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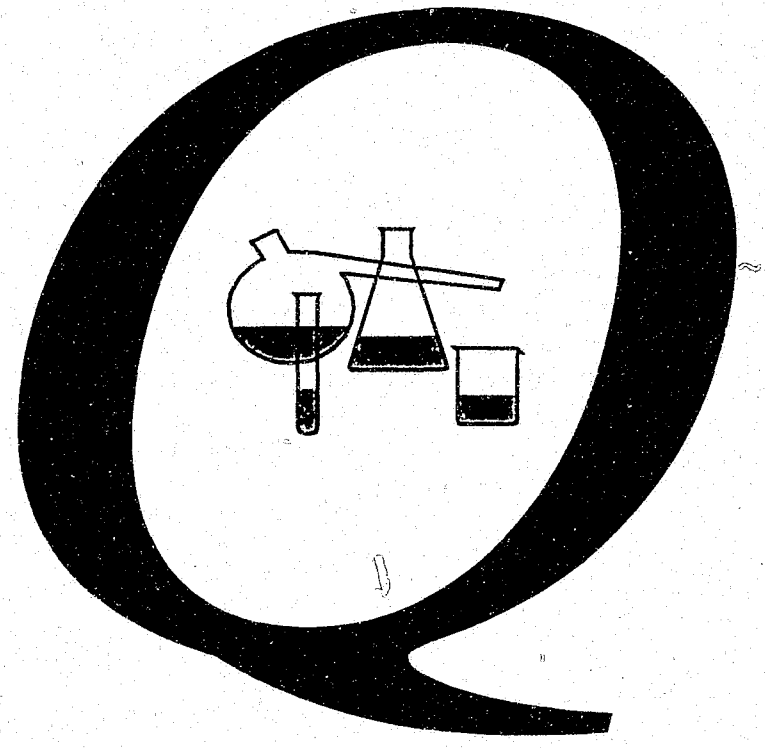

CRIME LABORATORY DIGEST

PUBLICATION POLICY

The Crime Laboratory Digest is published quarterly by the FBI Laboratory in cooperation with the American Society of Crime Laboratory Directors (ASCLD). It is intended to serve as a rapid means of communication between crime laboratories, permitting information of interest and value to be disseminated among crime laboratory scientists.

Inclusion of an article in the Crime Laboratory Digest in no way represents an endorsement or recommendation of any part of that article by the Federal Government, the Department of Justice or the FBI. Contributing authors assume total responsibility for the contents and accuracy of their submissions. Questions or requests concerning an article should be directed to the contributing agency.

All submissions are subject to editorial review in accordance with the editorial policy established by the FBI Laboratory and ASCLD. The editorial staff of the Crime Laboratory Digest reserves the right to edit all articles for style, grammar and punctuation. Comments and letters to the editor are encouraged and will be published when appropriate and as space permits. These should be forwarded to:

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Contents

CRIME LABORATORY DIGEST Vol. 20, No. 1, January 1993
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Feature Article

A Guide for Conducting a DNA Quality Assurance Audit

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Introduction

In 1989, the Technical Working Group on DNA Analysis Methods (TWGDAM) began efforts toward establishing DNA testing standards with the publication of the "Guidelines for a Quality Assurance Program for DNA Restriction Fragment Length Polymorphism Analysis" (Crime Laboratory Digest, April-July 1989, Vol. 16, No. 2, pp 40-59).

As DNA technology and laboratory practices have evolved, TWGDAM has revised the quality assurance guidelines in order to acknowledge and respond to these advancements. The "Guide for Conducting a DNA Quality Assurance Audit" in this issue builds on the foundation established by TWGDAM's "Guidelines for a Quality Assurance Program for DNA Analysis" (Crime Laboratory Digest, April 1991, Vol. 18, No. 2, pp 44-75).

