HOKLAS Supplementary Criteria No. 42

'Forensic Testing' Test Category

0. INTRODUCTION

(a) This criteria document serves to clarify and supplement the requirements of ISO/IEC 17025:2017 for accreditation of laboratories under the test category of 'Forensic Testing'. This criteria document shall be read in conjunction with ISO/IEC 17025:2017, HKAS Policy Document No. 1 and other relevant criteria documents. The following sections set out specific technical criteria for forensic testing. In areas not covered in this document, requirements stipulated in ISO/IEC 17025:2017, HKAS 002 and other relevant criteria documents shall apply.

(b) Laboratories should note that complying with this document might not necessarily meet all the requirements of test standards. Individual test standards may have specific requirements which shall be met when conducting the concerned tests.

(c) Forensic science work involves the examination of wide range of items and substances and much of this work belongs to objective tests to which ISO/IEC 17025:2017 is applicable. An objective test is defined as a test which, having been documented and validated, is under control so that it can be demonstrated that all appropriately trained analysts/examiners will obtain consistent results within defined limits. The following activities may be considered as objective tests in a forensic laboratory: controlled substances, toxicology, DNA profiling, document examination, etc.

(d) For interpretive methods such as comparison of marks, handwriting or microscopic comparison, HKAS will assess and accredit the processes put in place by the laboratory for the purposes of making statements of interpretations

and evaluate the laboratory's competence to do so, but will not accredit or otherwise endorse the statements themselves.

(e) This document does not cover investigation and examination conducted at scenes of crime. Accreditation of scene of crime investigation is offered under the Hong Kong Inspection Bodies Accreditation Scheme (HKIAS) of HKAS.

Note 1: As forensic testing includes diverse testing technologies and fields, HKAS may, from time to time, publish HOKLAS Supplementary Criteria specific to each discipline. Laboratory should visit HKAS website to find out the latest list of applicable HOKLAS Supplementary Criteria.

1. SCOPE

(No additional explanation)

2. NORMATIVE REFERENCES

(No additional explanation)

3. TERMS AND DEFINITION

(a) The term 'shall' is used throughout this document to indicate those provisions which are mandatory. The term 'should' is used to indicate recommendation which, although not mandatory, is provided by HKAS as a recognised means of meeting the requirements.

4. GENERAL REQUIREMENTS

(a) To ensure the impartiality and independence of all staff, the laboratory shall implement a Code of Conduct (however named). The Code of Conduct shall be applicable to all personnel. In some disciplines, there are well-defined and recognised standards established for ensuring the conduct of personnel in those

disciplines, for example, 'The Code of Practice for Expert Witnesses Engaged by the Prosecuting Authority' issued by the Prosecution Division of the Department of Justice of the HKSAR and 'Forensic Science Regulator: Code of Practice' issued by Forensic Science Regulator, UK. Those standards shall be adopted as far as possible in the Code of Conduct if they are relevant to the laboratory's work. Other requirements on Code of Conduct are detailed in HKAS 002 and HKAS Supplementary Criteria No. 6.

5. STRUCTURAL REQUIREMENTS

(a) The type and extent of the forensic testing services provided shall be defined and documented.

(b) The technical management of the laboratory shall include at least a staff member who has direct operational control of the forensic laboratory. He/she shall be knowledgeable of the forensic functions and forensic aspects of the laboratory work, preferably through experience as a forensic analyst/examiner. He/she shall possess sufficient authority commensurate with his/her responsibility.

Note 2: The above mentioned person should have a bachelor degree or advanced degree in science, criminalistics or in a closely related field. He/she should have at least five years of forensic experience. It is also recommended that the person should have additional training in management administration. If he/she lacks a scientific background, there shall be support within the technical management by personnel with appropriate scientific background.

(c) Each subordinate shall be accountable to one and only one immediate supervisor per function.

(d) The laboratory shall designate technical responsibility for each discipline. Each designee shall have appropriate technical training and technical experience in the discipline.

