

TENNESSEE BUREAU OF INVESTIGATION

Forensic Services Division



Quality Assurance Manual

Process Requirements-Control of Data and Information Management

7 Process Requirements

7.11 Control of Data and Information Management

7.11.1 Laboratory personnel will have access to data and information necessary to perform laboratory activities. This includes all policies and procedures, software, standard libraries, and the LIMS.

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

- The system is fit for the intended use prior to implementation and following any changes or modifications. Records of the validation shall be maintained;
- Any changes to the system will be scheduled in advance;
- Procedures are in place for protecting data.

7.11.2.1 Computer software developed in-house is documented, evaluated and validated prior to use. Operating conditions and maintenance are such that computers and automated equipment function properly and are detailed enough to maintain the integrity of the test and calibration data.

7.11.3 The LIMS is managed by the TBI-FSD LIMS administrator. The LIMS meets the following requirements:

- a) protected from unauthorized access;
- b) safeguarded against tampering and loss;
- c) meets the specifications of the TBI laboratory;
- d) properly maintained to ensure the integrity of data;
- e) system failures are recorded and appropriate actions are taken as necessary.

7.11.4 TBI-FSD LIMS is maintained by the TBI in-house IT Department.

7.11.5 The LIMS administrator has access to relevant material necessary for the continued functioning of the system.

7.11.6 Manual calculations and manual data transfers relevant to examinations are systematically checked for accuracy by another analyst. Automated calculations shall be validated before use with casework.

7.11.6.1 The check of calculations and data transfers will be documented in the technical record or electronically unless stated otherwise in the applicable Unit SOPs.