

Initials: *PCJ* Date: *6/5/95*

Department of Forensic Biology

Administrative and Quality Assurance Manual

Version 2.2

June 5, 1995

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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.	<i>Robert C. Shaler</i>
Co-Chairman: Howard Baum, Ph.D.	<i>Howard J. Baum</i>
QA Coordinator: Larry Quarino	<i>Larry Quarino</i>
Committee Members: Marie Samples	<i>Marie Samples</i>
Dora Wolosin	<i>Dora Wolosin</i>
Jocelyn Ferrara	<i>Jocelyn Ferrara</i>
Helen R. Rafaniello	<i>Helen R. Rafaniello</i>
Date: <i>6/5/85</i>	

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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, and other agencies within or serving New York City, criminal justice system; access to scientific analyses that compare biological evidentiary specimens with known exemplar biological specimens and to insure the quality, integrity, and accuracy of the department's analyses through the implementation of 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 analysis
4. Report Preparation
5. Testimony to results
6. Crime scene investigation

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 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

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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 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 (Figure 1, see Appendix A.) defines the relationships in the Department of Forensic Biology between individuals and the operational units of the department.

Within the department, a QA/QC committee sets QA/QC policy and is responsible for production and revisions of the QA Manual. A QA Coordinator is appointed by the Department director. The QA committee 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 Scientist(s) assigned to both the Forensic Biochemistry and Hematology (FBH) and Forensic Molecular Biology (FMB) laboratory

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subunits, the QA coordinator, and analysts responsible for the preparation of critical reagents are also members of the committee. Each Forensic Analyst is responsible to ensure that the QA/QC program guidelines, as they relate to their work and responsibilities, are adhered to.

D. OCMF and Department of Forensic Biology Organizational Structure

The OCMF is organized (Figure 2., see Appendix A) such that the director of the Department of Forensic Biology reports directly to the head of the agency, the Chief Medical Examiner.

The organization of the Department of Forensic Biology is organized into two operational units, the Forensic Biochemistry and Hematology Laboratory (FBH) and the Forensic Molecular Biology Laboratory (FMB) (Figure 1., see Appendix A). One Assistant Director reports directly to the departmental Director.

The Department has clerical staff assigned.

The scientific staff in the both laboratories includes Forensic Scientists and Forensic Analysts, the latter reporting to the former.

One laboratory associate (part-time) is assigned to the department. Each operational unit is allocated one clerical person. The organizational chart of the department defines, generally, the responsibility hierarchy in absences.

1. The Director is responsible for the overall scientific, quality assurance, and administrative operation of the Department.
2. The department's Assistant Director is responsible for the scientific operation of the FMB laboratory, procurement for the Department and, in the absence of the Director, assumes the responsibility for administering the department.
3. In absence of the Assistant Director and the Director, one (or more) Forensic Scientist(s) will be assigned responsibility for administering the department and its quality operations.

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4. Under no circumstances will the Director, the Assistant Director and all FBH and FMB Forensic Scientists be absent from the laboratory.

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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's initials and dates the manuals
signifying its official use in the laboratory.
- d. Archives of methods

B. Quality Control/Critical Reagent Documents

The QC documents in the departmental laboratories document 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 the procedure to be used in the preparation of solutions used in routine testing in the departmental laboratories.

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

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C. Case Files/Case Notes

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

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 and etc.
4. Chain-of-custody documentation.
5. Case contact sheets documenting conversations with detectives, attorneys and 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 by the Forensic Analyst assigned to the case and another laboratory staff scientist. Each independently observed result is dated and initiated. Discrepancies may be resolved by reanalysis, discussion with either the Forensic Scientist, Director or Assistant Director or 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 FBH Methods Manual version 2.0.

The format of the report 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).

3. Case Review

The case review process for laboratory reports takes place in distinct phases and is done for all cases in which 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.

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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 in either the Forensic Biochemistry and Hematology or Forensic Molecular Biology Laboratories.
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.
3	The original of the report 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

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will be discussed. The particular 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.

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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 if providing testimony is given. The Director and Assistant Director monitor each other. The Forensic Analysts are monitored by the Department al 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 will be the method used by the Department.

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 electronically 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., 89, 90, etc, and 0000 identifies a sequential number assigned to one specific investigation. There is one FB number per investigation, which can include multiple victims.

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

Homicides, unidentified bodies, 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, forensic paternities, and cases from other jurisdictions.

b. item numbers

Each item is assigned a number, usually corresponding to a police voucher number. Items taken at autopsy are assigned a sequential PM (post-mortem) number.

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. Generally, the following items are not accepted:

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- (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 signed in, discuss it with a Forensic Scientist.

At the time the evidence is received, the top part of the chain-of-custody form is filled out, listing name, ME number, police precinct, complaint 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. Once 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.

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	1/2/95
F123456	1-6	P. Ryan	----	shelf B	1/2/95

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	1/2/95
F123456	1-6	A. Anzalone	----	P. Ryan	1/2/95
F123456	1-6	P. Ryan	----	shelf B	1/2/95

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For post-mortem evidence:

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

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 a locked refrigerator 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. 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 begins the examination of the evidence, the chain of custody will be filled out to reflect that.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	1/2/95
F123456	1-6	P. Ryan	----	shelf B	1/2/95
F123456	1-6	shelf B	----	F. Baldi	1/4/95

Throughout the scientific analysis, the Forensic Analyst documents the evidence according to procedures delineated in the FBH Procedures Manual (Notetaking).

Each analyst is assigned a drawer in the cold room which is used to store evidence in progress.

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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	1/2/95
F123456	1-6	P. Ryan	----	shelf B	1/2/95
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, stored in the cold room for approximately 2 years, then stored at room temperature. Eventually, they are vouchered for entry into the NYPD evidence control system and transferred to the Evidence Unit. If a sample is consumed during DNA testing, its DNA extract is retained.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	1/2/95
F123456	1-6	P. Ryan	----	shelf B	1/2/95
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
DNA	extracts	F. Baldi	----	DNA storage	4/2/95

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i. disposition - non NYPD cases

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

2. Specific guidelines for different evidence types

a. post-mortem evidence, FB cases

(1). blood

A stain is prepared on clean cotton cloth or paper. The stain is retained frozen in the laboratory for approximately a year, stored in the cold room for approximately two years.

