

# Internal Audit Checklist (Year:\_\_\_\_)

ISO/IEC 17025:2017 and ANAB AR3125 (2/1/2023) Criteria

grey fields relate to calibration  
laboratories so are N/A  
Green fields represent a parent topic or  
a note and do not require a reply

Clause	Source	Accreditation Standard	YES	NO	N/A	Reference/Comment
4	17025:2017	General Requirements				
4.1	17025:2017	Impartiality				
4.1.1	17025:2017	Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.				
4.1.2	17025:2017	The laboratory management shall be committed to impartiality.				
4.1.3	17025:2017	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.				
4.1.3.1	AR 3125	The management system shall:				
a)	AR 3125	have a code of ethics as part of the management's commitment to good professional practice;				
b)	AR 3125	ensure annual review of the code of ethics by all personnel and retain a record of the review; and				
c)	AR 3125	ensure appropriate actions are taken when necessary.				
4.1.4	17025:2017	The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.				

	17025:2017	NOTE: A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.				
4.1.5	17025:2017	If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.				
<b>4.2</b>	<b>17025:2017</b>	<b>Confidentiality</b>				
4.2.1	17025:2017	The laboratory shall be responsible, through legal enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.				
4.2.2	17025:2017	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.				
4.2.3	17025:2017	Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.				

4.2.4	17025:2017	Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.				
<b>5</b>	<b>17025:2017</b>	<b>Structural requirements</b>				
5.1	17025:2017	The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.				
	17025:2017	NOTE: For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.				
5.2	17025:2017	The laboratory shall identify management that has overall responsibility for the laboratory.				
5.2.1	AR 3125	There shall be a director, whose duties shall be defined.				
5.3	17025:2017	The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.				
5.4	17025:2017	Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>

	AR 3125	NOTE: Examples of regulatory authorities are the Federal Bureau of Investigation for laboratories participating in the National DNA Index System (NDIS) and state forensic science commissions providing accreditation.				
5.4.1	AR 3125	Laboratories shall conform to requirements in <i>PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status</i> .				
5.4.2	AR 3125	Any event or nonconformity that could substantially affect the integrity of laboratory activities and is related to an accreditation requirement or the requirements of regulatory authorities shall be disclosed to ANAB within 30 calendar days of the occurrence. If the event or nonconformity is identified more than 30 calendar days after the occurrence, it shall be disclosed to ANAB immediately.				
	AR 3125	NOTE: See MA 3033 Section 4.6.				
5.5	17025:2017	The laboratory shall:				
a)	17025:2017	define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;				
b)	17025:2017	specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;				
c)	17025:2017	document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.				
	AR 3125	NOTE: 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.				

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5.6	17025:2017	The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:				
a)	17025:2017	implementation, maintenance and improvement of the management system;				
b)	17025:2017	identification of deviations from the management system or from the procedures for performing laboratory activities;				
c)	17025:2017	initiation of actions to prevent or minimize such deviations;				
d)	17025:2017	reporting to laboratory management on the performance of the management system and any need for improvement;				
e)	17025:2017	ensuring the effectiveness of laboratory activities.				
5.7	17025:2017	Laboratory management shall ensure that:				
a)	17025:2017	communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;				
b)	17025:2017	the integrity of the management system is maintained when changes to the management system are planned and implemented.				
<b>6</b>	<b>17025:2017</b>	<b>Resource Requirements</b>				
<b>6.1</b>	<b>17025:2017</b>	<b>General</b>				
	17025:2017	The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.				
<b>6.2</b>	<b>17025:2017</b>	<b>Personnel</b>				
6.2.1	17025:2017	All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.				

6.2.2	17025:2017	The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.				
	AR 3125	NOTE: See GD 3152 for guidance on the phrase "influence the result of laboratory activities".				
6.2.2.1	AR 3125	Personnel who authorize results, opinions, and/or interpretations in the following disciplines shall meet the minimum educational requirements established in the country in which the laboratory operates (see Annex A).				
<b>Annex A</b>	<b>Discipline</b>	<b>Minimum Education Requirements</b>				
	Biology	A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.				
	Fire Debris					
	Seized Drugs					
	Toxicology					
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
	Digital and Video/Imaging	Meet the educational requirement(s) specified for competence (see ISO/IEC 17025:2017 6.2.2).				
	Firearms/ Toolmarks					
	Friction Ridge					
	Impressions (Footwear/Tire)					
	AR 3125	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.				
6.2.2.2	AR 3125	The training program, for each function influencing the results of laboratory activities, to the extent necessary based on job function, shall include:				

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a)	AR 3125	the knowledge, skills, and abilities needed to perform work;				
b)	AR 3125	general knowledge of forensic science;				
c)	AR 3125	the application of ethical practices in forensic science;				
d)	AR 3125	criminal law, civil law, and testimony;				
e)	AR 3125	provisions for retraining;				
f)	AR 3125	provisions for maintenance of skills and expertise; and				
g)	AR 3125	criteria for acceptable performance.				
	AR 3125	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.				
	AR 3125	NOTE 2: ISO/IEC 17025:2017, section 7.3 may be applicable to training programs.				
6.2.3	17025:2017	The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.				
6.2.3.1	AR 3125	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.				
	AR 3125	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	AR 3125	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.				

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6.2.4	17025:2017	The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.				
6.2.5	17025:2017	The laboratory shall have procedure(s) and retain records for:				
a)	17025:2017	determining the competence requirements;				
b)	17025:2017	selection of personnel;				
c)	17025:2017	training of personnel;				
d)	17025:2017	supervision of personnel;				
e)	17025:2017	authorization of personnel;				
f)	17025:2017	monitoring competence of personnel.				
6.2.6	17025:2017	The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:				
a)	17025:2017	development, modification, verification and validation of methods;				
b)	17025:2017	analysis of results, including statements of conformity or opinions and interpretations;				
c)	17025:2017	report, review and authorization of results.				
	AR 3125	NOTE: Authorization of personnel includes all aspects of testing or calibration including, as applicable, the use of equipment.				
<b>6.3</b>	<b>17025:2017</b>	<b>Facilities and environmental conditions</b>				
6.3.1	17025:2017	The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.				
	17025:2017	NOTE: Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.				
6.3.2	17025:2017	The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.				



