14th National CODIS Conference

Update on the Scientific Working Group on DNA Analysis Methods

November 10, 2008

Ted Staples
SWGDAM Chairman

Outline

- Update on Committees
  - Ad Hoc Group on Partial Matches
  - CODIS
  - Missing Person and Mass Disasters
  - MtDNA
  - Mixture Interpretation
  - Y-STR
  - Quality Assurance

Scientific Working Group on DNA Analysis Methods

Ad Hoc Group on Partial Matches

Task

To provide scientific recommendations concerning the FBI's "Interim Plan for the Release of Information in the Event of a Partial Match at NDIS"

- *Is there a statistical approach that could provide guidance on which partial matches are of value for law enforcement investigative purposes*
- *Possible requirements for laboratories before an offender's name is released to law enforcement in instances of "partial matches"*

Summary of Recommendations

- The Committee did not support unconditional release of an offender's name based upon a Partial Match discovered through Moderate Stringency searches.

- However, the Committee did establish steps for releasing the name of an offender having a reasonable chance of a familial relationship to the perpetrator.

Recommendations

- “The crime scene sample should be from a single source.”
- “LDIS and SDIS searches should be done before searching at the NDIS level.”
- “All available CODIS core loci should be used for searching.”
- “Whenever possible, partial DNA matches that result from searching databases should have additional loci typed.”
- “An Expected Match Ratio (EMR) and an Expected Kinship Ratio (EKR) should be calculated for a partial match.”

Recommendations

- “Four individual EMRs and EKRs should be calculated on the assumption that the database searched is made of: 1. African Americans; 2. Caucasians; 3. SE Hispanics; 4. SW Hispanics. The partial match is only considered useful if either the EMR or the EKR satisfy the following thresholds: at least one of the four database values is ≥ 1.0 and all the others ≥ 0.1.”
- “In order to implement these recommendations it is important that CODIS Administrators have training in the evaluation of partial matches and in reporting the potential value of these matches.”
- “All laboratories using these recommendations will report the profiles and associated EMRs and EKRs to the FBI who will monitor the effectiveness of this approach.”

Recommendations

- SWGDAM reviewed Committee's recommendations and approved them with minor revisions
- SWGDAM recommendations provided to the FBI for consideration in formulating final plan for the release of information in the event of a partial match at NDIS

Scientific Working Group on DNA Analysis Methods

CODIS Committee

CODIS Committee

Tasks/objectives accomplished:

- Finalized Draft of Quality Assurance Standards (QAS) for Databasing Laboratories
- Submitted Hit Counting rules to NDIS Procedures Board for consideration as an NDIS Operational Procedure – approved as an NDIS Procedure
- Submitted finalized flowcharts for Hit Counting and Investigations Aided for posting on CJIS WAN for distribution to CODIS Administrators

Scientific Working Group on DNA Analysis Methods

Missing Person / Mass Disaster Committee

MP/MD Committee

Minifiler Validation

- 7 State and Local laboratories participating in this validation.
- Most labs have completed validation work
- Will result in request for NDIS Procedures Board consideration for approval of new kit at NDIS

MP/MD Committee

- Provide recommendations to the NDIS Procedures Board for procedures and revisions necessary for operation of CODIS v.6.0 software

Scientific Working Group on DNA Analysis Methods

mtDNA Committee

mtDNA Committee

- Bone exchange study poster for AAFS meeting (2008)
  - Reviewed poster data/layout
  - Conclusions of study include:
    - Different methods yield same results
    - Lack of bone proficiency test
      - Study could serve as possible prototype
    - Challenged bone sample for next phase of project

Scientific Working Group on DNA Analysis Methods

Mixture Interpretation Committee

AAFS 2008 Mixture Workshop

- AAFS (February 19, 2008)
  - **DNA Mixture Interpretation:** Principles and Practice in Component Deconvolution and Statistical Analysis
  - **John Butler (NIST)**
  - **Ann Gross** (MN)
  - **George Carmody** (Carleton U.)
  - **Gary Shutler** (WA)
  - **Joanne Sgueglia** (MA)
  - Angela Dolph (Marshall U./NIST)
  - Tim Kalafut (USACIL)

