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CRITERIA FOR LABORATORY ACCREDITATION IN THE FIELD OF FORENSICS

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1. Purpose and Scope

This document offers guidance to all managerial and technical requirements for laboratories accredited under the SANAS forensic science laboratory (accreditation program, appendix 14). These criteria have taken the following sources into consideration:

Note: Crime scene investigation does not form part of the scope of this document.

This document is applicable to all forensic science laboratories irrespective of the range or number of forensic services provided or the number of personnel. It can also be applied to forensic science laboratories which operate independently, forensic laboratories which are part of a parent (non-forensic) organisation, laboratories which operate one or more facilities under a centralised management, and laboratories which operate one or more independently managed facilities.

This document is applicable to all laboratories requiring accreditation for forensic activities.

2. References

- ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories
- NATA Accreditation Criteria for Forensic Science Laboratories
- ASCLD/LAB Accreditation Criteria

3. Introduction

ISO/IEC 17025 sets out the requirements which must be met by a laboratory if it is to be recognised as being competent to carry out tests and/or calibrations, including sampling (or sample procurements). It is applicable to all facilities performing tests and/or calibrations regardless of size or type of service provided. ISO/IEC 17025 in Annex B makes specific provision for what it calls amplification or interpretation of the standard. To make it as easy as possible for South African forensic science facilities, one document that details all criteria (ISO/IEC 17025 and the specific, technical criteria) has been developed. In an additional effort to make the criteria as readily understood as possible, the document has been formatted in a more logical sequence using terminology that is better understood by forensic science and paternity testing laboratories. This reformatting has also had the effect of removing as much repetition and redundancy as possible from the ISO/IEC 17025 elements of the accreditation criteria.

4. Terminology

The program recognises that not all forensic science services are performed in or provided by laboratories, hence the term “forensic science service provider” would be preferable. The expression “laboratory” is, however, in more common usage and is used throughout this document.

The words “shall” and “must” are used interchangeably throughout this document and are used to describe mandatory criteria. (It is accepted, however, that mandatory criteria may be ‘not applicable’ in some circumstances).

The notes provide clarification of the text, examples and guidance.

5. Legislation Requirements

It is the responsibility of each laboratory to ensure that it complies with all relevant national legislation. Legislative requirements will supersede the criteria detailed in this document. It is strongly recommended that laboratories hold copies of relevant legislation.

6. Accreditation Criteria

The following pages provide SANAS accreditation criteria for forensic science laboratories.

6.1 Organisation

6.1.1 General

6.1.1.1 The forensic science laboratory or organisation of which it is a part shall be legally identifiable.

6.1.1.2 Where the forensic science laboratory is part of a parent organisation, the position of the forensic science laboratory in the overall organisational structure must be documented, for example by the use of organisational charts.

6.1.1.3 The forensic science laboratory shall be organised and operate in such a way that, when performing work in its permanent facilities, regional laboratories and/or any temporary facilities, it meets accreditation requirements.

6.1.1.4 The laboratory shall clearly define and document the type and scope of the forensic science services it provides. Refer to appendix 14.

6.1.1.5 Arrangements shall be in place to ensure that:

a) the laboratory will not engage in any activities that might diminish trust in competence, impartiality, judgement or operational integrity; and
b) personnel are free from any commercial financial or other pressures that may adversely affect the quality of the work.

6.1.1.6 Documented policies and procedures must exist to ensure the protection of clients confidential information and propriety rights.

6.1.2 Objectives

6.1.2.1. The laboratory shall identify the policies and objectives to be achieved by implementing the quality system. The objectives shall be set out in a quality policy statement issued under the authority of the chief executive of the forensic science laboratory (who may be the laboratory manager) and documented in a quality manual.

It shall include:

a) a statement of the laboratory's intentions with respect to the standard of service it will provide;
b) the purpose of the laboratory's quality system;
c) the role and responsibilities of technical management and the quality manager (refer 5.1.4.4 and 5.1.4.5) including the responsibility for ensuring compliance with accreditation criteria
d) a requirement that all personnel be familiar with the quality system document and implementation of the policies and procedures at all times;
e) the laboratory's commitment to good professional practice and quality of its service to its clients

6.1.2.2 The objectives shall be relevant to the needs of the community serviced by the laboratory.

6.1.2.3 Laboratory personnel shall understand and support the relevant objectives.

Note: A written statement of the objectives provides direction through a careful analysis of what the manager and the parent organisation believe are the appropriate functions of the laboratory and the direction in which it shall be moving. Objectives make a significant contribution to the management process and serve as a basis for a sound management philosophy. Objectives will vary from laboratory to laboratory, depending on factors such as the size and range of services provided, nature of the parent organisation, whether the laboratory stands alone or is part of a system, the size of the population served and the nature of the area served (e.g. dense urban, dispersed rural). The objectives must be relevant to the needs of the community serviced. Regardless of the wording of the objectives, the objectives have no value unless clearly understood and supported by the personnel.

6.1.3 Administrative Practice

6.1.3.1 The laboratory shall document how it intends to meet its objectives. This document shall take available resources into consideration.

6.1.3.2 The laboratory shall have and use a management information system (MIS) where relevant, which provides information, to assist it in accomplishing its objectives.

The sophistication of the MIS will be dependent on the size and activity of the laboratory.

6.1.3.3 Prior to undertaking new contracts or commencing new forensic services, the laboratory must ensure that:

(a) Necessary requirements, (i.e. what tests shall be performed) including the methods, are adequately defined, documented and understood; and

(b) it has the capability (i.e. physical, intellectual and informational ability and personnel with appropriate skills and expertise) and resources to meet the client's needs and requirements.

Note 1: New work is any work falling outside normal work of the laboratory for which the laboratory has been accredited. This is done for all routine work.

Note 2: It is often the responsibility of the laboratory to guide the client in determination of the most appropriate test methods.

6.1.3.4 Records of such reviews must be maintained. Such records shall contain a conclusion on whether to accept/reject the contract.

6.1.4 Organisational Structure

Note: There is no single perfect organisational structure for a forensic laboratory. Interacting variables such as numbers of personnel, degree of interaction of personnel required, level of decision-making and congruence of personnel and organisation goals must be considered when grouping work and resources.

6.1.4.1 The organisational structure must group the work and personnel in a manner that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines.

6.1.4.2 The laboratory manager must consider and take appropriate action to correct any discrepancies with regard to numbers of personnel when grouping work and resources.

6.1.4.3 The laboratory shall normally use only personnel who are permanently employed by, or under contract to the laboratory. Where other personnel are used, the laboratory, shall ensure that all applicable accreditation criteria are met with respect to such personnel.

6.1.4.4 The laboratory must define with the aid of organisation charts, the organisation and management structure of the laboratory including the relations between management, technical operations, support services and the quality management system.

6.1.4.5 The responsibility, authority and interrelation of all personnel who manage or perform work affecting the quality of the forensic science services provided, must be documented in the form of job descriptions and/or organisation charts and/or in working instructions.

There must be job descriptions for all personnel involved in the provision of forensic science services.

6.1.4.6 The laboratory must have technical management or a responsible person(s), however named, which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.

The technical management or responsible person(s) shall be responsible for ensuring accreditation requirements are met.

The roles and responsibilities of technical management must be defined and documented.

6.1.4.7 A member of the laboratory's managerial personnel shall be appointed quality manager (however named) who, irrespective of other responsibilities, shall have defined authority for ensuring that the quality system is established, implemented and maintained and for reporting on the performance of the quality system to the management for review and as a basis for improvement of the quality system.

The quality manager shall have training in quality assurance concepts and techniques and ideally have organisational autonomy from the technical operations.

The quality manager and the technical manager and/or laboratory manager may be one and the same person in small laboratories.

Where the forensic science laboratory is part of a parent organisation, it may not be necessary for the laboratory to appoint its own quality manager. In such cases, however, a member of the laboratory's personnel must be designated as being responsible for co-ordinating the maintenance of the quality management system in the laboratory.

Where the forensic science laboratory operates multiple facilities with the one quality manager responsible for all facilities, a personnel at each facility must be designated as being responsible for co-ordinating the maintenance of the quality management system in the laboratory.

(a) The quality manager shall have direct access to the highest level of management at which decisions are taken for the laboratory on policy and resources.

(b) The scope of responsibilities and authority of the quality manager

must be clearly defined and documented and shall, at least include the following:

- Maintenance of the quality manual
- Monitoring of laboratory practices to verify continuing compliance with policies and procedures
- Evaluation of instrument calibration and maintenance records
- Periodic assessment of the adequacy of report review activities
- Ensuring the validation of new technical procedures
- Investigation of technical problems, proposal of remedial actions and verification of their implementation
- Administration of proficiency testing and evaluation of results
- Selection, training and evaluation of internal auditors
- Scheduling and co-ordination of quality system audits
- Maintenance of training records of laboratory personnel
- Training recommendations to improve the quality of laboratory personnel
- Proposal of corrections and improvements to the quality system

6.1.4.8 Where possible, deputies must be appointed for key personnel. This must include the laboratory manager, quality manager, technical manager and laboratory supervisors. Where necessary, other personnel may require designated deputies.

