



Specific Accreditation Guidance

ISO 15189:2022 Gap analysis

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ISO 15189:2022 Gap analysis

Purpose and background information

This document serves as an informative guide correlating the clauses in ISO 15189:2022 to the previous 2012 version of the standard.

CASCO is the ISO committee concerned with the development of policy and publishes standards related to conformity assessment, which includes ISO 15189.

ISO/CASCO specifies the minimal mandatory content of those standards it maintains or develops. This includes the structure and mandatory requirements relating to impartiality, confidentiality, complaints / appeals, and management systems.

ISO 15189 has adopted the revised structure specified by ISO/CASCO. Accordingly, the structure of the new standard is different to the previous 2012 version as noted below:

Informative preliminary	Title page
	Table of contents
	Foreword
	Introduction (including relationship to other standards)
Normative General	Title
	Scope
	Normative references
Normative Technical	Terms and definitions
	General requirements
	Structural and governance requirements
	Resource requirements (including personnel)
	Process requirements (including operational functions)
	Management system requirements
Informative supplementary	Normative annexes
	Any further explanations that are not part of the normative process
	Informative annexes
	Bibliography
	Indexes

The objective of this document is to promote the welfare of patients and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories. Activities are provided within an ethical and governance framework, that recognizes the obligations of healthcare providers to the patient.

The structure of the standard is different to the previous version in compliance with CASCO, however requirements are clearer and more direct (simplified). There is an increase in focus on the welfare of the patient by assessing, planning and implementing actions to address risk.

The main changes compared to the previous edition are as follows:

- the risk-based thinking has enabled some reduction in prescriptive requirements and their replacement by performance-based outcomes;
- there is greater flexibility in the requirements for processes, procedures, documented information and organisational responsibilities;
- the mandatory adoption of the ISO/CASCO structure and requirements relating to impartiality, confidentiality, complaints / appeals and management systems;

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
1	1		Scope / inclusions	The text has been simplified and duplication removed. Applicability to point-of-care testing (POCT) has been included.
2	2		Normative References	Reference to ISO/IEC 17000 & 17025 updated. ISO/IEC Guide 2 has been removed.
3	3		Terms and definitions	Reference to ISO/IEC Guide 2 has been removed. There have been a significant number of changes / inclusions.
4			General requirements	
4.1			Impartiality	
4.1	4.1.1.3a	Major	Laboratory to manage and structure its activities to safeguard impartiality. Laboratory management to be committed to impartiality. Any threats to impartiality shall be minimised so impartiality is not compromised.	4.1 expands on the requirements relating to impartiality including requirement to minimise any threats to impartiality.
4.2			Confidentiality	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
4.2.1	4.1.1.3e 4.14.3 5.1.5 5.10.1	Major	<p>Management of information</p> <p>The laboratory shall be responsible, through legally enforceable commitments, for the management of information obtained or created during its activities. Management of patient information shall include privacy and confidentiality. The laboratory shall inform the user and / or the patient in advance of the information it intends to place in the public domain. Except for the information that the user and /or the patient makes publicly available, or when agreed between the laboratory and the patient, all other information is considered propriety information and shall be regarded as confidential.</p>	<p>4.2.1, 4.2.2 & 4.2.3 expands on the requirements relating to confidentiality and management of patient information.</p> <p>Laboratories are required to inform patients if it intends to make information publicly available.</p>
4.2.2		New	<p>Release of information</p> <p>When the laboratory is required by law or authorised by contractual arrangements to release confidential information, the patient shall be notified, unless the notification is prohibited by law.</p> <p>The laboratory shall keep confidential information about the patient from a source other than the patient and the source of the information shall not be</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			shared with the patient unless agreed.	
4.2.3		New	Personnel responsibility Personnel must keep confidential all information obtained or created during the performance of laboratory activities	
4.3		New	<p>Requirements regarding patients</p> <p>Laboratory management shall ensure that patients' well-being, safety, and rights are the primary considerations. The following processes shall be established and implemented.</p> <ul style="list-style-type: none"> a) opportunities for patients & laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods and the interpretation of examination results; b) provision of patients and users with publicly available information about the examination process including costs when applicable, and when to expect results; c) periodic review of the examinations offered 	Patients' well-being, safety and rights must be the laboratories primary consideration.

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			<p>by the laboratory to ensure they are clinically appropriate and necessary;</p> <p>d) where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;</p> <p>e) treatment of patients, samples, or remains, with due care and respect;</p> <p>f) obtaining informed consent when required;</p> <p>g) ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory;</p> <p>h) making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;</p>	

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			i) upholding the rights of patients to care that is free from discrimination.	
5			Structural and governance requirements	
5.1	4.1.1.2	Editorial	Legal Entity The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.	
5.2			Laboratory director	
5.2.1	4.1.1.4	Editorial	Laboratory director competence The laboratory shall be directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document.	5.2.1, 5.2.2, 5.2.3 detail the requirements of the role of the laboratory director who maintains ultimate responsibility for overall laboratory operation, including risk management application. The prescriptive list of requirements for the role of laboratory director in ISO 15189:2012 has been removed
5.2.2	4.1.1.4	Editorial	Laboratory director responsibilities The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so	

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			that risks to patient care and opportunities to improve are systematically identified and addressed. The duties and responsibilities of the laboratory director shall be documented.	
5.2.3	4.1.1.4	Editorial	<p>Delegation of duties</p> <p>The laboratory director may delegate either selected duties or responsibilities, or both, to qualified and competent personnel and such delegation shall be documented. However, the laboratory director shall maintain the ultimate responsibility for the overall operation of the laboratory.</p>	
5.3			Laboratory activities	
5.3.1	5.2.1	New	<p>General</p> <p>The laboratory shall specify and document the range of laboratory activities, including laboratory activities performed at sites other than the main location (e.g. POCT, sample collection) for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes</p>	Laboratory required to detail all activities for which it claims conformity - including POCT.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			externally provided laboratory activities on an ongoing basis.	
5.3.2	4.1.2.5	New	<p>Conformance with requirements</p> <p>Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the users, regulatory authorities, and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.</p>	
5.3.3	4.1.2.2 4.7	New	<p>Advisory activities</p> <p>Laboratory management shall ensure that appropriate laboratory advice and interpretation are available and meet the needs of patients and users.</p> <p>The laboratory shall establish arrangements for communicating with laboratory users on the following when applicable:</p> <ul style="list-style-type: none"> a) advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods, 	Expands on the requirement for provision of advice and interpretation to meet patient and user needs.

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			<p>and the frequency of requesting the examination;</p> <p>b) providing professional judgments on the interpretation of the results of examinations;</p> <p>c) promoting the effective utilization of laboratory examinations;</p> <p>d) advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria.</p>	
5.4			Structure and authority	
5.4.1	4.1.1.4	Major	<p>General</p> <p>The laboratory shall:</p> <p>a) define its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services;</p> <p>b) specify the responsibility, authority, lines of communication and interrelationship of all personnel who</p>	Requirement for the laboratory to define the management structure and relationships between management, technical and support services.

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			<p>manage, perform or verify work affecting the results of laboratory activities;</p> <p>c) specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.</p>	
5.4.2	4.1.2.3 4.1.2.7	Editorial	<p>Quality management</p> <p>The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:</p> <ul style="list-style-type: none"> a) implementation, maintenance, and improvement of the management system; b) identification of deviations from the management system or from the procedures for performing laboratory activities; c) initiation of actions to prevent or minimize such deviations; d) reporting to laboratory management on the performance of the management system 	Specific reference to a quality manager as covered by ISO 15189:2012 has been removed.

