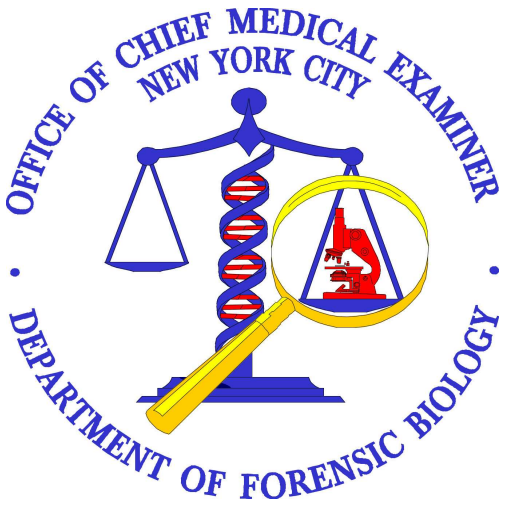
This Manual is compiled of the following sections. If a section was revised during the year, each revision and date effective is listed. Ensure to use the appropriate effective date.

Quality Assurance Manuals in use for 2013

Number order	Procedures	Effective Date	Comments
1	Audits and Assessments	2/9/10	
2	Control of Data	7/16/12	
3	Control of Data	2/9/10	
4	Control of Non-Conforming Work	6/20/12	
5	Control of Non-Conforming Work	2/15/11	
6	Control of Reference Collections	2/9/10	
7	Court Testimony Monitoring	7/16/12	
8	Court Testimony Monitoring	1/6/11	
9	Equipment Calibration and Maintenance	7/16/12	
10	Equipment Calibration and Maintenance	2/9/10	
11	Exogenous DNA Prevention	2/9/10	
12	Lab Types Database	2/9/10	
13	Lab Types Database	10/1/12	
14	Lab Types Database	04/30/12	
15	Lab Types Database	07/16/12	
16	Preventive Action	2/9/10	
17	Proficiency Testing Program	2/9/10	
18	Proficiency Testing Program	7/16/12	
19	Proficiency Testing Program	3/30/12	
20	Quality Incident Review	9/24/10	
21	Reagents	8/20/12	
22	Reagents	12/29/11	
23	Reagents	7/16/12	
24	Validation	2/9/10	



FORENSIC BIOLOGY
QUALITY ASSURANCE / QUALITY CONTROL MANUAL

Approving Authority: Eugene Y. Lien, Quality Assurance Manager

Procedures	Effective Date	Revision History
Audits and Assessments	2/9/2010	Initial Version of Procedure
Control of Data	2/9/2010	Initial Version of Procedure
Control of Non-Conforming Work	2/9/2010	Initial Version of Procedure
Control of Reference Collections	2/9/2010	Initial Version of Procedure
Court Testimony Monitoring	2/9/2010	Initial Version of Procedure
Equipment Calibration and Maintenance	2/9/2010	Initial Version of Procedure
Exogenous DNA Prevention	2/9/2010	Initial Version of Procedure
Lab Types Database	2/9/2010	Initial Version of Procedure
Preventive Action	2/9/2010	Initial Version of Procedure
Proficiency Testing Program	2/9/2010	Initial Version of Procedure
Quality Incident Review	2/9/2010	Initial Version of Procedure
Reagents	2/9/2010	Initial Version of Procedure
Validation	2/9/2010	Initial Version of Procedure
QUALITY CONTROL REAGENT SHEETS		
QUALITY CONTROL PROCEDURES		

AUDITS AND ASSESSMENTS		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 6

GUIDING PRINCIPLES AND SCOPE

Audits and assessments are conducted to improve the quality of the laboratory, as well as to maintain compliance with accreditation standards such as ISO 17025, the ASCLD/LAB-*International* Supplemental Requirements, and the FBI Quality Assurance Standards for Forensic DNA Testing.

An ***Internal Audit*** is an audit conducted by qualified and trained auditors employed by the Department of Forensic Biology. An ***External Audit or Assessment*** is an audit conducted by qualified and trained auditors/assessors employed by agency external to the Department of Forensic Biology.

This document describes the external audits/assessments to which the Department of Forensic Biology is subject and the internal audit program of the Department.

PROCEDURE

The management system of the Department of Forensic Biology is designed to conform to the following sets of standards:

ASCLD/LAB-*International* Standards: The ASCLD/LAB-*International* Standards encompasses the ISO/IEC 17025 requirements and the ASCLD/LAB-*International* Supplemental Requirements.

FBI Quality Assurance Standards for Forensic DNA Testing: The FBI Quality Assurance Standards for Forensic DNA Testing is issued by the FBI Director and is a set of standards specific to Forensic DNA Testing (mitochondrial and autosomal). ASCLD/LAB-*International* also requires compliance with these standards as a condition of accreditation.

I. External Audits/Assessments

A. The Department is subject to **external accreditation assessments/surveillance visits** as required by ASCLD/LAB.

1. Assessment scheduling and the assessment process are the responsibility of ASCLD/LAB.

2. Level 1 non-conformities (as defined by ASCLD/LAB) must be corrected to the satisfaction of ASCLD/LAB before a recommendation for accreditation is made.
3. Corrections for Level 2 non-conformities may commence immediately upon discovery. Otherwise, the Department shall obtain approval from ASCLD/LAB to correct the non-conformity prior to the next, annual on-site Surveillance Visit.

B. An **external DNA audit** to ensure the Department's conformance with the FBI DNA Quality Assurance Standards for Forensic DNA Testing is conducted at least once every two (2) calendar years.
1. An external DNA audit could occur as part of an ASCLD/LAB accreditation assessment or could be a stand-alone DNA audit such as those provided through the DNA laboratory audit program of the National Forensic Science Technology Center (NFSTC).
2. For an external DNA audit to "count," it must occur at least 6 months, but no more than 18 months, after an internal or external DNA audit conducted during the prior calendar year.
3. The audit must be conducted with the version of the FBI DNA QAS audit document in effect at the time of the audit.
4. The audit document and any Quality Incident Reviews stemming from non-conformities identified during the audit are submitted to the DNA Technical Leader(s) for review and for approval of proposed follow-up actions.
5. A copy of the DNA audit documentation and laboratory responses to non-conformities is provided to the NDIS Custodian at the FBI within 30 days of the laboratory's receipt of the audit report.
6. The laboratory maintains the following records from external DNA audits:
   a. Audit reports
   b. Self-verification forms completed by the members of the audit team to certify their qualifications as auditors and experience with the DNA technologies and platform(s) used by the Department.

C. External audits outside of normal accreditation assessment or external DNA audit schedules may be required by ASCLD/LAB or the New York State Commission on Forensic Science as a response to very serious quality incidents.

D. The Quality Assurance Manager (QAM) is the point of contact for any external audit of the laboratory that concerns the technical operations of the laboratory.

II. Internal Audits

The internal audit program is a critical component of the Department's management system. It is designed to ensure that the Department's management system is functioning correctly and that the Department is operating is in compliance with its own procedures as well as regulatory and accreditation requirements.

The internal audit program consists of two parts: (1) audits to evaluate the laboratory's conformance with respect to the management system, including the testing activities, and with the ISO 17025 and ASCLD/LAB-*International* Supplemental requirements and (2) DNA audits to evaluate the laboratory's conformance with respect to the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories.

A. General Internal Audit Information

1. The Quality Assurance Manager (QAM) is responsible for scheduling and planning the internal audits of the laboratory. Scheduling is done in consultation with the Technical Leaders, Deputy Director(s), and the Director.
   a. Should an audit require personnel from external organizations, the QAM will take into consideration the schedule and availability of these external auditors prior to agreeing to a date.

2. "ISO" audits are generally scheduled for the first half of the calendar year and DNA audits are generally scheduled for the second half of the calendar year.

3. The QAM selects auditors to ensure that an audit team is "qualified" as per the requirements for each type of audit.

4. The QAM develops an audit plan that, at a minimum, contains the audit schedule, the activities to be audited, and the audit team(s) assigned to audit the specified activities. Each audit team has a lead auditor/team leader.

5. The general process for any internal audit is as follows:

   a. The QAM notifies the laboratory that an internal audit will be conducted, the general scope of the audit, and provides an approximate timeframe.
   b. The QAM schedules an opening conference with the auditors to discuss the audit objectives, assignments, timing, and report format and distribution.
   c. The auditors perform their audit activities to assess the soundness of the quality system, management system, and technical operations.
   d. The audit teams provide the QAM with their audit findings, including potential non-conformities and observations.
   e. The QAM discusses preliminary observations (if any) with management.
      1) Non-conformities that are non-systemic, are easily corrected, and do not indicate serious deficiencies in the management system can be corrected prior to the completion of the audit.
      2) The correction is documented in the audit records, but is not included in the final audit report.
   f. The QAM, Technical Leaders, and other manager(s) as requested by the QAM review the audit results submitted by the audit teams and verify the findings that are true non-conformities supported by objective evidence.
   g. The QAM writes the audit report; laboratory managers are informed.
   h. The QUALITY INCIDENT REVIEW procedure is used for follow-up on audit non-conformities identified in the audit report.
   i. If audit non-conformities show that laboratory results may have been affected, the laboratory must notify its customers and accreditation agency of the results, in writing, within thirty (30) days of discovery.

j. Audit reports may need to be submitted to the NYS Commission on Forensic Science, ASCLD/LAB, or the board members of the National DNA Indexing System (NDIS). The Quality Assurance Manager shall ensure timely submission of audit reports when necessary.

k. Audit reports are a form of records and shall be retained according to the guiding principles of the laboratory. See CONTROL OF RECORDS for further information.

B. Information Specific to Internal "ISO" Audits

1. The scope of the internal audit must ensure that all elements of the management system are addressed. The QAM or designees may develop checklists to be used by the audit teams.

2. Auditors are "qualified" in any of the following ways:
   a. Documented completion of an ASCLD/LAB-International assessor training course.
   b. Documented completion of an external ISO 17025 training course and auditor training conducted in-house by a qualified auditor such as the QAM.
   c. Documented completion of ISO 17025 and auditor training conducted in-house by a qualified auditor such as the QAM.

3. Only qualified auditors will be selected to lead an internal audit team. Staff that has not completed the required training may be used as team auditors, but they must report directly to a qualified auditor.

C. Information Specific to Internal DNA Audits

1. DNA internal audits are conducted using "The FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories."

2. Auditors are "qualified" to conduct DNA audits if they have successfully completed an FBI-sponsored DNA Auditing Workshop/Course.

3. The DNA audit team must contain at least one qualified auditor and at least one person that is, or has previously been, a qualified analyst for each specific DNA technology (***technology*** *is used to describe the type of forensic DNA analysis performed in the laboratory, such as STR, YSTR, or mitochondrial DNA*) performed in the laboratory. This may be accomplished by having a single auditor who meets all of the specified qualifications or through a combination of various members of a multi-person audit team.

4. Internal DNA audits are optional in calendar years when external DNA audits have been conducted.

Revision History:

February 9, 2010 – Initial version of procedure.

CONTROL OF DATA		
DATE EFFECTIVE 07-16-2012	APPROVED BY EUGENE LIEN	PAGE 1 OF 2

GUIDING PRINCIPLES AND SCOPE

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:

1. Calculations and data transfers are subject to appropriate checks in a systematic manner.

2. Computer software developed by the laboratory is documented in sufficient detail and is suitably validated as being adequate for use.

3. Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.

4. Computer and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test data.

This section describes the procedures to achieve these guiding principles.

PROCEDURE

Only Department of Forensic Biology staff members have unlimited access to the Forensic Biology network drive. Exceptions may only be granted by the Director or designee. Access is controlled by the OCME Management Information Systems (MIS) Department. Unless otherwise authorized by an existing standard operating procedure, only the Quality Assurance Manager may authorize the release of data to any party (via any means) external to the Department of Forensic Biology.

Computer software may be used during the processing of case work; however, the results will be incorporated into the case record.

Any calculations and data transfers made using computer software are reviewed for its accuracy by a supervisor prior to its incorporation into a case record and/or are reviewed for its accuracy during the final technical review process of the case.

Computer software or software modifications developed by the laboratory are suitably validated depending on the purpose of the modification.

1. The appropriate Technical Leader must be consulted prior to validation to ensure that suitable validation tests are carried out.

2. If the software is used to streamline/transfer data, sufficient proof must be furnished to document that the intended purpose of the software is achieved. This may be accomplished by entering a simple set of data to ensure that the streamline/transfer of data is accurate.

3. If the software is used to calculate data, sufficient proof must be furnished to document that the intended purpose of the software is achieved. This may be accomplished by inputting a simple set of data and comparing it to hand calculated results to ensure that the calculations made are correct.

4. Computer software developed by the laboratory must be approved by the appropriate Technical Leader prior to its use in casework.

5. Validation records are stored by the Quality Assurance Unit.

Once calculations and data transfers have been reviewed by a supervisor, they may be deleted from the Forensic Biology network drive. For some data, such as DNA electropherograms, the electronic data will be maintained indefinitely.

Revision History:

February 9, 2010 – Initial version of procedure.
July 16, 2012 – Specific terminology was removed and replaced with generic terminology to accommodate LIMS.

CONTROL OF DATA		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 2

GUIDING PRINCIPLES AND SCOPE

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:

1. Calculations and data transfers are subject to appropriate checks in a systematic manner.

2. Computer software developed by the laboratory is documented in sufficient detail and is suitably validated as being adequate for use.

3. Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.

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Computer software may be used during the processing of case work; however, a copy of the print-out of the results will be incorporated in case files. The original print-out will be maintained as a record within the Department of Forensic Biology.

Any calculations and data transfers made using computer software are reviewed for its accuracy by a supervisor prior to its incorporation into a case file and/or are reviewed for its accuracy during the final technical review process of the case file.

CONTROL OF DATA		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 2 OF 2

Computer software or software modifications developed by the laboratory (such as simple spreadsheets to calculate data and macros to streamline/transfer data) are suitably validated depending on the purpose of the modification.

1. The appropriate Technical Leader must be consulted prior to validation to ensure that suitable validation tests are carried out.

2. If the software is used to streamline/transfer data, sufficient proof must be furnished to document that the intended purpose of the software is achieved. This may be accomplished by entering a simple set of data to ensure that the streamline/transfer of data is accurate.

3. If the software is used to calculate data, sufficient proof must be furnished to document that the intended purpose of the software is achieved. This may be accomplished by inputting a simple set of data and comparing it to hand-calculated results to ensure that the calculations made are correct.

4. Computer software developed by the laboratory must be approved by the appropriate Technical Leader prior to its use in casework.

5. Validation records are stored by the Quality Assurance Unit.

Once calculations and data transfers have been reviewed by a supervisor, they may be deleted from the Forensic Biology network drive. For some data, such as DNA electropherograms, both the print-out and the electronic data will be maintained indefinitely.

Revision History:

February 9, 2010 – Initial version of procedure.

CONTROL OF NONCONFORMING WORK		
DATE EFFECTIVE 06-20-2012	APPROVING AUTHORITY QUALITY ASSURANCE MANAGER	PAGE 1 OF 5

GUIDING PRINCIPLES AND SCOPE

Non-conforming work is any testing work which does not meet the Department's stated standards, either with respect to mode of execution or outcome, for example, quality of data. All non-conforming work must be dealt with upon discovery or at the earliest opportunity so that the work can be appropriately evaluated and corrected, and the Quality Incident Review procedure initiated where necessary.

This procedure describes the Department's process for evaluating nonconforming work and taking appropriate follow-up action. Technical problems or difficulties can arise in all phases of Department operations. Listing each potential problem is impractical, and this topic is considered in general terms.

It must be emphasized that apparently similar situations may result in different follow-up actions. This is because no two circumstances are exactly the same and the consequences of the particular nonconformity may be very different.

PROCEDURE

1. Any member of staff who discovers a technical error or realizes that there is *a technical problem that may compromise evidence integrity or the accuracy of casework analysis* must address the issue immediately or as soon as practicable.

   a. Technical problems related to the testing of a batch of samples are reported to the rotation supervisor for that batch.
      - Detection of exogenous DNA in negative controls is reported to a Quality Assurance Supervisor.

   b. Technical problems related to individual case samples, e.g., a possible sample mix-up, are reported to the affected rotation supervisor and/or the supervisor of the analyst assigned to the affected case.

   c. Technical problems identified during routine quality control activities such as instrument performance checks are reported to a Quality Assurance supervisor.

   The supervisor to whom the incident is reported becomes the ***principal investigating supervisor.***

2. The principal investigating supervisor evaluates the significance of the nonconforming work.

   a. Some nonconforming work can be easily corrected, such as by reanalysis. An example of this would be a sample that fails to give interpretable peaks in an electrophoresis run, but when re-injected an acceptable result is obtained. In such cases the action is documented on the batch worksheets, in case notes, or on performance check worksheets, as appropriate to the situation, but no further investigation is likely to be needed unless the incident was part of a pattern.

   b. Some nonconforming work, such as sample mix-ups or contamination incidents, requires more investigation as to the scope and cause of the nonconformity. The incident and its evaluation are documented on the **Non-Conformity Reporting Form**.
      - Should the cause of the nonconformity be attributed to an individual, the **Non-Conformity Reporting Form** must be completed by both the principal investigating supervisor and the immediate supervisor of the individual (if not already involved as the principal investigating supervisor).

   c. The Quality Manager and appropriate DNA Technical Leader are consulted if the nature of the issue indicates that testing work should be halted or test reports withheld.
      - The DNA Technical Leader(s) have the authority to suspend DNA analytical operations for the Department or an individual.
      - The Quality Manager has the authority to suspend serology analytical operations for the Department or an individual.
      - The Director, Deputy Director(s) and Assistant Directors are notified as soon as practicable when actions to suspend testing are proposed or taken.

3. The problem is corrected and/or the issue is referred to the Quality Assurance Manager to determine whether a Quality Incident Review is needed.

   a. A Quality Incident Review must be conducted when the evaluation indicates that:
      - The problem has a serious impact on casework and is likely to recur, and/or
      - There is doubt about the compliance of the Department's technical operations with its own policies and procedures.

4. Examples of nonconforming work that *might* require a Quality Incident Review are: use of expired reagents, contamination events, sample mix-ups, instrument malfunctions. See the **Quality Incident Review** procedure for additional guidance.

5. Any correction taken is documented on the Non-Conformity Reporting Form and on the batch worksheets, in case notes, or on performance check worksheets, as appropriate to the situation.

6. A manager is consulted if the situation seems to require notification of customer(s) other than through normal reporting processes. Special verbal or written notification of customers may be necessary when, for example, non-conforming work affects the usability of a previously issued report.