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6.3.3	17025:2017	The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.				
6.3.4	17025:2017	Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:				
a)	17025:2017	access to and use of areas affecting laboratory activities;				
b)	17025:2017	prevention of contamination, interference or adverse influences on laboratory activities;				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
c)	17025:2017	effective separation between areas with incompatible laboratory activities.				
6.3.4.1	AR 3125	There shall be a procedure that addresses security and access to areas where testing and calibration occur.				
	AR 3125	NOTE: Topics to consider may include, but are not limited to, access to buildings, access by personnel, access by visitors, security during operational hours and non-operational hours, and devices that grant access.				
6.3.5	17025:2017	When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.				
<b>6.4</b>	<b>17025:2017</b>	<b>Equipment</b>				
6.4.1	17025:2017	The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.				

	17025:2017	NOTE 1: A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.				
	17025:2017	NOTE 2: ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.				
6.4.2	17025:2017	When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.				
6.4.3	17025:2017	The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.				
6.4.3.1	AR 3125	In addition to the procedural requirements in ISO/IEC 17025:2017 clause 6.4.3, reagents prepared shall be labeled with the identity of the reagent and the date of preparation or lot number. Records shall be retained identifying who made the reagent and the components used in preparation.				

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6.4.3.2	AR 3125	Reference collections shall have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest.				
6.4.4	17025:2017	The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.				
6.4.5	17025:2017	The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.				
6.4.6	17025:2017	Measuring equipment shall be calibrated when:				
	17025:2017	-- the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or				
	17025:2017	-- calibration of the equipment is required to establish the metrological traceability of the reported results.				
	17025:2017	NOTE: Types of equipment having an effect on the validity of the reported results can include: -- those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; -- those used to make corrections to the measured value, e.g. temperature measurements; -- those used to obtain a measurement result calculated from multiple quantities.				
6.4.7	17025:2017	The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.				
6.4.7.1	AR 3125	The program for the calibration of equipment shall include:				
a)	AR 3125	a list of the equipment requiring calibration;				
b)	AR 3125	specifications for the calibration laboratory;				
c)	AR 3125	specified requirements for the calibration; and				

d)	AR 3125	the interval of calibration.				
6.4.8	17025:2017	All equipment requiring calibration or which has a defined period of validity shall be labeled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
6.4.9	17025:2017	Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent is use or clearly labeled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examinethe effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10)				
6.4.10	17025:2017	When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.				
	AR 3125	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.				
6.4.11	17025:2017	When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.				
6.4.12	17025:2017	The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.				

6.4.13	17025:2017	Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:				
a)	17025:2017	the identity of equipment, including software and firmware version;				
b)	17025:2017	the manufacturer's name, type identification, and serial number or other unique identification;				
c)	17025:2017	evidence of verification that equipment conforms with specified requirements;				
d)	17025:2017	the current location;				
e)	17025:2017	calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;				
f)	17025:2017	documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;				
g)	17025:2017	the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;				
h)	17025:2017	details of any damage, malfunction, modification to, or repair of, the equipment.				
<b>6.5</b>	<b>17025:2017</b>	<b>Metrological traceability</b>				
6.5.1	17025:2017	The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.				
	17025:2017	NOTE 1: In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".				

	17025:2017	NOTE 2: See Annex A for additional information on metrological traceability.				
	AR 3125	NOTE 3: If the quantitative value of a reference material is changed (e.g., diluted), then the calibration of the equipment used to alter the reference material impacts the traceability chain. See also ISO/IEC 17025:2017 6.4.6.				
6.5.1.1	AR 3125	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)	AR 3125	A National Metrology Institute that is a signatory to the BIPM - 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); or				
b)	AR 3125	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)	AR 3125	an accredited reference material producer that is accredited to ISO 17034 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.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>

6.5.1.2	AR 3125	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	AR 3125	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)	AR 3125	the calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel;				
b)	AR 3125	the calibration method shall be validated or verified prior to use;				
c)	AR 3125	certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties;				
d)	AR 3125	the calibration shall be carried out in an appropriate environment;				
e)	AR 3125	technical records of the calibration shall be established and retained;				
f)	AR 3125	the laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts; and				
g)	AR 3125	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.				
6.5.2	17025:2017	The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:				

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a)	17025:2017	calibration provided by a competent laboratory; or				
	17025:2017	NOTE 1: Laboratories fulfilling the requirements of this document are considered to be competent.				
b)	17025:2017	certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or				
	17025:2017	NOTE 2: Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.				
c)	17025:2017	direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.				
	17025:2017	NOTE 3: Details of practical realization of the definitions of some important units are given in the SI brochure.				
6.5.3	17025:2017	When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:				
a)	17025:2017	certified values of certified reference materials provided by a competent producer;				
b)	17025:2017	results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.				
<b>6.6</b>	<b>17025:2017</b>	<b>Externally provided products and services</b>				
6.6.1	17025:2017	The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:				
a)	17025:2017	are intended for incorporation into the laboratory's own activities;				



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b)	17025:2017	are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;				
c)	17025:2017	are used to support the operation of the laboratory.				
	17025:2017	NOTE: Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.				
6.6.2	17025:2017	The laboratory shall have a procedure and retain records for:				
a)	17025:2017	defining, reviewing and approving the laboratory's requirements for externally provided products and services;				
b)	17025:2017	defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;				
c)	17025:2017	ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;				
d)	17025:2017	taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.				
6.6.3	17025:2017	The laboratory shall communicate its requirements to external providers for:				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
a)	17025:2017	the products and services to be provided;				
b)	17025:2017	the acceptance criteria;				
c)	17025:2017	competence, including any required qualification of personnel;				

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d)	17025:2017	activities that the laboratory, or its customer, intends to perform at the external provider's premises.				
<b>7</b>	<b>17025:2017</b>	<b>Process requirements</b>				
<b>7.1</b>	<b>17025:2017</b>	<b>Review of requests, tenders and contracts</b>				
7.1.1	17025:2017	The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:				
a)	17025:2017	the requirements are adequately defined, documented and understood;				
b)	17025:2017	the laboratory has the capability and resources to meet the requirements;				
c)	17025:2017	where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;				
	17025:2017	NOTE: It is recognized that externally provided laboratory activities can occur when: - the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full; - the laboratory does not have the resources or competence to perform the activities.				
d)	17025:2017	the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.				
	17025:2017	NOTE 2: For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.				
7.1.2	17025:2017	The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.				