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			<p>and any need for improvement;</p> <p>e) ensuring the effectiveness of laboratory activities.</p>	
5.5	4.1.2.4 4.14.7	Editorial	<p>Objectives and policies</p> <p>a) Laboratory management shall establish and maintain objectives and policies (see 8.2) to:</p> <ol style="list-style-type: none"> 1) meet the needs and requirements of its patients and users; 2) commit to good professional practice; 3) provide examinations that fulfil their intended use; 4) conform to this document. <p>b) Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organization.</p> <p>c) Laboratory management shall ensure that the integrity of the management system is maintained when changes to the</p>	

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			<p>management system are planned and implemented.</p> <p>d) The laboratory shall establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives (see 8.8.2).</p>	
5.6	4.14.6	Major	<p>Risk management</p> <p>a) Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement (see 8.5).</p> <p>b) The laboratory director shall ensure that these processes are evaluated for effectiveness and</p>	<p>Laboratory shall establish processes for identifying risk to patients, develop actions to address the risks and opportunities for improvements. These processes shall be evaluated.</p>

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			modified, when identified as being ineffective.	
6	5		Resource requirements	
6.1	4.1.1.4c 4.1.2.1i	Editorial	General The laboratory shall have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.	
6.2	5.1		Personnel	
6.2.1	4.1.1.3 4.1.1.4c 4.1.2.1a 5.1.1 5.1.4	Editorial	General a) The laboratory shall have access to a sufficient number of competent persons to perform its activities. b) All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, ethically, be competent and work in accordance with the laboratory's management system. c) The laboratory shall communicate to laboratory personnel the importance of	

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			<p>meeting the needs and requirements of users as well as the requirements of this document.</p> <p>d) The laboratory shall have a programme to introduce personnel to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services.</p>	
6.2.2	4.1.1.4c 5.1.1 5.1.2 5.1.6	Editorial	<p>Competence requirements</p> <p>a) The laboratory shall specify the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience.</p> <p>b) The laboratory shall ensure all personnel have the competence to perform laboratory</p>	<p>The separate requirement for job descriptions has been included under 6.2.5 Personnel records.</p>

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			<p>activities for which they are responsible.</p> <p>c) The laboratory shall have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment.</p> <p>d) The laboratory shall have documented information demonstrating competence of its personnel.</p>	
6.2.3	5.1 5.7.1 5.9.1 5.10.2	Major	<p>Authorization</p> <p>The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:</p> <p>a) selection, development, modification, validation and verification of methods;</p> <p>b) review, release, and reporting of results;</p> <p>c) use of laboratory information systems, in particular: accessing patient data and information, entering patient data and examination results,</p>	Authorisation shall include method validation / verification.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			changing patient data or examination results.	
6.2.4	5.1.8	Editorial	<p>Continuing education and professional development</p> <p>A continuing education programme shall be available to personnel who participate in managerial and technical processes. All personnel shall participate in continuing education and regular professional development, or other professional liaison activities.</p> <p>The suitability of the programmes and activities shall be periodically reviewed.</p>	
6.2.5	5.1.9	Major	<p>Personnel records</p> <p>The laboratory shall have procedures and retain records for:</p> <ul style="list-style-type: none"> a) determining the competence requirements specified in 6.2.2 a); b) position descriptions; c) training and re-training; d) authorization of personnel; e) monitoring competence of personnel. 	Changed emphasis to include records covering selection, supervision and ongoing monitoring.
6.3	5.2		Facilities and environmental conditions	

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6.3.1	5.2.1	Editorial	<p>General</p> <p>The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results, or the safety of patients, visitors, laboratory users, and personnel. This shall include pre-examination related facilities and sites other than the main laboratory premises where examinations are performed, as well as POCT. The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be specified, monitored, and recorded.</p>	
6.3.2	5.2.6	Editorial	<p>Facility controls</p> <p>Facility controls shall be implemented, recorded, monitored, periodically reviewed, and shall include:</p> <ul style="list-style-type: none"> a) control of access, taking into consideration safety, confidentiality, quality, and safeguarding medical information and patient samples; b) prevention of contamination, interference, or 	

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			<p>adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste disposal;</p> <p>c) prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation;</p> <p>d) provision of safety facilities and devices, where applicable and regularly verifying their functioning;</p> <p>e) maintenance of laboratory facilities in a functional and reliable condition.</p>	
6.3.3	5.2.3	Editorial	<p>Storage facilities</p> <p>a) Storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records, shall be provided.</p> <p>b) Patient samples and materials used in</p>	

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			<p>examination processes shall be stored in a manner that prevents cross contamination and deterioration.</p> <p>c) Storage and disposal facilities for hazardous materials and biological waste shall be appropriate to the classification of the materials in the context of any statutory or regulatory requirements.</p>	
6.3.4	5.2.4 5.2.6	Editorial	<p>Personnel facilities</p> <p>There shall be adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment and clothing.</p> <p>Space for personnel activities, such as meetings, quiet study and a rest area, should be provided.</p>	
6.3.5	5.2.5	Editorial	<p>Sample collection facilities</p> <p>Sample collection facilities shall:</p> <p>a) enable collection to be undertaken in a manner that does not invalidate results or adversely affect the</p>	

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			<p>quality of examinations;</p> <p>b) consider privacy, comfort and needs (e.g. disabled access, toilet facility) of patients and accommodation of accompanying persons (e.g. guardian or interpreter) during collection;</p> <p>c) provide separate patient reception and collection areas;</p> <p>d) maintain first aid materials for both patients and personnel.</p>	
6.4	5.3		Equipment	
6.4.1	5.3.1.1	Minor	<p>General</p> <p>The laboratory shall have processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration.</p>	Expanded procedures required - including for acceptance testing and decommissioning of equipment
6.4.2	5.3.1.1	Editorial	<p>Equipment requirements</p> <p>a) The laboratory shall have access to</p>	An equipment register must be maintained.

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			<p>equipment required for the correct performance of laboratory activities.</p> <p>b) Where the equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional specification, laboratory management shall ensure that the requirements of this document are met.</p> <p>c) Each item of equipment that can influence laboratory activities shall be uniquely labelled, marked or otherwise identified and a register maintained.</p> <p>d) The laboratory shall maintain and replace equipment as needed to ensure the quality of examination results.</p>	Laboratory having access to equipment rather than being furnished with equipment.
6.4.3	5.3.1.2	Editorial	<p>Equipment acceptance procedure</p> <p>The laboratory shall verify that the equipment conforms to specified acceptability criteria before being placed or returned into service.</p>	Equipment shall be capable of the required measurement accuracy or measurement uncertainty to provide a valid result.

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			Equipment used for measurement shall be capable of achieving either the measurement accuracy or measurement uncertainty, or both, required to provide a valid result (see 7.3.3 and 7.3.4 for details).	
6.4.4	5.3.1.3 5.3.1.4f	Editorial	Equipment instructions for use a) The laboratory shall have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results. b) Equipment shall be operated by trained, authorized, and competent personnel. c) Instructions for the use of equipment, including those provided by the manufacturer, shall be readily available. d) The equipment shall be used as specified by the manufacturer, unless validated by the laboratory (see 7.1.3).	Unless otherwise validated equipment to be used as per manufacturer's specification
6.4.5	5.3.1.5	Editorial	Equipment maintenance and repair a) The laboratory shall have preventive	Any deviations from the manufacturers maintenance schedules or instructions must be recorded.