Cells and serum are separated from an aliquot of the original sample, retained frozen for two years, then discarded. The remainder of the original sample is discarded after two months.

Eventually, the dried stains are 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 processing. Following the guidelines in the FBH methods manual, items are retained or discarded. This will be reflected in the chain-of-custody.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
-----	PM 1-3	autopsy	----	P. Ryan	1/2/95
-----	PM 1-3	P. Ryan	----	PM cold storage	1/2/95
-----	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	----	discarded	1/6/95

(3). other PM items

Hairs, fingerprints, 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

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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	1/2/95
-----	PM 1-2	P. Ryan	----	PM cold storage	1/2/95
-----	PM 3	P. Ryan	----	PM freezer	1/2/95
-----	PM 3	P. Ryan	----	discarded	2/3/96

b. post-mortem items, non-FB cases

(1) . blood

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.

While these cases do not receive FB case numbers, the specimens and associated autopsy worksheets are transferred to the Forensic Molecular Biology (DNA) Laboratory and are tracked using a log book. Those which are appropriate for database samples receive an MB number. The DNA is isolated from these latter samples and a dried stain is also prepared if there is sufficient sample. All bloods, whether or not an MB number is assigned, 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:

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VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	1/2/95
F123456	1-6	P. Ryan	----	shelf B	1/2/95
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	----	D. Wolosin	3/4/95
retained	items	D. Wolosin	----	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 time-frame). In unusual instances, and if freshly preserved specimens are not available, formalin fixed specimens may be obtained from the Histology laboratory. The chain-of-custody will reflect this:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
toxicol.	blood	B. Marker	----	M. Samples	1/2/95

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	1/2/95
F123456	1-6	P. Ryan	----	shelf B	1/2/95
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

Initials: *RCJ* Date: *6/5/95*

e. unlabelled 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 which 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	1/2/95

When the evidence is returned to the Forensic Biology Department through mail services, the chain-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	1/2/95
retained	items	FBI via reg mail	----	M. Samples	4/4/95
extracts	items	FBI via reg mail	----	M. Samples	4/4/95
extracts	items	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

Initials: RC Date: 6/6/87

and the 30th Street entrance, the morgue entrance, is guarded.

b. Laboratory Security

The Department has laboratories on two floors: The Forensic Biochemistry and Hematology Laboratory (FBH) is located on the fifth. The Forensic Molecular Biology Laboratory (FMB) is located on the sixth floor. Both laboratories have minimum access by authorized personnel: departmental staff, visiting staff, students, and OCM employees with either floor or building master keys (students and visiting staff do not have keys and do not have access to the departmental laboratories except during 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; the combination is changed monthly and is used to gain entrance. At night, another lock system, a master key system, is used and the key pad is not usable.

(1). FBH Laboratory

The Forensic Biochemistry and Hematology Laboratory has a main entrance, room 530, where evidence is routinely analyzed. This room is off limits to all but authorized personnel and access is limited to those who have the combination to the key pad. At night, the laboratory is locked.

Physical evidence being analyzed is 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 and other exemplars are stored in the cold room in Room 530, which is locked at all times. Only departmental staff have access at other than normal working hours.

(2). FMB Laboratory

Received evidence is kept in the locked Forensic Molecular Biology Laboratory walk-in, cold room on the sixth floor. Analysts are assigned an evidence storage area within the cold room for storage of work in progress.

The Forensic Molecular Biology Laboratory on the sixth floor is locked at night. During normal working hours, the laboratory's only entrance is for authorized personnel, defined above.

Evidence is received in the Departmental clerical office section devoted to that purpose. Once evidence is signed in, an analyst puts it into the Forensic Molecular Biology Laboratory sixth floor

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Initials: JCS Date: 6/5/95

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Initials: RCS Date: 6/15/95

Medical Examiner Rotation Training Outline

Medical Examiner Rotation

The resident rotation in Forensic Biology is a program of a combination of discussions, laboratory observations and laboratory exercises. The program is designed to acquaint the resident with the practice of forensic biology as it relates to the mission of the Office of the Chief Medical Examiner and the Criminal Justice System of New York City.

The resident will become familiar with departmental policies relating to evidence handling and control, scientific testing procedures, quality assurance and control, and reporting procedures. Throughout the program, additional discussions will focus on the philosophy of forensic science and its relation to physical evidence collection, recognition and examination in the forensic biology laboratory.

The resident will have the opportunity to observe casework processing and to discuss with forensic analysts and scientists the rational for taking specific approaches in particular cases.

Initials: *AS* Date: *6/5/95*

cold room, which is locked at all times.

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 from 1989 to 1994 are kept in room 311, which is locked at all times with the building's master key lock system. Older case files are kept in Room 8, in the cellar, which is locked at all times.

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

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Initials: *RG* Date: *6/5/92*

G. Equipment Calibration and Maintenance Logs

Each piece of essential scientific apparatus has a log usage book and requires QC monitoring. Critical 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.

While equipment common to both the FBH and FMB laboratories is used, each laboratory may designate specific equipment critical or not. For example, the FMB laboratory considers micropipettes critical pieces of equipment which must be rigorously calibrated while the FBH laboratory, with the exception of ELISA micropipettes, does not.

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 be chiseled 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 QA Coordinator 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 QA Coordinator 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. 3.0, if necessary.

Initials: RCJ Date: 6/5/91

After appropriate repair or recalibration, the QA coordinator or QA Committee member may re-certify that the equipment may be used for case work. Recertification requires that the QA Coordinator 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 baths, ovens, and etc).

Temperatures are recorded daily on a temperature log specified for each piece of equipment. This is done by the technician responsible for the preparation of reagents or as assigned by the QA Coordinator or Laboratory Forensic Scientists. The log is dated and initiated 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 temperature log for that freezer/refrigerator.

