MINIMUM REQUIREMENTS FOR TOXICOLOGY

A document for emerging laboratories

International Forensic Strategic Alliance

Version 1

IFSA

International Forensic Strategic Alliance

INTERNATIONAL FORENSIC STRATEGIC ALLIANCE

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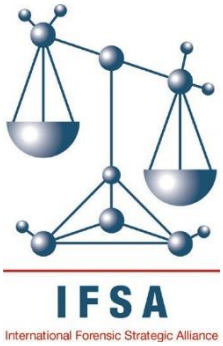

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INTRODUCTION

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 Toxicology Analysis. 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 Australian New Zealand (NIFS ANZ)
- the 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, United Nations Office on Drugs and Crime (UNODC), INTERPOL and Leverhulme Research Center for Forensic Science (LRCFS).

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 developed and revised. 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. Additional MRDs are in currently in development. For further information see the IFSA website: www.ifsa-forensics.org.

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

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

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 or equivalent academics qualification in chemistry or a specialized discipline associated with chemistry or toxicology. Coursework should include lectures and associated laboratory classes.

1.2 TRAINING

The laboratory shall have a documented training plan for new staff or new tasks, documenting the required standards of performance, competency, and assessment plan. The assessment shall be done, for example by fulfilling training plans or by performing the analysis of unknown samples. The training should be delivered by experienced staff who have been deemed competent to deliver training.

The training can comprise components such as relevant background information on toxicology, evidence handling, sampling protocols, analytical procedures, and instrumentation which the staff will employ during casework, including the code of ethics. Upon completion of the training, the staff shall be assessed as competent prior to assuming independent casework. A competency test will ensure appropriate skills and knowledge has been acquired during training. All training and competency tests should be documented, and records retained according to guidelines established by the laboratory. All analyst/technician(s) are recommended to participate in ongoing proficiency testing or interlaboratory comparison testing, and the results recorded.

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

[a] 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 Australian New Zealand (NIFS ANZ) – 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 FACILITIES

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

The laboratory should have appropriate utilities such as uninterrupted electrical power supply, air conditioning, air-tight windows, purified water, and adequate separated space and plumbing.

Biological specimens shall be stored in an area protected from bacterial contamination, cross-contamination, heat, and sunlight. Biological specimens (excluding hair specimens) require refrigeration or freezing. Refrigerators and freezers' temperatures shall be monitored and the laboratory shall specify an acceptable range of temperature for this equipment to ensure operation in accordance with sample storage requirements.

The facility shall be equipped with refrigerators and freezers dedicated to the storage of reference materials, chemicals and reagent, where applicable. Biological samples shall not be stored with reference materials. If having dedicated refrigerators and freezers is not practical, samples shall be physically separated from reference materials using measures such as robust plastic bags, boxes or other physical separators.

Analytical and sample storage areas shall be secured and access controlled.

2.2 EQUIPMENT & INSTRUMENTATION

All equipment and instruments used in casework for the identification of alcohols, drugs and poisons must be suitable and in proper working condition. The equipment and instruments shall be calibrated or undergo a performance check before use to ascertain reliable performance of test methods. Performance of equipment and instrument 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 equipment and instrument. 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 and instrumentation shall be appropriately validated and new equipment and instruments shall also be properly verified prior to application on casework.

2.3 CONSUMABLES

All chemicals, reagents and solvents used in Toxicology analysis 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 reagent should be dated and initialed when first opened.

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 references material, solvent checks, appropriate positive and negative control samples and blank samples. The results of the checks shall be recorded.

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3 COLLECTION, ANALYSIS, INTERPRETATION & REPORTING

3.1 COLLECTION

The proper selection, collection, and submission of specimens for toxicological analyses are of paramount importance if analytical results are to be accurate and their subsequent interpretation is to be scientifically sound and therefore useful in forensic casework. The laboratory should develop and provide detailed guidelines and instructions to all agencies or parties the laboratory serves. Instructions should:

- state the types and minimum amounts of specimens needed to accomplish the requisite analyses and subsequent interpretations.
- Whenever possible, the amount of specimen collected should be sufficient to ensure that enough remains for subsequent re-analysis if required.
- include the type and amount of preservative to be added to biological fluids, if required.

Submitting agencies should be instructed to indicate relevant medical history on living subjects or decedents who may carry a highly infectious disease such as tuberculosis, hepatitis or human immunodeficiency virus. However, laboratories should adopt “universal precautions” when handling biological specimens, regardless of reported medical history.

