MINIMUM REQUIREMENTS FOR IDENTIFICATION OF SEIZED DRUGS

A document for emerging laboratories

International Forensic Strategic Alliance

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IFSA
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INTERNATIONAL FORENSIC STRATEGIC ALLIANCE

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IFSA MRD 3

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INTRODUCTION

The International Forensic Strategic Alliance (IFSA) has developed this document to be minimum requirements which will enable emerging forensic providers in developing countries to produce scientific services to the Criminal Justice System.

The purpose of this document is to establish a baseline or starting point that must be followed in order to achieve reliable results. Forensic providers should build on this foundation and strive to continually improve the quality of services provided.

This document describes the minimum requirements for Crime Scene Investigation. It addresses the following framework:

1. Competence of Personnel.
2. Equipment and Consumables.
3. Collection, Analysis, Interpretation, Reporting.
4. Procedures, Protocols, Validation.
5. Quality Management.

FOREWORD

The International Forensic Strategic Alliance (IFSA) is a multilateral partnership between the six regional networks of operational forensic laboratories:

- the American Society of Crime Laboratory Directors (ASCLD)
- the European Network of Forensic Science Institutes (ENFSI)
- the Senior Managers of Australian and New Zealand Forensic Laboratories (SMANZFL)
- the Academia Iberoamericana de Criminalística y Estudios Forenses (AICEF)
- the Asian Forensic Sciences Network (AFSN)
- the Southern Africa Regional Forensic Science Network (SARFS)

and works closely with its two strategic partners, United Nations Office on Drugs and Crime (UNODC) and INTERPOL.

IFSA recognises the importance of a quality management framework in forensic laboratories to provide quality and standardised results, be it procedures undertaken in the field or in the laboratory.

In February 2012, at the special IFSA meeting hosted by UNODC and convened in Vienna to discuss the needs of the emerging forensic laboratories in developing countries, a decision was taken to create a set of minimum requirement documents (MRD) filling the gap in recommendations available for the current management of these laboratories.

The first series of three documents in the specific areas of identification of seized drugs, DNA analysis, and crime scene investigation have been created. These documents have focused on the critical quality areas, using simple terms and illustrations as well as a glossary to guide the users through the important concepts of the documents.

These documents are meant to act as a start-up guide for emerging forensic laboratories to quickly establish their quality management system and scientific/technical capabilities. Once achieved, the laboratories should continue to build on this foundation and strive to continually improve the quality of services through undergoing accreditations to established standards.

In the drafting of these documents, scientific working groups and experts from the six regional forensic science networks, as well as IFSA strategic partners, made valuable contributions during the various rounds of consultation. The final MRD documents presented in this series would not be possible without the involvement of all.

It is IFSA's hope that these documents will play an important role for emerging forensic laboratories in their journey towards building quality forensic services.

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1 COMPETENCE OF PERSONNEL

All laboratory staff must have a clear understanding of their duties and responsibilities and should fulfil these at all times according to a code of ethics1(see the examples in the footnote below) adopted by the laboratory.

This section recommends minimum education and training required for laboratory staff to conduct DNA analysis[1].

1.1 EDUCATION

Laboratory staff should have education, skills and abilities commensurate with their responsibilities. Staff who are issuing reports should have tertiary education with strong emphasis in analytical, physical or organic chemistry. Coursework should include lectures and associated laboratory classes.

1.2 TRAINING

The laboratory should have a documented training plan for new staff or new tasks, documenting the required standards of performance, competency, and assessment plan. The assessment can be done, for example by fulfilled training plans or the analysis of unknown samples. The training should be delivered by experienced staff.

The training can comprise components such as relevant background information on drugs of abuse, evidence handling, sampling protocols, analytical procedures and instrumentation which the staff will employ in the course of casework, as well as on the code of ethics. Upon completion of the training, the staff will be authorised to perform casework. All training should be documented.

A program for continuing education is necessary to ensure staff stays abreast of scientific advancement and development in the analysis of drugs. The program could include conference/ seminar/course attendance, webinars, and review of scientific literature and other methods of self-learning.

[1] Examples of Code of Ethics adopted by regional forensic science networks:

- The American Society of Crime Laboratory Directors (ASCLD) – www.ascld.org
- The European Network of Forensic Science Institutes (ENFSI) – www.enfsi.eu
- The Senior Managers of Australian and New Zealand Forensic Laboratories (SMANZFL) – www.anzfss.org
- The Academia Iberoamericana de Criminalística y Estudios Forenses (AICEF) – www.aicef.net
- The Asian Forensic Sciences Network (AFSN) – www.asianforensic.net

2 EQUIPMENT AND CONSUMABLES

2.1 EQUIPMENT

All equipment used in casework for the identification of drugs must be suitable and in proper working condition. The equipment should be calibrated or undergo a performance check before use to ascertain reliable performance of test methods[2]. Performance of equipment should be monitored and records of performance checks kept.