2. pH meters

These are calibrated as they are used 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.

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Initials: RCJ Date: 6/5/81

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.

Thermocyclers are checked weekly by a technician or analyst assigned to perform the calibration. The record of the calibration is recorded in the usage log. If the calibration is not performed, this is noted in the thermocycler log. Individual wells of a thermocycler may be taken out of service if they fail to pass QC.

6. Microtiter Plate Readers

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

Instrument and assay performance is evaluated by examining the controls run in each assay. If the controls are outside the range of accepted limits, the effects on casework is evaluated.

7. Micropipettes

Micropipettes will be checked using either standard calibration kits or gravimetrically. Each pipet will be assigned a control number and the date of calibration and the initials 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 three times annually.

Micropipettes are not considered a critical piece of equipment in the FBH laboratory. Therefore, with the exception of ELISA procedures, these are not calibrated.

8. Centrifuges

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

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9. Hoods

Biological hazard and chemical fume hoods are to be inspected and certified annually by an outside contractor.

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.

Initials: *gcy* Date: 6/5/95

H. Proficiency Testing

Proficiency testing is used to demonstrate the quality performance of the scientific service offered by the laboratory and 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 and interpreted according to the analytical protocols being used at the time the proficiency test is taken. All samples of "blind" evidence analyzed will be treated as normal casework. The scientific staff will be proficiency tested according to guidelines established by regulating and/or accreditation agencies or bodies, if available or required.

If not regulated, legislated, or compelled by certification/accreditation requirements, proficiency tests will be administered twice annually to each scientist; both proficiency tests will be open tests. Acceptable commercially available proficiency tests are available from the Collaborative Testing Service (CTS) and the Serological Research Institute (SRI) for the FBI Laboratory and Cellmark Diagnostics (IQAS), College of American Pathologists (CAP), and SRI for the FBI Laboratory. Unless provided by regulation, legislation or certification/accreditation requirements, the Forensic Biochemistry and Hematology Laboratory may use internally prepared proficiency samples or those obtained from an outside, public or private laboratory.

The Forensic Molecular Biology Laboratory must use commercially available testing services.

One blind test will be administered to the laboratory once annually, if available.

Each proficiency test is treated as a case and a case-like file folder is maintained, with all its appropriate reviews, just as any case submitted to the laboratory. With each proficiency test, a Proficiency Review sheet will be filled out and kept with the file. This review sheet is a check-list which enables the supervisory scientists to evaluate the performance of the analyst/scientist being tested. The review sheet is also a tool by which the departmental Director can evaluate the supervisory performances of the departmental supervisory scientists.

Initials: *AS* Date: 6/5/91

1. Types of Proficiency Testing

a. 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. This is the primary means by which the quality performance of the laboratory is judged and is an essential requirement prior to being assigned to perform casework.

(1) . Personnel

Each member of the scientific staff performing routine analyses on casework are required to take proficiency tests.

(2) . 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.

(3) . Sample Preparation and Storage

All specimens and proficiency tests should be uniformly prepared using materials and methods that ensure their integrity and identity.

All test specimens will be prepared on washed cotton cloth, swabs, or other suitable material.

Each specimen must be labeled with a unique identifier that should 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, as assigned by the assistant director or departmental director, should acknowledge receipt of each proficiency test and assign it to the laboratory staff.

b. Case Retesting

Reanalysis of case work permits an estimate to be made regarding

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the laboratory error rate. Reanalyses will be performed on those casework samples time where there is sufficient sample. Each reanalysis will be conducted by a different analyst, i.e., no analyst will analyze the same sample twice.

The results of the reanalyses will be compared with the results of the original analysis. If the results do not correlate, in other words, the results do not agree, a third analysis of the sample might be performed if the reason for the disagreement cannot be determined.

c. 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.

Specimens will be of the type commonly encountered in routine casework.

2. Deficiency and Corrective Action

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

a. 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.

The scientist's supervisor monitors the performance of the specific test until 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.

b. Class II or Systematic Errors

The discrepancy is due to a problem which may affect the quality of

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Initials: *RV* Date: *6/5/67*

the work, but is not persistent or serious enough to cause immediate concern for the over-all quality of the individual's work product and requires re-training.

A class II error may be the result of equipment, materials, environment, etc., 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.

c. Class III or Administrative Error

The 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 the individual's work product.

Class II 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.

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Initials: *LCJ* Date: *6/5/87*

3. Documentation of Open Proficiency Testing Results
Each proficiency test will be documented as follows:

- a. Proficiency Testing Identification Number
 - b. Name of analyst
 - c. Dates:
receipt by analyst
completion date (report date)
 - d. Copies of all data sheets, notes, photographs and reports
 - e. All data will conform to casework standards and include lot numbers, QC numbers, and etc.
 - f. The Proficiency Evaluation sheet will be filled out by the supervising scientist.
- The results of all proficiency tests will be maintained by the Department.

4. 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.

Errors can 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.

a. Determination Error Rates

- (1). Measuring the frequency that individual results on external open and/or blind proficiency testing are incorrect.
- (2). Measuring the frequency that sample duplication testing shows discordant results.
- (3). Measuring the frequency that sample re-testing analysis shows discordant results.

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Initials: *ad* Date: *6/5/87*

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.

Records of the training of each member of the scientific staff is a part of the personnel and/or proficiency file maintained for each member of the scientific staff.

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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Initials: *RG* Date: 6/5/85

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

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

Each analyst will be trained to perform the tests conducted in the departmental laboratories. This begins with a demonstration which is followed by supervised independent work by the supervisor and concludes with the trainee working alone on prepared specimens.

c. Testing Ability

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

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Initials: *RL* Date: 6/5/95

d. Training Outline

- (1). Laboratory Staff, see Appendix B
- (2). Medical Residents, see Appendix B

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.

Initials: *RS* Date: 6/5/95

J. Method Validation Records

Methods used in the departmental laboratories must be validated using accepted procedures which 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 regulating bodies in New York State.

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.

Initials: *PCS* Date: *6/5/95*

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.

