Initials: RCJ Date: 4/2/97

Department of Forensic Biology

Administrative and Quality Assurance Manual

Version 3.0

Initials: RCS Date: 4/2/97

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I. Historical

Effective this date, this Quality Assurance manual supersedes all previous QA manuals used in the Department of Forensic Biology.

QA Committee Members:

Chairman: Robert C. Shaler, Ph.D. Robert C. Shaler

Co-Chairman: Howard Baum, Ph.D. Howard J. Baum

Committee Members:

Lawrence Quarino

Marie Samples

David San Pietro

Mecki Prinz, Ph.D.

Helen Rafaniello

Ralph Ristenbatt

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II. Introduction

The Department of Forensic Biology Quality Assurance Manual is designed to provide a program through which all laboratory operations are scrutinized in an effort to provide a reliable laboratory result. The following definitions apply.

A. Quality Control

Those procedures used to maintain acceptable limits of variation for products and services. More specifically, these are the internal activities or activities according to externally established standards used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

B. Quality Assurance

Quality assurance pertains to those procedures used to insure that quality control parameters are appropriate and sufficient measures of variation. These are the planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality.

C. An Example

Measuring and recording the pH of a solution is a common quality control to insure that the variation between lots of solutions is maintained within a specified range. But this parameter is a meaningful measure of quality only if the pH meter has been calibrated, the technician making the measurement knows how to operate the pH meter, the water is sufficiently pure, and the technician has added the proper reagents. Quality assurance insures that quality control measures are meaningful measures of variation.

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III. Planning and Organization

A. Goals and Mission

It is the goal of the Department of Forensic Biology to provide users of its laboratory services; the NYPD, District Attorneys, Legal Aid, Capital Defenders Attorneys, and other agencies and attorneys within or serving New York City's criminal justice system; access to scientific analyses conducted in criminal investigations. These analyses are conducted such that the test results meet acceptable standards and are available in a timely fashion without affecting their quality, integrity, and accuracy as dictated by a detailed quality assurance (QA) program.

The Department develops information through the identification and individualization of physiological fluids such as blood, semen and saliva obtained from investigating agencies. Among other benefits, this information can aid in the investigation of a crime or suspected crime, help tie a victim to a crime scene, connect a suspect to a crime, or eliminate a suspect.

The scientific analyses include but are not limited to the following:

1. Sample identification
2. Species identification
3. Genetic marker/DNA analysis
5. Crime Scene Reconstruction
5. Report Preparation
6. Testimony to results

B. QA Objectives

1. Monitor, on a routine basis, the analytical testing procedures for all scientific testing performed in the laboratory by means of Quality Control (QC) standards, proficiency tests, and audits.

2. Verify that all scientific analyses operate within the established performance criteria and that the quality and validity of the analytical data is maintained.

3. Performance criteria are established in the Department's QC Manual and Laboratory Methods Manuals for each of the routine scientific procedures performed in the laboratory.

4. The quality and validity of the data is ensured by the quality control (QC) program for both critical reagents prepared in the laboratory and those

obtained commercially. The reliability of the critical instruments employed in the laboratory's routine testing is guaranteed by the quality assurance (QA) program for instrument use as delineated in the DNA QC Manual.

5. The qualifications of the laboratory staff are ensured by the position requirements of the Department of Personnel of the City of New York, by the educational requirements imposed by regulating bodies -- TWGDAM, NYSDCJS, or federal guidelines -- and by the proficiency testing program that is an integral part of the overall QA program of the Department of Forensic Biology.

6. The records for in-house reagent manufacture are maintained as are the QC documentation of their acceptability. Outside vendor QC documents (specification sheets, etc.) are retained.

7. The QA program insures that problems are noted and that corrective action is taken and documented. Each problem is recorded in an appropriate log book and the corrective action is noted, dated and signed by the appropriate laboratory supervisor or an appropriate QA committee member.

C. Authority and Accountability for the QA Program

The organizational structure defines the relationships in the Department of Forensic Biology among individuals and the operational units of the department.

Within this structure, a QA/QC committee sets QA/QC policy and is responsible for production and revisions of the QA Manual. The Forensic Scientist supervising the QC rotation is responsible for QC testing and reports directly to the Department Director or the Assistant Director.

QA responsibilities rest with the Director. QA policy is established by the QA Committee, which is comprised of the following members.

1. The chairman of the committee, with overall responsibility for the QA program, is the Director of the Department of Forensic Biology.

2. The Assistant Director is the co-chairman and assumes responsibility in the absence of the Director.

3. The Forensic Scientists in the laboratory.

Each Forensic Analyst must adhere to the QA/QC program guidelines, as they relate to their work

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and responsibilities.

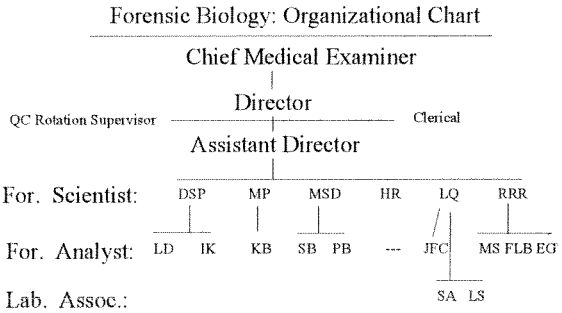
D. Department of Forensic Biology Organizational Structure

The OCME is organized such that the Director of the Department of Forensic Biology reports directly to the head of the agency, the Chief Medical Examiner, (Figure 1), as do the other laboratory directors of Toxicology and Histology.

The Department of Forensic Biology is a single operational unit with multiple responsibilities. The responsibilities of the Department are performed by the Forensic Molecular Biology Laboratory (FMB). One Assistant Director reports directly to the departmental Director as do the clerical staff.

The scientific staff includes Forensic Scientists, Forensic Analysts, and Laboratory Associates; the latter report to the former. Each Forensic Scientist supervises one or more Forensic Analyst(s) and may supervise Laboratory Associates for training, annual evaluations, and case review. This is diagramed in Figure 1 below.

Figure 1



Each Forensic Scientist also supervises Forensic Analysts and/or Laboratory Associates on a rotating basis (weekly or monthly depending on the functional rotation) in one or more functional areas or rotations where evidence is examined and analyzed: evidence examination, extraction, QC, Quantiblot, PCR -- amp, gel, hybe, and evidence sign-in. These functional areas are illustrated in Figure 2.

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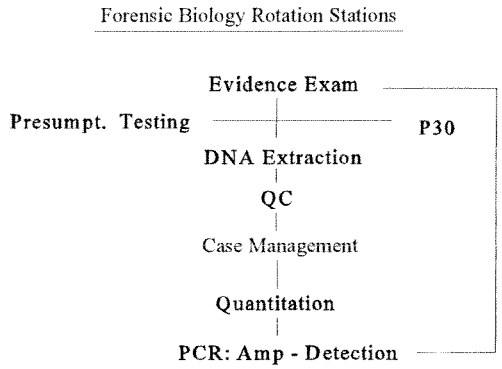
Figure 2



In this scheme, evidence is examined using a batch processing procedure, and may be processed by Forensic Scientists, Forensic Analysts, or Laboratory Associates. In general, the rotation works as follows: Specimens are removed from the evidence and tested presumptively, i.e, for the presence of blood, semen, or saliva. If the result is positive, the sample is sent to the extraction rotation and DNA is extracted. This extract goes to the Quantiblot rotation where the DNA concentration is determined. The extract is kept refrigerated pending a request, internal or external, for DNA profiling. When necessary, the samples are given to the PCR rotation where amplification and the PCR product is identified.

Forensic Analysts are divided into two groups: Interpreting Analysts or Rotating analysts (in-house titles). Their functions are similar in that they do the hands-on work in the rotations. Interpreting Analysts are Forensic Analysts/Scientists who meet TWGDAM guidelines as analysts. They are responsible for interpreting data for those cases assigned to them, writing reports, and testifying to the results. Rotating Analysts are Forensic Analysts who meet TWGDAM requirements for technicians. These analysts do not interpret data, do not prepare reports, and do not testify to the results (they may testify to what they did).

Two Laboratory Associates (one part-time and one full-time) are assigned to the Department. The Laboratory Associates function as technicians as described by TWGDAM (April 1995).

The general laboratory structure defines the following responsibilities.

1. The Director is responsible for the overall scientific operation, quality assurance, and administrative operation of the Department.

2. The department's Assistant Director is responsible for the daily scientific operation of the Department, procurement for the

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Department and, in the absence of the Director, assumes the responsibility for administrating the Department.

3. In absence of the Assistant Director and the Director, one (or more) Forensic Scientist(s) will assume responsibility, after assignment by the Director, for administering the department and its quality operations.

4. Under no circumstances will the Director, the Assistant Director, and Forensic Scientists all be absent from the laboratory at the same time during normal working hours.

