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1 SCOPE

1.1 This document supplements ISO/IEC 17025:2017 with applicable requirements from International Laboratory Accreditation Cooperation (ILAC) policies and specific accreditation requirements for forensic service providers. A requirement may not apply to the work conducted. In such instances, the requirement shall be regarded as "not applicable." In this document, notes (appearing as “NOTE”) are intended to provide clarification or examples of conformance and do not constitute additional accreditation requirements.

2 REFERENCES

For undated references, the latest edition of the referenced document (including any amendments) applies.

International Laboratory Accreditation Cooperation (ILAC), ILAC P9 - ILAC Policy for Participation in Proficiency Testing Activities.

International Laboratory Accreditation Cooperation (ILAC), ILAC P10 - ILAC Policy on the Traceability of Measurement Results.

International Laboratory Accreditation Cooperation (ILAC), ILAC P14 - ILAC Policy for Uncertainty in Calibration.

International Laboratory Accreditation Cooperation (ILAC), ILAC G19 - Modules in a Forensic Science Process.


Joint Committee for Guides in Metrology (JCGM), International vocabulary of metrology - Basic and general concepts and associated terms (VIM) (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200).
3 TERMS AND DEFINITIONS

The following words used in ISO/IEC 17025 or in this document have the following interpretation:

shall – a requirement
should – a recommendation

3.8 Verification - Provision of objective evidence that a given item fulfils specified requirements (ISO/IEC 17025:2017).

EXAMPLE 4: Confirmation of a test result/opinion by performance of the comparison between the unknown and the known by a different person.

3.10 Association - A determination that a relationship exists between individuals and/or objects.

3.11 Audit - A systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled (ISO/IEC 17000:2004).

3.12 Certified reference material (CRM) – Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO Guide 30:2015, modified).

Note 1 to entry: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence.

3.13 Competency test - The evaluation of a person’s knowledge, skills, and/or ability to perform work

3.14 Contract - The agreement between the forensic service provider and the customer. A fee for service is not required.

3.15 Customer - A person or organization that could or does receive a product or a service that is intended for or required by this person or organization. A customer can be internal or external to the forensic service provider.

3.16 Director - The highest ranking manager.

3.17 Discipline - A major area of activity in forensic science.
3.18 Individual characteristic database - A computerized, searchable collection of features, generated from samples of known origin from which individual characteristic information originates (e.g., DNA profiles, friction ridge data, or firearm bullet/cartridge case images).

3.19 Reagent - A substance used because of its known chemical or biological activity.

3.20 Reference collection - Data or materials of known origin or property, which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, motor vehicle paints, wood fragments, firearms, ammunition).

3.21 Reference material (RM) - Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO Guide 30:2015).

3.22 Reference material producer (RMP) - Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference material it produces (ISO 17034:2016).

3.23 Reference standard - A measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location (JCGM 200:2012).

NOTE Working measurement standard – Measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems (JCGM 200:2012).

3.24 Request - The process utilized by a customer when seeking services from the forensic service provider.

3.25 Sampling - Selection of a sample for testing, according to a procedure (ISO/IEC 17000, modified). The approach to sampling can be either non-statistical or statistical.

3.26 Tender - The response to the customer request for services. This may include an automated notification.

4 GENERAL REQUIREMENTS

4.1 Impartiality

4.1.3.1 The management system shall:
   a) have a code of ethics as part of the management’s commitment to good professional practice;
b) ensure annual review of the document by all personnel and maintain a record of the review; and

c) ensure appropriate actions are taken when necessary.

5 STRUCTURAL REQUIREMENTS

5.2.1 There shall be a director, whose duties shall be defined.

5.4

NOTE An example of a regulatory authority is the Federal Bureau of Investigation for laboratories participating in the National DNA Index System (NDIS).

5.4.1 Laboratories shall conform to requirements in PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status.

5.4.2 If a laboratory performs testing or calibration under the authority of a statute, regulation or other legal requirement, the laboratory shall make this readily available.

NOTE A legal requirement is created, imposed and enforced by a third-party external to the laboratory.

5.5

NOTE c) Documenting procedures to the extent necessary to ensure the consistent application of testing and calibration and the validity of the results includes analysis and data interpretation to arrive at a result, opinion or interpretation.