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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Initials: *ECJ* Date: *6/7/95*

K. Quality Assurance and Audit Records

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

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Initials: *KCJ* Date: 6/5/97

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.

Initials: *74* Date: *6/5/87*

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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Initials: *JS* Date: *6/7/95*

h. OCEM 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 OCEM has a Right to Know training program which is provided annually. Each OCEM 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 radiolabeled 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 OCEM is also required to have a copy of the most current MSDS sheets for those materials used in the OCEM building. The sheets are updated as required.

These are readily available from the departmental safety committee representative.

June 5, 1995

Initials: *ECJ* Date: *6/5/85*

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.

June 5, 1995

Initials: *PS* Date: *7-7/95*

0. Quality Audit

The Department is audited annually by an independent evaluator who is not responsible for any official function of the Department. Sheets for audits are filled out by the evaluator and submitted to the Department Director for evaluation by the QA Committee.

1. Guidelines

The quality audit is one of the primary tools used to evaluate, confirm or verify activities related to 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 well 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.

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

July 7, 1995

Initials: *gdy* Date: *6/5/95*

0. Quality Audit

The Department is audited annually by an independent evaluator who is not responsible for any official function of the Department. Sheets for audits are filled out by the evaluator and submitted to the Department Director for evaluation by the QA Committee.

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- 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.

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

June 5, 1995

Initials: / Date: 6/5/97

P. Problem Solving

Problems or difficulties can arise in all phases of laboratory operations and these must be dealt with appropriately. Listing each potential problem would be impracticable and would possibly miss some areas which should be considered. Instead, the topic is being considered in general terms. Nevertheless, the topic of how problems are solved must be addressed so that the laboratory has a mechanism with which to formally address the issues that may arise. General laboratory problems can be divided into large categories which reflect the laboratory's operations. These include: influences which reflect the laboratory's mission, external influences which reflect the laboratory's proper functioning and those of a specialized nature.

1. Problems which affect the laboratory's Mission

These are problems which directly affect the laboratory's mission and will usually be technical in nature. For example, these may include, among others, a method that has stopped working properly or an error has happened in the testing. These internal laboratory problems are solved using a decision tree which mimics the laboratory's supervisory hierarchy. In such a tree the schematic follows that shown in figure 1. and can be used either top-down or bottom-up.

In the top-down approach toward using the tree, the top management or director of the laboratory makes all decisions without consulting other laboratory supervisory staff. In this method, problem solving becomes unidimensional and most impractical because the director may be absent or for other reasons. The Department of Forensic Biology does not use a top-down mechanism for problem solving.

In the bottom-up approach, problems are solved from the bottom of the hierarchical management scheme toward the top. That is, each layer of supervision becomes the next layer to where problems are brought. Thus in the Forensic Biology Laboratory, the Forensic Scientist is the first supervisory layer and the appropriate persons who are first confronted with the problem.

If the problem cannot be solved at this level it moves up the decision tree to the Assistant Director and finally to the Director.

June 5, 1995

Initials: *24* Date: *6/5/95*

2. External Problems Which Affect Laboratory Operations

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 confronted by the problem.

3. Problems Which Require Specialized Personnel

There are certain functions within the laboratory that require specialized support. In these instances, i.e., health and radiation safety, there are appropriate personnel designated in the laboratory 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.

Initials: *PC* Date: *6/5/95*

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. Database

2. Medical Examiner casework database defined in Database

3. Procurement database/ordering system defined in Database.

4. E-Mail

5. Departmental and individual accounts

B. Departmental

The Forensic Biology Laboratory is located on the OCME network under H:\users\fbiology*.*. Individuals have access to their own private directory under: H:\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 (defined in Wordperfect).

June 5, 1995

Initials: *ACJ* Date: *6/5/91*

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).

June 5, 1995

June 5, 1995

Organizational Structure

Appendix A

Initials: *PS* Date: 6/5/95

5/23/2020

Figure #1A: For. Biochem. & Hematology

Director
(Shaler)

Assistant Director
(Baum)

Forensic Scientists

(Ristenbatt) (Quarino)
Forensic Analysts

(Gelber Baldi) (Shenouda)

5/23/86 RCU

Figure #1B: Forensic Molecular Biology

Director
(Shaler)

Assistant Director
(Baum)

Forensic Scientists
(SanPietro) (Prinz) (Wolosin) (Samples)

Forensic Analysts
(Galindo) (Boll) (Rafaniello)(Buffolino Basilious)

5/23/88 RCY

Figure # 1C: Quality Control

Director
(Shaler)

Assistant Director
(Baum)

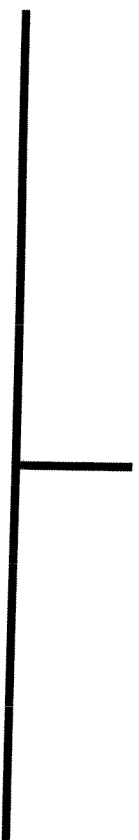
For. Scientist
(Quarino)

For. Analyst (Chernjawski)	Lab Associate (Shapiro Abraham)
-------------------------------	------------------------------------

5/23/96 ECJ

Figure # 1D: Crime Scene Investigation

Director
(Shaler)



Forensic Scientists
(Ristenbatt SanPietro)

Forensic Analysts
(Buffolino Boll)

