16.0 – OUTSOURCE LABORATORY

16.1 Shipments

16.1.1 Offender/arrestee samples to be sent to an outsource laboratory will be documented on an outsource manifest; see Appendix P for an example. The TBI may also utilize forms provided by the outsource laboratory.

16.1.2 The samples and accompanying paperwork will be given to the outsource laboratory in batches. Approved company personnel may pick up the samples, they may be hand delivered by CODIS/DNA personnel, or they may be sent to the outsource laboratory by an approved carrier company (e.g. FedEx or UPS).

16.1.3 The completed batches are returned to the crime laboratory by the vendor. In addition to the return of samples, the batches may contain all computer data pertaining to the generated DNA profiles on a CD/DVD-ROM. If not included with the returning sample batches, a CD/DVD-ROM of data may be sent separately via an approved carrier company.

16.1.4 Upon the return of samples, CODIS personnel will inventory the shipment in order to verify that the samples returned match the original outsource manifest.

16.1.5 The data is reviewed for accuracy by comparing the data tables with the information on the provided CD/DVD-ROM. The outsource laboratory will assure that any discrepancies detected are resolved to the satisfaction of the TBI, as per contract requirements with the state of Tennessee.

16.1.6 The outsource laboratory will provide TBI copies of any accreditation certificates and at least one copy of a yearly QAS audit.

16.1.7 CODIS/DNA personnel will do an on site visit to the outsource laboratory facility at least once during the outsource period. If an onsite visit is not possible, the TBI may rely on another government laboratory site visit for the same outsource laboratory. The other government laboratories must use the same technology, platform, and amplification kit as the TBI.
16.2 Quality Control

16.2.1 At least 5% of the samples shall be retested by the outsource laboratory to confirm previous results for Quality Assurance/Quality Control purposes. For each sample to be retested, a unique TBI QC identifier is generated. In addition to the QC samples, at least one sample from a member of the CODIS or Serology/DNA section shall be included as a QA sample. A list of the QC/QA samples and the corresponding TBI database number will be maintained by the CODIS administrator.

16.2.1.1 For QC purposes, one swab may be taken from each returning bundle of sex offender, arrestee, and convicted offender samples, placed in an envelope, and bound in groups.

16.3 Verification of Accuracy of DNA Data

Data is returned to the TBI from the outsource laboratory in two formats: raw data on a CD/DVD-ROM and tabular form. A qualified DNA analyst will analyze the raw data following procedures to determine if accurate STR typing results were obtained. A complete review of all samples and QA/QC samples will be performed.

16.3.1 QA/QC Samples

16.3.1.1 The QC sample data is reviewed and the profiles may either be put into CODIS as a quality control sample or the original profile and the quality control sample may be compared by hand. A CODIS autosearch may be performed and duplicates will be noted.

16.3.1.2 The original profile database number and the QA/QC samples will be compared and the match date and the correctness of the profiles will be recorded and maintained.

16.3.1.3 Discrepancies will be noted and will be resolved with the outsource laboratory to the satisfaction of the TBI as per initial contract negotiations with the state of Tennessee. QA/QC samples may be removed from the CODIS system once the matches are noted and resolved.
16.3.2 Offender/Arrestee Samples

16.3.2.1 A qualified DNA analyst will verify negative and positive controls, reagent blanks, internal size standards, and allelic ladders for compliance with TBI policy. The profiles are screened for stutter, pull-up peaks, -A peaks and off ladder alleles. Any peaks established as extraneous are removed before putting in tabular form on the computer. See Appendix Q for an example of a Data Review Sheet.

16.3.2.2 Discrepancies will be noted and will be resolved with the outsource laboratory to the satisfaction of the TBI as per initial contract negotiations with the state of Tennessee.

16.4 Uploading DNA Profiles

16.4.1 The DNA profiles are imported to CODIS computer using available storage media. Computer macros and instructions for conversion of DNA data into the required format are provided by the FBI.

16.4.2 After the data is imported, the qualified DNA analyst may mark for upload approved profiles or notify the CODIS administrator which profiles may be marked for upload. The CODIS administrator is given the list of any incorrect or incomplete profiles for further review.