7.1.3	17025:2017	When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.				
	17025:2017	NOTE: For further guidance on statements of conformity, see ISO/IEC Guide 98-4.				
7.1.4	17025:2017	Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.				
7.1.5	17025:2017	The customer shall be informed of any deviation from the contract.				
7.1.6	17025:2017	If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.				
7.1.7	17025:2017	The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.				
	17025:2017	NOTE: such cooperation can include: a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities; b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.				

7.1.8	17025:2017	Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.				
7.1.9	AR 3125	The extent of database (e.g., DNA profiles, friction ridge, ballistics, biometrics) searches shall be communicated to customers and updated as needed.				
	AR 3125	NOTE 1: The "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.				
	AR 3125	NOTE 2: This may be communicated on a case-by-case basis, in the report, or in a general customer communication.				
<b>7.2</b>	<b>17025:2017</b>	<b>Selection, verification and validation of methods</b>				
<b>7.2.1</b>	<b>17025:2017</b>	<b>Selection and verification of methods</b>				
7.2.1.1	17025:2017	The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.				
	17025:2017	NOTE: "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
7.2.1.1.1	AR 3125	The laboratory shall use appropriate methods and procedures for all associated data analysis and interpretation.				

7.2.1.1.2	AR 3125	All test methods that involve the comparison of an unknown to a known for the purpose of source association 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).				
	AR 3125	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 and features of handwriting.				
	AR 3125	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.				
7.2.1.1.3	AR 3125	For laboratories whose scope of accreditation includes calibration:				
a)	AR 3125	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				
	AR 3125	NOTE 1: The "needs of the customer" include regulatory or statutory limits.				
b)	AR 3125	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.				
	AR 3125	NOTE 2: Preference should be given to material(s) from different manufacturers, followed by different lot numbers of materials from the same manufacturer.				

7.2.1.2	17025:2017	All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).				
7.2.1.3	17025:2017	The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.				
	17025:2017	NOTE: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.				
7.2.1.4	17025:2017	When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.				

7.2.1.5	17025:2017	The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.				
7.2.1.6	17025:2017	When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.				
7.2.1.7	17025:2017	Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.				
	17025:2017	NOTE: Customer acceptance of deviations can be agreed in advance in the contract.				
<b>7.2.2</b>	<b>17025:2017</b>	<b>Validation of methods</b>				
7.2.2.1	17025:2017	The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.				
	17025:2017	NOTE 1: Validation can include procedures for sampling, handling and transportation of test or calibration items.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>

	17025:2017	NOTE 2: The techniques used for method validation can be one of, or a combination of, the following: a) calibration or evaluation of bias and precision using reference standards or reference materials; b) systematic assessment of the factors influencing the result; c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; d) comparison of results achieved with other validated methods; e) interlaboratory comparisons; f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principle of the method and practical experience of the performance of the sampling or test method.				
7.2.2.1.1	AR 3125	Method validation shall:				
a)	AR 3125	be conducted according to a validation plan;				
b)	AR 3125	include the associated data analysis and interpretation;				
c)	AR 3125	establish the data and acceptance criteria required to report a result, opinion, interpretation or statement of conformity; and				
d)	AR 3125	identify limitations of the method.				
7.2.2.2	17025:2017	When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.				
	AR 3125	NOTE: Changes to associated data analysis and interpretation are considered changes to a validated method.				



7.2.2.3	17025:2017	The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.				
	17025:2017	NOTE: Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.				
7.2.2.4	17025:2017	The laboratory shall retain the following records of validation:				
a)	17025:2017	the validation procedure used;				
b)	17025:2017	specification of the requirements;				
c)	17025:2017	determination of the performance characteristics of the method;				
d)	17025:2017	results obtained;				
e)	17025:2017	a statement on the validity of the method, detailing its fitness for the intended use.				
<b>7.3</b>	<b>17025:2017</b>	<b>Sampling</b>				
7.3.1	17025:2017	The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.				
7.3.2	17025:2017	The sampling method shall describe:				
a)	17025:2017	the selection of samples or sites;				

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b)	17025:2017	the sampling plan;				
b.1)	AR 3125	Statistical sampling at a stated level of confidence shall be used if an inference will be made to report on the whole population.				
c)	17025:2017	the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing for calibration.				
	17025:2017	NOTE: When received into the laboratory, further handling can be required as specified in 7.4.				
	AR 3125	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.				
7.3.3	17025:2017	The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:				
a)	17025:2017	reference to the sampling method used;				
b)	17025:2017	date and time of sampling;				
c)	17025:2017	data to identify and describe the sample (e.g. number, amount, name);				
d)	17025:2017	identification of the personnel performing sampling;				
e)	17025:2017	identification of the equipment used;				
f)	17025:2017	environmental or transport conditions;				
g)	17025:2017	diagrams or other equivalent means to identify the sampling location, when appropriate;				
h)	17025:2017	deviations, additions to or exclusions from the sampling method and sampling plan.				
7.4	17025:2017	<b>Handling of test or calibration items</b>				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>