Figure #1A: For. Biochem. & Hematology

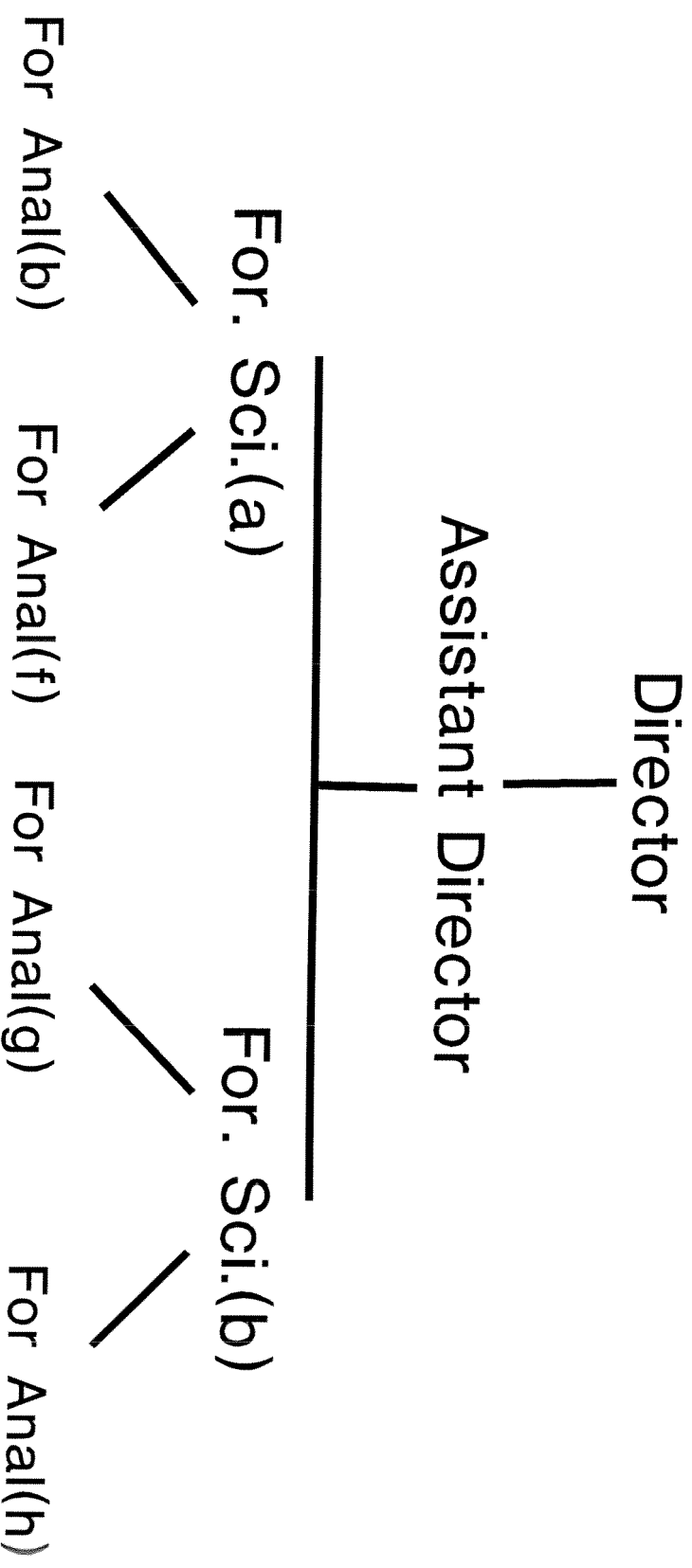


Figure #1B: Forensic Molecular Biology

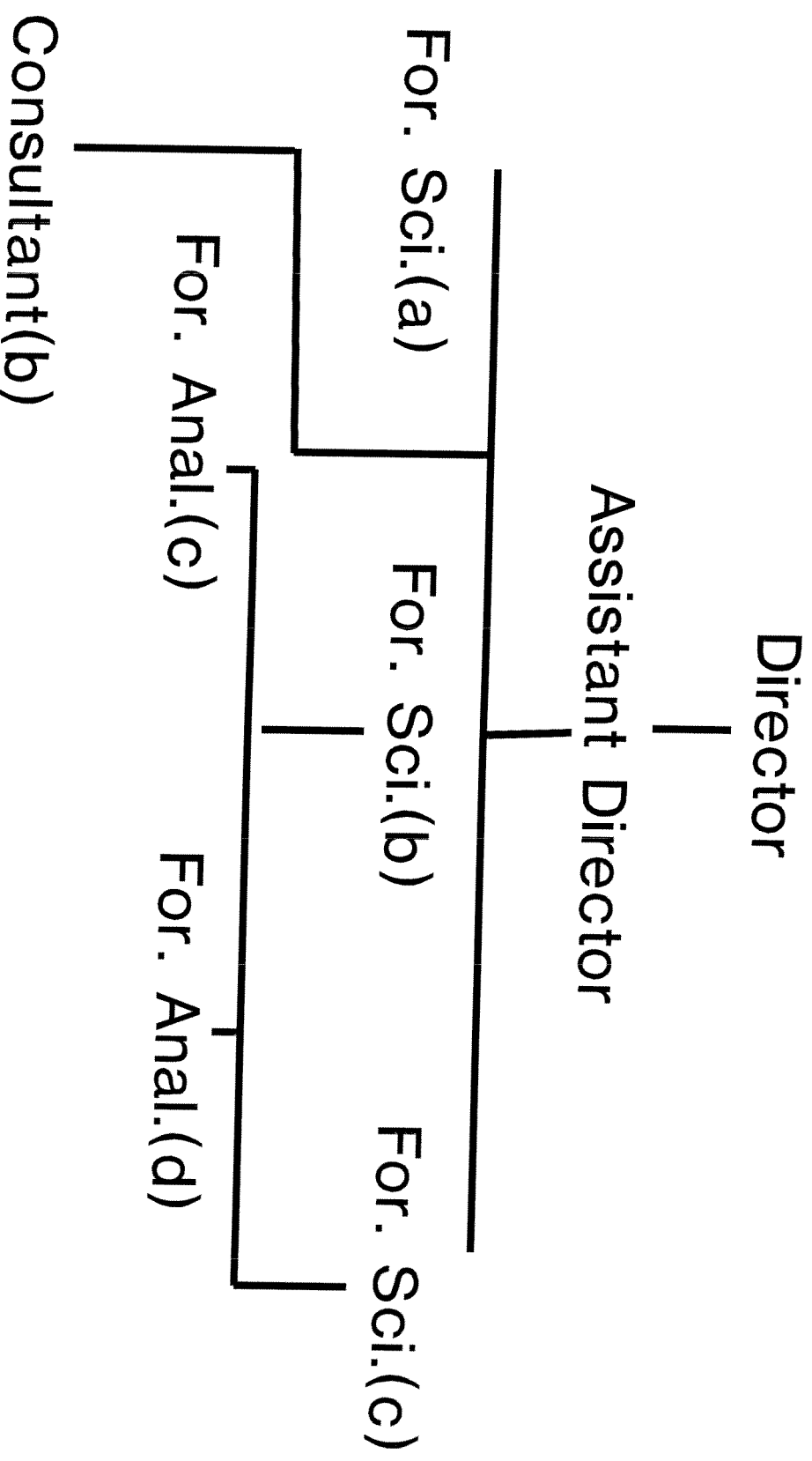


Figure # 1C: Quality Control

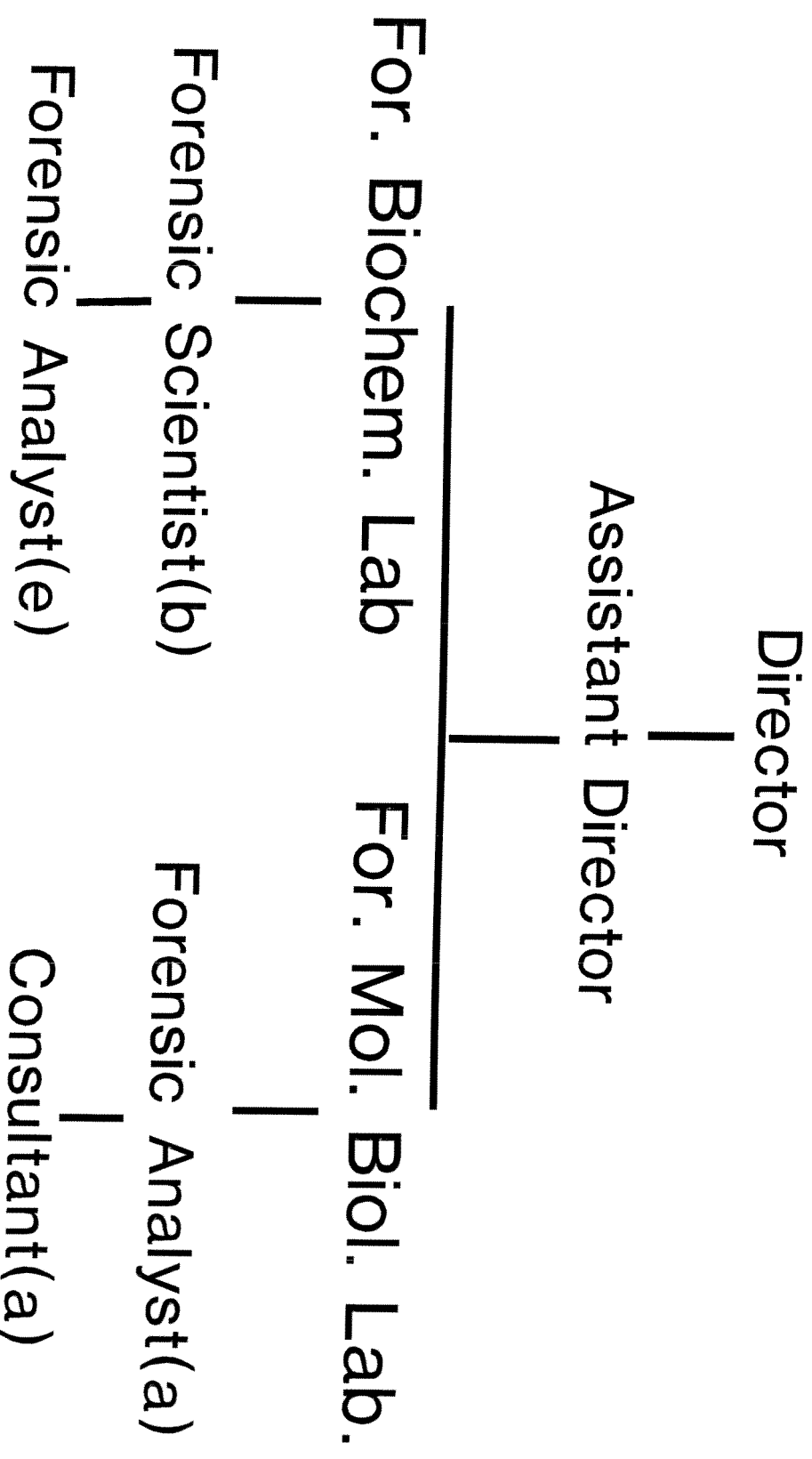
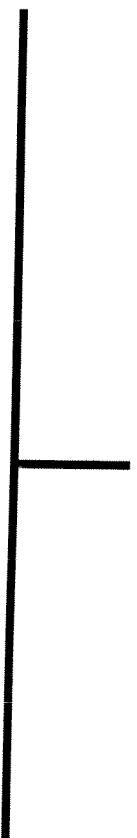


Figure # 1D: Crime Scene Investigation

Director



Forensic Analyst(b) Forensic Analyst(c)

Appendix B
Training

Initials: *RCJ* Date: *6/5/11*

FORENSIC BIOLOGY TRAINING OUTLINE

Initials: *ACS* Date: *6/5/95*

I. Notetaking

- A. Read about notetaking in the Forensic Biochemistry and Hematology Laboratory Methods Manual

- B. Take current files from the file cabinets and review the note-taking styles of the analysts. Think about what you like and dislike about the notes you see.

- C. When you run tests or receive samples for proficiency testing, take notes and fill out worksheets as if they were real casework.

II. Blood

- A. Blood composition

1. Read about blood components

2. Read about hemoglobin

- B. Kastle-Meyer (KM) and Leucomalachite green (LMG) presumptive tests

1. read about mechanisms of catalytic tests

2. read about cross-reacting materials

3. be aware of other tests besides KM and LMG

- C. Takayama confirmatory test

1. read about Takayama test for hemoglobin

- D. Do the following:

1. check the KM and LMG presumptive tests for sensitivity by testing serial dilutions of blood (to about 1/1,000,000)

2. check the KM and LMG presumptive tests for specificity by testing various other substances such as sweat, urine, rust, etc.