(e) The laboratory shall have personnel who are responsible for coordinating the implementation and maintenance of the management system. The scope of responsibilities and authority of the personnel shall be clearly defined and documented, which may include, but is not limited to, the following:

- maintenance of the quality manual and associated operations documentation;
- monitoring of laboratory practices to verify continuing compliance with policies and procedures;
- periodic assessment of the adequacy of report review activities;
- administration of proficiency testing and evaluating results;
- selection, training and evaluation of internal auditors;
- scheduling and coordination of management system audits;
- evaluating results of management system audits,
- training recommendations to improve the quality of laboratory staff;
- administrating court testimony monitoring, maintenance of records and provision of feedback on results;
- reviewing feedback received from customers;
- proposing corrections and improvements to the management system.

6. RESOURCE REQUIREMENTS

6.1 General

(No additional explanation)

6.2 Personnel

(a) Analysts/examiners, who are qualified to report test and examination results (including approved signatory signing endorsed reports), shall have education and experience/training commensurate with the examination and the testimony provided; they shall hold a bachelor degree or advanced degree in science, criminalistics or in a closely related field. On a case by case basis, lower academic qualifications may be acceptable but the analyst/examiner shall have extensive experience of at least ten years in the relevant testing area and have

received sufficient training on the work he/she is responsible for performing. Relevant professional qualifications in lieu of academic qualifications may also be considered as acceptable. The minimum level of qualification and experience necessary for staff in each discipline, especially for those involved in result interpretation, shall be clearly defined and documented by the laboratory.

Note 3: The minimum qualification requirement could be exempted in the event that the minimum Entrance Requirements are fulfilled by the staff member at the time of joining the service.

(b) The laboratory shall have a procedure in place for introducing an employee into the laboratory, and shall define the training and supervision required. A documented training programme shall be available for training the individual in the knowledge, skills and abilities needed to perform the testing. The laboratory's management system shall also include procedures for on-going training and maintenance of competence, skills and expertise.

Note 4: The training programme should be sufficiently detailed to provide evidence that staff performing particular tasks have been properly trained and that their subsequent competence to perform these tests has been formally assessed.

Note 5: A laboratory's training programme is expected to emphasise and provide training on the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice within a specific area of work. A training programme may be an outline with reference to more detailed training modules which may be in other laboratory document. Training programme for various disciplines may be maintained separately.

(c) The laboratory shall maintain up-to-date training records for all personnel including, but are not limited to, the following:

- relevant academic qualification and publications;
- participation in the laboratory's training programme;

- in-house and external training courses undertaken; and
- conference, seminars, workshops attended.

The training records shall be sufficiently detailed to provide evidence that each staff has been properly trained, their competence formally assessed and authorised to perform a given test or task.

(d) All analysts/examiners working in any category of testing of forensic science, regardless of academic qualification or past work experience, shall demonstrate that they have a good understanding of the principles, uses and limitation of instruments, and the methods and procedures as applied to the tasks performed. They shall satisfactorily complete competence assessment in each category of testing prior to assuming independent casework responsibility in a category of testing.

Note 6: Satisfactorily completing a competence assessment means achieving the intended results. Failure to achieve the intended results would require review or retraining until the intended results are achieved.

Note 7: Competence assessment may include evaluation of knowledge of existing literature, written and/or oral examination, examination and identification of known and unknown material, or direct observation by a qualified person.

(e) All analysts/examiners shall have been assessed and deemed competent before reporting any statements, particularly which include interpretations and opinions of results and findings. The competence requirements for performing interpretations and giving opinions shall be clearly defined.

(f) Access to literature resources such as relevant books, journals and other literature dealing with each discipline shall be maintained or provided by the laboratory.

(g) Technical support personnel, regardless of academic qualification or past work experience, shall satisfactorily complete a competence assessment prior to assuming independent responsibility for any task that could reasonably be

expected to affect the outcome of any test or calibration reported by the laboratory.