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			<p>maintenance programmes, based on manufacturer's instructions. Deviations from the manufacturer's schedules or instructions shall be recorded.</p> <p>b) Equipment shall be maintained in a safe working condition and working order. This shall include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous materials by authorized personnel.</p> <p>c) Equipment that is defective or outside specified requirements, shall be taken out of service. It shall be clearly labelled or marked as being out of service, until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate actions when non-conforming work occurs (see 7.5).</p>	

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			d) When applicable, the laboratory shall decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.	
6.4.6	5.3.1.6	Minor	Equipment adverse incident reporting Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required. The laboratory shall have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer.	Laboratory required to have a procedure for responding to manufacturers recalls or notices
6.4.7	5.3.1.7	Editorial	Equipment records Records shall be maintained for each item of equipment that influences the results of laboratory activities. These records shall include the following, where relevant:	

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			<ul style="list-style-type: none"> a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware; b) dates of receipt, acceptance testing and entering into service; c) evidence that equipment conforms with specified acceptability criteria; d) the current location; e) condition when received (e.g. new, used or reconditioned); f) manufacturer's instructions; g) the programme for preventive maintenance; h) any maintenance activities performed by the laboratory or approved external service provider; i) damage to, malfunction, modification, or repair of the equipment; j) equipment performance records such as reports or certificates of calibrations or verifications, or both, 	

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			<p>including dates, times, and results;</p> <p>k) status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete.</p> <p>These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in 8.4.3.</p>	
6.5			Equipment calibration and metrological traceability	
6.5.1		New	<p>General</p> <p>The laboratory shall specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results. For quantitative methods of a measured analyte, specifications shall include calibration and metrological traceability requirements. Qualitative methods and quantitative methods that measure characteristics rather than discrete analytes shall specify the characteristic being assessed and such requirements necessary for reproducibility over time.</p>	Includes qualitative methods.

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6.5.2	5.3.1.4	Editorial	<p>Equipment calibration</p> <p>The laboratory shall have procedures for the calibration of equipment that directly or indirectly affects examination results. The procedures shall specify:</p> <ul style="list-style-type: none"> a) conditions of use and manufacturer's instructions for calibration; b) recording of the metrological traceability; c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals; d) recording the calibration status and date of re-calibration; e) ensuring that, where correction factors are used, these are updated and recorded when recalibration occurs; f) handling of situations when calibration was out of control, to minimize risk to service operation and to patients. 	

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6.5.3	5.3.1.4	Major	<p>Metrological traceability of measurement result</p> <ul style="list-style-type: none"> a) 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. b) The laboratory shall ensure that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through: <ul style="list-style-type: none"> — calibration provided by a competent laboratory; or — certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; c) Where it is not possible to provide traceability according to 6.5.3 a) 	<p>Includes requirement for genetic examinations traceability to genetic reference sequences.</p> <p>Includes qualitative methods.</p>

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			<p>other means for providing confidence in the results shall be applied, including but not limited to the following:</p> <ul style="list-style-type: none"> — 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; — measurement of calibrator by another procedure; <p>d) For genetic examinations, traceability to genetic reference sequences shall be established.</p> <p>e) For qualitative methods, traceability may be demonstrated by testing of known material or previous samples sufficient to show consistent identification and, when applicable, intensity of reaction.</p>	
6.6	5.3.2		Reagents and consumables	

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6.6.1	5.3.2.1	No change	<p>General</p> <p>The laboratory shall have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables.</p>	
6.6.2	5.3.2.2	No change	<p>Reagents and consumables — Receipt and storage</p> <p>The laboratory shall store reagents and consumables according to manufacturers' specifications and monitor the environmental conditions where relevant.</p> <p>When the laboratory is not the receiving facility, it shall verify that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.</p>	
6.6.3	5.3.2.3	No change	<p>Reagents and consumables — Acceptance testing</p> <p>Each reagent or new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before placing into use, or before release of results, as appropriate.</p>	

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			Consumables that can affect the quality of examinations shall be verified for performance before placing into use.	
6.6.4	5.3.2.4	No change	<p>Reagents and consumables — Inventory management</p> <p>The laboratory shall establish an inventory management system for reagents and consumables.</p> <p>The system for inventory management shall segregate reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use.</p>	
6.6.5	5.3.2.5	Editorial	<p>Reagents and consumables — Instructions for use</p> <p>Instructions for the use of reagents and consumables, including those provided by manufacturers, shall be readily available. Reagents and consumables shall be used according to the manufacturer's specifications. If they are intended to be used for other purposes see 7.3.3.</p>	Reagents to be used according to manufacturer's specifications.
6.6.6	5.3.2.6	Editorial	Reagents and consumables - Adverse incident reporting	Laboratory requires procedure to respond to manufacturer's recall.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required.</p> <p>The laboratory shall have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer.</p>	
6.6.7	5.3.2.7	Editorial	<p>Reagents and consumables — Records</p> <p>Records shall be maintained for each reagent and consumable that contributes to the performance of Examinations. These records shall include, but not be limited, to the following:</p> <ul style="list-style-type: none"> a) identity of the reagent or consumable; b) manufacturer's information, including instructions, name and batch code or lot number; c) date of receipt and condition when received, the expiry date, date of first use 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>and, where applicable, the date the reagent or consumable was taken out of service;</p> <p>d) records that confirm the reagent's or consumable's initial and ongoing acceptance for use.</p> <p>Where the laboratory uses reagents prepared, resuspended or combined in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking the preparation, as well as the dates of preparation and expiry.</p>	
6.7	4.4		Service Agreements	
6.7.1	4.4.1 4.4.2	Editorial	<p>Agreements with laboratory users</p> <p>The laboratory shall have a procedure to establish and periodically review agreements for providing laboratory activities.</p> <p>The procedure shall ensure:</p> <p>a) the requirements are adequately specified;</p> <p>b) the laboratory has the capability and</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>resources to meet the requirements;</p> <p>c) when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants.</p> <p>Laboratory users shall be informed of any changes to an agreement that can affect examination results.</p> <p>Records of reviews, including any significant changes, shall be retained.</p>	
6.7.2		New	<p>Agreements with POCT operators</p> <p>Service agreements between the laboratory and other parts of the organization using laboratory supported POCT, shall ensure that respective responsibilities and authorities are specified and communicated.</p>	
6.8	4.5		Externally provided products and services	
6.8.1	4.4.1 4.4.2	Editorial	<p>General</p> <p>The laboratory shall ensure that externally provided products and services that affect laboratory activities are</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>suitable when such products and services are:</p> <ul style="list-style-type: none"> a) intended for incorporation into the laboratory's own activities; b) provided, in part or in full, directly to the user by the laboratory, as received from the external provider; c) used to support the operation of the laboratory. <p>It can be necessary to collaborate with other organizational departments or functions to fulfil this requirement.</p>	
6.8.2	4.5.1 4.5.2	Editorial	<p>Referral laboratories and consultants</p> <p>The laboratory shall communicate its requirements to referral laboratories and consultants who provide interpretations and advice, for:</p> <ul style="list-style-type: none"> a) the procedures, examinations, reports and consulting activities to be provided; b) management of critical results; c) any required personnel qualifications and 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>demonstration of competence.</p> <p>Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.</p> <p>A list of all referral laboratories and consultants shall be maintained.</p>	
6.8.3	4.4.2 4.5.1 4.5.2. 4.6	Editorial	<p>Review and approval of externally provided products and services</p> <p>The laboratory shall have procedures and retain records for:</p> <ul style="list-style-type: none"> a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services; b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers; c) referral of samples; d) ensuring that externally provided products and services conform to the 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>laboratory's established requirements, or where applicable to the relevant requirements of this document before they are used or directly provided to the user;</p> <p>e) taking any actions arising from evaluations of the performance of external providers.</p>	
7			Process requirements	
7.1		New	<p>General</p> <p>The laboratory shall identify potential risks to patient care in the pre-examination, examination, and post-examination processes. These risks shall be assessed and mitigated to the extent possible. The residual risk shall be communicated to users as appropriate.</p> <p>The identified risks and effectiveness of the mitigation processes shall be monitored and evaluated according to the potential harm to the patient.</p> <p>The laboratory shall also identify opportunities to improve patient care and</p>	Emphasise on risks to the patient during the pre-examination, examination and post examination processes.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			develop a framework to manage these opportunities (see 8.5).	
7.2	5.4		Pre-examination processes	
7.2.1	5.4.1	Editorial	General The laboratory shall have procedures for all pre-examination activities and make them accessible to relevant personnel.	
7.2.2	5.4.2	Editorial	<p>Laboratory information for patients and users</p> <p>The laboratory shall have appropriate information available for its users and patients. The information shall be sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements.</p> <p>The information shall include as appropriate:</p> <ul style="list-style-type: none"> a) the location(s) of the laboratory, operating hours and contact information; b) the procedures for requesting and the collection of samples; c) the scope of laboratory activities and time for expected availability of 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<ul style="list-style-type: none"> results; d) the availability of advisory services; e) requirements for patient consent; f) factors known to significantly impact the performance of the examination or the interpretation of the results; g) the laboratory complaint process. 	
7.2.3	4.14.2		Requests for providing laboratory examinations	
7.2.3.1	5.4.3 5.4.4.1	Editorial	<p>General</p> <ul style="list-style-type: none"> a) Each request accepted by the laboratory for examination(s) shall be considered an agreement. b) The examination request shall provide sufficient information to ensure: <ul style="list-style-type: none"> — unequivocal traceability of the patient to the request and sample; — identity and contact information of requester; — identification of the examination(s) requested; 	The general section provides a background on the request requirements. Collection activities now separated and detailed in 7.2.4.2.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>— informed clinical and technical advice, and clinical interpretation can be provided.</p> <p>c) The examination request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user.</p> <p>d) Where necessary for patient care, the laboratory shall communicate with users or their representatives, to clarify the user's request.</p>	
7.2.3.2	5.4.3 5.4.4.2	Editorial	<p>Oral requests</p> <p>The laboratory shall have a procedure for managing oral requests for examinations, if applicable, that includes the provision of documented confirmation of the examination request to the laboratory, within a given time.</p>	
7.2.4			Primary sample collection and handling	
7.2.4.1	5.4.4.1	Minor	<p>General</p> <p>The laboratory shall have procedures for the collection</p>	The risks and impact on patient outcomes associated with any