6.1.5 Delegation of Authority

6.1.5.1 The laboratory manager (however named) authority and responsibility must be fully defined.

6.1.5.2 The laboratory manager shall have authority to commensurate with his/her responsibilities.

6.1.5.3 There must be sufficient delegation of authority to managerial/supervisory personnel.

6.1.5.4 The authority of supervisors must be commensurate with their responsibilities.

6.1.5.5 Each subordinate must be accountable to only one immediate supervisor per specific function where relevant.

6.1.5.6 Performance expectations must be established and understood by laboratory personnel. The immediate supervisor shall document performance expectations.

Note: In every organisation, someone must be assigned responsibility for the efficient and effective performance of specific functions. It is important that the persons assigned such responsibilities also be delegated appropriate, well-defined authority to act or direct the actions of others. Effective organisation is precluded unless the ~~director~~ manager has the authority to accomplish the mission of the laboratory. As managerial responsibilities increase in scope and complexity, delegation of authority down the organisation becomes necessary. It is important, that all personnel clearly understand what is expected of them.

6.1.6 Supervision

6.1.6.1 General

Only personnel approved as technical signatories may perform accredited test work.

Personnel who are not technical signatories shall work under the supervision of a technical signatory.

Note: In small laboratories the nature of the structure may be such that supervisors are not required.

6.1.6.2 Multi-site Laboratories

Where a forensic science laboratory operates multiple facilities, procedures must be in place to verify each facility's continuing compliance with the laboratory's quality system.

As a minimum, each facility must be visited annually by the laboratory manager or a senior member of laboratory personnel with either administrative responsibility for the facility or relevant technical expertise.

Note: The person delegated responsibility for performing internal audits shall be considered appropriate for all such visits.

Such visits must include a review of the facility's compliance with the laboratory's quality system. (Documented evidence of such review shall be maintained by the laboratory).

6.2 Quality System

6.2.1 General

The forensic science laboratory shall establish, implement and maintain an effective quality management system appropriate to the type, range and volume of forensic science activities it undertakes.

The quality system shall include policies and procedures addressing all the relevant criteria detailed in these accreditation requirements.

6.2.2 Documentation

6.2.2.1 Quality Manual

(a) All elements of the laboratory's quality system shall be documented. This will include all policies, systems, programs, procedures, instructions etc where the absence of documentation would adversely affect the test or examination results.

All policies and procedures established to meet the criteria detailed in these accreditation requirements must be documented.

(b) Documentation of the quality system will be in a quality manual (however named) with cross-referencing to related operations documentation, and other relevant documentation.

Cross-referencing may include the reference after each appropriate statement or in an index with the paragraph number and cross-reference to related documentation.

(c) The quality manual and, where relevant, the associated operations documentation shall be kept up-to-date under the authority and responsibility of the quality manager.

(d) Documentation of the laboratory's quality system must include, where appropriate, the protocol(s) permitting departures from documented policies and procedures.

(e) Quality system documentation shall be readily available to all personnel.

6.2.2.2 Document and Information Control

(a) The forensic science laboratory shall establish and maintain documented procedures to control all documents and information that relate to its quality system and to the operation of the laboratory within the scope of accreditation.

A document is any medium used to record information or instructions. Documents include manuals, workbooks, worksheets, charts, posters, notices, memoranda, drawings, plans, software etc. Documents maintained in computerised systems must also be considered. It shall also include documents of external origin such as standards, regulations, manufacturers manuals etc.

(b) All documents, which form part of the quality management system, shall be reviewed and approved for use by authorised personnel prior to issue.

A master list or equivalent document control procedure identifying the current revision status of documents in the quality system shall be established and be readily available to preclude the use of obsolete documents.

The procedures shall also ensure that:

- the authorised and controlled issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed.

- documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

- obsolete documents are deleted from the master list and promptly removed from all points of issue or use, or otherwise assured against unintended use;

- any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified.

All documents shall be uniquely identified, such identification to include the date of issue and the revision number, the total number of pages and the authority for issue by e.g. name/initials.

(c) Changes to documents shall be reviewed and approved preferably by the same personnel who performed the review and approval unless specifically decided otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

Change to documents made within the most recent period shall be indicated, either in the document or the appropriate attachments.

If the laboratory's documentation control system allows for the temporary amendment of documents by hand pending their reissue, the procedures and authorities for such amendments shall be defined and shall ensure that amendments are initialled and dated. Documents amended by hand shall be formally reissued as soon as practicable. All amendments shall be in ink. Pencil is not permissible.

6.2.3 Control of Records

6.2.3.1 General

(a) The forensic science laboratory shall establish a system that will ensure that all records required by its quality system are maintained. (Refer to appendix 3)

Note: Some examples of records required by these accreditation criteria include case records, internal audit records, management review records, complaints, personnel training records, quality assurance records (including quality control, proficiency testing, court testimony monitoring, corrective action), equipment maintenance and calibration records.

(b) The laboratory must document its policies for the identification, collection, access, storage, maintenance and disposal of records, whatever their type of format.

(c) Retention times must be established and documented for all record types, but will not be less than three years. Where legislation requires longer or shorter retention periods, this shall be complied with.

(d) All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage, deterioration or loss.

Where hard copies exist for computer disks, it will not be necessary to store or retain the disks.

(e) All records must be accompanied by the identity or the person making the record.

(f) All observations and calculations shall be clearly and permanently recorded at the time they are made. (Refer also 5.2.3.2.(d)) Where computer programs are used this shall be recorded.

Corrections to records may be made by an initialled, single strikeout and be dated. No recorded information is to be obliterated or erased.

Corrections to results, data etc stored on computer must also be identified as such where possible. (Some record of changes to computer stored data shall be maintained). This is not applicable to any corrections made to typing errors on reports before the final signed report is dispatched by the examiner.

6.2.3.2 Case Records

(a) The laboratory must maintain a case record in a designated location under a unique designator, usually a laboratory case number.

Note: Administrative and analytical documentation generated by a laboratory on a particular case constitutes a case record.

(b) The laboratory must have documented policies:

- Describing its case designators systems; and
- Detailing the minimum information that is to be included in a case record.
- Describing the electronic storage of records

(c) All data and observations and any other analytical or administrative records which support conclusions must be generated and kept by the

laboratory.

(d) Where instrumental analyses are conducted, operating parameters must be recorded.

Note: Instrument charts and graphs on analyses that are batched (e.g. blood alcohol determinations, drug screening), may be more appropriately kept in a central location as specified in the laboratory's procedure manuals.

Abbreviations are acceptable only if they are readily comprehensible to a reviewer.

(e) Where appropriate, observations or test results must be preserved by hard copy either by photography or electronic scanning thereof (e.g. electrophoretic runs, physical matches). In paternity testing, hard-copy records may not be viable Photocopies may also be suitable (e.g. thin-layer chromatography results, questioned documents).

(f) When a test result or observation is rejected, the reason(s) must be recorded.

(g) All calculations and manual data transfers must be checked, preferably by a second person. The case record must include an indication that such checks have been performed.

(h) Each page of every document in the case record must bear the laboratory's unique case identifier. Machine-generated records meet this requirement if they include the printed case identifier.

(i) If more than one person works on a case, it must be clear from the case record who has performed all stages of the analysis/examination.

(j) Since case notes and records of observations are subject to subpoena or discovery, they must be of a permanent nature. Hand-written notes and observations shall be in permanent ink not pencil. Pencil (including colour) may, however, be appropriate for diagrams or making tracings. Any relevant non-permanent media shall be photocopied, in order to generate a permanent record.

It must be clear from the case record when each stage of the analysis/examination was performed (e.g. relevant date(s) and, where appropriate, time(s)).

(k) Laboratory generated examination records must be paginated using a page numbering system indicating total number of pages (e.g. page x of y).

Note: An index system may be added to the case file to allow for incorporation of further information/documentation as investigations continue.

6.2.3.3 Computers

When computers are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test/examination data or other information pertaining to an investigation, the laboratory must ensure that:

- The requirements of these accreditation criteria are met;
- Computer software is documented in sufficient detail and validated or otherwise checked as being adequate for use;

Note: As a minimum indirect verification by using positive and negative controls with a proficiency test may be used to verify the correct functioning of the computer software.

- All computer data is backed-up on a regular basis. The procedure for back-up shall be documented.
- Appropriate procedures are documented and implemented to maintain the integrity and security of data, including the prevention of unauthorised access to amendment of computer records.

Where computers are used to analyse and process the result, manuals that are sufficiently descriptive and the use of the necessary controls and reference materials will suffice to demonstrate the validity of the computer software.

6.2.4 Internal Audits (Refer to appendix 4)

6.2.4.1 The forensic science laboratory shall, at least once per year, conduct internal audits of all its activities to verify that its operations continue to comply with the requirements of its quality system and accreditation criteria. All elements of the quality system must be audited at least annually.

6.2.4.2 Audit procedures must be documented.

6.2.4.3 It is the responsibility of the quality manager to plan and organise audits. Audits must be carried out in accordance with a documented predetermined schedule that covers all aspects of the quality system.

6.2.4.4 Personnel trained as internal auditors shall be formally authorised to perform the assessments and they shall conduct internal audits.