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IV. Documentation

Laboratory personnel record all significant laboratory activities to create a useable audit trail that documents the department's routine scientific testing. The documentation will be kept for the following topic areas:

A. Manuals

1. Scientific Manuals

These documents describe **in detail** the current protocols used for the analytical testing of biological specimens for all the scientific procedures used in the departmental laboratories. They include the following information before they are certified to be used as acceptable procedural manuals:

a. Date the procedure was adopted
b. Revision dates
c. The Director initials and dates the manuals signifying their official start for use in the laboratory.
d. Archives of methods

B. Quality Control/Critical Reagent Documents

The QC documents in the departmental laboratories demonstrate that all critical reagents **(Critical reagents are defined as those reagents which are required for a specific test and which must undergo QC testing prior to use to insure that they meet performance expectations)** are prepared according to guidelines established within the Department and according to accepted procedures. The documents available for each testing procedure include the following.

1. QC Procedures Manuals

Details the procedures used in determining the quality of reagents prepared either in-house or those purchased from outside vendors. It also details procedures used to calibrate instruments used as a QC monitor, i.e., thermocouples and etc., and the other critical instrumentation used in the department.

The QC Manuals also detail the operating instructions and maintenance of the critical instruments.

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2. Solutions Manual

Details procedures used for preparing solutions used in routine testing.

3. Reagent Preparation Records

1. Lot and/or Batch Numbers
2. Date of Preparation
3. Initials of Preparer
4. Documentation of QC Pass/Fail and Evaluation
5. Archive of QC Evaluation Data

4. Equipment Instruction Manuals

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C. Case Files/Case Notes

Case files contain sufficient information for an outside assessment of the laboratory's work product and may include the following.

1. OCME paperwork such as the autopsy sheet summary.

2. Analytical laboratory work sheets including analyst's notes and original laboratory data (or copies with references to the location of original data if not present in the case file).

3. Police paperwork including copies of evidence control vouchers, request for examinations, etc.

4. Chain-of-custody documentation and sample tracking in the laboratory.

5. Case contact sheets documenting conversations with detectives, attorneys, etc.

6. Documentation of supervisory review through initials and dates.

7. Reports reflecting the results and their interpretation.

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D. Data Analysis and Reporting

1. Data Analysis

All analytical case data are interpreted independently, usually by the Interpreting Analyst assigned to the case and the Forensic Scientist assigned to a rotation. Additionally, the data are reviewed again by the Interpreting Forensic Analyst while preparing a final report and then by the supervising Forensic Scientist who reviews that Interpreting Forensic Analyst's reports. The data are reviewed subsequently by the Assistant Director and then the Director. If discrepancies occur, they must be resolved by mutual agreement after a discussion between the Interpreting Forensic Analyst and Supervising Forensic Scientist. If a consensus is not reached, the discrepancy is resolved by one or more of the following:

a. Reanalysis of the sample in dispute.
b. Discussion with either the Forensic Scientist, the Director or the Assistant Director
c. By rendering the result inconclusive.

All original data must be archived by one of several acceptable methods (if possible or if applicable), i.e., densitometry, photography, xerox, and digitization, for future retrieval and analysis.

Where identifications are made using DNA profiling, specific matching criteria have been established and are part of the methods manual.

Known standards are recorded and monitored by means of established criteria and are part of the methods manual.

2. Reporting

All reports accurately reflect the data produced and the opinions are based upon objective scientific observations, see Departmental Methods Manual version 1.0.

The report format allows the reader to identify the following for the administrative review.

a. The Forensic Biology case number (FB-)
b. The Medical Examiner case number (if applicable).
c. Deceased or victim's name (if known).
d. Police Precinct and Complaint Numbers (if applicable).
e. Medical Examiner and date of autopsy.

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3. Case Review

The case review process for laboratory reports takes place in distinct phases before final reports are generated. The first phase, Phase I, reflects preliminary review and generation of a draft report. Once the draft report is generated, the case file is examined by the Director and/or the Assistant Director and is considered Phase II of the process. In this phase both an analytical and administrative review takes place.

The routine review process is illustrated in the tables below.

Phase I

Step	Activity
1	A draft, hand written or computer generated, report is prepared by the Forensic Analyst assigned to the case according to the guidelines established for uniform report preparation.
2	Review of the draft report by a supervisor. At this point additional work may be required which will necessitate performing additional tests to either provide additional data or to resolve a discrepancy in the data. This will cause a delay in the case being completed. If this occurs, and after the additional work is completed, the reporting process will begin again with Phase I.
3	Correcting the final report and final typing of the report by departmental clerical staff, analyst or scientist.
4	Second review of the report by the supervisor.

Once the supervisor is satisfied that the laboratory has complied with the original request and/or that appropriate laboratory examinations have been completed, the second phase of the review process takes place.

Phase II

Step	Activity
1	Final review of the report by the Assistant Director and/or by the departmental Director.
2	Statistical information to obtain departmental and individual productivity data will be obtained at this time by the Director.

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3	The original of the report, if applicable, is sent to the OCME records department, a copy is retained in the case file and copies are sent upon legitimate request to requesting agencies and attorneys.

In phase II, the Director and/or Assistant Director will review the completed case file. Any discrepancies discovered will be discussed with the supervisor and resolution of the discrepancy will be discussed. The procedure used to resolve the discrepancy will be agreed upon by the Director and/or Assistant Director and the supervisor.

At times either a Forensic Scientist or Assistant Director will conduct the scientific investigations on casework. In these instances, the review process begins with the next higher level of authority in the laboratory.

At times, the Director may conduct scientific investigations on casework. In these instances, the Assistant Director will review the case.

4. Case Prioritization

Cases that are received into the laboratory are assigned a target date by when the analytical work will be finished. For routine cases, those that require no special attention, are automatically assigned a target date of 90 days. Cases that require special attention are assigned target dates less than 90 days.

All cases are tracked in a Paradox database.

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E. Court Testimony

Court testimony is the culmination of the work performed by the laboratory's scientists. Each Forensic Analyst or Forensic Scientist will be monitored at least once a year providing testimony is given. The Director and Assistant Director monitor each other. The Forensic Analysts are monitored by the Director, Assistant Director, or the analyst's supervisor. Forensic Scientists will be observed by either the Director or the Assistant Director. Although monitoring can take different forms, direct court room observation is the preferred method.

Each evaluation will be documented in a written memorandum to the testifying scientist and will include comment on the following areas. The review will also prescribe remedial action that should be taken if the evaluation is less than satisfactory. The following points will be considered.

1. Appearance
2. Poise
3. Effectiveness of presentation (technical knowledge, ability to convey scientific concepts).
4. Interpretation of laboratory results.

A form will be filled out and maintained in the testifier's personnel file. A copy of the evaluation will be given to the testifier by the reviewer. Any problems with the testimony will be discussed. Any deficiencies in the testimony presentation will be corrected by having the testifier watch someone who is accomplished at court room presentation and deficiencies in knowledge will be addressed through remedial education.

Remedial education might include one or both of the following:

1. Retraining on technical information if the testimony was inaccurate.
2. Moot court if the testimony showed deficiencies in the ability to express the concepts clearly.

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F. Evidence Handling Protocols

1. General guidelines

Chain-of-custody refers to the documentation that allows evidence tracking from receipt of evidence (either post-mortem autopsy specimens or physical evidence obtained through investigations), through the analytical process, until it leaves the control of the laboratory.

Evidence is received primarily from the NYPD but other agencies and jurisdictions submit cases as well. Post-mortem items are received from all of the OCME locations.

At the conclusion of the scientific testing, the evidence is transferred to the Evidence Unit, if an NYPD case, or returned to the submitting agency.

a. case numbers

Evidence is assigned a sequential FB--0000 number where FB refers to Forensic Biology, -- refers to the year, i.e., 90, 91, and etc, and 0000 identifies a sequential number assigned to one specific investigation. One FB Number is assigned to each homicide investigation (a single FB number will be assigned to a multiple homicide). For sexual assaults, where the victim is alive, one number is assigned to each incident, i.e., for serial rapists, a separate FB Number is assigned for each victim.

Multiple police voucher numbers may be used for a single death investigation. All will be assigned the same FB number.

Homicides and hit-and-runs are always assigned FB numbers. Other cases may receive FB numbers as well, such as NYPD investigations, sexual assaults, missing persons, civil and forensic paternities, and cases from other jurisdictions.

b. item numbers

Each item is assigned a unique number, usually corresponding to a police voucher number. Items taken at autopsy are assigned a sequential PM (post-mortem, i.e., PM1, PM2, and etc, which is made unique by the FB Number, i.e., FB96, and etc.

c. evidence receipt

All evidence received in the laboratory must be properly sealed. This includes evidence tape, labels, security envelopes, etc. **Staples are not an acceptable seal.**

The paperwork brought with the evidence is reviewed to ensure that the evidence belongs in the Forensic Biology Department.

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Generally, the following items are not accepted:

(1). items intended for print exams
(2). items intended for hair/fiber exams
(3). items intended for gunshot residue exams
(4). hair, fiber, or other trace evidence
(5). clothing from the deceased

If there is a question about whether evidence should be accepted, discuss it with a Forensic Scientist, the Assistant Director, or the Director.

At the time the evidence is received, the top part of the chain-of-custody form is filled out, listing name, ME number, evidence voucher, and item descriptions.

d. signatures

Evidence, whether specimens collected during the autopsy or from user agencies, is received by a member of the Evidence Unit or by a member of the Forensic Biology Department. After the evidence is received by a member of the Forensic Biology Department, it is transferred for storage. The bottom part of the chain-of-custody form will be filled out to reflect this. All dates are recorded contemporaneously.