The function of an audit program is to provide the evidence or documentation needed to assure laboratory managers that the laboratory's quality program is being executed adequately. The objectives of this publication are to provide laboratory managers and supervisors with a tool to determine the extent to which their laboratories meet the TWGDAM "Guidelines for a Quality Assurance Program for DNA Analysis" and to identify those in which the laboratory's performance may be improved. This audit checklist guide may be used by laboratory managers and supervisors in establishing their own audit programs and may be modified as needed to meet a specific laboratory's quality assurance program for DNA analysis. This document should not be construed as a mandate; it does not mean that a laboratory's failure to meet each and every item in the checklist implies that its quality assurance program is inadequate or that the laboratory is likely to produce incorrect or unreliable results.

A. OBJECTIVES

The objectives of an audit are (1) to provide laboratory managers with a tool to determine the extent to which their laboratories meet the TWGDAM *Guidelines for a Quality Assurance Program for DNA Analysis* and (2) to identify the areas in which a laboratory's performance may be improved.

This guide is for the internal use of the DNA typing laboratory and may be modified as needed. It is not intended to be used for the purpose of accrediting or certifying a laboratory to perform forensic DNA analysis. Failure by a laboratory to comply with each and every item in this guide should not be interpreted as poor quality performance or that the laboratory is likely to produce incorrect or unreliable results.

B. DOCUMENTATION

Quality Assurance Program

Does the laboratory have a documented quality assurance program?

Has the quality assurance program been approved by the current laboratory manager(s)?

Is there a quality assurance officer or other designated individual(s)?

Does the quality assurance officer or other designated individual(s) have clearly defined and documented responsibilities with adequate authority to administer the quality assurance program?

1. Planning and Organization

Have the goals and objectives of the laboratory's quality assurance program been clearly defined?

Have the organizational structure, functional responsibilities and levels of authority been clearly defined in the laboratory's quality assurance program?

2. Personnel

Are the job descriptions available for all DNA personnel which include responsibilities, duties and skills?

Do the minimum qualification requirements of the laboratory personnel meet the current TWGDAM quality assurance guidelines?

Is there an approved documented training program for all technical personnel?

Do the supervisor/technical leader, examiner/analyst, and/or technicians meet the minimum qualifications of the laboratory?

Do the examiners/analysts participate in continuing education and training programs?

Do records exist which document the training and experience of the professional staff?

3. **Documentation**

Does the DNA laboratory have a single document or a series of documents that cover all significant aspects of the DNA analysis procedure?

Are the following topic areas covered in laboratory documentation?

Test methods and procedures for DNA typing?

Population data bases?

Quality control of critical reagents?

Case files/case notes?

Data analysis and reporting?

Evidence handling protocols?

Equipment calibration and maintenance logs?

Proficiency testing?

Personnel training and qualification records?

Method validation records?

Quality assurance and audit records?

Quality assurance manual?

Equipment inventory?

Safety manuals?

Material Safety Data Sheets?

Historical or archival records?

Licenses and certificates?

4. **Validation**

Have validation studies been conducted by the laboratory or the scientific community for each DNA analysis procedure in use?

Has the DNA laboratory completed internal, in-house, validation studies of those procedures validated by another laboratory as described in section 4.5 of the current TWGDAM quality assurance guidelines?

Are method validation records or references available?

Does the laboratory have access to a population data base for use in population statistics?

Does the data base information include the number, source, and ethnic and/or racial classification of samples?

5. **Equipment, Materials, and Facilities**

Equipment Inventory

Does the laboratory maintain an inventory of all equipment used in the DNA analysis procedures?

Are the manufacturer's operation manuals available?

Equipment Calibration and Maintenance Logs

Does the laboratory maintain an inventory of equipment requiring calibration and maintenance?

Are the schedules and procedures for calibration and maintenance available?

Are equipment calibration and maintenance logs current?

Are traceable standards used in the calibration of critical equipment?

Are there written procedures for cleaning and sterilization?

Quality Control of Critical Reagents

Are records kept of commercial reagents and supplies identified to include, where appropriate, lot number or batch number, manufacturer's specifications, and internal evaluations?

Are critical reagents checked against known material prior to being placed into service?

Are the results of critical reagent quality control checks documented?

If reagents are used as received from the manufacturer, are records maintained of the manufacturer supplied quality control data sheets for each reagent?