7. If the initial action taken fails to correct the problem, the issue should be referred to the Quality Assurance Manager and/or appropriate DNA Technical Leader for further investigation.

8. The Non-Conformity Reporting Form is forwarded to the Quality Assurance Manager.

    a. If an individual is confirmed to be the cause of an issue, the immediate supervisor is also notified. The supervisor shall track performance issues to ensure that repeated occurrences of similar issues are corrected through counseling, retraining, or other measures appropriate to the situation.

9. Testing that had been suspended is resumed after the technical issues have been resolved.

    a. The DNA Technical Leader(s) have the authority to resume DNA analytical operations for the Department or an individual.

    b. The Quality Manager has the authority to resume serology analytical operations for the Department or an individual.

10. The Quality Assurance Team analyzes the Non-Conformity Reporting Forms on a regular basis in order to track issues so that trends can be identified.

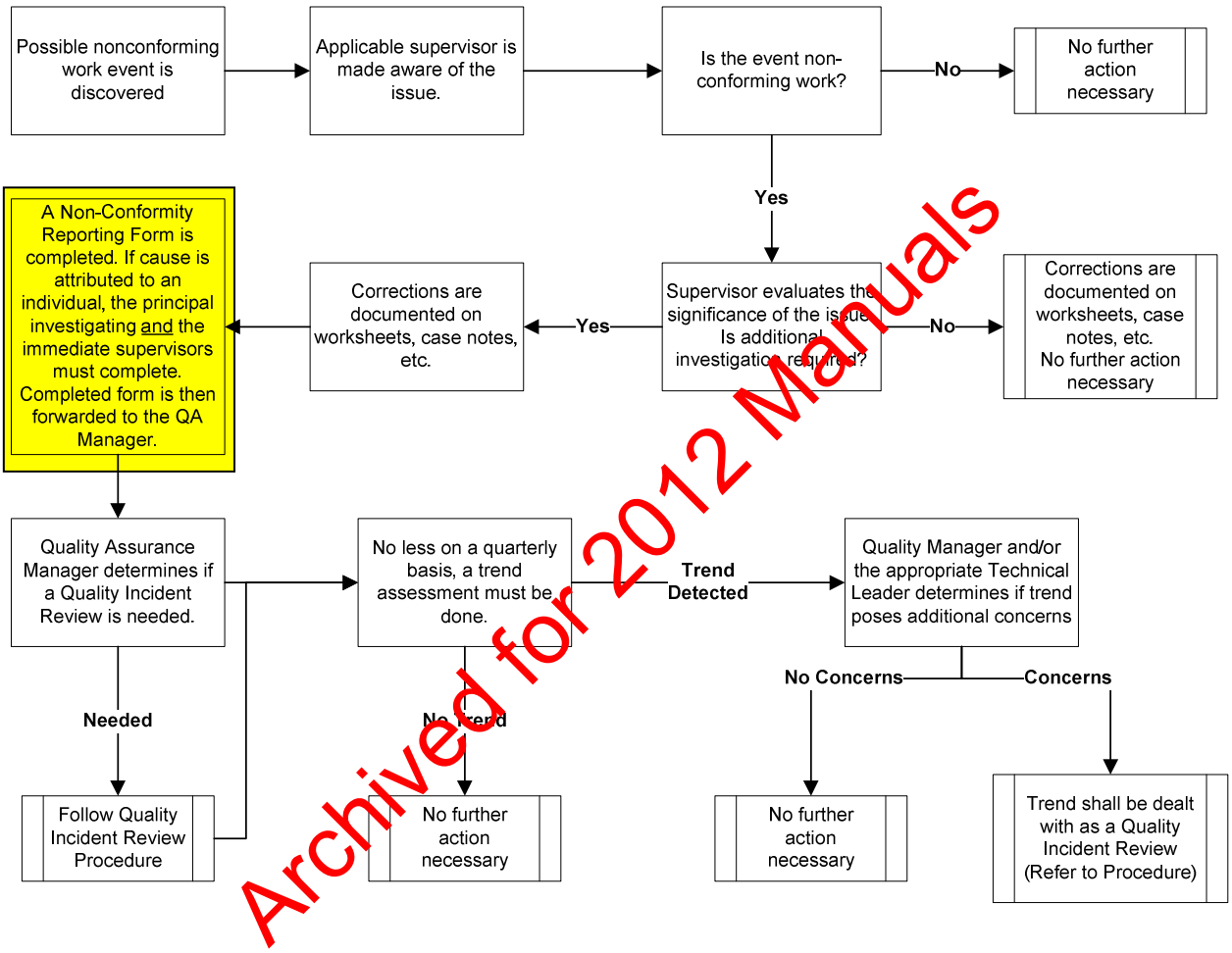
    a. Non-Conformity Reporting Forms are assessed at least quarterly to determine if similar events occurred (such as those in the same area or caused by the same individual) within an unreasonable timeframe.

    b. The Quality Assurance Manager and the appropriate Technical Leader determine if any trends pose additional concerns to the Management System of the laboratory.

    c. A trend that poses additional concerns with respect to the Management System of the laboratory is dealt with through the Quality Incident Review process.

CONTROL OF NONCONFORMING WORK		
DATE EFFECTIVE 06-20-2012	APPROVING AUTHORITY QUALITY ASSURANCE MANAGER	PAGE 5 OF 5

Nonconforming Work Flowchart



Revision History:

February 9, 2010 – Initial version of procedure.
September 24, 2010 – Added step in procedure to document non-conformities on the Non-conformity Reporting Form.
February 15, 2011 – Added specific language and flow-chart to clarify process.
June 20, 2012 – Introduced the term "principal investigating supervisor." Non-conformity reporting form must be completed by both the principle investigating supervisor and the immediate supervisor if the cause is attributed to an individual.

CONTROL OF NONCONFORMING WORK		
DATE EFFECTIVE 02-15-2011	APPROVED BY EUGENE LIEN	PAGE 1 OF 4

GUIDING PRINCIPLES AND SCOPE

Non-conforming work is any testing work which does not meet the Department's stated standards, either with respect to mode of execution or outcome, for example, quality of data. All non-conforming work must be dealt with upon discovery or at the earliest opportunity so that the work can be appropriately evaluated and corrected, and the Quality Incident Review procedure initiated where necessary.

This procedure describes the Department's process for evaluating nonconforming work and taking appropriate follow-up action. Technical problems or difficulties can arise in all phases of Department operations. Listing each potential problem is impractical, and this topic is considered in general terms.

It must be emphasized that apparently similar situations may result in different follow-up actions. This is because no two circumstances are exactly the same and the consequences of the particular nonconformity may be very different.

PROCEDURE

1. Any member of staff who discovers a technical error or realizes that there is *a technical problem that may compromise evidence integrity or the accuracy of casework analysis* must address the issue immediately or as soon as practicable.

    a. Technical problems related to the testing of a batch of samples are reported to the rotation supervisor for that batch.
        - Detection of exogenous DNA in negative controls is reported to a Quality Assurance Supervisor.

    b. Technical problems related to individual case samples, e.g., a possible sample mix-up, are reported to the affected rotation supervisor and/or the supervisor of the analyst assigned to the affected case.

    c. Technical problems identified during routine quality control activities such as instrument performance checks are reported to a Quality Assurance supervisor.

2. The supervisor evaluates the significance of the nonconforming work.

   a. Some nonconforming work can be easily corrected, such as by reanalysis. An example of this would be a sample that fails to give interpretable peaks in an electrophoresis run, but when re-injected an acceptable result is obtained. In such cases the action is documented on the batch worksheets, in case notes, or on performance check worksheets, as appropriate to the situation, but no further investigation is likely to be needed unless the incident was part of a pattern.

   b. Some nonconforming work, such as sample mix-ups or contamination incidents, requires more investigation as to the scope and cause of the nonconformity. The incident and its evaluation are documented on the **Non-Conformity Reporting Form**.

   c. The Quality Manager and appropriate DNA Technical Leader are consulted if the nature of the issue indicates that testing work should be halted or test reports withheld.
      - The DNA Technical Leader(s) have the authority to suspend DNA analytical operations for the Department or an individual.
      - The Quality Manager has the authority to suspend serology analytical operations for the Department or an individual.
      - The Director, Deputy Director(s) and Assistant Directors are notified as soon as practicable when actions to suspend testing are proposed or taken.

3. The problem is corrected and/or the issue is referred to the Quality Assurance Manager to determine whether a Quality Incident Review is needed.

   a. A Quality Incident Review must be conducted when the evaluation indicates that:
      - The problem has a serious impact on casework and is likely to recur, and/or
      - There is doubt about the compliance of the Department's technical operations with its own policies and procedures.

   b. Examples of nonconforming work that *might* require a Quality Incident Review are: use of expired reagents, contamination events, sample mix-ups, instrument malfunctions. See the **Quality Incident Review** procedure for additional guidance.

4. Any correction taken is documented on the Non-Conformity Reporting Form and on the batch worksheets, in case notes, or on performance check worksheets, as appropriate to the situation.

5. A manager is consulted if the situation seems to require notification of customer(s) other than through normal reporting processes. Special verbal or written notification of customers may be necessary when, for example, non-conforming work affects the usability of a previously issued report.

6. If the initial action taken fails to correct the problem, the issue should be referred to the Quality Assurance Manager and/or appropriate DNA Technical Leader for further investigation.

7. The Non-Conformity Reporting Form is forwarded to the Quality Assurance Manager.

    a. If an individual is confirmed to be the cause of an issue, the immediate supervisor is also notified. The supervisor shall track performance issues to ensure that repeated occurrences of similar issues are corrected through counseling, retraining, or other measures appropriate to the situation.

8. Testing that had been suspended is resumed after the technical issues have been resolved.

    a. The DNA Technical Leader(s) have the authority to resume DNA analytical operations for the Department or an individual.

    b. The Quality Manager has the authority to resume serology analytical operations for the Department or an individual.

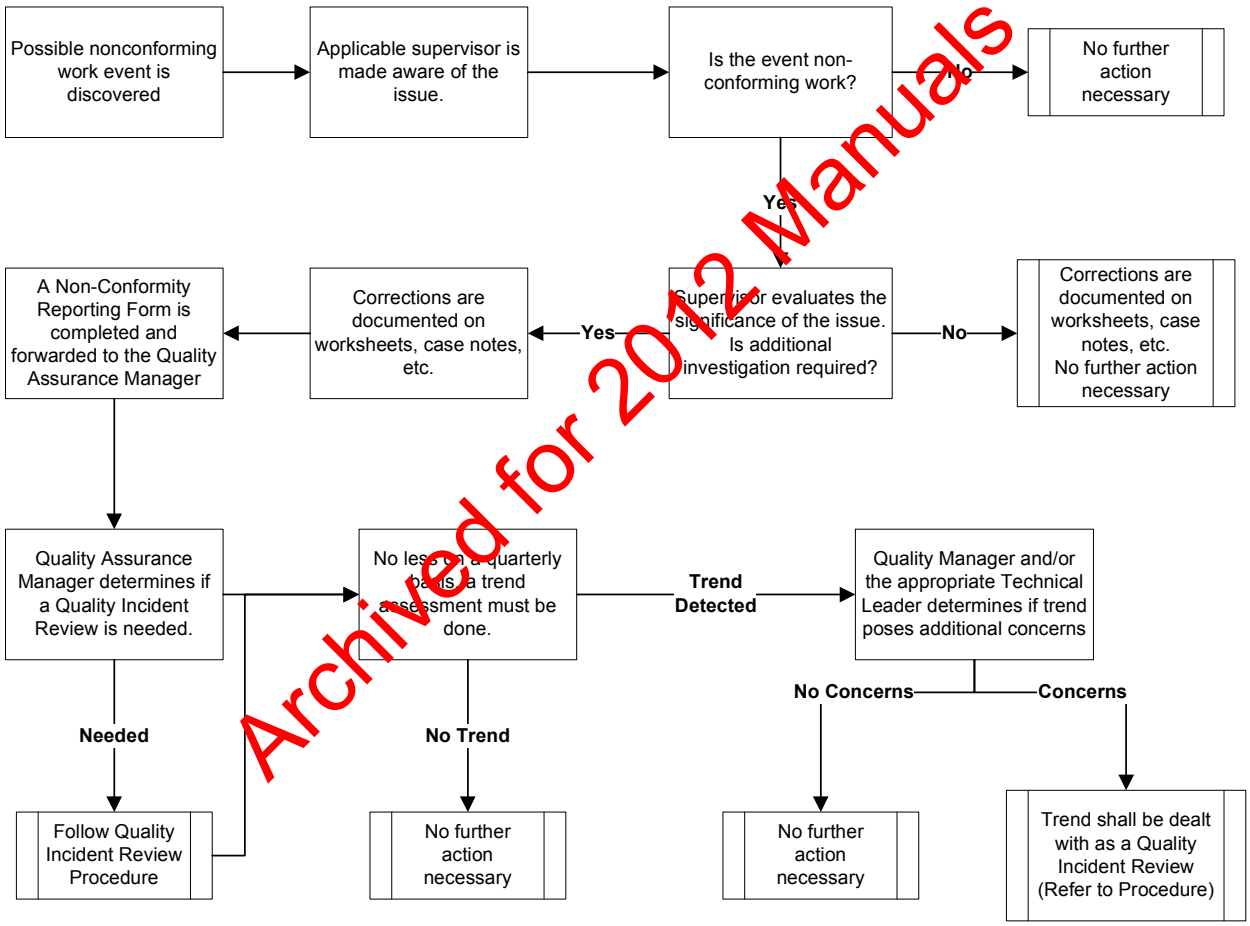
9. The Quality Assurance Team analyzes the Non-Conformity Reporting Forms on a regular basis in order to track issues so that trends can be identified.

    a. Non-Conformity Reporting Forms are assessed at least quarterly to determine if similar events occurred (such as those in the same area or caused by the same individual) within an unreasonable timeframe.

    b. The Quality Assurance Manager and the appropriate Technical Leader determine if any trends pose additional concerns to the Management System of the laboratory.

c. A trend that poses additional concerns with respect to the Management System of the laboratory is dealt with through the Quality Incident Review process.

Nonconforming Work Flowchart



Revision History:

February 9, 2010 – Initial version of procedure.
September 24, 2010 – Added step in procedure to document non-conformities on the Non-conformity Reporting Form.
February 15, 2011 – Added specific language and flow-chart to clarify process.

CONTROL OF REFERENCE COLLECTIONS		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 3

GUIDING PRINCIPLES AND SCOPE

Reference standards and reference materials shall be stored in a manner that ensures the prevention of contamination or deterioration in order to protect their integrity. Procedures for safe handling, transport, and use of reference standards are outlined below.

PROCEDURE

A. Reference Standards

Reference standards of measurement are to be used for calibrations only and for no other purpose. Since the laboratory does not conduct any calibrations, reference standards do not exist within the laboratory.

B. Reference Materials

Reference materials used to conduct intermediate performance checks of instruments and equipment are, where possible, traceable to certified reference materials such as those from the National Institute of Standards and Technology (NIST). Reference materials that cannot be traceable to certified reference materials must be certified according to original manufacturer's specification. Internal reference materials are checked as far as is technically and economically possible.

Where possible, reference materials are obtained from sources that can supply appropriate traceability information such as a Certificate of Analysis.

Reference materials are stored according to manufacturer's specifications. If the manufacturer's specification does not indicate storage conditions, the laboratory determines how similar materials are stored within the laboratory and applies those storage conditions to the reference materials.

Storage conditions must ensure the safe handling and safe transport of reference materials. Furthermore, storage conditions must minimize contamination or deterioration, where possible.

Checks needed to maintain confidence in the calibration status of the reference materials shall be carried out periodically. Where practical, reference materials must be re-certified on or before the expiration date or they must be removed from use. Any reference material that does not have an expiration date must be re-certified or removed from use after one (1) year of its first use.

1. Standard Reference Materials (SRMs)
   The use of standard reference materials is essential to reliable methodology. The laboratory will check its DNA typing procedures against an appropriate and available SRM annually or whenever substantial changes are made to the typing procedure. SRMs will be purchased from the National Institute of Standards and Technology (NIST) and shall have an associated Certificate of Analysis available. The laboratory may choose to use other SRMs to check any of its procedures, but it is not required to do so. SRMs must not be used beyond its expiration date unless a Certificate of Analysis is issued from NIST to document its recertification.

   Secondary standards that are traceable to SRMs may be created by the laboratory for use in lieu of purchasing them directly from NIST. To create a secondary standard, a "lot" of DNA samples (such as a blood stain) must be run and analyzed in parallel with an appropriate NIST SRM. Documentation must be maintained to demonstrate that the results for the SRM are correct (as compared to the certificate of analysis) and the results of the secondary standard are consistent (as compared to a prior result).

2. Weights
   The laboratory will conduct intermediate performance checks of balances using Class 1 weights that are traceable to NIST Standards. Weights must be calibrated prior to the expiration date of the Certificate of Analysis, or must be removed from use. Various companies exist that can calibrate weights traceable to NIST Standards. However, the Department of Forensic Biology will endeavor to select a company that is accredited in accordance with ISO 17025 standards for calibration laboratories.

   Prior to each use, analysts should visually inspect the weights to ensure that there are no physical defects that would affect their performance.

C. Reference Collections

The laboratory uses a DNA "Lab Types" reference collection for comparison to casework DNA profiles to ensure that no exogenous DNA is present in samples and a "suspect database" to determine if there is an association between a named suspect and DNA profiles from previously tested cases. The use of these reference collections are outlined in the Forensic Biology CODIS Manual and the LAB-TYPES DATABASE procedure. These manuals identify these reference collections and describe how they are controlled.

Revision History:

February 9, 2010 – Initial version of procedure.

COURT TESTIMONY MONITORING		
DATE EFFECTIVE 07-16-2012	APPROVED BY EUGENE LIEN	PAGE 1 OF 3

GUIDING PRINCIPLES AND SCOPE

Court testimony is the culmination of the work performed by the laboratory's scientists. To ensure that court testimonies are relevant, and presented in a clear and professional manner, the testimony of each testifying examiner is monitored at least once during a calendar year, providing testimony is rendered.

This document describes the Department of Forensic Biology's courtroom testimony monitoring program.

