

2011 SWGDAM Public Meeting



17th Annual CODIS Conference



About Us



Responsibilities

- (1) to recommend revisions, as necessary, to the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the *Quality Assurance Standards for DNA Databasing Laboratories*;
- (2) to serve as a forum to discuss, share, and evaluate forensic biology methods, protocols, training, and research to enhance forensic biology services; and
- (3) to recommend and conduct research to develop and/or validate forensic biology methods.



Organization

- Chair: **Anthony Onorato**
- Vice Chair: **Phil Kinsey**
- Executive Board: **Angelo Della Manna, Eric Pokorak, Peg Schwartz, Taylor Scott, and Gary Sims**
- Members are technical leaders, CODIS Administrators, or like scientists from local, state and federal crime laboratories
 - 22 Regular Members
 - 3 year membership term(s)
- Invited Guests may be invited to meetings and have full participatory privileges in Committee business
 - Over 20 routinely Invited Guests
 - 41 total Invited Guests to the July 2011 Meeting



Recent Meetings



SWGDAM 2011 Meetings

- Two SWGDAM Meetings held in 2011
 - January 11-13, 2011
 - July 12-14, 2011
- SWGDAM Public Meeting at 2011 Annual CODIS Conference on November 14, 2011 in Jacksonville, FL.



Winter 2011 Meeting

- Held in the Spotsylvania Conference Center on January 11 – 13, 2011.
- Weather wreaked havoc with attendee travel.
- Ted Staples of the Georgia Bureau of Investigation resigned as the SWGDAM Chair.
- Heather Seubert of the Federal Bureau of Investigation resigned as the SWGDAM Vice Chair.
- Tony Onorato of the Federal Bureau of Investigation was appointed SWGDAM Chair by the FBI Director (SWGDM Bylaws II.B.1).



Highlights Winter 2011

- International Barcode of Life (iBOL)
 - Robert Hanner of the International Barcode of Life presented on efforts to develop biological barcodes for the planets' 1.7 million species of plants and animals.
- Clopper and Pearson “Exact” Confidence Intervals
 - George Carmody explained and contrasted the various confidence interval approaches: Standard, Clopper-Pearson, Wilson, and Agresti-Couli.
- NDIS Enhancement Review
 - Jennifer Luttmann reviewed the status of the NDIS enhancement review process and proposed changes to the Quality Assurance Standards.



Highlights Winter 2011

- Expert System Mixture Tools
 - Three commercial entities: Applied Biosystems, Promega, and Cybergenetics, reviewed their systems for performing allele designations for casework. (A fourth, Armed Expert, was unable to attend due to travel difficulties).
- International Commission of Missing Persons
 - Thomas Parsons presented on the ongoing identification efforts in Haiti on the 1 year anniversary and on the establishment of the SWGDVI.
- Criminal Justice and Forensic Science Reform Act of 2011
 - Dawn Herkenham reviewed the provisions contained in Senator Leahy's draft legislative proposal.



Highlights Winter 2011

- International Production Standard for Consumables
 - Ingo Bastisch reviewed the European Network of Forensic Science Institutes' efforts for an international database for known contaminants and the development of production standards for consumables used in DNA testing.
- Centre of Forensic Sciences Update
 - Cecilia Hageman reviewed the Centre's plans for building a new facility and service expansion.
- Royal Canadian Mounted Police Update
 - Sylvain Lalonde provided a retrospective of the National DNA Databank in Canada on its tenth anniversary.



Highlights Winter 2011

- Rapid DNA Update
 - Thomas Callaghan provided an update on the Rapid DNA project which will provide the nation's law enforcement agencies the capability to collect and develop an arrested individual's DNA during the time it takes to process a subject at intake.
- The SWGDAM membership voted to approve the revisions to the "Forensic Quality Assurance Standards" (IV.C.5.a).
 - The revised "Forensic Quality Assurance Standards" have been approved by the FBI Director and will be effective September 1, 2011.



