Elements of a Quality Assurance (QA)/Quality Control (QC) Program for DNA Testing

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With the advent of DNA typing technology in the forensic laboratory, the forensic examiner now has the potential to individualize various body fluids and tissues. Since the results of these tests can have a significant impact on the outcome of a trial, it is important that they be accurate and reproducible. Consequently, the use of appropriate standards and controls, as part of a QA program, is essential in order to ensure scientifically sound and reliable results from the analysis of forensic evidence.

Although often used interchangeably, quality control (QC) and quality assurance (QA) refer to different, specific quality functions (American National Standard ANSI/ASQC A3-1978; Kilshaw 1986; 1987a,b). The QC measures would be employed by a DNA analysis laboratory to ensure that the quality of the product (DNA typing) will meet and satisfy specified criteria. The function of the QA program, on the other hand, is to provide the evidence needed to establish with confidence that the QC function is being performed adequately. This is accomplished in part through the use of proficiency tests and audits.

In November, 1988, the first meeting of the Technical Working Group on DNA Analysis Methods (TWGDAM) was hosted by the FBI Laboratory at the FBI Academy. This group consisted of 31 scientists representing 16 forensic laboratories in the United States and Canada and two research institutions. During the first meeting, a subcommittee was established to formulate suggested guidelines for a QA program for crime laboratories conducting restriction fragment length polymorphism (RFLP) analysis of variable number of tandem repeats (VNTR) loci.

These guidelines represent the minimum QA requirements for DNA RFLP analysis and are intended to serve only as a guide to laboratory managers in establishing their own QA programs for DNA RFLP analysis.

The objectives of the QA program are: (1) to monitor on a routine basis the analytical testing procedures for DNA typing by means of QC standards, proficiency tests and audits; (2) to ensure that proper equipment, materials and procedures are employed during the analysis of forensic evidence; (3) to verify that the entire DNA typing procedure is operating within the established performance criteria; (4) to ensure that the

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quality and validity of the analytical data is maintained; (5) to maintain adequate documentation and records concerning how the evidence was analyzed, what was done and by whom; (6) to ensure that problems are noted and that corrective action is taken and documented; and (7) to demonstrate to the forensic science community, the judicial system, and the scientific community at large, the laboratory's commitment to maintaining excellence in all areas of its work.

While most forensic laboratories have a tradition of providing reliable and accurate results without the benefit of a formally established QA program, the formal establishment and implementation of a comprehensive QA program would provide essential support to the accuracy and reproducibility of the results presented in court by the DNA laboratory examiner or analyst. The QA program would provide the necessary evidence, through documentation, that the quality control requirements established for the RFLP procedure are being performed adequately and that the DNA analysis process is operating within the established performance criteria; it would also provide a measure of the quality of the results. In addition, the documentation requirements of a QA program would serve as an archive for retrospective scientific inspection, reevaluation of the data, and reconstruction of the DNA procedure.

The QA guidelines ("Guidelines for a Quality Assurance Program for DNA RFLP Analysis", *Crime Laboratory Digest*, April-July 1989, V. 16, No. 2, pp. 40 - 59) were developed by the TWGDAM QA subcommittee using established quality functions (American National Standard ANSI/ASQC C1-1968; ANSI/ASQC Z-1.15-1979; ANSI/ASQC Q90-1987a,b; Juran 1979; Ruzicka 1979) and follow systematically the DNA RFLP typing procedure. These guidelines cover all significant aspects of the laboratory process including: Planning and Organization, Personnel, Documentation, Materials and Equipment, Validation of Analytical Procedures, Evidence Handling Procedures, Internal Controls and Standards, Data Analysis and Reporting, Proficiency Testing, Audits, and Safety. These guidelines provide the necessary documentation to ensure that the DNA analysis process is operating within the established performance criteria and ensure that the quality, integrity, and accuracy of the RFLP data is maintained.

These guidelines form the basis of a quality assurance program for RFLP analysis and are subject to future revisions as the state of the art and experience dictate.

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