PROCEDURE

When a case goes to grand jury or trial, the Reporting Analyst (RA) will be contacted to testify either by phone or subpoena. An informal request by phone should be directed to the RA's supervisor to gather details of the testimony. OCME counsel should be consulted if the request is via a subpoena. In either case, a pre-trial with the Assistant District Attorney (ADA) or defense attorney is advisable to discuss or go over the line of questioning. The RA should pull the case and all cross-referenced cases and/or suspect files. The RA should also bring a copy of his/her curriculum vitae and a spell-sheet to court.

If this is the RA's first testimony for the year or if the RA is inexperienced, their supervisor should be present at the pre-trial and trial. In addition to answering questions and providing support, the supervisor is responsible for evaluating the RA's testimony at trial. Evaluation of the RA's testimony at grand jury is left to the ADA, since no observers are allowed into court for grand jury.

A. Documenting Court Attendance

Staff members who are called to appear in court must have each court appearance documented, regardless of whether testimony was provided and/or evaluated.

B. Testimony Monitoring

1. The testimony of each examiner is monitored at least once each calendar year, assuming that testimony is rendered. It is the responsibility of each testifying examiner to ensure that this is done.

2. Acceptable methods of courtroom monitoring are:
   a. Direct courtroom observation by a higher-level supervisor (Criminalist Level IV or above).
      i. This is the preferred method for trial testimony.
      ii. In most cases the "higher-level supervisor" will be the immediate supervisor of the testifying examiner; however, a peer of the immediate supervisor or a higher level manager may perform the monitoring.
   b. Direct courtroom observation by an ADA and/or defense attorney present during the testimony.
      i. Evaluation by the ADA is the preferred method for Grand Jury testimony.
      ii. For evaluation of trial testimony, the testifying examiner should attempt to get feedback from both the ADA and the defense attorney. The testifying employee can ask the attorney who summoned them to court to provide an evaluation form to the opposing counsel; however, if the attorney is not willing to do so it is not necessary to insist that it be done.

3. The testimony evaluator completes a Forensic Biology Court Testimony Evaluation Form. The form includes evaluations/comments on the following areas:
   a. Appearance
   b. Poise
   c. Effectiveness of presentation (technical knowledge, ability to convey scientific concepts)
   d. Interpretation of laboratory results

4. Evaluation forms completed by someone other than the testifying employee's immediate supervisor are returned to the Quality Assurance Unit, and are then forwarded to the testifying examiner's immediate supervisor.

5. Immediate supervisors review the evaluation with the testifying examiner, discussing areas of strengths and weaknesses.

    a. The immediate supervisor may prescribe remedial action if the evaluation is unsatisfactory. Deficiencies in knowledge or courtroom presentation may require remedial training that includes one or both of the following:
        i. Retraining on technical information if the testimony was inaccurate.
        ii. Moot court retraining if the testimony showed deficiencies in the ability to express the concepts clearly.

6. The immediate supervisor and the testifying examiner sign/initial and date the evaluation form.

7. Completed evaluation forms are forwarded to the Quality Assurance Unit for storage.

Revision History:

February 9, 2010 – Initial version of procedure.

January 6, 2011 – Modify section B.2 to allow for courtroom testimony evaluation at trial by defense attorneys and to describe a possible mechanism for supplying forms to both ADAs and defense counsel.

July 16, 2012 – Specific forms and worksheets were removed and replaced with generic terminology to accommodate LIMS.

COURT TESTIMONY MONITORING		
DATE EFFECTIVE 01-06-2011	APPROVED BY EUGENE LIEN	PAGE 1 OF 3

GUIDING PRINCIPLES AND SCOPE

Court testimony is the culmination of the work performed by the laboratory's scientists. To ensure that court testimonies are relevant, and presented in a clear and professional manner, the testimony of each testifying examiner is monitored at least once during a calendar year, providing testimony is rendered.

This document describes the Department of Forensic Biology's courtroom testimony monitoring program.

PROCEDURE

When a case goes to grand jury or trial, the Reporting Analyst (RA) will be contacted to testify either by phone or subpoena. An informal request by phone should be directed to the RA's supervisor to gather details of the testimony. OCME counsel should be consulted if the request is via a subpoena. In either case, a pre-trial with the Assistant District Attorney (ADA) or defense attorney is advisable to discuss or go over the line of questioning. The RA should pull the case and all cross-referenced cases and/or suspect files. The RA should also bring a copy of his/her curriculum vitae and a spell-sheet to court.

If this is the RA's first testimony for the year or if the RA is inexperienced, their supervisor should be present at the pre-trial and trial. In addition to answering questions and providing support, the supervisor is responsible for evaluating the RA's testimony at trial. Evaluation of the RA's testimony at grand jury is left to the ADA, since no observers are allowed into court for grand jury.

If the RA is not available, another qualified analyst may substitute. However, the case record must be reviewed by the analyst prior to testimony. This review must be documented on the Case Record Review Form unless the analyst who will be providing the testimony conducted a full technical review of the case record.

A. Documenting Court Attendance

1. Staff members who are called to appear in court complete a "Court Attendance/Evaluation/Observation Tracking" form for each court appearance and submit the form to the Quality Assurance Unit.

2. The form is completed for all court appearances, regardless of whether testimony was provided and/or evaluated.

B. Testimony Monitoring

1. The testimony of each examiner is monitored at least once each calendar year, assuming that testimony is rendered. It is the responsibility of each testifying examiner to ensure that this is done.

2. Acceptable methods of courtroom monitoring are:
   a. Direct courtroom observation by a higher-level supervisor (Criminalist Level IV or above).
      i. This is the preferred method for trial testimony.
      ii. In most cases the "higher-level supervisor" will be the immediate supervisor of the testifying examiner; however, a peer of the immediate supervisor or a higher level manager may perform the monitoring.
   b. Direct courtroom observation by an ADA and/or defense attorney present during the testimony.
      i. Evaluation by the ADA is the preferred method for Grand Jury testimony.
      ii. For evaluation of trial testimony, the testifying examiner should attempt to get feedback from both the ADA and the defense attorney. The testifying employee can ask the attorney who summoned them to court to provide an evaluation form to the opposing counsel; however, if the attorney is not willing to do so it is not necessary to insist that it be done.

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   a. Appearance
   b. Poise
   c. Effectiveness of presentation (technical knowledge, ability to convey scientific concepts)
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4. Evaluation forms completed by someone other than the testifying employee's immediate supervisor are returned to the Quality Assurance Unit, and are then forwarded to the testifying examiner's immediate supervisor.

5. Immediate supervisors review the evaluation with the testifying examiner, discussing areas of strengths and weaknesses.

    a. The immediate supervisor may prescribe remedial action if the evaluation is unsatisfactory. Deficiencies in knowledge or courtroom presentation may require remedial training that includes one or both of the following:
        i. Retraining on technical information if the testimony was inaccurate.
        ii. Moot court retraining if the testimony showed deficiencies in the ability to express the concepts clearly.

6. The immediate supervisor and the testifying examiner sign/initial and date the evaluation form.

7. Completed evaluation forms are forwarded to the Quality Assurance Unit for storage.

Revision History:

February 9, 2010 – Initial version of procedure.

January 6, 2011 – Modify section B.2 to allow for courtroom testimony evaluation at trial by defense attorneys and to describe a possible mechanism for supplying forms to both ADAs and defense counsel. Modified Procedure to require the use of the Case Record Review Form, when necessary.

EQUIPMENT CALIBRATION AND MAINTENANCE		
DATE EFFECTIVE 07-16-2012	APPROVED BY EUGENE LIEN	PAGE 1 OF 3

GUIDING PRINCIPLES AND SCOPE

Equipment maintenance, calibration, and performance checks are essential for establishing confidence in the results that are generated during routine testing of forensic DNA samples. The Department of Forensic Biology uses equipment that is suitable for the tests conducted and will not use equipment that is outside of its permanent control.

PROCEDURE

A. CRITICAL EQUIPMENT

"**Critical equipment" is that which requires calibration or a performance check prior to its use in casework and periodically thereafter.** Such equipment must have records of calibration and/or preventative maintenance. Specific calibration, performance check, and/or preventative maintenance programs and procedures for critical equipment are found in the Quality Assurance/Quality Control Procedures Manual.

Critical equipment must have maintenance usage logs.

The following is "critical equipment" used within the Department of Forensic Biology for DNA testing:

- Balances/scales
- Thermal cyclers
- Real-time PCR systems
- Genetic analyzers
- Robotic systems
- Mechanical pipetters
- Thermal cycler temperature-verification systems.

The FBI Quality Assurance Standards for Forensic DNA Testing (July 2009) lists traceable thermometers used for conducting performance checks and electrophoresis detection systems as "critical equipment," however, the Department of Forensic Biology does not utilize these items.

B. NON-CRITICAL EQUIPMENT

All other equipment that is not covered under the definition of a "critical equipment," as per the FBI Quality Assurance Standards for Forensic DNA Testing (July 2009) is considered "non-critical." Examples of such equipment include pH meters, vortexers, and thermomixers.

The Department shall strive to conduct preventative maintenance on all non-critical equipment whenever feasible; however, it is not required to do so.

C. GENERAL PREVENTIVE MAINTENANCE

Maintaining cleanliness of any scientific equipment is the key to preventive maintenance. Spills must be taken care of **IMMEDIATELY.** Some spills may be corrosive to neighboring equipment and cause more damage than necessary. While some spills can be cleaned at the desk, some will require special treatment and/or additional follow-up. It is always best to contact the Forensic Biology Safety Coordinator or the OCME Health and Safety Unit for further information where needed.

D. EQUIPMENT DECONTAMINATION

Various Quality Control Procedures have been developed to help maintain a DNA-free environment at the points of sample contact with the equipment used in DNA analysis. A 10% bleach solution is extremely effective in degrading DNA and is thus used for general cleanup procedures of equipment and the laboratory environment (e.g. laboratory desks and benches). Because of its corrosive nature, the use of 10% bleach should be followed by the use of 70% ethanol and/or deionized water.

E. INSTRUMENT IRREGULARITIES

Anyone observing any irregularities with any equipment may suspend the equipment from casework use to prevent the potential loss of sample. If this occurs, the Quality Assurance Unit and/or the appropriate Technical Leader must be notified shortly thereafter for follow-up. If the irregularity cannot be repaired and must be taken offline, the Quality Assurance Unit member or the appropriate Technical Leader must properly mark the equipment to prevent further use.

Should repair and/or re-calibration occur, only a Quality Assurance Unit supervisor or the appropriate Technical Leader may re-certify that the equipment is available for casework. Any equipment taken offline for an extended period of time must either be removed from the bench, or a sign must be placed on the equipment to ensure that it is not used until appropriate repairs are made.

Re-certification requires that the Quality Assurance Unit supervisor and/or the appropriate Technical Leader ensure that any required performance checks have been successfully completed, documentation that the instrument is available for casework has been entered in the appropriate maintenance log (if it exists), and any signage to indicate otherwise is removed.

Revision History:

February 9, 2010 – Initial version of procedure.

July 16, 2012 – Specific terminology was removed and replaced with generic terminology to accommodate LIMS.

EQUIPMENT CALIBRATION AND MAINTENANCE		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 3

GUIDING PRINCIPLES AND SCOPE

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PROCEDURE

A. CRITICAL EQUIPMENT

"**Critical equipment" is that which requires calibration or a performance check prior to its use in casework and periodically thereafter.** Such equipment must have records of calibration and/or preventative maintenance. Specific calibration, performance check, and/or preventative maintenance programs and procedures for critical equipment are found in the Quality Assurance/Quality Control Procedures Manual.

Critical equipment must have maintenance logbooks. Maintenance logbooks must be kept near the associated critical equipment or in the Quality Assurance Unit, whichever is more practical.

The following is "critical equipment" used within the Department of Forensic Biology for DNA testing:

- Balances/scales
- Thermal cyclers
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- Genetic analyzers
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D. EQUIPMENT DECONTAMINATION

Various Quality Control Procedures have been developed to help maintain a DNA-free environment at the points of sample contact with the equipment used in DNA analysis. A 10% bleach solution is extremely effective in degrading DNA and is thus used for general cleanup procedures of equipment and the laboratory environment (e.g. laboratory desks and benches). Because of its corrosive nature, the use of 10% bleach should be followed by the use of 70% ethanol and/or deionized water.

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Anyone observing any irregularities with any equipment may suspend the equipment from casework use to prevent the potential loss of sample. If this occurs, the Quality Assurance Unit and/or the appropriate Technical Leader must be notified shortly thereafter for follow-up. If the irregularity cannot be repaired and must be taken offline, the Quality Assurance Unit member or the appropriate Technical Leader must properly mark the equipment to prevent further use.

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Re-certification requires that the Quality Assurance Unit supervisor and/or the appropriate Technical Leader ensure that any required performance checks have been successfully completed, documentation that the instrument is available for casework has been entered in the appropriate maintenance log (if it exists), and any signage to indicate otherwise is removed.

Revision History:

February 9, 2010 – Initial version of procedure.

EXOGENOUS DNA PREVENTION		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 3

GUIDING PRINCIPLES

Exogenous DNA is defined as the addition of DNA/biological fluid to evidence or controls subsequent to the crime. Sources of exogenous DNA could be first responders, crime scene technicians, NYPD personnel, or laboratory personnel, to name a few.

It is the goal of the Department of Forensic Biology to not transfer any DNA from employees to any casework sample. Several measures have been taken to prevent this, and this document will cover these measures in general.

PROCEDURE

A. Facility

The laboratory is divided into physically isolated areas for evidence examination, DNA extraction, pre-amplification (amplification setup) and post-amplification (amplification and DNA typing). Each area has its own dedicated equipment. Once samples are accepted into the laboratory, they move through these areas in one direction only. Samples are first processed in the evidence examination area. They are then moved to the DNA extraction area. Following DNA extraction, aliquots of each sample are quantitated in the DNA quantitation area. Following DNA quantitation, aliquots of each sample are moved into the pre-amplification area. Here fresh kit reagents are stored and samples are prepared for amplification. Finally, the samples are amplified and typed in the post-amplification area. This laboratory setup helps eliminate the travel of DNA from post-amplification areas back into non-amplified DNA areas.

B. Laboratory Clean-up

In addition to the separation of space between analyses, the Department has implemented a documented clean-up program on a monthly basis. The documented clean-up program may be more frequent in areas where High Sensitivity DNA Testing is performed. The clean-up program involves the decontamination of instruments/equipment, bench/counter tops, sinks, etc. While 10% Bleach is extremely effective in destroying exogenous DNA, it is also very corrosive. Care should be taken so that when 10% Bleach is used, it is immediately followed by 70% Ethanol and/or water to wash off the Bleach from the surface of instruments/equipment.

C. Sample Processing

Exemplar samples are processed separately from evidence samples. Also, only one sample is processed at a time using single-use disposable supplies whenever possible (e.g,. pipet tips), and scissors/tweezers are thoroughly cleaned between each sample.

D. Personal Protective Equipment (PPE)

PPE is designed to protect employees from serious workplace injuries or illnesses resulting from contact with chemical, reagents, or biological hazards. PPE includes a variety of devices and garments such as goggles, gloves, lab coats, etc. Proper PPE must be worn during analysis, and required PPE may vary from location to location depending on the hazards of the area. While PPE is designed to protect employees, it can also prevent the transfer of DNA from employees to work surfaces or evidence.

E. Contamination Prevention Equipment (CPE)

CPE is designed to prevent the occurrence of exogenous DNA in samples. While all PPE are considered as CPE, not all CPE can be considered as PPE. For example, in clean-rooms of the laboratory where high sensitivity DNA testing takes place, the wearing of booties or bouffant caps is to prevent the transfer of DNA from employees. CPE must be worn when designated and available. If not available, employees must first seek permission to work in that area from the appropriate Technical Leader and exercise extreme caution to maintain a clean environment.

F. Identification

Exogenous DNA may be indicated by 1) the presence of signal in reagent blanks, 2) the presence of extraneous alleles in positive controls, or 3) the presence of extraneous alleles in case samples. The confirmation of exogenous DNA may reflect a system failure or contamination of the samples by an outside source. The source may be equipment, reagents, the working environment, laboratory/law enforcement personnel, or an analytical error. It can either be a single isolated event (such as cross-contamination between two samples) or it can be persistent (such as dirty reagents or equipment). To remedy a single isolated event, the appropriate extraction, quantitation, amplification and/or STR analysis is repeated.

To aid in the identification of exogenous DNA, the LAB TYPES DATABASE procedure is used.

The Quality Assurance Manager and/or the appropriate Technical Leader must be notified if exogenous DNA is detected. The source of this DNA should be identified, if possible, and eliminated. For persistent events, the QUALITY INCIDENT REVIEW procedure must be followed to prevent the recurrence of the problem.

G. Interpretation and reporting

Samples containing exogenous DNA must be interpreted and reported carefully. This is further discussed in the GENERAL GUIDELINES FOR DNA CASEWORK procedure.

Revision History:

February 9, 2010 – Initial version of procedure.

LAB TYPES DATABASE		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 7

GUIDING PRINCIPLES AND SCOPE

"Lab Types" is a DNA database that contains the DNA profiles of individuals who have access to laboratory space and/or may come into contact with an item of evidence prior to or during processing. It also contains nationally-recognized exogenous DNA profiles. This database is a part of the Quality Assurance Program of the laboratory and must be searched in order to assure that no casework DNA profile was contributed by someone during or after the investigation.

The individuals included in Lab Types include past and present personnel of the OCME, members of housekeeping staff, equipment vendors, select members of NYPD, and various visitors to the laboratory.

This procedure describes the collection, identification, processing, and disposition of samples used to create the DNA profiles stored in the database. It also describes the processes for the operation and maintenance of the database as well as how the database is used by casework analysts.

PROCEDURE

A. Sample Collection

1. All samples collected internally for Lab Types processing must be collected by an authorized individual (most often a member of the Exemplar Team).

2. The proper consent form must be filled out and signed by the donor prior to the collection of the swabs. This form will be stored with the Exemplar Team.

3. A five-digit sample ID number is generated for each donor. The five-digit ID number meets the following conditions:
   i. It falls within the numerical range 00000 to 99999, inclusive
   ii. It is generated randomly each time a new swab is collected (a Microsoft Excel formula or macro may be used for generating random numbers).
   iii. It is unique to all other assigned ID numbers, past or present.

4. This number is placed on a large coin envelope that is also labeled with the donor's name. The information is recorded in the Lab Types excel spreadsheet. This number becomes the sample identifier.

5. The donor should apply two cotton swabs to the inside of their buccal (cheek) area. These swabs should them be placed swab-end first into their original wrappers and handed to the authorized collector.

6. Once collected, the swabs are placed into the labeled envelope and brought to the Exemplar Examination room for processing.

