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June 2010

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Introduction

1.0 Scope

This document describes the requirements for forensic testing organizations seeking A2LA accreditation. For the purposes of this document forensic testing refers to testing performed on submitted or collected items where the result of that testing will be used in criminal or civil litigation.

All organizations seeking accreditation for forensic testing must meet the general requirements of ISO/IEC 17025:2005.

When testing is performed outside the organization's permanent facility, R104 – *General Requirements – Accreditation of Field Testing and Field Calibration Laboratories* applies.

Organizations seeking accreditation for forensic testing must also meet A2LA policy and requirements documents:

P101 – *Reference to A2LA Accredited Status – A2LA Advertising Policy*

P102 – *A2LA Policy on Measurement Traceability*

R101 – *General Requirements – Accreditation of ISO/IEC 17025 laboratories*

R102 – *Conditions of Accreditation*

R103 – *General Requirements – Proficiency Testing for ISO/IEC 17025 Laboratories*


This document describes additional accreditation requirements specifically applicable to organizations performing forensic testing. The information contained in this document constitutes either additions to the general accreditation requirements or clarifications of the general requirements as they relate to forensic examinations. For ease of use, sections 4 and 5 of this document reflect the sections listed in ISO/IEC 17025.

A testing laboratory which is engaged in forensic inspection work may apply for accreditation for this work concurrently with its application for accreditation for testing.

2.0 References

P101 – Reference to A2LA Accredited Status-A2LA Advertising Policy.

P102 – A2LA Policy on Measurement Traceability.

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P103 – Policy on Estimating Measurement Uncertainty for Testing Laboratories

R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories.

R102 – Conditions for Accreditation.

R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories.


R104 – General Requirements: Accreditation of Site Testing and Site Calibration Laboratories.

ILAC G19:2002, Guidelines for Forensic Science Laboratories.

Quality Assurance Standards DNA Testing Laboratories, Federal Bureau of Investigation CODIS Unit, July 2009. <http://www.fbi.gov/hq/lab/html/codis1.htm>

3.0 Definitions

- 3.1 For the purposes of these requirements, the relevant terms and definitions given in ISO/IEC 17000, the VIM, and ISO/IEC Guide 2 apply. As used herein the following terms shall have the meanings specified:
- 3.2 Case Record – A coordinated record relating to each case under investigation.
- 3.3 Case Review – Administrative and technical review of all data to ensure quality and reliability of the work conducted.
- 3.3.1 Administrative Review – A review of the report and all supporting documentation for consistency with organization policies and for editorial correctness.
- 3.3.2 Technical Review – An evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions.
- 3.4 Court Statement – A written report of the results and interpretations of forensic tests/examinations submitted to court. Such reports may be in a format prescribed in legislation.
- 3.5 Examiner/Analyst – An individual who conducts and/or directs the analysis of forensic casework samples, interprets data, reaches conclusions and testifies in court.

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- 3.6 Forensic Science – The examination of scenes of crime, recovery of evidence, examination of evidence, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in court.
- 3.7 Known Samples – Those samples whose identity or type is established.
- 3.7.1 Exemplar¹ – A specimen of physical evidence collected from a known origin.
- 3.7.2 Control¹ – A material of established origin that is used to evaluate the origin of a test or comparison.
- 3.8 Objective Test – A test which having been demonstrated and validated is under control so it can be demonstrated that all appropriately trained staff will obtain the same results within defined limits. These defined limits relate to expressions of degrees of probability as well as numerical values.
- 3.9 Physical Evidence – Items collected or submitted for examination in relation to a crime or criminal act.
- 3.10 Reference Collection – A collection of stable materials, substances, objects or artifacts of known properties or origin that may be used in the determination of the properties or origins of unknown items.

4.0 Management Requirements

4.1 Organization

- 4.1 F1.1 The management system requirements of ISO/IEC 17025 and the additional requirements of this document apply to the organization's permanent facilities and examinations performed at on and off-site locations.
- 4.1 F1.2 The forensic organization, when applicable, shall:
- a. Have a policy and procedure for meeting required health and safety standards as outlined by the pertinent government, environmental and health and safety authorities and including:
 - A blood borne pathogen and chemical hygiene plan;

¹ 1. ASTM Standards, ASTM E 1732, Standard Terminology Related to Forensic Science

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- The use of personal protective equipment when in the laboratory or out in the field.

Health and Safety manual(s) and applicable Material Safety Data Sheets shall be readily available to all personnel. Documented training in health and safety standards shall be readily available.

