreadsheet to SWGDAM members through Chair

Opening Data Collection to SWGDAM and Beyond…

- Labs are being asked to report 2 months (or more) of cases to assess numbers and complexity of mixture cases along with the sample types observed in their lab – ***purpose is to understand how often mixture samples are observed and how complex these mixtures are***

- Timeline for response: **Send to Ann Gross** by end of September

AAFS Feb 2008 Mixture Workshop

- Discussed potential topics and speakers
- John Butler will submit proposal for workshop (due August 1, 2007)
- Topics to include:
  - mixture interpretation variability,
  - ISFG Recommendations,
  - mixture classification scheme,
  - worked examples with statistical approaches,
  - thresholds

Mixture Interpretation Committee

Accomplished this meeting (2):

- Discussed UK and German responses to ISFG Recommendations
- Reviewed flow chart developed for mixture classification
- Discussed NIST research on mixture replicates and software evaluations

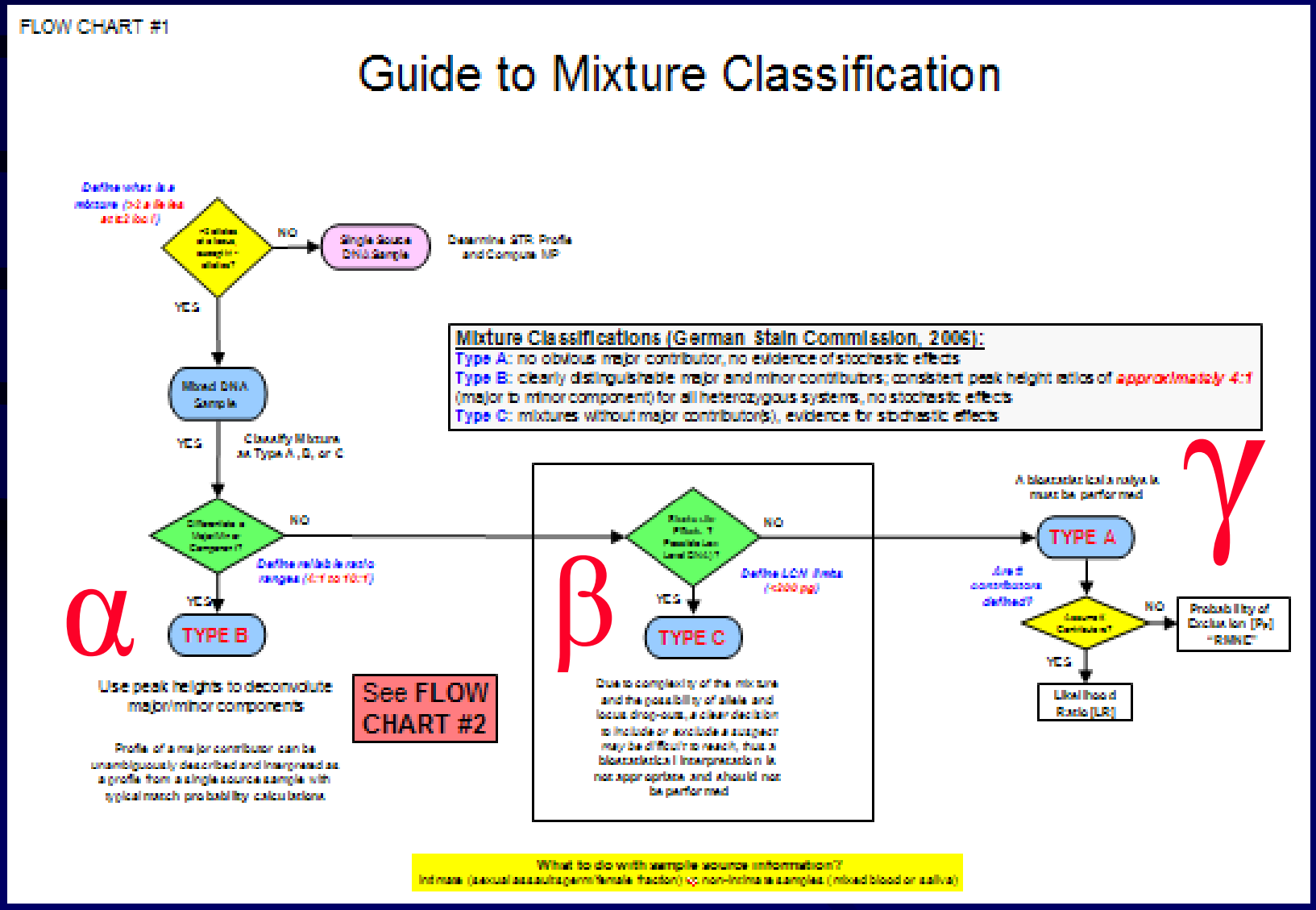
Mixture Classification Scheme

(German Stain Commission, 2006):

- **Type A**: no obvious major contributor, no evidence of stochastic effects
- **Type B**: clearly distinguishable major and minor contributors; consistent peak height ratios of ***approximately 4:1*** (major to minor component) for all heterozygous systems, no stochastic effects
- **Type C**: mixtures without major contributor(s), evidence for stochastic effects

Plan to reorder classifications and change designations to α (alpha), β (beta), and γ (gamma)

Flow Chart Under Development



Software for Mixtures

- Discussed NIST work with i-STReam (mixture deconvolution part of FSS-i^3), USACIL program (Tom Overson)

- Summary: Software tools are not ready for prime-time yet…

Mixture Interpretation Committee

Next Steps

- Collect data on number and type of mixture cases observed in various labs
- Begin collecting mixture data files for creating a training workbook with worked examples – prepare for AAFS 2008 mixture workshop
- Continue flow chart development and mixture interpretation guidelines
- Prepared detailed responses to ISFG Recommendations

Mixture Interpretation Committee

Committee Point of Contact:

- John Butler (chair) – john.butler@nist.gov
- Gary Sims (co-chair) – gary.sims@doj.ca.gov

Scientific Working Group on DNA Analysis Methods

Y-STR Interpretation Committee