7. Forensic Biology may also receive oral swab samples collected by outside agencies and submitted to the laboratory in sealed envelopes. These samples are given ID numbers prior to processing.

8. Lab Types samples are classified as reference materials.

B. Sample Processing

1. Lab Types samples can be processed along with casework exemplar samples.

2. After cutting, the swabs are returned to their envelopes. In most cases, these envelopes are placed in the appropriate container for long-term storage. For situations where samples are not to be stored by Forensic Biology, see the *Sample Disposition* section.

3. Extraction, quantitation, amplification, and STR analysis are performed identically to casework exemplar samples. Copies of relevant paperwork and/or results are sent to the Lab Types Custodian.

C. Sample Disposition

1. Lab Types samples and extracts are stored like all other exemplar swabs. In certain circumstances, a swab and extract may need to be destroyed or returned to an individual.
   i. NYPD swabs and extracts will be returned to the NYPD Integrity Control Officer.

2. To return a sample, the envelope is cut open so that the Eppendorf tube containing the sample extract can be inserted along with the swabs. The five-digit ID number written on the envelope is obscured or removed.

3. In circumstances where samples need to be destroyed, the swabs and extract can be disposed of in the appropriate biohazard containers.

D. Database Maintenance

1. The Lab Types Custodian is in charge of keeping the main Lab Types Database up to date with all relevant information as results arrive.

2. The information is maintained as an Access database and must include, but is not limited to:

   i. ID number
   ii. department/agency/employer of donor
   iii. Date of swab receipt
   iv. Date and time of extraction, quantitation, and amplification
   v. quantitation value
   vi. STR run name
   vii. DNA profile

E. Lab Types Reference Databases

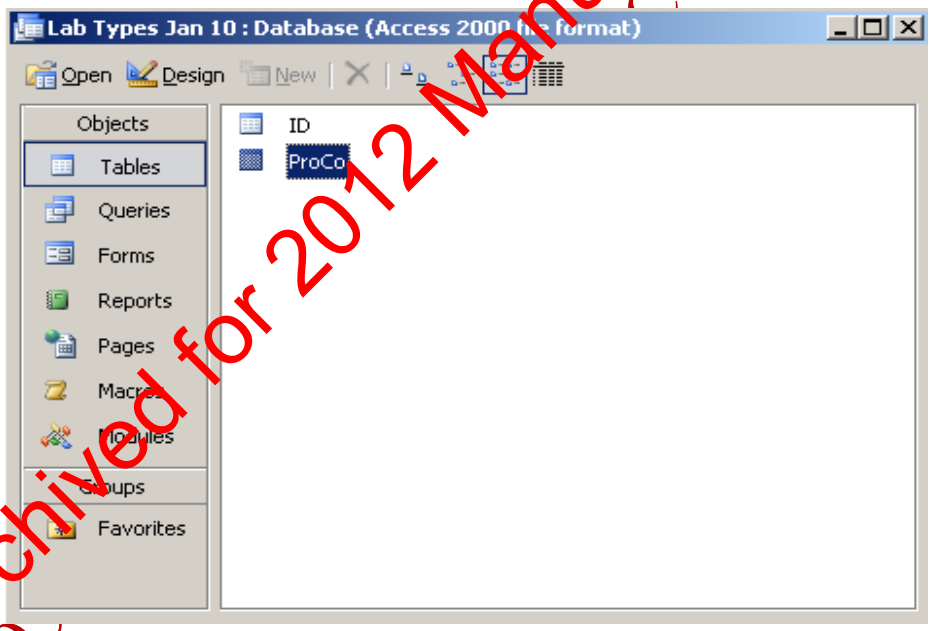
1. Due to the nature of the information kept in the main Lab Types Databank, the full version is not suitable for general usage by analysts for comparison to evidence profiles. For this reason, copies of the main Lab Types Databank are created with various data fields deleted or hidden from view.

2. Two versions of the main Lab Types Databank are periodically created for routine use by analysts or managers.
   i. One version contains only the ID numbers and the corresponding DNA profiles and is designed for use by analysts for comparison with casework DNA profiles.
   ii. A second version is designed for use by management, and has ID numbers, DNA profiles, and names of sample donors.

3. Each version is spot-checked and write-protected prior to placement online.
   i. To spot-check a truncated version of the database, an authorized analyst other than the Lab Types Custodian checks the database entries against electropherograms of the samples.
   ii. After this has been completed, the copies are created and write-protected. These copies are then directed to the Lab Types Manager for approval and placement on the network for general usage.

F. Searching the Lab Types Database

1. The Lab Types databank in Access can be sorted by genotype at each locus. The databank has two tables, **ID** and **ProCo,** which has the same profiles, but with the loci arranged in different orders. (See diagram on the next page)
   - **i.** **ID** has all profiles with the locus order of Identifiler results. **ProCo** has all profiles with the locus order of combined **Profiler Plus** and **Cofiler** results.
   - ii. It is recommended that ID be used to compare against STR results, while ProCo is organized to make comparison against CODIS paperwork easier.

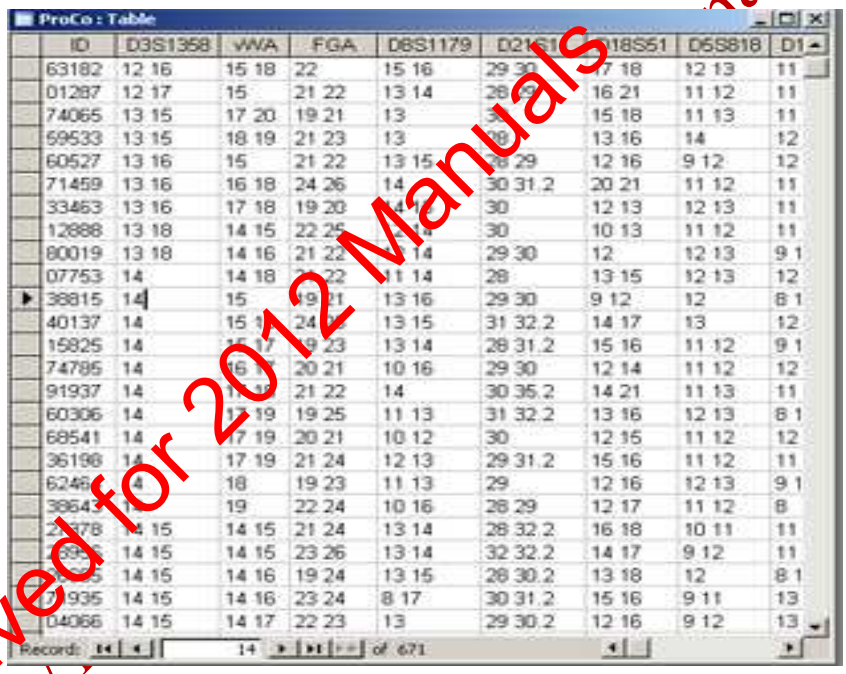


2. Double click the desired table.

3. There are two ways to search: manual and filtered. In both tables, profiles are automatically sorted in numerical order from top to bottom across all columns.

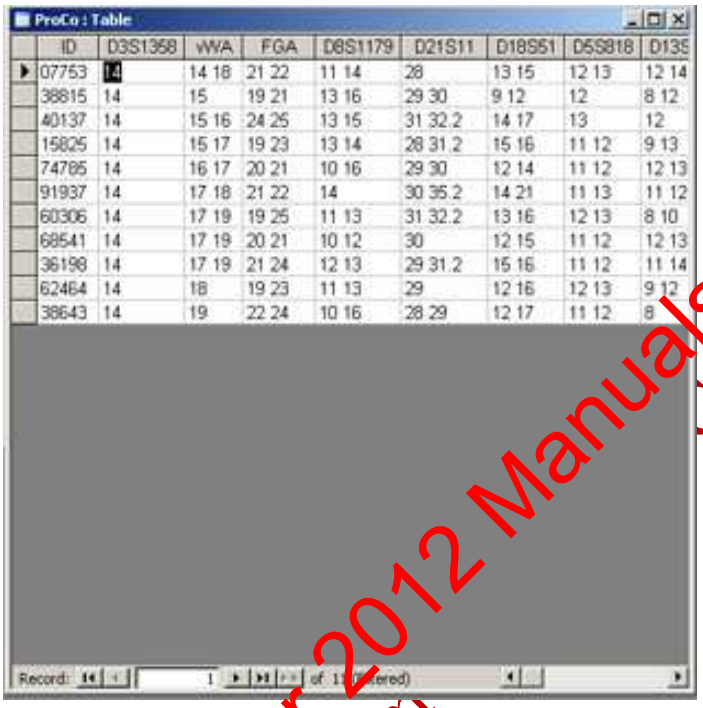
4. **Manual Search.** To search manually, an analyst scrolls down until they find the genotype at the locus in the first column.

5. **Filtered Search.** To perform a filtered search, scroll until the genotype at the first locus is visible. Click on the box that contains this genotype. In the example that follows, the profile being compared against Lab Types has a genotype of 14 at locus D3S1358. A box in the D3S1358 column with the genotype 14 was clicked, as indicated by the cursor which is visible as a blinking vertical bar inside the box.

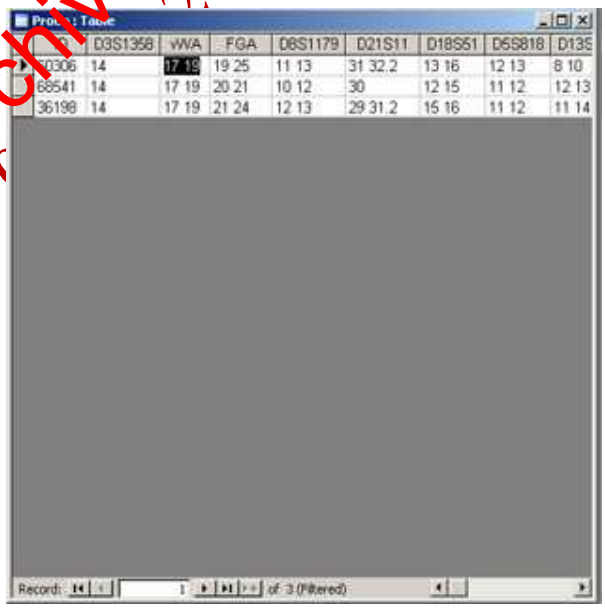


The toolbar near the top of the screen should have a Filter By Selection icon that looks like a gray funnel with a yellow lightning bolt.

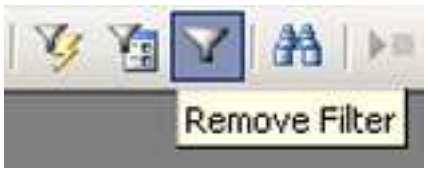
Clicking the icon will filter out all profiles except those that have the genotype at the locus selected. This is a visual filter; no profiles are removed from the databank.



The results can be further filtered by clicking another box and again clicking the "Filter by Selection" icon. Here, the 17, 19 genotype at vWA has been selected to further narrow the profiles.



This process can be done with as many subsequent loci as necessary. To reset the filter and display the entire database again, click Remove Filter icon on the toolbar (looks like a gray funnel.)



LAB TYPES DATABASE		
DATE EFFECTIVE 10-01-2012	APPROVED BY EUGENE LIEN	PAGE 1 OF 7

GUIDING PRINCIPLES AND SCOPE

"Lab Types" is a DNA database that contains the DNA profiles of individuals who have access to laboratory space and/or may come into contact with an item of evidence prior to or during processing. It contains locally- and nationally-recognized exogenous DNA profiles. This database is a part of the Quality Assurance Program of the laboratory and must be searched in order to assure that no casework DNA profile was contributed by someone during or after the investigation.

The individuals included in Lab Types include past and present personnel of the OCME, members of housekeeping staff, equipment vendors, select members of NYPD, and various visitors to the laboratory. Any DNA profiles that link cases together but are found to be exogenous will be kept in Lab Types under a contaminant listing.

This procedure describes the collection, identification, processing, and disposition of samples used to create the DNA profiles stored in the database. It also describes the processes for the operation and maintenance of the database as well as how the database is used by casework analysts.

PROCEDURE

A. Sample Collection

1. All samples collected internally for Lab Types processing must be collected by an authorized individual (most often a member of the Exemplar Team).

2. The proper consent form must be completed by the donor prior to the collection of the swabs. This form will be stored with the Exemplar Team.

3. A five-digit sample ID number is generated for each donor. The five-digit ID number meets the following conditions:
   i. It falls within the numerical range 00000 to 99999, inclusive
   ii. It is generated randomly each time a new swab is collected.
   iii. It is unique to all other assigned ID numbers, past or present.

4. This number is placed on a large coin envelope that is also labeled with the donor's name. The information is recorded in Lab Types. This number becomes the sample identifier.

5. The donor should apply two cotton swabs to the inside of their buccal (cheek) area. These swabs should them be placed swab-end first into their original wrappers and handed to the authorized collector.

6. Once collected, the swabs are placed into the labeled envelope and brought to the Exemplar Examination room for processing.

7. Forensic Biology may also receive oral swab samples collected by outside agencies and submitted to the laboratory in sealed envelopes. These samples are given ID numbers prior to processing.

8. Lab Types samples are classified as reference materials.

9. Lab Types samples have a Target Date of 60 days from the date of collection or from the date of receipt of samples collected by outside agencies.

B. Sample Processing

1. Lab Types samples can be processed along with casework exemplar samples.

2. After cutting, the swabs are returned to their envelopes. In most cases, these envelopes are placed in the appropriate container for long-term storage. For situations where samples are not to be stored by Forensic Biology, see the *Sample Disposition* section.

3. Extraction, quantitation, amplification, and STR analysis are performed identically to casework exemplar samples. The results are sent to the Lab Types Custodian.

C. Sample Disposition

1. Lab Types samples and extracts are stored like all other exemplar swabs. In certain circumstances, a swab and extract may need to be destroyed or returned to an individual.
   i. NYPD swabs and extracts will be returned to the NYPD Integrity Control Officer.

2. To return a sample, the envelope is cut open so that the Eppendorf tube containing the sample extract can be inserted along with the swabs. The five-digit ID number written on the envelope is obscured or removed.

3. In circumstances where samples need to be destroyed, the swabs and extract can be disposed of in the appropriate biohazard containers.

D. Database Maintenance

1. The Lab Types Custodian is in charge of keeping the main Lab Types Database up to date with all relevant information as results arrive.

2. The information is maintained as an Access database and must include, but is not limited to:

   i. ID number
   ii. department/agency/employer of donor
   iii. Date of swab receipt
   iv. Date and time of extraction, quantitation, and amplification
   v. quantitation value
   vi. STR run name
   vii. DNA profile

E. Lab Types Reference Databases

1. Due to the nature of the information kept in the main Lab Types Databank, the full version is not suitable for general usage by analysts for comparison to evidence profiles. For this reason, copies of the main Lab Types Databank are created with various data fields deleted or hidden from view.

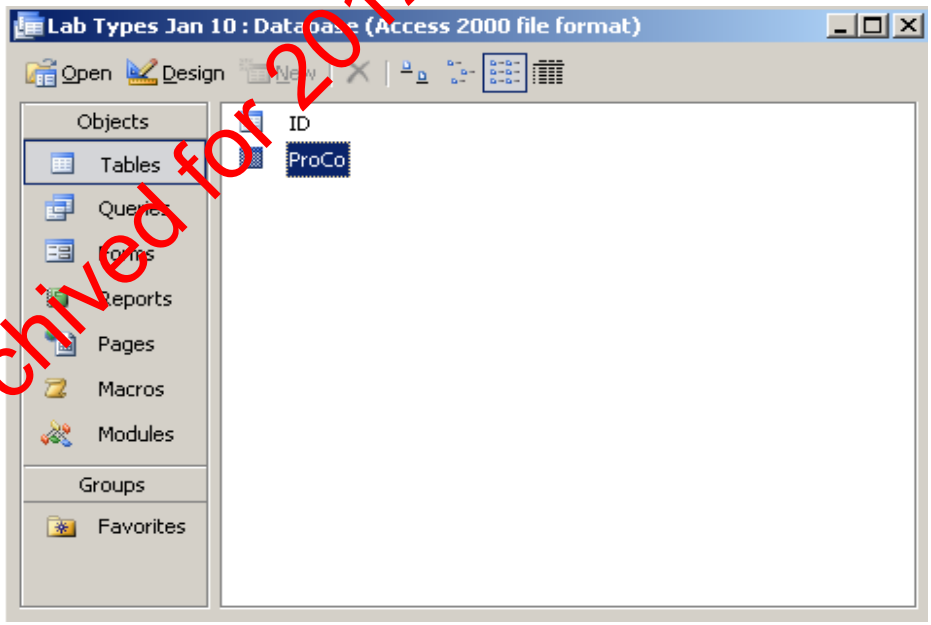
2. Two versions of the main Lab Types Databank are periodically created for routine use by analysts or managers.
   i. One version contains only the ID numbers and the corresponding DNA profiles and is designed for use by analysts for comparison with casework DNA profiles.
   ii. A second version is designed for use by management, and has ID numbers, DNA profiles, and names of sample donors.

3. Each version is spot-checked and write-protected prior to placement online.
   i. To spot-check a truncated version of the database, an authorized analyst other than the Lab Types Custodian checks the database entries against electropherograms of the samples.

ii. After this has been completed, the copies are created and write-protected. These copies are then directed to the Lab Types Manager for approval and placement on the network for general usage.

F. Searching the Lab Types Database

1. The Lab Types databank in Access can be sorted by genotype at each locus. The databank has two tables, **ID** and **ProCo,** which has the same profiles, but with the loci arranged in different orders. (See diagram on the next page)
   i. **ID** has all profiles with the locus order of Identifiler results. **ProCo** has all profiles with the locus order of combined **Profiler Plus** and **Cofiler** results.
   ii. It is recommended that ID be used to compare against STR results, while ProCo is organized to make comparison against CODIS paperwork easier.



