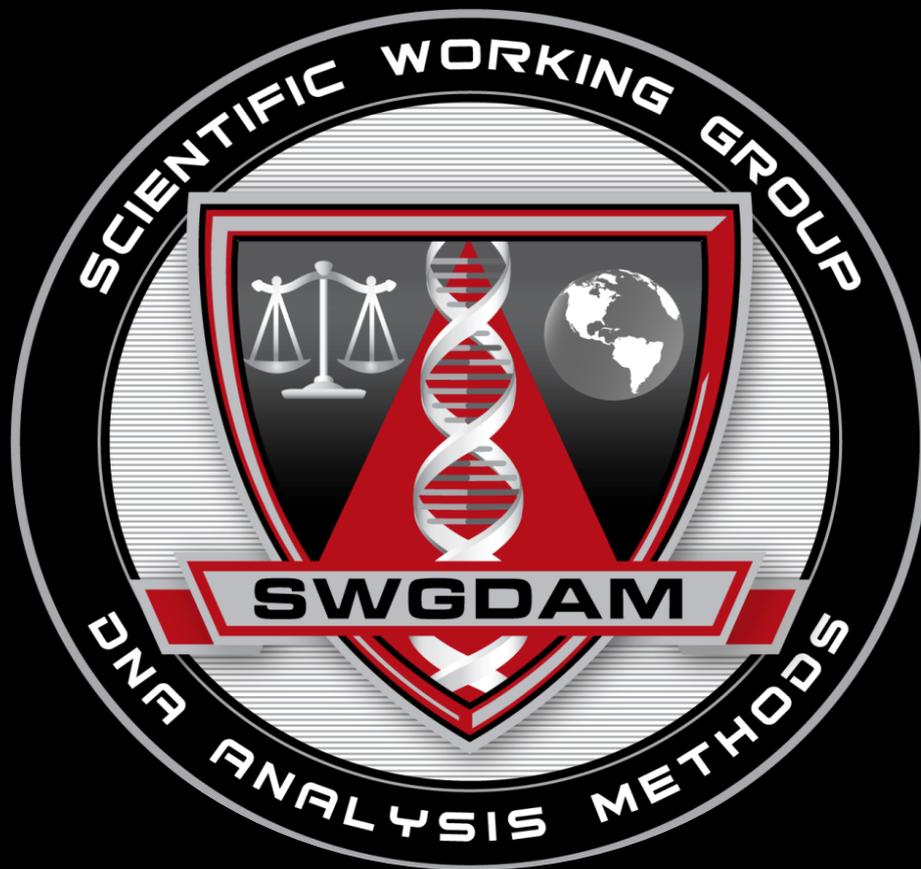


# History & Evolution of DNA QA Standards



July 2015



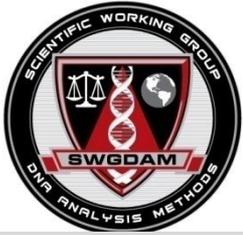
# Outline

- Background
- TWGDAM Guidelines
- Federal DNA Identification Act
- Quality Assurance Standards (QAS)
- QAS Audit Document
- Revisions



# Timeline

- 1986 First use of forensic DNA analysis in criminal case in United States: *Pennsylvania v. Pestinikas*
- 1987 First person convicted as a result of DNA evidence – Tommy Lee Andrews
- 1988 First TWGDAM Meeting held at FBI Academy in Quantico, VA
- 1989 *Frye* hearing in *People v. Castro* resulting in ruling that DNA evidence was generally accepted but evidence in *Castro* inadmissible because approved procedures were not followed
- 1989 TWGDAM Guidelines published in *Crime Laboratory Digest*; *State v. Schwartz* recognizes TWGDAM Guidelines
- 1989 *DNA: Report of New York Forensic DNA Analysis Panel*
- 1990 *United States v. Yee* pre-trial hearing on admissibility of DNA evidence
- 1990 Office of Technology Assessment Report: *Genetic Witness: Forensic Uses of DNA Tests*
- 1991 Revised TWGDAM Guidelines Published
- 1992 National Research Council Report: *DNA Technology in Forensic Science* (NRC 1)
- 1994 Passage of Federal DNA Identification Act
- 1995 Federal DNA Advisory Board Established
- 1996 National Research Council Report: *The Evaluation of Forensic DNA Evidence* (NRC 2)
- 1998 *Quality Assurance Standards for Forensic DNA Testing Laboratories*
- 1998 National DNA Index System Implemented
- 1999 *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories*
- 1999 TWGDAM renamed Scientific Working Group on DNA Analysis Methods (SWGAM)