For evidence delivered from an outside agency to a member of the Forensic Biology Department:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	**Det. Smith**	4567	**P. Ryan**	½/95
F123456	1-6	**P. Ryan**	----	**shelf B**	½/95

For evidence delivered from an outside agency to a member of the Evidence Unit:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	**Det. Smith**	4567	**A. Anzalone**	½/95
F123456	1-6	**A. Anzalone**	----	**P. Ryan**	½/95

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F123456	1-6	**P. Ryan**	----	**shelf B**	½/95

For post-mortem evidence:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
-------	PM 1-3	**autopsy**	----	**P. Ryan**	½/95
-------	PM 1-3	**P. Ryan**	----	**PM cold storage**	½/95

e. storage of evidence

Evidence is generally stored in the departmental cold rooms until it is assigned to a Forensic Analyst. Evidence delivered to the Evidence Unit during hours that the Forensic Biology Department is closed is stored in the Evidence Unit, then transferred to the Forensic Biology Department during normal business hours.

f. case assignment

Normally, a supervising Forensic Scientist is responsible for deciding what testing must be performed on specific cases. The case is then assigned to a Forensic Analyst, also known as an Interpreting Analyst (IA). On occasion, the Director, Assistant Director, or Forensic Scientists may assign cases to themselves. The Director and/or Assistant Director may assign cases.

When an Analyst or Scientist begins the examination of the evidence, the chain of custody will be filled out to reflect that the work has begun. The date in the notes reflect the first day that the work began.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	½/95
F123456	1-6	P. Ryan	----	shelf B	½/95
F123456	1-6	**shelf B**	----	**F. Baldi**	1/4/95

Throughout the analysis process, the Forensic Analyst or Forensic Scientist documents the evidence according to procedures delineated in the Departmental Procedures Manual (Note taking). When

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samples are processed in bulk (during a rotation), the chain-of-custody is reflected in the worksheet for that rotation: the Rotating Analyst signs the worksheet indicating that the evidence has been received.
Each analyst is assigned a drawer in the cold room which is used to store evidence in progress.

g. disposition - vouchered items

When the analytical work is completed, the evidence is packaged according to protocols accepted by the NYPD and transferred to the Evidence Unit. The date and signatures are recorded on the chain-of-custody form.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	½/95
F123456	1-6	P. Ryan	----	shelf B	½/95
F123456	1-6	shelf B	----	F. Baldi	1/4/95
F123456	1-6	**F. Baldi**	**----**	**A. Anzalone**	1/6/95

h. disposition - retained items

Retained evidence from casework refers to those specimens which have been chosen for analysis and which have not been consumed. Examples of these are stains cut from clothing, blood swabbed off of items, or entire small items such as blood samples collected at the scene.

Retained evidence is kept frozen for approximately 6 months, then it is stored at room temperature. Eventually, they are vouchered for entry into the NYPD evidence control system and transferred to the Evidence Unit.

All DNA extracts are retained.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	½/95
F123456	1-6	P. Ryan	----	shelf B	½/95

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F123456	1-6	shelf B	----	F. Baldi	1/4/95
F123456	1-6	F. Baldi	----	R. Burgos	1/6/95
retained	items	**F. Baldi**	----	**retained storage**	2/4/95
DNA	extracts	**F. Baldi**	----	**DNA storage**	4/2/95

i. disposition - non NYPD cases

If a case came from a non-NYPD agency, all items are returned to the submitting agency. Nothing will be retained in the laboratory.

j. transport of specimens from outer boroughs

Autopsy evidence sent from the OCME offices in Brooklyn, Queens, The Bronx, and Staten Island is received in sealed, plastic containers. Inside each container is a Transport Manifest that has a Transport Container Number and is dated. Pasted to that Transport Manifest are stickers with case numbers and/or bar codes for those specimens inside the container.

k. sample tracking in the laboratory

After samples are removed from the evidence and to insure that mix-ups do not occur, a witnessing procedure is used to show that testing is being performed on the correct sample. Witnessing occurs at several points during the analysis: at the point where exemplar whole bloods are removed from a made into a dried stain and at the DNA extraction, amplification set-up, gel loading, and hybridization stages to insure that the sequence of tubes containing DNA or sample matches the appropriate worksheet. The witnessing person must sign the worksheet.

l. consumption of samples

If a sample is going to be consumed during analysis, testing on that sample must be stopped. Testing will resume only after appropriate information is received by the Director, Assistant Director, or a Forensic Scientist that indicates that the testing can continue.

2. Specific guidelines for different evidence types

a. FB cases

(1). blood

A stain is prepared on stain cards. The stain is retained frozen in the laboratory for approximately a year then stored in the cold room for approximately two years. Eventually, the dried stains are

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vouchered for entry into the NYPD evidence control system and transferred to the Evidence Unit.

(2). sexual assault evidence

Sexual assault evidence is stored in the cold room until processed. Following the guidelines in the Departmental Methods Manual, specific items are retained or sent to the Evidence Unit. This will be reflected in the chain-of-custody.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
-------	PM 1-3	autopsy	----	P. Ryan	½/95
-------	PM 1-3	P. Ryan	----	PM cold storage	½/95
-------	PM 2	PM cold storage	----	P. Ryan	1/5/95
-------	PM 2D-H	P. Ryan	----	retained samples	1/6/95
-------	PM 2A-C	**P. Ryan**	----	**Rosemary Burgos**	1/6/95

(3). other PM items

Hairs, fingernails, etc. are also received from autopsy. These are stored in the cold room. Eventually, they are vouchered for entry into the NYPD evidence control system and transferred to the Evidence Unit.

Other specimens such as tissues, bone etc. may be stored frozen. After one year, these specimens may be discarded if a dried bloodstain has been retained. This will be reflected on the chain-of-custody form.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
-------	PM 1-3	autopsy	----	P. Ryan	½/95
-------	PM 1-2	**P. Ryan**	----	**PM cold storage**	½/95
-------	PM 3	**P. Ryan**	----	**PM freezer**	½/95
-------	PM 3	**P. Ryan**	----	**discarded**	2/3/96

b. Non-FB cases

(1). blood

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The Forensic Biology department receives EDTA blood, if available, from all Medical Examiner cases. Most of these do not fall within the mission of the Department of Forensic Biology and are not the subject of an homicide investigation.

Blood samples that are appropriate for database samples may receive an MB number. The DNA is isolated and a dried stain is prepared, if there is sufficient sample. **All blood samples, whether or not an MB number is assigned to them, are discarded after two months.**

The isolated DNA is retained in the laboratory for two years or until it has been consumed.

(2). other PM items

Other post-mortem items are occasionally received on non-FB cases. The specimens and associated autopsy worksheets are transferred to the Forensic Molecular Biology (DNA) Laboratory and are tracked using a log book. **All items, whether or not an MB number is assigned, are discarded after two months.**

c. additional analysis on retained samples

When analysis is done on samples that were previously retained, the chain-of-custody will reflect this:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	½/95
F123456	1-6	P. Ryan	----	shelf B	½/95
F123456	1-6	shelf B	----	F. Baldi	1/4/95
F123456	1-6	F. Baldi	----	R. Burgos	1/6/95
retained	items	F. Baldi	----	retained storage	2/4/95
retained	items	**retained storage**	----	**P. Buffolino**	3/4/95
retained	items	**P. Buffolino**	----	**retained storage**	4/4/95

d. items transferred to or from other OCME departments

Specimens are sometimes transferred from other OCME departments. For example, sometimes evidence is received on cases for which autopsy specimens are not received. In these instances, appropriate specimens are obtained from the Toxicology Department (if within that department's specimen holding time-frame) or from DNA database specimens (if within that laboratory's holding

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time-frame). In unusual instances, and if freshly preserved specimens are not available, formalin fixed specimens may be obtained from the Toxicology laboratory. The chain-of-custody will reflect this:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
toxicol.	blood	**B. Marker**	----	**M. Samples**	½/95

Evidence is occasionally transferred to another OCME department, such as a knife a medical examiner wishes to examine. The chain-of-custody will reflect this:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	½/95
F123456	1-6	P. Ryan	----	shelf B	½/95
F123456	1	**shelf B**	----	**P. Ryan**	1/3/95
F123456	1	**P. Ryan**	----	**Dr. Gilson**	1/3/95
F123456	1	**Dr. Gilson**	----	**M. Samples**	1/3/95
F123456	1	**M. Samples**	----	**shelf B**	1/3/95

e. unlabeled items

Sometimes autopsy specimens are received with no identifying case numbers, specimen types or other identifying information. These specimens are discarded.

f. submittal to other agencies

Instances arise that require the department to send evidence to other agencies or laboratories. Under most circumstances this is accomplished using overnight mail services; the shipping paperwork is kept in the case file. The chain-of-custody will reflect this.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
retained	items	**M. Samples**	----	**FBI via FedEx**	½/95

When the evidence is returned to the Forensic Biology Department through mail services, the chain-

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of-custody will be filled out similarly.