2. Double click the desired table.

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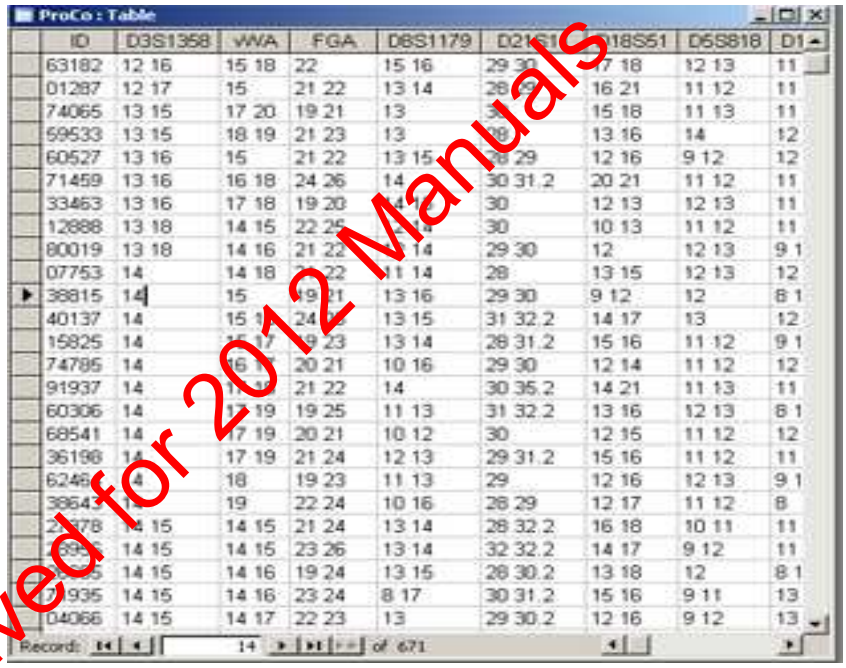
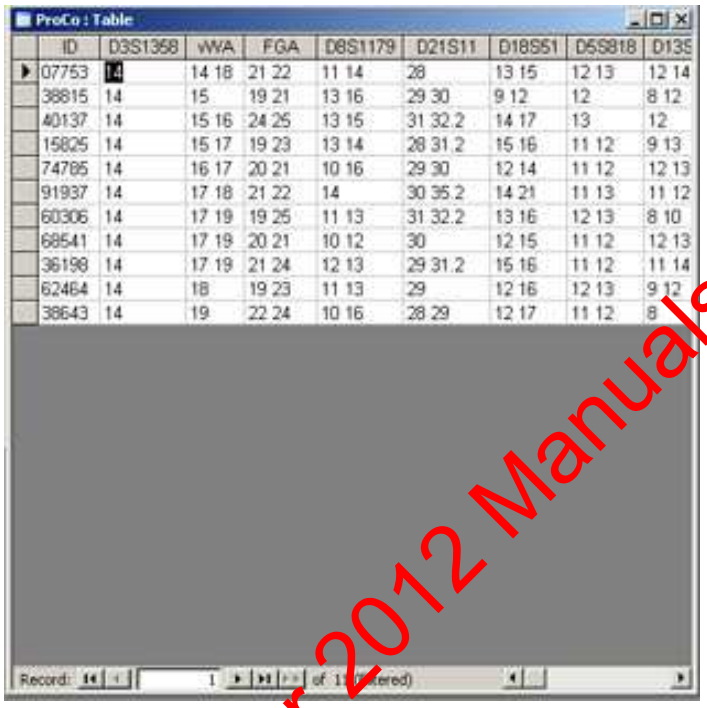
4. **Manual Search.** To search manually, an analyst scrolls down until they find the genotype at the locus in the first column.

5. **Filtered Search.** To perform a filtered search, scroll until the genotype at the first locus is visible. Click on the box that contains this genotype. In the example that follows, the profile being compared against Lab Types has a genotype of 14 at locus D3S1358. A box in the D3S1358 column with the genotype 14 was clicked, as indicated by the cursor which is visible as a blinking vertical bar inside the box.

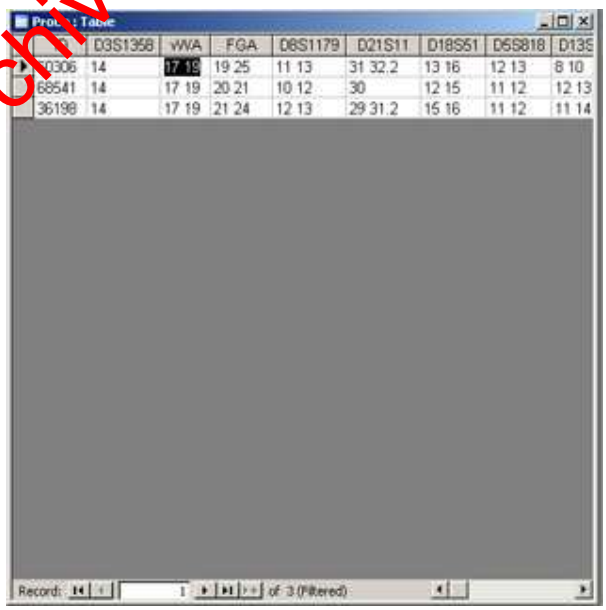


The toolbar near the top of the screen should have a Filter By Selection icon that looks like a gray funnel with a yellow lightning bolt.

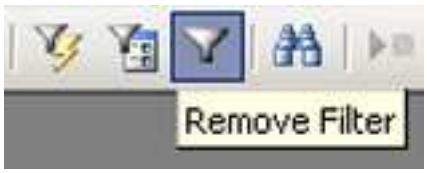
Clicking the icon will filter out all profiles except those that have the genotype at the locus selected. This is a visual filter; no profiles are removed from the databank.



The results can be further filtered by clicking another box and again clicking the "Filter by Selection" icon. Here, the 17, 19 genotype at vWA has been selected to further narrow the profiles.



This process can be done with as many subsequent loci as necessary. To reset the filter and display the entire database again, click Remove Filter icon on the toolbar (looks like a gray funnel.)



Revision History:

February 9, 2010 – Initial version of procedure.
April 30, 2012 – Revised the "Guiding Principles and Scope" section. Lab Types contains both locally- and nationally-recognized exogenous DNA profiles and are kept under a "contaminant" listing.
July 16, 2012 – Specific terminology was removed and replaced with generic terminology to accommodate LIMS.
October 1, 2012 – A Target Date of 60 days for Lab Types samples was added to "Section A – Sample Collection."

LAB TYPES DATABASE		
DATE EFFECTIVE 04-30-2012	APPROVING AUTHORITY QUALITY ASSURANCE MANAGER	PAGE 1 OF 7

GUIDING PRINCIPLES AND SCOPE

"Lab Types" is a DNA database that contains the DNA profiles of individuals who have access to laboratory space and/or may come into contact with an item of evidence prior to or during processing. It contains locally- and nationally-recognized exogenous DNA profiles. This database is a part of the Quality Assurance Program of the laboratory and must be searched in order to assure that no casework DNA profile was contributed by someone during or after the investigation.

The individuals included in Lab Types include past and present personnel of the OCME, members of housekeeping staff, equipment vendors, select members of NYPD, and various visitors to the laboratory. Any DNA profiles that link cases together but are found to be exogenous will be kept in Lab Types under a contaminant listing.

This procedure describes the collection, identification, processing, and disposition of samples used to create the DNA profiles stored in the database. It also describes the processes for the operation and maintenance of the database as well as how the database is used by casework analysts.

PROCEDURE

A. Sample Collection

1. All samples collected internally for Lab Types processing must be collected by an authorized individual (most often a member of the Exemplar Team).

2. The proper consent form must be filled out and signed by the donor prior to the collection of the swabs. This form will be stored with the Exemplar Team.

3. A five-digit sample ID number is generated for each donor. The five-digit ID number meets the following conditions:
   i. It falls within the numerical range 00000 to 99999, inclusive
   ii. It is generated randomly each time a new swab is collected (a Microsoft Excel formula or macro may be used for generating random numbers).
   iii. It is unique to all other assigned ID numbers, past or present.

4. This number is placed on a large coin envelope that is also labeled with the donor's name. The information is recorded in the Lab Types excel spreadsheet. This number becomes the sample identifier.

5. The donor should apply two cotton swabs to the inside of their buccal (cheek) area. These swabs should them be placed swab-end first into their original wrappers and handed to the authorized collector.

6. Once collected, the swabs are placed into the labeled envelope and brought to the Exemplar Examination room for processing.

7. Forensic Biology may also receive oral swab samples collected by outside agencies and submitted to the laboratory in sealed envelopes. These samples are given ID numbers prior to processing.

8. Lab Types samples are classified as reference materials.

B. Sample Processing

1. Lab Types samples can be processed along with casework exemplar samples.

2. After cutting, the swabs are returned to their envelopes. In most cases, these envelopes are placed in the appropriate container for long-term storage. For situations where samples are not to be stored by Forensic Biology, see the *Sample Disposition* section.

3. Extraction, quantification, amplification, and STR analysis are performed identically to casework exemplar samples. Copies of relevant paperwork and/or results are sent to the Lab Types Custodian.

C. Sample Disposition

1. Lab Types samples and extracts are stored like all other exemplar swabs. In certain circumstances, a swab and extract may need to be destroyed or returned to an individual.
   i. NYPD swabs and extracts will be returned to the NYPD Integrity Control Officer.

2. To return a sample, the envelope is cut open so that the Eppendorf tube containing the sample extract can be inserted along with the swabs. The five-digit ID number written on the envelope is obscured or removed.

3. In circumstances where samples need to be destroyed, the swabs and extract can be disposed of in the appropriate biohazard containers.

D. Database Maintenance

1. The Lab Types Custodian is in charge of keeping the main Lab Types Database up to date with all relevant information as results arrive.

2. The information is maintained as an Access database and must include, but is not limited to:

   i. ID number
   ii. department/agency/employer of donor
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   iv. Date and time of extraction, quantitation, and amplification
   v. quantitation value
   vi. STR run name
   vii. DNA profile

E. Lab Types Reference Databases

1. Due to the nature of the information kept in the main Lab Types Databank, the full version is not suitable for general usage by analysts for comparison to evidence profiles. For this reason, copies of the main Lab Types Databank are created with various data fields deleted or hidden from view.

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1. The Lab Types databank in Access can be sorted by genotype at each locus. The databank has two tables, **ID** and **ProCo,** which has the same profiles, but with the loci arranged in different orders. (See diagram on the next page)
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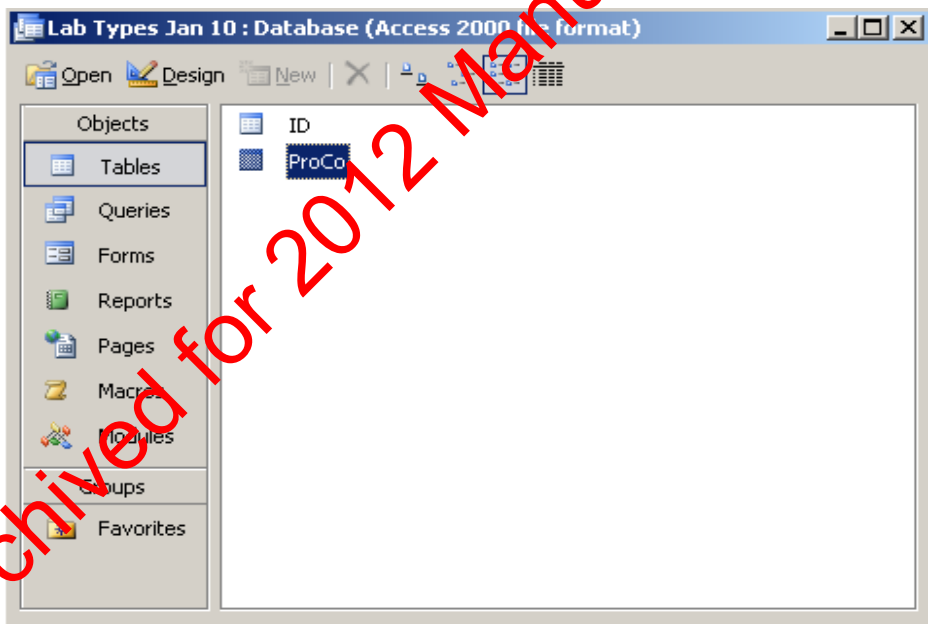

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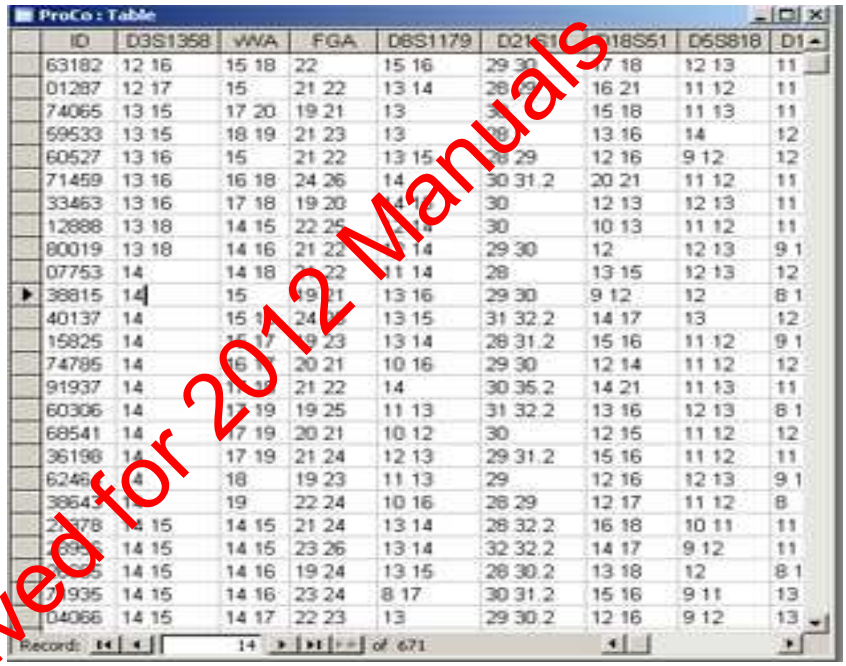

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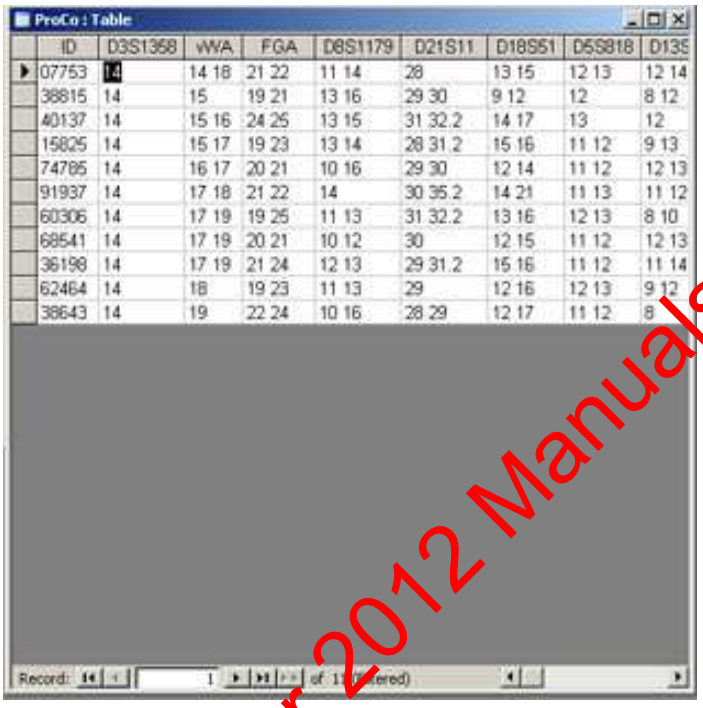

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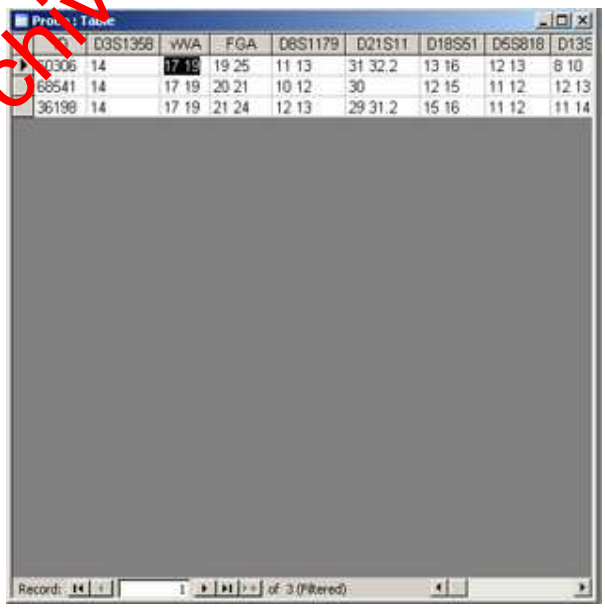

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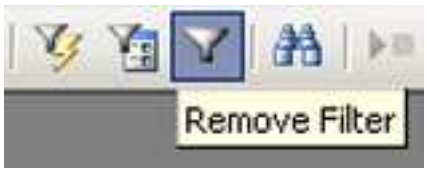

Revision History:

February 9, 2010 – Initial version of procedure.

April 30, 2012 – Revised the "Guiding Principles and Scope" section. Lab Types contains both locally- and nationally-recognized exogenous DNA profiles and are kept under a "contaminant" listing.