Points for Discussion

- Agreed with Bruce Budowle that more studies are needed to ascertain the effects of population substructure on the precision of expected haplotype frequencies provided by the counting method
- Collaborative studies
  - 5 regions in the US, 3 separate populations, 500 samples per population-total of 7500 samples
  - Problem of East Asians and Native Americans
- Interpretation Guidelines
  - Discussed pros and cons of whether SWGDAM should issue 'interim' Y-STR interpretation guidelines
    - "It is recognized that population substructure exists for Y-STR haplotypes and that further studies are being conducted in this area. Until these studies are completed, the counting method offers an adequate statistical approach to evaluating the probative value of a match".

Scientific Working Group on DNA Analysis Methods

Quality Assurance Committee

QAS

- Required for laboratories participating in the National DNA Index System (NDIS)
- Federal DNA Identification Act [42 U.S.C. 14132(b)(1)] requires that all DNA records submitted to NDIS be generated in accordance with minimum standards for quality assurance issued by the Director of the FBI

Quality Assurance Committee

- The goal of the QA Committee is to update the DAB Standards to address new technology and audit concerns.
  - Standards
  - Definitions
  - References

Forensic QAS

- Distributed to Public for Comment on March 14, 2007
  - Posted on CJIS WAN
  - CODIS Bulletin sent to all NDIS Participating Laboratories
  - E-mailed to ASCLD, ASCLD/LAB, FQS, NFSTC
- Comments due May 14, 2007
- A total of **49** comments were received by the due date
- An additional **10** comments were received after the due date
- All comments were reviewed

Forensic QAS

- Breakdown of Comments
  - **22** State Laboratories
  - **25** Local Laboratories
  - **3** Accrediting Organizations
  - **3** Private Laboratories
  - **3** International Laboratories
  - **3** Other Organizations

Forensic QAS

- Final Forensic QAS Revisions provided to SWGDAM Members and Invited Guests on July 3, 2007 for review at July 2007 meeting
- Voted to accept all revisions during July Meeting and recommend revisions to the FBI Director

Process for QAS Revisions

- Once completed, 1st draft of revisions to Databasing QAS will also be e-mailed to membership for review
- Comments may be e-mailed to Executive Secretary
- Discussion of Databasing QAS at January 2008 Meeting