# Timeline

**1986 -1987**

First use of DNA analysis in a criminal case, First person convicted as a result of DNA evidence

**1988 -1989**

First TWGDAM Meeting held at Quantico, VA, People v. Castro, TWGDAM Guidelines, *State v. Schwartz*, NY Report, CLIA

**1990 -1991**

US v. Yee, OTA Report, Revised TWGDAM Guidelines, Ass. Zaleski bill on DNA

**1992**  
NRC 1

**1994 - 1995**

Federal DNA Identification Act, DNA Advisory Board

**1996**  
NRC 2

**1998 -1999**

QAS for Forensic DNA Testing Laboratories, NDIS, QAS for Convicted Offender DNA Databasing Laboratories

**2000**

DAB designates SWGDAM to recommend revisions to QAS



# Technical Working Group on DNA Analysis Methods

- In November 1988, TWGDAM held its first meeting at the FBI Academy
  - 31 scientists representing 16 forensic laboratories in the U.S. and Canada and 2 research institutions
  - 1<sup>st</sup> SWGDAM Chair was James J. Kearney, Chief of the Forensic Science Research and Training Center at the FBI Laboratory



# Technical Working Group on DNA Analysis Methods

## Purpose

- “To pull together a select number of individuals from the forensic science community who are actively pursuing the various DNA analysis methods
- To discuss the methods now being used
- To compare the work that has been done
- To share protocols
- To establish guidelines where appropriate”



# Technical Working Group on DNA Analysis Methods

- At the first meeting, a subcommittee was established to formulate suggested guidelines for a QA program in crime laboratories conducting RFLP DNA analysis
- Chaired by James Mudd, the group developed guidelines “intended to serve only as a guide to laboratory managers in establishing their own QA program for DNA RFLP analysis.”



# Technical Working Group on DNA Analysis Methods

- Published in the Crime Laboratory Digest April-July 1989 issue, the QA guidelines “were designed using established quality functions to follow systematically the DNA RFLP typing procedure and cover all significant aspects of the laboratory process. In addition, they provide the necessary documentation to ensure that the DNA analysis process is operating within the established performance criteria, and they provide a measure of the overall quality of the results.”



# Technical Working Group on DNA Analysis Methods

## The Introduction to the 1989 Guidelines:

- “With the advent of DNA typing technology in the forensic laboratory, the forensic examiner now has the potential to individualize various body fluids and tissues. In addition, since the tests performed by crime laboratories can have a significant impact on the outcome of a trial, it is important that any test procedure used by the laboratory possess a high degree of accuracy and reproducibility. Consequently, the use of appropriate standards and controls is essential in order to ensure reliable results.
- As any technology becomes more discriminating and practiced, it is essential that the quality of the analytical data be more closely monitored. A detailed and flexible quality assurance program can assist in establishing a basis for scientifically sound and reliable forensic analysis.”



# Technical Working Group on DNA Analysis Methods

The 1989 Guidelines covered the following areas:

- Planning and Organization
- Personnel
- Documentation
- Validation
- Equipment, Materials and Facilities
- Evidence Handling Procedures
- Analytical Procedures
- Case Work Documentation, Interpretation, Report Writing and Review
- Proficiency Testing
- Audits
- Safety



# Technical Working Group on DNA Analysis Methods

- The 1989 Guidelines were supplemented in 1990 with the “Guidelines for a Proficiency Testing Program for DNA Restriction Fragment Length Polymorphism Analysis”
- In 1991, the revised and expanded “Guidelines for a Quality Assurance Program for DNA Analysis” were jointly prepared by TWGDAM and the California Association of Criminalists Ad Hoc Committee on DNA Quality Assurance



# DNA: Report of the New York State Forensic DNA Analysis Panel

- The Panel concluded that “Questions about the quality of the work being done by private laboratories have not been satisfactorily answered, and the laboratories’ adherence to accepted scientific procedures has not been demonstrated.”
- The Panel endorsed the development of national standards:  
“The creation of national standards would enable one state to search the databases of every other jurisdiction. Further, by establishing national standards against which to measure laboratories’ performances, the important goal of ensuring that appropriate quality controls are observed by laboratories would be furthered.”