6.3 Facilities and environmental conditions

(a) The laboratory shall have documented policies and procedures to ensure laboratory securities, including:

- Access to the operational areas shall be controlled and restricted.
- All exterior entrance/exit points to the laboratory facility shall be controlled in order to prevent entrance by unauthorised personnel and all security doors shall have keys or other access devices limited to authorised personnel.
- Each access device (keys, magnetic cards etc.) assigned to designated personnel shall be properly recorded in a register.
- Internal areas requiring limited/controlled access shall have a lock system.
- The laboratory shall be monitored during vacant hours by intrusion alarms or security personnel.
- Each access to the operational area of the laboratory after office hours shall be recorded.
- Visitors shall not have unrestricted access to the operational areas and they shall be accompanied by a laboratory staff within the operation areas during the visit.
- Record of all visitors to operational areas of the laboratory shall be retained.
- Evidence storage areas shall be secured to prevent theft or interference and there shall be restricted/controlled access. The storage conditions shall be such as to prevent loss, contamination, and as far as possible deterioration, and to maintain the integrity and identity of the evidence, which apply to both before and after examination has been performed.

Note 8: Secure storage of evidence can be achieved with the use of locked cabinet, refrigerators, vaults, or rooms. Evidence storage areas could be shared by laboratory

personnel. It is not necessary to place locks on refrigerators and freezers which are located in rooms and/or areas which are secure and restricted.

Note 9: Fire detection system should be installed in the laboratory.

(b) The environmental conditions within the laboratory premises, or any location where examinations and testing are performed, shall be defined if the conditions are critical for the outcome of the results. The specified conditions shall be monitored and recorded.

(c) The laboratory shall have policies and procedures for the prevention, monitoring and detection of contamination.

(d) The laboratory should consider the health and safety risks of its personnel.

Note 10: The laboratory should establish and maintain a health and safety programme that is able to safeguard employees from service-related injury and health problems. Such programme should be monitored regularly to ensure that its requirements are met. The laboratory should have personnel who have the defined responsibilities and authority for ensuring the implementation of the health and safety programme at all times. Appropriate corrective action should be taken when a departure from the health and safety policy or procedures is identified.

6.4 Equipment

(No additional explanation)

6.5 Metrological traceability

(a) Procedures for the calibration of equipment shall be established depending on the specific requirements of the testing or analytical work being carried out. Normally, the calibration shall be checked after any shut down, whether deliberate or otherwise, and after services or other substantial maintenance. The intervals of calibration shall take into consideration of the manufacturer's recommendations.

(b) Where a test requires a reliable quantitative result and construction of calibration curve using reference materials, as a general rule, at least three standards (excluding blank) shall be used to establish a linear calibration graph. The standards used shall cover the range of concentration of test samples. The lowest standard shall be at a level at or below the reporting limit of the test method. Criteria for the correlation coefficient of linear calibration graph shall be set and implemented. Guidelines given in ISO 11095 'Linear calibration using reference materials' should be consulted for further details. More calibration standards are required for non-linear calibration functions. Bracketing technique should be used, if appropriate.

(c) Reference material, certified reference material and collections of reference data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes such as mass spectra, motor vehicle paint, drug samples, currency, travel and identification documents, typewriter print styles, DNA profile, etc. shall be well documented, uniquely identified and properly controlled. The purchase, issue and use of these materials shall be controlled and recorded. For chemical reference materials, requirements in HOKLAS Supplementary Criteria No. 1 also apply.

6.6 Externally provided products and services

(a) The quality of critical reagents and standards shall be fit for purpose for the test performed. Lot/batch numbers of the critical reagents and standards shall be recorded where applicable. The reliability of all critical reagents shall be routinely tested.

(b) Appropriate quality records of external services, supplies and purchased products shall be established and maintained for a defined period of time. Relevant records include the date of receipt, the date the material being placed in service, etc.

(c) Standards and reagents shall be labeled with:

• name of the reagent/standard;
• concentration, where appropriate;
• date of preparation and expiry;
• identity of the preparer.

Where applicable, the following shall also be included on labels:
• storage conditions;
• hazard warning.