196 page handout prepared

http://www.cstl.nist.gov/biotech/strbase/training/AAFS2008_MixtureWorkshop.htm

All Laboratory Data Combined
(as of AAFS-Feb 2008)

12 different labs

 # contributors

Case type

N = 3106		1	2	3	4	>4
Sexual Assault	N = 1408	**51%**	40%	8%	--	--
Major Crime	N = 1388	**66%**	24%	8%	2%	--
High Volume	N = 310	**43%**	37%	19%	1%	--

Single source

Mixtures

Overall Summary – 3106 samples

- 57% of samples from all types of cases are single source
- **43% of samples from all types of cases are mixtures**
  - 33% at least two contributors
  - 9% at least three contributors
  - 1% at least four contributors

Differs between types of cases (types of samples?)

Scientific Working Group on DNA Analysis Methods

Y-STR Interpretation Committee

Y-STR

- "Y-Chromosome Short Tandem Repeat (Y-STR) Interpretation Guidelines" submitted to membership at July 2008 Meeting and approved by membership
- Publication of Guidelines in *Forensic Science Communications* for January 2009 issue
- Guidelines recommend use of consolidated U.S. database

  YES, formal recommendation to use consolidated database (www.usystrdatabase.org)

Scientific Working Group on DNA Analysis Methods

Quality Assurance Committee

Forensic Quality Assurance Standards (QAS)

- Revisions to the *Quality Assurance Standards for Forensic DNA Testing Laboratories* approved by SWGDAM at July 2007 Meeting and recommended to FBI Director

- Approved by FBI Director to take effect July 1, 2009

- Available at http://www.fbi.gov/hq/lab/codis/forensic.htm (fbi.gov web site, Laboratory Services, CODIS)

Databasing Quality Assurance Standards (QAS)

- Revisions to *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories* approved by SWGDAM at January 2008 Meeting and retitled *Quality Assurance Standards for DNA Databasing Laboratories*
- Approved by FBI Director to take effect July 1, 2009
- Available at http://www.fbi.gov/hq/lab/html/databasinglab.htm (fbi.gov web site, Laboratory Services, CODIS)

Quality Assurance Committee

- Working on revisions to the FBI Audit Document to incorporate recommended revised standards, comments and discussion

FBI’s Quality Assurance Standards

Effective July 1, 2009

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

QAS

- Owing to time constraints, targeting major substantive changes to the Standards, please review the Standards, in their entirety, at the FBI's web site.
- www.fbi.gov – Laboratory Services – CODIS -- Standards

QAS Effective July 1, 2009

- Introduction for the Databasing QAS notes that these are applicable to databasing labs performing DNA analyses on DNA samples obtained from identified subject(s) for purposes of entering the resulting DNA profile into a DNA database.

QAS Effective July 1, 2009

- If performing DNA analyses on known or casework reference samples considered evidence by the laboratory, the databasing laboratory shall:
  - (1) Follow the QAS for Forensic DNA Testing Laboratories for the known or casework reference samples; or
  - (2) Follow the Databasing Standards including the additional requirements for known and casework reference samples in 5.1.2.1.1 (training program) and 7.1.2.1 (chain of custody)

QAS Effective July 1, 2009

- Many NEW Definitions….
  - Accredited Laboratory
  - Analytical documentation
  - Biochemistry
  - Casework CODIS Administrator
  - Casework Reference Sample
  - Competency Test
  - Continuing Education
  - Critical equipment or instruments
  - Differential amplification
  - DNA type
  - FBI
  - Genetics
  - Integral Component
  - Accuracy
  - Annual
  - CODIS
  - Competency
  - Contamination
  - Coursework
  - Developmental validation
  - DNA record
  - Employee
  - Forensic Sample
  - Guidelines
  - Internal Validation…..