# Genetic Witness: Forensic Uses of DNA Tests

- “Another nonregulatory Federal initiative presently under way is the FBI’s Technical Working Group on DNA Analysis Methods (TWGDAM), which among other issues is examining quality assurance, population statistics, and databanking. Consisting of representatives of crime laboratories at or near implementation of DNA profiling techniques, as well as of commercial laboratories, TWGDAM has been praised by some as the nucleus around which national expertise will develop. Other have criticized it for being generally closed—by invitation only—in its early stages of decision making. Some, both within and outside the forensic science community, are bothered that any largely investigative and enforcement body serve as the lead player in developing standards in which it has a vested interest. For many, TWGDAM represents the first step in a probable multistage process that will unfold as efforts to ensure the quality of forensic applications of DNA typing develop.”



# DNA Technology in Forensic Science (NRC 1)

## On Standards

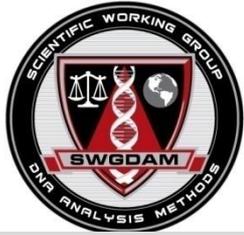
- “Quality assurance can best be described as a documented system of activities or processes for the effective monitoring and verification of the quality of a work product (in this case, laboratory results). A comprehensive quality-assurance program must include elements that address **education, training, and certification of personnel; specification and calibration of equipment and reagents; documentation and validation of analytical methods; use of appropriate standards and controls; sample handling procedures; proficiency testing; data interpretation and reporting; internal and external audits of all of the above; and corrective actions** to address deficiencies and weigh their importance for laboratory competence.



# DNA Technology in Forensic Science (NRC 1)

## Recommendations

- “Each forensic-science laboratory engaged in DNA typing must have a formal, detailed quality-assurance and quality-control program to monitor work, on both an individual and a laboratory-wide basis.
- The Technical Working Group on DNA Analysis and (sic) Methods (TWGDAM) guidelines for a quality-assurance program for DNA RFLP analysis are an excellent starting point for a quality-assurance program, which should be supplemented by the additional technical recommendations of this committee.
- The TWGDAM group should continue to function, playing a complementary role to that of the National Committee on Forensic DNA Typing (NCFDT). To increase its effectiveness, TWGDAM should include additional technical experts from outside the forensic community who are not closely tied to any forensic laboratory.”



# Federal DNA Identification Act

## House Report 103-45 (1993)

- “The purpose of the DNA Identification Act of 1993 is to promote the use of DNA identification technology for law enforcement purposes, in accordance with appropriate quality control and privacy standards.”
- “The NRC recommended a comprehensive quality assurance program. It found that the TWGDAM guidelines are an excellent starting point, and it noted the importance of professional societies such as ASCLD. The NRC went on to recommend that the Federal Government establish a mandatory accreditation program for laboratories, to be developed and administered by the Department of Health and Human Services in consultation with the Department of Justice....”
- “The DNA Identification Act does not mandate accreditation. Nor does it follow the NRC’s recommendation that the advisory committee be convened under the auspices of an agency not related to law enforcement. **However, the Committee intends to monitor closely the FBI’s DNA program and the deliberation of the DNA advisory policy board, in the event that further legislation is necessary to ensure high standards in forensic DNA analysis.**”



# Federal DNA Identification Act

## Section 14131 . Quality assurance and proficiency testing standards

- Not later than 180 days after September 13, 1994, the
- The FBI Director shall appoint an advisory board on DNA quality assurance methods from among nominations proposed by the head of the National Academy of Sciences and professional societies of crime laboratory officials.
  - The advisory board shall include as members scientists from State, local, and private forensic laboratories, molecular geneticists and population geneticists not affiliated with a forensic laboratory, and a representative from the National Institute of Standards and Technology.
- The advisory board shall develop, and if appropriate, periodically revise, recommended standards for quality assurance, including standards for testing the proficiency of forensic laboratories, and forensic analysts, in conducting analyses of DNA.