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7.4.1	17025:2017	The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.				
7.4.1.1	AR 3125	For all test items received except known origin individual characteristic database samples, the procedure shall:				
a)	AR 3125	address requirements for storage, packaging, and sealing of items to:				
a.1)	AR 3125	protect the integrity of all items; and				
a.2)	AR 3125	require items to be re-sealed as soon as practicable;				
b)	AR 3125	address measures to be taken to secure unattended items;				
c)	AR 3125	require chain-of-custody for:				
c.1)	AR 3125	all items received; and				
c.2)	AR 3125	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);				
	AR 3125	NOTE 1: An item being tracked could contain multiple components and be tracked as one item.				
d)	AR 3125	require chain-of-custody to securely and accurately identify:				
d.1)	AR 3125	the individual(s) or location(s) receiving or transferring the item(s); and				
	AR 3125	NOTE 2: Documentation of internal transfers does not need to include use of personal storage locations.				
d.2)	AR 3125	the item(s) being transferred; and				

d.3)	AR 3125	the chronological order of all transfers, including the date;				
e)	AR 3125	require communication to the customer regarding the disposition of all items received; and				
f)	AR 3125	address communication to the customer regarding items collected or created and preserved for future testing.				
7.4.2	17025:2017	The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.				
7.4.2.1	AR 3125	The system used to identify items shall cover all items received.				
7.4.3	17025:2017	Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.				
7.4.4	17025:2017	When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.				
<b>7.5</b>	<b>17025:2017</b>	<b>Technical records</b>				

7.5.1	17025:2017	The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.				
	AR 3125	NOTE: Options for recording observations include but are not limited to: written notes, photography, drawing, photocopying, and scanning.				
7.5.1.1	AR 3125	Define the technical record(s) to be retained if all related technical records are not retained.				
7.5.1.2	AR 3125	Where abbreviations or symbols specific to the laboratory are used, the meaning of the abbreviations or symbols shall be defined.				
7.5.1.3	AR 3125	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	AR 3125	Records shall be created or maintained in a permanent manner.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
	AR 3125	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	AR 3125	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	AR 3125	For laboratories that perform calibration, 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.				
	AR 3125	NOTE: See related clause ISO/IEC 17025:2017, 7.8.4.1.d).				
7.5.2	17025:2017	The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.				
	AR 3125	NOTE: Contemporaneous revisions are not considered amendments.				
<b>7.6</b>	<b>17025:2017</b>	<b>Evaluation of measurement uncertainty</b>				
7.6.1	17025:2017	Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.				
7.6.1.1	AR 3125	The method of analysis for evaluation of measurement uncertainty shall:				
a)	AR 3125	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)	AR 3125	include the process of rounding the expanded uncertainty;				

c)	AR 3125	require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and				
d)	AR 3125	specify the schedule to review and/or recalculate the measurement uncertainty.				
7.6.2	17025:2017	A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.				
7.6.3	17025:2017	A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.				
	17025:2017	NOTE 1: In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.				
	17025:2017	NOTE 2: For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.				
	17025:2017	NOTE 3: For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.				
7.6.3.1	AR 3125	Measurement uncertainty shall be evaluated, or estimated when applicable, for all reported quantitative results.				

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	AR 3125	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	AR 3125	The following records shall be retained for each evaluation and estimation of measurement uncertainty:				
a)	AR 3125	statement defining the measurand;				
b)	AR 3125	statement of how traceability is established for the measurement;				
c)	AR 3125	the equipment (e.g., measuring device[s] or instrument[s]) used;				
d)	AR 3125	all uncertainty components considered;				
e)	AR 3125	all uncertainty components of significance and how they were evaluated;				
f)	AR 3125	data used to estimate repeatability, intermediate precision, and/or reproducibility;				
g)	AR 3125	all calculations performed; and				
h)	AR 3125	the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.				
<b>7.7</b>	<b>17025:2017</b>	<b>Ensuring the validity of results</b>				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
7.7.1	17025:2017	The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:				
a)	17025:2017	use of reference materials or quality control materials;				
b)	17025:2017	use of alternative instrumentation that has been calibrated to provide traceable results;				
c)	17025:2017	functional check(s) of measuring and testing equipment;				



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d)	17025:2017	use of check or working standards with control charts, where applicable;				
e)	17025:2017	intermediate checks on measuring equipment;				
f)	17025:2017	replicate tests or calibrations using the same or different methods;				
g)	17025:2017	retesting or recalibration of retained items;				
g.1)	AR 3125	When a verification of a result is carried out:				
g.1.a)	AR 3125	it shall be conducted by personnel who are currently authorized or an external service provider qualified to perform the testing;				
	AR 3125	NOTE 1: See requirements of 6.2.6 and 6.6 in ISO/IEC 17025:2017.				
g.1.b)	AR 3125	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				
	AR 3125	NOTE 2: Verification may be recorded for each result verified or as a summary for all results verified.				
g.1.c)	AR 3125	the resolution of any discrepancy shall be recorded.				
h)	17025:2017	correlation of results for different characteristics of an item;				
i)	17025:2017	review of reported results;				
j)	17025:2017	intralaboratory comparisons;				
k)	17025:2017	testing of blind sample(s).				
l)	AR 3125	There shall be a procedure for the technical review of technical records, including reports, and testimony. The procedure shall:				
1.1)	AR 3125	require the individual performing the technical review to have been competency tested to perform the testing or calibration work that is being reviewed;				
1.2)	AR 3125	preclude an individual from technically reviewing their own work;				

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1.3)	AR 3125	define the process to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review;				
1.4)	AR 3125	define the process to be used to ensure testimony in each discipline is reviewed;				
1.5)	AR 3125	define the process to be used to conduct and record the review;				
1.6)	AR 3125	ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record;				
1.7)	AR 3125	ensure conformance with methods and applicable management system documents; and				
1.8)	AR 3125	describe a course of action to be taken in a discrepancy is found.				
	AR 3125	NOTE 1: An individual conducting the technical review need not be an employee of the laboratory, currently proficiency tested or currently performing the work.				
	AR 3125	NOTE 2: An individual who performs a verification can also perform a technical review.				
	AR 3125	NOTE 3: The frequency may vary for different disciplines.				
7.7.2	17025:2017	The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:				
a)	17025:2017	participation in proficiency testing;				
	17025:2017	NOTE: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.				
b)	17025:2017	participation in interlaboratory comparisons other than proficiency testing.				