LAB TYPES DATABASE		
DATE EFFECTIVE 07-16-2012	APPROVED BY EUGENE LIEN	PAGE 1 OF 7

GUIDING PRINCIPLES AND SCOPE

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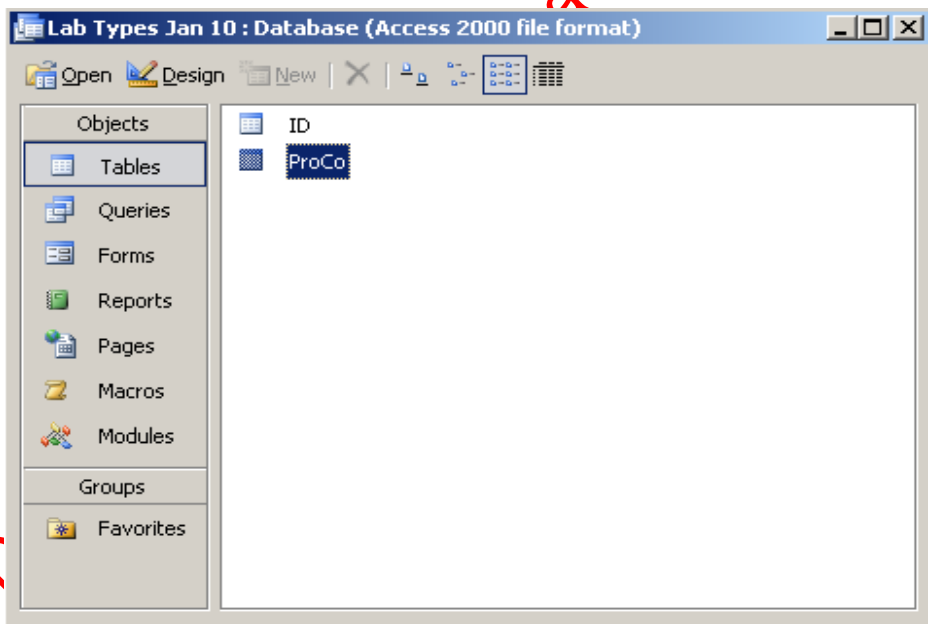

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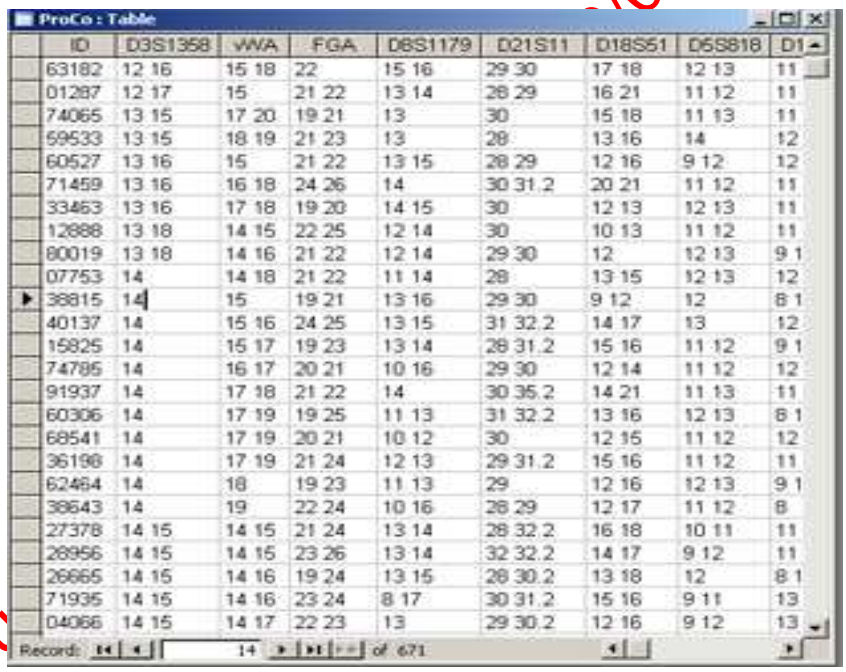

ProCo : Table

ID	D3S1358	vWA	FGA	D8S1179	D21S11	D18S51	D5S818	D1
63182	12 16	15 18	22	15 16	29 30	17 18	12 13	11
01287	12 17	15	21 22	13 14	28 29	16 21	11 12	11
74065	13 15	17 20	19 21	13	30	15 18	11 13	11
59533	13 15	18 19	21 23	13	28	13 16	14	12
60527	13 16	15	21 22	13 15	28 29	12 16	9 12	12
71459	13 16	16 18	24 26	14	30 31.2	20 21	11 12	11
33463	13 16	17 18	19 20	14 15	30	12 13	12 13	11
12888	13 18	14 15	22 25	12 14	30	10 13	11 12	11
80019	13 18	14 16	21 22	12 14	29 30	12	12 13	9 1
07753	14	14 18	21 22	11 14	28	13 15	12 13	12
38815	14	15	19 21	13 16	29 30	9 12	12	8 1
40137	14	15 16	24 25	13 15	31 32.2	14 17	13	12
15825	14	15 17	19 23	13 14	28 31.2	15 16	11 12	9 1
74785	14	16 17	20 21	10 16	29 30	12 14	11 12	12
91937	14	17 18	21 22	14	30 35.2	14 21	11 13	11
60306	14	17 19	19 25	11 13	31 32.2	13 16	12 13	8 1
68541	14	17 19	20 21	10 12	30	12 15	11 12	12
36198	14	17 19	21 24	12 13	29 31.2	15 16	11 12	11
62464	14	18	19 23	11 13	29	12 16	12 13	9 1
38643	14	19	22 24	10 16	28 29	12 17	11 12	8
27378	14 15	14 15	21 24	13 14	28 32.2	16 18	10 11	11
28956	14 15	14 15	23 26	13 14	32 32.2	14 17	9 12	11
26665	14 15	14 16	19 24	13 15	28 30.2	13 18	12	8 1
71935	14 15	14 16	23 24	8 17	30 31.2	15 16	9 11	13
04066	14 15	14 17	22 23	13	29 30.2	12 16	9 12	13

Record: 14 of 671

The toolbar near the top of the screen should have a Filter By Selection icon that looks like a gray funnel with a yellow lightning bolt.

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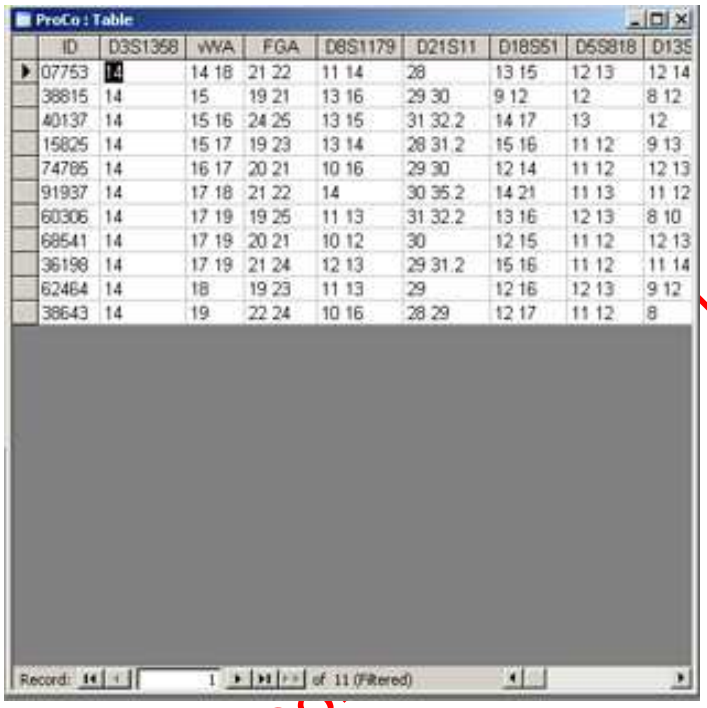
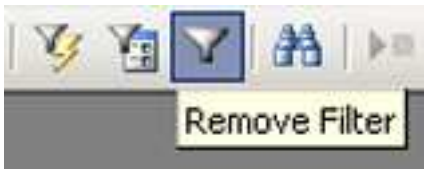


The results can be further filtered by clicking another box and again clicking the "Filter by Selection" icon. Here, the 17, 19 genotype at vWA has been selected to further narrow the profiles.

This process can be done with as many subsequent loci as necessary. To reset the filter and display the entire database again, click Remove Filter icon on the toolbar (looks like a gray funnel.)



Revision History:

February 9, 2010 – Initial version of procedure.

April 30, 2012 – Revised the "Guiding Principles and Scope" section. Lab Types contains both locally- and nationally-recognized exogenous DNA profiles and are kept under a "contaminant" listing.

July 16, 2012 – Specific terminology was removed and replaced with generic terminology to accommodate LIMS.

PREVENTIVE ACTION		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 2

GUIDING PRINCIPLES AND SCOPE

Preventive action is a pro-active process to identify opportunities for improvement and potential sources of non-conformities rather than a re-active process to the identification of problems or complaints. Aside from the review of the operational procedures, preventive action may involve analysis of data including trend and risk analyses and proficiency test results.

This document describes the Department's procedure to identify potential preventive actions, either technical or concerning the Management System, and the steps to be taken to deal with the issues identified.

PROCEDURE

1. Any staff member that becomes aware of potential sources of non-conformities in laboratory operations informs their immediate supervisor and/or Assistant Director as soon as practicable.
   a. Immediate supervisors notify their Assistant Director if the AD was not part of the initial notification. The initial process to communicate potential preventive actions up the chain-of-command ensures that any follow-up action is implemented sooner, rather than later.

2. The immediate supervisor and/or Assistant Director investigates the potential problem and conducts a preliminary review of the root cause(s) of any potential non-conformity to determine if action is necessary. The appropriate Technical Leader (if the potential problem is a technical problem), the Quality Assurance Manager, and/or other supervisors/managers may be consulted for assistance.
   a. If the investigating supervisor/manager does not agree that a potential problem exists, no further action is necessary.

3. If the investigating supervisor/manager agrees that a potential problem exists, and if a root cause of the potential non-conformity is determined, the immediate supervisor and/or Assistant Director develops a plan of action to deal with the issue. This may include a change in technical procedures and/or the initiation of new guiding principles. The plan of action shall include the initiation of controls to ensure that the preventive actions are effective. A description of the potential problem, root cause, and plan of action is documented on a **Preventive Action Form** and submitted to the Quality Assurance Manager. If the preventive action is of a technical nature, the Quality Assurance Manager will forward the form to the appropriate Technical Leader for review.

4. If the preventive action is of a technical nature, the appropriate Technical Leader either approves the plan or decides on an alternate arrangement.

   If the preventive action concerns a potential non-conformity in the Management System, the Director or his/her designee either approves the plan or decides on an alternate arrangement.

5. The Preventive Action Form and any associated documentation (such as Manual Change Forms, copies of emails, etc.) are filed with the Quality Assurance Unit.

6. The Quality Assurance Manager reviews the Preventive Action Form within six months to determine if the preventive action plan that was put into place has been effective.
   a. The Quality Assurance Manager records their evaluation of effectiveness on the Preventive Action form, e.g., a notation that none of the anticipated non-conformities had occurred.
   b. If the action plan is determined to have been effective, the preventive action is considered to be complete.
   c. If the action plan is determined not to have been effective, the Quality Manager will determine whether the changes made as a result of the action plan need to be discontinued or revised.

PROFICIENCY TESTING PROGRAM		
EFFECTIVE DATE 02-09-2010	APPROVED BY EUGENE LIEN & ELI SHAPIRO	PAGE 1 OF 5

GUIDING PRINCIPLES AND SCOPE

Proficiency tests are given to qualified analysts to evaluate both their individual competence and the quality performance of the laboratory. Proficiency tests must be analyzed using only approved methods and/or procedures. While there are several types of proficiency tests, the Department of Forensic Biology utilizes open-external proficiency testing and blind-reanalysis proficiency testing.

The proficiency testing program is designed to meet the requirements of ASCLD/LAB and the Quality Assurance Standards for Forensic DNA Testing Laboratories. The external proficiency testing program is not just a requirement; it is also a quality assurance measure used to monitor performance and identify areas in which improvement may be needed.

External DNA proficiency tests are obtained from New York State and ASCLD/LAB approved proficiency test providers, for example, Collaborative Testing Service (CTS), Orchid Cellmark (IQAS), and the College of American Pathologists (CAP).

Serology results are reported on DNA tests obtained from CTS.

PROCEDURE

A. DNA OPEN-EXTERNAL PROFICIENCY TESTING PROGRAM

1. All analysts, technical reviewers, and technicians undergo semiannual external proficiency testing to the full extent in which they perform each technology in casework. Technology refers to the type of forensic DNA analysis performed (i.e. STR, YSTR, mtDNA.) The program is administered in an open proficiency-testing format and in accordance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

2. One test is assigned to each participant in the first six months of the calendar year and the second test is assigned in the last six months of the calendar year.
   a. The interval between consecutive tests must be at least four months and cannot exceed eight months.
   b. **The laboratory uses the <u>assigned date</u> to calculate the interval between tests**.
   c. Newly qualified individuals enter the external proficiency testing program within six months of the date of their qualification.

3. The scheduling of external proficiency tests is completed by a member of the Quality Assurance Unit prior to the start of each calendar year. While minor changes may be made during the year (test vendor, paired analyst, addition/removal of personnel, etc.), the schedule of each analyst/technician is not changed unless a change is necessary due to an extended leave of absence.

4. All specimens of an external proficiency test are analyzed according to current standard operating procedures. However, some exceptions are made in order to comply with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. For example, the following sample types, which during normal casework analysis might only be tested in one or two multiplex reactions, must be amplified at all CODIS core loci or CODIS core sequences and tested in all applicable technologies (Autosomal STR, Y-STR and/or Mitochondrial DNA) to the full extent that the analyst participates in casework:

   1) Excluded suspects
   2) Mixtures, even if there are other clean profiles
   3) Epithelial cell fractions from an unknown stain or from a body orifice swab, even if the results match the victim type.

5. The laboratory utilizes a team approach for casework testing. Therefore, proficiency tests are conducted in the same manner. However, each individual is proficiency tested at least once per year in each methodology to the full extent of his or her participation in casework.

   Methodology refers to analytical procedures used to support a DNA-typing technology [i.e. extraction methods (manual v. automated,) quantification methods, typing test kits and instrument platforms]. The extent in which each individual participates in casework may be team dependent.

   Individuals who perform STR, YSTR, and/or mtDNA amplification, analysis and/or review must perform these skills twice per year per technology.

   a. Unlike other titles, Criminalist Level I's are competent only in selected areas of the analytical process and their competency differs between the different teams within the laboratory. Criminalist I's cannot interpret the final DNA typing data or prepare an associated written scientific report. Thus, their participation in proficiency tests is limited to the methodologies that they are competent in and they are paired with a DNA Analyst on proficiency tests.

b. Individuals using both manual and automated methods are proficiency-tested in each at least once per year.

6. A laboratory report to summarize the results of the Proficiency Test is written by the DNA interpreting analyst. The DNA interpreting analyst is also responsible for completing any vendor paperwork to document the results. The DNA interpreting analyst must ensure that the data transcribed to the vendor's paperwork is accurate. The proficiency test file is then forwarded to the analyst's supervisor, manager, and/or designee for a full technical review.

7. In addition to conducting a full technical review of the proficiency test file, the reviewer(s) must also review the completed vendor's paperwork to ensure that data has been transcribed correctly. Furthermore, the reviewer(s) must complete a Proficiency Test Review Form to document the review of the proficiency test.

8. The Proficiency Test Review Form contains a checklist specific for the evaluation of proficiency tests and an area for the technical reviewer to document any non-conformity. This form gives supervisors a mechanism to evaluate an analyst's overall performance and gives the manager a mechanism to evaluate the supervisor's case review skills.

9. After the proficiency test has been completed (including a full administrative review), the DNA interpreting analyst assigned to the proficiency test is responsible for delivering the test results to the test vendor. The delivery method may vary from vendor to vendor, but is typically either by fax or e-mail.

10. After official results have been received by the proficiency test provider, a Quality Assurance Unit supervisor grades the tests. The Proficiency Test Evaluation Form contains a checklist for the supervisor to document any discrepancies.

a. Non-administrative discrepancies on proficiency tests that affect typing results and/or conclusions should be reported to the appropriate Technical Leader at the time of discovery. If confirmed, the Technical Leader must inform the CODIS Custodian/Supervisor so that appropriate follow-up action can be initiated. A formal QUALITY INCIDENT REVIEW may be required.

11. All proficiency-test participants are informed of their final test results. Participants are required to sign the appropriate area on the Proficiency Test Evaluation Form to document that they have received and have been informed of the final test results.

12. After the grading of all proficiency tests within the series, the supervisor informs the appropriate Technical Leader of the results of all participants.

B. SEROLOGY OPEN-EXTERNAL PROFICIENCY TESTING PROGRAM

Serology is a sub-discipline of the Biology discipline (as per ASCLD/LAB). The laboratory will endeavor to arrange for each employee to annually complete a serology proficiency test, but it is not required to do so.

Forensic Biology proficiency tests purchased from CTS allows the participant to report results for serology tests as well as for DNA testing. Therefore, serology proficiency testing is satisfied in this manner. The management of this test is identical to the management of DNA external proficiency tests – tests are reported, reviewed, and participants are evaluated in the same manner.

C. BLIND RE-ANALYSIS PROFICIENCY TESTING PROGRAM

1. The Blind Re-analysis Proficiency Testing Program is a quality assurance program where a previously examined sample is re-examined by a different analyst to check for correctness of the initial examination and results.

2. **DNA Blind Reanalysis Program.** The Quality Assurance Unit is responsible for reanalyzing DNA samples, reviewing the results, and comparing them to the original analyses.
   a. Each month, a minimum of two (2) exemplar samples are selected from cases completed within the previous year.

b. Each sample is submitted for extraction, quantitation, amplification (in at least one casework multiplex system), analyzed for STR results, and the results compared to the original results. Re-examined results are documented separate from the case file and maintained as a record by the Quality Assurance Unit.

c. A second reanalysis must be performed if the results are not concordant. All follow-up actions must be documented and maintained.

3. **Serology Blind Reanalysis Program.** The laboratory has a blind serology re-analysis program for negative cases. The purpose of this program is to ensure that negative serology results are accurate.

a. Each month, a minimum of four (4) cases are selected by a supervisor for re-analysis. The re-analysis must occur prior to the release of any report.

b. Re-analysis of negative serology cases is conducted by casework analysts that are not involved in the original analysis. Each sample within the case that was previously analyzed is re-analyzed to ensure consistent results and checked for correct itemization. Examination notes and confirmatory-test results are compared. Original and re-examined results are retained in the case file.

c. If discrepancies between results occur, the Quality Assurance Manager and/or the Quality Assurance Supervisors must be contacted to determine what follow-up action is necessary. All follow-up actions must be documented and maintained.

PROFICIENCY TESTING PROGRAM		
EFFECTIVE DATE 07-16-2012	APPROVING AUHORITY DNA TECHNICAL LEADERS	PAGE 1 OF 5

GUIDING PRINCIPLES AND SCOPE

Proficiency tests are given to qualified analysts to evaluate both their individual competence and the quality performance of the laboratory. Proficiency tests must be analyzed using only approved methods and/or procedures. While there are several types of proficiency tests, the Department of Forensic Biology utilizes open-external proficiency testing and blind-reanalysis proficiency testing.

The proficiency testing program is designed to meet the requirements of ASCLD/LAB and the Quality Assurance Standards for Forensic DNA Testing Laboratories. The external proficiency testing program is not just a requirement; it is also a quality assurance measure used to monitor performance and identify areas in which improvement may be needed.

External DNA proficiency tests are obtained from New York State and ASCLD/LAB approved proficiency test providers, for example, Collaborative Testing Service (CTS), Orchid Cellmark (IQAS), and the College of American Pathologists (CAP).

Serology results are reported on DNA tests obtained from CTS.