6 RESOURCE REQUIREMENTS

6.2 Personnel

6.2.2

NOTE See GD 3152 for guidance on the phrase “influence the result of laboratory activities”.

6.2.2.1 Personnel who authorize results, opinions and/or interpretations shall meet the minimum educational requirements established in the country in which the laboratory operates (see Annex A).

6.2.2.2 The training program for each function influencing the results of laboratory activities, to the extent necessary based on job function, shall include:

a) the knowledge, skills, and abilities needed to perform work;

b) general knowledge of forensic science;

c) the application of ethical practices in forensic science;

d) criminal law, civil law, and testimony;

e) provisions for retraining;

f) provisions for maintenance of skills and expertise; and

g) criteria for acceptable performance.

NOTE 1 Past work experience and training may be substituted for portions of the training program to the extent that it has been demonstrated to be relevant and sufficient.
NOTE 2 ISO/IEC 17025:2017, section 7.3 may be applicable to training programs.

6.2.3.1 All personnel who perform testing or calibration shall be competency tested. Testing or calibration includes the review and authorization of results and expressing an opinion or an interpretation. The competency test shall include practical examination(s) that cover the spectrum of anticipated tasks related to the test or calibration. The competency test intended results shall be achieved prior to performing the tasks on a test or calibration item.

NOTE Competency testing can be conducted for an individual task or a group of tasks covered by a module of a training program.

6.2.3.2 Personnel who perform technical review of results or testimony, shall meet the competency requirements as specified in 6.2.3.1 for the testing or calibration tasks being reviewed.

6.2.6 NOTE Authorization of personnel includes all aspects of testing or calibration including, as applicable, the use of equipment.

6.3 Facilities and environmental conditions

6.3.4.1 There shall be a procedure that addresses security and access to areas where testing and calibration occur.

NOTE Topics to consider may include, but are not limited to, access to building, access by personnel, access by visitors, security during operational hours and non-operational hours, and devices that grant access.

6.4 Equipment

6.4.3.1 In addition to the procedural requirements in ISO/IEC 17025:2017, clause 6.4.3, reagents prepared shall be labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records shall be maintained identifying who made the reagent and the components used in preparation.

6.4.3.2 Reference collections shall have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest.

6.4.7.1 The program for the calibration of equipment shall include:
   a) a list of the equipment requiring calibration;
   b) specifications for the calibration laboratory;
   c) specified requirements for the calibration; and
   d) the interval of calibration.

6.4.10 NOTE When evaluating the need for intermediate checks, topics to consider include, but are not limited to: the calibration interval, the use of the equipment, the stability of the equipment, the method specifications, and risk associated with a failed check.
6.5 Metrological traceability

6.5.1.1 The laboratory shall establish and maintain metrological traceability of its measurement results by utilizing products and services from suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials that are:

a) a National Metrology Institute that is a signatory to the BIPM\(^1\) - CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB)\(^2\); or

b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation; or

c) an accredited reference material producer that is accredited to ISO 17034\(^3,4\) by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material to be purchased.

6.5.1.2 In situations where a supplier that meets 6.5.1.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased shall be confirmed. Objective evidence of the confirmation shall be available for review.

6.5.1.3 For the purpose of establishing traceability of a measurement, an accredited laboratory may calibrate its own equipment that supports an accredited parameter on the scope if the related requirements in ISO/IEC 17025 and this document are met:

a) the calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel;

b) the calibration method shall be validated or verified prior to use;

c) certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties;

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2 International Bureau of Weights and Measures (BIPM) key comparison database (KCDB), Appendix C: Available at: http://kcdb.bipm.org/appendixC/


4 Reference material producers accredited to ISO Guide 34:2009 may also be used until November 1, 2019.
d) the calibration shall be carried out in an appropriate environment;
e) technical records of the calibration shall be established and maintained;
f) the laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts; and
g) a technical review of the technical records including any data transfers and calculations shall be completed by an individual other than the person(s) who performed the work.

6.5.1.4 If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material shall be evaluated for applicability of measurement traceability accreditation requirements.

7 PROCESS REQUIREMENTS

7.1 Review of requests, tenders and contracts

7.1.9 The extent of database (e.g., DNA profiles, friction ridge, ballistics, biometrics) searches shall be communicated to customers and updated as needed.