7.7.2.1	AR 3125	The laboratory's monitoring of performance by comparison with results of other laboratories shall, where available and appropriate for the laboratory activities:				
a)	AR 3125	demonstrate successful performance in at least one proficiency test or an approved alternative means of interlaboratory comparison for each discipline for which the laboratory is seeking accreditation; and				
b)	AR 3125	demonstrate successful performance in at least one proficiency test or an approved alternative means of interlaboratory comparison for each accredited discipline per calendar year at each location.				
	AR 3125	NOTE 1: To be considered an interlaboratory comparison, there must be participants from two or more laboratories operating under separate management systems.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
	AR 3125	NOTE 2: For proficiency tests taken at the end of one calendar year, evaluation of successful performance can occur in the subsequent calendar year.				
7.7.3	17025:2017	Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.				

7.7.4	AR 3125	The laboratory shall monitor the performance of all personnel who perform laboratory activities. The monitoring shall demonstrate successful performance in at least one proficiency test, other interlaboratory comparison, or intralaboratory comparison per calendar year in each accredited discipline in which the individual is authorized to conduct work. In the event that the preceding options are not available or appropriate, observation-based performance monitoring is acceptable.				
	AR 3125	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.				
	AR 3125	NOTE 2: Solely performing verifications (7.7.1.f).1) or solely reviewing and authorizing results (7.8.1.1) are considered to be testing or calibration and are subject to these requirements.				
	AR 3125	NOTE 3: For performance monitoring conducted at the end of one calendar year, evaluation of successful performance can occur in the subsequent calendar year.				
7.7.5	AR 3125	The process for monitoring the performance of the laboratory and personnel shall:				
a)	AR 3125	ensure that results are not known or readily available to the participant being monitored;				
b)	AR 3125	ensure use of approved methods by individual(s) whose performance is being monitored;				
c)	AR 3125	establish criteria for successful performance prior to the monitoring activity being conducted;				
d)	AR 3125	require a mechanism to ensure the quality of the monitoring activity prior to personnel performance being monitored;				

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e)	AR 3125	for calibration laboratories, require the monitoring activity to be performed using an item that was calibrated by the person whose performance is being monitored; and				
f)	AR 3125	require notification to ANAB within 30 days when the expected result is not attained during any monitoring activity.				
	AR 3125	NOTE 1: For a consensus-based proficiency test, the consensus result is the expected result.				
	AR 3125	NOTE 2: When an identification or exclusion is the expected result, an outcome of inconclusive is considered an unexpected result.				
7.7.6	AR 3125	The laboratory shall have a performance monitoring plan that:				
a)	AR 3125	demonstrates conformance with the requirements stated in clause 7.7.2.1.b) and 7.7.4; and				
b)	AR 3125	ensures inclusion of a portion of the components/parameters and equipment/technologies within each accredited discipline.				
7.7.7	AR 3125	To satisfy the proficiency test or interlaboratory comparison requirements in clauses 7.7.2.1.a) and b), the laboratory shall:				
a)	AR 3125	use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the ILAC MRA and has the applicable proficiency test on its scope of accreditation, and				
b)	AR 3125	submit results to the proficiency test provider on or before the date determined by the test provider; and				
c)	AR 3125	authorize the proficiency test provider to release the test results to ANAB; or				
d)	AR 3125	gain approval from ANAB for an alternative means of interlaboratory comparison (FM 3041 Alternative Proficiency Test Request Form).				

	AR 3125	NOTE: To obtain approval for an interlaboratory comparison other than proficiency testing, the laboratory must demonstrate that the proposed alternative means of monitoring performance is substantially similar to proficiency testing.				
7.7.8	AR 3125	The following records shall be retained for all performance monitoring of the laboratory and its personnel:				
a)	AR 3125	discipline(s) monitored:				
b)	AR 3125	design of the monitoring activity;				
c)	AR 3125	expected results;				
d)	AR 3125	location, when more than one location is associated with a single accreditation certificate;				
e)	AR 3125	records submitted to a proficiency test provider, if applicable;				
f)	AR 3125	appropriate technical records;				
	AR 3125	NOTE: See requirements of 7.5 in ISO/IEC 17025:2017 and this document.				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
g)	AR 3125	evaluation of results and action taken for unexpected results: and				
h)	AR 3125	feedback on individual performance provided to the participant.				
<b>7.8</b>	<b>17025:2017</b>	<b>Reporting of results</b>				
<b>7.8.1</b>	<b>17025:2017</b>	<b>General</b>				
7.8.1.1	17025:2017	The results shall be reviewed and authorized prior to release.				
7.8.1.1.1	AR 3125	The authorizer of results shall review the technical record and document the review.				

7.8.1.2	17025:2017	The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.				
	17025:2017	NOTE 1: For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.				
	17025:2017	NOTE 2: Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.				
7.8.1.2.1	AR 3125	The results shall be provided in a written report or through electronic access.				
	AR 3125	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.				
7.8.1.2.2	AR 3125	There shall be a procedure for reporting of results that:				
a)	AR 3125	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)	AR 3125	requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement;				
	AR 3125	NOTE: 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.				

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c)	AR 3125	requires communicating the reason(s) in the report when the reported results are inconclusive; and				
d)	AR 3125	requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics).				
7.8.1.2.3	AR 3125	The documented process for reporting of results of calibration shall:				
a)	AR 3125	identify what information will be reported in the calibration certificate: and				
b)	AR 3125	require the issuance of an endorsed calibration certificate if requested by the customer.				
7.8.1.3	17025:2017	When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.				
7.8.1.3.1	AR 3125	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 laboratory reports results in a simplified way.				
<b>7.8.2</b>	<b>17025:2017</b>	<b>Common requirements for reports (test, calibration or sampling)</b>				
7.8.2.1	17025:2017	Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:				
	17025:2017	NOTE: Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.				