QAS Effective July 1, 2009

- Many NEW Definitions….
  - Laboratory
  - Molecular biology
  - Multiplex system
  - On-site visit
  - Ownership
  - Platform
  - Precision
  - Procedure
  - Quantitative PCR
  - Review
  - Service
  - Technology
  - Underlying scientific principle
  - Work product
  - Methodology
  - Multi-laboratory system
  - Negative amplification control
  - Outsourcing
  - Performance check
  - Positive amplification control
  - Preferential amplification
  - Qualified auditor
  - Reproducibility
  - Semi-annual
  - Technical reviewer
  - Test kit
  - Vendor laboratory

QAS Effective July 1, 2009

- Definitions
- Analyst (replaces examiner/analyst) – an employee who has successfully completed the laboratory's training requirements for casework sample analysis, passed a competency test, and has entered into a proficiency testing program according to these Standards. This individual conducts and/or directs the analysis of forensic samples, interprets data and reaches conclusions.

QAS Effective July 1, 2009

- Definitions
- Employee – a person: (1) in the service of the applicable federal, state or local government, subject to the terms, conditions and rules of federal/state/local employment and eligible for the federal/state/local benefits of service; or (2) formerly in the service of a federal, state or local government who returns to service in the agency on a part time or temporary basis. For purposes of a vendor laboratory, an employee is a person in the service of a vendor laboratory and subject to the applicable terms, conditions and rules of employment of the vendor laboratory.

QAS Effective July 1, 2009

- Definitions
- Laboratory – a facility: (1) employing at least two full time employees who are qualified DNA analysts; and (2) having and maintaining the capability to perform the DNA analysis of forensic and /or casework reference samples at that facility.

QAS Effective July 1, 2009

- Definitions
- Methodology – 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 system).

QAS Effective July 1, 2009

- Definitions
- Technology – used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR or mitochondrial DNA.

QAS Effective July 1, 2009

- Definitions
- Technical reviewer – an employee who is a current or previously qualified analyst in the methodology being reviewed that performs a technical review of, and is not an author of, the applicable report or its contents.

QAS Effective July 1, 2009

- Standard 3 – Quality Assurance Program [*Reinforces annual review provisions*]
  - Elements of quality system to be documented in a manual [may be system-wide manual, multiple manuals or unit specific 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

QAS Effective July 1, 2009

- Standard 3 – Quality Assurance Program
  - The following now a required element of the quality program
    - Outsourcing

QAS Effective July 1, 2009

- 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 [can be a single policy or combination of policies]

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for 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 must include all methodologies that the analyst will routinely use 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

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for the training program]*
- Hiring of experienced personnel -- responsibility of the technical leader to ensure previous training for staff member who has not otherwise completed the laboratory's formal training program was adequate
  - For example, the hiring of fully trained personnel from a separate organization or the assignment of experienced forensic DNA case working analysts to validate a new DNA testing procedure

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for continuing education*]
- Technical leader, casework CODIS administrator and analyst(s) shall participate in continuing education at least once per calendar year – a minimum of 8 cumulative hours annually and shall be documented
- 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 of continuing education
  - Multimedia or internet programs are subject to the approval of the technical leader and documented

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for annual review of scientific literature*]
- Lab shall have a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature. Maintain, have physical or electronic access to a collection of current books, reviewed journals or other literature applicable to DNA analysis [laboratory must describe its process for the annual review of scientific literature, including how personnel will document their ongoing reading]

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for technical leader's education*]
- Technical leader position 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 [coursework must be completed successfully]

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for technical leader's education*]
- 12 semester or equivalent credit hours
  - Shall include 1 graduate level course having 3 or more semester hours
  - Subject areas above shall constitute an integral component of any course work [to be considered an integral component of any coursework, it must be determined that the specific subject area component of the coursework accounts for a minimum of one or more semester or equivalent hours awarded for the course]

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for technical leader's education*]
- Compliance with this Standard by course work with titles other than those previously listed can be demonstrated through transcript, syllabus, letter from the instructor or other document that supports the course content
- A list of those individuals in compliance with this Standard will be documented by the auditor in an Appendix to the audit document

