FORENSIC BIOLOGY QUALITY ASSURANCE/QUALITY CONTROL MANUAL

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Control of Data

GUIDING PRINCIPLES AND SCOPE

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

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

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

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

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

This section describes the procedures to achieve these guiding principles.

PROCEDURE

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

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

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

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

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

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

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

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

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

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