Review of Proposed Revisions to Forensic QAS

Proposed QAS Revisions

- Standard 3 – Quality Assurance Program [*Reinforces annual review provisions*]
  - Elements of quality system to be documented in a manual
  - Quality system to be reviewed annually independent of the required audit
  - Annual review to be under the supervision of the Technical Leader and Technical leader approval documented

Proposed QAS Revisions

- Standard 3 – Quality Assurance Program
  - The following elements added to the quality program
    - Outsourcing

Proposed QAS Revisions

- Standard 4 - Organization & Management [*New additions*]
- Multi-laboratory systems shall have at least one technical leader
- Laboratory shall have a documented contingency plan that is approved by laboratory management if the technical leader position is vacated

Proposed QAS Revisions

- Standard 4 - Organization & Management [*New additions*]
- Laboratory shall have at least two full-time employees who are qualified DNA analysts
- Laboratories shall have a casework CODIS Administrator who is accountable for CODIS on-site at each facility using CODIS

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail/requirements relating to the training program*]
- Requirement to have a training manual covering all DNA analytical procedures that the analyst will perform. Practical exercises include the examination of a range of samples routinely encountered in casework.
  - Training program to teach and assess the technical skills and knowledge required to perform DNA analyses
    - Competency test
    - Hiring of experienced personnel, responsibility of the Technical Leader to ensure previous training was adequate

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail relating to continuing education*]
- At least once per calendar year and a minimum of 8 hours
- When conducted internally: title, record of presentation, date, attendance list, CV of the presenter
  - When conducted externally, documentation of attendance (certificates, program agenda, syllabus or travel)
  - Attendance at a regional, national or international conference provides a minimum of 8 hours
  - Multimedia or internet programs are subject to the approval of the technical leader and documented

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional details for annual review of scientific literature*]
- Maintain, have physical or electronic access to a collection of current books, reviewed journals or other literature applicable to DNA analysis

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail/requirements relating to Technical Leader educational requirements*]
- Maintained Master's degree requirements
- 12 semester or equivalent credit hours from a combination of undergraduate and graduate course work covering biochemistry, genetics, molecular biology and statistics or population genetics
  - Shall include 1 graduate level course having 3 or more semester hours
  - Subject areas above shall constitute an integral component of any course work

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail for Technical Leader educational requirements*]
- Compliance with this Standard by course work with other titles than those listed on the previous slide can be demonstrated through transcript, syllabus, letter from the instructor or other document that supports the course content

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail for Technical Leader experience requirements*]
- Clarifies that it is forensic DNA laboratory experience obtained at a facility where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters.
- Technical Leaders appointed on or after the effective date of the revised QAS, shall have a minimum of 3 years of human DNA (current or previous) experience as a qualified analyst on forensic samples

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional requirement for Technical Leader*]
- Technical Leader to have completed or complete within 1 year of appointment, the DNA Auditor training

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail on Technical Leader duty requirements*]
- Authority to initiate, suspend and resume DNA analytical operations for the laboratory or an individual

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail on Technical Leader specific responsibilities*]
- Evaluate & document validations/methods
- Review transcripts/records & approve qualifications
- Approve technical specifications for outsourcing agreements
- Review internal and external DNA audit documents
- Review laboratory procedures on an annual basis
- Review & approve training, QA and proficiency testing programs

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail on Technical Leader accessibility*]
- Multi-laboratory system may have 1 Technical Leader over a system of separate laboratory facilities – for such systems, the Technical Leader shall conduct a site visit to each laboratory at least semi-annually

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail on Technical Leader accessibility*]
- Technical Leader shall be a full time employee of the laboratory or multi-laboratory system
  - If TL position vacated and no one who meets the Standard and can serve as TL, Laboratory shall immediately contact the FBI and submit contingency plan for approval within 14 days. Work in progress may be completed during 14 day period but new casework shall not be started until plan is approved by FBI.