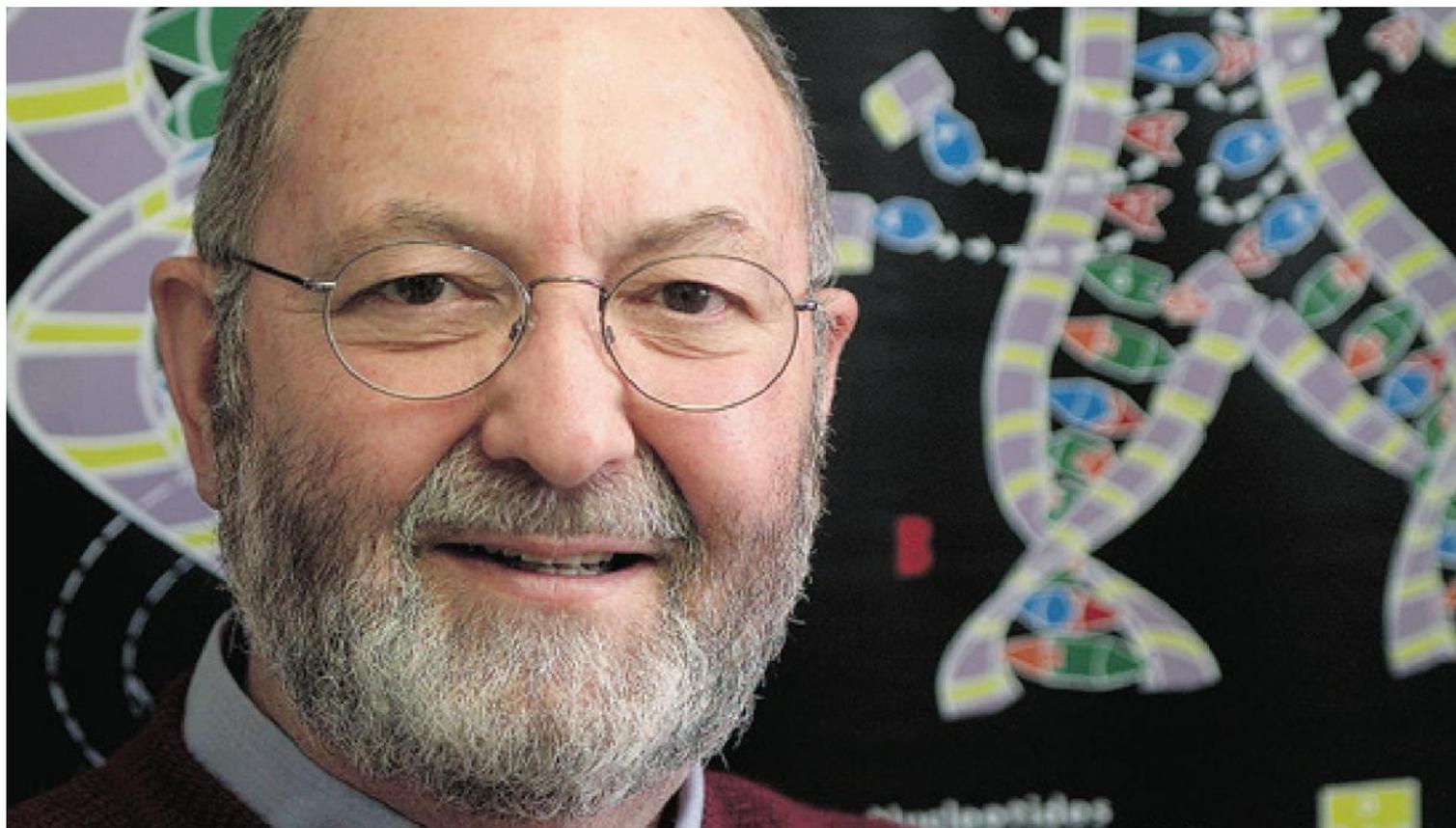
Summer 2011 Meeting

- **Dawn Herkenham** of SAIC was re-appointed to the Office of SWGDAM Executive Secretary (II.B.3).
- **Phil Kinsey** of the Montana Forensic Science Division was appointed to the Office of SWGDAM Vice Chair (II.B.2).
- **Angelo Della Manna, Eric Pokorak, Peg Schwartz, Taylor Scott, and Gary Sims** were selected by the SWGDAM membership to serve on the SWGDAM Executive Board (II.B.4).
- SWGDAM thanks out going EB member **Ken Konzak** for his 2 terms of service and counsel (II.B.4).



Summer 2011 Meeting

- Held in the Spotsylvania Conference Center on July 12 – 14, 2011.
- Weather much more cooperative but the temperatures and humidity were the highest of the Northern Virginia summer.
- 53 in attendance with 25 federal and 28 non-federal attendees.
- The first meeting with Tony Onorato of the Federal Bureau of Investigation serving as SWGDAM Chair (II.B.1).