# Federal DNA Identification Act

## Section 14131 . Quality assurance and proficiency testing standards

- The FBI Director, after taking into consideration such recommended standards, shall issue (and revise from time to time) standards for quality assurance, including standards for testing the proficiency of forensic laboratories, and forensic analysts, in conducting analyses of DNA.
- The standards described in paragraphs (1) and (2) shall specify criteria for quality assurance and proficiency tests to be applied to the various types of DNA analyses used by forensic laboratories. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory is performing acceptably.
- Until such time as the advisory board has made recommendations to the FBI Director and the Director has acted upon those recommendations, the quality assurance guidelines adopted by the technical working group on DNA analysis methods shall be deemed the Director's standards for purposes of this section.



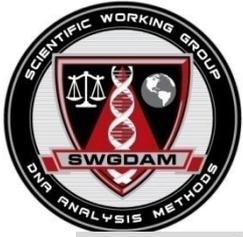
# Federal DNA Identification Act

- Federal DNA Advisory Board empaneled and first meeting held in May 1995
- Board developed draft standards over the next two years; public comment at a Board meeting held at American Academy of Forensic Sciences Meeting in February 1997
- Recommendation of quality assurance standards for forensic and convicted offender DNA databasing laboratories to the FBI Director



# Quality Assurance Standards

- Issuance of FBI Director's *Quality Assurance Standards for Forensic DNA Testing Laboratories* effective October 1, 1998
- Issuance of FBI Director's *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories* effective April 1, 1999



# Quality Assurance Standards

- Addressed the following
  - Definitions
  - QA Program
  - Organization & Management
  - Personnel
  - Facilities
  - Evidence Control
  - Validation
  - Analytical Procedures
  - Equipment Calibration & Maintenance
  - Reports
  - Review
  - Proficiency Testing
  - Corrective Action
  - Audits
  - Safety
  - Outsourcing



# SWGDAM

- Federal DNA Advisory Board's term ended in December 2000 and at that time, it designated the Scientific Working Group on DNA Analysis Methods (SWGDAM) with recommending revisions to the Standards to the FBI Director.



# QAS Audit Document

- Collaborative effort between ASCLD/LAB and NFSTC
- Presented to the Federal DNA Advisory Board
- Issued as the FBI Audit Document in October 2000 (Revision 5 reflecting the number of revisions since initial draft/development)
- Covered both Forensic and Convicted Offender Databasing Standards



# QAS Audit Document

- FBI to develop and sponsor auditor training on the QAS Audit Document
- FBI trained over 800 Federal, State and Local personnel over a period of 6 years
- Auditor training session for State CODIS Administrators in September 2006 in Scottsdale, AZ



# Review of External QAS Audits

- Effective January 1, 2002
- In response to a finding by the Office of Inspector General (June, 2001) that the self-certification of compliance with the FBI Director's QAS was insufficient to ensure that audit findings, if any, were appropriately resolved, the FBI Laboratory developed a program to review the external QAS audits of NDIS Participating Laboratories.
- Therefore, to fulfill its obligations under the DNA Identification Act of 1994, the FBI Laboratory will review the external QAS audits of NDIS Participating Laboratories to evaluate any findings and determine if further action is warranted.



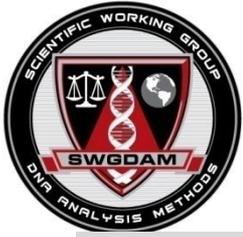
# Review of External QAS Audits

- Chaired by a designated FBI representative (rep), External Audit Review Panels consisting of 2 FBI reps and 2 State/Local reps review external QAS audits of NDIS Participating Laboratories that have findings to ensure the findings and corrective action are appropriate
  - If appropriate, audit closed
  - If any issue or concern, additional information requested or presentation to NDIS Procedures Board for recommendation/resolution
  - Opportunity for appeal to FBI Deputy Assistant Director of the Laboratory