Proposed QAS Revisions

- Standard 5 – Personnel [*Additional detail on Newly Appointed Technical Leader*]
- Newly appointed Technical Leaders shall be responsible for the documented review of
  - Validation studies and methodologies currently in use
  - Educational qualification and training records of currently qualified analysts

Proposed QAS Revisions

- Standard 5 – Personnel [*NEW STANDARD*]
- Casework CODIS Administrator
- Employee of the Laboratory responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples
- Satisfy Analyst education requirements
- For those appointed prior to effective date of revisions, deemed to have satisfied the minimum educational requirements and applicable to specific laboratory employing the Administrator (not portable)

Proposed QAS Revisions

- Standard 5 – Personnel [*NEW STANDARD*]
- Casework CODIS Administrator experience requirements – be or have been a current or previously qualified DNA analyst with documented mixture interpretation training
- For those appointed prior to the effective date of these revisions who are not or have never been qualified analysts (with documented training in mixture interpretation) deemed to have satisfied the minimum experience requirements upon completion of FBI sponsored CODIS training and applicable to specific laboratory employing the Administrator (not portable)

Proposed QAS Revisions

- Standard 5 – Personnel [*NEW STANDARD*]
- Casework CODIS Administrator training requirements
  - Participate in FBI sponsored training in CODIS software within 6 months of assuming duties if no previous training
  - Successfully complete the FBI sponsored auditor training within 1 year of assuming their duties if no previous training

Proposed QAS Revisions

- Standard 5 – Personnel [*NEW STANDARD*]
- Casework CODIS Administrator duties
  - Administration of local CODIS network
  - Scheduling & documentation of CODIS computer training of analysts
  - Assurance that security of data stored in CODIS is in accordance with State/Federal law and NDIS operational procedures
  - Assurance that the quality of data stored in CODIS is in accordance with State/Federal law and operational procedures
  - Assurance that matches are dispositioned in accordance with operational procedures

Proposed QAS Revisions

- Standard 5 – Personnel [*NEW STANDARD*]
- Casework CODIS Administrator shall be authorized to terminate an analyst's or the laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified
- A laboratory shall not upload DNA profiles to NDIS in the event that the casework CODIS Administrator position is unoccupied

Proposed QAS Revisions

- Standard 5 – Personnel [*Clarifies analyst educational requirements*]
- Bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry-, or forensic science-, related area and successful completion of course work (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic DNA analysis.
  - Subjects listed above shall be an integral component of any course work

Proposed QAS Revisions

- Standard 5 – Personnel [*Clarifies analyst educational requirements*]
- Analysts appointed or hired after the effective date of these revisions must have a minimum of 9 cumulative semester hours or equivalent that cover the required subjects
- Compliance with this Standard by course work with other titles than those listed on the previous slide can be demonstrated through transcript, syllabus, letter from the instructor or other document that supports the course content

Proposed QAS Revisions

- Standard 5 – Personnel [*Clarifies analyst experience requirements*]
- 6 months of forensic *human* DNA experience. If prior forensic human DNA experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed, in the analytical methodologies, platforms, and interpretations of human DNA results used by the laboratory
  - Analysts shall complete the range of samples routinely encountered in forensic casework prior to independent work using DNA technology
  - Analyst shall successfully complete a competency test before beginning independent DNA analysis

Proposed QAS Revisions

- Standard 6 – Facilities [*Clarifies and provides additional details on limited access*]
- Clarifies that all exterior/exit points require security control
- Clarifies that doors between rooms containing amplified DNA and other areas shall remain closed
- If robotic workstations used, can carry out DNA extraction, quantitation and amplification in a single room as long as the analytical process has been validated. If robot performs analysis through amplification, the robot shall be in a separate room from initial evidence examinations.