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>and handling of primary samples. Information shall be available to those responsible for sample collection.</p> <p>Any deviation from the established collection procedures shall be clearly recorded. The potential risk and impact on the patient outcome of acceptance or rejection of the sample shall be assessed, recorded and shall be communicated to the appropriate personnel.</p> <p>The laboratory shall periodically review requirements for sample volume, collection device and preservatives for all sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte</p>	deviation in the collection process shall be determined.
7.2.4.2	5.4.3 5.4.4.2 5.4.6	Editorial	<p>Information for pre-collection activities</p> <p>The laboratory shall provide information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised.</p> <p>This shall include:</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<ul style="list-style-type: none"> a) preparation of the patient (e.g. instructions to caregivers, sample collectors and patients); b) type and amount of the primary sample to be collected with descriptions of the containers and any necessary additives, and when relevant the order of collecting samples; c) special timing of collection, where relevant; d) provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs); e) sample labelling for unequivocal identification of the patient, as well as source and site of sample, and labelling, when several samples from the same patient are to be collected, including multiple pieces of tissue or 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			slides; f) the laboratory's criteria for acceptance and rejection of samples specific to the examinations requested.	
7.2.4.3	5.4.2 5.4.4.1	Editorial	<p>Patient consent</p> <ul style="list-style-type: none"> a) The laboratory shall obtain the informed consent of the patient for all procedures carried out on the patient. b) Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, may need a more detailed explanation and, in some cases, recorded consent. c) If obtaining consent is not possible in emergency situations, the laboratory may carry out necessary procedures, provided they are in the patient's best interest. 	
7.2.4.4	5.4.4.3	Editorial	Instructions for collection activities	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>To ensure safe, accurate and clinically appropriate sample collection and pre-examination storage, the laboratory shall provide instructions for:</p> <ul style="list-style-type: none"> a) verification of the identity of the patient from whom a primary sample is collected; b) verification and when relevant, recording that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals]; c) collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant; d) labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected; 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<ul style="list-style-type: none"> e) recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time; f) requirements for separating or dividing the primary sample when necessary; g) stabilization and proper storage conditions before collected samples are delivered to the laboratory; h) safe disposal of materials used in the collection process. 	
7.2.5	5.4.5	Minor	<p>Sample transportation</p> <ul style="list-style-type: none"> a) To ensure the timely and safe transportation of samples, the laboratory shall provide instructions for: <ul style="list-style-type: none"> 1) packaging of samples for transportation; 2) ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations; 3) maintaining the 	Importance of sample integrity during transport recognised and any risk to the general public to be mitigated.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>temperature interval specified for sample collection and handling;</p> <p>4) any specific requirements to ensure integrity of samples, e.g. use of designated preservatives.</p> <p>b) If the integrity of a sample has been compromised and there is a health risk, the organization responsible for the transport of the sample shall be notified immediately and action taken to reduce the risk and to prevent recurrence.</p> <p>c) The laboratory shall establish and periodically evaluate adequacy of sample transportation systems.</p>	
7.2.6			Sample receipt	
7.2.6.1	5.4.6	Editorial	<p>Sample receipt procedure</p> <p>The laboratory shall have a procedure for sample receipt that includes:</p> <p>a) the unequivocal traceability of samples</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>by request and labelling, to a uniquely identified patient and when applicable, the anatomical site;</p> <p>b) criteria for acceptance and rejection of samples;</p> <p>c) recording the date and time of receipt of the sample, when relevant;</p> <p>d) recording the identity of the person receiving the sample, when relevant;</p> <p>e) evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s);</p> <p>f) instructions for samples specifically marked as urgent, which include details of special labelling, transport, any rapid processing method, turnaround times, and special reporting criteria to be followed;</p> <p>g) ensuring that all portions of the sample shall be unequivocally traceable to the original sample.</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
7.2.6.2	5.4.6	Editorial (New)	<p>Sample acceptance exceptions</p> <ul style="list-style-type: none"> a) the laboratory shall have a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to <ul style="list-style-type: none"> 1) incorrect patient or sample identification; 2) sample instability due to, for example, delay in transport; 3) incorrect storage or handling temperature; 4) inappropriate container(s); and 5) insufficient sample volume. b) when a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report shall indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected. 	The best interest of the patient to be part of the consideration when compromised samples reported on.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
7.2.7			Pre-examination handling, preparation, and storage	
7.2.7.1	5.4.7	Editorial	Sample protection The laboratory shall have procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during, handling, preparation and storage.	
7.2.7.2	5.4.7	Editorial	Criteria for additional examination requests Laboratory procedures shall include time limits for requesting additional examinations on the same sample	
7.2.7.3		New	Sample stability Considering the stability of the analyte in a primary sample, the time between sample collection and performing the examination shall be specified and monitored where relevant.	Emphasise considering analyte stability requirements
7.3	5.5		Examination processes	
7.3.1	5.5.1.1 4.14.2	Editorial	General a) The laboratory shall select and use examination methods which have been validated for their	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>intended use to assure the clinical accuracy of the examination for patient testing.</p> <p>b) The performance specifications for each examination method shall relate to the intended use of that examination and its impact on patient care.</p> <p>c) All procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and be readily available to personnel (see 8.3).</p> <p>d) Personnel shall follow established procedures and the identity of persons performing significant activities in examination processes be recorded, including POCT operators.</p> <p>e) Authorized personnel shall periodically evaluate the examination methods provided by the laboratory to ensure they are clinically</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			appropriate for the requests received.	
7.3.2	5.5.1.2	Minor	<p>Verification of examination methods</p> <ul style="list-style-type: none"> a) The laboratory shall have a procedure to verify that it can properly perform examination methods before introducing into use, by ensuring that the required performance, as specified by the manufacturer or method, can be achieved. b) The performance specifications for the examination method confirmed during the verification process shall be those relevant to the intended use of the examination results. c) The laboratory shall ensure the extent of the verification of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making. d) Personnel with the appropriate authorization and 	<p>When methods are revised by the issuing body the laboratory shall repeat the verification.</p> <p>Records of verification shall be retained</p>