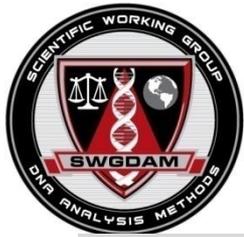
# Audit Document Revision #1

- 1<sup>st</sup> revision to QAS Audit Document issued in July 1, 2004
- Federal DNA Identification Act amended to replace “every 180 days” with semi-annual proficiency testing requirement so revision needed to address change in Federal law
- Revisions made to the discussion sections for clarification of existing interpretations, such as the outsourcing Standard (100% technical review)



# June 2005 SWGDAM Meeting

- The U. S. Department of Justice, the FBI and the National Institute of Justice were meeting on the FBI Director's Quality Assurance Standards as a result of concerns by some in the CODIS community that the FBI QAS (specifically Standard 17) were too stringent.
- FBI Laboratory Director Dwight Adams requested SWGDAM's position on the following issues:
  - Should private contract laboratories have direct access to upload DNA data to CODIS?
  - What level of quality review is necessary to upload DNA data to CODIS?



# June 2005 SWGDAM Meeting

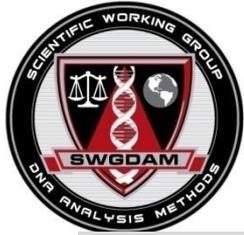
- SWGDAM responded to Dr. Adams with its position that:
- Direct access to CODIS must remain solely with law enforcement forensic DNA laboratories; and
- 100% of outsourced DNA data must be technically reviewed by the NDIS Participating Laboratory prior to CODIS entry in accordance with the NDIS Procedures.



# QAS Revision #1

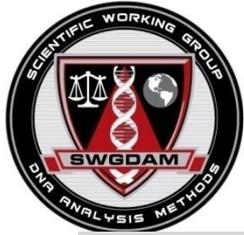
Two year effort under SWGDAM Chair David Coffman

- January 2006 – 1<sup>st</sup> draft of revisions to the Forensic QAS was presented to the SWGDAM membership (Standard 17 revised)
- Review of Forensic QAS revisions at SWGDAM Public Meeting held in conjunction with Annual CODIS Conference
- January 2007 – Discussion of revisions to Databasing QAS at SWGDAM



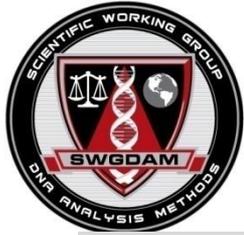
# QAS Revision #1

- March – May, 2007 – Public Comment period on Forensic QAS
- November, 2007 - Review of Databasing QAS revisions at SWGDAM Public Meeting at Annual CODIS Conference in San Francisco
- SWGDAM recommended revised QAS to FBI Director
- July 2008 – Revised Forensic and Databasing QAS approved by FBI Director to take effect July 1, 2009



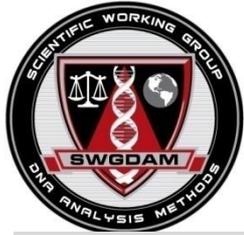
# QAS Revision #1

- Substantial revisions to original QAS (Highlights)
  - Added many new definitions
    - Analyst
    - Employee
    - Laboratory
    - Methodology
    - Technology
  - Contingency Plan if Technical Leader position vacated
  - NEW CODIS Administrator and casework CODIS Administrator position descriptions with education, experience, responsibilities requirements



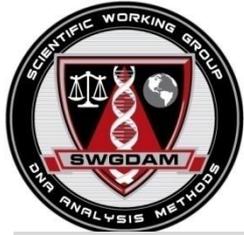
# QAS Revision #1

- Substantial revisions to original QAS (Highlights)
  - Technical Leader education, experience, training and responsibilities clarified
  - Analyst education and experience clarified
  - Developmental and internal validation clarified
  - Clarified use of positive and negative amplification controls, reagent blank controls
  - Require procedure for mixture interpretation
  - Allow use of Expert System for data interpretation
  - Confidentiality of reports, case files and DNA records



# QAS Revision #1

- Substantial revisions to original QAS (Highlights)
  - Clarified and new requirements for technical reviews
    - Technical reviewer qualifications
    - Describes the elements of technical and administrative reviews
  - Clarified proficiency testing in technology performed; recognizes team approach
  - Approval of personnel for 2 successive external audits; Approval of validation studies for 1 external audit