Note: Personnel shall be trained in audit/assessment techniques either in-house or using an external training organisation. Records of all such training shall be maintained.

6.2.4.5 Personnel shall not audit their own activities. Auditors shall be, wherever resources permit, independent of the activity to be audited.

6.2.4.6 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test results, the laboratory must take timely corrective action and must notify, in writing, any client whose work may have been affected.

The laboratory management must ensure that these actions are discharged within the agreed time frame.

6.2.4.7 Findings from internal audits and any corrective actions that arise must be recorded.

6.2.5 Management Review

6.2.5.1 The quality management system and testing and related activities shall be reviewed at least once a year by management to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

The review shall take account of reports from managerial and supervisory personnel, the outcome of internal audits, external assessments, proficiency testing performance, changes to the volume and/or type of work undertaken, feedback from clients and other relevant factors.

6.2.5.2 Procedures for management review shall be documented.

6.2.5.3 Any actions that arise from management review must be recorded. Conclusions from the management review shall be recorded.

6.2.5.4 The quality manager shall ensure that these actions are discharged within the agreed time frame.

Note: An annual review of the quality system is important for ensuring that laboratory management can continue to be confident that all measures are being taken to provide the highest quality service.

6.2.6 Service to the Client Feedback/Complaints

6.2.6.1 The laboratory must establish and document its policies and procedures for the resolution of complaints or other feedback received from clients and other parties about its activities.

6.2.6.2 When a complaint raises doubt about the laboratory's compliance with its documented procedures and/or with accreditation criteria, the areas of activity or responsibility involved must be investigated and, if necessary, audited and the necessary action taken.

6.2.6.3 A record shall be maintained of all complaints and of the investigations and any corrective action(s) taken.

6.2.6.4 The laboratory shall seek feedback form its customer. The feedback shall be analysed and used to improve the management system, testing activities and customer service. Records of feedback given to clients shall also be kept.

6.2.7 Corrective Actions

6.2.7.1 General

The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

6.2.7.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

6.2.7.3 Selection and implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

6.2.7.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

6.2.8 Preventative Action

6.2.8.1 All operational procedures shall be systematically reviewed at regular intervals to identify any potential sources of non-conformance and any opportunities for improvement, either technical or with the quality management system. Action plans shall be developed, implemented and monitored, to reduce the likelihood of the occurrence of non-conformance and to take advantage of improvement opportunities.

6.2.8.2 After the implementation of preventive actions, the laboratory shall monitor the results to establish any reduction in deficiencies or improvements to operations, thereby establishing the effectiveness of the preventive action.

6.2.8.3 The results of preventive actions shall be submitted for the management review

6.2.9 Control of Non-conforming work (Refer to appendix 11 and 12)

The laboratory shall have a policy and procedures that shall be implemented when it establishes that any aspect of its service, including the results of tests/examinations, do not conform with its own procedures or the agreed requirements of its clients. The policy and procedures shall ensure that:

- responsibilities and authorities for the management of non-conforming work are designated;
- the actions to be taken when non-conforming work is identified are defined;
- an evaluation of the significance of the non-conforming work is made;
- work is halted and results/reports are withheld, as necessary;
- remedial actions are taken immediately together with any decisions about the acceptability of the non-conforming work;
- where necessary, the results of non-conforming work released to clients are recalled;
- the responsibility for authorising the resumption of work is defined.

6.3 Accommodation and Safety

Note: One key responsibility of the laboratory manager is to provide an adequate and safe working environment. Laboratory facilities should reflect due consideration of space, design, security, health and safety. It is recognised that laboratories will be required to comply with building and safety legislation. The requirements of such legislation will supersede the requirements of the accreditation criteria.

6.3.1 Security

6.3.1.1 Access to the operational area of the laboratory must be controllable and limited.

(a) Visitors must not have unrestricted access to the operational areas of the laboratory.

(a) Each out-of-hours access to the operational area of the laboratory must be recorded.

(b) Where a laboratory exists within a host agency facility, documented procedures may be required to permit entry during off-hours for emergencies. Such arrangements are acceptable if they include, for example, the breaking of a storage seal to access a key, code etc and notifying an authorised laboratory person. A record system shall record each emergency access to the laboratory.

6.3.1.2 All security doors must have keys or other access devices limited to authorised personnel.

The entire exterior perimeter of a forensic science laboratory must inhibit unauthorised access.

6.3.1.3 Short-term and long-term evidence storage areas require limited/controlled access.

6.3.1.4 Each access device (key, magnetic cards etc) shall be accounted for in a register and their distribution limited.

6.3.1.5 The laboratory must be monitored during vacant hours by an intrusion alarm or by security personnel.

6.3.1.6 In keeping with any relevant statutory requirements appropriate fire extinguishing devices must be available.

6.3.1.7 Policies and procedures on laboratory security must be clearly documented.

6.3.2 Environmental Conditions

6.3.2.1 The environment in which tests/examinations are undertaken shall not invalidate the results or otherwise adversely affect the required quality of the work performed. Particular care must be taken when work is performed at sites other than the permanent laboratory facility.

6.3.2.2 The laboratory shall monitor, control and record environmental conditions where they influence the quality of results.

6.3.2.3 There must be effective separation of adjacent areas in which incompatible activities are performed. Appropriate measures must be taken to prevent cross-contamination.

6.3.3 Space

6.3.3.1 Sufficient space must be provided for storage of supplies, equipment and tools.

6.3.3.2 Where possible, there must be a clear delineation of areas used for the clerical aspects of laboratory work and areas used for testing/examinations.

6.3.3.3 Adequate and appropriate space must be available for records, reference works and other necessary documents.

(a) Sufficient space (i.e. compliance with the manufacture's specification for the equipment) must be available for each instrument to facilitate its operation.

(b) Accessories should be stored near each instrument to facilitate its use and operation or specifically designated area.

6.3.4 Design

The design should maximise laboratory functions and activities, safeguard the physical evidence, protect the confidential nature of the laboratory operation and provide a safe and healthy working environment. Lack of space and/or fiscal resources are not acceptable reasons for unacceptable laboratory practices.

6.3.4.1 The physical design should permit the efficient flow of evidence from the time of its acceptance until its proper disposal.

6.3.4.2 The relative locations of functional areas should facilitate the use of equipment and instruments.

6.3.4.3 Adequate and proper lighting must be available for personnel to carry out assigned tasks.

6.3.4.4 Adequate and proper plumbing and wiring must be available and accessible to carry out assigned tasks.

6.3.4.5 The laboratory must have proper general ventilation.

6.3.4.6 There should be adequate heating, cooling and humidity control in the laboratory.

6.3.4.7 Bench and floor surfaces must be appropriate for the work performed

6.4 Personnel

6.4.1 Qualifications (Refer to appendix 5)

6.4.1.1 Management

The laboratory director shall preferably have an appropriate scientific and/or technical background. If the director lacks a scientific background, there must be support within management by personnel with appropriate scientific background.

Note 1: Appropriate scientific and/or technical background implies that they have sufficient knowledge to make an informed and appropriate decision.

Note 2: Where a laboratory director lacks forensic experience or experience in management, there must be support within management by other staff who have forensic science and management experience.

6.4.1.2 Analyst/Examiners

(a) Controlled Substances

- Analysts must have education and experience/training commensurate with the examinations and testimony provided. A Bachelor degree, or Diploma or equivalent, in a natural science is required.
- Analysts must have a good understanding of the principles, uses and limitations of the instruments and the methods and procedures as applied to the tasks performed.
- Each analyst must successfully complete a competency test prior to assuming casework responsibility.

(b) Toxicology

- Analysts must have education and experience/training commensurate with examinations and testimony provided. A Bachelor degree, or Diploma or equivalent, in a natural science is required.
- Analysts must have a good understanding of the principles, uses and limitations of the instruments and the methods and procedures applied to the tasks performed.
- Each analyst must successfully complete a competency test prior to assuming casework responsibility.

(c) Trace Evidence

- Analysts must have education and experience/training commensurate with the examinations and testimony provided. A Bachelor degree, or Diploma or equivalent, in a natural science is required.
- Examiners must have a good understanding of the principles, uses and limitations of the instruments and the methods and procedures applied to the tasks performed.
- Each examiner must successfully complete a competency test prior to assuming casework responsibility.

(d) Serology

- Analysts must have education and experience/training commensurate with the examinations and testimony provided. A Bachelor degree, or Diploma or equivalent, in a natural science is required.
- Analysts must have a good understanding of the principles, uses and limitations of the instruments and the methods and procedures applied to the tasks performed.
- Each analysts must successfully complete a competency test prior to assuming casework responsibility.

(e) DNA and Body Fluid Identification

- Each analyst must have education, training and experience consistent with the requirements detailed in the approved Standards for DNA analysis. A Bachelor degree, or Diploma or equivalent, in a natural science is required. Analyst who have been actively been doing work prior to these the regulations coming into effect.
- Analysts must have a good understanding of the principles, uses and limitations of the instruments and the methods and procedures applied to the tasks performed.
- Each analysts must successfully complete a competency test prior to assuming casework responsibility.