3. test bloodstains of various ages with the KM and LMG tests

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Initials: *RC* Date: *6/5/95*

4. check the Takayama test for sensitivity by testing different amounts of sample
5. check the Takayama test for specificity by testing other substance such as sweat (salt), urine, rust, etc.
6. test various ages of bloodstains with the Takayama test

III. Species Determination

A. Immunology

1. read about antibodies and antigens
2. read about how anti-sera are made
3. read about cross-reactivity

B. Ouchterlony (double-diffusion)

1. read about diffusion methods in general
2. understand the "bands of identity"

C. Crossover electrophoresis

1. read about crossover theory
2. think about sensitivity vs. specificity

D. Do the following:

1. Ouchterlony's and crossover of:

- a. anti-human sera against dilutions of human blood
- b. dilutions of anti-human sera against blood
- c. anti-human sera against common animals
- d. animal anti-sera against their corresponding animals
- e. animal anti-sera against other animals including human

- E. Obtain a bloodstain identification proficiency test and complete it before going on.

IV. Semen

Initials: *RCJ* Date: *6/5/87*

A. semen composition

1. read about seminal fluid components
2. read about sperm morphology

B. Acid phosphatase presumptive test

1. read about seminal acid phosphatase
2. read about interfering substances
3. read about AP quantitation
4. be aware of different substrates available for the test

C. Spermatozoa identification

1. read about Christmas tree stain
2. read about fluorescent staining

D. P30 identification

1. read about semen specific proteins
2. read about P30 quantitation

- a. rocket electrophoresis
- b. crossover electrophoresis
- c. ELISA

E. Semen quantitation

1. read about the relationship between amounts of AP, spermatozoa, P30

F. Do the following:

1. check the presumptive test for sensitivity by testing dilutions of semen extracts

2. check the presumptive test for specificity by testing other substances such as vaginal fluid, urine, and saliva

3. make slides from semen stains, semen-stained

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vaginal swabs, and semen-free vaginal swabs both by:

- a. extracting the stains and pelleting cellular debris
 - b. "mashing" the stains/swabs onto a slide
 - c. stain using the Christmas tree stain
4. Sensitivity of P30 methods

- a. check the sensitivity of Ouchterlony by testing dilutions of semen
 - b. check the sensitivity of crossovers by testing dilutions of semen
 - c. check the sensitivity of ELISA by testing dilutions of semen
 - d. compare the sensitivity of the different methods of semen testing.
5. Specificity of P30 testing

- a. check the specificity of anti-P30 by testing other substances such as vaginal fluid, urine, and saliva using crossover electrophoresis
- b. review P30 ELISA validation records

V. Saliva

A. read about amylases

B. Detection methods

1. read about various detection methods
 2. read publication on AMY1, AMY2 differentiation using lectins
- C. do the following:

1. amylase diffusion on dilutions of saliva, semen, semen-stained vaginal swabs, semen-free vaginal swabs and urine

2. perform amylase differentiation test using lectins on samples of saliva, semen, semen-stained vaginal swabs, semen-free vaginal swabs and urine.

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D. Obtain an amylase identification proficiency test and complete it before going on.

VI. Urine

A. read about urine components

B. read about various detection methods

C. do the following:

1. urea diffusion on dilutions of urine, saliva, semen, and serum.

D. Obtain a urea identification proficiency test and complete it before going on.

VII. Typing of liquid blood

A. ABO

1. read about ABO system

2. read about ABH antigens and structures

3. read about forward and reverse typing

B. Lewis

1. read about Lewis and secretor systems

2. read about Lewis antigens and structures

3. understand the relationship between secretor/non-secretor and Lewis antigens

C. Do the following:

1. ABO and Lewis type some PM bloods which have already been typed

a. use capillary method for Lewis typing

D. Obtain an ABO and Lewis typing proficiency test and complete it before going on.

VIII. ABO typing of stains

A. Read about absorption-elution typing

Initials: *PCJ* Date: 6/5/95

- B. Read about Latex typing
- C. Absorption-inhibition (AI)
1. read about soluble antigens
- D. Do the following:
2. read about different techniques for AI
1. AI on known saliva stains
2. AI on known vaginal swabs, semen stains, and semen/vaginal mixes
- E. Obtain an AI proficiency test and complete it before going on.

IX. Genetic Marker typing in stains

A. Methods

1. read about various electrophoresis methods - starch, agarose, cellulose acetate
2. read about various isoelectric focusing methods - thick, thin, ultrathin, agarose, acrylamide
- B. Esterase D/Phosphoglucosaminidase (modified Group I)

1. read about ESD

- a. function of enzyme
- b. protein structure - monomer, dimer, etc
- c. genetics - alleles and phenotypes
- d. discrimination potential
- e. longevity of enzyme in stains

2. read about PGM

- a. function of enzyme
- b. protein structure - monomer, dimer, etc
- c. genetics - alleles and phenotypes
- d. discrimination potential
- e. longevity of enzyme in stains

3. read about Group I and modified methods

4. do the following:

- a. run several plates using blood from lab

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- personnel
- b. run several plates using recent PM samples
 - c. run several plates using PM samples aged 3, 6, 9, and 12 months
 - d. run a plate using casework samples where there is very large amounts of stain
 - e. compare the differences, i.e., clarity, streaking, extra bands, etc, between isozyme patterns obtained between fresh, PM and stains.

5. obtain an ESD/PGM proficiency test and complete it before going on

C. ESD by IEF

1. read about ESD alleles as revealed by IEF
2. read about various methods available, comparing pH ranges, run times and ability to differentiate types
3. do the following:

- a. run several plates using blood from lab personnel
- b. run several plates using recent PM samples
- c. run several plates using PM samples aged 3, 6, 9, and 12 months
- d. run a plate using casework samples where there is very large amounts of stain
- e. compare the differences, i.e., clarity, streaking, extra bands, etc, between isozyme patterns obtained between fresh, PM and stains.