If additional items (DNA extracts, membranes) are returned, a new chain-of-custody formed must be filled out to reflect that.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
retained	items	M. Samples	----	FBI via FedEx	½/95
retained	items	FBI via reg mail	----	M. Samples	4/4/95
extracts	----	FBI via reg mail	----	M. Samples	4/4/95
extracts	----	M. Samples	----	DNA storage	4/4/95

3. Security

a. Building Security

All Department of Forensic Biology laboratory functions for the OCME are carried out at the Manhattan facility. The building has two entrances: One on the 30th Street side and the other, the main entrance, on First Avenue. Each entrance is guarded during the day by either a security guard or by an OCME employee. All visitors are required to sign into the building. Employees, visitors, part-time workers, students, and visiting scientists are issued passes.

After normal working hours, the entrance on First Avenue is locked and the 30th Street entrance, the morgue entrance, is guarded.

b. Laboratory Security

The Department is located on the sixth floor and has minimum access by authorized personnel: departmental staff, visiting staff, students, and OCME employees with either floor or building master keys. With advanced permission of the Director or Assistant Director, students and staff may use the laboratory after normal working hours.

The laboratories have two lock systems and are locked all the time. During the day, each laboratory uses a combination pad-lock, which is changed frequently, and is used to gain entrance. At night, another lock system, a master key system, is used in addition to the combination pad-lock.

Physical evidence being analyzed may be present in the laboratory during normal working hours. At night the evidence is returned to the sixth floor cold room, which is locked at all times. Post-mortem

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G. Equipment Calibration and Maintenance Logs

Each piece of essential scientific apparatus has a log usage book and requires QC monitoring. **Essential is defined as equipment which is required for a testing procedure and its malfunctioning will compromise the reliability and accuracy of the results obtained. Such equipment has usage and/or QA/QC records available.** Specific equipment QC procedures for critical scientific apparatus are found in the Forensic Molecular Biology QC Manual.

The first step for all preventative maintenance is cleanliness. If there is any kind of spill, inside or outside a piece of equipment, it is to be cleaned up **IMMEDIATELY** (this includes hybridization solution, buffers, salts, and etc.). Some spills may be corrosive to the equipment and cause more damage than necessary. It is easier to clean reagents before they dry rather than to wait and have to chisel them off.

The usage log for each item begins with the date of purchase of the piece of equipment. In addition to daily entries in the log, each calibration of the apparatus is also maintained in the usage log. For equipment purchased before the institution of this manual, if the date of purchase is known, that date will be used, if the date of purchase is not known, then the date the manual was placed into service will be used instead. An approximate date of purchase will be entered into the log beside the date.

Any irregularities observed during routine monitoring or use of all equipment are recorded in the comments section of the log and reported to a the Forensic Scientist supervising the QC rotation or a QA Committee member. The irregularity will be investigated and its cause determined, if possible.

A decision whether the equipment is unsuitable for casework use will be made by the Forensic Scientist supervising the QC rotation or a QA Committee member and corrective action will be taken and recorded in the appropriate log. If the equipment has been removed from use, for whatever reason, an entry is made into the log book, and an appropriate standard for reviewing casework is used (see DNA Quality Control Manual v. 4.0) if necessary.

After appropriate repair or recalibration, the Forensic Scientist supervising the QC rotation or QA Committee member may re-certify that the equipment may be used for case work. Recertification requires that the Forensic Scientist supervising the QC rotation or QA Committee member record that the instrument is available for casework in the instrument's log book.

The schedule of equipment maintenance follows:

1. Temperature Maintenance Equipment (refrigerators, freezers, water baths, cooling

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and other exemplars are also stored in the cold room. Only departmental staff have access at other than normal working hours.

The Department's current case files are located in the sixth floor Departmental office, which is open to OCME personnel who have the combination to the key pad lock. At night this door is locked with the building's master key system. During normal working hours this door works on a combination key pad lock.

Case files older than two years are kept in room 311, which is locked at all times with the building's master key lock system. Cases prior to 1989 are stored in the cellar.

Retained samples that are no longer refrigerated are kept in room 311, which is locked at all times.

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baths, ovens, and etc).

Temperatures are recorded daily on a temperature log specified for each piece of equipment. For those using an electronic recording device, these are checked weekly to insure that the recording device is working properly. This is done by the technician responsible for the preparation of reagents **Or As Assigned By The Forensic Scientist supervising the QC rotation Or a QA committee member.** The log is dated and initialed by the person performing the temperature recording.

Appropriate equipment has its own permissible temperature range. Variations which exceed the permissible range will be evaluated relating to its suitability for continued usage on a per situation basis. Acceptable ranges are related to the type of equipment and its determined use by the Departmental staff.

(a.) Non-Frost-Free Refrigerators/Freezers

These freezers/refrigerators must be defrosted annually. Defrosting of freezers is recorded on the maintenance log for that freezer/refrigerator.

2. pH meters

These are calibrated weekly and are checked for each measurement by scientific staff performing pH measurements. The technician responsible for preparation of reagents keeps a record of the pH measurements used to prepare critical laboratory reagents.

3. Electrophoresis Equipment

Electrophoresis power supply logs are filled out for each use by the analyst using the equipment and are dated, initialed, purpose, and comments. Each electrophoresis tank usage is documented on a log sheet as to date, initials, purpose, and comments.

4. Balances

Balances are checked weekly and are calibrated annually by an outside service. The calibration date is recorded in the usage log. In the event that an outside service is not available or, for other reasons, cannot be contracted for, the calibration will be performed by laboratory personnel. The usage log will reflect this information.

5. Thermocyclers

Each thermocycler has a usage log which is documented as to date, initials, purpose, and comments.

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QC of thermocyclers are specified in the DNA Quality Control Manual v 4.0.

6. Microtiter Plate Readers

Each microtiter plate reader has a usage log which is documented as to date, initials, purpose, and comments. Specific assay performance is evaluated by examining the controls run with each assay. If the controls are outside the range of accepted limits, the effects on casework are evaluated. Instrument QC is performed monthly.

7. Micropipettes

Micropipettes will normally be checked using an outside vendor. For those calibrated in-house, a gravimetric procedure is used. Each pipet will be assigned a control number and the date of calibration and the initials (vendor if applicable) of the person performing the calibration will be recorded in the log. Each pipette will have a piece of tape on the handle indicating the last time a calibration was conducted. Each pipet will be calibrated twice annually.

8. Centrifuges

Centrifuges are not considered critical equipment, are not normally used for precise centrifugations, and do not need to be calibrated.

9. Hoods

Biological hazard and chemical fume hoods are to be inspected and certified annually by an outside contractor. Filters are changed on ductless hoods annually. Also, when or if biological hoods are moved, someone must decontaminated them before the move and recertify them after the move. Hood flow rates are monitored periodically.

10. Survey Meters

Survey meters for measuring radioactive contamination of work surfaces are calibrated according to the specifications of the radiation license. A record of the calibration is maintained in a maintenance log.

11. Liquid Scintillation Counter

If the liquid scintillation counter is used routinely, it must be checked monthly with a standard radiation source. A use log is maintained and standard reference anomalies are recorded. The instrument is calibrated as required.

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H. Proficiency Testing

1. Overview

Proficiency testing is used to demonstrate the quality of the scientific service offered by the laboratory, and it serves as a mechanism for critical self evaluation. This is accomplished by the analysis and reporting of results from appropriate biological specimens submitted to the laboratory as open and/or blind case evidence. All specimens submitted as part of a proficiency test must be analyzed like any case -- including case folder, review, and a Proficiency Review sheet, which is a check-list that allows the supervisor to evaluate the overall performance of the analyst and also allows the Director and Assistant Director to evaluate the supervisor's evaluation -- and must be performed and interpreted according to the laboratory analytical protocols being used at the time the test is taken.

All scientific staff performing scientific testing on casework will take proficiency tests according to guidelines established by regulating and/or accrediting agencies or bodies, if available or required. Acceptable commercially available proficiencies are available: The Collaborative Testing Service (CTS), The Serological Research Institute (SERI), Cellmark Diagnostics (IQAS), and the College of American Pathologists (CAP).

Where required, proficiency test results will be made available to an external accreditation review committee, the Proficiency Review Committee - PRC.

2. Definitions

a. Types of Proficiency Testing

(1). Open Proficiency Testing

Open proficiency test specimens are presented to the laboratory staff as proficiency specimens and are used to demonstrate the capability of the laboratory's analytical methods as well as the interpretive capability of the analyst/scientist. Proficiency testing is the primary means by which the quality performance of the laboratory is judged. All analysts must successfully pass a proficiency test prior to being assigned casework. Because of scheduling conflicts in purchasing external proficiencies, the first proficiency test may be prepared internally.

For analysts who perform laboratory work, but who are not assigned cases to report and do not interpret laboratory data, an internal proficiency (a competency) test is administered and must be passed.

(a). Personnel

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Each member of the scientific staff who interprets laboratory data, writes reports, and testifies must take appropriate proficiency tests.

(b). Specimens

Each open proficiency test may consist of dried specimens of blood and/or other physiological fluids, either singly or as a mixture. Each sample to be analyzed will contain sufficient sample so that a conclusion can be drawn from the results of the analysis.

(c). Sample Preparation and Storage

All specimens and proficiency tests should be uniformly prepared on washed cotton cloth, swabs, or other suitable material to ensure their integrity and identity. Each specimen must be labeled with a unique identifier that can be independently verified by at least one other person to ensure proper assignment.

A portion of each specimen used to prepare the test should be retained by the preparing laboratory until sufficient time has passed for all participating individuals to register complaints and referee analysis and comparison is completed.