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>competence shall review the verification results and record whether the results meet the specified requirements.</p> <p>e) If a method is revised by the issuing body, the laboratory shall repeat verification to the extent necessary.</p> <p>f) The following records of verification shall be retained:</p> <p>1) performance specifications to be achieved,</p> <p>2) results obtained, and</p> <p>3) a statement of whether the performance specifications were achieved and if not, action taken.</p>	
7.3.3	5.5.1.3	Minor	<p>Validation of examination methods</p> <p>a) The laboratory shall validate examination methods derived from the following sources:</p> <p>1) laboratory designed or developed methods,</p> <p>2) methods used outside their originally</p>	Required records of validation expanded.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>intended scope (i.e. outside of the manufacturer's instructions for use, or original validated measurement range; third party reagents used on instruments other than intended instruments and where no validation data are available), 3) validated methods subsequently modified.</p> <p>b) The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence in the form of performance specifications, that the specific requirements for the intended use of the examination have been fulfilled. The laboratory shall ensure that the extent of validation of an examination method is sufficient to ensure the validity of results pertinent to clinical decision making.</p> <p>c) Personnel with the appropriate authorization and</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>competence shall review the validation results and record whether the results meet the specified requirements.</p> <p>d) When changes are proposed to a validated examination method, the clinical impact shall be reviewed, and a decision made as to whether to implement the modified method.</p> <p>e) The following records of validation shall be retained:</p> <p>1) the validation procedure used, 2) specific requirements for the intended use, 3) determination of the performance specifications of the method, 4) results obtained, 5) a statement on the validity of the method, detailing its fitness for the intended use.</p>	
7.3.4	5.5.1.4	Minor	<p>Evaluation of measurement uncertainty (MU)</p> <p>a) All measurements have a certain bias and imprecision. The MU of</p>	Where the estimation of MU is not possible or applicable, rational for exclusion from estimates must be detailed.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>measured quantity values shall be evaluated and maintained for its intended use, where relevant. The MU shall be compared against performance specifications and documented.</p> <p>b) MU evaluations shall be regularly reviewed.</p> <p>c) For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU estimation shall be documented.</p> <p>d) MU information shall be made available to laboratory users on request.</p> <p>e) When users have inquiries on MU, the laboratory's response shall take into account other sources of uncertainty, such as, but not limited to biological variation.</p> <p>f) If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or</p>	<p>Qualitative results relying on a test which produces quantitative output shall have MU estimated. This needs to be considered for all key (high risk) parts of the process.</p>

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>negative, based on a threshold, MU in the output quantity shall be estimated using representative positive and negative samples.</p> <p>g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process.</p> <p>h) MU should be taken into consideration when performing verification or validation of a method, when relevant.</p>	
7.3.5	5.5.2	Minor	<p>Biological reference intervals and clinical decision limits</p> <p>Biological reference intervals and clinical decision limits, when needed for interpretation of examination results, shall be defined and communicated to users.</p> <p>a) Biological reference intervals and clinical decision limits shall be defined, and their basis recorded, to reflect the patient population</p>	<p>Biological reference intervals and clinical decision limits shall be reviewed periodically and when changes are made to applicable methods.</p>

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>served by the laboratory, while considering the risk to patients.</p> <p>b) Biological reference intervals and clinical decision limits shall be periodically reviewed, and any changes communicated to users.</p> <p>c) When changes are made to an examination or pre-examination method, the laboratory shall review the impact on associated biological reference intervals and clinical decision limits and communicate to the users when applicable.</p> <p>d) For examinations that identify presence or absence of a characteristic, the biological reference „interval is the characteristic to be identified, e.g. genetic examinations.</p>	
7.3.6	5.5.3	Minor	Documentation of examination procedures	Laboratory shall document procedures to the extend necessary to ensure consistent

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<ul style="list-style-type: none"> a) The laboratory shall document its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results. b) Procedures shall be written in a language understood by laboratory personnel and be available in appropriate locations. c) Any abbreviated document content shall correspond to the procedure. d) Information from product instructions for use, that contain sufficient information, can be incorporated into procedures by reference. e) When the laboratory makes a validated change to an examination procedure which could affect interpretation of results, the implications of this shall be explained to users. f) All documents associated with the examination process 	<p>application of activities and validity of results.</p> <p>(list of specific requirements to be included in documents removed)</p>

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			shall be subject to document control (see 8.3).	
7.3.7	5.6		Ensuring the validity of examination results	
7.3.7.1	5.5.1.1 5.6 5.6.1	New	General The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed.	Validity of laboratory results shall be monitored and recorded so any trends / shifts are detectable.
7.3.7.2	5.6 5.6.2.1 5.6.2.2 5.6.2.3	Major	Internal quality control (IQC) a) The laboratory shall have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making. 1) the intended clinical application of the examination should be considered, as the	The standard now includes additional quality control tools. These would already be adopted by laboratories.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>performance specifications for the same measurand can differ in different clinical settings.</p> <p>2) the procedure should also allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure should avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both.</p> <p>3) the use of third-party IQC material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer.</p> <p>b) The laboratory shall select IQC material that is fit for its intended purpose. When selecting IQC material, factors to be considered shall include:</p> <p>1) stability with regard</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>to the properties of interest.</p> <p>2) the matrix is as close as possible to that of patient samples.</p> <p>3) the IQC material reacts to the examination method in a manner as close as possible to patient samples.</p> <p>4) the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.</p> <p>c) If appropriate IQC material is not available, the laboratory shall consider the use of other methods for IQC. Examples of such other methods may include:</p> <p>1) trend analysis of patient results, e.g. with moving average of patient results, or percentage of samples with results below or</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>above certain values or associated with a diagnosis;</p> <p>2) comparison of results for patient samples on a specified schedule to results for patient samples examined by an alternative procedure validated to have its calibration metrologically traceable to the same or higher order references as specified in ISO 17511;</p> <p>3) retesting of retained patient samples.</p> <p>d) IQC shall be performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result.</p> <p>e) The resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results.</p> <p>f) IQC data shall be reviewed with defined acceptability criteria at</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>regular intervals, and in a timeframe that allows a meaningful indication of current performance.</p> <p>g) The laboratory shall prevent the release of patient results in the event that IQC fails the defined acceptability criteria.</p> <p>1) When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error has been corrected (see 7.5).</p> <p>2) The results from patient samples that were examined after the last successful IQC event shall be evaluated.</p>	
7.3.7.3	5.6.3 5.6.3.1 5.6.3.2 5.6.3.3 5.6.3.4	Major	<p>External quality assessment (EQA)</p> <p>a) The laboratory shall monitor its performance of examination methods, by comparison with results of other</p>	<p>The standard now includes additional external quality assessment tools. These would already be adopted by laboratories.</p> <p>EQA participation shall include POCT examination methods.</p>