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for technical leader's experience*]
- 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 or hired on or after the effective date of these QAS, shall have a minimum of 3 years of human DNA (current or previous) experience as a qualified analyst on forensic samples

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for technical leader's experience*]
- If appointed or hired prior to the effective date of these QAS, it is not necessary for the technical leader to function (or have functioned) as a qualified analyst
- If technical leader has experience in a specific DNA technology different from that currently used in casework analysis, the laboratory must demonstrate that the technical leader has fulfilled his or her defined duties and keeps abreast of technical developments

QAS Effective July 1, 2009

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

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for the technical leader's duties]*
- Authority to initiate, suspend and resume DNA analytical operations for the laboratory or an individual

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for the technical leader's 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

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for the technical leader's accessibility*]
- Multi-laboratory system may have 1 technical leader over a system of separate laboratory facilities – for such systems, the technical leader shall conduct and document a minimum of 2 on-site visits to each laboratory
  - The technical leader will generate a documented summary of he on-site visit performed capturing the dates and any points identified in the annual review

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional detail on the technical leader's accessibility*]
- Technical leader shall be a full time employee of the laboratory or multi-laboratory system
  - If technical leader 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.

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional detail on the technical leader's accessibility*]
- Technical leader vacancy
  - If a contingency plan was submitted to the FBI, then documentation must be reviewed to ensure that DNA analytical procedures on new casework were not initiated until FBI approval was granted. New casework is casework in which DNA analytical procedures have not been initiated at the time of the technical leader's vacancy.

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Additional requirements for a 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

QAS Effective July 1, 2009

- 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 education requirements of an analyst if appointed on or after July 1, 2009
- For those appointed prior to July 1, 2009 and having the appropriate documentation from the FBI, deemed to have satisfied the minimum educational requirements and applicable to specific laboratory employing the administrator (not portable)

QAS Effective July 1, 2009

- 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)

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 5 – Personnel [*NEW STANDARD*]
- Casework CODIS Administrator duties
  - Administration of local CODIS network
  - Scheduling & documentation of CODIS computer training of casework 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 NDIS operational procedures
  - Assurance that matches are dispositioned in accordance with NDIS operational procedures

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 5 – Databasing QAS Personnel [*NEW STANDARD*]
- CODIS Administrator
- Employee of the Laboratory responsible for administration and security of the laboratory's CODIS at a laboratory that owns the database and/or known samples
- Satisfy education requirements of an analyst if appointed on or after July 1, 2009
- For those appointed prior to July 1, 2009, deemed to have satisfied the minimum educational requirements and applicable to specific laboratory employing the administrator (not portable)

QAS Effective July 1, 2009

- Standard 5 – Databasing QAS Personnel [*NEW STANDARD*]
- CODIS Administrator experience requirements – be or have been a current or previously qualified forensic or database 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)

QAS Effective July 1, 2009

- Standard 5 – Databasing QAS Personnel [*NEW STANDARD*]
- 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

QAS Effective July 1, 2009

- Standard 5 – Databasing QAS Personnel [*NEW STANDARD*]
- CODIS Administrator duties
  - Administration of local CODIS network
  - Scheduling & documentation of CODIS computer training of database 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 NDIS operational procedures
  - Assurance that matches are dispositioned in accordance with NDIS operational procedures

QAS Effective July 1, 2009

- Standard 5 – Databasing QAS Personnel [*NEW STANDARD*]
- 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 CODIS Administrator position is unoccupied

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Clarifies analyst educational requirements*]
- Analysts shall be employees of the laboratory
- 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

QAS Effective July 1, 2009

- 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 – biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic DNA analysis

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Clarifies analyst educational requirements*]
- [Analysts may satisfy the statistics and/or population genetics coursework or training requirement through internal or external training
  - For external training, a variety of methods may be used, including academic coursework, workshops at local, nation, regional or international meetings or symposia or other external technical leader-approved training courses; documentation of attendance must be maintained by the laboratory
  - For internal training, the documentation must comply with Standard 5.1.3.1.1]
- 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

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 5 – Personnel [*Clarifies analyst experience requirements*]
- [A competency test serves to test an individual's knowledge, skills and abilities as they relate to his or her individual position. A laboratory may select from a variety of approaches for administering a competency test, including but not limited to a written, oral or practical examination.
  - If a laboratory uses an internal or external proficiency test as a qualifying or competency test, the laboratory must have phenotyping/genotyping results to assess an individual's performance.
- The date of qualification of an individual must be documented,. The qualification date has particular relevance to proficiency testing requirements discussed in Standards 13 which requires that newly qualified individuals participate in an external proficiency test within six months of qualification date.]