Proposed QAS Revisions

- Standard 7 – Evidence Control [*Clarifies and provides additional details*]
- Clarifies that evidence should be marked with a unique identifier on the evidence package
- Laboratory shall define what is evidence and work product
- Laboratory shall have a method to distinguish each sample throughout processing that may not require the assignment of unique identifiers or individual evidence seals
- Clarifies that chain of custody shall be maintained in hard or electronic format

Proposed QAS Revisions

- Standard 7 – Evidence Control [*Clarifies and provides additional details*]
- Laboratory shall have and follow a documented policy for the disposition of evidence that includes a policy on sample consumption

Proposed QAS Revisions

- Standard 8 – Validation [*Clarifies and provides additional details*]
- Clarifies that there are 2 types of validation – developmental and internal
- Developmental validation shall precede the use of a novel methodology for forensic DNA analysis
  - Characterization of the genetic marker - Species specificity
  - Sensitivity studies - Stability studies
  - Reproducibility - Case-type samples
  - Population studies - Mixture studies
  - Precision & Accuracy studies - PCR-based studies

  * Peer-reviewed publication of the underlying scientific principle(s) of a technology shall be required

Proposed QAS Revisions

- Standard 8 – Validation
- Internal Validation of all manual and robotic methods shall be conducted and reviewed & approved by the Technical Leader prior to using a procedure for forensic applications
  - Known and non-probative evidence samples or mock evidence samples
  - Reproducibility & Precision
  - Sensitivity and Stochastic studies
  - Mixture Studies including interpretation guidelines
  - Contamination assessment

Proposed QAS Revisions

- Standard 8 – Validation [*Clarifies requirements for multi-laboratory systems*]
- Internal validation data may be shared by all locations in a multi-laboratory system. Each laboratory shall complete and maintain applicable precision, sensitivity and contamination assessment studies. Summary validation data shall be available at each site.

Proposed QAS Revisions

- Standard 8 – Validation [*Clarifies requirements*]
- Complete change of detection platform or test kit shall require internal validation studies
- Requires completion of a competency test before introducing a methodology in the laboratory
- Performance of a modified procedure shall be evaluated by comparison with the original procedure using similar DNA samples

Proposed QAS Revisions

- Standard 8 – Validation [*Clarifies requirements*]
- Each additional critical instrument or software modification (upgrade) requires a performance check
- New software or significant software change that may impact interpretation or the analytical process shall require a validation prior to implementation

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Clarifies and provides additional details*]
- Clarifies that the Technical Leader must review the standard operating procedures each year, independent of the QAS audit

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Clarifies and provides additional details*]
- Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory
- In-house reagents shall be labeled with the identity of the reagent, the date of preparation and/or expiration, and the identity of the individual preparing the reagent

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Clarifies and provides additional details*]
- Critical reagents include
  - Test kits or systems for performing quantitative PCR and genetic typing
  - Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Clarifies and provides additional details*]
- Quantitation of human DNA is not required for casework reference samples if the laboratory has a validated system that has been demonstrated to reproducibly and reliably yield successful DNA amplification and typing without prior quantitation.

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Clarifies and provides additional details on controls and standards*]
- Positive & negative amplification controls associated with samples being typed shall be amplified concurrently with the samples at all loci and with the same primers as the forensic samples.

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Clarifies and provides additional details on controls and standards*]
- Reagent blank controls associated with each extraction set being analyzed shall be
  - Extracted concurrently;
  - Amplified utilizing the same primers, instrument model and concentration conditions as required by the sample(s) containing the least amount of DNA; and
  - Typed utilizing the same instrument model, injection conditions and most sensitive volume conditions of the extraction set

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Additional details*]
- A laboratory performing genetic analyses not addressed by NRC II, such as Y-chromosome or mtDNA typing shall have and follow documented statistical interpretation guidelines specific for such testing
- Laboratories analyzing forensic samples shall have a procedure for mixture interpretation that addresses
  - Major and minor contributors
  - Inclusions and exclusions
  - Reporting of results and reporting of statistics

Proposed QAS Revisions

- Standard 9 – Analytical Procedures [*Additional details*]
- Laboratory shall have and follow a documented policy for the detection and control of contamination

Proposed QAS Revisions

- Standard 10 – Equipment Calibration and Maintenance [*Clarifies and provides additional details*]
- Clarifies that the following require annual performance checks
  - Thermometer used for performance checks
  - Balances/scales
  - Thermal Cycler temperature verification system
  - Thermal Cycler including quantitative –PCR
  - Electrophoresis detection systems
  - Robotic systems
  - Genetic Analyzers
  - Mechanical pipettes