NOTE 1 “extent” will be specific to the database but may include aspects of the scope or range of the search (e.g., local, state, national, international), the frequency of the search or if the customer is required to make a request to elevate the scope of the search or to have a search performed.

NOTE 2 This may be communicated on a case-by-case basis, in the report, or in a general customer communication.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1.1 The laboratory shall use appropriate methods and procedures for all associated data analysis and interpretation.

7.2.1.1.2 All test methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s).

NOTE 1 Characteristics include, but are not limited to, alleles in a DNA profile, friction ridge detail in a latent print, striation detail on a bullet, features of handwriting, or criteria for evaluation of mass spectrometry fragments and ratios in a seized drug sample or a toxicology sample extract.

NOTE 2 This requirement is not focused on the process of assessing an unknown in order to identify the test item that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known prior to the assessment of the unknown.

7.2.1.3 For laboratories whose scope of accreditation includes calibration:
a) measuring instrument calibration methods shall assess accuracy (bias and precision) of the instrument across a range of values that meets the needs of the customer; and
b) the source of material(s) used to calibrate a measuring instrument shall be different from that used to adjust a measuring instrument and that used to verify calibration status.

**NOTE 1** a) “needs of the customer” include regulatory or statutory limits.

**NOTE 2** b) Preference should be given to material(s) from different manufacturers, followed by different lot numbers of material from the same manufacturer.

### 7.2.2 Validation of methods

**7.2.2.1.1** The laboratory shall have a procedure for method validation that:

a) includes the associated data analysis and interpretation;
b) establishes the data required to report a result, opinion, or interpretation; and
c) identifies limitations of the method, reported results, opinions, and interpretations.

**7.2.2.2** **NOTE** Changes to associated data analysis and interpretation are considered changes to a validated method.

### 7.3 Sampling

**7.3.2** **NOTE 2** The intent of ISO/IEC 17025 is that the activity of sampling occurs prior to the item being submitted to the laboratory. A laboratory can choose to perform further sampling after receipt of the item, in which case the requirements for sampling are applicable.

**7.3.2.b).1** Statistical sampling at a stated level of confidence shall be used if an inference will be made to report on the whole population.

### 7.4 Handling of test or calibration items

**7.4.1.1** For all test items received except known origin individual characteristic database samples, the procedure shall:

a) address requirements for storage, packaging, and sealing of items to:
   1. protect the integrity of all items; and
   2. require items to be re-sealed as soon as practicable;
b) address measures to be taken to secure unattended items;
c) require chain-of-custody for:
   1. all items received; and
   2. items that are collected or created and preserved for future testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, trace evidence, DNA extracts);
d) require chain-of-custody to securely and accurately identify:
   1. the individual(s) or location(s) receiving or transferring the item(s); and
   2. the item(s) being transferred; and
3. the chronological order of all transfers, minimally including the date;
e) require communication to the customer regarding the disposition of all items received; and
f) address communication to the customer regarding items collected or created and preserved for future testing.

NOTE 1 c) An item being tracked could contain multiple components and be tracked as one item.

NOTE 2 d) Documentation of internal transfers does not need to include use of personal storage locations.

7.4.2.1 The system used to identify items shall cover all items received.

7.5 Technical records

7.5.1 NOTE Options for recording observations include, but are not limited to: written notes, photography, drawing, photocopying, or scanning.

7.5.1.1 Define the technical record(s) to be retained if all related technical records are not maintained.

7.5.1.2 Where abbreviations or symbols specific to the forensic service provider are used, the meaning of the abbreviations or symbols shall be defined.

7.5.1.3 Technical records to support a report (including results, opinions, and interpretations) shall be such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data.

7.5.1.4 Records shall be created or maintained in a permanent manner.

NOTE For example, technical records originally captured in pencil (e.g., a rough sketch) can be maintained in a permanent manner by photocopying, scanning, or taking a photo.

7.5.1.5 If an observation, data, or calculation is rejected, the reason, the identity of the individual(s) taking the action and the date shall be recorded in the technical record.

7.5.1.6 If an adjustment or repair is performed due to a calibration that does not meet specifications, pre and post adjustment/repair data shall be retained.