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods.</p> <p>b) The laboratory shall establish a procedure for EQA enrolment, participation and performance for examination methods used, where such programmes are available.</p> <p>c) EQA samples shall be processed by personnel who routinely perform pre-examination, examination, and post-examination procedures.</p> <p>d) The EQA programme(s) selected by the laboratory shall, to the extent possible:</p> <p>1) have the effect of checking pre-examination, examination, and post-examination processes.</p> <p>2) provide samples that mimic patient samples</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>for clinically relevant challenges.</p> <p>3) fulfill ISO/IEC 17043 requirements.</p> <p>e) When selecting EQA programme(s), the laboratory should consider the type of target value offered. Target values are:</p> <p>1) independently set by a reference method, or</p> <p>2) set by overall consensus data, and/or</p> <p>3) set by method peer group consensus data, or</p> <p>4) set by a panel of experts.</p> <p>f) When an EQA programme is either not available, or not considered suitable, the laboratory shall the alternative methodologies to monitor examination method performance. The laboratory shall justify the rationale for the chosen alternative and provide evidence of its effectiveness.</p> <p>g) EQA data shall be reviewed at regular intervals with specified acceptability criteria, in a time frame which</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>allows for a meaningful indication of current performance.</p> <p>h) Where EQA results fall outside specified acceptability criteria, appropriate action shall be taken (see 82), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.</p> <p>i) Where it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment shall be considered and users advised as appropriate.</p>	
7.3.7.4	5.6.4	Minor	<p>Comparability of examination results</p> <p>a) When either different methods or equipment, or both, are used for an examination, and/or the examination is performed at different sites, a procedure for establishing the comparability of results for patient samples throughout the</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>clinically significant intervals shall be specified.</p> <p>b) The laboratory shall record the results of comparability performed and its acceptability.</p> <p>c) The laboratory shall periodically review the comparability of results.</p> <p>d) Where differences are identified, the impact of those differences on biological reference intervals and clinical decision limits shall be evaluated and acted upon.</p> <p>e) The laboratory shall inform users of any clinically significant differences in comparability of results.</p>	
7.4	5.7		Post-examination processes	
7.4.1			Reporting of Results	
7.4.1.1	5.8.1 5.8.2 5.9.1	Editorial	General a) Examination results shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>the examination procedure. The report shall include all available information necessary for the interpretation of the results.</p> <p>b) The laboratory shall have a procedure to notify users when examination results are delayed, based on the impact of the delay on the patient.</p> <p>c) All information associated with issued reports shall be retained in accordance with management system requirements (see a4).</p>	
7.4.1.2	5.7.1 5.9	Editorial	<p>Result review and release</p> <p>Results shall be reviewed and authorized prior to release. The laboratory shall ensure that authorized personnel review the results of examinations and evaluate them against IQC and, as appropriate, available clinical information and previous examination results. Responsibilities and procedures for how examination results are released for reporting, including by whom and to whom, shall be specified.</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
7.4.1.3	5.7.1 5.8.2	New	<p>Critical result reports</p> <p>When examination results fall within established critical decision limits:</p> <ul style="list-style-type: none"> a) the user or other authorized person is notified as soon as relevant, based on clinical information available. b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification. c) the laboratory shall have an escalation procedure for laboratory personnel when a responsible person cannot be contacted. 	Critical results to be notified as soon as relevant.
7.4.1.4	5.9.1 Note 1&2	Editorial	<p>Special considerations for results</p> <ul style="list-style-type: none"> a) When agreed with the user, the results may be reported in a simplified way. Any information listed in 7.4.1.6 and 7.4.1.7 that 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>is not reported to the user shall he readily available.</p> <p>b) When results are transmitted as a preliminary report, the final report shall always be forwarded to the user.</p> <p>c) Records shall be kept of all results which are provided orally, including details of verification of accuracy of communication, as in 7.4.1.3 b). Such results shall always be followed by a report.</p> <p>d) Special counselling may be needed for examination results with serious implications for the patient (e.g. for genetic or certain infectious diseases). Laboratory management should ensure that these results are not communicated to the patient without the opportunity for adequate counselling.</p> <p>e) Results of laboratory examinations that have been anonymized may be used for such purposes as</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			epidemiology, demography, or other statistical analyses, provided that all risks to patient privacy and confidentiality are mitigated and in accordance with any either legal or regulatory requirements, or both.	
7.4.1.5	5.9.2	Editorial	<p>Automated selection, review, release and reporting of results</p> <p>When the laboratory implements a system for automated selection, review, release and reporting of results, it shall establish a procedure to ensure that:</p> <ul style="list-style-type: none"> a) The criteria for automated selection, review and release are specified, approved, readily available and understood by personnel responsible for authorizing the release of results. b) the criteria are validated and approved before use, regularly reviewed and verified after changes to the reporting system that can affect their proper functioning and place 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>patient care at risk.</p> <p>c) results selected by an automated reporting system for manual review are identifiable; and as appropriate, date and time of selection and review, as well as identity of the reviewer are retrievable.</p> <p>d) when necessary, rapid suspension of automated selection, review, release and reporting is applied.</p>	
7.4.1.6	5.8.3	Editorial	<p>Requirements for reports Each report shall include the following information, unless the laboratory has documented reasons for omitting any items:</p> <p>a) unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report.</p> <p>b) identification of the laboratory issuing the report</p> <p>c) name or other unique identifier of the user;</p> <p>d) type of primary sample and any specific information necessary</p>	The laboratory must have documented reasons for omitting any report requirements.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>to de-scribe the sample (e.g. source, site of specimen, Macroscopic description)</p> <p>e) clear, unambiguous identification of the examinations performed.</p> <p>f) identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle.</p> <p>g) examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units.</p> <p>h) biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms, supporting clinical decision limits as necessary.</p> <p>i) identification of examinations undertaken as part of a</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>research or development programme and for which no specific claims on measurement performance are available.</p> <p>j) identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);</p> <p>k) identification of any results that need to be considered as preliminary.</p> <p>l) indications of any critical results.</p> <p>m) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end (e.g. page number to total number of pages).</p>	
7.4.1.7	5.8.3	Minor	<p>Additional information for reports</p> <p>a) When necessary for patient care, the time of primary sample collection shall be included.</p>	Report interpretation comments shall include comments on discrepancies when testing is performed by different procedures (e.g. POCT) or in different locations.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>b) Time of report release, if not contained in the report, shall be readily available when needed.</p> <p>c) Identification of all examinations or parts of examinations performed by a referral laboratory, including information provided by consultants, without alteration, as well as the name of the laboratory performing the examinations.</p> <p>d) When applicable, a report shall include interpretation of results and comments on:</p> <p>1) sample quality and suitability that can compromise the clinical value of examination results.</p> <p>2) discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations;</p> <p>3) possible risk of misinterpretation when different units of measurement are in</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>use regionally or nationally.</p> <p>4) result trends or significant changes over time.</p>	
7.4.1.8	5.9.3	Editorial	<p>Amendments to reported results</p> <p>Procedures for the issue of amended or revised results shall ensure that:</p> <ul style="list-style-type: none"> a) The reason for the change is recorded and included in the revised report, when relevant. b) Revised results shall be delivered only in the form of an additional document or data transfer, and clearly identified as having been revised, and the date and patient's identity in the original report shall be indicated. c) The user is made aware of the revision. d) When it is necessary to issue a completely new report, this shall be uniquely identified and shall contain a reference and traceability to the 	Emphasise on traceability of amendments

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>original report that it replaces.</p> <p>e) When the reporting system cannot capture revisions, a record of such shall be kept.</p>	
7.4.2	5.7.2	Minor	<p>Post-examination handling of samples</p> <p>The laboratory shall specify the length of time samples are to be retained following examination and conditions under which samples are to be stored.</p> <p>The laboratory shall ensure that after the examination, the</p> <ul style="list-style-type: none"> a) patient and source identification of the sample are maintained, b) suitability of the sample for additional examination is known, c) sample is stored in a manner that optimally preserves suitability for additional examination, d) sample can be located and retrieved, and e) sample is discarded appropriately. 	
7.5	4.9	Minor (focus on risk)	<p>Nonconforming work</p> <p>The laboratory shall have a process for when any aspect of its laboratory activities or</p>	Emphasise on actions taken to reduce risk