QAS Effective July 1, 2009

- 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.

QAS Effective July 1, 2009

- Standard 7 – Evidence & Sample (Databasing) Control [*Clarifies and provides additional requirements*]
- 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

QAS Effective July 1, 2009

- Standard 7 – Evidence & Sample (Databasing) Control [*Clarifies and provides additional requirements*]
- If the databasing laboratory is processing known or casework reference sample(s) as evidence, a chain of custody shall be documented and maintained in hard or electronic format. The chain of custody shall include the signature, initials or electronic equivalent of each individual receiving or transferring the known or casework reference sample(s), the corresponding date for each transfer, and the known or casework reference sample(s) transferred.

QAS Effective July 1, 2009

- Standard 7 – Evidence & Sample (Databasing) Control
- Laboratory shall have and follow a documented policy for the disposition of evidence that includes a policy on sample consumption
- For Databasing Laboratories, where possible, the laboratory shall retain the database sample for retesting for quality assurance and sample confirmation purposes

QAS Effective July 1, 2009

- Standard 8 – Validation [*Clarifies and provides additional requirements*]
- 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

QAS Effective July 1, 2009

- Standard 8 – Validation [*Clarifies and provides additional requirements*]
- Developmental validation shall precede the use of a novel methodology for forensic DNA analysis
  - [A laboratory may rely upon another laboratory's developmental validation studies: however, the citations and/or publications referencing that validation must be available to support the underlying scientific basis.]

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- 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.
  - The internal validation materials must be documented, summarized, and approved by the technical leader. Summaries of a system's internal validation studies must be available at all sites.

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 8 – Validation [*Clarifies requirements*]
- [If a laboratory modifies a procedure that would require a protocol change, the modified procedure shall be evaluated by comparing the original procedure to the modified procedure using similar DNA samples.

  Modifications must be documented and approved by the technical leader before implementing into laboratory operations.]

QAS Effective July 1, 2009

- Standard 8 – Validation [*Additional requirement*]
- For Databasing Laboratories, for inclusion into NDIS of profiles reviewed by an expert system, the expert system shall be validated in accordance with applicable NDIS procedures

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 8 – Validation [*Clarifies requirements*]
- [A software upgrade that would not impact interpretation, the analytical process, or sizing algorithms shall require a performance check.]

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Clarifies and provides additional requirements*]
- Clarifies that the technical leader must review the standard operating procedures each year, independent of the QAS audit
  - [This review must be documented and performed independent of the audit required by Standard 15. Standard operating procedures must be readily available to laboratory personnel, reflect the current practices employed by the laboratory and be supported through a laboratory's validation.]

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Clarifies and provides additional requirements*
- 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 [If the laboratory has determined an expiration date, supporting documentation must be available at 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

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Clarifies and provides additional requirements*]
- 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
  - [A laboratory must identify the reagents critical to the analytical processes used and evaluate each, prior to their use]

QAS Effective July 1, 2009

- 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 [These methods are suitable for use on known reference samples from casework and evidentiary items that are subjected solely to mitochondrial DNA analysis]

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Clarifies and provides additional requirements 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 (or database, known and casework reference) samples.

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Clarifies and provides additional requirements on controls and standards*]
- [A laboratory shall associate a reagent control with each extraction set, and that reagent control shall be extracted concurrently with that extraction set. If a laboratory does not quantitate its reagent blanks, it must document and verify that the reagent blanks are amplified concurrently with the sample(s) being characterized from an extraction set.]