NOTE See related clause ISO/IEC 17025:2017, 7.8.4.1.d)

7.5.2 NOTE Contemporaneous revisions are not considered amendments.

7.6 Evaluation of measurement uncertainty

7.6.1.1 The method of analysis for evaluation of measurement uncertainty shall:
a) require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;
b) include the process of rounding the expanded uncertainty;
c) require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and
d) specify the schedule to review and/or recalculate the measurement uncertainty.

7.6.3.1 Measurement uncertainty shall be evaluated, or estimated when applicable, for all reported quantitative results.

NOTE An item descriptor that includes a number is not considered a result. This difference should be clear to the reader of the report.

7.6.4 The following records shall be maintained for each evaluation and estimation of measurement uncertainty:
   a) statement defining the measurand;
   b) statement of how traceability is established for the measurement;
   c) the equipment (e.g., measuring device[s] or instrument[s]) used;
   d) all uncertainty components considered;
   e) all uncertainty components of significance and how they were evaluated;
   f) data used to estimate repeatability, intermediate precision, and/or reproducibility;
   g) all calculations performed; and
   h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

7.7 Ensuring the validity of results

7.7.1.g).1 When a verification of a result is carried out:
   a) it shall be conducted by an individual who is currently authorized to perform the testing;
   b) a record of the verification shall be made and the record shall identify who performed the verification, when it was performed, and the result of the verification; and
   c) the resolution of any discrepancy shall be recorded.

NOTE 1 a) See requirements of 6.2.6 in ISO/IEC 17025:2017.

NOTE 2 b) Verification may be recorded for each result verified or as a summary for all results verified.
7.7.1.l) There shall be a procedure for the technical review of technical records, including reports, and testimony. The procedure shall:
1. require the individual performing the technical review to have been competency tested to perform the testing or calibration work that is being reviewed.
2. preclude an individual from technically reviewing their own work;
3. define the method to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review;
4. define the method to be used to ensure testimony in each discipline is reviewed;
5. define the method to be used to conduct and record the review;
6. ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record;
7. ensure conformance with methods and applicable management system documents; and
8. describe a course of action to be taken if a discrepancy is found.

NOTE 1 An individual conducting the technical review need not be an employee of the forensic service provider, currently proficiency tested or currently performing the work.

NOTE 2 An individual who performs a verification can also perform a technical review.

NOTE 3 The frequency may vary for different disciplines.

7.7.2.1 The process for monitoring performance by comparison with results of other forensic service providers shall at a minimum:

a) ensure successful completion of at least one proficiency test for each discipline prior to accreditation being granted in that discipline; and

b) ensure each location on the scope of accreditation successfully completes, per calendar year, at least one proficiency test for each discipline in which accredited services are provided, with authorized release of the test results to ANAB from the test provider.

NOTE 1 Accreditation occurs in the discipline of Toxicology in both Calibration and Testing. The above requirements apply to the Testing scope of accreditation and Calibration scope of accreditation separately.

NOTE 2 For proficiency tests taken at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

7.7.4 The performance of personnel shall be monitored. This monitoring shall ensure that all personnel who perform testing or calibration shall successfully complete at least one intralaboratory comparison, interlaboratory comparison or proficiency test per calendar year in each discipline on the scope of accreditation in which the individual conducts work. In the event that the preceding options are not available or appropriate, observation-based performance monitoring is acceptable.

NOTE 1 The monitoring should be varied over time to cover all aspects of assigned job functions but does not have to include all aspects of the work performed each time.

NOTE 2 Solely performing verifications (7.7.1.g.1) or solely reviewing and authorizing results (7.8.1.1) are considered to be testing or calibration and are subject to these requirements.
NOTE 3  Accreditation occurs in the discipline of Toxicology in both Calibration and Testing. The above requirements apply to the Testing scope of accreditation and Calibration scope of accreditation separately.

NOTE 4  For performance monitoring conducted at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

7.7.5  The process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing shall at a minimum:

a) ensure that results are not known or readily available to the participant being monitored;

b) ensure use of approved methods;

c) establish criteria for determining successful completion prior to the monitoring activity;

d) require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity; and

e) for calibration laboratories, require intralaboratory comparisons, interlaboratory comparisons and proficiency tests to be performed using an item that was calibrated by the person performing the comparison or test.

7.7.6  There shall be a plan that will:

a) demonstrate conformance with the requirements stated in clause 7.7.2.1.b) and 7.7.4; and

b) ensure inclusion of a representative sample of the components/parameters and equipment/technologies within each discipline listed on the scope of accreditation.