7. PROCESS REQUIREMENTS

7.1 Review of requests, tenders and contracts

(a) As the person who is going to undertake the examination and testing may not have prior knowledge of the case, it is important that the laboratory has a documented contract review procedure defining the purpose of the examinations or tests to be performed. Necessary background information on the case should be made available to the person undertaking the work without compromising the impartiality of subsequent activities.

(b) During the review of requests, tenders and contracts, the following aspects shall be discussed and agreed with the customer where appropriate:

- turnaround times;
- report formats;
- case assessment;
- methods to be used;
- use of subcontractor; and
- collection, retention, disposal and/or return of evidence.

(c) When the laboratory needs to discuss work requirements with the customer, it shall maintain records of such discussion and document appropriate justifications. Authorisations from designated personnel of the laboratory are required if the work undertaken is not within the scope defined in the original contract.

(d) Where verbal agreements are acceptable, the laboratory shall keep a record of all requests and instructions received verbally, dates and the identity of the person making the request.

7.2 Selection, verification and validation of methods

(a) Test/examination methods and procedures used shall be generally accepted in the field or supported by data gathered and recorded in a scientific manner. They shall be fully validated. Test procedures, including the process of making statements of conclusion for interpretive methods, shall be fully documented. Laboratories may refer to 'Guidance - Validation' published by the Forensic Science Regulator, UK, for further guidance.

Note 11: In forensic science, a variety of scientific procedures may appropriately be applied to a given problem, well established procedures are often scattered throughout peer reviewed literature as well as in less formal documents obtained from conference proceedings and in-house laboratory manuals; standards and criteria for assessing procedures need to remain flexible. Furthermore, minor modifications to improve published methods could be implemented by a laboratory as appropriate to the particular need. The important point is that the procedures shall be validated.

(b) Where a laboratory implements a new validated method, the reliability of the procedure shall be demonstrated in-house against any documented performance characteristics of that procedure. Records of performance verification shall be maintained for future reference.

(c) The validation of interpretive methods shall concentrate on the competence requirements for the staff involved and how the staff shall demonstrate that they can provide consistent, reproducible, valid and reliable results that are compatible with the results of other competent staff. This should be achieved by a combination of the followings, wherever practicable:

- independent confirmation of results/opinions by another competent analyst/examiner,

- participation in interlaboratory comparisons,
- external recognition with a recognised and relevant professional body; and
- designing frequent in-house assessment into the process using positive and negative competence tests.

(d) Whenever destructive tests are necessary, procedures shall be in place to ensure the retaining of as much material as possible for reanalysis, if necessary.

(e) Records of all in-house validations shall be available for review at the assessment.

7.3 Sampling

(a) Laboratories shall ensure that documented procedures are available for the selection, recovery, prioritisation and sampling of materials received for testing and examination. Staff involved in this aspect of work shall be trained and relevant training and competence assessment records shall be available.

Note 12: Each discipline may have a unique sampling process of evidence/samples.

7.4 Handling of test or calibration items

(a) The laboratory shall ensure that the exhibits/evidence/samples examined and reported on were those submitted to the laboratory. A 'chain of custody' record shall be properly maintained to reflect the receipt, handling/transfer and storage of the exhibits/evidence/samples. The chain of custody record shall include the date of receipt or transfer and a description or unique identifier of the exhibits/evidence/samples. The person involved shall acknowledge by a signature/initial at the time of transfer, when they take possession of the exhibits/evidence/samples or return them to a storage location. Electronic equivalent of handwritten signature or initial is acceptable provided the laboratory demonstrates that the electronic equivalent can only applied by the individual it represents. Where exhibits are generated in the laboratory, a chain

of custody record shall be started and included in the case records.

Note 13: Laboratory should have procedures to ensure that exhibits, evidence or samples cannot be tampered with or contaminated unknowingly. This could be achieved by storing the item under tamper evident seals.