Proposed QAS Revisions

- Standard 10 – Equipment Calibration and Maintenance [*Clarifies and provides additional details*]
- The following critical equipment shall undergo a performance check following repair, service or calibration:
  - Electrophoresis detection systems
  - Genetic Analyzers
  - Thermal cycler including quantitative-PCR

Proposed QAS Revisions

- Standard 11 – Reports [*Clarifies and provides additional detail*]
- Clarifies that the laboratory shall retain sufficient documentation for each analysis to support the report conclusions so that another qualified individual could evaluate and interpret the data
- Except as otherwise provided by state or federal law, reports, case files, DNA records and databases shall be confidential

Proposed QAS Revisions

- Standard 12 – Review [*Clarifies and provides details*]
- Clarifies that the technical reviewer shall be an analyst currently or previously qualified in the methodology being reviewed

Proposed QAS Revisions

- Standard 12 – Review [*Provides details*]
- Technical Review shall include the following elements:
  - Review of case notes, worksheets and electronic data
  - Review of all DNA types to verify that they are supported by the raw or analyzed data
  - Review of all profiles to verify correct inclusions and exclusions
  - Review of all controls, internal lane standards and allelic ladders to verify that the expected results were obtained
  - Review of statistical analysis, if applicable
  - A review of the final report to verify that the results/conclusions are supported by the data

Proposed QAS Revisions

- Standard 12 – Review continued [*Provides details*]
- Technical Review shall include the following elements:
  - Verification that all profiles entered into CODIS are eligible, have the correct DNA types and correct specimen category
    - Prior to upload to or search of SDIS, verification of the following criteria for DNA profiles: eligibility for CODIS, correct DNA types and appropriate specimen category
    - For entry into a searchable category at SDIS, verification of the following criteria for DNA profiles by two concordant assessments by a qualified analyst or technical reviewer: eligibility for CODIS, correct DNA types, and appropriate specimen category

Proposed QAS Revisions

- Standard 12 – Review [*Provides details*]
- Administrative review shall include the following elements (any or all of which may be included in the technical review):
  - Review of the case file and final report for clerical errors
  - Review of chain of custody and disposition of evidence
  - Procedure documents the completion of the technical review

Proposed QAS Revisions

- Standard 12 – Review [*NEW*]
- Laboratory shall have and follow a documented procedure for the verification and resolution of database matches

Proposed QAS Revisions

- Standard 13 – Proficiency Testing [*Clarifies and provides more details*]
- Analysts, technical reviewers, technicians and other personnel designated by the Technical Leader shall undergo semi-annual external proficiency testing in each technology performed to the full extent in which they participate in casework.
  - Technology is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR or mtDNA.

Proposed QAS Revisions

- Standard 13 – Proficiency Testing [*Clarifies and defines*]
- Semiannual is an event that takes place 2 times during one calendar year
  - Once in the 1st six months of the calendar year
  - Once in the last six months of the calendar year
  - Internal between the 2 tests shall be at least 4 months and not more than 8 months

Proposed QAS Revisions

- Standard 13 – Proficiency Testing [*More details*]
- 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
- Newly qualified individuals shall enter the external proficiency testing program within 6 months of the date of their qualifications
- Laboratory to define the date that the proficiency test is performed – received date, assigned date, submitted date or due date

Proposed QAS Revisions

- Standard 13 – Proficiency Testing [*More details*]
- Except as provided below, each analyst shall be assigned and complete his/her own proficiency test
  - Laboratories that use a team approach to casework examinations may do so on external proficiency tests. However, all analysts, technicians and technical reviewers shall be proficiency tested at least once per year in each of the DNA technologies, including test kits for DNA typing, and each platform in which they perform forensic DNA analysis.