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>examination results do not conform to its own procedures, quality specifications, or the user requirements (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The process shall ensure that:</p> <ul style="list-style-type: none"> f) the responsibilities and authorities for the management of nonconforming work are specified. g) Immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory. h) Examinations are halted, and reports withheld when there is a risk of harm to patients. i) an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the nonconformance. j) a decision is made on 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>the acceptability of the nonconforming work.</p> <p>k) when necessary, examination results are revised, and the user is notified.</p> <p>l) the responsibility for authorizing the resumption of work is specified.</p> <p>The laboratory shall implement corrective action commensurate with the risk of recurrence of the nonconforming work (see 8.7). The laboratory shall retain records of nonconforming work and actions as specified in 7.5 a) to g).</p>	
7.6	5.10		Control of data and information management	
7.6.1	5.10.1	Editorial	<p>General</p> <p>The laboratory shall have access to the data and information needed to perform laboratory activities</p>	Standard references ISO/ IEC 27001:2013 in Note.
7.6.2	5.10.2	Minor	<p>Authorities and responsibilities for information management</p> <p>The laboratory shall ensure that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			modification to the information systems that can affect patient care. The laboratory is ultimately responsible for the laboratory information systems.	
7.6.3	5.10.3	Editorial	<p>Information systems management</p> <p>The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:</p> <ul style="list-style-type: none"> a) validated by the supplier and verified for functionality by the laboratory before introduction. Any changes to the system, including laboratory software configuration or modifications to commercial off-the-shelf software, shall be authorized, documented and validated before implementation. b) documented, and the documentation readily available to authorized users, including that for day to day functioning of the system; c) implemented taking 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>cybersecurity into account, to protect the system from unauthorized access and safeguard data against tampering or loss.</p> <p>d) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcriptions.</p> <p>e) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions.</p> <p>Calculations and data transfers shall be checked in an appropriate and systematic manner.</p>	
7.6.4	5.10.3	Editorial	<p>Downtime plans</p> <p>The laboratory shall have planned processes to maintain operations in the event of</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			failure or during downtime in information systems that affects the laboratory's activities. This includes automated selection and reporting of results.	
7.6.5	5.10.3	Editorial	Offsite Management When the laboratory information system(s) are 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.	
7.7			Complaints	The requirements have been significantly expanded however many of the revised / new requirements would already be implemented by laboratories.
7.7.1	4.8	Major	Process The laboratory shall have a process for handling complaints that shall include at least the following: a) a description of the process for receiving, substantiating and investigating the complaints, and deciding what actions	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>shall be taken in response.</p> <p>b) tracking and recording the complaint, including the actions undertaken to resolve it.</p> <p>c) ensuring appropriate action is taken.</p> <p>A description of the process for handling complaints shall be publicly available.</p>	
7.7.2		New	<p>Receipt of complaint</p> <p>a) Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, shall resolve the complaint. (see 8.7.1).</p> <p>b) The laboratory receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.</p> <p>c) Whenever possible the laboratory shall acknowledge receipt of the complaint, and provide the</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			complainant with the outcome and, if applicable, progress reports.	
7.7.3		New	<p>Resolution of complaint</p> <p>Investigation and resolution of complaints shall not result in any discriminatory actions.</p> <p>The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.</p>	
7.8		New	<p>Continuity and emergency preparedness planning</p> <p>The laboratory shall ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption.</p> <p>Plans shall be periodically tested and the planned response capability exercised, where practicable.</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>The laboratory shall:</p> <ul style="list-style-type: none"> a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel. b) provide information and training as appropriate to relevant laboratory personnel. c) respond to actual emergency situations. d) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact. 	
8	4.2		Management system requirements	
8.1	4.2.1		General requirements	
8.1.1	4.2.1	Major	<p>General</p> <p>The laboratory shall establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document.</p>	<p>Details overview of the requirements for the Management system.</p> <p>The management system now includes requirements for actions to address risks and opportunities.</p>

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>As a minimum, the management system of the laboratory shall include the following:</p> <ul style="list-style-type: none"> — responsibilities (8.1) — objectives and policies (8.2) — documented information (8.2, B.,3. and 8.4) — actions to address risks and opportunities for improvement (8.5) — continual improvement (8.6) — corrective actions (8.7) — evaluations and internal audits (8.8) — management reviews (8.9) 	
8.1.2	4.2.1	New	<p>Fulfilment of management system requirements</p> <p>The laboratory may meet 8.1.1 by establishing, implementing, and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001) (see Table B 1). This quality management system shall support and demonstrate the</p>	Laboratories may meet 8.1.1 management system requirements by establishing, implementing, and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001)