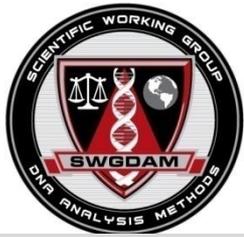
# QAS Revision #1

- Substantial revisions to original QAS (Highlights)
  - Outsourcing clarified and new requirements
    - Described ownership concept
    - Technical Leader approval of technical specification of outsourcing agreement/acceptance of ownership
    - Technical review by qualified analyst or technical reviewer prior to upload or searching
    - Technical review described/defined
    - On-site visit requirements described/defined



# Audit Document Revision #2

- Effective with the July 2009 Audit Documents and for audits conducted in accordance with the Quality Assurance Standards effective July 1, 2009, **separate** Audit Documents will be used for forensic and databasing laboratories. If a laboratory performs both functions, each Audit Document must be completed and submitted to the laboratory at the conclusion of the audit process.



# NDIS Enhancement Efforts

## March 23, 2010 Press Release “ FBI Laboratory Seeks to Enhance the Efficiency of the National DNA Index System”

“In order to enhance the efficiency of the nation’s DNA database, also known as the National DNA Index System (NDIS), the FBI has established an ongoing dialogue with various groups to gain a broader perspective and better understand the needs of the entire law enforcement community. Those groups include the American Society of Crime Laboratory Directors (ASCLD), the Scientific Working Group on DNA Analysis Methods (SWGAM), CODIS State Administrators, the Police Executive Research Forum (PERF), the International Association of Chiefs of Police (IACP), and various federal, state, local, and tribal agencies. The FBI is committed to seeking common ground in the interest of protecting the public, reducing backlogs, ensuring privacy, and maintaining the integrity of the National DNA database.

Many public law enforcement agencies collaborate with private laboratories for analysis of their DNA samples. The FBI Laboratory is currently re-evaluating existing policies, standards, and protocols, including requirements for outsourcing DNA analysis to private laboratories and review of their results by public law enforcement laboratories. Private laboratories continue to be an integral part of the process and share in the success of NDIS. The current policy assessment will focus on these contributions and will engage both public and private laboratories.

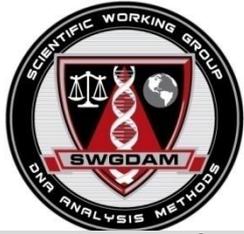
The administration and operation of the National DNA database is an inherently governmental function that supports criminal investigations conducted by our federal, state, local, and tribal law enforcement partners. Therefore, the FBI’s assessment does not include re-evaluating access to NDIS. Necessary improvements can be gained by enhancing the efficiency of NDIS procedures.

DNA analysis and, by extension, DNA databases, have proven to be invaluable to the law enforcement community and to victims of violent crimes and their families. Since more violent crimes are solved as more records are placed into the database, enhancing the operational procedures for optimal efficiency of NDIS is imperative.”



# QAS Revision #2

- The FBI received comments and suggestions from its stakeholders (ASCLD, CODIS State Administrators, NDIS Laboratories, Law Enforcement Agencies, and Congressional Representatives) that offer States additional flexibility in performing the required technical review.
- These comments/suggestions were shared with SWGDAM which had been working on revisions to the Quality Assurance Standards to provide additional flexibility in the Standard 17 review process.
- These draft revisions were presented to the public at the 2010 Annual CODIS Conference where the public and CODIS community were encouraged to share their comments and additional suggestions.
- SWGDAM voted to recommend minor revisions to the Quality Assurance Standards to the FBI Director.
- The FBI provided a public comment period (February – March 2011) on the proposed revisions.



# QAS Revision #2

- Less than 1 year under direction of SWGDAM Chair Ted Staples and CODIS Unit Chief Jennifer Wendel
- Minor revisions to the QAS effective September 1, 2011 provided additional flexibility in data processing, analysis and technical review.
  - Revised Standards 17.3 and 17.5 to remove the references to searching the DNA data in Standard 17.3 and thus facilitate, at a State's discretion, the searching of outsourced DNA data at the State level (SDIS) provided that the specimen eligibility and correct specimen category have been confirmed by the laboratory.
  - Added a new definition for contract employee that would authorize contractors to serve as analysts, technical reviewers, technicians, and laboratory support personnel contingent on the contract employee satisfying QAS qualifications and disclosure/approval of any additional employment by the contract employee to the laboratory's Technical Leader. These contract employees cannot, however, fill the positions of Technical Leader or CODIS Administrator.
  - Minor revisions to Standard 17 provided additional options for NDIS laboratories by authorizing the use of an on-site visit conducted by another NDIS laboratory or by designated FBI personnel to satisfy the requirement for an initial on-site visit. The revisions also clarify that an on-site visit is NOT required when only technical review services are being provided.