PROCEDURE

A. DNA OPEN-EXTERNAL PROFICIENCY TESTING PROGRAM

1. All analysts, technical reviewers, and technicians undergo semiannual external proficiency testing to the full extent in which they perform each technology in casework. Technology refers to the type of forensic DNA analysis performed (i.e. STR, YSTR, mtDNA.) The program is administered in an open proficiency-testing format and in accordance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

2. One test is assigned to each participant in the first six months of the calendar year and the second test is assigned in the last six months of the calendar year.
   a. The interval between consecutive tests must be at least four months and cannot exceed eight months.
   b. **The laboratory uses the <u>assigned date</u> to calculate the interval between tests**.
   c. Newly qualified individuals enter the external proficiency testing program within six months of the date of their qualification.

3. The scheduling of external proficiency tests is completed by a member of the Quality Assurance Unit prior to the start of each calendar year. While minor changes may be made during the year (test vendor, paired analyst, addition/removal of personnel, etc.), the schedule of each analyst/technician is not changed unless a change is necessary due to an extended leave of absence.

4. All specimens of an external proficiency test are analyzed according to current standard operating procedures. However, some exceptions are made in order to comply with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. For example, the following sample types, which during normal casework analysis might only be tested in one or two multiplex reactions, must be amplified at all CODIS core loci or CODIS core sequences and tested in all applicable technologies (Autosomal STR, Y-STR and/or Mitochondrial DNA) to the full extent that the analyst participates in casework:

    1) Excluded suspects
    2) Mixtures, even if there are other clean profiles
    3) Epithelial cell fractions from an unknown stain or from a body orifice swab, even if the results match the victim type.

5. The laboratory utilizes a team approach for casework testing. Therefore, proficiency tests are conducted in the same manner. However, each individual is proficiency tested at least once per year in each methodology to the full extent of his or her participation in casework.

    Methodology refers to analytical procedures used to support a DNA-typing technology [i.e. extraction methods (manual v. automated,) quantification methods, typing test kits and instrument platforms]. The extent in which each individual participates in casework may be team dependent.

    Individuals who perform STR, YSTR, and/or mtDNA amplification, analysis and/or review must perform these skills twice per year per technology.

    a. Unlike other titles, Criminalist Level I's are competent only in selected areas of the analytical process and their competency differs between the different teams within the laboratory. Criminalist I's cannot interpret the final DNA typing data or prepare an associated written scientific report. Thus, their participation in proficiency tests is limited to the methodologies that they are competent in and they are paired with a DNA Analyst on proficiency tests.

b. Individuals using both manual and automated methods are proficiency-tested in each at least once per year.

6. A laboratory report to summarize the results of the Proficiency Test is written by the DNA interpreting analyst. The DNA interpreting analyst is also responsible for completing any vendor paperwork to document the results. The DNA interpreting analyst must ensure that the data transcribed to the vendor's paperwork is accurate. The proficiency test file is then forwarded to the analyst's supervisor, manager, and/or designee for a full technical review.

7. In addition to conducting a full technical review of the proficiency test file, the reviewer(s) must also review the completed vendor's paperwork to ensure that data has been transcribed correctly.

8. After the proficiency test has been completed (including a full administrative review), the DNA interpreting analyst assigned to the proficiency test is responsible for delivering the test results to the test vendor. The delivery method may vary from vendor to vendor, but is typically either by fax or e-mail.

9. After official results have been received by the proficiency test provider, a Quality Assurance Unit supervisor grades the tests.

   a. Non-administrative discrepancies on proficiency tests that affect typing results and/or conclusions should be reported to the appropriate Technical Leader at the time of discovery. If confirmed, the Technical Leader must inform the CODIS Custodian/Supervisor so that appropriate follow-up action can be initiated. A formal QUALITY INCIDENT REVIEW may be required.

10. All proficiency-test participants are informed of their final test results. Participants are required to sign the appropriate area on the Proficiency Test Evaluation Form to document that they have received and have been informed of the final test results.

11. After the grading of all proficiency tests within the series, the supervisor informs the appropriate Technical Leader of the results of all participants.

B. SEROLOGY OPEN-EXTERNAL PROFICIENCY TESTING PROGRAM

Serology is a sub-discipline of the Biology discipline (as per ASCLD/LAB). The laboratory will endeavor to arrange for each employee to annually complete a serology proficiency test, but it is not required to do so.

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1. The Blind Re-analysis Proficiency Testing Program is a quality assurance program where a previously examined sample is re-examined by a different analyst to check for correctness of the initial examination and results.

2. **DNA Blind Reanalysis Program.** The Quality Assurance Unit is responsible for reanalyzing DNA samples, reviewing the results, and comparing them to the original analyses.
   a. Each month, a minimum of two (2) exemplar samples are selected from cases completed within the previous year.

b. Each sample is submitted for extraction, quantitation, amplification (in at least one casework multiplex system), analyzed for STR results, and the results compared to the original results. Re-examined results are documented separate from the case file and maintained as a record by the Quality Assurance Unit.

c. A second reanalysis must be performed if the results are not concordant. All follow-up actions must be documented and maintained.

3. **Serology Blind Reanalysis Program.** The laboratory has a blind serology re-analysis program for negative cases. The purpose of this program is to ensure that negative serology results are accurate.

a. Each month, a minimum of four (4) cases are selected by a supervisor for re-analysis. The re-analysis must occur prior to the release of any report.

b. Re-analysis of negative serology cases is conducted by casework analysts that are not involved in the original analysis. Each sample within the case that was previously analyzed is re-analyzed to ensure consistent results and checked for correct itemization. Examination notes and confirmatory-test results are compared. Original and re-examined results are retained in the case file.

c. If discrepancies between results occur, the Quality Assurance Manager and/or the Quality Assurance Supervisors must be contacted to determine what follow-up action is necessary. All follow-up actions must be documented and maintained.

Revision History:

February 9, 2010 – Initial version of procedure.

March 30, 2012 – Removed the requirement to use the Proficiency Test Review Form to document the review of proficiency tests (consistent with current practice).

July 16, 2012 – Specific forms and worksheets were removed and replaced with generic terminology to accommodate LIMS.

PROFICIENCY TESTING PROGRAM		
EFFECTIVE DATE 03-30-2012	APPROVING AUTHORITY DNA TECHNICAL LEADERS	PAGE 1 OF 5

GUIDING PRINCIPLES AND SCOPE

Proficiency tests are given to qualified analysts to evaluate both their individual competence and the quality performance of the laboratory. Proficiency tests must be analyzed using only approved methods and/or procedures. While there are several types of proficiency tests, the Department of Forensic Biology utilizes open-external proficiency testing and blind-reanalysis proficiency testing.

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Serology results are reported on DNA tests obtained from CTS.

PROCEDURE

A. DNA OPEN-EXTERNAL PROFICIENCY TESTING PROGRAM

1. All analysts, technical reviewers, and technicians undergo semiannual external proficiency testing to the full extent in which they perform each technology in casework. Technology refers to the type of forensic DNA analysis performed (i.e. STR, YSTR, mtDNA.) The program is administered in an open proficiency-testing format and in accordance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

2. One test is assigned to each participant in the first six months of the calendar year and the second test is assigned in the last six months of the calendar year.
   a. The interval between consecutive tests must be at least four months and cannot exceed eight months.
   b. **The laboratory uses the <u>assigned date</u> to calculate the interval between tests**.
   c. Newly qualified individuals enter the external proficiency testing program within six months of the date of their qualification.

3. The scheduling of external proficiency tests is completed by a member of the Quality Assurance Unit prior to the start of each calendar year. While minor changes may be made during the year (test vendor, paired analyst, addition/removal of personnel, etc.), the schedule of each analyst/technician is not changed unless a change is necessary due to an extended leave of absence.

4. All specimens of an external proficiency test are analyzed according to current standard operating procedures. However, some exceptions are made in order to comply with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. For example, the following sample types, which during normal casework analysis might only be tested in one or two multiplex reactions, must be amplified at all CODIS core loci or CODIS core sequences and tested in all applicable technologies (Autosomal STR, Y-STR and/or Mitochondrial DNA) to the full extent that the analyst participates in casework:

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7. In addition to conducting a full technical review of the proficiency test file, the reviewer(s) must also review the completed vendor's paperwork to ensure that data has been transcribed correctly.

8. After the proficiency test has been completed (including a full administrative review), the DNA interpreting analyst assigned to the proficiency test is responsible for delivering the test results to the test vendor. The delivery method may vary from vendor to vendor, but is typically either by fax or e-mail.

9. After official results have been received by the proficiency test provider, a Quality Assurance Unit supervisor grades the tests. The Proficiency Test Evaluation Form contains a checklist for the supervisor to document any discrepancies.

   a. Non-administrative discrepancies on proficiency tests that affect typing results and/or conclusions should be reported to the appropriate Technical Leader at the time of discovery. If confirmed, the Technical Leader must inform the CODIS Custodian/Supervisor so that appropriate follow-up action can be initiated. A formal QUALITY INCIDENT REVIEW may be required.

10. All proficiency-test participants are informed of their final test results. Participants are required to sign the appropriate area on the Proficiency Test Evaluation Form to document that they have received and have been informed of the final test results.

11. After the grading of all proficiency tests within the series, the supervisor informs the appropriate Technical Leader of the results of all participants.

B. SEROLOGY OPEN-EXTERNAL PROFICIENCY TESTING PROGRAM

Serology is a sub-discipline of the Biology discipline (as per ASCLD/LAB). The laboratory will endeavor to arrange for each employee to annually complete a serology proficiency test, but it is not required to do so.

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C. BLIND RE-ANALYSIS PROFICIENCY TESTING PROGRAM

1. The Blind Re-analysis Proficiency Testing Program is a quality assurance program where a previously examined sample is re-examined by a different analyst to check for correctness of the initial examination and results.

2. **DNA Blind Reanalysis Program.** The Quality Assurance Unit is responsible for reanalyzing DNA samples, reviewing the results, and comparing them to the original analyses.
   a. Each month, a minimum of two (2) exemplar samples are selected from cases completed within the previous year.

b. Each sample is submitted for extraction, quantitation, amplification (in at least one casework multiplex system), analyzed for STR results, and the results compared to the original results. Re-examined results are documented separate from the case file and maintained as a record by the Quality Assurance Unit.

c. A second reanalysis must be performed if the results are not concordant. All follow-up actions must be documented and maintained.

3. **Serology Blind Reanalysis Program.** The laboratory has a blind serology re-analysis program for negative cases. The purpose of this program is to ensure that negative serology results are accurate.

a. Each month, a minimum of four (4) cases are selected by a supervisor for re-analysis. The re-analysis must occur prior to the release of any report.

b. Re-analysis of negative serology cases is conducted by casework analysts that are not involved in the original analysis. Each sample within the case that was previously analyzed is re-analyzed to ensure consistent results and checked for correct itemization. Examination notes and confirmatory-test results are compared. Original and re-examined results are retained in the case file.

c. If discrepancies between results occur, the Quality Assurance Manager and/or the Quality Assurance Supervisors must be contacted to determine what follow-up action is necessary. All follow-up actions must be documented and maintained.

QUALITY INCIDENT REVIEW		
DATE EFFECTIVE 09-24-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 5

GUIDING PRINCIPLES AND SCOPE

Action must be taken when serious non-conforming work or major departures from the policies and procedures in the management system or technical operations have been identified. These quality incidents shall be identified and reported so that appropriate follow-up action can be implemented. The identification of problem areas and follow-up action that encourages innovative solutions and avoids the potential for future errors will improve the quality of our Department.

This document describes the Department's process for dealing with quality incidents. Problems or difficulties can arise in all phases of laboratory operations, and these must be evaluated and dealt with appropriately. Listing each potential problem is impractical, and this topic is considered in general terms.

This procedure ensures that, when required, our accrediting bodies and/or the NYC Criminal Justice Coordinator's Office are notified in a timely manner.

PROCEDURE

A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of non-conforming work, internal or external audits, management reviews, feedback from customers, and from staff observations.

Not every quality incident or departure from management system policies and procedures is serious enough to require a Quality Incident Review.

It is impossible to anticipate all situations in which a Quality Incident Review must be conducted; therefore, sound judgment is required in determining the extent and level of reporting and documentation required.

Technical errors or problems related to casework testing are initially dealt with as per the CONTROL OF NONCONFORMING TESTING procedure. The procedure provides direction with respect to when such problems must be dealt with via a Quality Incident Review.

Issues which require a Quality Incident Review include, but are not limited to:

- Technical problems (e.g., continuity errors such as mislabeled samples or chain of custody problems, detection of exogenous DNA in evidence, equipment or reagent failure, errors in documentation) that were not caught during the quality assurance process of the laboratory and resulted in a laboratory report containing incorrect information to be released to the laboratory's customers
- Proficiency test errors
- Repeated or systemic occurrences of a technical problem, even if not resulting in a serious impact on the quality of testing or erroneous laboratory reports
- Individual occurrences of technical problems that have a serious impact on the quality of testing and are likely to recur unless action is taken
- Repeated errors in documentation by the same analyst
- Systemic non-conformance with the policies and procedures in the management system (e.g., failure to properly document staff qualifications and training)
- Non-conformities identified during internal or external audits/assessments

The appropriate Technical Leader, Quality Assurance Manager, and/or managers should be consulted if there is any question as to which action is required and taken.

A. Quality Incident Reporting

1. All staff members are responsible for reporting apparent quality incidents that come to their attention.
   i. Non-supervisory staff report technical problems as soon as practicable either to the relevant rotation/area supervisor or, if a quality incident cannot be attributed to a rotation, the staff member's immediate supervisor. Non-technical quality incidents are reported to the staff member's immediate supervisor.
   ii. Supervisors or managers who become of aware of any quality incidents—either directly or through notification from other staff members--proceed to Step 2.
   iii. Any member of staff who believes that the potential quality incident is of major concern, but is concerned about confidentiality, may inform the Quality Assurance Manager immediately and directly

2. The supervisor or manager investigates the issue to determine the details of the potential problem. For technical issues, see the CONTROL OF NON-CONFORMING TESTING procedure.

3. If the initial investigation indicates that a quality incident occurred, but that a formal Quality Incident Review is not needed, the investigating supervisor/manager shall document the incident on the Non-Conformity Reporting Form and forward it to the Quality Assurance Manager.

4. If the initial investigation indicates that a formal Quality Incident Review is needed, the investigating supervisor/manager consults with the Quality Assurance Manager.

5. The Quality Assurance Manager determines whether to proceed with a formal Quality Incident Review. A DNA technical leader and/or other supervisors or managers may be consulted for discussion prior to making the decision.

6. The Quality Assurance Manager informs the investigating supervisor/manager of the decision.

7. The decision not to proceed with a formal Quality Incident Review does not prevent a supervisor or manager from conducting other follow-up action, e.g., counseling of an individual.

B. Quality Incident Review

1. The Quality Assurance Manager assigns a supervisor or manager to conduct the Quality Incident Review.

2. A Quality Incident Review (QIR) form guides the steps of the process.

3. The incident is described in detail on the QIR, including the effect(s) of the discrepancy.

4. The assigned supervisor/manager conducts an investigation to determine the **root cause** of the incident. The root cause(s) may not be obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include, but are not limited to, problems with:
   - customer requirements
   - the samples
   - sample specifications
   - methods and procedures
   - staff skills and training
   - consumables, or
   - equipment and its calibration.

5. Follow-up actions are proposed to correct the immediate problem and minimize the potential for recurrence of the problem. Follow-up actions may include, for example, personnel counseling, retraining, or monitoring; instrument repair, replacement, or re-calibration; modifying procedures or forms, etc. The follow-up action plans should also include:
   - The parties responsible for conducting the follow-up activities
   - The monitoring that will be conducted to ensure that the proposed actions have been effective. Very serious and/or systemic issues may require follow-up audits of the affected areas of activity.

6. The QIR is forwarded to the Quality Assurance Manager for review and approval of the proposed follow-up actions. The approval of the appropriate DNA Technical Leader is also required for issues stemming from casework analysis or proficiency test performance.

C. Close-out of Quality Incident Reviews

1. The completion of follow-up actions is documented on the QIR.

2. If the monitoring activities indicate that the initial follow-up actions were insufficient to address the quality incident, the Quality Assurance Manager and Technical Leader(s) initiate additional follow-up actions.

3. Per a cooperative agreement with the District Attorney's Offices of the City of New York, all case files containing unusual quality incidents, as determined by the Quality Assurance Manager, are clearly indicated by attaching a red sticker on the front cover of the case file.
   i. The Quality Assurance Manager consults with the Director, Deputy Director, and the corresponding Technical Leader to determine quality incidents that are considered "unusual."
   ii. The Quality Assurance Manager informs the affected personnel to flag their case files.

4. The Quality Assurance Manager determines which incidents must be disclosed to accrediting bodies and/or the NYC Criminal Justice Coordinator's Office.

5. The QIR is "closed" when monitoring activities are completed and all individuals agree that follow-up action(s) have been satisfactorily implemented and effectively addressed the quality issue.

6. The QIR and any supporting records are filed with the Quality Assurance Unit.

Revision History:

February 9, 2010 – Initial version of procedure.

September 24, 2010 – Added step in procedure to document quality incidences that do not rise to the level of a Quality Incident Review on the Non-conformity Reporting Form.

REAGENTS		
DATE EFFECTIVE 08-20-2012	APPROVED BY EUGENE LIEN	PAGE 1 OF 8

GUIDING PRINCIPLES AND SCOPE

A reagent is any substance used because of its chemical or biological activity. Reagents are used directly, or at a dilution, in a given analytical procedure. Reagents are different than *chemicals*, which are used in the preparation of in-house reagents.

Only reagents suitable for the methods employed may be used in the Department of Forensic Biology. This procedure describes in general terms the requirements for the documentation and quality control of commercial reagents and for the formulation, documentation, and quality control of in-house reagents. The last section in this document is a list of the reagents used by the Department.

PROCEDURE

Reagents are classified into two general categories:

A **critical reagent** is determined by empirical studies or routine practice to require testing on established samples before use on evidentiary or casework reference samples in order to prevent unnecessary or irreparable loss of sample. "Critical reagents" includes a variety of test kits or systems used in DNA testing.

A **non-critical reagent** is a reagent whose failure to work properly will not cause irreparable loss of sample. Therefore, the use of a QC test procedure to check the reliability of the reagent prior to its use in casework is not an absolute requirement, but will be performed by the Department on a reagent-by-reagent basis.