6. **Evidence Handling Procedures**

Does the laboratory have an established policy for "chain of custody" and the disposition of evidence?

Are there written procedures or guidelines for handling evidence samples so as to protect against loss, contamination or deleterious change?

Is evidence collected, received, handled, sampled and stored so as to preserve the identity, integrity, condition and security of the item(s)?

Is each evidence sample labeled with a unique identifier in accordance with established agency policy?

7. Analytical Procedures

Are all methods and procedures used in the DNA laboratory adequately described in an established protocol?

Is the protocol dated and signed or initialled by the laboratory supervisor or technical leader to reflect the most recent supervisory review?

Is there a mechanism to approve and document all changes to the protocol manual?

Are copies of all procedures and the dates on which they were initiated maintained for reference?

Does the established protocol include the following?

Step-by-step procedure for performing DNA analysis?

Preparation of reagents, standards and controls?

Specific quality control procedures for critical reagents (enzymes, buffers, probes, etc.) used in the analysis?

Does the established protocol include or make reference to the following?

Index or table of contents for quick retrieval of information?

Directions for equipment and instrument use in performing DNA analysis?

Notes, special requirements or safety precautions?

Guidelines for interpretation of results?

References?

General Considerations

Are there procedures in place for assessing whether evidence samples are appropriate for DNA analysis?

Are the appropriate procedures and controls used to assess and monitor the entire DNA analysis procedure?

Does the DNA isolation procedure protect against contamination?

Is a procedure used to estimate the quality and quantity of DNA recovered from the specimens?

When semen is identified, is a differential extraction procedure used when appropriate?

When appropriate, is each DNA fraction obtained from the differential extraction typed?

Whenever possible, does the laboratory retain or return a portion of the original sample to the submitting agency?

Are written procedures available for cleaning and decontamination of facilities and equipment used in DNA analysis, where necessary?

RFLP Analytical Procedures

Has each new lot of restriction enzyme been tested against an appropriate DNA standard?

Are test gels used to demonstrate the completeness of DNA digestion?

Are size markers, appropriate to the RFLP procedure, used when necessary?

Is an appropriate human DNA control included on the test gel?

Do the analytical gels contain a visual marker to determine the end point of electrophoresis?

Do molecular weight size markers bracket the case samples at appropriate intervals on the analytical gel?

Is a human DNA control having a known fragment pattern included on each analytical gel?

Have minimum and maximum size values been established for the control(s) for each probe used?

Is there a procedure for appropriate action to be taken when controls exceed defined limits?

Are procedures employed to monitor the efficiency of blotting, hybridization and stringency washes?

Are procedures employed to monitor the exposure intensity during autoradiography?

Are image analysis and data processing functions monitored by human DNA allelic control values?

Are procedures employed for the interpretation of altered migration of DNA fragments?

PCR Analytical Procedures

Are negative controls (reagent blank and amplification blank) included with each sample set?

Is a human DNA of known type used as a positive control?

Is the positive control introduced at the amplification step?

Where appropriate, are substrate controls collected from the evidence?

Are substrate controls processed at the same time as the evidence samples?

Where feasible, are samples split for duplicate analysis as early as possible prior to amplification?

When typing amplified fragment length polymorphisms, are the case samples bracketed by marker lanes which span the allelic size range?

8. **Case Work Documentation, Interpretation, Report Writing and Review**

Are there written documents which describe the laboratory's policy and procedures for case work documentation, interpretation, report writing and review?

Is all the documentation used to support the analyst's conclusions preserved as a record according to agency policy?

Are there written guidelines for interpreting and acting upon positive and/or negative control results?

If appropriate to the DNA procedure, are there procedures available for statistical monitoring of the human DNA control?

Are there written guidelines for concluding when samples are, or are not, the same type?

Are there written general guidelines for concluding when the results of an analysis are uninterpretable and/or inconclusive?

Is a documented, scientifically valid method used to calculate the frequency of occurrence from an established population data base?

Do case reports contain the following information?

Case identifier?

Identity of examiner/analyst?

Date of report?

The DNA locus as identified by a particular probe(s) or sequence(s)?

Restriction enzyme, primer pair, or other descriptor of the methodology?