We dedicated the Summer 2011 SWGDAM Meeting to the memory of our good friend and colleague, George Carmody.



Highlights Summer 2011

- Expert System Mixture Tool
 - USACIL presented on Armed Expert™, a system for performing allele designations for casework used in their laboratory.
- Consumable Contamination
 - Tamyra Moretti reviewed the circumstances surrounding the FBI's identification and mitigation of a contaminated consumable used in its nuclear DNA casework program.



Highlights Summer 2011

- Mitochondrial DNA Testing
 - Les McCurdy reviewed the contamination considerations in a forensic mitochondrial DNA Laboratory.
- Low Copy Number Testing
 - Eugene Lien reviewed the contamination considerations in a Laboratory performing LCN testing.
- GINA Act
 - Dawn Herkenham reviewed the specifics of the Genetic Information Nondiscrimination Act of 2008.



Highlights Summer 2011

- ISO Standard Development
 - Kermit Channell reviewed ASCLD's participation in the development of an ISO Standard for forensic consumables.
- Guideline Impact
 - Shawn Montpetit reviewed the experience of the SDPD Crime Laboratory in using the SWGDAM Interpretation Guidelines for Autosomal STR Testing (1/10).
- Subcommittee on Forensic Science
 - Ken Melson, Director of the Bureau of Alcohol, Tobacco, Firearms, and Explosives reviewed the progress of the Interagency Working Groups.



Winter 2012 Meeting

- To be held in the Northern Virginia area on January 17 – 19, 2012.
- Will generally be a working meeting for the various SWGDAM Committees.
- A joint session with the MS/mtDNA, Mass Disaster, and Mixture Committees will be held to discuss haplotype frequency estimation.



Recent Business



EXECUTIVE BOARD

- The Executive Board held teleconferences on April 7, 2011; May 5, 2011; and June 2, 2011.
- The EB currently has a standing teleconference scheduled for the first Thursday of the month at 2 pm ET.
- A personal “Thank You” to all of the SWGDAM Executive Board members for making my transition to the “Chair” a seamless one.



BUSINESS NOTES

- The SWGDAM EB accepted the report submitted by the Enhanced Detection Methods and Interpretation (EDMI) Committee clarifying the terms “Enhanced Detection Methods” and “Low Template or Low Copy DNA Analyses” and the Chair forwarded this report to the NDIS Board Chair for consideration (V.C.5.b).
 - At its June 14, 2011, the NDIS Procedures Board voted to maintain its current definition of LCN to avoid the potential for confusion based on the non-exclusive nature of these 2 definitions and to await SWGDAM’s recommendations for validation and interpretation of EDMs.

- The SWGDAM membership voted to approve the revisions to the “*Quality Assurance Standards for DNA Databasing Laboratories*” by electronic ballot (VII.D) and the Chair forwarded the recommended revisions to the FBI Director under cover of a letter dated May 25, 2011.
 - The revised “*Quality Assurance Standards for DNA Databasing Laboratories*” have been approved by the FBI Director and took effect September 1, 2011.



BUSINESS NOTES

- The SWGDAM membership voted to approve the revisions to the “*Forensic Quality Assurance Standards (QAS) Audit Document*” by electronic ballot (VII.D) and the Chair forwarded the recommended revisions to the FBI Director under cover of a letter dated June 16, 2011.
 - The revised “*Forensic Quality Assurance Standards (QAS) Audit Document*” has been approved by the FBI Director and took effect September 1, 2011.

- The SWGDAM membership voted to approve amendments to Sections I.A., II.C.1, II.C.2, and II.D, of the SWGDAM Bylaws as well as the insertion of a “*SWGDM Code of Ethics*” as a new Section IV at its July 2011 Regular Meeting (VII.C).



BUSINESS NOTES

- The SWGDAM membership voted to approve the “*SWGDM Ethical and Conflict of Interest Statement*” at its July 2011 Regular Meeting (V.C.5.a).
- The SWGDAM Chair, with the concurrence of the SWGDAM EB, re-empanelled and populated the QA Committee (V.A.1). This Committee met for business during the Committee Session on Wednesday, July 13, 2011 and selected Jodi Dahl and Beth Ann Marne as its Chair and Co-Chair, respectively (V.A.2).