- b. Have a policy and procedure for maintaining adequate security for personnel and operations.

4.2 Quality Management System

4.2 F1.1 The organization shall have a technical manager(s), however named, who is responsible for:

- a. Overseeing the technical operations of the organization;
- b. Initiating, suspending and authorizing the resumption of work;
- c. Overseeing the validation and approval of all methods used by the organization and to propose new or modified procedures;
- d. Overseeing staff training and continuing education;
- e. Authorizing technical staff to perform particular types of sampling, test and/or calibration, to issue reports, to give opinions and interpretations and to operate particular types of equipment.

4.2 F1.2 When applicable, the organization shall appoint a member of staff as Health and Safety Manager, however named, who is responsible for maintaining the Health and Safety program and who monitors compliance with the program.

4.3 Document Control


4.3 F1.1 The organization shall have and maintain or have access to:

- a. Reference documents (i.g. text books, scientific journals) and
- b. A Reference Collection of forensic items of known origin, when applicable.

To be used for research, education, identification, comparison or interpretation purposes. (See section 5.6 F1.4)

4.4 Review of requests, tenders and contracts

No additional requirements

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4.5 Subcontracting of tests and calibrations

4.5 F1.1 When an organization subcontracts work, the work shall be placed with a competent subcontractor. Competency shall be clearly defined and may include:

- Compliance to regulatory requirements for the discipline in which examination is sought;
- Compliance to ISO/IEC 17025 specific to the subcontracted activities being sought;
- Compliance to this requirements document.

4.5 F1.2 Records of actions taken to check compliance shall be maintained.

4.5 F1.3 Result data produced by subcontractors shall undergo technical review and approval prior to release to customers. (See section 4.13 F1.10)

4.6 Purchasing services and supplies

No additional requirements.

4.7 Service to the client

No additional requirements.

4.8 Complaints

No additional requirements.

4.9 Control of nonconforming work


No additional requirements.

4.10 Improvement

No additional requirements.

4.11 Corrective action

No additional requirements.

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4.12 Preventive action

No additional requirements.

4.13 Control of records

4.13 F1.1 The forensic science organization shall have documented procedures to ensure that it maintains a coordinated record relating to each case under investigation. The information that is to be included in case records shall be documented and may include:

- Case Identifier;
- Records of requests, tenders or contracts;
- List of all items submitted and date of submission;
- Evidence receipts;
- Chain of Custody records for each item of evidence;
- Descriptions of items and examinations performed;
- Examination results and reports;
- Reference to procedures used;
- Diagrams, print-outs, auto radiographs, photographs, etc.

4.13 F1.2 The forensic organization shall have written procedures for the documentation and maintenance of case notes.


4.13 F1.3 The records required to support conclusions shall contain sufficient information to enable another competent analyst/examiner to evaluate what had been performed and interpret the data.

4.13 F1.4 Where instrumental analyses are conducted, operating parameters shall be recorded.

4.13 F1.5 Where appropriate, observations or test results shall be preserved by photography or electronic scanning (e.g. electrophoretic runs, physical matches). Photocopies, tracings or hand-drawn facsimiles may also be suitable (e.g. thin-layer chromatography results, questioned documents).

4.13 F1.6 When a test result or observation is rejected, the analyst shall document the reason(s) for rejection in the case record.

4.13 F1.7 All examination records shall be paginated using a page numbering system which indicates the total number of pages and end of record.

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4.13 F1.8 Each page within the case record shall be traceable to the analyst/examiner and where appropriate, to a uniquely identified case or exhibit. It shall be clear from the case record who has performed each stage of the analysis/examination and when each stage of the analysis/examination was performed (e.g. relevant date(s)).

4.14 Internal Audits

No additional requirements.

4.15 Management reviews

No additional requirements.

5.0 Technical Requirements

5.1 General

No additional requirements.


5.2 Personnel

5.2 F1.1 The forensic science organization shall have a defined policy and procedure that ensures that all staff working in the organization is competent to perform the work required. The term 'competent' implies possessing the requisite knowledge, skills and abilities to perform the job duties, demonstrated acceptable performance of testing duties and ongoing maintenance of skills and expertise through continuing education. The organization's policy and procedure shall include personal certification, procedures for training and retraining, a period of supervised casework and maintenance of skills and expertise through continuing education.

Where test, examination or technique specific training is given, acceptance criteria shall be assigned. Where necessary, training programs shall also include training in the presentation of evidence in court.

5.2 F1.2 All examiners/analysts shall maintain or be in the process of obtaining personal certification for each discipline in which they perform testing, where available and applicable.