7.7.7  To satisfy the proficiency test requirements in clauses 7.7.2.1.a) and b), the forensic service provider shall:

a) where available and appropriate for the work conducted, use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APAC MRA or IAAC MLA\(^5\) and has the applicable proficiency test(s) on its scope of accreditation; or

b) where not available or not appropriate for the work conducted, gain approval from ANAB for alternative means by which the laboratory’s performance can be assessed (FM 3041 Alternative Proficiency Test Request Form); and

c) submit results to the proficiency test provider, if applicable, on or before the agreed upon due date.

7.7.8  The following records shall be maintained for all intralaboratory comparisons, interlaboratory comparisons, proficiency tests and observation-based monitoring:

a) discipline(s) monitored;

b) design of the monitoring activity;

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\(^5\) ILAC is currently in the process of extending the MRA to include the accreditation of proficiency test (PT) providers. Once the MRA is in place, PT providers must be accredited by an accreditation body that is a signatory to the ILAC MRA for PT providers.
c) expected results;
d) location, when more than one location is associated with a single accreditation certificate;
e) records submitted to a proficiency test provider, when applicable;
f) appropriate technical records;
g) evaluation of results and action taken for unexpected results; and
h) feedback on individual performance provided to the participant.

NOTE f) See requirements of 7.5 in ISO/IEC 17025:2017 and this document.

7.8 Reporting of results

7.8.1 General

7.8.1.1 The authorizer of results shall review the technical record and document the review.

7.8.1.2 The results shall be provided in a written report or through electronic access.

NOTE The reporting of results does not include testing of known origin samples for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.

7.8.1.2.1 There shall be a procedure for reporting of results that:
a) identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for partial work performed;
b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement;
c) requires communicating the reason(s) in the report when the reported results are inconclusive; and
d) requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics).

NOTE b) Associations for multiple results may be qualified by a single statistic or qualitative statement if the statistics are identical or, where applicable, meet or exceed a defined minimum threshold.

7.8.1.2.3 The documented process for reporting of results of calibration shall:
a) identify what information will be reported in the calibration certificate; and
b) require the issuance of an endorsed calibration certificate if requested by the customer.

7.8.1.3 When results are reported in a simplified way, the agreement with the customer shall specify which information in 7.8.2 through 7.8.7 of ISO/IEC 17025:2017 will not be included in a written report or through electronic access. The requirements 7.8.2 through 7.8.7 in this document are applicable even if the forensic service provider reports results in a simplified way.
7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 NOTE 2 A legal requirement that dictates the information to be included in a report is a valid reason to not include one or more listed report elements.

NOTE 3 i) Date(s) may be reflected as a range of dates or the date of each test or calibration.

NOTE 4 o) Authorization of the report does not have to be performed by the same person(s) who authorized the results. (see ISO/IEC 17025:2017 7.8.1.1)

7.8.3 Specific requirements for test reports

7.8.3.1.c).1 The measurement uncertainty shall:

a) be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;

b) include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;

c) be in the format of y ± U;

d) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and

e) be reported to the same level of significance (i.e., same number of decimal places or digits) as the measurement result.

NOTE 1 a) A legal requirement is created, imposed, and enforced by a third-party external to the laboratory agency.

NOTE 2 c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.

NOTE 3 e) Reducing or simplifying a fraction is not a change in level of significance.

7.8.3.1.1 If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, the forensic service provider shall:

a) have objective evidence of the regulation, statute, case law or other legal requirement; and

b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

7.8.4 Specific requirements for calibration certificates

7.8.4.1.a).1 The measurement uncertainty shall:

a) include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, and the coverage probability;

b) be in the format of y ± U;
c) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and
d) be reported to the same level of significance \( (i.e., \) same number of decimal places or digits) as the measurement result.

**NOTE** c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than \( y \pm U \) may be needed.

### 7.8.4.1.1
If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a calibration result or prohibits including measurement uncertainty in the calibration certificate, the forensic service provider shall:

a) have objective evidence of the regulation, statute, case law or other legal requirement; and

b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the calibration result.