BUSINESS NOTES

- The SWGDAM membership voted to approve the “*Databasing Quality Assurance Standards (QAS) Audit Document*” at its July 2011 Regular Meeting (V.C.5.a) and the Chair forwarded the recommended revisions to the FBI Director under cover of a letter dated July 20, 2011.
 - The revised “*FBI Quality Assurance Standards Audit for DNA Databasing Laboratories*” has been approved by the FBI Director and will be effective September 1, 2011



BUSINESS NOTES

- The SWGDAM Chair, with the concurrence of the SWGDAM EB, dissolved the Communication Committee (IV.C.6) and re-assigned its tasks to the SWGDAM Executive Board.
 - “Provide communication from SWGDAM based upon requests for information from the Interagency Working Groups, in addition to fostering improved communication and outreach to the DNA community.”
 - Regularly review SWGDAM guidance documents and make recommendations to the Chair for potential actions.
 - A major tasking of this group will be the development of a SWGDAM Internet site.



Membership



SWGDM Members

- Angelo Della Manna
- Ann Marie Gross
- Richard Guerrieri
- Bruce Heidebrecht
- Brian Hoey
- Phil Kinsey
- Ken Konzak
- George Li
- Eugene Lien
- Jennifer Luttmann
- Beth Ann Marne
- Cathy McCord
- Amy McGuckian
- Steven Myers
- Tony Onorato
- John Planz
- Eric Pokorak
- Peg Schwartz
- Taylor Scott
- Gary Sims
- John Tonkyn
- Russell Vossbrink

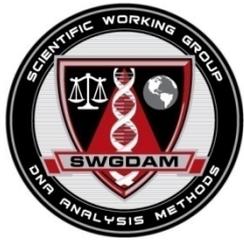


SWGAM

Committees and

Ad Hoc Working Group

Updates



SWGAM

CODIS Committee

Update



CODIS Committee

Mission:

“To identify, evaluate and research issues relating to the use of CODIS in federal, state and local forensic laboratories.”



CODIS Committee

Objectives:

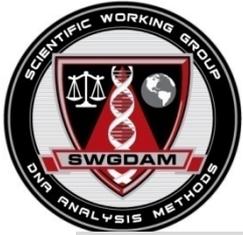
- If in the course of the review of such issues, the CODIS committee determines that revisions to the FBI Director's Quality Assurance Standards for Forensic DNA Testing Laboratories and Convicted Offender DNA Databasing Laboratories are needed, the committee shall recommend such changes to the Chair of SWGDAM for consideration by SWGDAM.
- If the CODIS committee is presented with issues relating to the operation of CODIS, such as software functionality and performance, the committee shall forward such issues and their findings/recommendations through the SWGDAM chair to the Chief of the CODIS Unit.
- The CODIS committee will review issues requested by the NDIS Procedures Board through the SWGDAM chair and will provide their findings and recommendations through the SWGDAM chair to the Board.



CODIS Committee

Tasks/objectives to accomplish:

- Evaluate/edit specimen category definitions for CODIS 7.0
- Evaluate/edit disposition definitions for CODIS 7.0
- Evaluate/edit hit counting definitions not captured in the above 2 bullets



CODIS Committee

- Analyze current NDIS searches and discuss other potential NDIS searches that can be done either on a routine or non-routine basis



CODIS Committee

Dispositions

Arrestee Hit

Benchmark Match

Candidate Match

Conviction Match

Detainee Hit

Duplicate

Duplicate Match

Forensic Hit

ID Confirmed

ID Pending

Insufficient Data

Investigative Information

Legal Index Hit

Maternal Relatives

No Match

No Profile

Offender Duplicate

Offender Hit

Pending

Pending Local Disposition

Paternal Relatives

Requesting More References

Siblings

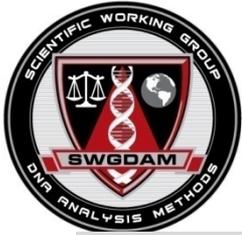
Twins

User Defined #1

User Defined #2

User Defined #3

Waiting for More Data



CODIS Committee

Specimen Categories

Alleged Father

Alleged Mother

Arrestee

Biological Child

Biological Father

Biological Mother

Biological Sibling

CO Duplicate

Convicted Offender

Deceased

Deduced Missing Person

Deduced Suspect

Detainee

Elimination, Known

Forensic Mixture

Forensic, Unknown

Juvenile

Legal

Maternal Relative

Missing Person

Other

Paternal Relative

Population

Proficiency

Spouse

Staff

Suspect, Known

Unidentified Person

Unreviewed Offender

Victim, Known

Volunteer



CODIS Committee

Other Hit Counting Definitions

Association

Casework Laboratory

Forensic Sample

Hit

Investigation Aided

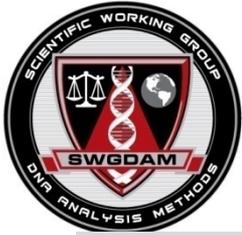
Match

Offender Laboratory

Qualified DNA Analyst

Source ID

Unsolved Case



CODIS Committee

Future Tasks

- Finish Definitions via web meetings in August and September
- Discuss non-routine searches via web meetings