5.2 F1.3 The forensic organization shall maintain records of all continuing education completed. These records shall include:

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- Title of class or program;
- Brief description of teaching points;
- Date completed;
- Name and qualifications of presenter;
- Record of Performance (if applicable).

5.2 F1.4 An organization shall have clear statements of the competencies required for all jobs and records shall be maintained to demonstrate the competency of staff for all job duties that they are authorized to perform.

Each organization or organization section shall have a documented training program and maintain an up-to-date record of the training that each member of staff has received. These records shall include academic and professional qualifications, external or internal courses attended, and relevant training (and retraining, where necessary) received whilst working for the organization.

Records shall be sufficiently detailed to provide evidence that staff performing particular tasks have been properly trained and that their subsequent ability to perform these tasks has been formally assessed.

5.2 F1.5 The organization shall, at a minimum annually, assess the competence of all staff to perform testing in the disciplines in which they have been authorized.


5.2 F1.6 Technical personnel, regardless of previous experience, shall complete a qualifying test or tests in all areas for which they have been deemed competent before being approved for casework. Records of acceptable performance shall be maintained.

5.2 F1.7 Educational Requirements

The forensic organization shall set minimum educational and experience requirements for all job descriptions. Consideration should be given to each forensic discipline and related published guidelines when determining degree or subject matter requirements.

Technical staff who were previously authorized by management to perform examinations, but do not meet current educational requirements may be authorized to perform such functions at the discretion of the organization if the staff member's experience exceeds that of the minimum needed to be considered competent. Evidence of prior authorization must be available.

5.2 F1.7.1 Educational requirements included within a given test method or federal or state requirement shall be met by all technical staff for which they apply.

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5.2 F1.7.2 Forensic DNA

The technical manager, however named, shall have at a minimum, a master's degree in biology, chemistry, or forensic science-related area. Each technical manager shall have completed at least one graduate class comprised of three semester or equivalent credit hours and nine semester or equivalent credit hours from a combination of undergraduate and graduate course work covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics. The technical manager shall have three years of testing experience in the forensic biology discipline.

Technical staff authorized to perform testing and testify in a court of law shall have at a minimum a bachelor's degree, or equivalent in a biology, chemistry, or forensic science related area. Each technical analyst shall have completed nine semester or equivalent credit hours from a combination of undergraduate or graduate course work, covering the following subject areas: biochemistry, genetics, molecular biology, statistics or population genetics. Technical staff authorized to perform testing and testify in a court of all shall have at a minimum, six months of testing experience in the forensic biology discipline.

5.3 Accommodation and Environmental Conditions

- 5.3 F1.1 Special care is needed in forensic organizations involved in the analysis or determination of trace levels of materials, including DNA. Physical separation of work that has a high sensitivity to cross-contamination and work that has a low sensitivity to cross-contamination is required. Where special areas are set aside for this type of work, access to these areas shall be restricted and the work undertaken carefully controlled. Appropriate records shall be maintained to demonstrate this control. It may also be necessary to carry out environmental monitoring of equipment, work areas, clothing and consumables.
- 5.3 F1.2 Access to the operational area of the organization shall be controlled and limited. Visitors shall not have unrestricted access to the operational areas of the facility. A record shall be retained of all visitors to the operational areas of the organization.
- 5.3 F1.3 Evidence storage areas shall be secure to prevent theft or tampering and there shall be limited, controlled access. The storage conditions shall be such as to prevent loss, deterioration and contamination and to maintain the integrity and identity of the evidence. Appropriate storage conditions shall be used both before and after examinations are performed.

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5.3 F1.4 Procedures to prevent cross contamination, exposure to biohazardous materials and loss of evidence shall be established.

5.4 Methods and method validation

5.4 F1.1 All methods shall be fully documented including procedures for quality control, the use of reference materials, where appropriate, and guidelines for the interpretation and reporting of results.

5.4 F1.2 All technical procedures used by a forensic science organization shall be fully validated before being used on casework. A written procedure for the validation of test methods and test procedures shall be followed.


Methods may be validated by comparison with other established methods using certified reference materials (where available) or materials of known characteristics. In validating test methods, the following issues (among others) may need to be determined, as appropriate:

- matrix effects;
- interferences;
- sample homogeneity;
- concentration ranges;
- specificity;
- stability of measured compounds;
- linearity range;
- population distribution;
- precision;
- measurement uncertainty;
- limit of detection;
- sensitivity.

Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the forensic science organization itself (as in case of methods developed in-house or where significant modifications are made to previously validated methods).