# Audit Document Revision #3

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## Laboratory Services

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### Combined DNA Index System (CODIS)

**Mission**

The CODIS Unit manages the Combined DNA Index System (CODIS) and the National DNA Index System (NDIS) and is responsible for developing, providing, and supporting the CODIS Program to federal, state, and local crime laboratories in the United States and selected international law enforcement crime laboratories to foster the exchange and comparison of forensic DNA evidence from violent crime investigations. The CODIS Unit also provides administrative management and support to the FBI for various advisory boards, Department of Justice (DOJ) grant programs, and legislation regarding DNA.

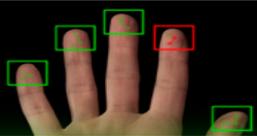
**The Team**

Program manager, forensics system program managers, biologist, auditors, management and program analysts, and paralegal specialists.

**The Work**

See below for more information.

- CODIS and NDIS Fact Sheet
- Rapid DNA Analysis
- Familial Searching
- Missing Person Comparison Request
- Planned Process and Timeline for Implementation of Additional CODIS Core Loci
- NDIS Statistics
- NDIS Operational Procedures Manual
- Crime
- The Future
- Quality Assurance
  - QAS Revisions Effective September 1, 2011:
    - Summary of new QAS revisions effective 9-1-2011
    - Quality Assurance Standards for Forensic DNA Testing Laboratories effective 9-1-2011
    - Summary of new Database QAS revisions effective 9-1-2011
    - Quality Assurance Standards for DNA Databasing Laboratories effective 9-1-2011
    - Audit Document for Forensic QAS effective 9-1-2011
    - Audit Document for Database QAS effective 9-1-2011
  - Rapid DNA QAS Addenda Effective December 1, 2014
    - Summary of Rapid DNA Addenda effective 12-1-2014
    - Rapid DNA Addendum to QAS effective 12-1-2014
    - Audit Document for Rapid DNA QAS Addendum 12-1-14
- SWGDAM Interpretation Guidelines for Autosomal STR Typing by DNA Testing Forensic Laboratories
- CODIS Brochure
- DNA Fingerprint Act of 2005, Expungement Policy
- Amended 1999/2001 FBI STR Population Datasets
- Expanded 2015 FBI STR Population Datasets



**Biometric Analysis**

- Combined DNA Index System (CODIS)
- DNA Casework
- Federal DNA Database
- Latent Print

**Forensic Response**

- Chemical, Biological, Radiological, & Nuclear Sciences
- Crime Scene Documentation
- Evidence Response Team
- Forensic Imaging
- Hazardous Evidence Response
- Operational Projects
- Scientific Response
- Technical Hazards Response

**Scientific Analysis**

- Chemistry
- Counterterrorism & Forensic Science Research
- Cryptanalysis & Racketeering
- Firearms/Toolmarks
- Questioned Documents
- Trace Evidence

**Terrorist Explosive Device Analytical Center (TEDAC)**

- Explosives

**More About Us**

- Laboratory Annual Report
- Forensic Services Handbook (pdf)
- Quick Reference Guide (pdf)
- Forensic Science Communication
- Scientific Working Groups
- News and Features
- Laboratory Positions
- Visiting Scientist Program

**BIOMETRIC ANALYSIS**





# Rapid DNA Technology

- SWGDAM empaneled first a Working Group (January 2011) and then a Committee (July 2011) to identify, evaluate, and research issues relating to Rapid DNA technology. The Committee is tasked with the following:
  - Generate and review performance data using Rapid DNA instruments and make regular reports to the SWGDAM Membership
  - Receive and respond to inquiries made by Rapid DNA developers as detailed in the SWGDAM Open Letter dated February 15, 2013.
  - **Review and, as necessary, recommend revisions to the FBI's Quality Assurance Standards (QAS) for the use of Rapid DNA typing by forensic DNA testing laboratories.**
  - Review and, as necessary, recommend revisions to the NDIS Operational Procedures Manual for the interpretation of DNA records generated by Rapid DNA and will provide its recommendations to the NDIS Procedures Board.