CODIS Committee

Committee Point of Contact:

Committee Chair:

Douglas Hares

703-632-8315

douglas.hares@ic.fbi.gov

Committee Co-Chair:

Cathy McCord

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SWGDM

Enhanced Detection

Methods and

Interpretation Committee

Update



EDMI Committee Mission

- To write interpretation and validation procedures for Enhanced Detection Methods, including Low Template DNA Analysis.



Recap from before

- After the January 2011 SWGDAM Meeting, the EDM I Committee submitted two (2) definitions to the Executive Board for its consideration for submittal to the NDIS Board.



Submitted Definitions

Enhanced Detection Methods are those employed during or subsequent to the STR amplification step that increase the sensitivity of analysis and are typically employed with low quantity and/or low quality samples. These methods include, but are not limited to, increased cycle number, increased injection time, and post-amplification purification. When using enhanced detection methods, the potential for stochastic effects (i.e., higher stutter, allele drop-out, and intra-locus peak imbalance) may increase. Stochastic effects can be addressed through appropriate interpretation guidelines and relevant thresholds (e.g., an increased injection time may require the adjustment of the stochastic threshold). Therefore, prior to any enhanced detection protocol being employed, which may include one or more enhanced detection methods, appropriate validations must be performed to address the potential increase in stochastic effects. Appropriate validations shall include assessments of stutter percentages, peak-height ratios, stochastic thresholds, locus-to-locus balances, and the potential for non-reproducible alleles.



Submitted Definitions

Low Template or Low Copy DNA Analyses are types of Enhanced Detection Methods that, in addition to the increased potential for stochastic effects, have an increased potential for non-reproducible alleles. Reproducible alleles shall only be confirmed through replicate analysis.



Result

- At its June 14, 2011 meeting, the NDIS Board voted to maintain its current definition of LCN to avoid the potential for confusion based on the non-exclusive nature of these 2 definitions and to await SWGDAM's recommendations for validation and interpretation of EDMs.



Problem!

- How can we write validation and interpretation procedures for Enhanced Detection Methods and Low Template DNA Analysis if the Revised Validation Guidelines are outdated (issued July 10, 2003)?



EDM Committee Agenda

- Revise the SWGDAM Revised Validation Guidelines



Revision Plan

- The old Guidelines were kept very general.
 - Idea is to revise it now in a general sense.
 - Will explore adding specifics afterwards.
- Updated the Guidelines to be consistent with the current FBI DNA Quality Assurance Standards
 - Looked at the Audit Document for guidance. Even took definitions from it (verbatim).
 - If not in the QAS, consulted with NIST presentations and went to the drawing board.



Next Step – Add Some Specifics

- Old Guidelines indicated “at least 50 samples” for Internal Validations and listed all the possible studies that may need to be performed (sensitivity, reproducibility, etc.)
- Problem: if you’re validating a procedure that doesn’t require mixture studies, then the other studies will need more samples to make it “at least 50 samples.”
- Solution: Will break down the number of samples according to the study conducted.



Next Step – Add More Specifics

- Will make recommendations for different types of validations (extraction, quantitation, amplification, instrument, analysis software, technology, etc).
- For example, which studies must you perform if you are to validate a new extraction procedure?
- Hope to accomplish these “next steps” through teleconferencing by the next meeting.