One person in the laboratory, assigned by the Assistant Director or Departmental director, should acknowledge receipt of each proficiency test and assign it to the laboratory staff.

(2). Case Retesting and Positive Control-Internals

Reanalysis of case work permits an estimate to be made regarding the laboratory error rate. Reanalysis samples may be performed on casework samples, where sufficient sample remains. The Forensic Scientist supervising the QC rotation, after request by the Director, will submit a reanalysis sample into the rotation at the DNA extraction (Chelex) stage. The Forensic Scientist supervising the QC rotation is responsible for giving the results to the Director, who will compare the reanalysis results of the reanalysis with the results of the original analysis. If the results do not correlate, in other words, the results do not agree, a second reanalysis will be performed, if the reason for the disagreement cannot be determined. A corrective report will be issued, if necessary.

Also, the laboratory requires that a positive control-internal, which has previously been tested as a database sample, be run successfully during each STR run. Additionally, a positive control-external, which is heterozygotic for each quad locus, must be run successfully.

(3). Blind Proficiency Testing

If a procedure for blind proficiency testing is established, blind proficiency tests will be administered

to the laboratory annually and will be presented as a routine case. The samples in the "blind case" will be analyzed as a regular case and reported as such.

b. Deficiency and Corrective Action

It is the responsibility of the Director or QA committee designee to assure that deficiencies are acknowledged and that any corrective or remedial action is documented. If an error is found, the Director or QA committee designee will ascertain the cause of the error, i.e., a determination of what class the error(s) is.

(1). Class I or Analytical/Interpretative Errors

These errors, i.e., mistyping or misinterpreting analytical results whether correct or not, raise immediate concern regarding the quality of the individual's work product. A class I error is cause for failure of the proficiency test and requires suspension from performing the test in casework and re-training. Casework can be resumed after passing a new proficiency test.

An appropriate supervisor monitors the performance of the specific test until a satisfactory performance is obtained. At that time a proficiency test will be administered.

In addition, the QA Coordinator reviews cases signed by the analyst since the last successful proficiency test in order to ascertain whether similar errors have passed the case review process.

(2). Class II or Systematic Errors

This discrepancy is due to a problem which may affect the quality of the work, but is not persistent or serious enough to cause immediate concern for the over-all quality of the individual's work product. Retraining is necessary.

A class II error may be the result of equipment, materials, environment, etc., and may require a review of all relevant casework since the unit's last successfully completed proficiency test. Once the cause of the error has been identified and corrected, all analysts will be notified in writing of the appropriate corrective action in order to minimize the recurrence of the discrepancy.

Any casework performed during the relevant period will be reviewed and selected samples will be repeated in order to verify that the results are correct.

(3). Class III or Administrative Errors

This discrepancy is determined to have only minimal effect or significance, be unlikely to recur, is not

systematic and does not significantly affect the fundamental reliability of an individual's work product.

Class III or Administrative errors, i.e., clerical, sample switching, improper storage, documentation, etc., once identified as such, will be corrected by instructing the analyst of the problem. Depending on the nature of the error, the analyst may be required to submit to re-training in the relevant area. For example, if the error is in sample storage, the analyst will be re-trained concerning the proper storage of biological specimens.

Simple clerical errors will be pointed out to the analyst. Subsequent casework will be closely monitored, more than normal checking, for clerical errors.

In the event of an unresolved disagreement between the designated QA individual and the laboratory, the matter will be resolved by the departmental director.

Errors of failing to follow established laboratory QA/QC procedures will result in its being documented on the Proficiency Evaluation sheet. The analyst will be instructed in the appropriate procedures which will be documented on the Proficiency Evaluation sheet.

Each analyst will receive a copy of the Proficiency Evaluation Sheet and their comments will be recorded there.

c. Documentation of Open Proficiency Testing Results

Proficiency test results will be maintained by the department and will be documented as follows:

(1). Proficiency Testing Identification Number
(2). Name of analyst
(3). Dates:
receipt by analyst
completion date (report date)
(4). Copies of all data sheets, notes, photographs and reports
(5). All data will conform to casework standards and include lot numbers, QC numbers, and etc.
(6). The Proficiency Evaluation sheet will be filled out by the supervising scientist.

d. Laboratory Error Rates

Different types of errors occur but those that result in a wrong result being reported must be evaluated in order to assess the laboratory's reliability as an analytical resource.

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Incorrect results occur, theoretically, as a result of simply performing a test incorrectly, inadvertently switching samples, or misinterpreting testing results. These can be estimated in a variety of ways.

(1). Determining of Error Rates

(a). Measuring the frequency of incorrect responses on external open and/or blind proficiency tests.

(b). Measuring the frequency that sample duplication testing shows discordant results.

(c). Measuring the frequency that sample re-testing analysis shows discordant results.

(d). Measuring the frequency that Internal and External controls give incorrect results.

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I. Personnel Training and Qualification Records

Personnel training falls into several categories: Courses taken at universities and colleges, workshops designed to educate on specific topics and techniques, on-the-job training where theoretical and practical information and experience is obtained from the scientific staff, seminars and lectures held at local universities where scientists are invited to speak on various topics, scientific literature, and professional meetings. Each of these will be discussed in relation to training requirements in the Department of Forensic Biology.

Training records for each scientific staff member are kept as part of that person's personnel and/or proficiency test file.

1. Courses at Universities

The Scientific professional staff in the department have met the minimum educational requirements necessary to meet the title descriptions. However, continuing education is important and recognized as a mechanism of maintaining a state-of-the-art staff and fostering an academic environment within the service mission of the department.

Because tuition reimbursement through the City of New York is not normally available, the department cannot require staff to attend courses at universities.

Staff will be made aware of the courses available.

2. Workshops

Workshops are routinely offered in the local area by companies on specific topics, i.e., Roche on PCR, and etc., usually as an aid to their marketing functions. Normally there is a charge for these courses. The staff will be made aware of these workshops, but because reimbursement cannot be guaranteed, attendance will not be mandatory.

Workshops are also offered in conjunction with local universities specializing in forensic science training, i.e., John Jay College of Criminal Justice, University of New Haven, as well as through The Northeastern Association of Forensic Scientists for a reasonable cost. Although the staff cannot be guaranteed reimbursement for the workshop costs, recommendations will be made to attend those which are deemed important to the function of the department.

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3. On-The-Job-Training

Most training in the department will be of the on-the-job variety. This training will emphasize theory and the practical aspects of the work which is conducted in the department. The philosophical approach has three parts: theoretical, practical and examination or testing ability.

a. Theoretical background

Theoretical background information required to understand the scientific basis, perform, and interpret the analytical tests performed in the laboratory will be provided to each staff member hired. This training will take place over a number of weeks.

This training will be presented in lecture and/or video tape format. Each member of the scientific staff will have access to literature references and reference books which are maintained by the department. Specific methods used will be referenced to the scientific literature and copies of publications pertaining to in-house methods will be available in a laboratory file.

The OCME has an in-house library service which will obtain original scientific and forensic articles by interlibrary loans. Additionally, OCME professional staff has library privileges at the New York University Medical School library which is next door.

Before testifying in court or grand jury, each analyst will participate in moot court. Supervisory scientific staff will conduct the moot court. The purpose of the moot court is not punitive but for the analyst to learn to appreciate the adversary process. It is also a mechanism for the supervisory staff to identify and correct obvious problems the analyst may have in his/her knowledge or ability to communicate effectively.

b. Practical experience

Each analyst will be trained to perform the analytical procedures conducted in the department. This has three phases: the trainee observes the procedure being done, then demonstrates the procedure to the trainer. This is followed by the trainee using the procedure independently on practice specimens.

c. Competency testing

At the conclusion of training in any particular analytical procedure, the analyst will be asked to successfully complete a competency test on that analytical procedure. Each analyst being trained in procedures used in the Department must take a competency test before using the procedure in case work.

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d. Court preparation

There are several ways to prepare an analyst for court and other public speaking. Each analyst should accompany laboratory personnel to court and observe testimony, as well as attend pre-trial conferences at the laboratory. In addition, an analyst will be required to give at least one presentation in the laboratory's Journal Club.

The primary preparation for court will be mock court. The trainee will participate in at least three mock courts, acting as the expert witness. Traditionally, the supervisor acts as the prosecutor, with additional personnel taking the roles of defense attorney and judge.

To prepare for mock court, the trainee should review court transcripts and lists of suggested questions prepared by laboratory personnel. The trainee then meets with the Director, Assistant Director, and supervisors of the rotations for questioning on individual topics. These sessions should involve question and answers, constructive criticism of the answers, and specific suggestions for improvement.

The first two mock courts will be after the completion of the classical forensic biology training and the completion of the DNA training; these will involve mocked-up or actual case files which cover the topics completed at each stage of training. The last mock court will take place after the analyst has completed several cases, approximately three to six months after training is completed. If it felt necessary by laboratory supervisors, additional mock courts will be scheduled.

e. Training Outline for Classical Forensic Biology

The goal of training and competency testing in the classical forensic biology methods is to establish consistency of performance between individual analysts and to maintain the highest possible level of performance over time. These analytical procedures for identifying physiological fluids are the foundation on which further individualization (DNA testing) is based and their behavior and limitations need to be understood. The classical forensic biology training program is monitored by the Director and/or members of the QA committee. Training may be performed by a member of the QA Committee or by a proficient analyst with the appropriate level of experience.