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 of the evidence. Exhibits shall be stored under appropriate conditions as far as possible so as to minimize the likelihood that the composition of the content is not altered.

The laboratory shall record the chain of custody of all exhibits, starting from the receipt until disposal/return of the exhibits. Only authorised staff shall have access to exhibits.

3.2 ANALYSIS

3.2.1 Screening Tests

In most instances where a laboratory is asked to look for drugs in biological specimens, screening tests are employed.

- Screening tests shall be appropriate and validated for the type of biological specimens being analyzed. For example, immunoassays used on whole blood shall be appropriately validated for that purpose. If a reporting cut-off is used, the accuracy and precision of the assay around that cut-off shall be demonstrated.
- Drug screening tests may be specific for a class of drugs (e.g opiates) or be a broad-based screen capable of targeting compounds of different classes.
- A positive result from a screening test indicates that the sample may contain drug(s) above the cut-off level. Similarly, a negative result does not necessarily indicate the absence of drug(s) in the samples but rather the absence of drug(s) above the cut-off level. It is standard practice that all positive screening test results are verified using a confirmatory technique (see Section 3.2.2).
- It is good practice to segregate the analysis of biological fluids from other exhibits suspected of containing drugs (e.g. spoons, syringes). If physical separation of the analytical areas is not practical, such as using different rooms, every effort should be made to use separate glassware and pipettes.

- Lack of residual contamination and carry over shall be demonstrated after high concentration exhibits have been analysed.

3.2.2 Confirmatory Tests

Results of positive screening tests shall be confirmed whenever possible by a second technique based on a different chemical principle. Reference materials should be included in all confirmatory analysis. Where possible, the confirmatory (second) test should be more specific than the screening test for the target analyte(s). The use of mass spectrometry is recommended as the confirmatory technique, where possible and practical[1].

In some circumstances, confirmation using the same system as the first might be acceptable if chemical derivatization (e.g. silylation or acylation) is used to change the retention times. However, confirmation using a second GC system with a similar though not identical column, is not usually acceptable since the retention indices of many analytes may not differ substantially from one system to the other (e.g. DB-1 and DB-17)[1].

It is a good practice to confirm the identity of an analyte in a different extract of the same specimen from that used for the first test, or in a second specimen.

The quantitation of an analyte may serve as acceptable confirmation of its identity if it was initially detected by a significantly different method (e.g. GC/MS SIM of a drug detected by immunoassay).

3.3 QUALITY MANAGEMENT

Quality assurance assumes a unique role in the forensic science disciplines because results are subject to challenge in the adversarial or inquisitorial justice system. One purpose of a quality assurance program is to detect error, whether random or systemic, and to initiate appropriate remedial action[2].

- Reference materials used shall be appropriate for the test being performed, and documentation shall be maintained describing their sources and dates of acquisition.
- Reference materials shall be stored according to the manufacturer's recommendation so as to ensure its stability and integrity.
- Where practical, the identity and purity of reference materials shall be verified by the laboratory.
- If a reagent is prepared in the laboratory, the source(s) of the chemical(s), the method of preparation, and verification of the final product should be recorded and maintained on file.

A control is a test sample, identical to the unknown, containing the analyte at a known concentration.

Generally, an adequate set of controls should include, at a minimum, a specimen that does not contain the analyte (defined as a negative control) and a specimen containing the analyte at a concentration (defined as a positive control) that realistically monitors the performance of the assay[2].

With each batch of specimens, whether a single specimen or multiple ones, controls should be carried through the procedure in parallel with the unknowns[2]. Controls are not analyzed for calibration purposes.

- The controls must include one positive and one negative control.
- In qualitative analysis, for positive and negative controls, the acceptable results may simply be positive or negative, respectively.
- In quantitative analysis, the negative controls should give results that indicate the analyte is absent, or below the Limits of Detection (LOD) for the assay. The positive controls should give results within an acceptable working range.

  (Note: An acceptable positive control result of ±20% is recommended for most drugs, except for controls that are at or close to the Limits of Quantitation (LOQ) of the assay, when ±25-30% may be more realistic.

- The control must give a result within a predetermined deviation from its mean value, or the test is deemed "out of control" and therefore, the result generated from the unknown specimen is unacceptable.

Each batch should be reviewed by an appropriately trained individual prior to being released.

Routine maintenance of equipment is an important part of any quality assurance program. It is a good practice to document all routine and non-routine maintenance, including tasks such as changing septa and liners on GCs.

(Note: Documentation may be in a logbook, which can be kept by larger equipment, or check-sheets filed in a ring binder. Multiple items of similar equipment (e.g. pipettors) should be labelled in order to readily differentiate them).