Maintenance and servicing should be done routinely to ensure it is fit for casework. Preventive maintenance and servicing records shall be kept by the laboratory.

Only trained staff shall operate the instruments. The manufacturer's operation manual and other relevant documentation, for example, Standard Operation Procedures (SOP) for each equipment shall be readily available in the laboratory. Methods used on the equipment should be validated prior to application on casework.

2.2 CONSUMABLES

All chemicals, reagents and solvents used in drug testing should be of appropriate grade suitable for the type of analysis performed.

The laboratory shall have written procedures for the preparation of reagents and solvents.

It is good laboratory practice that chemicals should be labelled with their identity and expiration date and that commercial reagents should be dated and initialled when first opened[3].

The efficacy of all critical reagents used in casework shall be checked prior to use (initially after the reagents are made up and then either prior to each use or on a regular basis; or concurrently with casework). Checks may include testing with drug standards, solvent checks, appropriate positive and negative control samples and blank samples.

3 COLLECTION, ANALYSIS, INTERPRETATION & REPORTING

3.1 COLLECTION

Collection of evidence at crime scenes is covered under the Crime Scene Investigation Minimum Requirements publication and is applicable to a laboratory that also processes crime scene and collects evidence.

The laboratory shall have records of requests for analysis and the items of evidence submitted. A unique identifier shall be assigned to each exhibit. Should there be significant discrepancy between the submission documentation and physical evidence, the client must be informed as soon as possible and the discrepancy shall be recorded with the case notes.

Each exhibit shall be properly stored to maintain the integrity of the evidence. Exhibits should be stored under appropriate conditions as far as possible to ensure the composition of the content is not altered. Special storage conditions may apply to some drugs.

(For example, heroin exhibits should be not exposed to excessive heat and moisture; cannabis should not be exposed to excessive heat and where possible stored in breathable packaging to prevent formation of mould; GHB should be stored in the fridge (approximately 4oC), khat should be stored in the freezer (<0oC) and cannabis/LSD kept away from long exposure to light).

A system to document a chain of custody for the evidence shall be established in the laboratory. Only authorised staff shall have access to exhibits.

3.2 ANALYSIS

Analysis of exhibits shall be performed on a cleaned surface to prevent any contamination. Precautions shall be taken to ensure there are no other factors contributing to possible contamination, cross transfers, loss, deterioration or damage of evidence. Items should be examined separately to avoid cross-contamination. The laboratory should have a procedure to address the analysis of traces.

Sampling

Whenever possible (i.e. in line with legislative requirements of particular country) the laboratory is advised to develop a sampling strategy and implement sampling schemes appropriate to the case with minimum number of required analytical determinations, while assuring all relevant legal and scientific requirements are met. Depending on the inference to be drawn from the analysis for a multiple unit population, the sampling plan may be statistical or non-statistical. A statistical sampling plan allows one to draw inference to the whole population with a desired confidence level that at least a certain percentage of the population is tested positive for the drug.

Examples of a statistical approach are hypergeometric, binomial and bayesian while examples of a non-statistical approach are the 'square root' method or selection of a single or fixed units from a multiple unit population[4,5].

There should be quality assurance measures employed to ensure that the results correspond to the exhibit. Measures could include:

- The use of two separate samplings;
- The use of sample identification procedures such as use of bar-code or witness checks; and
- Good laboratory practices such as positive and negative controls, opening of one exhibit at a time and procedural blanks.

Identification

For identification of a substance with the use of analytical techniques, the Scientific Working Group for the Analysis of Seized Drugs' (SWGDRUG) Recommendations[6] has classified some commonly used analytical techniques into three categories as shown in Table 1.

CATEGORY A	CATEGORY B	CATEGORY C
Infrared Spectroscopy	Capillary Electrophoresis	Color Tests
Mass Spectrometry	Gas Chromatography	Fluorescence Spectroscopy
Nuclear Magnetic Resonance Spectroscopy	Ion Mobility Spectrometry	Immunoassay
Raman Spectroscopy	Liquid Chromatography	Melting Point
X-ray Diffractometry	Microcrystalline Tests	Ultraviolet Spectroscopy
	Pharmaceutical Identifiers	
	Thin Layer Chromatography	
	Cannabis only: Macroscopic Examination Microscopic Examination	

TABLE 1: CATEGORIES OF ANALYTICAL TECHNIQUES[6]

3.3 INTERPRETATION

Laboratories shall adhere to the minimum guidelines as recommended by SWGDRUG[6] to positively identify commonly seized drugs:

- When a validated Category A technique is incorporated into an analytical scheme, at least one other technique (from either Category A, B or C) shall be used.
- When a Category A technique is not used, at least three different validated techniques shall be employed. Two of the three techniques shall be based on uncorrelated techniques from Category B.
    - For cannabis, macroscopic and microscopic examination will be considered as uncorrelated techniques from Category B when observations include detailed botanical features. Laboratories shall define the acceptance criteria for these features for each examination.
- All Category A and botanical identifications shall have data that are reviewable. Where a Category A technique is not used, the requirement for reviewable data applies to Category B techniques. Reviewable data includes printed spectra, chromatograms, digital images, photographs or photocopies (of foils, Thin layer Chromatography plates etc), and reference to library matches. For cannabis, detailed descriptions of morphological characteristics shall be documented.
- For the use of any method to be considered of value, test results shall be considered 'positive'.
- In cases where hyphenated techniques are used (for example, gas chromatography-mass spectrometry), these will be considered two separate techniques provided results from each are used.
- The chosen analytical scheme shall demonstrate the identity of the specific drug present and preclude a false positive identification and minimize false negatives.

- Relevant limitations of an analytical scheme such as the inability to differentiate isomers or unavailability of reference material should be documented.
- Positive and negative controls should be used where appropriate to ensure the reliability and accuracy of the technique/instrument employed.

3.4 REPORTING

All efforts shall be directed to produce reports that are accurate, clear, objective and meet the requirements of the jurisdiction served. The reports shall include the following information unless there are documented reasons for not doing so (for example, specific accreditation, client or jurisdictional consideration) and the information must be available for review in the casework documentation:

- Title of report;
- Date of report;
- Name and address of testing laboratory;
- Unique identification of the report on every page;
- Page number and total number of pages;
- Submitting agency;
- Date of receipt of evidence;
- Descriptive list of submitted evidence (including items not examined);
- Results; and
- Identity and signature of staff issuing the report.

The laboratory shall determine a framework for a systemic review of reports by a reviewer. Casework documentation shall contain sufficient information such that the reviewer is able to evaluate case notes and interpret data. Before a report is released it should go through a technical and administrative review. In the event where the staff-in-charge of the case does not agree with the opinion of the reviewer, the matter will be referred to a higher authority who is competent to determine the disputed issue.

4 PROCEDURES, PROTOCOLS AND VALIDATION

4.1 PROCEDURES AND PROTOCOLS

Analytical procedures and sampling protocols should be adopted from internationally-recognized published methodologies or from validated in-house methods. These procedures should be sufficiently detailed so that processes can be strictly followed to ensure analyses are carried out consistently and accurately. Laboratories should monitor the analytical procedures using appropriate controls and/or drug standards to ensure the quality of analysis.

Significant changes in protocols or procedures must be verified, documented and approved by an authorised person before use. Examples of significant changes include using a new, non-validated colour test or use of a different instrument not previously approved to identify a controlled substance. Approved changes shall be communicated effectively to all staff involved.

In-house developed methods must produce acceptable results with reference drug standards or previously validated methods prior to implementation.

4.2 VALIDATION

All methods (published or in-house methods) used for identification of drugs shall be validated to demonstrate that they are fit for intended purpose of use. Validation should be performed by staff competent in the methods and equipment used. The following objectives of validation shall be established during validation studies:

- Selectivity – to assess the capability of the method to identify the drug of interest without interference from other drugs or compounds that could be present in the mixture.
- Limits of Detection (LOD) – to determine the lowest amount of drug that can be detected.
- Robustness – the robustness of an analytical procedure is a measure of its capacity to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage (EURACHEM, ICH Q2A, CPMP/CH/381/95).

All documentation of validation processes shall be retained (hardcopy/electronically). Documentation shall include:

- Procedure of validation;
- Date of studies conducted;
- Data;
- Summary/conclusion of results; and
- Authorisation approval.

5 QUALITY MANAGEMENT

The objective of the laboratory is to provide clients with quality drug analysis. As such, the laboratory shall establish and maintain a quality framework for the management and processing of drug casework. This includes handling of evidence, management practices, analysis and reporting.

The quality management system shall cover all procedures and reports related to drug analysis3. Staff responsible for the quality management system shall be designated and have the authority to fulfil their duties accordingly.