All classical forensic biology methods training records (notes, worksheets, photographs) will be retained in a folder labeled with the trainee's name and type of training.

Notetaking:

Study the Notetaking section of the Forensic Biology Methods Manual. Then retrieve current case files from the file cabinet and study the note-taking styles of various analysts. Think about what you like and dislike about the different styles. When you run analytical procedure or receive samples for

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proficiency testing, take notes and fill out worksheets as if they are real cases.

Blood:

Read about blood composition and hemoglobin. Read about the presumptive tests for blood: Kastle-Meyer (KM), leucomalachite green (LMG), and luminol. Study the history of presumptive testing and the different presumptive tests that have been used historically. Understand the mechanisms of these three presumptive tests. Make sure that you know what substances cross-react with which presumptive test. Read about the Takayama confirmatory test for hemoglobin.

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then the following practical experiments are done:

A. Sensitivity. Check this for the KM and LMG presumptive tests by testing serial dilutions of blood up to 1/1,000,000.

B. Specificity. Check this for both presumptive reagents by testing various substances such as sweat, urine, rust, plant extracts (onions), etc.

C. Age. Test bloodstains of various ages with both presumptive reagents.

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then the following practical experiments are done:

A. Sensitivity. Check this by testing different amounts of blood serially diluted up to 1/10,000.

B. Specificity. Check this by testing other substances such as sweat (salt), urine, rust, etc.

C. Age. Test bloodstains of various ages (up to 6 months).

Species:

Read about the immunology of antibodies and antigens. Understand how antisera are made, both polyclonal and monoclonal. Study about cross-reactivity and understand why cross-reactivity occurs.

Study diffusions methods used to identify antigens and antibodies, specifically the Ouchterlony (double-diffusion) method. Understand why the precipitin bands form and how this relates to the identity of a specific antigen. Be sure you know what 'bands of identity' are.

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Study crossover electrophoresis. Understand the theory of why antigens and antibodies move in different directions in some agar and agarose gels. Know what endosmosis is and why it is important in immuno-crossover electrophoresis. Consider the relationship between specificity and sensitivity.

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then the following practical experiments are done (for both Ouchterlony and crossover electrophoresis):

A. Run both procedures using anti-human sera against dilutions of human blood.

B. Run both procedures using dilutions of anti-human sera against human blood.

C. Run both procedures using anti-human sera against dilutions of human blood.

D. Run both procedures using anti-human sera against the blood of various common animals that you might encounter in New York City.

E. Run both procedures using anti-sera of various animals against their corresponding animal blood.

F. Run both procedures using anti-sera of various animal against other animals and against human blood.

Practice:

Obtain or prepare samples so that you can use each of the procedures that you have learned. After you feel confident that you have mastered each of the above techniques, continue the training program.

First competency test:

Obtain a bloodstain identification competency test from the Forensic Scientist who is supervising the Evidence Documentation rotation. You must successfully complete this practical examination before continuing the training program.

Semen:

Read about seminal fluid. Know about its composition and sperm morphology. Get a general feeling about the how sperm morphology differs in various animals. Also, learn what abnormal human sperm look like in humans.

Read about different presumptive tests for seminal fluid, i.e., acid phosphatase, choline, etc. Read

the history of the presumptive tests. Then concentrate on the acid phosphatase test. Know what substances interfere with the test or might give a false positive test in post-mortem vaginal swabs. Read about acid phosphatase quantitation and the relationship, if any, between the amount of acid phosphatase and time since intercourse. Also, the relationship, if any, between the amount of acid phosphatase and the amount of semen or sperm present.

Next, concentrate on the identification of sperm. Study the different methods for staining sperm. Understand why sperm stain different colors or exhibit differential staining. Concentrate on the Christmas Tree stain and fluorescent staining.

Read about semen specific proteins. Concentrate on the prostate specific antigen, P30 (also called Prostate Specific Antigen or PSA), and how it is identified and quantitated. Study rocket electrophoresis, crossover electrophoresis, and ELISA techniques used to quantitate P30. Understand the relationship, if any, between the amount of acid phosphatase, P30, spermatozoa, and the amount of semen present.

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then the following practical experiments are done:

for the acid phosphatase test:

A. Sensitivity. Using the acid phosphatase test, test various dilutions of semen extracts up to 1/1,000,000.

B. Specificity. Check for specificity of the acid phosphatase test against other substances: vaginal fluid, urine, saliva, etc.

C. Make slides of semen stains, semen-stained vaginal swabs, and semen-free vaginal swabs both by:

1. Extracting the stains and pelleting cellular debris by centrifugation.
2. 'Mashing' the stains/swabs onto a slide.
3. Stain these slides using the Christmas Tree stain procedure.

for P30:

A. Sensitivity. Compare the sensitivity of Ouchterlony, crossover electrophoresis, and ELISA methods for identifying P30 by using various dilutions of wet semen up to 1/10,000,000

B. Specificity. Check the specificity of anti-P30 (polyclonal antibody) by using other

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substances such as vaginal fluid, urine, and saliva using crossover electrophoresis.

C. Review the P30 ELISA validation records.

Practice:

Obtain and/or prepare samples and practice the methods for semen identification until you feel competent with them. Then continue the training program.

Second competency test:

Obtain a semen identification competency test from the Forensic Scientist supervising the Evidence Examination rotation. You must successfully complete this practical examination before continuing with your training.

Saliva:

Read about amylase and understand the difference between AMY1 and AMY2 and in which body fluids each is found. Read publications on differentiating AMY1 and AMY2 using lectins. Study the different detection method for amylase and understand the difference between them.

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then the following practical experiments are done:

A. Run the amylase diffusion procedure on dilutions -- up to 1/10,000 -- of saliva, semen, semen-stained vaginal swabs, semen-free vaginal swabs, and urine.

B. If reagents are available, perform the amylase differentiation procedure using lectins on the same samples tested in 'A' above.

Practice:

Obtain and/or prepare samples and practice the techniques that you have just learned. When you feel competent, continue with the training program.

Third competency test:

Obtain a competency test from the Forensic Scientist supervising the Evidence Examination rotation. You must successfully pass the practical examination before continuing with the training program.

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Hemoglobin:

Read about hemoglobin. Study the structure/function relationship of the protein and know its structure (monomer, dimer, etc.), genetics (phenotypes, alleles), and discrimination potential. Also read about its longevity in dried stains.

Review the different separation/detection methods of different phenotypes (cellulose acetate electrophoresis, starch gel electrophoresis, polyacrylamide gel electrophoresis, and isoelectric focusing methods).

Read about isoelectric focusing in ultrathin gels. Understand the concepts and why isoelectric focusing is the method of choice for hemoglobin phenotype analysis.

Read about methemoglobin. Know why it forms and how to identify it in isoelectric focusing gels.

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then the following practical experiments are done:

A. Prepare and run several isoelectric focusing hemoglobin plates using standards and known variants.

B. Find and analyze samples from 15 recent post-mortem bloods from blacks.

C. Find and analyze 10 samples each from post-mortem bloods from blacks of ages: 3, 6, 9, and 12 months.

D. Run samples from recent non-probative casework. Choose stains that are very large.

Practice:

Obtain and/or prepare several samples and practice hemoglobin phenotyping using isoelectric focusing until you feel proficient with the procedure. Then continue with the training program.

Fourth competency test:

Obtain a competency test from the Forensic Scientist supervising the Evidence Examination rotation. You must successfully pass this practical examination before beginning the DNA training program.

First mock court

The trainee will participate in a classical forensic biology mock court, using either an actual case file

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or a mock case file that addresses only the training completed so far.

f. Training Outline for DNA Analysis

The goal of training and competency testing in the DNA laboratory is to establish consistency of performance between individual analysts and to maintain the highest possible level of performance over time. The DNA training program is monitored by the Director and/or members of the QA committee. Training may be performed by a member of the QA Committee or by a proficient analyst with the appropriate level of experience. The three-phase method (trainee observes the analytical procedure, trainee demonstrates the analytical procedure, and independent practice) is used for DNA training.

All DNA methods training records (notes, worksheets, photographs) will be retained in a folder labeled with the trainee's name and type of training.

New analysts are trained to perform a variety of different procedures, each relating to analyzing physical evidence DNA for DNA typing. Each analyst progress through a series of rotations in sequence: DNA Extraction, Quantiblot, and PCR amplification and typing. An analyst might also be trained in the RFLP procedure.

PCR Concepts

The most important concept to stress at the earliest stage of training is the physical separation of the extraction, pre-amplification, and post-amplification areas. It is important to emphasize that dedicated equipment should never be moved from one area to another, except for the transfer racks which are used to move samples. Physical separation includes a habit as simple as changing gloves when entering or leaving a PCR area in order to prevent contamination.

It is important to stress that a contamination problem may require two or three complete testing runs to pinpoint and correct. Consequently, it is better to avoid possible problems by taking plenty of time to do the procedure and by using the best technique. It is also important to remember that carelessness on the part of one analyst may adversely affect others' test results. If there is any doubt about whether a glove, a reagent, or a tip is contaminated, it must be replaced.