(f) Firearms/Toolmarks

- A Bachelor degree, diploma or equivalent, in a natural science or in criminalistics is desirable for firearms/toolmarks examiners. The successful completion of an intensive training program is required.
- Examiners must have a good understanding of the principles, uses and limitation of the instrument and the methods and procedures used as applied to the tasks performed.
- Examiners must have education and experience/training commensurate with the examinations and testimony provided. Independent case examinations must not be undertaken until after extensive instructions from a qualified examiners has been completed.
- Each examiner must successfully complete a competency test prior to assuming casework responsibility.

(g) Forensic Ballistic Specialist (FBS)

- A Bachelor degree, diploma or equivalent, in a natural science or in criminalistics is desirable for Forensic Ballistic Specialists. The successful completion of an intensive internal training program is required.
- An FBS must have a good understanding of the principles, uses and limitation of the instruments and the methods and procedures used as applied to the tasks performed.
- An FBS must have education and experience/training commensurate with the examinations and testimony provided. Independent case examinations must not be undertaken until after extensive instruction from a qualified examiner has been completed
- An FBS must be conversant with one or more of the following tasks: ammunition identification; microscopic identification of fired cartridge cases and/or bullets; investigation of firearm mechanisms; restoration of obliterated numbers; investigation of home-made firearms and ammunition; investigation of tool and toolmarks; investigation of firearms, received with fired cartridge cases and/ or bullets; shot distance determination; crime scene investigation; court testimony and assistance of Council must be conversant with one or more of the following tasks: ammunition

(h) Latent Prints

- A Bachelor degree, diploma or equivalent, in science is *desirable* for latent print examiners. The successful completion of an intensive internal training program is required.
- Examiners must have a good understanding of the principles, uses and limitation of the instruments and the methods and procedures used as applied to the tasks performed.
- Examiners must have education and experience/training commensurate with the examinations and testimony provided. Independent case examinations must not be undertaken until after extensive instruction from a qualified examiner has been completed.
- Each examiner must successfully complete a competency test prior to assuming casework responsibility.

6.4.1.3 Technical Support and laboratory assistants (Specialised auxiliary services officer)

(a) Support personnel must meet the requirements of their job descriptions.

(b) The job description and the duties performed must be in agreement.

(c) Adequate proficiency testing and/or competency testing (when appropriate) must be completed prior to assignment of tasks.

(d) Technical support personnel/Laboratory assistants must have received adequate training and have practical knowledge of the specific function or test performed.

Technical support may be personnel that assist the forensic examiner with his/her testing systems.

6.4.2 Training and Development (Refer to appendix 6)

6.4.2.1 The laboratory shall have a documented procedure for the evaluation of personnel competency and effectiveness of personnel training.

6.4.2.2 A training program must be established and documented for each functional testing area of the laboratory.

(a) The training program shall include:

- Induction into the forensic science laboratory which includes the laboratory's quality management system.
- Knowledge of the field of forensic science in general, including criminal law and procedures.
- The knowledge and skills essential to performing work and good laboratory practice at an appropriate standard of competence in a specific work area.
- the performance of competency test(s) in applicable areas; and
- where relevant, the presentation of evidence in court.

(b) Competency testing shall include:

- an evaluation of knowledge of existing literature; and
- the examination and identification of known and unknown materials relevant to their operational area.

Note: Material from previously analysed/examined and evaluated proficiency tests may serve this purpose.

6.4.2.3 Continued Development Performance

New members of staff, whatever their qualifications or previous experience, shall have satisfactorily completed the laboratory's training program before being authorised to work independently.

Laboratory management shall formally authorise personnel to perform work independently.

6.4.2.4 Training records shall be maintained for all personnel. Such records must include details and dates of:

(a) relevant academic qualifications.

(b) participation in the laboratory's training program and their level of success.

(c) in-house and external training courses undertaken and their level of success.

(d) conferences, seminars, workshops etc attended , relevant publications or presentations (talks or posters) at seminars/conferences

(e) Records of regular (at least annually) evaluation of competency.

Records must be sufficiently detailed to show that personnel members have been properly trained, that their subsequent ability to perform casework has been formally assessed and that they have been authorised to perform work independently.

6.4.2.5 The laboratory shall have an employee development program. (e.g.. Identification of possible courses, seminars, training that are available to the analyst/examiner).

6.4.2.6 The forensic laboratory shall have access to relevant reference material and journals.

6.4.3 Evidence management / Handling of Test Items.

6.4.3.1 Evidence Control

6.4.3.1.1 The forensic science laboratory must have a documented evidence control system. This must include procedures for the receipt, handling, protection and storage of evidence.

The control system is effectively designed when it ensures and documents the integrity of physical evidence.

6.4.3.1.2 A chain of custody record (e.g. signature, date, description of evidence) must be maintained which provides a comprehensive history of each evidence transfer over which the laboratory has control.

When there is any doubt as to the suitability of an item for test or examination, or when an item does not conform to the description provided, or the test/examination is not specified in sufficient detail, the client shall be consulted for further instruction before proceeding. The conclusion of such consultations shall be recorded.

6.4.3.1.3 Each individual item of evidence must be marked with the unique case designator for identification. Should the item not lend itself to marking, its proximal container must be marked. Labelling on caps/lids alone is not acceptable because of the risk of wrongly replacing lids during testing of batches of like samples.

(a) The identification shall be retained throughout the life of the item in the laboratory.

(b) The system shall be designed and operated to ensure that items cannot be confused physically or when referred to in records of other documents.

6.4.3.1.4 Upon receipt of evidence, any abnormalities or departures from normal or specified conditions shall be recorded.

When there is any doubt as to the suitability of an item for test or examination, or when an item does not conform to the description provided, or the test/examination is not specified in sufficient detail, the client shall be consulted for further instruction before proceeding.

6.4.3.1.5 Evidence must be stored under proper seal. Evidence seals must be designed and used to protect the integrity of the evidence. (Refer to appendix 7)

Tape used to seal containers must be initialled (or otherwise identified) to record the person sealing the evidence or an evidence tamper proof seal with a unique number must be used. (The number of the seal must be appropriately documented)

Note: An examiner in the process of examining evidence who needs to store it temporarily in a secure area need not seal the evidence each time it is stored. Containers must be closed for overnight storage to prevent evidence from accidental loss or contamination.

Evidence must be protected from loss, cross-transfer, contamination and/or deleterious change.

(a) When destructive tests are necessary, procedures must ensure that as much material as possible is retained for reanalysis if necessary.

(b) Procedures for sub-sampling must ensure that sample integrity is

maintained.

(c) When items have to be stored under specified environmental conditions, these conditions shall be appropriately maintained, monitored and recorded.

A secure area for overnight and/or long-term storage of evidence must be available.

Note: If, during the process of examining evidence, an examiner needs to leave for a short time, such as for lunch, it is not necessary to pack up the evidence being examined if it is in a secure area (e.g. a limited-access laboratory room). This is also true for large and/or cumbersome items where it is advantageous to have the evidence remain out and there is limited access to the area.

Access to evidence storage areas must be restricted to authorised personnel only. A list of authorised personnel shall be maintained by the Laboratory manager.

The laboratory must establish and document its policy and procedures for the retention and disposal of exhibits following the completion of examinations and/or testing.

6.5 Methods and Procedures

6.5.1 General

6.5.1.1 Test methods and procedures used must be generally accepted in the field or supported by data gathered and recorded in a scientific manner. (Refer to 5.5.3)

Note: Since a variety of scientific procedures may validly be applied to a given problem, standards and criteria for assessing procedures need to remain flexible. Furthermore, minor modifications to improve published methods can be implemented by a laboratory as appropriate to the particular need, subsequent to validation of the change implemented.

6.5.1.2 Examiners in serology or DNA must have:

(a) Access to relevant population databases on the distribution of all genetic markers which are typed in the laboratory.

(b) Access to and generate regional and/or local population databases on the distribution of all genetic markers, which are typed in the laboratory.

6.5.1.3 Where sampling is carried out as part of the test method, documented procedures that include a sampling plan using appropriate statistical techniques must be used.

6.5.1.4 Accreditation cannot be granted for tests/examinations that a laboratory has never performed or for which records of the validation are not available.

It is accepted, however, that forensic science laboratories are called upon, from time to time, to undertake analyses/examinations not covered by the scope of their accreditation. In such cases a laboratory may choose from the following options:

(a) The laboratory can perform the test/examination and report the result ensuring that no inference can be drawn that accreditation is held for the service.

(b) The laboratory can seek accreditation prior to performing the test/examination and reporting the result.

6.5.2 Documentation of test methods and related procedures

6.5.2.1 Test methods and related procedures (e.g. sample procurement) must be documented and readily available to the analysts/examiners.

In addition to a description of the steps involved in the analysis/examination, documentation of methods and procedures must include, where appropriate:

(a) description of the sample/item to be tested/examined

(b) parameters or quantities to be determined

(c) equipment/instrumentation required

(d) descriptions of sample preparation methods, controls, standards and calibration procedures

(e) a discussion of precautions, possible sources of error or limitations of the procedure

(f) criteria for the rejection of suspect results

(g) data/observations to be recorded and method of analysis and presentation

(h) literature references

In general, the level of detail must be sufficient for a new staff member with basic scientific training in the relevant area to be able to perform the procedure.

