

TENNESSEE BUREAU OF INVESTIGATION

Forensic Services Division

Quality Assurance Manual

Resource Requirements; Externally Provided Products and Services



6 Resource Requirements

6.6 Externally Provided Products and Services

6.6.1 TBI Laboratory Unit Technical Leader, Section/Unit Supervisor, and/or Quality Assurance Manager will be responsible for the quality of a subcontractor's work, unless the customer specifies the subcontractor. A representative sampling of the completed cases will be reviewed to further substantiate the subcontractor's work, unless the customer specifies the subcontractor.

6.6.2 The following guidelines will be followed when selecting and approving products and services from vendors and subcontractors:

- a) The TBI-FSD will select competent subcontractors to conduct forensic examinations/calibrations when necessary. TBI-FSD Technical Leaders, Supervisors, and/or the Quality Assurance Manager are responsible for evaluating the competency of subcontractors. A subcontractor's competence can be demonstrated with their accreditation by ANAB or by satisfactory results of an audit conducted by the TBI-FSD personnel or another accredited laboratory.
- b) The appropriate personnel may also determine a subcontractor to be competent for testing services, on a case-by-case basis, if the subcontractor is accredited by another ISO 17025 accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement with a scope of accreditation covering the services being subcontracted.
- c) The appropriate personnel may also determine a subcontractor to be competent for calibration services, on a case-by-case basis, if the subcontractor is accredited by another ISO 17025 accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement with a scope of accreditation covering the services being subcontracted or by a National Metrology Institute that is a signatory to the BIPM-CIPM Mutual Recognition Arrangement with the required calibration listed in Appendix C of the BIPM key comparison database (KCDB).
- d) Unit Technical Leader and/or the Unit Supervisor will be responsible for the quality of a subcontractor's work, unless the customer specifies the subcontractor. A representative sampling of the completed cases will be reviewed to further substantiate the subcontractor's work, unless the customer specifies the subcontractor.
- e) Laboratory Supervisors and/or the Quality Assurance Manager will maintain a list of all competent subcontractors who are approved for conducting forensic examination/calibration services. Documentation will be maintained of the subcontractor's conformance with the requirements of ANAB for the work in question as it relates to the scope of their accreditation.

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- f) When the TBI-FSD subcontracts work, the laboratory will advise the customer of the arrangement in writing. This will be documented in the case file.
- g) Unit SOPs will define specifications to evaluate quality affecting supplies, reagents, and consumables purchased by each unit. These materials will not be used until they have been verified. Units will maintain records of materials and verifications.

6.6.3 TBI_FSD will communicate requirements to vendors and subcontractors for supplies and services when they may affect the quality of laboratory activities.

- a) Purchase request documents will contain information describing the supplies and services ordered if they affect the quality of examinations. These requests will be reviewed and approved for technical content by the Unit Supervisor or designee prior to ordering.
- b) Suppliers of quality-affecting consumables, supplies and services will be evaluated and records of evaluations maintained (e.g. verifying and maintaining a certificate of analysis). Evaluation will be based on the ability of the vendor to provide the service/product in the necessary time frame, the ability of the vendor to provide the service/product at an acceptable cost, and the quality of the product/service provided by the vendor as related to requirements in SOPs. List(s) will be maintained identifying approved suppliers. If the vendor is not ISO 17025 certified, then the acceptance of this vendor may be based on prior use of this vendor and a quality control check of the product/service prior to use.
- c) Reference standards, reference materials, and calibrations of equipment/reference standards used to establish and/or maintain measurement traceability shall be viewed as quality-affecting.