EDM Committee

Committee Points of Contacts:

Eugene Lien (Chair)

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Brian Hoey (Co-Chair)

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Brian.Hoey@mshp.dps.mo.gov



SWGAM

Mass Spectrometry/ MtDNA Committee

Update



Mass Spec/MtDNA Committee

- Goals & Objectives
 - Selection of chair and co-chair
 - Revise the 2003 SWGDAM mtDNA sequence interpretation guidelines
 - Review the 2004 SWGDAM validation guidelines to provide mito specific recommendations
 - Discuss recent modifications to mtDNA population database with MP/MD subgroup
 - Clopper Pearson



Mass Spec/MtDNA Committee

2003 SWGDAM mtDNA interpretation guidelines

- Section by section review & discussion
- Assignment of responsibilities and timeline
- Goal of having all reviews & approvals achieved prior to Jan 2012 mtg



Mass Spec/MtDNA Committee

2004 SWGDAM validation guidelines

- focus on internal validation
 - 3.1 - 3.6
- Can provide mito-centric wording to fit within overall general DNA validation guidelines (when ready)



Mass Spec/MtDNA Committee

Interaction with MP/MD sub-group

- Recent population database quality review
 - Susan Cropp
 - susan.cropp@ic.fbi.gov
 - 703-632-7591
- Any impact on missing person operations within CODIS?



Mass Spec/MtDNA Committee

Clopper Pearson

- Comparison of estimates derived from normal & binomial distributions
- Project population group sizes for future targeting
- Appropriate tool for skewed mtDNA data distribution
- 1-tailed or 2?
 - Precedence for 1-tailed test
 - Will determine best approach for mito purposes & contribute to consensus message along with Y and MP/MD



Contact Info

- Les McCurdy
 - 703-632-7601
 - leslie.mccurdy@ic.fbi.gov



SWGDM

Missing Persons – Mass

Disaster Committee

Update



Missing Persons - Mass Disaster Committee

- SWGDVI Update (Parsons)
- Parallels between molecular biology committee of SWGDVI and MP-MD committee were discussed, as well as possible collaborations



Missing Persons - Mass Disaster Committee

- Committee members developed and delivered an introductory training block on Missing Persons processes at the Fall 2010 National CODIS Conference in Salt Lake City UT
- Additional training will be presented at the National CODIS Conference in Jacksonville FL in November 2011



Missing Persons - Mass Disaster Committee

- Discussion focused on outline of presentation:
“You have a rank – now what?”
 - Types of searches – Identity and Pedigree Tree
 - JPLR – how to interpret
 - Evaluating genetic data – what else is needed?
 - Metadata and its use in assessing search results
 - Interlab communication
 - Communicating with submitting agencies
 - Dispositions



Missing Persons - Mass Disaster Committee

- Based on 2010 CODIS Conference Training, “Guidelines” document to aid laboratories is being developed



Missing Persons- Mass Disaster Committee

Document 1: Sample procedures (Reference sample vs. Remains), Metadata, Client/Lab communications and resources

Document 2: Missing persons searches, Search statistics, association management and dispositions

Document 3: Missing persons reporting, Pedigree statistics, Information release



Missing Persons- Mass Disaster Committee

Joint Meeting with Mass Spec/mtDNA Committee

- Discussed reduction in size of mtDNA population database and how it impacts search and reporting statistics
- Discussed efforts to increase population databases and coverage of entire control region (not just HVI/HVII)
- Discussed Clopper-Pearson statistic and development of guideline document for use with both Y-STRs and mtDNA



Contact Info

- John C. Tonkyn
(510) 620-3315 (office)
john.tonkyn@doj.ca.gov



SWGAM

Mixture Committee

Update



Mixture Committee

Goals & Objectives

- Help the community to better understand and implement the SWGDAM Autosomal STR Interpretation Guidelines (and revise as needed)
 - Request for training at Public SWGDAM (Nov 2010)
- Provide guidance and examples on
 - Report wording
 - Setting and using analytical & stochastic thresholds
 - Validating mixture interpretation software



Mixture Committee

Completed this meeting

- **Reviewed recent training materials & workshops on mixtures**
 - Experiences and questions raised at 12 workshops
 - AAFS 2011 workshop, lectures to labs (AZ, FL, IN, LA, MI, OK, TX)
 - **Bruce Heidebrecht (voice-over slides) – intended for SWGDAM website**
- **Report writing examples were reviewed**
 - Examples to be further refined **for eventual inclusion on SWGDAM website**
- **Discussed setting and using thresholds**
 - Discussed how labs are setting and using thresholds
 - Reviewed NIST data on 3500 validation of analytical and stochastic thresholds
- **Discussed mixture interpretation software**
 - New York State Police validation experiments with TrueAllele
 - Massachusetts State Police studies with TrueAllele