6.5.2.2 Where a test can be performed by more than one method, there must be documented criteria for method selection.

Where appropriate, the degree of correlation between the methods must be established and documented.

6.5.3 Method Validation (Refer to TG 41)

6.5.3.1 All technical procedures used by a forensic science laboratory must be fully validated before being used on casework.

The minimum acceptable validation is the use of known samples (10 off) or proficiency test samples from an external proficiency-testing scheme preferably independently accredited to ISO guide 43.

Note 1: Validation is the developmental process used to acquire the necessary information to assess the ability of a procedure to obtain a result reliably, to determine the conditions under which such results can be obtained and to determine the limitations of the procedure. The validation process identifies critical aspects of a procedure, which must be carefully controlled and monitored.

Note 2: Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the forensic laboratory itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

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
- sample homogeneity
- specificity
- sensitivity
- linearity range
- precision

interferences
concentration-ranges
stability of measured compounds
measurement uncertainty
population distribution

Specific validation requirements for DNA procedures are detailed in the current version of the SANAS *Standards for DNA Analysis (TG 42)* .

(a) Methods developed in-house for both qualitative and quantitative work must be validated by the laboratory prior to use.

(b) Where a significant modification is made to a validated method, the modification must be appropriately validated by the laboratory before the method is used.

(c) Records of all in-house validations must be maintained for future reference.

6.5.3.2 Where a laboratory introduces a new (validated) method, it must first demonstrate the reliability of the procedure in-house against any documented performance characteristics of that procedure e.g. by proficiency test sample.

(a) As a minimum, the method must be tested using known samples (e.g. proficiency test samples, samples from an external agency).

It is recommended that the method also be tested using non-probative samples.

(b) Records of performance verification must be maintained for future reference.

6.5.4 Reference Materials/ Measurement Traceability.

6.5.4.1 Reference materials must be traceable to national or international certified standard reference materials, where possible.

6.5.4.2 Reference materials, certified reference materials and reference collections must be uniquely identified and full details recorded.

6.5.4.3 Purchase, issue and use of these materials must be controlled and records must be maintained.

6.5.4.4 If checks are needed to maintain confidence in the integrity of reference materials, these must be performed at defined intervals in accordance with a documented procedure.

6.5.4.5 The laboratory must have procedures for the handling, transport, storage and use of reference materials in order to prevent deterioration and contamination.

6.5.5 Standards and Reagents

6.5.5.1 The quality of the standard samples and reagents must be adequate for the procedure used.

6.5.5.2 Lot/batch numbers of standards and critical reagents must be recorded.

6.5.5.3 All critical reagents must be routinely tested for their reliability.

6.5.5.4 Standards and reagent must be labelled with or be traceable back to the following:

(a) name of the reagent/standard
(b) concentration, where appropriate
(c) preparation date
(d) identity of the preparer (If applicable)

Where necessary, the following must also be included on labels:

(e) expiry date
(f) storage conditions
(g) hazard warning

6.5.6 Sub-contracting of technical work where allowed by applicable legislation

6.5.6.1 Should a laboratory have to sub-contract any part of its normal service, the work must be placed with a laboratory complying with accreditation requirements, where possible.

Note: Where it is not possible to do this the laboratory shall satisfy itself that its subcontracted laboratory complies with all accreditation criteria.

6.5.6.2 The laboratory must advise and seek the approval of its client(s) in writing whenever it sub-contracts any portion of its work to another laboratory.

6.5.6.3 A register of all sub-contractors and sub-contracted services must be maintained.

A record must be maintained of assessments made of sub-contractors and sub-contracted tests.

Note: Subcontracting of test work where allowed by applicable e.g. the South African law, criminal procedures Act etc.

6.6 Quality Assurance

6.6.1 Quality Control (Refer to appendix 8)

6.6.1.1 Analytical performance must be monitored by using quality control procedures appropriate to the type and frequency of the testing undertaken.

6.6.1.2 Quality Control procedures shall be documented.

6.6.1.3 A record must be retained to show that appropriate quality control measures have been taken, that the quality control results are acceptable or, if not, that remedial action has been taken.

6.6.1.4 Where appropriate, quality control data must be recorded in such a way that trends in analysis can be readily evaluate.

6.6.2 Proficiency Testing (Refer to appendix 9); see also SANAS R80

6.6.2.1 The laboratory shall participate in or shall have a documented program of proficiency testing which measures that capabilities of its examiners and the reliability of its analytical results.

Note: Where a laboratory manages its own proficiency scheme the documentation of a laboratory's proficiency testing program must include how the test samples are obtained/prepared, who is tested and in what time frame,

which laboratory personnel member directs the program, how and where the testing information is maintained, what corrective actions are taken if required and who oversees them.

6.6.2.2 Each laboratory shall, where viable, participate in proficiency testing programs which are provided by external test providers approved by ASCLD/LAB and/or SANAS where such schemes are available and where such schemes allow for added value. (The laboratory must complete a formal agreement with the test provider permitting release of the laboratory's test results directly to ASCLD/LAB and SANAS.)

Such testing, where viable, shall be conducted annually in every discipline in which a laboratory seeks or holds accreditation. The frequency of proficiency testing for DNA laboratories must comply with the SANAS Standards for DNA Analysis (TG 42).

(a) Where laboratories subscribe to proficiency testing programs that issue samples/items for test/examination on more than one occasion throughout the year, results shall be submitted on each occasion as required by the program.

(b) In addition to participating in external proficiency testing, a laboratory should conduct interlaboratory or intralaboratory proficiency testing using blind tests (where practically possible) prepared internally or externally and submitted as normal casework evidence or re-examination by another examiner of evidence on which casework was previously completed or known samples prepared internally or externally.

(c) Refer to SANAS R80 document.

6.6.2.3 Each analyst/examiner must complete at least one proficiency test (either internal or External) annually in which they perform casework and for which they are a signatory. The frequency of proficiency testing for DNA examiners must comply with the current version of the SANAS Standards for DNA Analysis (TG 42).

When participating in proficiency testing programs, the laboratory's routine test procedures must be used.

6.6.2.4 Performing in proficiency testing programs must be reviewed by the manager and relevant supervisory personnel. Where necessary, corrective action must be taken. Feedback must be provided to all relevant personnel.

6.6.2.5 Proficiency testing records must include:

(a) full details of the analyses/examinations undertaken and the results and conclusions obtained

(b) an indication that performance has been reviewed; and

(c) details of the corrective action undertaken, where necessary

6.6.3 Case Record Review (Refer to appendix 10)

6.6.3.1 General

(a) The laboratory must have documented its policies and procedures for the technical and administrative reviews of case records. This must include:

- the criteria to be used for each type of review
- the number/percentage of case reports to be reviewed
- the course(s) of action, should a discrepancy be found.

(b) Case records that have been reviewed must bear evidence (e.g. by initials of the reviewer) of the review. A record of the review shall be maintained.

6.6.3.2 Technical Review

Conclusions reported must fall within the range of acceptable opinions of knowledgeable individuals in the field of forensic science or be supported by sufficient scientific data. The laboratory must, therefore, review a sample of case records to ensure that the conclusions of its examiners are reasonable and within the constraints of scientific knowledge.

6.6.3.3 Administrative Review

Administrative reviews must be conducted as documented to ensure the completeness and correctness of the report issued.

Note: Sufficient cases shall be reviewed to allow confidence in the review process. SANAS reserves the right to require an increase in the number of cases reviewed by the laboratory.

6.6.4 Court Testimony Monitoring (Refer to appendix 13)

6.6.4.1 the laboratory shall have a documented procedure in place for the evaluation of the court testimony.

6.6.4.2 The procedure shall include:

- Who is responsible for the evaluation
- How areas to be covered will evaluated (see 6.6.4.3 (a) below)
- Proposed remedial action for an unsatisfactory evaluation

6.6.4.3 The laboratory shall have and follow a documented procedure whereby the testimony of each examiner is monitored at least once every second year. For analyst/examiners who frequently appear in court monitoring shall be at least once in 12 months.

(a) Areas that must be covered in the evaluation include appearance, poise, performance under cross-examination as well as effectiveness of presentation (e.g. technical knowledge, ability to convey scientific concepts in understandable terms).

(b) The monitoring procedure must also prescribe the remedial action that is to be taken should the evaluation be less than satisfactory.

6.6.4.4 A record must be kept of each evaluation.

6.6.4.5 Each analyst/examiner must be given timely feedback from the evaluation.

6.6.4.6 The monitoring may include any of the following:
6.6.4.6.1 A review of transcripts
6.6.4.6.2 Feedback form completed by prosecutor
6.6.4.6.3 Physical attendance of court proceedings by the evaluator

6.7 Equipment

6.7.1 General

6.7.1.1 The laboratory shall have instruments and equipment that are adequate for the procedures used. Where the laboratory needs to use equipment outside its permanent control, it must ensure that all relevant accreditation criteria are met.