5.4 F1.3 When an organization introduces a new (validated) method, the organization shall first:

- a. Demonstrate the reliability of the procedure in-house against any documented performance characteristics of that procedure;

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- b. Confirm staff competency to perform the procedure.

Records of method validation and performance verification shall be maintained for future reference and shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.


- 5.4 F1.4 Forensic science organizations shall institute a procedure to identify infrequently performed tests or analyses. For these tests or analyses there are two methods of demonstrating competence, either of which would be equally valid. These are:
 - a. Regular analysis of control samples and use of control charts even when casework samples are not being analyzed; or
 - b. Reverification before the test or analysis in question is performed on a casework sample involving at least the use of an appropriate reference material, followed by replicate testing or analysis of a known sample.
- 5.4 F1.5 Calculations and data transfers which do not form part of a validated electronic process shall be checked, preferably by a second qualified person. The case record shall include an indication that such checks have been carried out and by whom.

5.5 Equipment

- 5.5 F1.1 As part of a quality system, all organizations are required to operate a program for the maintenance and calibration of equipment used in the organization. The equipment used in a forensic science organization is diverse and will span across a number of different scientific and technical disciplines.

5.6 Measurement Traceability

- 5.6 F1.1 The forensic organization shall meet the requirements of A2LA document *PI02 – A2LA policy on Measurement Traceability* for all calibrations and verifications of measurement and test equipment and reference standards.
- 5.6 F1.2 Individual calibration programs shall be established depending on the specific requirements of the testing or analytical work being carried out. It will normally be necessary to check instrument calibration after any shut down, whether deliberate or


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otherwise, and following service or other substantial maintenance. In general, calibration intervals shall not be less stringent than manufacturers' recommendations.

- 5.6 F1.3 The forensic science organization shall have written procedures for the reception, handling, preparation and storage of reagents and laboratory consumable materials relevant for testing, calibration and examination.
- 5.6 F1.4 The quality of standard materials and reagents shall be adequate for the procedure used. Lot/batch numbers of standard materials and critical reagents shall be recorded. All critical reagents shall be checked for their reliability prior to use.

Standard materials and reagents shall be labeled with:

- name;
 - concentration, where appropriate;
 - preparation date, if applicable, and expiration date;
 - identity of preparer;
 - storage conditions, if relevant;
 - hazard warning, where necessary.
- 5.6 F1.5 Collections of reference data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes (e.g. mass spectra, motor vehicle paints or headlamp lenses, drug samples, typewriter print styles, wood fragments, bullets, cartridges, DNA profiles, frequency databases) shall be fully documented, uniquely identified and properly controlled.

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5.7 Sampling

5.7 F1.1 Selection, recovery, prioritization and sampling of materials from physical evidence are important parts of the forensic process. In the area of forensic science emphasis is placed on the competence of the scientist and the training of staff in these activities is therefore of prime importance. Organizations shall ensure that there are documented procedures and training programs to cover this aspect of their work and that detailed competency and training records are kept for all staff involved.

5.8 Handling of test and calibration items


5.8 F1.1 For legal purposes, forensic science organizations shall be able to demonstrate that the items examined and reported on were those collected by or submitted to the organization. A 'chain of custody' record shall be maintained for the collection of items which details each person who takes possession of an item or alternatively the location of that item (e.g. if in storage).

At a minimum, a chain of custody record for each item of evidence shall include:

- Evidence identifier;
- Description of collection location;
- Description of item collected and any packaging and identifying marks;
- Date and time of collection;
- Printed name and signature of initial individual to collect the evidence;
- Date of transfer and printed name and signature of each subsequent individual receiving or transferring the item.

Chain of Custody for items not delivered by hand may include a description of the packaging, description of delivery method and any tracking information on the package.

5.8 F1.2 The forensic organization shall have documented procedures which describe, where applicable, the collection, packaging, transportation, handling and disposition of collected or submitted items and the measures to be taken to prevent loss, deterioration, contamination and cross contamination and to secure exhibits which must be left unattended. Where possible, sampled items should be preserved for potential reanalysis.

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5.8 F1.3 Where it is possible to record or copy an item or significant features on an item of evidence (e.g. photographs, tape lifts, casts), the laboratory shall clearly define what is considered evidence and what is considered documentation.