4. obtain an ESD proficiency test and complete it before going on

D. PGM by IEF

1. read about PGM alleles as revealed by IEF
2. read about various methods available, comparing pH ranges, run times and the use of separators
3. do the following:

- a. run several plates using blood from lab personnel

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4. obtain a PGM proficiency test and complete it before going on
- b. several plates using recent PM samples
 - c. run several plates using PM samples aged 3, 6, 9, and 12 months
 - d. run a plate using casework samples where there is very large amounts of stain

Initials: *ACJ* Date: *6/5/95*

Initials: *AC* Date: *6/5/91*

E. Group specific component

1. read about Gc

- a. function of protein
- b. protein structure - monomer, dimer, etc
- c. genetics - alleles and phenotypes
- d. review actin-Gc complexes and understand why they can cause typing problems
- e. discrimination potential
- f. longevity of protein in stains

3. do the following:

- a. run several plates using blood from lab personnel
- b. run several plates using PM samples
- c. run several plates using PM samples aged 3, 6, 9, and 12 months
- d. run a plate using casework samples where there is very large amounts of stain

4. obtain a Gc proficiency test and complete it before going on

F. Hemoglobin

1. read about Hb

- a. function of protein
- b. protein structure - monomer, dimer, etc
- c. genetics - alleles and phenotypes
- d. discrimination potential
- e. longevity of protein in stains
- f. review different detection methods, i.e., cellulose acetate, starch gel agarose gel, polyacrylamide gel electrophoretic methods and isoelectric focusing methods.

2. do the following:

- a. run several plates using the standards and variants available
- b. find blood samples from 10 recent black PM's and run those
- c. run several plates using black PM's aged 3, 6, 9, and 12 months
- d. run a plate using casework samples where there is very large amounts of stain

Initials: *AC* Date: 6/5/95

3. obtain an Hb proficiency test and complete it before going on

G. Erythrocyte acid phosphatase (ACP1)

1. read about ACP1 (EAP)

- a. function of enzyme
b. protein structure - monomer, dimer, etc.
c. genetics - alleles and phenotypes
d. review banding patterns of rare phenotypes
e. longevity of enzyme in stains
f. review degradation process of isoenzymes

2. do the following:

- a. run a few plates using blood from lab personnel
b. run a few plates using recent PM samples
c. run a few plates using PM samples aged 3, 6, 9, and 12 months
d. run a plate using casework samples where there is very large amounts of stain

3. obtain an ACP proficiency test and complete it before going on

June 5, 1995

DNA Laboratory Training and Proficiency

A. Training Outline

The goal of training and proficiency testing 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 or Assistant Director of Forensic Biology. Training may be performed by either a supervisor or an analyst in the Forensic Molecular Biology with the appropriate level of experience.

1. Theory

Prior to beginning laboratory exercises, the analyst will be provided with a list of articles or books which will form the basis of his or her theoretical knowledge. The list will change depending on the specific procedure being learned. For PCR procedures, the analyst will receive articles relating to PCR and those specific loci being analyzed. For RFLP procedures, the analyst will receive articles about the procedure as well as information about the loci being analyzed.

2. Demonstration/Practice

New analysts first observe either the PCR or RFLP procedures being taught. Samples are first typed by the instructor. Each learning stage reflects the step-by-step process involved in performing the actual test. For PCR this involves: extraction, quantitation, amplification and the detection of specific loci. For RFLP this involves: extraction, quantitation (Yield gel), endonuclease digestion, test gel, analytical gel, southern transfer, hybridization, and autoradiography.

Each demonstration is performed in steps and is followed by the instructor observing the student performing each one alone. By the end of the demonstrations, the analyst will have hands-on experience with the complete test. During the instruction the student is instructed on the importance of filling out the worksheets used to document sample analyses. Also, the instructor will insure that the student is familiar with the operation of the equipment necessary to perform the test.

By the end of the demonstration period, the analyst will have acquired a theoretical understanding of each step of the test being studied. For example, it is important to understand what is happening to the DNA during the extraction procedures for each test. Likewise, it is important to understand what happens in PCR

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Initials: *AC* Date: 6/5/95

Initials: *RS* Date: *6/5/85*

reaction tubes during each step of the amplification cycle. Also, for the RFLP procedure, the specifics of endonuclease digestion and the southern blot. The student should understand the purpose of the various hybridization washing steps for both the PCR and RFLP techniques. Also, the basic mechanism visualization of final results, i.e., color, silver, or autorad development, must be understood.

3. Individual Practice

The analyst will then practice each of the procedures under supervision. At first, the analyst will require direct supervision and assistance throughout the entire test. But after sufficient practice, the analyst should be comfortable with the typing procedures. At this point, direct supervision may be limited. Eventually, the analyst will complete the entire test without supervision.

During this phase, the analyst will perform practice runs for each of the methods being learned. Three to six samples are sufficient for each of the practice tests. The results from the analyst's tests will be evaluated in terms of sensitivity, consistency, and contamination. Problems will be addressed at this point and tests repeated if necessary.

Before being certified to perform independent testing, each analyst must complete a clean practice test for each of the methods. For PCR tests, this refers to low-level contamination, for example, results where extra dots are less intense than the 'c' or 's' dots in the HLA-DQ α and PM tests respectively. For RFLP tests this refers to autorads without extra bands.

4. Proficiency

At the end of the practice stage, the analyst will take a proficiency test. The test consists of two or more samples for each of the procedures which the analyst has practiced. The final proficiency test is filed in the analyst's folder.

5. Supplemental Training

The analysts who have completed their initial round of proficiency testing will be introduced to new procedures as they are amended to the DNA protocol. As before, they will observe a demonstration run, and they will be given time to practice the procedure on their own. In this case, practice samples may be processed at the same time as other samples. Once the analysts are comfortable with the new procedure, they will type unknown samples as an internal proficiency. At least two samples must be successfully typed for each new procedure before the analyst is considered proficient.