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Clarifies and provides additional requirements for controls*]
- 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

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Clarifies and provides additional requirements for controls*]
- [For extraction sets being amplified, a laboratory shall concurrently amplify at all loci a set of positive and negative amplification controls using the same primers as the sample(s), amplified in the same instrument model as the sample(s), and amplified using the same concentration conditions as required by the sample that contains the least amount of DNA.]

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Additional requirements*]
- 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

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Additional requirements*]
- For databasing laboratories, an NDIS approved and internally validated Expert System may be sued to complete the data interpretation process.
  - A laboratory shall verify that all control results meet the laboratory's interpretation guidelines for all data to be entered into CODIS.

QAS Effective July 1, 2009

- Standard 9 – Analytical Procedures [*Additional requirements*]
- Laboratory shall have and follow a documented policy for the detection and control of contamination
  - This policy should include the procedures used by a laboratory for monitoring, decontaminating, and detecting of contamination.
  - In addition, a laboratory shall have and follow policies and/or procedures for interpreting data potentially affected by contamination.

QAS Effective July 1, 2009

- Standard 10 – Equipment Calibration and Maintenance [*Clarifies and provides additional requirements*]
- Clarifies that the following critical equipment or instruments 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

QAS Effective July 1, 2009

- Standard 10 – Equipment Calibration and Maintenance [*Clarifies and provides additional requirements*]
- For databasing laboratories, the following critical equipment requires quarterly recertification –
  - Expert systems approved for use at NDIS

QAS Effective July 1, 2009

- Standard 10 – Equipment Calibration and Maintenance [*Clarifies and provides additional requirements*]
- [A laboratory's documentation must include all critical equipment and instruments listed above at a minimum. The laboratory's documentation must include the scheduled for and records of all repairs, service, or calibrations for the critical equipment and instruments.]

QAS Effective July 1, 2009

- Standard 10 – Equipment Calibration and Maintenance [*Clarifies and provides additional requirements*]
- The following critical equipment shall undergo a performance check following repair, service or calibration:
  - Electrophoresis detection systems
  - Robotic systems
  - Genetic Analyzers
  - Thermal cycler including quantitative-PCR
  - & Databasing Laboratories – Expert systems approved for NDIS

QAS Effective July 1, 2009

- Standard 11 – Reports & Documentation/Reports (for Databasing QAS)
- 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
  - [An amplification system (PCR test kit) may be used as long as the laboratory documents the loci characterized in the kit used.]
  - [Results may be considered the data generated by the analysis and may include analyst's evaluation of the results. The quanitative or qualitative interpretation provides a statement of the weight of the conclusion.]
  - [Only one person must accept responsibility for the content of the report.]
  - [A secure electronic signature is equivalent identification.]

QAS Effective July 1, 2009

- Standard 11 – Reports & Documentation/Reports (for Databasing QAS)
- Except as otherwise provided by state or federal law, reports, case files, DNA records and databases shall be confidential
- For databasing laboratories – laboratory shall have and follow a procedure for the release of personally identifiable information in connection with a database hit

QAS Effective July 1, 2009

- Standard 12 – Review [*Clarifies and provides additional requirements*]
- For Databasing Laboratories – review of DNA data generated external to the laboratory is governed by Standard 17

QAS Effective July 1, 2009

- Standard 12 – Review [*Clarifies and provides additional requirements*]
- Clarifies that the technical reviewer shall be an analyst currently or previously qualified in the methodology being reviewed
  - The technical reviewer must be proficiency tested semi-annually to the extent to which they perform casework or database analysis.
  - A qualified analyst proficiency tested in the specific DNA methodology is qualified to serve as technical reviewer without the necessity of taking an additional proficiency test as a technical reviewer.
  - An analyst whose sole responsibility is technical review must be qualified under Standard 5.4 and its subsections to the extent of their interpretative role as a technical reviewer.