Reagents are prepared **in-house** or are obtained **commercially.**

Personnel preparing reagents, and those who use reagents, are to exercise care at all times to ensure that no exogenous DNA will be introduced to a stock reagent.

A. Reagents Prepared In-House

1) Reagents are prepared in-house according to an approved formula or procedure. Reagent preparation is usually performed by a member of the Quality Assurance Unit.

2) A **reagent sheet** form exists for every reagent prepared in the laboratory and is used as a guide for the preparation of the reagent.

3) Each reagent record contains the following information:
   i. the identity of the reagent
   ii. date of preparation
   iii. identity of individual preparing the reagent
   iv. standard batch size
   v. ingredients of the reagent
   vi. data entry section

4. Some reagent records (such as critical reagents) may also include:
   i. lot numbers
   ii. expiration dates
   iii. quality control procedures (aka, "reliability checks") to be performed and passed before the reagent is released for use in the laboratory.

5. Reagents prepared in the laboratory are labeled with, at a minimum:
   i. the identity of the reagent
   ii. the lot number
   iii. the expiration date

   When a reagent is aliquotted into tubes that are too small to be labeled with all of the required information, each tube is marked with the identity of the reagent and its lot number and stored in a "cryobox" that is labeled with the required identifying information listed above.

6. Staff is notified via email by the Quality Assurance Unit regarding reagents that are expiring.

B. Commercial Reagents

1. Commercial reagents include, but are not limited to, kits for DNA quantitation and genetic typing.

2. A **Raw Materials** form exists for each commercial reagent that requires quality testing prior to use in casework. The applicable quality control procedure is contained on the form.

3. Commercial reagents are labeled with, at a minimum:
   i. The identity of the reagent
   ii. The expiration date as provided by the manufacturer or as determined by the laboratory.
      1) If identical reagents with the same lot number are assigned different expiration dates by the manufacturer, then the expiration date will be extended to the latest date provided that it passes quality control testing.

         For example, Lot #1234 of a regent was received on June 1, 2011 (Bottle A) and has a manufacturer-assigned expiration date of June 1, 2012. A second bottle of Lot #1234 was received on December 1, 2011 (Bottle B) and has has a manufacturer-assigned expiration date of December 1, 2012. Since the manufacturer supports the use of this particular lot of reagents until December 1, 2012, the expiration date of Bottle A will be extended to December 1, 2012 provided that Bottle B passes quality control testing.

      2) Commercial reagents without an expiration date provided by the manufacturer shall expire two years *after receipt* unless data exists to support a longer period.

C. Reagent Quality Control Testing

Quality control (QC) tests are reliability checks and may be used by the Department to ensure that reagents are performing as expected. If needed, these tests must be completed prior to the reagent being used in actual casework. A reliability check may be a combination of several quality control tests and, for ease of classification, are assigned QC testing procedure numbers. If a reagent sheet lists a "procedure" for its quality control test, then the reagent must pass all the quality control tests listed below. If it only lists a specific "QC" number, then the reagent must pass that quality control test only.

	QC Tests Included	Analysis
Procedure 1	QC620	Real Time Quantitative PCR
Procedure 2	QC240, QC350	PCR Amplification and STRs
Procedure 3	QC145A, QC620, QC350	Organic Extraction, Real Time Quantitative PCR, PCR Amplification, and STRs
Procedure 4	QC145/165, QC160, QC620, QC350	Chelex/M48 Extraction, Real Time Quantitative PCR, PCR Amplification, and STRs
Procedure 5	QC350	3130xl STRs

D. Reagent Records

Reagent records, such as reagent sheets and Raw Materials Forms are a form of Quality Record, and shall be stored in accordance to the guiding principles and procedures that govern such records. See CONTROL OF RECORDS in the Quality Assurance/Quality Control Manual for further information.

REAGENTS USED BY THE DEPARTMENT

This section shows a list of reagents used in the Department of Forensic Biology. The list includes reagents prepared in-house as well as commercial reagents. Each reagent is classified as "Critical" or "Non-Critical".

REAGENT	CRITICAL
Acid Phosphatase Test Reagent	Y
Agarose	N
Alkaline Substrate Buffer	Y
Agilent DNA 1000 Kits	N
AmpFℓSTR Identifiler PCR Amplification Kit	Y
AmpFℓSTR MiniFiler PCR Amplification Kit	Y
AmpliTaq Gold DNA Polymerase Kit (all components)	Y
Amylase Gel Buffer	Y
BigDye Terminator Cycle Sequencing Kit	Y
BSA Solution, 5 mg/mL	Y
Calibrator for Real Time Quantitative PCR	Y
Casein Stock Solution	Y
Cells	Y
Centrisep columns, strips, and plates	N
Chelex, 20%	Y
Chelex, 5%	Y
Chloroform-Isoamyl Alcohol	N
Chromogen	Y
Citrate Buffer	N
Deoxynucleotide Triphosphates, 2.5 mM (dNTPs)	Y
Digest Buffer	Y

REAGENT	CRITICAL
Dithiothreitol (DTT), 1M	Y
DMSO	N
EB1	Y
EB2	Y
EDTA, 0.5 M	N
Enzyme Conjugate	Y
Ethidium Bromide (mtDNA)	N
ExoSAP-IT	Y
Fish Sperm DNA	Y
Genetic Analyzer Buffer (ABI)	N
HiDi Formamide	N
Human Leukemia 60 (HL60)	Y
Hydrogen Peroxide, 3%	N
Iodine Solution, 0.01 N	N
Kastle-Meyer (KM) Reagent	Y
Leucomalachite Green (LMG) Reagent	Y
Linear Array Denaturation Solution	N
Linear Array Wash Buffer	Y
MagAttract DNA Mini M48 Kit (Qiagen)	Y
Magnesium Chloride (MgCl2)	N
Negative female control DNA for Y STR analysis	Y
Nuclear Fast Red	Y
Orange G Loading Dye	N
Organic Extraction Buffer	Y
PBS for Chelex Extraction	Y

REAGENT	CRITICAL
PBS for Nail Extraction, 25mM EDTA	Y
PBS Solution for P30 ELISA (PBS tablets)	Y
PBS Solution, Irradiated (LCN DNA)	Y
PBS-BSA Solution	N
Phase lock gel tubes	N
Phenol Chloroform Isoamyl Alcohol (PCIA)	Y
Picric Indigo Carmine (PIC)	Y
POP-4	N
POP-6	N
Poly A RNA	Y
Positive Male Control DNA for Y STR Analysis	Y
PowerPlex® Y System	Y
Primer, DYS19/1	Y
Primer, DYS19/2	Y
Primer, DYS389/1	Y
Primer, DYS389/2	Y
Primer, DYS390/1	Y
Primer, DYS390/2	Y
Primer, FBI – A1, B1, C1, D1, C2, D2, A4, B4, HVIF, HVIR, HVIIF, HVIIR (mtDNA)	Y
Proteinase K solution	Y
Roche Primer and Reaction Mix	Y
Saline (0.85% NaCl)	N
SDS, 2%	N
SDS, 20%	Y
SDS, 0.01%, 0.05%, and 1% (LCN DNA)	Y

REAGENT	CRITICAL
Sequencing Loading Buffer	Y
Sodium Acetate, 0.1 M	N
SSPE, 20X	N
Standard DNA for Real Time Quantitative PCR	Y
Starch	N
Sterile Deionized Water	Y
SYBR Green I	Y
Terg-a-zyme	N
TAE, 1X	Y
TBE buffer	N
Tris-EDTA, 1X	Y
Tris-HCl, 1M (pH 8.0)	N
Water, Irradiated	Y
XIV molecular weight ladder	N
Xylene	N
YM1 STR/PCR Reaction Mixture	Y

Revision History:

February 9, 2010 – Initial version of procedure.

October 28, 2010 – Added the MagAttract DNA Mini M48 Kit and the MiniFiler PCR Amplification Kit to the list of reagents.

December 29, 2011 – Revised Section B.3 to clarify how the laboratory determines the expiration dates of commercial reagents.

July 16, 2012 – Portions revised to generalize terminology to accommodate LIMS.

August 20, 2012 – Revised Section B.3 to clarify how the laboratory determines the expiration dates of commercial reagents.

REAGENTS		
DATE EFFECTIVE 12-29-2011	APPROVING AUTHORITY QUALITY MANAGER	PAGE 1 OF 8

GUIDING PRINCIPLES AND SCOPE

A reagent is any substance used because of its chemical or biological activity. Reagents are used directly, or at a dilution, in a given analytical procedure. Reagents are different than *chemicals*, which are used in the preparation of in-house reagents.

Only reagents suitable for the methods employed may be used in the Department of Forensic Biology. This procedure describes in general terms the requirements for the documentation and quality control of commercial reagents and for the formulation, documentation, and quality control of in-house reagents. The last section in this document is a list of the reagents used by the Department.

PROCEDURE

Reagents are classified into two general categories:

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3) Each reagent sheet records the following information:
   i. the identity and application of the reagent
   ii. date of preparation
   iii. identity of individual preparing the reagent
   iv. standard batch size
   v. ingredients of the reagent
   vi. procedure to follow when preparing the reagent
   vii. data entry section

4. Some reagent sheets (such as critical reagents) may also include:
   i. lot numbers
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5. Reagents prepared in the laboratory are labeled with, at a minimum:
   i. the identity of the reagent
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   iii. the lot number
   iv. the expiration date
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   When a reagent is aliquotted into tubes that are too small to be labeled with all of the required information, each tube is marked with the identity of the reagent and its lot number and stored in a "cryobox" that is labeled with the required identifying information listed above.

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         For example, Lot #1234 of a regent was received on June 1, 2011 (Bottle A) and has a manufacturer-assigned expiration date of June 1, 2012. A second bottle of Lot #1234 was received on December 1, 2011 (Bottle B) and has has a manufacturer-assigned expiration date of December 1, 2012. Since the manufacturer supports the use of this particular lot of reagents until December 1, 2012, the expiration date of Bottle A will be extended to December 1, 2012 provided that Bottle B passes quality control testing.

      2) Commercial reagents without an expiration date provided by the manufacturer and require a quality control test shall expire one year *after first use* unless data exists to support a longer period. The laboratory has the discretion to retest these commercial reagents before the one year expiration has passed and extend the expiration date appropriately for the reagent. The results of retesting must be compared to the original quality control results to ensure similar performance for that commercial reagent lot number.

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Procedure 5	QC350	3130xl STRs

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Amylase Gel Buffer	Y
BigDye Terminator Cycle Sequencing Kit	Y
BSA Solution, 5 mg/mL	Y
Calibrator for Real Time Quantitative PCR	Y
Casein Stock Solution	Y
Cells	Y
Centrisep columns, strips, and plates	N
Chelex, 20%	Y
Chelex, 5%	Y
Chloroform-Isoamyl Alcohol	N
Chromogen	Y
Citrate Buffer	N
Deoxynucleotide Triphosphates, 2.5 mM (dNTPs)	Y
Digest Buffer	Y

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Dithiothreitol (DTT), 1M	Y
DMSO	N
EB1	Y
EB2	Y
EDTA, 0.5 M	N
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Ethidium Bromide (mtDNA)	N
ExoSAP-IT	Y
Fish Sperm DNA	Y
Genetic Analyzer Buffer (ABI)	N
HiDi Formamide	N
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Hydrogen Peroxide, 3%	N
Iodine Solution, 0.01 N	N
Kastle-Meyer (KM) Reagent	Y
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POP-4	N
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Poly A RNA	Y
Positive Male Control DNA for Y STR Analysis	Y
PowerPlex® Y System	Y
Primer, DYS19/1	Y
Primer, DYS19/2	Y
Primer, DYS389/1	Y
Primer, DYS389/2	Y
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REAGENTS		
DATE EFFECTIVE 07-16-2012	APPROVED BY EUGENE LIEN	PAGE 1 OF 8

GUIDING PRINCIPLES AND SCOPE

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Amylase Gel Buffer	Y
BigDye Terminator Cycle Sequencing Kit	Y
BSA Solution, 5 mg/mL	Y
Calibrator for Real Time Quantitative PCR	Y
Casein Stock Solution	Y
Cells	Y
Centrisep columns, strips, and plates	N
Chelex, 20%	Y
Chelex, 5%	Y
Chloroform-Isoamyl Alcohol	N
Chromogen	Y
Citrate Buffer	N
Deoxynucleotide Triphosphates, 2.5 mM (dNTPs)	Y
Digest Buffer	Y

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DMSO	N
EB1	Y
EB2	Y
EDTA, 0.5 M	N
Enzyme Conjugate	Y
Ethidium Bromide (mtDNA)	N
ExoSAP-IT	Y
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Linear Array Denaturation Solution	N
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Negative female control DNA for Y STR analysis	Y
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Phase lock gel tubes	N
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Poly A RNA	Y
Positive Male Control DNA for Y STR Analysis	Y
PowerPlex® Y System	Y
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Primer, DYS19/2	Y
Primer, DYS389/1	Y
Primer, DYS389/2	Y
Primer, DYS390/1	Y
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Proteinase K solution	Y
Roche Primer and Reaction Mix	Y
Saline (0.85% NaCl)	N
SDS, 2%	N
SDS, 20%	Y

REAGENT	CRITICAL
SDS, 0.01%, 0.05%, and 1% (LCN DNA)	Y
Sequencing Loading Buffer	Y
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SSPE, 20X	N
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SYBR Green I	Y
Terg-a-zyme	N
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XIV molecular weight ladder	N
Xylene	N
YM1 STR/PCR Reaction Mixture	Y

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VALIDATION		
DATE EFFECTIVE 02-09-2010	APPROVED BY EUGENE LIEN	PAGE 1 OF 4

GUIDING PRINCIPLES AND SCOPE

Validation is the process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis. It is the accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected. Only validated methods and procedures may be used with casework samples.

This is different from a performance check, which is a quality assurance measure to assess the functionality of laboratory instruments, equipment, and software that affect the accuracy and/or validity of forensic sample analysis.

The validation process identifies the critical aspects of a procedure which must be carefully controlled and monitored. Validation studies must have been conducted by the Department of Forensic Biology prior to the adoption of a procedure by our laboratory. This procedure describes the requirements of the validation process.

PROCEDURE

All staff members are encouraged to propose new technologies, methodologies, or procedures to be used in casework. Proposals may be forwarded to the Forensic Biology Future Technologies Planning Team. The Director shall make a final determination on whether or not to validate any proposed new technology, methodology, or procedure.

Validations are a planned activity, and the exact tests of one validation may differ from another depending on the new technology, methodology, or procedure being tested. The appropriate Technical Leader shall be consulted to determine which studies must be conducted to ensure efficacy and reliability for forensic casework use. If the technology, methodology, or procedure concerns DNA testing, the Technical Leader must ensure that the appropriate tests, as listed in the FBI's Quality Assurance Standards for Forensic DNA Testing, are conducted.

Validation plans may differ from the initial assessment of the Technical Leader. They may be updated as development proceeds.

While not required, prior to starting any validation, a preliminary assessment may be done to ensure the time and effort that will be dedicated to the validation will be worthwhile.

A. Developmental Validation

1. Developmental validation is the acquisition of test data and determination of conditions and limitations of a ***new or novel*** methodology for use on forensic samples.

2. If another laboratory's developmental validation studies are being used, appropriate documentation or citations for these studies must be available.

3. Developmental validation studies must include the following, where applicable:

   i. Testing using case-type samples, including samples from adjudicated cases or mock samples that mimic casework samples
   ii. Characterization of genetic markers
   iii. Sensitivity, stability, and species specificity studies
   iv. Reproducibility studies
   v. Population studies, such as allele frequency distributions and independence of the population databases
   vi. Mixture studies
   vii. Precision and accuracy studies
   viii. PCR-based studies, including reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies.

4. All developmental validations conducted by the Department must include an executive summary, which summarizes all the studies conducted. The executive summary must include specific recommendations (such as settings, quality assurance parameters, interpretation guidelines, or mixture interpretation guidelines) and must include a statement as to whether the method is fit for the intended use. While not required, it is recommended that each study conducted have an individual summary of results.

B. Internal Validation

1. Internal validation is an accumulation of test data within the laboratory to demonstrate that ***established*** methods and procedures (such as forensic DNA methods or procedures that are published in peer reviewed articles) perform as expected in the laboratory.

2. Prior to implementing a new or revised methodology or procedure, the Department must first demonstrate the reliability of the method or procedure internally. This includes changes in detection platform, changes in DNA test kits, or the implementation of new body-fluid identification procedures. Internal validation studies must be sufficient to support and document the reliability of the method or procedure and must include the following, where applicable:

   i. Testing using known samples
   ii. Testing using non-probative evidence samples or mock evidence samples
   iii. Reproducibility and precision
   iv. Sensitivity and stochastic studies
   v. Mixture studies
   vi. Contamination assessment

3. As a result of the internal validation studies, quality assurance parameters, interpretation guidelines, and mixture interpretation guidelines (where applicable) shall be defined.

4. The documentation of an internal validation includes an executive summary, which summarizes all the testing conducted. The executive summary must include specific recommendations (such as settings, quality assurance parameters, interpretation guidelines, or mixture interpretation guidelines) and a statement as to whether or not the method is fit for the intended use. While not required, it is recommended that each study conducted have an individual summary of results.

C. Review and Approval of Validation

1. Completed validation project packages are submitted to the appropriate Technical Leader for review and approval. The package includes:
   i. Test records and all required summaries
   ii. Draft technical procedure

2. All validations must be reviewed and approved by the appropriate Technical Leader before the technology and/or procedure is used in casework.

Note: Approval of a validation does not necessarily denote that a technology or procedure is online for casework. Training needs, budgetary concerns, etc., must be taken into consideration before the technology or procedure is implemented.

3. At the Technical Leader's discretion, the technology or procedure may be used on select cases prior to lab-wide implementation. However, the technology or procedure are not be used on any casework until standard operating procedures are written and have been approved by the appropriate Technical Leader.

D. Training

Training commences after approval of the validation by the appropriate Technical Leader. The initial training of analysts can be considered a "dry-run" of the procedure, and the technology, methodology, and/or procedure are not used in casework until all concerns that may be raised during the initial training have been addressed.

E. Storage of Validation Records

Records of validation studies are stored by the Quality Assurance Unit indefinitely. In general, validations that have been reviewed by an external audit team will be stored on the fourth floor of the DNA Building (Records Storage), while validations that have not been reviewed by an external audit team will be stored within the operational areas of the Quality Assurance Unit. However, general convenience and spacing issues may alter the exact location of any validation study.

Revision History:

February 9, 2010 – Initial version of procedure.