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	AR 3125	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.				
a)	17025:2017	a title (e.g. "Test Report", "Calibration Certificate", or "Report of Sampling");				
b)	17025:2017	the name and address of the laboratory				
c)	17025:2017	the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;				
d)	17025:2017	unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;				
e)	17025:2017	the name and contact information of the customer;				
f)	17025:2017	identification of the method used;				
g)	17025:2017	a description, unambiguous identification, and, when necessary, the condition of the item;				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
h)	17025:2017	the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;				
i)	17025:2017	the date(s) of performance of the laboratory activity;				
	AR 3125	NOTE 3: Date(s) may be reflected as a range of dates or the date of each test or calibration.				
j)	17025:2017	the date of issue of the report;				
k)	17025:2017	reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;				
l)	17025:2017	a statement to the effect that the results relate only to the items tested, calibrated or sampled;				
m)	17025:2017	the results with, where appropriate, the units of measurement;				
n)	17025:2017	additions to, deviations, or exclusions from the method;				

o)	17025:2017	identification of the person(s) authorizing the report;				
	AR 3125	NOTE 4: 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).				
p)	17025:2017	clear identification when results are from external providers.				
7.8.2.2	17025:2017	The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.				
<b>7.8.3</b>	<b>17025:2017</b>	<b>Specific requirements for test reports</b>				
7.8.3.1	17025:2017	In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the results, include the following:				
a)	17025:2017	information on specific test conditions, such as environmental conditions;				
b)	17025:2017	where relevant, a statement of conformity with requirements or specifications (see 7.8.6);				
c)	17025:2017	where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:				
	17025:2017	-- it is relevant to the validity or application of the test results;				
	17025:2017	-- a customer's instruction so requires, or				
	17025:2017	-- the measurement uncertainty affects conformity to a specification limit;				
c.1)	AR 3125	The measurement uncertainty shall:				

c.1.a)	AR 3125	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;				
	AR 3125	NOTE: A legal requirement is created, imposed, and enforced by a third-party external to the laboratory agency.				
c.1.b)	AR 3125	include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;				
c.1.c)	AR 3125	be in the format of $y \pm U$ ;				
	AR 3125	NOTE: 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.				
c.1.d)	AR 3125	be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and				
c.1.e)	AR 3125	be reported to the same number of decimal places or digits as the measurement result.				
d)	17025:2017	where appropriate, opinions and interpretations (see 7.8.7)				
e)	17025:2017	additional information that may be required by specific methods, authorities, customers or groups of customers.				
7.8.3.1.1	AR 3125	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 laboratory shall:				
a)	AR 3125	have objective evidence of the regulation, statute, case law or other legal requirement; and				
b)	AR 3125	if prohibited from reporting measurement uncertainty, have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.				

7.8.3.2	17025:2017	Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.				
<b>7.8.4</b>	<b>17025:2017</b>	<b>Specific requirements for calibration certificates</b>				
7.8.4.1	17025:2017	In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:				
a)	17025:2017	the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
	17025:2017	NOTE: According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.				
a.1)	AR 3125	The measurement uncertainty shall:				
a.1.a)	AR 3125	include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, and the coverage probability;				
a.1.b)	AR 3125	be in the format of $y \pm U$ ;				
a.1.c)	AR 3125	be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and				
	AR 3125	NOTE: For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentation other than $y \pm U$ may be needed.				
a.1.d)	AR 3125	be reported to the same number of decimal places or digits as the measurement result.				
b)	17025:2017	the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;				
c)	17025:2017	a statement identifying how the measurements are metrologically traceable (see Annex A);				

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d)	17025:2017	the results before and after any adjustment or repair, if available;				
e)	17025:2017	where relevant, a statement of conformity with requirements or specifications (see 7.8.6);				
f)	17025:2017	where appropriate, opinions and interpretations (see 7.8.7).				
7.8.4.1.1	AR 3125	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 laboratory shall:				
a)	AR 3125	have objective evidence of the regulation, statute, case law or other legal requirement; and				
b)	AR 3125	if prohibited from reporting measurement uncertainty, have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the calibration result.				
7.8.4.2	17025:2017	Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.				
7.8.4.3	17025:2017	A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.				
7.8.4.4	AR 3125	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)	AR 3125	the name of the accredited calibration laboratory or its accreditation certificate number;				
b)	AR 3125	the unambiguous identification of the item calibrated;				
c)	AR 3125	the date of the current calibration; and				

d)	AR 3125	cross reference to the calibration certificate issued in respect to the calibration.				
<b>7.8.5</b>	<b>17025:2017</b>	<b>Reporting sampling - specific requirements</b>				
	17025:2017	Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:				
a)	17025:2017	the date of sampling;				
b)	17025:2017	unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);				
c)	17025:2017	the location of sampling, including any diagrams, sketches or photographs;				
d)	17025:2017	a reference to the sampling plan and sampling method;				
d)1	AR 3125	If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.				
e)	17025:2017	details of any environmental conditions during sampling that affect the interpretation of the results;				
f)	17025:2017	information required to evaluate measurement uncertainty for subsequent testing or calibration.				
<b>7.8.6</b>	<b>17025:2017</b>	<b>Reporting statements of conformity</b>				
7.8.6.1	17025:2017	When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.				
	17025:2017	NOTE: Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.				
7.8.6.2	17025:2017	The laboratory shall report on the statement of conformity, such that the statement clearly identifies:				

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a)	17025:2017	to which results the statement of conformity applies;				
b)	17025:2017	which specifications, standards or parts thereof are met or not met;				
c)	17025:2017	the decision rule applied (unless it is inherent in the requested specification or standard).				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
	17025:2017	NOTE: For further information, see ISO/IEC Guide 98-4.				
<b>7.8.7</b>	<b>17025:2017</b>	<b>Reporting opinions and interpretations.</b>				
7.8.7.1	17025:2017	When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.				
	17025:2017	NOTE: It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.				
7.8.7.2	17025:2017	The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.				
7.8.7.3	17025:2017	When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.				
<b>7.8.8</b>	<b>17025:2017</b>	<b>Amendments to reports</b>				
7.8.8.1	17025:2017	When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified, and, where appropriate, the reason for the change included in the report.				