QAS Effective July 1, 2009

- 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 (NOT APPLICABLE to Databasing Labs)
  - 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 (NOT APPLICABLE to Databasing Labs)

QAS Effective July 1, 2009

- Standard 12 – Review [*Provides details*]
- [Final reports of forensic casework shall address each tested item or its probative fraction. Any stain, sample or item on which an attempt is made to isolate DNA, regardless of the outcome or result, must be addressed in the final report. In the case of a differential extraction, the laboratory will describe what it considers to be the probative fraction and the probative fraction must be included in the final report.]

QAS Effective July 1, 2009

- Standard 12 – Review continued [*Additional requirements*]
- For Forensic Laboratories, the technical review shall include the following:
  - 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

QAS Effective July 1, 2009

- Standard 12 – Review continued [*NEW*]
- For Databasing Labs, laboratory shall have a system in place to ensure that the correct CODIS specimen categories have been assigned

QAS Effective July 1, 2009

- Standard 12 – Review [*Additional requirements*]
- For Forensic Laboratories -- 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

QAS Effective July 1, 2009

- Standard 12 – Review continued [*Additional requirements*]
- For Databasing Laboratories, the release of personally identifiable information associated with a database hit shall require an administrative review of the official correspondence. The administrative review shall include the following elements, any or all of which may be included within the technical review:
  - A review of the supporting administrative documentation and correspondence for clerical errors, accuracy and adherence to agency policy
  - A review of the individual's biographical data, qualifying offense, and DNA profile generated from reanalysis, as applicable

QAS Effective July 1, 2009

- Standard 12 – Review
- [Laboratories must describe the method used for documenting the completion of technical and administrative reviews, as well as a procedure that the course of action necessary in the event of an unresolved discrepancy. Laboratories that include some or all of the administrative review elements in their technical review procedure must also document the completion of the administrative review.]

QAS Effective July 1, 2009

- Standard 12 – Review [*NEW*]
- For Forensic Labs, laboratory shall have and follow a documented procedure for the verification and resolution of database matches.

QAS Effective July 1, 2009

- Standard 13 – Proficiency Testing [*Clarifies and provides additional requirements*]
- 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 or database analysis.
  - Technology is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR or mtDNA.
  - [It is permissible for multiple technologies to be reported on a single proficiency test]

QAS Effective July 1, 2009

- Standard 13 – Proficiency Testing [*Clarifies*]
- 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

QAS Effective July 1, 2009

- Standard 13 – Proficiency Testing [*Additional requirements*]
- 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

QAS Effective July 1, 2009

- Standard 13 – Proficiency Testing [*Additional requirements*]
- 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.

QAS Effective July 1, 2009

- Standard 13 – Proficiency Testing [*Additional requirements*]
- [Laboratories that have both manual and automated methods shall proficiency test each individual that is qualified in both manual and automated in each method at least once per year to the full extent in which they participate in casework or database analysis.
  - For example, if an individual is qualified in both manual and automated methods for DNA extraction in casework, then each method must be used at least once per year during a proficiency test to the full extent in which he or she participates in casework.
- Laboratories that have more than one platform shall proficiency test each individual that is qualified in more than one platform on each platform at least once per year to the full extent in which he or she participates in casework or database analysis.
- Laboratories that have more than one amplification test kit shall proficiency test each individual that is qualified in more than one amplification test kit once per year to the full extent in which he or she participates in casework or database analysis.]

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 14 – Corrective Action *[Additional requirements]*
- 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

QAS Effective July 1, 2009

- Standard 14 – Corrective Action *[Additional requirements]*
- [This addresses only those corrective actions resulting from DNA proficiency tests, or casework or database analysis. The elements listed on the previous slide – level/type of discrepancy, cause, effect, corrective action, preventative measures – may be assessed through a review of existing laboratory documentation.]

QAS Effective July 1, 2009

- Standard 15 – Audits [*Clarifies requirements*]
- 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

QAS Effective July 1, 2009

- Standard 15 – Audits [*Clarifies requirements*]
- [Audit teams may consist of one or more individuals.
- An auditor must verify his or her qualifications to ensure that the auditor, or the auditing team, consists of appropriately qualified individuals.
- Regardless of the audit (internal or external), it is the laboratory's responsibility to ensure that there is at least one person that is, or has previously been, a qualified forensic analyst for each specific DNA technology (e.g., STRs, mtDNA) performed and that there is at least one person who is a qualified auditor on the audit team. This may be accomplished by having a single auditor who meets all of the specified qualifications or through a combination of the various members of a multi person audit team.]