3.4 INTERPRETATION

A laboratory shall have a documented acceptance criteria for analytical techniques utilized in their laboratory. The criteria should include the personnel responsible for performing the interpretation (including their knowledge and experience) and the principles for interpretation. An example for GC/MS-EI full scan mass spectra interpretation is provided below:

GC/MS-EI full scan mass spectra is performed by the instrument's software as a semi-automated search against a commercial or user-compiled library. The quality of the match or "fit" may be aided by the factor that is generated, either as a ratio or percentage, where 1.0 or 100% are "perfect" matches. However, such "match factors" must be used as guides only and are not sufficiently reliable to be used as the final determinant of identification.

Final review of a "library match" must be performed by a toxicologist with considerable experience in interpreting mass spectra; experience and critical judgement are essential. Interpretation, at a minimum, should be based on the following principles[2]:

- For a match to be considered "positive", all of the major and diagnostic ions present in the known (reference) spectrum must be present in the "unknown". Occasionally, ions that are in the reference spectra may be missing from the "unknown" due to the low overall abundance of the mass spectrum.
- If additional major ions are present in the "unknown" it is good practice to try to determine if the "extra" ions are from a co-eluting substance or "background" such as column bleed or diffusion pump oil. Examination of reconstructed ion chromatograms of the suspected co-eluting substance relative to major ions from the reference spectrum will help to determine this.
- When GC/MS-EI selected ion monitoring mode is used for the identification of an analyte, whether as part of a quantitative procedure or not, the use of at least one qualifying ion for each analyte and internal standard, in addition to a primary ion for each, is strongly encouraged.

  (Note: An example of a commonly used acceptance criteria for ion ratios is ±20% relative to that of the corresponding control or calibrator. However, ion ratio ranges of up to ±25% or 30% may be appropriate depending on the circumstances of the instrument used and as determined by the individual laboratories.)

3.5 REPORTING

All efforts shall be directed to produce reports that are accurate, clear, objective and meet the requirements of the clients or 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 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);
- Type of tests performed
- An appendix or scope of analysis of drugs that can be reliably and reproducibly tested
- Results of analysis; 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 shall 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 that is competent to determine the disputed issue.

4 PROCEDURES, PROTOCOLS AND VALIDATION

4.1 PROCEDURES AND PROTOCOLS

The laboratory procedure should include administrative procedures as well as analytical methods and be reviewed, signed, and dated whenever it is first placed into use or changed. The analytical procedure manual should include, for each analytical procedure if appropriate, the following:

- theory and principle of the method,
- instructions for preparation of reagents,
- details of the analytical procedure,
- instructions for preparation of calibrators and controls,
- information about any special requirements for handling reagents or for ensuring safety,
- validation parameters (e.g. LOQ, linearity), and
- criteria for the acceptance or rejection of qualitative or quantitative results or a reference to this information.

Analytical procedures can 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 reference materials to ensure the quality of analysis. Significant changes in protocols or procedures must be either validated or verified, documented and approved by an authorised person before use.

(Note: Examples of significant changes include using an alternate chromatography stationary phase, altering the polarity of the extraction solvent or mobile phase or modifying the GC oven temperature).

Approved changes shall be communicated effectively to all staff involved. In-house developed methods must produce acceptable results consistent with specific requirements or previously validated methods prior to implementation.

4.2 VALIDATION[3]

All methods (published or in-house methods) used for toxicology analysis 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.

Toxicology methods are typically categorized as screening methods, qualitative confirmation/identification methods, or quantitative methods. The following validation parameters shall be evaluated, where applicable:

- Limit of detection (LOD) – to estimate the lowest concentration of an analyte in a sample that can be reliably differentiated from the matrix and identified by the analytical method.
- Carryover – to check the appearance of unintended analyte signal in samples after the analysis of a positive sample.
- Interference studies -non-targeted analytes (i.e, matrix componens, other drugs and metabolites, internal standard, impurities) which may impact the ability to detect, identify or quantitate a targeted analyte.
- Precision – to measure the closeness of agreement between a series of measurements obtained from multiple samplings of the same homogenous sample. It is expressed numerically as the coefficient of variation.
- Bias – to estimate a systematic measurement error, calculated as the difference between the mean of several measurements, to a known true value and reported as percent difference.

- Lower LOQ – to estimate the lowest concentration of an analyte in a sample that can be reliably measured with acceptable bias and precision.
- Calibration model – to demonstrate the relationship between the concentration of analyte and the corresponding instrument response.
- Estimation of the measurement of uncertainty.