Results and/or conclusions?

Statistical evaluation?

Signature of the reporting analyst?

Are case files sufficiently complete to permit a scientific review of the data?

Are the reports reviewed by a second qualified individual?

Is there evidence of a supervisory review?

Are the conclusions of the reports justified by the data?

9. **Proficiency Testing**

Does the laboratory participate in an open proficiency testing program?

Have the examiners/analysts and technicians actively engaged in DNA analysis completed an open proficiency test at least twice a year?

Are proficiency test records current for each examiner/analyst?

Does the laboratory participate in a blind proficiency testing program at least once a year?

Do the type of specimens used in the open proficiency test meet the requirements listed under "Proficiency Testing" in the current TWGDAM quality assurance guidelines?

Are the proficiency test results reviewed by the quality assurance coordinator or other designated individual(s)?

Do the proficiency test reports contain the test data and information suggested under "Documentation of Proficiency Test Results" in the current TWGDAM quality assurance guidelines?

Are there written policies for taking corrective action as a result of a discrepancy in a proficiency test?

Are corrective action steps documented and retained?

Are the results of all proficiency tests maintained by the laboratory according to established policy?

10. Audits

Are audits of the DNA laboratory conducted on an annual basis?

Are the auditors separate from and independent of the DNA laboratory?

Are records of each inspection maintained according to laboratory policy?

11. Safety

Is there an appointed laboratory safety officer?

Is there a laboratory safety manual?

Are the contents of the safety manual appropriate to the scope of operations and analysis conducted by the laboratory?

Is there a Material Safety Data Sheet file?

Does the laboratory have a chemical hygiene plan?

If radioactivity is used in the laboratory, does the laboratory have the necessary radiation license?

Is there a radiation safety manual?

Are there established procedures for the safe disposal of contaminated or broken glassware or plasticware?

Are there established procedures for the storage, use and disposal of all chemicals and radioactive materials in a manner conforming with established safety requirements?

C. LABORATORY INSPECTION

General Considerations

Do the personnel assigned to the DNA analysis laboratory have adequate space to accomplish their assigned tasks?

Is there a secure area for the overnight and/or long term storage of evidence?

Is there sufficient space available for the use and operation of required instrumentation?

Are the manufacturer's operation manuals readily available to the laboratory personnel?

Are those reagents currently in use properly labeled?

PCR Analysis

Are the areas for examination, photography and microscopy separate in time or space from the extraction and amplification setup areas?

Is the area used for sample extraction, concentration and digestion physically separate from the amplified DNA work area (includes the amplification area with thermal cyclers and space for all procedures which use the amplified product for typing)?

Is the PCR setup area separate in time or space from the extraction area?

Is the PCR setup area physically separate from the amplified DNA work area?

Is the amplified DNA stored and disposed of in the amplified DNA work area?

D. PERSONNEL INTERVIEWS

Quality Assurance Program

Are the personnel of the DNA laboratory aware of the goals, objectives and policies of the DNA laboratory's quality assurance program?

Is the quality assurance program being followed?

Personnel

Does the laboratory manager(s) provide the examiner/analyst with an opportunity for continuing education and training?

Is there adequate supervision?

Is there adequate technical leadership?

Are DNA personnel aware of both the extent and limitations of their area of responsibility?

Documentation

Does the approved protocol reflect current practices?

Are copies of the current procedures readily available to the personnel performing the DNA analysis procedure?

Evidence Handling Procedures

Is evidence collected, received, handled, sampled and stored so as to preserve the identity, integrity, condition and security of the item(s)?

Does the laboratory policy for "chain of custody" and disposition of evidence reflect current practices?

Case Work Documentation, Interpretation, Report Writing and Review

Are the conclusions of the reports justified by the data?

Proficiency Testing

Are all examiners/analysts and technicians aware of the written policies concerning the handling of a discrepancy in a proficiency test?

Safety

Is the laboratory safety manual available to all personnel?

Is the radiation safety manual available to all personnel?

Do all employees have access to the Material Safety Data Sheets?

Are established safety procedures as outlined in the safety manuals being followed?