# QAS Addendum on Rapid DNA

- SWGDAM Rapid DNA Committee, in conjunction with the QA Committee recommended Addenda to the current Databasing Quality Assurance Standards and Audit Document on Rapid DNA.
- The Rapid DNA Addendum was approved by the SWGDAM membership at the July 2014 meeting and posted for 30 day public comment period. The CODIS community and accrediting agencies were notified of the public comment.
- Following the public comment period, additional minor revisions were incorporated to address the comments and the final Addenda were presented to the SWGDAM Executive Board who recommended the Addenda for transmittal to the FBI Laboratory Director for consideration.



# QAS Addendum on Rapid DNA

- Approved by the FBI Director to take effect on December 1, 2014, the Addenda on Rapid DNA for the Databasing QAS provide for the following:
- New definitions for
  - Cartridge lot number
  - Modified Rapid DNA analysis
  - Negative sample control
  - Positive sample control
  - Rapid DNA analysis
  - Rapid DNA cartridge
  - Rapid DNA instrument
  - Reference samples
- Two new standards added to Standard 5 to require that analysts and technicians have documented training for operating the Rapid DNA instrument and that their successful completion of a competency test is documented prior to their independent operation of a Rapid DNA instrument.
- Clarified that Standard 6.1.4 is not applicable to a Rapid DNA instrument. New standards added to authorize the use of a Rapid DNA instrument for processing reference samples if validated in accordance with Standard 8; such analysis must be performed in a pre-amplification room.
- Clarified that Standards 9.5.1, 9.5.2 and 9.5.3 are not required for a Rapid DNA instrument. New standards added to: include a Rapid DNA cartridge as a critical reagent; require an annual check of the procedures against an appropriate NIST standard; to require documented procedures for the use of positive and negative sample controls for Rapid DNA instruments, including Internal Lane Standards (ILS) and allelic ladders. Standards have been added for Modified Rapid DNA analysis: to require verification of the ILS and allelic ladder; and perform manual interpretation of the data.



# QAS Addendum on Rapid DNA

- The Addenda on Rapid DNA for the Databasing QAS provide for the following:
  - Clarified that Standards 10.2.1 through 10.2.1.8 and 10.4.1.1 through 10.4.1.5 are not applicable to a Rapid DNA instrument. New standards added to include a Rapid DNA instrument as critical equipment requiring a quarterly recertification and/or performance check, recertification and/or performance check following repair, service or calibration, or if the instrument remains idle longer than recommended instrument specifications or a period established by the laboratory.
  - New standards added to Standard 12 to allow the review of DNA types by an internally validated Rapid DNA instrument that uses an NDIS-approved expert system; and that the review include all controls, Internal Lane Standards and allelic ladders. Added a standard to require a manual technical review of the data for Modified Rapid DNA analysis.
  - Added new standard to Standard 13 to require that analysts or technical reviewers that perform Modified Rapid DNA analysis be proficiency tested on the interpretation of data generated by a Rapid DNA instrument at least once per year.
  - Added new standards to Standard 17 to require that a vendor laboratory using a Rapid DNA instrument with an approved STR typing kit and NDIS–approved and internally validated expert system verify the correct specimen category as part of the technical review; that a technical review include, for Modified Rapid DNA analysis, a review of all notes, worksheets and the electronic data supporting the results; and that a technical review include, if using a Rapid DNA instrument, a review of the data associated with applicable performance checks.



# Audit Document Addendum

- This Addendum shall be completed in addition to the FBI Quality Assurance Standards Audit documents for laboratories performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument. This addendum is not required for laboratories not performing Rapid DNA analysis or modified Rapid DNA analysis using a Rapid DNA instrument.



# QAS Revision #3

- SWGDAM community invited to provide comments and suggested wording for revisions to the QAS prior to the July 2015 meeting.
- More to come.....