Other important issues are raised as the analyst observes different extractions. During the extraction of whole bloods, it is important to emphasize the techniques used to prevent sample to sample cross contamination. During the extraction of stains, cross contamination techniques should be reinforced. In addition, the typing results from stains should be evaluated in terms of sensitivity and consistency which are harder to maintain for these types of samples. By the end of the training period, the analyst will have acquired a basic theoretical understanding of each step of the test. It is important to know what is happening to the DNA during the extraction procedure, what happens in the reaction tubes

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during each step of the amplification cycle, the purpose of the various washing steps during hybridization and the basic mechanism for color development.

Review procedures

The results from the trainee's practice samples and competency tests will be evaluated by his or her supervisor in terms of sensitivity, consistency, and contamination at each of the steps in the training. In addition, the supervisor should ensure that the trainee is analyzing the proper control samples, is correctly and completely filling out worksheets and logbooks used to document sample analyses, and is familiar with the operation of the equipment necessary to perform the test. It may be helpful to include the trainer in this review process.

Problems will be addressed at each rotation and practice continued if necessary. For example, the supervisor will check the trainee's work, for contamination, for example. Low-level contamination (contamination which is less intense than the 'c' dot in the HLA-DQA1 test or small peaks in STR analysis) may not affect the typing results. Such contamination may often be eliminated by simply changing a reagent. However, if the analyst consistently demonstrates low-level contamination, he/she will be observed more closely during subsequent practice runs to determine the reason for the problem. These practice tests are filed in the trainee's training folder.

Practice samples:

The person in charge of organizing the training should prepare practice samples of known DNA types for the trainee. These can be stains representing laboratory personnel, exemplar stains from casework, or stains from previous external proficiency tests. The samples should include blood stains, semen stains (mixed and neat), saliva stains, and hair samples in sufficient quantity for the trainee to be able to do more than one analysis if necessary. For practice purposes, approximately three of each type should be sufficient.

The trainee will use these same practice samples for all DNA procedures - Chelex extraction, Quantiblot, amplification and DNA typing.

Since these are practice samples, the DNA types should be supplied to the trainee along with the samples.

Competency test samples:

The person in charge of organizing the training should also prepare competency test samples of known DNA types for the trainee. It is preferable that these be from previous external proficiency tests; assigning a new coding system to render them anonymous to the trainee. The samples should include blood stains and mixed semen stains in sufficient quantity for the trainee to be able to do more

than one analysis if necessary. For competency test purposes, a workable number is three bloodstains and one or two mixed semen stains.

The trainee will use these same competency test samples for all DNA procedures - Chelex extraction, Quantiblot, amplification and DNA typing. Since these are competency test samples, the DNA types are not to be supplied to the trainee.

Chelex extraction:

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then perform four separate Chelex extractions:

a. bloodstains
b. semen stains (differential extraction)
c. saliva samples
d. hair samples

As each extraction is finished, submit aliquots for DNA quantitation. Review the results with the supervisor; once satisfactory results are obtained on the practice samples, perform extractions on the competency test samples. Submit aliquots for DNA quantitation and review the results with the supervisor before continuing.

Quantiblot DNA quantitation:

After the trainee has observed the procedure and demonstrated the procedure to the trainer, then:

a. repeat DNA quantitation of the Chelex extracts of the practice samples
b. if desired, practice Quantiblot further

Review the results with the supervisor; once satisfactory results are obtained on the practice samples, perform DNA quantitation on the competency test samples. Review the results with the supervisor before continuing.

PCR amplification and product gel:

After the trainee has observed the procedures and demonstrated the procedures (all PCR amplification systems used in casework) to the trainer, then:

a. amplify all practice samples using casework PCR systems
b. perform product gel analysis on practice samples

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Review the results with the supervisor; once satisfactory results are obtained on the practice samples, perform PCR amplification on the competency test sample. Perform product gel analysis on the competency test samples. Review the results with the supervisor before continuing.

PCR DNA typing

After the trainee has observed the procedures and demonstrated the procedures (all PCR typing systems used in casework) to the trainer, then:

a. type all practice samples using casework PCR typing systems

Review the results with the supervisor; once correct PCR typing results are obtained on the practice samples, perform PCR typing on the competency test samples. Submit the PCR typing results to the supervisor, then the laboratory Assistant Director and Director for review.

If the reviewers feel that additional work is necessary for the trainee, it should be completed before continuing. Once the trainee is passed, continue to the last part of practical analytical procedure training.

PCR dilution and mixture studies:

At this point, the trainee will be working independently, performing dilution and mixture studies which will aid in the eventual interpretation of complex PCR typing results.

a. using either practice or competency test Chelex extracts, prepare a dilution series of DNA (100, 10, 5, 2, 1, 0.1 and 0.01 ng) in the final amplification volume for each of the PCR systems used in casework and amplify; evaluate results by product gel

b. pick two practice or competency test samples which have different DNA types and prepare mixtures of the samples (20:1, 10:1, 5:1, 1:1, 1:5, 1:10, and 1:20); amplify and type in each of the PCR systems used in casework.

Prepare a short experiment summary outlining the results and the interpretation of the results; review with the supervisor.

PCR data interpretation exercise:

The supervisor will provide the trainee with a series of data tables representing the range of results that are seen in PCR DNA typing cases. The trainee will evaluate the data tables and write Forensic Biology reports reporting the data and their interpretation of it. This will then be reviewed with the supervisor r and the interpretations discussed and corrected if necessary.

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Supplemental Training

Analysts who have completed their initial round of proficiency testing will be introduced to new procedures as they are ammended to the DNA protocol. The three-phase method (trainee observes the analytical procedure, trainee demonstrates the analytical procedure, and independent practice) is used for supplemental DNA training.

In this case, practice samples may be processed at the same time as other samples. Once the analysts are comfortable with the new extraction procedure, they will type competency test samples. At least two samples must be successfully typed for each new procedure before the analyst can use the procedure in casework.

4. Seminars and Lectures

Seminars and lectures offered at the OCME, at local universities, the Department of Health, and by corporations on selected topics will be announced to staff members.

5. Scientific Literature

All scientific staff are required to read the appropriate scientific literature related to the forensic aspects of the analytical work performed in the department.

The supervisory staff will provide copies of articles deemed to enhance the scientific theoretical background necessary for the understanding of current testing procedures or for current research being conducted in the department.

6. Professional Meetings

Each staff scientist is permitted to attend one scientific conference per year, depending on the approval of the Chief Medical Examiner and Mayor's Office. Because of budgetary constraints that exist, reimbursement of expenses cannot be guaranteed.

The annual national conference of forensic scientists (AAFS) and the regional association of forensic scientists (NEAFS) are recommended to scientific staff.

Other scientific meetings of interest to the department, i.e., American Society of Human Genetics Meetings, Gene Probe Conference, AAAS conference, Int. Assn. Forensic Scientists, NY Acad. Sci., FEBS and etc., are acceptable substitutions for the forensic conferences.

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J. Method Validation Records

Methods used in the departmental laboratories must be validated using accepted procedures -- according to TWGDAM Guidelines -- that demonstrate that the methods are capable of providing reliable results using specimens commonly received for analysis. Procedures used will be approved for use, if appropriate, by any New York State regulating bodies that have proper jurisdiction.

The specific validation protocols for each laboratory procedure must be written and rigorously followed (see J.1 below). Before validation on any procedures are begun, the senior scientific staff and validation staff members will specify the appropriate validation details and the specific steps which will be completed before the procedure can be adopted for routine casework. The approach will become a permanent, written record to be retained with the validation experimental results.

The analytical test results and the validation protocols used for each test must be available and will be kept in a file and/or log book. For data maintained in staff notebooks, the file or log books referred to above will reference the appropriate pages in the research notebooks or will contain photocopies of these notebooks.

1. Validation Procedures

a. Existing Procedures

For purposes of categorizing which validation procedures to use, existing procedures are classified as follows:

(1). Those which exist and have been published in peer review journals but have not yet been validated for forensic testing.
(2). Those which are not published and for which no validation records are known.
(3). Those which have been published and the validation studies have also been published.

For those procedures in categories J.1.a.1 and J.1.a.2, validation for forensic investigations must be performed. The testing to be performed will be carried out according to validation testing procedures as discussed above. Once the validation work has been completed and all records are available, the work will be incorporated as an analytical procedure and will also be submitted for publication in a peer review journal, if applicable.

The procedures in category J.1.a.3. do not require extensive validation. However, limited validation, including proficiency testing, will be conducted to insure that the test procedure behaves as published.

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b. New Procedures

New procedures are those which have been developed as a result of a research project in the Department of Forensic Biology and appear to have potential as analytical tests that might be used in routine testing.

All new procedures must go through an extensive validation process which must include:

(1). Staff review of process including appropriate experiments
(2). Testing on all appropriate sample types
(3). Examination of environmental and aging effects
(4). Variability in results due to experimental protocol drift
(5). Proficiency testing
(6). Collaborative testing
(7). Publish in peer review journal, if applicable

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K. Quality Assurance and Audit Records

Records documenting that the program is implemented and maintained are kept as a normal course of business. The Director or another QA committee member is responsible for maintaining these records. The departmental director coordinates the departmental quality assurance program.