6.7.1.2 Each item of equipment shall, when appropriate, be uniquely labelled, marked or otherwise identified.

6.7.1.3 Each significant item of equipment must be recorded in an inventory which may include:

(a) the name of the item of equipment

(b) the manufacturer's name, type identification and serial number or other unique identification

(c) date received and date placed in service, where appropriate

(d) current location, where appropriate

(e) condition when received (e.g. new, reconditioned), where appropriate

6.7.1.4 Instruments/equipment must be maintained in proper working order.

(a) Maintenance procedures must be documented.
(b) Records must be kept of maintenance, servicing and repairs.

(c) Equipment known or suspected to be defective shall be taken out of service and clearly labelled or marked until it has been repaired and shown by calibration, verification or test to perform correctly.

(d) Whenever practicable, all equipment under the control of the laboratory and requiring calibration or verification, shall be labelled, coded or otherwise identified to indicate the status of the calibration or verification and the date when re-calibration or re-verification is due.

6.7.1.5 Documented operating instructions (e.g. manufacturer's operating instructions) must be available for each significant item of equipment.

6.7.1.6 When, for whatever reason, equipment goes outside the direct control of the laboratory for a period of time, it shall be ensured that the function and, where necessary, the calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

6.7.1.7 The laboratory shall have procedures for safe handling, transport, storage and use of equipment in order to prevent contamination and deterioration.

6.7.1.8 Special procedures shall be necessary for equipment used for testing and related activities performed outside the permanent laboratory facilities.

6.7.2 Calibration

It is the responsibility of the laboratory to ensure that all equipment requiring calibration is done at intervals determined by SANAS documentation (TR 25).

6.7.2.1 Instrument/equipment must be adequately calibrated.

(a) Where equipment used for tests, including equipment used for subsidiary measurements, has a significant effect on the accuracy or validity of the test result, that equipment shall be calibrated or otherwise verified before being put into service and shall be subject to a program of re-calibration and/or re-verification. Maintenance procedures must be documented.

(b) The calibration/verification program must be documented. It must include:

- the nature of the calibration/verification (e.g. calibration by a SANAS accredited laboratory, internal check against reference standard, etc.
- the maximum interval between the calibrations/verifications based on a history of previous calibrations/verifications.
- Where appropriate acceptable performance criteria.

(c) The program for the calibration of equipment in forensic science laboratories shall ensure that, where the concept is applicable, all significant measurements are traceable, through certificates of calibration held by the laboratory, to national standards of measurement.

6.7.2.2 Where a laboratory performs compiles a response model in-house by means of comparisons between reference standards and working measuring instruments, the calibration procedure must be documented.

6.7.2.3 Calibration records (e.g. calibration certificates, calibration data) must be suitably maintained.

6.7.2.4 The laboratory must have a mechanism that alerts personnel when calibrations and subsidiary checks are due and indicates the nature of the work required.

Whenever practicable, all equipment under the control of the laboratory and requiring calibration or verification, shall be labelled, coded or otherwise identified to indicate the status of the calibration or verification.

6.7.2.5 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that any copies (e.g. in computer software) are correctly updated.

6.7.2.6 Calibration records (e.g. calibration certificates, calibration data) shall be maintained.

Note: It is recognised that equipment in forensic science laboratories is used for a variety of tests and examinations with a wide range of accuracy and/or precision requirements. Each laboratory should determine the accuracy and precision requirements for each item of equipment and set its calibration/verification program accordingly. It should also be noted that similar items of equipment used for different functions may have different calibration/verification requirements.

6.8 Reporting the results

6.8.1 The information that should be included in reports of test/examinations is detailed below:

(a) a title (e.g. test certificate, test report or affidavit)

(b) the name and address of the laboratory and, if different from the address, the location where tests were performed

(c) unique identification of the report (e.g. by report number or case file number) on each page

(d) the date of issue of the report

(e) the page number and the total number of pages (i.e. page x of y) on each page

(f) the name and address of the client, where applicable

(g) description, unambiguous identification and date of receipt of the item(s) tested or examined

(h) date(s) of performance of test(s) and/or examination(s)

(i) identification of critical test/examination method(s) of procedure(s), where appropriate

(j) test/examination result(s)

(k) reference to sampling procedure(s) used by the laboratory where these are relevant to the validity or application of the results (if appropriate)

(l) reference to other information where this may be relevant to the validity or application of results

(m) the name, title and signature or equivalent identification of the person authorised to release the report

It is accepted that forensic science laboratories may not be able to comply with all these requirements. In such cases, the case record or laboratory record book pertaining to a particular investigation should include this information.

6.8.2 Where the results of tests not performed by the laboratory are included in reports, the source of those results must be clearly and unambiguously identified on the report. It shall also indicate that such results fall outside the accreditation.

6.8.3 Preliminary or interim reports must be clearly indicated as such.

Where preliminary or interim reports are issued by telephone, the following must be recorded in the case record:

(a) the date and time of the telephone call

(b) the test/examination result(s) given

(c) the name of the person to whom the result(s) were given. The laboratory shall identify those persons authorised to give interim reports and reports issued by telephone.

6.8.4 A copy of the report issued for a test/examination must be retained in conjunction with the case record.

6.8.5 If, after the issue of a report, test data are found to be invalid, the original report must be withdrawn and, where necessary, replaced by one, which is clearly indicated as, being a replacement report. A record of the replacement must be kept on file as shall a copy of the amended report.

6.8.6 The laboratory's policies and procedures for issuing reports must be documented. These shall include:

(a) prescribed formats for reports, certificates, affidavits, witness statements etc.

(b) issuing of preliminary or interim reports

(c) reporting of results by telephone

(d) electronic transmission of reports

(e) retention of reports in the case record

(f) report authorisation

(g) withdrawal of invalid reports

6.9 Purchasing Services and Supplies

The laboratory shall have policies and procedures for the selection and purchases of services and supplies that affect the quality of test/examinations.

Note: This requirement also applies to the selection of services for test/examinations not performed by the laboratory.

6.9.1 The laboratory shall use, for services and supplies that affect the quality of its test and/or related activities, only those that can be demonstrated to be of adequate quality.

Formal assurance of quality could be demonstrated by SANAS accreditation, certification to relevant quality management system standards e.g. SABS ISO 9000, product certification by approved bodies.

Where no formal assurance of the quality of external services and supplies is available, the laboratory shall have procedures to ensure that purchased materials and services comply with specified requirements.

6.9.2 Records must be maintained of suppliers, from whom support services, and equipment are obtained. An approved supplier's list shall be available.

6.9.3 Documented procedures must exist for the purchase, receipt and storage of consumable materials whose properties could affect the quality of testing and related activities.

6.9.4 Wherever possible, the laboratory must ensure that purchased equipment and consumable materials are not used until they have been visually inspected, calibrated or otherwise verified as complying with the laboratory's requirements.

APPENDIX 1 : PCR Cyclers/DNA Sequencers Guidance

The temperature of the heating block and time intervals of the cyclers must be regularly checked and verified against a calibrated temperature verification system and stopwatch respectively.

DNA Sequencers

The DNA Sequencer should be annually serviced by the manufacturer and the optical alignment must be checked for accuracy.

This instrument does not have any critical measurement.

Regular documented matrix, runs (at least once per annum) must be performed on the dye to do necessary adjustments on the instruments.

APPENDIX 2: Overview Comparison Reference of SANAS ASCLD & NATA Documents

Appendix 2 is an overview of the SANAS accreditation based upon the NATA & ASCLD/LAB and ISO/IEC 17025 criteria listing the source of the specific criteria.

MANAGEMENT REQUIREMENTS

* **General**

ISO/IEC 17025 - 4.1 Management requirements

* **Objectives**

ISO/IEC 17025 - 4.2 Quality System
ASCLD/LAB - 1.1.1, Objectives

* **Administrative Practices**

ISO/IEC 17025 - 4.4 Review of Requests, Tenders and Contracts
ASCLD/LAB - 1.1.2, Administrative Practices

* **Organisational Structure**

ISO/IEC 17025 - 4.2 Quality System
ISO/IEC 17025 - 4.1 Organisation
ISO/IEC 17025 - 5.5 Personnel
ASCLD/LAB - 1.2.1, Organisational Structure

* **Delegation of Authority**

ASCLD/LAB - 1.2.2, Delegation of Authority

* **Supervision**

ASCLD/LAB - 1.1.2, Administrative Practices
ASCLD/LAB - 1.3.1, Supervision

* **Communication**

ASCLD/LAB - 1.1.2, Administrative Practices
ASCLD/LAB - 1.3.2, Communication

QUALITY SYSTEM

* **General**

ISO/IEC17025 - 4.2 Quality System

* **Documentation**

Quality Manual

ISO/IEC 17025 - 4.2 Quality System
ASCLD/LAB - 1.4.2, Quality System

Documentation Control

ISO/IEC 17025 - 4.3 Document Control

* **Records**

General

ISO/IEC 17025 - 4.13 Control of Records
ASCLD/LAB 1.1.2 - Administrative Practices

Case Records

ISO/IEC 17025 - 4.13 Control of Records
ASCLD/LAB - 1.1.2, Administrative Practices
ASCLD/LAB - 1.4.2, Quality System