There should be documented procedures/programs and maintenance of records in the following areas:

- Staff training, competency, responsibilities and continual development.
- Health and safety program to provide a healthy, safe and secure environment for staff and operations.
- Monitoring of evidence to ensure the integrity of all physical drug exhibits, including the chain of custody on receiving, transfer, storage and disposal/return of exhibits.
- Analytical procedures for drug analysis with protocols for sampling, validation of methods and instruments, identification of drugs in compliance with quality assurance measures and preventing contamination of exhibits during analysis.
- Maintenance and calibration of instrument/equipment to ensure that proper performance is maintained.
- Drug reference standards, chemicals and reagents used in casework.
- Records of casework to ensure the proper documentation of results and all instrument printouts, and reports are retained and secured.
- Annual proficiency testing for monitoring the laboratory's performance.
- Annual laboratory audits and any necessary corrective actions.
- Procedures for corrective actions when non-conforming work has been observed.

6 GLOSSARY

The following glossary is not to be considered an exhaustive list of terminology encountered in DNA testing however these terms are widely utilized in the forensic DNA community.

ADMINISTRATIVE REVIEW	A procedure where the content of the laboratory report is checked for consistency with laboratory policy, administrative documents, and case documentation, as well as editorial correctness. This review may be performed by a non-technical laboratory staff.
ANALYTICAL PROCEDURE	An orderly step-by-step procedure designed to ensure operational uniformity and to minimize analytical drift.
ANNUAL	Occurs once per calendar year.
ASSESSMENT	Systematic, independent examinations to determine whether actual activities comply with planned activities. Assessments usually include a comparison of actual results to expected results.
AUDIT	An independent review conducted to compare the various aspects of the laboratory's performance with a standard for performance.
AUTHORISED PERSON	A person who has the knowledge, expertise and necessary skills to make decisions and is authorised by the laboratory to do so.
CALIBRATE	To set measurement equipment against a known standard.
CALIBRATION	The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system and the corresponding known values of a measurement.
CASE NOTES	The documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photographs, and other documents generated which are used to support the examiner's conclusions.
CHAIN OF CUSTODY	Procedures and documents that account for the integrity of an exhibit by tracking its handling and storage from its point of collection to its final disposition.
COMPETENCE	Ability to perform a specific task according to procedures.
COMPETENCY	The demonstration of technical skills and knowledge necessary to perform drug analysis successfully.
COMPETENT	Capable of performing an allotted or required function and the ability to achieve the correct result.
CONTAMINATION	The introduction of foreign substances to an unrelated exhibit, usually unintentional.
CONTINUING EDUCATION	An educational activity (such as a class, lecture series, conference, seminar or short course) that is offered by a recognized organization or individual that brings participants up-to-date in their relevant area of knowledge.
CORRECTIVE ACTION	An activity performed to eliminate the root cause of an existing non-conformance or other undesirable situation in order to prevent recurrence.
CRITICAL	Of decisive importance with respect to the outcome.
EQUIPMENT	A durable item, instrument, or device used in a process or procedure.
LABORATORY	A facility providing drug analysis service.

LABORATORY STAFF	Scientific personnel analysing drug exhibits (such as Analyst, Scientist, Laboratory Officer, Technician). The level of responsibility and involvement of each type of staff in the analysis of the exhibits depend on the organisation of the laboratory and the workflow used by the laboratory.
METHOD	The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.
PERFORMANCE CHECK	A quality-assurance measure to assess the functionality of laboratory equipment that affects the accuracy and/or validity of analysis. This can include the use of drug mixture or sample control.
PREVENTIVE MAINTENANCE	A procedure of inspecting, and reconditioning an equipment at regular intervals according to specific instructions, intended to prevent failures in service or to retard deterioration.
PROCEDURE	The manner in which an operation is performed; a set of directions for performing an examination or analysis.
PROCESS	A set of related tasks and activities that accomplish a work goal, i.e., that transforms input into output products and services.
PROFICIENCY TESTING	An ongoing process where unknown samples are tested on a regular basis by the laboratory and compared with the known/ consensus identities or values. Internal proficiency tests are conducted by the laboratory itself; external proficiency tests are conducted by an independent agency.
QUALITY	Characteristics of a product or service that bear on its ability to meet requirements, including those defined during agreement review.
QUALITY ASSURANCE	Those planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality.
REAGENT	A chemical used to react with another chemical, often to identify the presence or absence of the second chemical/analyte.
RECORD (NOUN)	Information captured in writing or through an electronically generated medium that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.
REVIEW	An evaluation of records to check for consistency, accuracy and completeness. A review comprises technical and administrative review.
REVIEWER	A person performing technical and/or administrative review.
STANDARD	A statement which describes an acceptable level of performance, excellence, or attainment in that particular activity.
TECHNICAL REVIEW	An evaluation of appropriateness of analytical method, sampling procedure, data, results and conclusions. This review must be conducted by a qualified laboratory staff who has the relevant casework experience.
VALIDATION	The process of performing a set of experiments which establish the appropriateness, suitability, accuracy and robustness of a technique or procedure.

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