7.8.8.2	17025:2017	Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number...[or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this document.				
7.8.8.3	17025:2017	When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.				
<b>7.9</b>	<b>17025:2017</b>	<b>Complaints</b>				
7.9.1	17025:2017	The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.				
7.9.2	17025:2017	A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.				
7.9.3	17025:2017	The process for handling complaints shall include at least the following elements and methods:				
a)	17025:2017	description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;				
b)	17025:2017	tracking and recording complaints, including actions undertaken to resolve them;				
c)	17025:2017	ensuring that any appropriate action is taken.				
7.9.4	17025:2017	The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.				
7.9.5	17025:2017	Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.				



7.9.6	17025:2017	The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.				
	17025:2017	NOTE: This can be performed by external personnel.				
7.9.7	17025:2017	Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.				
<b>7.10</b>	<b>17025:2017</b>	<b>Nonconforming work</b>				
7.10.1	17025:2017	The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:				
a)	17025:2017	the responsibilities and authorities for the management of nonconforming work are defined;				
b)	17025:2017	actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;				
c)	17025:2017	an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;				
d)	17025:2017	a decision is taken on the acceptability of the nonconforming work;				
e)	17025:2017	where necessary, the customer is notified and work is recalled;				
f)	17025:2017	the responsibility for authorizing the resumption of work is defined.				
7.10.2	17025:2017	The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>

7.10.3	17025:2017	Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.				
<b>7.11</b>	<b>17025:2017</b>	<b>Control of data and information management</b>				
7.11.1	17025:2017	The laboratory shall have access to the data and information needed to perform laboratory activities.				
7.11.2	17025:2017	The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented, and validated before implementation.				
	17025:2017	NOTE 1: In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non- computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.				
	17025:2017	NOTE 2: Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.				
7.11.2.1	AR 3125	There shall be a plan for validation of computer software developed by the user and records of the validation shall be retained.				
7.11.3	17025:2017	The laboratory information management system(s) shall:				
a)	17025:2017	be protected from unauthorized access;				
b)	17025:2017	be safeguarded against tampering and loss;				

c)	17025:2017	be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;				
d)	17025:2017	be maintained in a manner the ensures the integrity of the data and information;				
e)	17025:2017	include recording system failures and the appropriate immediate and corrective actions.				
7.11.4	17025:2017	When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.				
7.11.5	17025:2017	The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.				
7.11.6	17025:2017	Calculations and data transfers shall be checked in an appropriate and systematic manner.				
	AR 3125	NOTE: This requirement does not apply if the calculation or data transfer is secure and not subject to human error.				
7.11.6.1	AR 3125	The technical record shall indicate that the check of calculations and data transfers was conducted and who conducted the check. When possible, this check shall be conducted by individuals other than the personnel who performed the calculation(s) or the data transfers.				
	AR 3125	NOTE: This check may be part of a technical review.				
<b>8</b>	<b>17025:2017</b>	<b>Management system requirements</b>				
<b>8.1</b>	<b>17025:2017</b>	<b>Options</b>				

8.1.1	17025:2017	General. The laboratory shall establish, document, implement, and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.				
	17025:2017	NOTE: See <i>Annex B</i> for more information.				
<b>8.1.2</b>	<b>17025:2017</b>	<b>Option A</b>				
	17025:2017	As a minimum, the management system of the laboratory shall address the following:				
	17025:2017	-- management system documentation (see 8.2);				
	17025:2017	-- control of management system documents (see 8.3);				
	17025:2017	-- control of records (see 8.4);				
	17025:2017	-- actions to address risks and opportunities (see 8.5);				
	17025:2017	-- improvement (see 8.6);				
	17025:2017	-- corrective actions (see 8.7);				
	17025:2017	-- internal audits (see 8.8);				
	17025:2017	-- management reviews (see 8.9).				
<b>8.1.3</b>	<b>17025:2017</b>	<b>Option B</b>				
	17025:2017	A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfillment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.			x	
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>

8.1.3.1	AR 3125	In order for Option B to be available to a laboratory, the laboratory must maintain an accredited ISO 9001 certification. The certification body, which certified the laboratory to ISO 9001, must be accredited for ISO 9001 by an IAF MLA signatory accreditation body for management systems. Any laboratory that does not meet this criterion must choose Option A.			x	
8.1.3.2	AR 3125	The Option A requirements under 8.2 through 8.9 in this document are also applicable to laboratories who choose Option B.			x	
<b>8.2</b>	<b>17025:2017</b>	<b>Management system documentation (Option A)</b>				
8.2.1	17025:2017	Laboratory management shall establish, document, and maintain policies and objectives for the fulfillment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.				
8.2.1.1	AR 3125	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: <i>agreed, authorize, define, instructions, method, plan (noun only), procedure, program, record, schedule, specify</i>				
8.2.2	17025:2017	The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.				
8.2.3	17025:2017	Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.				
8.2.4	17025:2017	All documentation, processes, systems, records, related to the fulfillment of the requirements of this document shall be included in, referenced from, or linked to the management system.				

8.2.5	17025:2017	All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.				
<b>8.3</b>	<b>17025:2017</b>	<b>Control of management system documents (Option A)</b>				
8.3.1	17025:2017	The laboratory shall control the documents (internal and external) that relate to the fulfillment of this document.				
	17025:2017	NOTE: In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.				
8.3.2	17025:2017	The laboratory shall ensure that:				
a)	17025:2017	documents are approved for adequacy prior to issue by authorized personnel;				
b)	17025:2017	documents are periodically reviewed, and updated as necessary;				
c)	17025:2017	changes and the current revision status of documents are identified;				
d)	17025:2017	relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;				
e)	17025:2017	documents are uniquely identified;				
f)	17025:2017	the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.				
<b>8.4</b>	<b>17025:2017</b>	<b>Control of records (Option A)</b>				
8.4.1	17025:2017	The laboratory shall establish and retain legible records to demonstrate fulfillment of the requirements in this document.				