QAS Effective July 1, 2009

- 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.
  - [The two independent external auditor approvals of personnel are not transferable and are only valid within the laboratory or laboratory system for which those personnel are employed at the time of the approvals. The Standards applied by external auditors in their approval of technical personnel are those Standards that are in effect as of the date that those personnel are "approved as qualified" by the technical leader. Example: Analysts qualified by the technical leader on or before June 30, 2009, are assessed against the October 1, 1998, Quality Assurance Standards. Analysts qualified by technical leader on or after July 1, 2009, are assessed against the July 1, 2009, Standards.]

QAS Effective July 1, 2009

- Standard 15 – Audits [*NEW*]
- Review of validation studies during 1 external audit. Approval shall be documented in the audit document.
  - [When documentation of the required reviews has been memorialized in previous external audit documents, the auditor is not required to perform additional review with respect to the personnel or validations that were previously reviewed and documented except training in new methodologies and/or technologies by previously qualified personnel. However, this in no way prohibits the auditor from performing such additional reviews as that auditor may deem appropriate or necessary.]

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 16 – Safety [*Additional requirements*]
- 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)

QAS Effective July 1, 2009

- Standard 16 – Safety [*Additional requirements*]
- [All information addressing environmental health and safety program must be current and available to laboratory staff. This information must be updated to reflect changes in a technical procedure (e.g. radioisotopes) or the remodeling of laboratory space (e.g. changed evacuation plans) that may have an effect on the laboratory's environmental health and safety program.]

QAS Effective July 1, 2009

- Standard 17 – Outsourcing [*NEW*]
- Outsourcing is the use of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data for entry into CODIS, when applicable. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.
- A vendor laboratory is a government or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 17 – Outsourcing [*NEW*]
- [Compliance with this Standard is required when an NDIS laboratory outsources any DNA–related services for which the NDIS laboratory will take or retain ownership, or when the NDIS laboratory will take or retain ownership of data from any other law enforcement agency or entity.
- Compliance with this Standard is required of a vendor laboratory whenever the vendor laboratory performs DNA analysis pursuant to any request from an NDIS laboratory, law enforcement agency or any other entity, and it may reasonably be anticipated that ownership of the results of such an analysis may subsequently be taken or retained at some time by an NDIS laboratory.
- Compliance with this Standard is NOT required when an NDIS laboratory outsources a specific DNA analysis using a technology that the NDIS laboratory is not qualified to perform or when the NDIS laboratory will not take or retain ownership of the data.]

QAS Effective July 1, 2009

- 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.

QAS Effective July 1, 2009

- Standard 17 – Outsourcing [*NEW*]
- [It is incumbent on the vendor laboratory to maintain the dated, documented approval obtained from the technical leader of the NDIS laboratory, accepting ownership of the DNA data; as well as the date that the laboratory first initiated analysis for a specific case or set of cases.]

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 17 – Outsourcing [*NEW*]
- [It is incumbent on the NDIS laboratory to maintain the dated, documented approval of the technical specifications of the outsourcing agreement and/or documented approval of acceptance of ownership of the DNA data by the NDIS laboratory's technical leader; as well as the date that the NDIS laboratory first uploaded, first accepted DNA data for upload or first searched such data in CODIS.]

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 17 – Outsourcing [*NEW*]
- [All reviews associated with the previous slides must be sufficient to assess the integrity of the subcontractor's DNA data.]

QAS Effective July 1, 2009

- 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

QAS Effective July 1, 2009

- Standard 17 – Outsourcing [*NEW*]
- [An on-site visit is different from an external audit and does not necessarily require that an external audit be performed.]

QAS Effective July 1, 2009

- 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

Questions