When analyses are being performed on unusual specimens (decomposed tissue, vitreous fluid, etc.), appropriate matrix-matched calibrators or controls should, when possible, be prepared and tested concurrently with the specimens.

For immunoassays, a laboratory should, at a minimum, be able to demonstrate that the blank or negative calibrator plus two standard deviations does not overlap with the cut-off or the lowest positive calibrator. Alternatively, the laboratory may determine the LOD. One way of determining the LOD is to take the mean value for the blank and add three standard deviations (LOD= Xm + 3SD).

The use of a suitable internal standard for all chromatographic assays (e.g. GC, HPLC, GC/MS) is recommended. The internal standard should have chemical and physical properties as similar to the analyte as possible. If the analyte is to be derivatized, an internal standard should be chosen which will form an analogous derivative. The internal standard should be added to the sample at the earliest possible stage in the method, and in any event before buffering and extraction of the sample.

Linearity of the procedure should be established by using at least three calibrators. The concentration of the calibrators should be such that they bracket the anticipated concentration of the specimen(s) and are evenly spaced, where possible.

If the concentration of the specimen exceeds the concentration of the highest calibrator, the specimen should be diluted and re-extracted if accurate quantitation is required. Otherwise, the specimen should be reported as having a concentration greater than the highest calibrator. If the concentration of the specimen should be less than that of the lowest calibrator, an additional calibrator should be set up which falls below the expected range of the analyte in the sample.

Criteria for acceptance of a chromatographic calibration should be stated in the method. For a multi-point calibration this factor is usually the correlation coefficient. For most applications, an acceptable correlation coefficient is 0.99. However, there may be circumstances where a correlation coefficient of 0.98 is minimally acceptable. In addition, it is good practice to evaluate the range of the calibration by calculating the value of each calibrator against the curve.

For specimens having concentrations significantly higher than the highest calibrator, the laboratory should exercise precautions so that carry-over of analyte into the next specimen does not occur. Similarly, specimens with very low concentrations should be checked to ensure that carry-over from a previous very high positive has not occurred.

Retention time should be part of the acceptance criteria for chromatographic assays. For example, in GC based assays, deviations of 1 - 2% from the calibrators or controls may be acceptable. Slightly larger deviations may be acceptable for HPLC based assays, particularly where the mobile phase is being programmed non-isocratically.

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
- Approval and authorisation.

5 QUALITY MANAGEMENT

5.1 QUALITY SYSTEM

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

The quality management system shall cover all procedures and reports related to toxicology analysis. 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, where applicable:

- 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.
- Reference materials, 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.
- Proficiency testing for monitoring the laboratory's performance.
- Laboratory audits and the follow up of 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 Toxicology however these terms are widely utilized in the forensic 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.
Assessments	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 instrument 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.
Calibrator	A solution, either prepared from the reference material or purchased, used to calibrate the assay. Where possible, calibrators should be prepared in a matrix similar to that of the specimens.
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 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.
Control	A solution either prepared from the reference material (separately from the calibrators; that is, weighed or measured separately), purchased, or obtained from a pool of previously analyzed samples. Controls from any of these sources are used to determine the validity of the calibration; that is, the stability of a quantitative determination over time. Where possible, controls should be matrix-matched to specimens and calibrators, as indicated above.
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.
Forensic Urine Drug Testing	Determines the absence or presence of drugs and their metabolites in urine to demonstrate prior use or abuse.
Human-Performance Forensic Toxicology	Determines the absence or presence of ethanol and other drugs and chemicals in blood, breath, or other appropriate specimen(s), and evaluates their role in modifying human performance or behaviour. *(The analysis of ethanol in breath, although important, was not considered by the committee because such tests are not conducted in a laboratory setting)*
Laboratory	A facility providing Toxicology analysis service.
Laboratory staff	Scientific personnel analysing 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.
Post Mortem Forensic Toxicology	Determines the absence or presence of drugs and their metabolites, chemicals such as ethanol and other volatile substances, carbon monoxide and other gases, metals, and other toxic chemicals in human fluids and tissues, and evaluates their role as a determinant or contributory factor in the cause and manner of death.
Preventive maintenance	A procedure of inspecting, and reconditioning 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.
Reference Material	A reference material possessing one or more properties that are sufficiently well established that it can be used to prepare calibrators.
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 reviewer	An evaluation of appropriateness of analytical method, sampling procedure, data, results and conclusions. This review must be conducted by 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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