8.4.2	17025:2017	The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.				
	17025:2017	NOTE 1: Additional requirements regarding technical records are given in 7.5.				
	AR 3125	NOTE 2: Contractual obligations for records retention include legal requirements and customer expectations.				
<b>8.5</b>	<b>17025:2017</b>	<b>Actions to address risks and opportunities (Option A)</b>				
8.5.1	17025:2017	The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:				
a)	17025:2017	give assurance that the management system achieves its intended results;				
b)	17025:2017	enhance opportunities to achieve the purpose and objectives of the laboratory;				
c)	17025:2017	prevent, or reduce, undesired impacts and potential failures in the laboratory activities;				
d)	17025:2017	achieve improvement.				
8.5.1.1	AR 3125	Risks and opportunities related to health and safety shall be considered.				
8.5.2	17025:2017	The laboratory shall plan:				
a)	17025:2017	actions to address these risks and opportunities;				
b)	17025:2017	how to:				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
	17025:2017	-- integrate and implement these actions into its management system;				
	17025:2017	-- evaluate the effectiveness of these actions.				

	17025:2017	NOTE: Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.				
8.5.3	17025:2017	Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.				
	17025:2017	NOTE 1: Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.				
	17025:2017	NOTE 2: Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.				
<b>8.6</b>	<b>17025:2017</b>	<b>Improvement (Option A)</b>				
8.6.1	17025:2017	The laboratory shall identify and select opportunities for improvement and implement any necessary actions.				
	17025:2017	NOTE: Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.				
8.6.2	17025:2017	The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service.				



	17025:2017	NOTE: Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.				
<b>8.7</b>	<b>17025:2017</b>	<b>Corrective actions (Option A)</b>				
8.7.1	17025:2017	When a nonconformity occurs, the laboratory shall:				
a)	17025:2017	react to the nonconformity and, as applicable:				
	17025:2017	-- take action to control and correct it;				
	17025:2017	-- address the consequences;				
b)	17025:2017	evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:				
	17025:2017	-- reviewing and analyzing the nonconformity;				
	17025:2017	-- determining the causes of the nonconformity;				
	17025:2017	-- determining if similar nonconformities exist, or could potentially occur;				
c)	17025:2017	implement any action needed;				
d)	17025:2017	review the effectiveness of any corrective action taken;				
e)	17025:2017	update risks and opportunities determined during planning, if necessary;				
f)	17025:2017	make changes to the management system, if necessary.				
g)	AR 3125	The process for corrective action shall establish a reasonable timeframe for completion for each corrective action.				
8.7.2	17025:2017	Corrective actions shall be appropriate to the effects of the nonconformities encountered.				
8.7.3	17025:2017	The laboratory shall retain records as evidence of:				
a)	17025:2017	the nature of the nonconformities, cause(s) and any subsequent actions taken;				
b)	17025:2017	the results of any corrective action.				
<b>8.8</b>	<b>17025:2017</b>	<b>Internal audits (Option A)</b>				
8.8.1	17025:2017	The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:				

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a)	17025:2017	conforms to:				
	17025:2017	-- the laboratory's own requirements for its management system, including the laboratory activities;				
	17025:2017	-- the requirements of this document;				
a).1	AR 3125	Internal audits shall provide information on whether the management system conforms to the requirements of this document.				
8.8.1.1	AR 3125	Internal audits shall be conducted at least annually, as well as prior to the initial accreditation assessment.				
8.8.2	17025:2017	The laboratory shall:				
a)	17025:2017	plan, establish, implement, and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;				
b)	17025:2017	define the audit criteria and scope for each audit;				
b).1	AR 3125	Internal audits shall include direct observation of a portion of accredited laboratory activities within each discipline.				
c)	17025:2017	ensure that the results of the audit are reported to relevant management;				
<b>Clause</b>	<b>Source</b>	<b>Accreditation Standard</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>Reference/Comment</b>
d)	17025:2017	implement appropriate correction and corrective actions without undue delay;				
e)	17025:2017	retain records as evidence of the implementation of the audit programme and the audit results.				
	17025:2017	NOTE: ISO 19011 provides guidance for internal audits.				
<b>8.9</b>	<b>17025:2017</b>	<b>Management reviews (Option A)</b>				

## CT DESPP Division of Scientific Services

8.9.1	17025:2017	The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this document.				
8.9.1.1	AR 3125	Management reviews shall be conducted at least annually, as well as prior to the initial accreditation assessment.				
8.9.2	17025:2017	The inputs to management review shall be recorded and shall include information related to the following:				
a)	17025:2017	changes in internal and external issues that are relevant to the laboratory;				
b)	17025:2017	fulfillment of objectives;				
c)	17025:2017	suitability of policies and procedures;				
d)	17025:2017	status of actions from previous management reviews;				
e)	17025:2017	outcome of recent internal audits;				
f)	17025:2017	corrective actions;				
g)	17025:2017	assessments by external bodies;				
h)	17025:2017	changes in the volume and type of the work or in the range of laboratory activities;				
i)	17025:2017	customer and personnel feedback;				
j)	17025:2017	complaints;				
k)	17025:2017	effectiveness of any implemented improvements;				
l)	17025:2017	adequacy of resources;				
m)	17025:2017	results of risk identification;				
n)	17025:2017	outcomes of the assurance of the validity of results; and				
o)	17025:2017	other relevant factors, such as monitoring activities and training.				
8.9.3	17025:2017	The outputs from the management review shall record all decisions and actions related to at least:				
a)	17025:2017	the effectiveness of the management system and its processes;				

b)	17025:2017	improvement of the laboratory activities related to the fulfillment of the requirements of this document;				
c)	17025:2017	provision of required resources;				
d)	17025:2017	any need for change.				
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