Computers

ISO/IEC 17025 - 4.10 Corrective Actions
ISO/IEC 17025 - 4.12 Control of Records

* **Internal Audits**

ISO/IEC 17025 - 4.14 Internal Audits
ASCLD/LAB - 1.4.2, Quality System

* **Management Review**

ISO/IEC 17025 - 4.15 Management Reviews
ASCLD/LAB - 1.4.2, Quality System

* **Complaints**

ISO/IEC 17025 - 4.7 Service to the Client

PERSONNEL

* **Qualifications**

Management	ASCLD/LAB - 2.1
Analysts and Examiners	
- Controlled Substances	ASCLD/LAB - 2.2
- Toxicology	ASCLD/LAB - 2.3
- Trace Evidence	ASCLD/LAB - 2.4
- Serology	ASCLD/LAB - 2.5
- DNA	ASCLD/LAB - 2.6
- Firearms and Toolmarks	ASCLD/LAB - 2.7

- Questioned Documents ASCLD/LAB - 2.8
- Latent Prints ASCLD/LAB - 2.9
- Crime Scene Investigation SANAS

Technical Support ASCLD/LAB - 2.10

* **Training and Development**

ISO/IEC 17025 - 5.2 Personnel
ASCLD/LAB - 1.3.3, Training and Development (SANAS □ Important)
ASCLD/LAB - 2. Personnel Qualifications

EVIDENCE MANAGEMENT

* **Evidence control**

ISO/IEC 17025 - 5.3, Accommodation and Environmental Conditions
ISO/IEC 17025 - 5.4 Test and Calibration Methods and Method Evaluation
ISO/IEC 17025 - 5.8, Handling of Test and Calibration Items
ASCLD/LAB 1.1.2, Administrative Practices
ASCLD/LAB 1.4.1, Evidence Control

* **Evidence Retention and disposal**

ISO/IEC 17025 - 5.8, Handling of Test and Calibration Items

METHODS AND PROCEDURES

* **General**

ISO/IEC 17025 - 5.4, Test and Calibration Methods and Method Evaluation
ISO/IEC 17025 - 5.7, Sampling
ASCLD/LAB - 1.4.2, Quality System

* **Documentation**

ISO/IEC 17025 - 5.4, Test and Calibration Methods and Methods Evaluation (5.4)
ASCLD/LAB - 1.4.2, Quality System

* **Method Validation**

ISO/IEC 17025 - 5.4, Test and Calibration Methods and method Evaluation
ASCLD/LAB - 1.4.2, Quality System

* **Reference Materials**

ISO/IEC 17025 - 5.6, Measurements Traceability

* **Standards and Reagents**

ASCLD/LAB - 1.4.2, Quality System

* **Subcontracting of Technical Work**

ISO/IEC 17025 - 4.5, Subcontracting of Tests and Calibrations

QUALITY ASSURANCE

ISO/IEC 17025 - 5.9, Assuring the Quality of Test and Calibration Results

* **Quality Control**

ASCLD/LAB - 1.4.2, Quality System

* **Proficiency Testing**

ASCLD/LAB - 1.4.3, Proficiency Testing

* **Case Record Review**

General

ISO/IEC 17025 - 4.13 Control of Records
ASCLD/LAB - 1.4.2, Quality System

Technical Review

ASCLD/LAB - 1.4.2, Quality System

Administrative Review

ASCLD/LAB - 1.4.2, Quality System

* **Court Testimony Monitoring**

ASCLD/LAB - 1.4.2, Quality System

EQUIPMENT

* **General**

ISO/IEC 17025 - 5.4, Test and Calibration Methods and Methods Evaluation
ISO/IEC 17025 - 5.5, Equipment
ASCLD/LAB - 1.1.2, Administrative Practices
ASCLD/LAB - 1.4.2, Quality System

* **Calibration**

ISO/IEC 17025 - 5.6, Measurement Traceability
ASCLD/LAB - 1.4.2, Quality System
SANAS

REPORTS

ISO/IEC 17025 - 5.10, Reporting the Results

PROCUREMENT OF SERVICES AND SUPPLIES

ISO/IEC 17025 - 4.6, Purchasing Services and Supplies

ACCOMMODATION AND SAFETY

* **Security**

ISO/IEC 17025 - 5.3, Accommodation and Environmental Conditions
ASCLD/LAB - 1.1.2, Administrative Practices
ASCLD/LAB - 3.3, Security

* **Environmental Conditions**

ISO/IEC 17025 - 5.3, Accommodation and Environmental Conditions

* **Space**

  ASCLD/LAB - 3.1, Space

* **Design**

  ASCLD/LAB - 3.2, Design

* **Health and Safety**

  ASCLD/LAB - 3.4, Health and Safety

APPENDIX 3: Records Guidance

Examples of administrative records include records of case-related conversations, evidence receipts, description of evidence packaging and seals, subpoenas and other pertinent information. Examples of analytical records would include reference to procedures followed, tests conducted, standards and controls used, diagrams, printouts, autoradiographs, photographs, observations and results of examinations.

Where helpful, diagrams should be used in addition to narratives to record observation (e.g. appearance of micro crystals, location of blood/semen stains and substrate control area sampled).

In general, the records required to support conclusions must be such that in the absence of the analyst/examiner, another competent analyst/examiner or supervisor could evaluate what was done and interpret the data.

APPENDIX 4: Internal Audit Guidance

The internal audit is one of the primary tools used to evaluate, confirm or verify activities related to quality. Its purpose is to assess compliance with the operational requirements of the quality system. Periodic audits, along with day-to-day review of scientific reports, provide an effective means for ensuring that quality control activities are being implemented and that each forensic examiner performs in a manner consistent with the quality system.

An audit program is more likely to succeed if the auditors are selected and trained by the quality manager. Auditors, generally selected from among the employees, must be tactful, thorough, objective and self-confident as well as technically competent. They must receive specific training in what is expected of them including a comprehensive understanding of the quality system.

Audits must be scheduled and announced well in advance. A checklist is essential to ensure complete coverage of the important aspects of the audit. It also enhances objectivity of findings and credibility of the audit team. The checklist should include at least the following:

- staff awareness of the quality manual
- analytical procedure selection, control and validation
- control of reagents and standards
- equipment calibration and maintenance records
- adequacy of case reports and notes and their disposition
- evidence handling procedures
- proficiency testing and inter-laboratory comparison studies
- personnel training records
- handling of deficiencies and remedial action
- laboratory orderliness and health and safety measures

After the audit is completed, the team should brief the laboratory director and the quality manager regarding the results. This discussion should include commendable findings as well as deficiencies. The written report must be prepared soon after the audit has been conducted and must identify problem areas and the remedial

action required. The degree of concern pertaining to any deficiency must be indicated with major defects being highlighted. The report should also contain any suggestions that the auditors would have to improve the quality system. The report and responsive comments from the laboratory director are to be submitted to the quality manager for ensuring that corrective actions are taken in a timely manner.

APPENDIX 5: Education Guidance

It is recognised that courses now exist at tertiary institutions or have been registered with the South African Qualification Authority which, although not programs offering Bachelor degrees, are specifically tailored for forensic science. Individuals holding such qualifications will be considered to meet the criteria for holding a Bachelor degree or equivalent qualification.

Common to the standards for personnel in each of the functional areas is a requirement that examiners have a good understanding of the principles, uses and limitations of the instruments and the methods and procedures used. Since these vary with the functional area, some examples of the special knowledge for each functional area are given below:

Regular substances analysts must be able to select the appropriate procedure and equipment necessary for reliable qualitative and quantitative analyses of controlled substances and, if necessary, to develop a valid procedure. They must also be able to evaluate the significance of test results.

Toxicologists must be competent to perform qualitative and quantitative analyses for drugs, metabolites and other toxic substances in biological materials. They must also be able to make systematic and other toxic substances in biological materials. They must also be able to make a systematic search for such substances and apply appropriate extractive and separatory procedures.

Trace evidence examiners must have a basic knowledge of chemistry, microscopy and the concept of individualisation.

Serologists/Body fluid examiners must have a knowledge of basic biological sciences and sufficient knowledge of chemistry to understand the procedures used. They should also have adequate knowledge of the statistics used in forensic serology.

DNA analysts must have a knowledge of basic biological sciences and sufficient knowledge of biochemistry, chemistry and molecular biology to understand the mechanisms of the test procedures used. They must also have an adequate knowledge of population genetics and the statistics used in forensic DNA examinations.

Firearms/Toolmarks examiners must have adequate knowledge of microscopy, special lighting techniques, preparation of impressions or casts, techniques of comparative examination and the concept of individualisation. They should also have adequate knowledge of the nomenclature, operability/operation of firearms, bullet and cartridge case comparisons, powder and shot patterns, distance determinations and types of firearm determination from a discharged cartridge case or bullet.

Questioned documents examiners must have knowledge of the principles of photography, microscopy, comparative examination and individualisation. They must also have adequate knowledge of writing or printing instruments, ink, paper and copying processes.

Latent prints examiners must have knowledge of comparative examination techniques, methods for processing, recovery and preservation of latent prints and common systems of classification.

Crime scene investigators must be competent in the application of the principles of crime scene photography, scene examination and exhibit handling, safety and have an appreciation of the capabilities of other disciplines.