(b) Each individual item of evidence shall be marked with the unique case identifier [see clause 7.5(a)] for identification. Should the item not lend itself to marking, its proximal container shall be marked.

Note 14: Labelling on caps/lids alone is not acceptable because of the risk of wrongly replacing lids during testing of batches of like samples.

(c) A secure area for overnight and/or long-term storage of exhibits/evidence/samples shall be available.

Note 15: Proper security can be achieved by storing the exhibits/evidence/samples in locked cabinets, vaults, or rooms.

(d) Illicit drugs in the process of being examined and requiring overnight storage shall be secured in lockers, safe or designated exhibit storage areas with controlled access.

Note 16: Items of evidence, other than illicit drugs, which are in the process of being examined, can be left in examination areas overnight, provided that the areas are adequately secured and staff with access to the areas are aware of the need to ensure that such items be protected from loss, damage or contamination.

(e) All exhibits/evidence/samples not in the process of examination shall be maintained in secure storage areas with controlled access.

Note 17 If, during the process of examining evidence, an analyst/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 controlled access to the area.

Note 18: Additional protective measures may be required for items being examined for trace evidence to minimise the possibility of loss or cross-transfer of evidence.

(f) Access to all evidence storage areas shall be restricted to authorised personnel.

Note 19: Special measures to restrict access may not be required for 'sub-samples', which are defined as a portion taken from the original sample (or item) submitted to the laboratory for examination. Examples of subsamples are cut-out stains, DNA extracts or reference bloods.

(g) Appropriate consideration of potential further examinations/testing shall be given when determining the most appropriate packaging and storage of exhibits. If a case requires examination and testing by different disciplines, an arrangement shall be in place to ensure that appropriate examinations or tests could be performed on the exhibit, and the sequence of work does not unintentionally preclude the possibility of further examination/testing.

7.5 Technical Records

(a) The laboratory shall maintain a case record in a designated location(s) under a unique case identifier, usually a laboratory case number for identifying and indexing case record (see Note 20 for explanation of case record).

(b) The laboratory shall have documented policies:

- describing its case designator system(s); and
- identifying those records, which are available and relevant, that shall be maintained in a case record.

(c) All data and observations and any other analytical/examination or administrative records which support conclusions shall be generated and kept in the case record by the laboratory. The records required to support conclusions shall be such that in the absence of the original member of staff,

another competent member of staff could evaluate what had been performed, interpret the data and if necessary repeat the activity.

(d) A copy of the report issued for a test/examination shall be retained in the case record.

Note 20: Administrative, examination records and analytical documentation generated by a laboratory on a particular case, either on paper or electronically, constitutes a case record. Examples of administrative records may include, but are not limited to, records of case-related conversations which support or impact on the outcome, evidence receipts, description of evidence packaging and seals, subpoenas and other pertinent information. Examples of analytical/examination records may include, but are not limited to, reference to procedures followed, tests conducted, standards and controls used, diagrams, printouts, autoradiographs, photographs, digital records (including digital photographs, video and audio records), observations and results and reports of examinations. Electronic storage of records is acceptable.

(e) Case notes and records of observations shall be of a permanent nature as they are subject to subpoena or discovery. Handwritten notes and observations shall be written in ink not pencil. Pencil (including colour) may, however, be appropriate for diagrams or making tracings only.

(f) Where appropriate, observations or test results shall be preserved by photography or electronic means (e.g. electrophoretic runs, physical matches, quantitation results). Photocopies may also be used for record purposes (e.g. thin-layer chromatography results, questioned documents).

(g) Applicable operating parameters, including those not specified in the method, shall be recorded where instrumental analyses are conducted.

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

Note 21: Abbreviations are acceptable only if they are readily comprehensible to a reviewer.

Note 22: The reason(s) for rejection may include instrument or standard failure, a result off

scale or outside acceptance criteria for the method.

(i) Each page of every document (including administrative and examination records) in the case record shall bear the laboratory's unique case identifier, the analyst/examiner's handwritten initials and page number. When records are made on both sides of a page, each side shall be treated as a separate page. Other systems which identify the person who takes responsibility of the content of the records and which also demonstrate that each page of the case records has been reviewed are also acceptable.