Training Materials

- Discussed bad practices to avoid and core principles that need to be understood
- Some mixture training material on STRBase:
 - <http://www.cstl.nist.gov/biotech/strbase/mixture.htm>
- Promega meeting workshop – October 3, 2011
 - FREE to state & local labs through an NIJ grant to Boston University
 - Being restructured compared to last year's workshop



President John F. Kennedy

Yale University commencement address (June 11, 1962)

“For the greatest enemy of truth is very often not the lie – deliberate, contrived and dishonest – but the myth – persistent, persuasive, and unrealistic. Too often we hold fast to the clichés of our forebears. We subject all facts to a prefabricated set of interpretations. **We enjoy the comfort of opinion without the discomfort of thought.**”

People need to be thinking more about their mixture interpretation!



Mixture Committee

Future Directions Discussed

- Continue to produce and review training materials and report wording examples
 - Committee will vote on materials and submit to SWGDAM chair for inclusion on SWGDAM website (when available)
- Validation assistance
 - Experimental design and thought behind setting thresholds
- Casework expert software tools (not “expert systems”)
 - Collecting experiences with software programs



Use of SWGDAM Website

- Work products to potentially be included to enable further understanding of guidelines:
 - Training materials to illustrate the principles described in the STR interpretation guidelines
 - Report wording examples (suggested wordings and how not to word something)
 - Excel programs for mixture deconvolution or statistical calculations
 - Worksheet examples for profile interpretation



Proposed Revisions (v1.1) to Y-STR Interpretation Guidelines

5.3.1.2. The haplotype has been observed in the database:

A conservative formula for calculating the upper 95 percent confidence limit in this case would be

$$\sum_{k=0}^x \binom{n}{k} p_0^k (1 - p_0)^{n-k} = 0.05$$

where n = database size, x = the number of observations of the haplotype in the database, k = 0, 1, 2, 3 ... x observations, and p = the haplotype frequency at which x or fewer observations are expected to occur 5% of the time.

This cumulative binomial distribution formula is solved for p through serial iterations and therefore requires the use of a computer program.

[Add Clopper-Pearson \(1934\) to reference list](#)

Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of the binomial. *Biometrika* 1934; 26:404–413.

5.3.1.1. The haplotype has not been previously observed in the database:

The formula for calculating the upper 95 percent confidence limit in this case would be

$$1 - (0.05)^{1/n}$$

where n is the size of the database.

5.3.1.2. The haplotype has been observed in the database:

The formula for calculating the upper 95 percent confidence limit in this case would be

$$p + 1.96 \sqrt{\frac{(p)(1-p)}{n}}$$

where p is x/n , n = database size, and x = the number of observations of the haplotype in the database.

5.4. For Y-STR mixtures that cannot be deconvoluted, calculations may be performed for the probability of exclusion and likelihood ratios.

5.5. If both autosomal and Y-STR data are collected on a sample, the product rule may be used to combine the autosomal STR genotype match probability and Y-STR haplotype frequency information.

5.6. It is recognized that population substructure exists for Y-STR haplotypes. Studies with current population databases have shown that the F_{ST} values are very small for most populations. Thus the use of the counting method that incorporates the upper-bound estimate of the count proportion offers an appropriate and conservative statistical approach to evaluating the probative value of a match.

Current Y-STR Interpretation Guidelines

Proposed replacement

These sections need work (a future v2.0) as well as further data and expert input

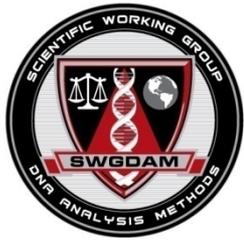


Mixture Committee

Contact Info

Committee Points of Contact:

- John Butler (chair) – john.butler@nist.gov
- Bruce Heidebrecht (co-chair) – bheidebrecht@mdsp.org



SWGDM

Quality Assurance

Committee Update



QA Committee

Mission

To provide guidance on QA issues.



QA Committee

Tasks for July 2011 Meeting

- Review and recommend action for the January 2001 SWGDAM “Training Guidelines.”
- Review and recommend action for the April 2003 SWGDAM document entitled “Guide for Manager and Auditor during a DNA Laboratory Health and Safety Inspection.”
- Recommendations for the revision or creation of any existing/new QA guidance document(s)



QA Committee

Tasks/objectives accomplished:

- Reviewed 2001 SWGDAM “Training Guidelines” and determined updating was needed
 - Began revisions
 - Assigned remaining sections for fall teleconference



QA Committee

Tasks/objectives accomplished:

Reviewed April 2003 SWGDAM document entitled "Guide for Manager and Auditor during a DNA Laboratory Health and Safety Inspection."