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9.	
8.1.3	4.1.2.7	New	<p>Management system awareness</p> <p>The laboratory shall ensure that persons doing work under the laboratory's control are aware of:</p> <ul style="list-style-type: none"> a) relevant objectives and policies. b) their contribution to the effectiveness of the management system, including the benefits of improved performance. c) the consequences of not conforming with the management system requirements. 	
8.2			Management system documentation	
8.2.1	4.2.2.1 4.2.2.2	Editorial	<p>General</p> <p>Laboratory management shall establish, document, and maintain objectives and policies for the fulfilment of the purposes of this document and shall ensure that the objectives and policies are acknowledged</p>	The standard no longer prescribes a quality policy or specifically a quality manual. Procedures, however, still need to be maintained.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			and implemented at all levels of the laboratory organization.	
8.2.2	4.2.2.1	Editorial	Competence and quality The objectives and policies shall address the competence, quality and consistent operation of the laboratory.	
8.2.3	4.1.2.1	Editorial	Evidence of commitment Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.	Requirements now less prescriptive.
8.2.4	4.2.1	Editorial	Documentation All documentation, processes, systems, and records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.	
8.2.5	4.2.2.2	Editorial	Personal access 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.	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
8.3	4.3		Control of management systems documents	
8.3.1	4.3	Editorial	General The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.	
8.3.2	4.3	Editorial	Control of documents The laboratory shall ensure that: <ul style="list-style-type: none"> a) documents are uniquely identified. b) documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy. c) documents are periodically reviewed and updated as necessary. d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled. e) changes and the current revision status of documents are identified. 	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>f) documents are protected from unauthorized changes and any deletion or removal.</p> <p>g) documents are protected from unauthorized access.</p> <p>h) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.</p> <p>i) at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.</p>	
8.4			Control of records	
8.4.1	4.13	Editorial	<p>Creation of records</p> <p>The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements of this document.</p> <p>Records shall be created at the time each activity that affects the quality of an examination is performed.</p>	Prescriptive list of records no longer included.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
8.4.2	4.13	Minor	Amendment of records The laboratory shall ensure that amendments to records can be traced to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations	
8.4.3	4.13		Retention of records a) The laboratory shall implement the procedures needed for the identification, storage, protection from unauthorized access and changes, back-up, archive, retrieval, retention time, and disposal of its records. b) The retention times for records shall be specified. c) Reported examination results shall be retrievable for as long as necessary or as required. d) All records shall be accessible throughout	Retention times to be based on risks.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review (see 8.9).	
8.5		New	Actions to address risks and opportunities for improvement	
8.5.1	4.11 4.14.6	New	<p>Identification of risks and opportunities for improvement</p> <p>The laboratory shall identify risks and opportunities for improvement associated with the laboratory activities to:</p> <ul style="list-style-type: none"> a) prevent or reduce undesired impacts and potential failures in the laboratory activities. b) achieve improvement, by acting on opportunities. c) assure that the management system achieves its intended results. d) mitigate risks to patient care. e) help achieve the purpose and objectives of the laboratory. 	Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results. The laboratory is responsible for deciding which risks and opportunities need to be addressed.
8.5.2	4.11 4.14.6	New	Acting on risks and opportunities for improvement	Actions taken to address risk shall be proportional.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>The laboratory shall prioritize and act on identified risks. Actions taken to address risks shall be proportional to the potential impact on laboratory examination results, as well as patient and personnel safety.</p> <p>The laboratory shall record decisions made and actions taken on risks and opportunities.</p> <p>The laboratory shall integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness.</p>	
8.6			Improvement	
8.6.1	4.12	Editorial	<p>Continual improvement</p> <ul style="list-style-type: none"> a) The laboratory shall continually improve the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies. b) The laboratory shall identify and select opportunities for improvement and develop, document, 	Improvement activities shall be directed at areas of highest priority based on risk and opportunities.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>and implement any necessary actions. Improvement activities shall be directed at areas of highest priority based on risk assessments and the opportunities identified (see 8.5)</p> <p>c) The laboratory shall evaluate the effectiveness of the actions taken.</p> <p>d) Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.</p> <p>e) Laboratory management shall communicate to personnel its improvement plans and related goals</p>	
8.6.2	4.8 4.14.3 4.14.4	Editorial	<p>Laboratory patients, user, and personnel feedback</p> <p>The laboratory shall seek feedback from its patients, users, and personnel. The feedback shall be analyzed and used to improve the</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>management system, laboratory activities and services to users.</p> <p>Records of feedback shall be maintained including the actions taken. Communication shall be provided to personnel on actions taken arising from their feedback.</p>	
8.7	4.9		Nonconformities and corrective actions	
8.7.1	4.9 4.14.8		<p>Actions when nonconformity occurs</p> <p>When a nonconformity occurs, the laboratory shall:</p> <ul style="list-style-type: none"> a) Respond to the nonconformity and, as applicable: <ul style="list-style-type: none"> 1) take immediate action to control and correct the nonconformity. 2) address the consequences, with a particular focus on patient safety including escalation to the appropriate person. b) Determine the cause(s) of the nonconformity. c) Evaluate the need for corrective action to eliminate the cause(s) of the nonconformity, in 	A key change is that the impact of any nonconformity in relation to risks and opportunities must be determined.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>order to reduce the likelihood of recurrence or occurrence elsewhere, by:</p> <ul style="list-style-type: none"> 1) reviewing and analyzing the nonconformity. 2) determining whether similar nonconformities exist or could potentially occur. 3) assessing the potential risk(s) and effect(s) if the nonconformity recurs. d) Implement any action needed. e) Review and evaluate the effectiveness of any corrective action taken. f) Update risks and opportunities for improvement, as needed. g) Make changes to the management system, if necessary. 	
8.7.2	4.10	Editorial	<p>Corrective action effectiveness</p> <p>Corrective actions shall be appropriate to the effects of the nonconformities encountered and shall mitigate the identified cause(s).</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
8.7.3	4.10	Editorial	Records of nonconformities and corrective actions The laboratory shall retain records as evidence of the <ul style="list-style-type: none"> a) nature of the nonconformities, cause(s) and any subsequent actions taken, and b) evaluation of the effectiveness of any corrective action. 	
8.8	4.14		Evaluations	
8.8.1	4.14.1	Editorial	General The laboratory shall conduct evaluations at planned intervals to demonstrate that the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document.	Emphasise on the requirements of the patient.
8.8.2	4.14.7	Editorial	Quality indicators The process of monitoring quality indicators [see 5.5 c)] shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			monitoring. The indicators shall be periodically reviewed, to ensure continued appropriateness.	
8.8.3			Internal audits	
8.8.3.1	4.14.5	Editorial	<p>The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system.</p> <ul style="list-style-type: none"> a) conforms to the laboratory's own requirements for its management system, including the laboratory activities, b) conforms to the requirements of this document, and c) is effectively implemented and maintained. 	
8.8.3.2	4.15.5	Minor	<p>The laboratory shall plan, establish, implement and maintain an internal audit programme that includes:</p> <ul style="list-style-type: none"> a) priority given to risk to patients from laboratory activities. b) a schedule which takes into consideration identified risks; the 	Emphasise on risk to patients.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities.</p> <p>c) specified audit objectives, criteria and scope for each audit.</p> <p>d) selection of auditors who are trained, qualified and authorized to assess the performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited.</p> <p>e) ensuring objectivity and impartiality of the audit process.</p> <p>f) ensuring that the results of the audits are reported to relevant personnel.</p> <p>g) implementation of appropriate correction and corrective actions without undue delay.</p> <p>h) retention of records as evidence of the implementation of the audit programme and</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			audit results.	
8.9			Management reviews	
8.9.1	4.15	Editorial	General Laboratory management shall review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document	
8.9.2	4.15.2 4.15.3	Editorial	Review input The inputs to management review shall be recorded and shall include evaluations of at least the following: <ul style="list-style-type: none"> a) status of actions from previous management reviews, internal and external changes to the Management system, changes in the volume and type of laboratory activities and adequacy of resources. b) fulfilment of objectives and suitability of policies and procedures. c) outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis 	Review input to include evaluation of POCT activities.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>of non-conformities, corrective actions, assessments by external bodies.</p> <p>d) patient, user and personnel feedback and complaints.</p> <p>e) quality assurance of result validity.</p> <p>f) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement.</p> <p>g) performance of external providers.</p> <p>h) results of participation in interlaboratory comparison programmes.</p> <p>i) evaluation of POCT activities.</p> <p>j) other relevant factors, such as monitoring activities and training</p>	
8.9.3	4.15.4		<p>Review output</p> <p>The output from the management review shall be a record of decisions and actions related to at least:</p> <p>a) the effectiveness of the management system and its processes;</p>	Standard now specifies requirements for review output.

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
			<p>b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;</p> <p>c) provision of required resources;</p> <p>d) improvement of services to patients and users;</p> <p>e) any need for change.</p> <p>Laboratory management shall ensure that actions arising from management review are completed within a specified time frame.</p> <p>Conclusions and actions arising from management reviews shall be communicated to laboratory personnel.</p>	
			Annex A (Normative)	Refer to the Standard for details.
			Additional requirements for Point-of-Care Testing (POCT)	
A.1		New	<p>General</p> <p>This annex describes the additional requirements for the laboratory for POCT that are distinct from, or in addition to, those outlined in the main text. These requirements specify the laboratory's responsibilities towards organizations,</p>	

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			<p>departments and their personnel regarding the selection of devices, training of personnel, quality assurance, and the management review of the complete POCT process.</p> <p>Patient self-testing is excluded, but elements of this document may be applicable.</p>	
A.2		New	<p>Governance of POCT</p> <p>The governing body of the organization shall be ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organization. Service agreements between the laboratory and all locations using laboratory supported POCT shall ensure that respective responsibilities and authorities are specified and communicated within the organization.</p> <p>These agreements shall have clinical approval, and where applicable, financial approval.</p> <p>These service agreements shall be with POCT areas and may be managed via a health professional grouping (e.g. medical advisory committee).</p>	

ISO 15189:2022 Clause No.	Corresponding ISO 15189:2012 Clause No.	Emphasis of Change	Summary of text/extract from ISO 15189:2022	Comments
A.3		New	<p>Quality assurance programme</p> <p>The laboratory shall appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of this document as related to POCT</p>	
A.4		New	<p>Training programme</p> <p>A person with appropriate training and experience shall be appointed to manage training and competency assessment of personnel performing POCT.</p> <p>The trainer shall develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel.</p>	