(j) It shall be clear from the case records on which date(s) each stage of the analysis/examination was performed. All analysts/examiners and checkers shall also be identified.

(k) When examination records are prepared by an individual(s) other than the analyst who interprets the findings, prepares the report and/or testifies concerning the records, the handwritten initials of the individual(s) shall be on the page(s) of examination records representing his/her work.

Note 23: Electronically-generated records meet the requirements of Clauses 7.5 (i), (j) and (k) if each page is traceable to the case and the corresponding analyst/examiner/checker can be identified.

(l) The laboratory shall have a system to uniquely identify all records in or pertaining to the case record. This system shall also indicate that the case record is complete. This can be done by, for example, giving the total number of pages in the case record or having an index showing the complete content of the record.

Note 24: Documented laboratory procedures should include a description of the storage of records that are not stored in the case record. It is acceptable for physical records such as chromatograms, photographs, impressions/molds etc. to be stored in a bag/envelope secured to prevent loss, which contains an itemised description of contents, case number, analyst's identification and that the bag/envelope itself is

identified as part of the case file. Appropriate measures to protect the integrity of this type of case record should be implemented. Proper recording of original state of the record can safeguard any future query or challenge on interpretation.

7.6 Evaluation of measurement uncertainty

(a) Although estimation of measurement uncertainty of test results that are not numerical (e.g. pass/fail, positive/negative, detected/not detected or other qualitative data) is not a requirement, the laboratory should understand the variability of such results they generate, where possible.

7.7 Ensuring the validity of results

(a) The performance of tests/examinations shall be monitored by using quality control procedures appropriate to the type and frequency of the tests/examinations undertaken. Appropriate controls and standards shall be specified in the method and recorded their use in the case record.

Note 25: The range of quality control activities available to laboratories includes the following:

- reference collections;
- certified reference materials;
- internally generated reference materials/collections;
- independent checks by other analysts/examiners;
- positive and negative controls;
- replicate testing/examination;
- alternative methods;
- spike samples, standard additions and internal standard
- proficiency testing or interlaboratory comparison.

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

(b) Critical findings shall be checked before being reported. Records indicating that each critical finding has been checked, by whom and when the checks

were performed shall be maintained. The records shall also indicate if the critical finding has been agreed, or the action taken if this was not the case.

Note 26: Critical findings, as defined in ILAC G19, are observations and results that have a significant impact on the conclusion reached and the interpretation and opinion provided. In addition, these observations and results cannot be repeated or checked in the absence of the exhibit or sample, and/or could be interpreted differently.

(c) Where a check of critical finding is the only quality control measure, it shall be performed without knowledge of the original result and this independence shall be identifiable from the records. The frequency of performing such measure shall be defined.

(d) Proficiency Testing

(i) The laboratory shall have a documented programme of proficiency testing for the purpose of measuring the capability of its examiners and the reliability of its analytical results.

(ii) The laboratory shall maintain records of proficiency testing which shall include at least the following:

- The test set identifier
- How test samples were obtained or created
- Identity of the analyst conducting the test
- Duration of examination (date of starting and completion of tests)
- Full details of all data and notes of the examination or analyses undertaken to support the results and conclusion
- The proficiency test results
- Any discrepancies found
- Details of necessary corrective action taken, if any,
- Record of review of performance and feedback from analyst/examiner

(iii) The laboratory shall participate in at least one proficiency testing

programme which is provided by external test providers annually in each discipline and major subdiscipline in which a laboratory seeks or holds accreditation. The laboratory shall implement appropriate internal proficiency testing (e.g. intralaboratory comparison) where an external programme is not available.

(iv) Each analyst, examiner and other technical support personnel engaged in examination/testing activities shall successfully complete at least one internal or external proficiency testing annually in his/her forensic science discipline(s).

(v) The laboratory shall use the routine testing procedures to carry out the proficiency tests.

