MINIMUM REQUIREMENTS FOR IDENTIFICATION OF SEIZED DRUGS

A document for emerging laboratories

International Forensic Strategic Alliance

Version 2

IFSA
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INTERNATIONAL FORENSIC STRATEGIC ALLIANCE

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IFSA MRD 3

Version 1 of this document was first released October 2014. The document has been updated and is now released as Version 2.

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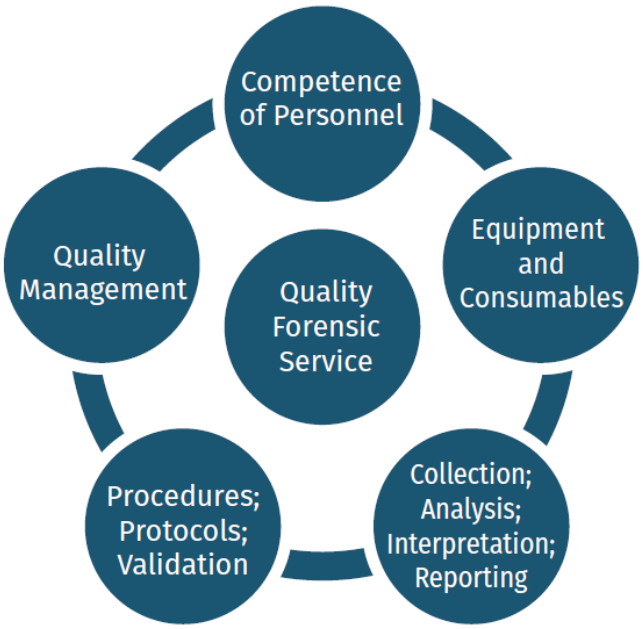
INTRODUCTION

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 analysis of seized drugs. 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 National Institute of Forensic Science Australia New Zealand (NIFS ANZ)
- la Academia Iberoamericana de Criminalística y Estudios Forenses (AICEF)
- the Asian Forensic Sciences Network (AFSN)
- the Southern Africa Regional Forensic Science Network (SARFS).

IFSA works closely with its three strategic partners, Leverhulme Research Centre for Forensic Science, 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.

In October 2014, the first series of three documents in the specific areas of identification of seized drugs, DNA analysis, and crime scene investigation were created. These documents have focused on the critical quality areas, using simple terms and illustrations. All three MRDs have now undergone update and further review with version 2 of these documents published in December 2020. At the time of writing, a further three MRDs in the areas of digital and media evidence, document examination and latent fingerprint analysis are currently in development. A separate glossary document has also been created to guide the users through the important concepts of this documents.

These MRDs 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 MRDs 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.

IFSA Board

January 2021

1 COMPETENCE OF PERSONNEL

All laboratory staff shall have a clear understanding of their duties and responsibilities and should fulfil these at all times according to a code of ethics/professional practice/conduct [1](see the examples in the footnote below) adopted by the laboratory.

This section recommends minimum education and training required for laboratory staff to conduct identification of seized drugs[1].

1.1 EDUCATION

Laboratory staff shall have education, skills and abilities commensurate with their responsibilities.

Technician: Higher education requirements should be based on the nature and complexity of tasks to be performed.

Analyst: Staff issuing reports should have tertiary education with strong emphasis in 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 carried out, for example, through fulfilling training plans or by the satisfactory analysis of unknown samples. The training should be delivered by experienced and competent staff.

The training program shall include a training manual covering all procedures that the analyst/technician will employ in the course of casework, as well as on the code of ethics. The program may comprise components such as relevant background information on drugs of abuse, evidence handling, sampling protocols, analytical procedures and instrumentation. Staff should be assessed as competent prior to assuming independent casework. A competency test will ensure proper skills and knowledge was acquired during training. Training may be augmented by participation in external courses or workshops.

A program for continued education should be established as an extension of credentialing and to ensure analysts stay abreast of scientific advancement and development in the analysis of drugs. The program may include conference/ seminar/course attendance, webinars, and review of scientific literature and other methods of self-learning.

Training and competency tests should be documented, and records retained according to guidelines established by the laboratory. All analyst/technician(s) shall participate in ongoing proficiency testing, and the results recorded.

[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 National Institute of Forensic Science Australia New Zealand (NIFS ANZ) – www.anzfss.org
- La 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 FACILITIES

Evidence receipt and storage shall be separated from the analytical areas.

The laboratory shall have appropriate utilities such as electricity, clean water, and adequate separated space and plumbing. More advanced laboratories working towards accreditation should include air conditioning, airtight windows and purified water.

Specimens shall be stored in an area protected from contamination, heat, and sunlight. Some chemical samples may require refrigeration or freezing. Refrigerators and freezers' temperatures shall be monitored to prevent sample degradation and the laboratory shall specify an acceptable range of temperature for this equipment.

The facility shall be equipped with refrigerators and freezers dedicated to the storage of consumables. Samples shall not be stored with consumables. If the laboratory is unable to provide dedicated refrigerators and freezers, samples shall by physically separated from consumables using measures such as robust plastic bags, boxes or other physical separators.

Reference material, evidence and sample storage areas shall be secured, and access controlled.

2.2 EQUIPMENT

The laboratory shall use equipment that is suitable for the methods employed by the laboratory.

At a minimum, the laboratory shall have a procedure for conducting performance checks and calibration of all equipment deemed critical.

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

Maintenance and servicing shall 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 equipment shall be readily available in the laboratory. Methods used on the equipment should be validated prior to application on casework.

The laboratory shall have and follow a written procedure for monitoring, cleaning, and decontaminating facilities and equipment. It is the responsibility of laboratory management to design and implement appropriate cleaning techniques and protocols.

