

FORENSIC BIOLOGY EVIDENCE AND CASE MANAGEMENT MANUAL

SUBCONTRACTING		
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Subcontracting

GUIDING PRINCIPLES AND SCOPE

Subcontracting is the utilization of another laboratory to provide services within the Department's scope of accreditation. It does not pertain to situations in which the Department uses an external laboratory to conduct a specific analysis using a technology that the laboratory is not qualified to perform or when the Department will not take or retain ownership of the data. For example, using another laboratory to provide mitochondrial DNA testing is "subcontracting" since our laboratory provides mitochondrial DNA testing services. However, the utilization of another laboratory to provide RFLP work is not "subcontracting" since our laboratory does not provide RFLP services.

A sub-set of subcontracting is **outsourcing**, which is the utilization of a vendor laboratory to provide DNA services in which the Department takes or retains ownership of the DNA data for entry into CODIS, when applicable.

It is not the usual practice of the Department of Forensic Biology to subcontract/outsourcing work. Should the need arise; however, the Department would use only competent subcontractors. This document describes the general process for establishing a subcontracting agreement that meets the requirements of ISO 17025 and the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

PROCEDURE

In the event that the Department of Forensic Biology needs to subcontract work, the Department notifies the affected customers, e.g., the NYPD and/or District Attorney's Offices, in writing. In most cases the Department requests the customer to provide their approval, preferably in writing.

The Department seeks subcontractors that it believes to be appropriate for the tests to be conducted.

- If a subcontractor is selected by the Department, then the Department is responsible to the customer for the subcontractor's work.
- If a subcontractor is selected by the customer, the Department follows all steps in the subcontractor qualification process. The Department informs the customer of the results of

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the results of that process, and the ramifications of using vendor laboratories that do not meet the Department's requirements.

A. General Requirements for Subcontractor Qualification

1. A subcontractor must be accredited, preferably to ISO/IEC 17025.
2. The Quality Assurance Unit maintains a register of the subcontractors that the Department of Forensic Biology uses for tests, as well as the records that support subcontractor competence, for example, accreditation certificates and audit documents.
 - i. The records include the date on which the subcontractor was approved.

B. DNA Subcontractor Qualification

1. The appropriate Technical Leader determines whether an external laboratory is competent to act as a subcontractor for the Department. The minimum requirements for DNA laboratory competence are:
 - i. Compliance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, as verified by a review of the vendor laboratory's external audit document report, the vendor laboratory's responses, and/or follow-up actions to any findings detailed in the report.
 - ii. Compliance with federal accreditation requirements.
2. Where the vendor laboratory will perform DNA analysis for the Department (and not for a law enforcement agency or entity other than the Department), the appropriate Technical Leader reviews and approves the technical specifications of the subcontracting agreement prior to the awarding of any agreement.
3. Prior to the initiation of analysis under a subcontracting agreement, the following steps take place:
 - i. The appropriate Technical Leader or designee performs an initial on-site visit to subcontracting laboratory.
 - The employee performing the visit is a qualified or previously qualified analyst in the technology, platform, and DNA typing kit used to generate the DNA data.
 - It is not necessary to conduct a full DNA audit during this visit, but at a minimum the visit must include an assessment of the work site and documentation of the subcontractor's ability to perform analysis on the outsourced work.

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- ii. The appropriate Technical Leader documents in writing that the Department accepts ownership of the subcontractor's DNA data. A copy of the approval is provided to the subcontractor.
4. Subcontracting agreements that extend beyond one year require an annual on-site visit to the subcontractor laboratory.
 - i. An on-site visit conducted by another NDIS laboratory using the same technology, platform, and DNA typing kit is acceptable. The records provided to the appropriate Technical Leader must include:
 - The date of the visit
 - A summary of the visit
 - Documentation of the qualified personnel who performed the visit.

The Technical Leader documents their review and acceptance of the records of the on-site visit.

A new "initial visit" is required when renewals or re-awards involve gaps in the agreement of greater than 6 months, or where there are changes to the technical specifications.

C. Data Integrity

All data and/or reports generated by a subcontractor as well as any vendor-generated profiles uploaded to or searched in CODIS by the Department are technically reviewed in the same manner as data and reports generated wholly within the Department. See the TECHNICAL REVIEW procedure for details.