### 7.8.4.4
If applicable, a label (in addition to the calibration certificate) attached to a calibrated item shall not give the impression that the item itself is approved and shall include:

a) the name of the accredited calibration laboratory or its accreditation certificate number;

b) the unambiguous identification of the item calibrated;

c) the date of the current calibration; and

d) cross reference to the calibration certificate issued in respect to the calibration.

### 7.8.5 Reporting sampling – specific requirements

### 7.8.5.d).1
If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.

### 7.11 Control of data and information management

#### 7.11.2.1
There shall be a plan for validation of computer software developed by the user and records of the validation shall be maintained.

**NOTE** This requirement does not apply if the calculation or data transfer is secure and not subject to human error.

#### 7.11.6.1
The technical record shall indicate the check was performed and who performed the check. When possible, this check shall not be conducted by the person who performed the calculation(s) or the data transfers.

**NOTE** This check may be part of a technical review.

## 8 MANAGEMENT SYSTEM REQUIREMENTS

### 8.1.3 Option B
8.1.3.1 In order for Option B to be available to a forensic service provider, the provider must maintain an accredited ISO 9001 certification. The certification body, which certified the provider to ISO 9001, must be accredited for ISO 9001 by an IAF MLA signatory accreditation body for management systems. Any forensic service provider that does not meet this criterion must choose Option A.

8.1.3.2 The Option A requirements under 8.2 through 8.9 in this document are also applicable to forensic service providers who choose Option B.

8.2 Management system documentation (Option A)

8.2.1.1 The following words (to include forms of the same word) used in ISO/IEC 17025:2017 or in this document require addressing the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.

8.4 Control of records (Option A)

8.4.2 NOTE 2 Contractual obligations for records retention include legal requirements and customer expectations.

8.5 Actions to address risks and opportunities (Option A)

8.5.1.1 Risks and opportunities related to health and safety shall be considered.

8.7 Corrective actions (Option A)

8.7.1.1 The process for corrective action shall establish a reasonable timeframe for completion for each corrective action.

8.8 Internal audits (Option A)

8.8.1.a).1 Internal audits shall provide information on whether the management system conforms to the requirements of this document.

8.8.1.1 Internal audits shall be conducted at least annually, as well as prior to the initial accreditation assessment.

8.8.2.b).1 Internal audits shall include direct observation of a sample of accredited services within each discipline.

8.9 Management reviews (Option A)

8.9.1.1 Management reviews shall be conducted at least annually, as well as prior to the initial accreditation assessment.
ANNEX A (normative)

Educational requirements for personnel

A.1 General
This annex provides educational requirements for personnel based on the country in which the laboratory operates.

A.2 Requirements for United States laboratories
A.2.1 Personnel who authorize results or express opinions and/or interpretations in the following disciplines shall meet the minimum educational requirements below.

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Minimum Education Requirements</th>
</tr>
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<tbody>
<tr>
<td>Biology</td>
<td>A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.</td>
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<tr>
<td>Fire Debris and Explosives</td>
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<tr>
<td>Geological Materials</td>
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<tr>
<td>Gunshot Residue</td>
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<tr>
<td>Materials (Trace)</td>
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<tr>
<td>Seized Drugs</td>
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<tr>
<td>Toxicology</td>
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<tr>
<td>Wildlife Forensics</td>
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<tr>
<td>Anthropology</td>
<td>Meet the educational requirement(s) specified for competence (see ISO/IEC 17025:2017 6.2.2).</td>
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<tr>
<td>Bloodstain Pattern Analysis</td>
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<tr>
<td>Crime Scene Investigation</td>
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<tr>
<td>Digital Evidence</td>
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<tr>
<td>Disaster Victim Identification</td>
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<tr>
<td>Document Examination</td>
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<tr>
<td>Facial Identification</td>
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<tr>
<td>Fire and Explosion Investigation</td>
<td></td>
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<tr>
<td>Firearms/Toolmarks</td>
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<td>Footwear and Tire</td>
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<td>Friction Ridge</td>
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<td>Medicolegal Death Investigation</td>
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<td>Odontology</td>
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<td>Speaker Recognition</td>
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<tr>
<td>Video/Imaging Technology and Analysis</td>
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</tbody>
</table>

NOTE 1 Minimum educational requirements apply to personnel working in any discipline for which training begins after the date of initial accreditation to ISO/IEC 17025 in that discipline.

NOTE 2 This table is not exhaustive and additional disciplines may be added as appropriate.