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L. Equipment

1. Inventory

An inventory of all equipment is maintained in the department. The inventory includes a list of essential equipment and includes the following (if available or known):

a. manufacturer
b. model
c. serial number
d. agency inventory number (if applicable)
e. purchase date (if available)

2. Operations Manuals

All equipment operations manuals are kept as a part of a centralized operations manual.

3. Calibration/Maintenance Procedures

Procedures for the calibration and maintenance are part of the QC manual.

4. Calibration/Maintenance Logs

Calibration and Maintenance logs are a part of the usage log.

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M. Safety

1. Manuals

The departmental safety manual is a compendium of manuals maintained at the OCME.

a. Chemical Spill and Clean-up

This manual details the OCME guidelines and regulations specifically related to chemical spills and notification procedures.

b. Blood Borne Pathogen Standard

This manual provides the regulations regarding blood borne pathogens standard, 29 CFR 1910.1030.

c. NYC Department of Health Infection Control Manual

This manual has been prepared to provide DOH employees with the information required to protect their own safety and their patients. It provides specific precautionary techniques and guidelines in order to reduce injury and disease.

d. OCME Hazard Communication Plan

This manual is to ensure that OCME is in compliance with the OSHA Hazard Communication Standard (HCS) 29 CFR 1910.1200 and delineates responsibilities regarding chemical hazards.

e. OCME Hazard Contingency Plan

This plan applies to all unplanned releases of hazardous waste or hazardous waste constituents at the OCME. Its purpose is to minimize hazards to human health or the environment from an unplanned or sudden release of hazardous waste or its constituents.

f. Chemical Hygiene Plan

The chemical hygiene plan delineates responsibilities, procedures and guidelines regarding the handling of chemicals at the OCME.

g. NYFD Regulations on Chemical Storage

This manual delineates the fire department's regulations for the storage and use of chemicals, acids and gases in college, university, hospital, research and commercial laboratories.

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h. OCME Radiation Safety Manual

This manual delineates the responsibility, procedures and training required when handling radioactive substances.

I. Working With Chemicals

This manual provides information for employees on how to use the NYS Right to Know Law.

2. Right to Know Training

The OCME has a Right to Know training program which is provided annually. Each OCME employee is required to attend. Each employee is required to take a written test after each training session.

3. Radiation Safety Training

The Forensic Biology department provides an annual training seminar which is mandatory for those using radio labeled materials.

4. Material Safety Data Sheets (MSDS)

MSDS sheets are kept in a separate file for all reagents and chemicals used in the departmental laboratories. The OCME is also required to have a copy of the most current MSDS sheets for those materials used in the OCME building. The sheets are updated as required, and they are readily available in the laboratory.

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N. Historical or Archival Records

Records for all laboratory operations are maintained with the case file under the laboratory case number (FBXX-), where XX refers to the year. For years prior to 1990 the records are maintained under a different nomenclature system.

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O. Quality Audit

The Department is audited annually by an independent evaluator who is not responsible for any official function of the Department. Audit reports are sent by the evaluator to the Department Director for evaluation by the QA Committee.

1. Guidelines

The quality audit is a primary tool used to evaluate, confirm or verify activities related to laboratory quality. Its purpose is to assess compliance with the operational requirements of the quality system. Periodic audits, coupled with day-to-day review of scientific reports, provide an effective means for ensuring that quality control activities are being implemented and that each forensic examiner performs in a manner consistent with the quality system.

Quality audits will be scheduled and announced in advance by the Director. A checklist will be used to ensure complete coverage of the important aspects of the audit and will include inspection of the following areas:

a. Staff's awareness of its quality manuals
b. Analytical procedure selection, control, and validation.
c. Control of reagents and standards.
d. Equipment calibration and maintenance records.
e. Adequacy of case reports and notes and their disposition.
f. Evidence handling procedures.
g. Proficiency testing and interlaboratory comparison studies.
h. Personnel training records.
I. Handling of deficiencies and remedial action.
j. Laboratory orderliness and health and safety measures.

Audit results will be sent to the departmental Director who will reply, in writing, by addressing the auditor's comments. The reply will discuss corrective action taken or reasons why corrective action will not be taken.

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P. Non-Conformity and Corrective Actions

Problems or difficulties can arise in all phases of laboratory operations, which must be dealt with appropriately. Listing each potential problem is impractical. Instead, this topic is considered in general terms.

General laboratory problems can be divided into major categories which reflect the laboratory's operations. These include: a. operations which reflect the laboratory's mission, b. external influences which reflect the laboratory's proper functioning, and c. those of a specialized nature.

Problems that directly affect the laboratory's mission are usually technical problems. These may include, among others, a method that has ceased to work properly or a laboratory error that has been discovered. These internal problems are solved using a decision tree that mimics the laboratory's supervisory hierarchy.

Some problems, i.e., the building's heating, cooling, lighting, etc., are operational problems which are solved using the OCME's support staff. In these instances problems can be directed to the OCME support staff either by the first level supervisory personnel or directly by the person who discovers the problem.

Certain laboratory functions require specialized support. In these instances, i.e., health and radiation safety, there are appropriate personnel designated in the laboratory and at the OCME who are responsible for these functions. For example, there is a laboratory representative on the health and safety committee whom is consulted in these instances. Similarly, there is a resident RSO (Radiation Safety Officer) who is consulted in problems related to radiation.

1. Corrective Action

This section prescribes what actions must be taken when non-conformity exists or is suspected as a result of analytical errors, proficiency errors, internal or external audits, user agency complaints, or equipment malfunction.

When a non-conformity is discovered or suspected, the occurrence must be reported immediately to an appropriate supervisor, i.e., if the non-conformity occurs at the Chelex rotation, the Forensic Scientist supervisor in that rotation must be informed. In all instances, that supervisor must notify the Forensic Scientist who is supervising the QC rotation. The QC supervising Forensic Scientist will determine the seriousness of the non-conformity according to the following:

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Class I Non-conformity

Definition: The nature of the non-conformity raises concern about the quality of the work product.

For Class I problems, the following procedures must be followed:

a. The non-conformity will be brought to the attention of the Quality Control Supervising Forensic Scientist immediately. The Forensic Scientist will notify the Director of the laboratory or the Assistant Director in the Director's absence.

b. If necessary, laboratory activities pertaining to that non-conformity will be stopped until the investigation is completed.

c. The following investigation will be taken and documented on the appropriate QA/QC Non-conformity Form:

(1). Identify the problem source.
(2). Formulate a solution.
(3). Test the solution to see if it is appropriate.
(4). Identify cases that may be affected.
(5). Re-work affected cases, if necessary.
(6). Re-train analysts, if necessary.
(7). Inform affected customers.
(8). Document the non-conformity and corrective actions in the QC section of the laboratory.

Class II Non-conformity

Definition: A problem exists which may affect the quality of the work, but is not persistent or serious enough to cause immediate concern for the overall quality of the laboratory's work product.

For Class II problems, the following procedures must be followed:

a. The analyst will notify the Forensic Scientist supervisor that the problem exists.

b. The Forensic Scientist supervisor must notify the Forensic Scientist supervisor of QC and either the Assistant Director or Director that the problem exists.

c. The Forensic Scientist supervisor in QC must insure that steps (1) - (8) above are done.

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Class III Non-conformity

Definition: The problem is unlikely to recur and is not likely to significantly affect the reliability of the laboratory's work. These problems are readily corrected.

For Class III problems, the following procedures must be followed:

a. The analyst must notify the Forensic Scientist supervisor that the problem exists.
b. The Forensic Scientist supervisor must verify that the problem exists.
c. The Forensic Scientist supervisor must review affected cases, if any, and have the work re-done.
d. The Forensic Scientist supervisor must document the corrective action taken and inform the Forensic Scientist supervisor of the QC rotation of what has happened and what has been done.

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V. Management Information System (MIS)

A. OCME

The OCME's headquarters and satellite autopsy suites (The Bronx, Brooklyn, Queens and Manhattan) are linked by a computer network. The components of the system include:

1. **Software programs for productivity**

   a. WordPerfect and WordPerfect Office
   b. Quattro Pro
   c. DataEase

2. **Medical Examiner casework database is defined in DataEase**

3. **Procurement database/ordering system is defined in DataEase.**

4. **E-Mail**

5. **Departmental and individual accounts**

B. Departmental

The Forensic Biology Laboratory is located on the OCME network under g:\users\fbiology. Individuals have access to their own private directory under: g:\users\fbiology\NAME*.*.

Departmental functions are maintained on the network and these include.

1. **Reports (defined in WordPerfect).**

2. **Productivity statistics (defined in Paradox).**

3. **Current updates of Departmental manuals and forms are defined in WordPerfect.**

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VI. References

1. Guidelines for a Quality Assurance Program for DNA Restriction Fragment Length Polymorphism Analysis. Crime Laboratory Digest Vol 16(2): 40-59 (1989).

2. Guidelines for a Quality Assurance Program for DNA Analysis. Crime Laboratory Digest Vol 18(2): 44-75 (1991).

3. A guide for Conducting a DNA Quality Assurance Audit. Crime Laboratory Digest Vol 20(1): 8-18 (1993).

4. Guidelines for a Quality Assurance Program for DNA Analysis. Crime Laboratory Digest Vol 22(2),21-43 (1995)