2.3 CONSUMABLES

The laboratory shall use chemicals, reagents, solvents and consumables in drug testing that are of the appropriate grade suitable for the type of analysis performed.

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

Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory. It is good laboratory practice that commercial reagents should be dated and initialled when first opened[3].

All in-house prepared chemicals, reagents and solvents shall be labeled with their identity, the identity of the individual who prepared it and the date of preparation or lot number. Expiration date should also be available.

The laboratory shall identify critical reagents. The efficacy of all critical reagents used in casework shall be checked after initial preparation and then prior to each use or on a regular basis, or concurrently with casework. Checks may include testing with drug reference material, solvents, appropriate positive and negative controls and blanks. All consumables shall be stored at appropriate temperatures as recommended by manufacturer. All chemicals, reagents and solvents shall be stored at the appropriate temperature. Reagents shall be protected from direct sunlight.

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3 COLLECTION, ANALYSIS, INTERPRETATION & REPORTING

3.1 COLLECTION

This section addresses collection of drugs from items submitted to the laboratory. Collection of evidence at crime scenes is covered under the Crime Scene Investigation Minimum Requirements publication (IFSA MRD 1) 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 shall 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 and chemical composition of the evidence, under appropriate conditions as far as possible. Special storage conditions may apply to some drugs.

(For example, heroin exhibits should not be 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; ; dried khat should be stored in a freezer (< 0°C), fresh khat in a refridgerator 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 trace and residue exhibits.

Sampling

Whenever possible (i.e. in line with legislative requirements of a particular jurisdiction) 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 case, legal and scientific requirements are met. The use of ENFSI DWG sampling guidelines is recommended. 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 unit from a multiple unit population[4,5].

Identification

A reliable and scientifically supported identification of a substance depends on the use of an appropriate analytical scheme by competent laboratory staff in a quality-controlled process. The Scientific Working Group for the Analysis of Seized Drugs' (SWGDRUG) Recommendations[6] provides techniques that may be incorporated within an analytical scheme for the identification of a substance. Techniques are grouped according to their highest potential level of selectivity 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	Pharmaceutical Identifiers
	Supercritical Fluid Chromatography	
	Thin Layer Chromatography	
	Ultraviolet/Visible Spectroscopy	
	Cannabis only: Macroscopic Examination Microscopic Examination	

TABLE 1: CATEGORIES OF ANALYTICAL TECHNIQUES[6]

Quality Assurance Practices

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

- Removing two aliquots from the sample and testing them independently;
- Using sample identification procedures such as use of barcoding and witness checks;
- Using procedural blanks; and
- Analyzing/opening of one sample at a time.

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, which exploits different chemical of physical properties of the analyte, (from either Category A, B or C) shall be used to support the identification.
- When a Category A technique is not used, at least three separate techniques shall be employed; two shall be from Category B, the combination of which provides a high degree of selectivity. A third technique (either Category B or C) is required to support the identification.
- For cannabis, macroscopic and microscopic examination will be considered as different techniques from Category B when observations include documented details of botanical features. Laboratories shall define the acceptance criteria for these botanical features for each examination. . For narcotic plants, no additional techniques are required if sufficient diagnostic features are present.
- All Category A and B techniques shall have data that are reviewable to allow an independent interpretation of the result. Reviewable data includes spectra, chromatograms, digital images, photographs or photocopies (of foils, Thin layer Chromatography plates etc), and reference to library matches. For cannabis, this should include a detailed description of morphological characteristics.

- For the results of the techniques within the analytical scheme to be considered of value towards the identification of the analyte, the test results shall be 'positive,' and meet all quality control practices, and achieve the selectivity required.
- In cases where hyphenated techniques are used (for example, gas chromatography-mass spectrometry), these may be considered as two separate techniques within the analytical scheme provided the criteria for 'positive' results are fulfilled for both techniques.
- The analytical scheme provides a scientifically supported conclusion when each technique achieves the level of selectivity required and the 'positive' test results corroborate each other.
- Relevant limitations of an analytical scheme such as the inability to differentiate isomers or unavailability of reference material should be reported.
- 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 shall be available for review in the casework documentation:

- Title of report;
- Date issued;
- 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);
- Sampling;
- Methodology used;
- Additions to, deviations or exclusions from the test method (if applicable);
- Clear identification of results of tests performed by external service provider (if applicable);
- Results and conclusions of analysis; and
- Identity of staff member issuing the report.

Reports may only be issued by personnel who are experienced, appropriately trained and have been authorized to do so.

Peer review

The laboratory shall determine a framework for a systemic review of reports by a reviewer competent in the testing/procedure being reviewed. This review helps ensure that all conclusions reached and supporting data are consistent with laboratory policy and guidelines.

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 developed 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 reference material to ensure the quality of analysis.

Significant changes in protocols or procedures shall be verified, documented by an authorised person and approved 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 shall produce acceptable results with drug reference material prior to implementation.

4.2 VALIDATION

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

- 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[2].

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

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

[2] More detailed guidlelines for validation studies can be found at www.eurachem.org and www.ema.europa.eu (ICH Q2A and CPMP/ICH/381/95).

5 QUALITY MANAGEMENT

The laboratory shall enhance its activities to be undertaken impartially and with confidentiality in management of all information obtained or created in the laboratory.

Laboratory shall consider and identify possible risks, evaluate them and develop procedures to control the risks.

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 analysis[3]. Staff responsible for the quality management system shall be designated and have the authority to fulfil their duties accordingly.

There shall 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 final disposition 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.
- Performance checks, maintenance and calibration of instrument/equipment to ensure that proper performance is maintained.
- Verification checks of drug reference material, chemicals and reagents used in casework.
- Records of casework to ensure the proper documentation of results and all instrument data, 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.
- Opportunities and actions for quality improvements shell be identified and implemented.

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