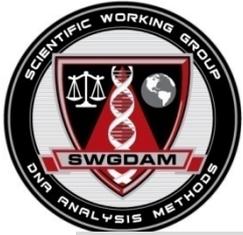
- Determined document can be additional resource on SWGDAM web site
- Rename and use as a checklist
- Minor revisions will be needed



QA Committee

Tasks/objectives accomplished:

- Identify other SWGDAM Guidelines/Documents that may be dated but none found
- Validation, Y-STR and Interpretation SWGDAM Guidelines are under consideration by other Committees at this time and will wait for revisions to those documents before determining if additional or new guidance document(s) are needed



QA Committee

Future Tasks:

- Teleconference for October on Training Guidelines with goal of providing membership and invited guests with draft for January 2012 SWGDAM meeting



QA Committee

Committee Point of Contact:

Committee Chair:

Jodi Dahl

703-632-8425

Jodi.Dahl@ic.fbi.gov

Committee Co-Chair:

Beth Ann Marne

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bmarne@state.pa.us



SWGAM

Rapid DNA Committee

Update



Testing and Validation of a Rapid DNA System

Purpose of the instrument: Generate a STR profile for each swab loaded into the instrument



Rapid DNA Instrument
'The Box'
(Various vendors)

Common message format
File for CODIS
Text File

The basic workflow 1 - 3 hours

- A swab is collected from an individual
- Swab is loaded into the instrument
- A disposable cartridge containing reagents for DNA extraction, PCR, and separation is loaded
- Push go
- The electropherogram is interpreted by an (integrated) expert system software
- The appropriate genotypes for the sample are collected



Rapid DNA Committee

- Review of R-DNA machine development
 - status discussed
- The first generation of instruments to be tested in the next 6 -12 months (5 instruments, same mfr)
 - Performance test plan
 - Coordinate with NIST (5 sets of test samples)
 - 10-12 unique samples in replicate
 - Approximately 80 samples/machine (buccal swabs)
 - NIST will evaluate fsa files
 - **Concordance, success rate**, sensitivity, peak height ratios, stutter, PCR artifacts, resolution, manual vs. expert software allele calls



Rapid DNA Committee

Initial discussions of validation

- Developmental validation
 - Performed by vendors, testing groups
- Input from the results of our initial evaluation testing will help determine what is required for performance metrics
 - Concordance – high priority
 - Threshold for failure (90%?)
- Internal validation
 - Concordance (# of samples?)
 - Sensitivity
 - Sizing precision, resolution
- Certification
 - Can these instruments be certified?



Rapid DNA Committee

Positive Controls?

- Adds expense, decreases sample throughput
 - example: a 4 channel system
 - Evaluation experiments will help guide
- Cell-line DNA on a swab, operator buccal swab, other, non-human spike in (internal control)?
- Run with every run, once a week, once a year?



Rapid DNA Committee

- Initial discussion of a universal file format for electropherogram data (fsa, HID)
- In addition to R-DNA data – the ability to export the e-gram file in an universal format
- Discussed with support from the CODIS group
- How to proceed/discussion...?



Rapid DNA Committee

- Initial discussion of laboratory pilot studies
 - 2-3 years
- Cannot go forward until performance evaluation and developmental validation are completed



Rapid DNA Committee

Thoughts on validation and QAS

- An Appendix “R”? – NDIS Procedure
- QAS Standard 18 for R-DNA or new R-DNA QAS document
- FBI fingerprint model certified equipment list



Rapid DNA Committee

Booking Station Issues (4-7 years)

- Sample/cartridge disposal – chemical waste
- Queuing of samples (if booking station throughput is low)
- How will validation be addressed ?
 - Can the instrument be certified?
 - Will a performance check of a certified instrument be acceptable?



Rapid DNA Committee

- Moving forward...
- Results of R-DNA evaluation testing this fall/winter
- Discussion of additional members
- Pending funding – plan to meet at the BCC meeting (Biometrics Consortium Conference) (Tampa, FL) Sept 28, 2011



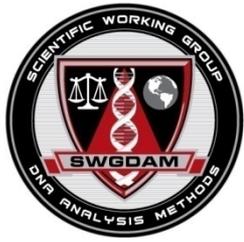
Rapid DNA Committee

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Questions?



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