(vi) Relevant supervisory staff of the analyst/examiner shall review the performance in proficiency testing programmes; corrective action shall be taken if unsatisfactory performance arises.

(vii) Feedback from the analyst/examiner, if any, shall be collected and recorded.

Note 27: Proficiency test samples are expected to be representative of items tested/ examined in normal forensic laboratory operations. A proficiency test sample may be apportioned among analysts/examiners if doing so does not alter the character of the testing.

(e) Case record review

(i) The laboratory shall establish policies and procedures for the technical and administrative reviews of examination records and test reports prior to their release to the clients. Laboratory policy shall define the scope of the reviews, such as percentage of cases under review, who should conduct the reviews, and how they are documented.

(ii) Technical reviews shall be conducted by authorised individuals who have expertise in the discipline of the testing being reviewed. The technical reviewer shall be equipped with sufficient knowledge of the discipline to verify compliance with the technical procedures and the conclusion reached are supported by examination record.

(iii) Technical and administrative reviews shall be conducted by someone other than the person responsible for the examination record and report.

(iv) Case records that have been reviewed shall bear the identity and handwritten initial or signature (or its electronic equivalents) of the reviewer and the date of the review.

Note 28: It is acceptable for the technical and administrative reviews of case files to be performed as part of one review process.

7.8 Reporting of results

(a) The laboratory shall document the policies and procedures for issuing reports as well as policies and procedures describing reasons or conditions for not producing a report of analytical work.

(b) The laboratory shall have procedures for controlling the release of case report information.

Note 29: The laboratory may require issuing report in a prescribed format under legal requirement. It is accepted that the laboratory may not be able to include all the items in laboratory reports that are detailed in applicable clauses of ISO/IEC 17025:2017. In such case, all the relevant information required by ISO/IEC 17025:2017 should be included in the case record or in the form of an annex to the Court Statement pertaining to a particular investigation.

(c) When comparative examinations are conducted, the results shall be based upon robust studies and methodologies that are widely accepted in the field as being adequate for the purpose. The usage of terminology in the expression of opinion shall be clear and comprehensible, the basis and rationale behind the selection of terminology shall also be documented. When comparative examinations result in the elimination of an individual or object, the report shall clearly communicate the reason for the decision; when association are made, the significance of the association shall also be communicated clearly and qualified properly in the report. Limitations of the examination or testing used that gives rise to the conclusion shall be fully considered.

(d) When no definitive conclusions can be reached, the report shall clearly communicate the reasons for the decision.

7.9 Complaints

(No additional explanation)

7.10 Nonconforming work

(No additional explanation)

7.11 Control of data and information management

(No additional explanation)

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

(No additional explanation)

8.2 Management system documentation (Option A)

(a) Policies, systems, programmes, procedures and instructions shall be documented and the relevant documentation shall be kept up to-date.

(b) The policies and objectives of the laboratory shall be relevant to the needs of the community it serves.

(c) The objective shall be clearly understood and supported by laboratory personnel.

(d) The laboratory shall implement an information management system for the collection, storage and retrieval of information such as caseload distribution, turnaround time and information, which will assist in accomplishing the laboratory's objective.

8.3 Control of management system documents (Option A)

(a) Obsolete documents that are related or being referred to in case records (e.g. examination procedures) shall be retained for the same period as the case records to which they may pertain.

(b) The requirements for document control shall apply to all sites or locations where work is performed.

8.4 Control of records (Option A)

(No additional explanation)

8.5 Actions to address risks and opportunities

(No additional explanation)

8.6 Improvement (Option A)

(No additional explanation)

8.7 Corrective actions (Option A)

(No additional explanation)

8.8 Internal audits (Option A)

(No additional explanation)

8.9 Management reviews (Option A)

(No additional explanation)

Annex

(Informative)

List of references

1. ILAC G19, Modules in a Forensic Science Process

2. Forensic Science Regulator: Code of Practice, Forensic Science Regulator UK

3. Guidance – Validation, Forensic Science Regulator UK