5.9 Assuring the quality of test and calibration results

5.9 F1.1 Analytical performance shall be monitored by operating quality control schemes which are appropriate to the type and frequency of testing undertaken by an organization. The range of quality control activities available to forensic organizations includes the use of:


- Reference collections;
- Certified reference materials and internally generated reference materials;
- Statistical tables;
- Positive and negative controls;
- Control charts;
- Replicate testing;
- Alternative methods;
- Repeat testing;
- Spiked samples, standard additions and internal standards;
- Independent checks (verification) by other authorized personnel.

Depending on the particular test being performed, the organization may make use of one or several of these examples to demonstrate that the test or examination is 'under control'.

The quality control procedures necessary in any particular area of work shall be determined by the organization responsible for the work, based on best professional practice. The procedures shall be documented and records shall be retained to show that all appropriate QC measures have been taken, that all QC results are acceptable or, if not, that remedial action has been taken.

5.9 F1.2 An effective means for a forensic science organization to monitor its performance, both against its own requirements and against the performance of peer forensic organizations, is to take part in proficiency testing programs. When participating in proficiency testing programs, the organization's own documented test procedures shall be used. Performance in the programs shall be reviewed regularly and where necessary, corrective action shall be taken.

Proficiency testing records shall include:

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- Full details of the analyses/examinations undertaken and the results and conclusions obtained;
- An indication that performance has been reviewed and the outcome of that review;
- Details of the corrective action undertaken, where necessary.

5.9 F1.3 In addition to the requirements outlined in *R103 - General Requirements- Proficiency Testing for ISO-IEC 17025 Laboratories*; all forensic personnel actively engaged in forensic testing shall participate in commercial proficiency testing, intralaboratory or interlaboratory or round robin testing annually for each sub-discipline in which they are competent.


5.9 F1.4 The laboratory shall have a defined procedure to ensure that personnel participating in the same round of commercial proficiency testing, intralaboratory or interlaboratory or round robin testing do not share or compare results prior to reporting.

5.9 F1.5 The organization shall have documented policies and procedures for the administrative and technical review of case records, including test reports.

Each case file and final report shall undergo administrative review for completeness and accuracy, in relation to case information and required elements of the case file, and shall be conducted and documented in accordance with written procedures.

The technical review of case records shall be performed at a frequency sufficient to ensure the continued reliability of test results and test conclusions. Technical reviews shall be conducted in accordance with a predetermined schedule and shall ensure that the work of each analyst is reviewed at least once per year. Each technical review shall be carried out by personnel who were not involved in the testing performed and who are competent to perform the examinations being reviewed. Technical reviews shall be documented and shall include an indication that all associated test/examination results have been reviewed, by whom the review was performed and the technical findings of the review. This may be indicated in a number of ways including entries against finding, entry on a summary of findings or a statement to this effect in the records.

Where administrative or technical review results in incongruent results, opinions or interpretations between technical staff and the reviewer, further investigation following written procedures for the investigation and corrective action, where applicable, of nonconforming results shall be applied. A record of each determination and resolution shall be kept within the case file.

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5.9 F1.6 The organization shall have and follow a documented procedure whereby the testimony of each examiner is monitored. Monitoring shall be performed at a minimum annually. The evaluation shall be documented and shall include appearance, performance and effectiveness of presentation. The laboratory's corrective action procedures shall be followed whenever less than satisfactory results are obtained. The procedure shall also address alternate methods of evaluation when an inspector is not called to give testimony in a given year.

5.10 Reporting the results

5.10 F1.1 It is accepted that forensic testing organizations may not be able to include all of the items in 'Court Statements' that are detailed in sub-clause 5.10 of ISO/IEC 17025 as the format of these documents is prescribed in legislation. Forensic testing laboratories may therefore elect to adopt one or more of the following means of meeting these requirements:


- The preparation of a test report which includes all of the information required by ISO/IEC 17025;
- The preparation of an annex to the Court Statement which includes any additional information required by ISO/IEC 17025;
- Ensuring that the case record relating to a specific investigation contains all the relevant information required by ISO/IEC 17025.

5.10 F1.2 Reports produced by the forensic organization shall be dated and shall include a description of all evidence or items of evidence collected by or submitted to the organization.

5.10 F1.3 Reports produced by the forensic organization shall include a description of the error rate, measurement uncertainty or uncertainty of the determination where available and in accordance with written guidelines.

5.10 F1.4 The results of each examination, test or series of tests or examinations carried out by the organization shall identify the analyst who performed the test or examination and shall be reported in sufficient detail to facilitate, if possible, identification of factors affecting the uncertainty and to enable the examination to be repeated under conditions as close as possible to the original.

5.10 F1.5 Case records and reports shall be released to requesting persons, agencies and organization in accordance with federal and state law and following a written policy and procedure.

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