Proposed QAS Revisions

- Standard 13 – Proficiency Testing [*More details*]
- Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology performed
- Technical Leader shall be informed of the results of all participants
  - Technical Leader shall inform casework CODIS Administrator of all non-administrative discrepancies that affect the typing results and/or conclusions at the time of discovery

Proposed QAS Revisions

- Standard 14 – Corrective Action *[More details]*
- Corrective Action Plan shall define what level/type of discrepancy is applicable and identify the cause, effect, corrective actions taken and preventative measures (where applicable).
- Corrective Actions shall not be implemented without the documented approval of the Technical Leader

Proposed QAS Revisions

- Standard 15 – Audits [*Clarifies*]
- Clarifies that audits shall be conducted every calendar year and shall be at least 6 months and no more than 18 months apart
- Clarifies that at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform

Proposed QAS Revisions

- Standard 15 – Audits [*NEW*]
- Review of the education, experience and training qualifications for analysts, casework CODIS Administrators and Technical Leaders during two successive, separate external audits conducted after July 1, 2004. Approval shall be documented in the audit document.
- Review of validation studies during 1 external audit. Approval shall be documented in the audit document.

Proposed QAS Revisions

- Standard 15 – Audits [*NEW*]
- For internal audits, auditor or audit team shall be a currently qualified auditor and current or previously qualified analyst in the laboratory's current DNA technologies and platform
- Clarifies that all audits shall be conducted using the FBI DNA Quality Assurance Audit Document
- Technical Leader shall review the internal and external audit documents to ensure findings, if any, were appropriately addressed
  - For NDIS laboratories, all external audit documentation and laboratory responses shall be provided to the FBI within 30 days of laboratory receipt of the audit documents
- Clarifies that the laboratory shall retain internal and external audit documentation and make it available for subsequent audits

Proposed QAS Revisions

- Standard 16 – Safety [*More details*]
- Clarifies that the laboratory's environmental health and safety program includes a blood borne pathogen and chemical hygiene plan and documented training on the plan
- Safety plan shall be reviewed once each calendar year (and the review documented)

Proposed QAS Revisions

- Standard 17 – Outsourcing [*NEW*]
- Requires vendor laboratory performing forensic DNA analysis to comply with the QAS and accreditation requirements of federal law
  - An NDIS laboratory that outsources shall require the vendor laboratory to provide documentation of the above

Proposed QAS Revisions

- Standard 17 – Outsourcing [*NEW*]
- Except as provided below, an NDIS laboratory's technical Leader shall document approval of the technical specification of the outsourcing agreement before it is awarded
  - A vendor laboratory performing forensic DNA analysis for a law enforcement agency and generating DNA data that may be entered into or searched in CODIS shall not initiate analysis for a specific case or set of cases until documented approval has been obtained from the appropriate NDIS laboratory's Technical Leader of acceptance of ownership of the DNA data.

Proposed QAS Revisions

- Standard 17 – Outsourcing [*NEW*]
- An NDIS laboratory shall not upload or accept DNA data for upload to or search in CODIS from any vendor laboratory without the documented prior approval of the technical specifications of the outsourcing agreement and/or acceptance of ownership by the laboratory's Technical Leader

Proposed QAS Revisions

- Standard 17 – Outsourcing [*NEW*]
- Prior to the upload or search of data to SDIS, the technical review shall be performed by an analyst or technical reviewer employed by the NDIS laboratory who is qualified or previously qualified in the technology, platform, and typing amplification test kit used to generate the data and participates in the laboratory's proficiency testing program

Proposed QAS Revisions

- Standard 17 – Outsourcing [*NEW*]
- Technical review shall include the following
  - Review of all DNA types to verify that they are supported by the raw or analyzed data
  - Review of all associated controls, internal lane standards and allelic ladders to verify that the expected results were obtained
  - Review of the final report to verify that the results/conclusions are supported by the data. Report shall address each tested item (or its probative fraction) submitted to the vendor laboratory
  - Verification of the DNA types, eligibility and the correct specimen category for entry into CODIS

Proposed QAS Revisions

- Standard 17 – Outsourcing [*NEW*]
- NDIS Laboratory shall have and follow a procedure to perform an on-site visit of the vendor laboratory
  - Initial on-site visit prior to beginning casework analysis
    - Performed by the Technical Leader or his/her designee who is a qualified or previously qualified DNA analyst in the technology, platform and typing amplification kit used to generate the data

Proposed QAS Revisions

- Standard 17 – Outsourcing [*NEW*]
- If outsourcing agreement extends beyond 1 year, an annual on-site visit shall be required
    - An NDIS laboratory may accept an on-site visit from another NDIS Laboratory using the same technology, platform and typing amplification test kit

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