Forensic Ballistic Specialist must be conversant with one or more of the following tasks: ammunition identification; microscopic identification of fired cartridge cases and/or bullets; investigation of firearm mechanisms; restoration of obliterated numbers; investigation of home-made firearms and ammunition; investigation of tool and toolmarks; investigation of firearms, received with fired cartridge cases and/ or bullets; short distance determination; crime scene investigation; court testimony and assistance of Council

APPENDIX 6: Training Program Guidance

A laboratory's training program must emphasise and teach the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice within a specific area of work. Training must also include a substantial knowledge of forensic science across its wide spectrum and of criminal and civil law and procedures. A demonstration of competence to perform what is expected must be included in the program. It is recommended that the laboratory establish a formal means of recognition of successful completion of the training such as a certificate, letter or memorandum. The field of forensic science requires examiners to present and defend their findings in open court. Because of this unusual requirement, practitioners must develop the technical and personal skills to perform competently.

Some experience/training must be received in a forensic laboratory. Credit for other experience/training can be evaluated as appropriate in a particular case. Work experience and training should be considered with respect to intensity and diversity. Experience/training outside the crime laboratory may be substituted for experience/training in the crime laboratory to the extent that it has been demonstrated to be relevant and sufficient. If there is little diversity in the person's work, correspondingly shorter periods of training/experience may be sufficient.

Analysts/examiners must be acquainted with the methods that are generally accepted in the discipline. All examiners must be able to articulate concepts and provide opinion testimony relevant to assigned tasks. Pertinent training must be given to all trainees prior to appearance as an expert witness in court. This may include moot court, actual court observation and appropriate reading materials.

APPENDIX 7: Guidance on Sealing

A container is properly sealed only if its contents cannot readily escape or become contaminated and only if entering the container results in obvious damage/alteration to the container or its seal.

It is acknowledged that some items of evidence cannot be sealed in accordance with these criteria e.g. motor vehicles. In such cases, appropriate measures must be taken to ensure their security and integrity.

APPENDIX 8: Guidance on Quality Control

The range of quality control activities available to laboratories includes the use of:

- reference collections
- certified reference materials
- internally generated reference materials
- independent checks by other analysts/examiners
- statistical tables
- positive and negative controls
- control charts
- replicate testing/examination
- alternative methods
- spiked samples, standard additions and internal standards

Depending on the particular test/examination, one or more of these examples may be appropriate.

APPENDIX 9: Proficiency Testing

A proficiency-testing program is a reliable method of verifying that the laboratory's technical procedures are valid and that the quality of each examiner's work is being maintained. The primary focus must be to identify areas where additional training or more stringent quality control may be of benefit and to demonstrate the current competence of the laboratory. To obtain the optimum benefit from proficiency testing, the laboratory must emphasise the educational aspects of the program and avoid a punitive approach when taking any corrective actions.

Proficiency test samples must be representative of items examined in normal forensic laboratory operations. A proficiency test sample may be appointed among examiners if doing so does not alter the character of the testing.

It is essential that proficiency tests be properly designed, appropriately and fairly evaluated. The testing process must be well understood by all participants.

The proficiency of analysts/examiners is tested only if they complete the testing unaware of the results expected.

APPENDIX 10: Guidance on Technical Review

Technical review, often performed by a peer, may be carried out on a sample of completed case records (e.g. 20% or six cases, whichever is fewer, per examiner per month). The sampling rate could vary depending upon the situation (e.g. a new examiner may have 100% of cases reviewed while a very experienced examiner may have only a few cases reviewed each month). Technical review, while important to the laboratory's quality assurance program, must not be carried out to the extent that it shifts the perceived responsibility for the scientific findings from the examiner to the reviewer keeping in mind that it is the examiner who presents sworn testimony to the findings.

APPENDIX 11: Monitoring of Corrective Action Reports

Internal audits, SANAS and/or ASCLD/LAB assessments, customer feedback, quality control data, proficiency testing etc generate recommendations for corrective action which must be evaluated, prioritised, implemented and evaluated for effectiveness. Consequently, the system for monitoring progress must be comprehensive and adequately cross-referenced. The quality manager should co-ordinate this system.

APPENDIX 12: Preventative Action

Preventive action is a proactive process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints. Total Quality Management tools such as brainstorming, flowcharting, Pareto charts etc may assist this process.

A system should exist whereby staff are encouraged to contribute to improvement of the laboratory's quality system.

APPENDIX 13: Presentation of Testimony

The presentation of testimony is the culmination of the work performed by a forensic scientist. Accordingly, it is vitally important that the effectiveness of each examiner in this respect be reviewed. Methods by which monitoring may be carried out include:

- observation of the testimony by a supervisor or a peer
- the completion by officers of the court of a testimony evaluation form (checklist and/or comment sheet) provided by the laboratory
- telephonic solicitation by a laboratory director or supervisor to one or more officers of the court for responses to the evaluation form

A laboratory may choose to use one or a combination of methods to accomplish the monitoring. Review of transcripts of testimony alone is not sufficient since such reviews cannot address demeanour, appearance or conduct.

APPENDIX 14: Scope of Accreditation

Accreditation in the field of Forensic Science is described by classes and sub-classes of tests.

These classes and sub-classes are fixed descriptors, free text being used to qualify or amplify terms as necessary. Where the scope of testing of a laboratory cannot be adequately described by existing descriptors, the Forensic Science Accreditation Specialist Technical Committee (STC) may from time to time establish new classes and/or sub-classes of test.

Below follows classes of tests:

1. Controlled substances
Drugs
Precursors, intermediates, by-products and diluents
Botanical identification
Clandestine drug laboratory investigation

2. Toxicology
Blood alcohol
Breath alcohol measurement
Drugs in drivers
Toxicology

3. Trace/Forensic chemistry/criminalistics
Fires and explosions (including firearm discharge residues)
Polymers (including paint, plastics and textile fibres)
Glass (and other mineralogical materials)
General chemical and physical examinations
Materials characterisation

4. Forensic biology
Serology
Blood splash pattern examination
DNA analysis
Biological fluid identification

5. Forensic ballistics
Firearms examination and identification
Marks comparisons
Scene investigation
Ammunition identification;
Microscopic identification of fired cartridge cases and/or bullets;
Investigation of firearm mechanisms;
Restoration of obliterated numbers;
Investigation of home-made firearms and ammunition;
Investigation of tool and toolmarks;
Investigation of firearms, received with fired cartridge cases and/ or bullets;
Short distance determination;
Court testimony and assistance of Council

6. Document Examination
Signature and handwriting examination
General document examination

7. Fingerprints
Fingerprint identification
Scene investigation

8. Forensic electronic examinations
Voice recognition
Audio tape analysis
Computer fraud

Diverse forensic electronic examinations
Arson related casework pertaining to electrical faults/cause

9. Polygraph
All types of polygraphy examinations

ADDENDUM 1: Amendment Record

Proposed By:	Section	Change
STCs	Whole document	• Changes “Forensic laboratory” to “Forensic science laboratories” • Replaced “staff” with “personnel” • Replaced the word “director” with “manager • Replaced the word “should” with “shall”
STCs	4 bullets	Deleted all the bullet points
STCs	5 heading	Deleted Definitions
STCs	6.1.3	Deleted section 6.1.3.1
STCs	Section 6.1.6.1	Rephrased sentence from “Only staff approved as signatories may perform accredited test work. Staff who have not been approved as signatories shall be supervised by a signatory” to “.Only personnel approved as technical signatories may perform accredited test work. Personnel who are not technical signatories shall work under the supervision of a technical signatory”.
STCs	6.2.2.2 (b)	Deleted: Documents should be reviewed once in 12 months
STCs	6.2.5.4	Added the Paragraph 6.2.5.4, 6.2.6 Corrective actions and 6.2.7 Preventive action.
STCs	6.3	Added accommodation and safety
STCs	6.4.1.2	Elaborated on section (e) bullet point 1. Deleted: • section (c) “note” • section (h) Questioned documents • section (j) Crime scene investigation Body Fluids merged with DNA
STCs	6.4.2.2	Included additional information on the training program “bullet point 1 -3”
STCs	6.4.2.2 (b) Note 1	Deleted: “Competency testing of crime scene investigators should include the independent assessment of a crime scene. Comparison of reports between the crime scene investigators under training with that of a qualified investigators’ is permissible”
STCs	6.5.2	Changed heading form only Documentation to Documentation of test methods and related procedures
STCs	6.5.3.1	Added sensitivity as one of the factory to be included in validations.
STCs	6.5.6.3	Added: Note: Subcontracting of test work where allowed by applicable e.g. the South African law, criminal procedures Act etc.
STCs	6.6.2.2	Deleted: **Note**: The STC shall review each laboratory’s participation in proficiency testing each year.
STCs	6.6.2.2	Added point (c) Refer to SANAS R80 document
STCs	6.6.4	Rephrased the whole paragraph included: section 6.6.4.1 - 6.6.4.2 and also 6.6.4.6
STCs	6.6.5 and 6.6.6	Deleted corrective and preventive actions, moved to 6.2
STCs	6.5	Moved accommodation and safety from 6.5 to 6.3
STCs	Whole document	Spelling and grammar check.