Analysis of major changes and additional requirements of ISO 15189: 2022 over and above in ISO 15189: 2012

Introduction

This document sets out primarily to identify the additional requirements contained within ISO 15189: 2022 and previous 2012 version of the standard. It is not intended to be an examination of all of the differences between the two standards, but rather to assist organisations who wish to identify the changes that they may need to make to their quality management systems and to cover during audits conducted against the new standards. In this analysis we have not 'graded' the significance of the changes, just state what they are. Many are minor or even insignificant and likely already to have been considered by organisations implementing ISO 15189:2012.

Where the intent of both standards is the same with minor wording or terminology change, no comment is given for the purpose of clarity. Unfortunately we are unable to provide the full text for comparison for copyright reasons. Where additional requirements have been identified, these requirements are generally abridged rather than re-stating the text. The comparison is based upon the clause references given in ISO 15189:2012 to assist organisations relate the changes to their existing systems. Where no additional requirements/comments are made the text is substantially the same as 2012 version of the standard.

Every effort has been made to ensure the accuracy of the information provided however Qualimetric Ltd cannot be held responsible for use of the information given. Users are advised to check with the published standards themselves prior to utilising the information. We would however welcome any feedback to improve the document which can be provided to www.qualimetric.co.uk. Changes to date are highlighted in italics.

General comments

The major change has been to align the new version of the standard with ISO/IEC 17025 which underwent significant changes since the last edition of ISO 15189. Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated into the standard and ISO 22870 which is now being withdrawn.

Common changes throughout include the wording 'tests' are now referred to as 'examinations' and the requirements for 'documented' procedures has been removed, although of course the procedures still need to be defined in some way and so it would be expected that organisations would still wish to retain the documented procedures that they currently have.

Clause No (2012)	ISO 15189: 2012 Clause Title	Clause No (2022)	ISO 15189: 2022 Clause Title	ISO 15189: 2022 Additional Requirements/Comments
	Foreword		Forward	This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives) in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, In vitro diagnostic medical devices, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement). Text added regarding patent rights. Overview of the main changes from the previous edition.
	Introduction		Introduction	Requirements for risk management are aligned with the principles of ISO 22367 and sample collection and transport with ISO 20658.1. Point of care requirements from ISO 22870 have been incorporated in ISO 15189. Format of the document is based upon the 2017 edition of ISO/IEC 17025.

Medical laboratories — Requirements for quality and competence			Medical laboratories — Requirements for quality and competence	
1	Scope	1	Scope	Point of care requirements from ISO 22870 have been incorporated in ISO 15189. Note added stating that ISO/TS 22583 provides guidance for non-laboratory supported services. Also that ISO 15190 and ISO 22367 provide guidance on safety and risk aspects of POCT.
2	Normative references	2	Normative references	New point regarding normative references… in that for dated references, only the edition cited applies
3	Terms and definitions	3	Terms and definitions	Reference made to the ISO and IEC databases for standardization.
3.1	accreditation		-	Definition removed from the standard.
3.2	alert interval		-	Definition removed from the standard.
3.3	automated selection and reporting of results		-	Definition removed from the standard.
		3.1	bias	Definition of bias/measurement bias added.
3.4	biological reference interval	3.2	biological reference interval	-
		3.3	clinical decision limit	Definition of clinical decision limit added.
		3.4	commutability of a reference material	Definition of commutability of a reference material added.
3.5	competence	3.5	competence	Definition of competence now includes..' to achieve intended results'.
		3.6	complaint	Definition of complaint added.
		3.7	consultant	Definition of consultant added.
3.6	documented procedure		-	Definition removed from the standard
3.7	examination	3.8	examination	Definition of 'examination' now includes 'numerical' and 'text' values.
		3.9	examination procedure	Definition of 'examination procedure' added.
		3.10	external quality assessment - EQA	Definition of 'external quality assessment EQA' added
		3.11	impartiality	Definition of 'impartiality' added.
3.8	interlaboratory comparison	3.12	interlaboratory comparison	Interlaboratory comparison definition modified — "tests" has been replaced by "examinations". "items" has been replaced by "materials". "laboratories" has been replaced by "independent laboratories".
		3.13	internal quality control IQC - quality control QC	Definition of 'internal quality control - IQC quality control QC' added,
		3.14	in vitro diagnostic medical device IVD	Definition of 'in vitro diagnostic medical device IVD' added.
3.9	laboratory director		-	Definition removed from the standard.
3.10	laboratory management	3.15	laboratory management	Change of wording to include 'responsibility' and 'authority'.
		3.16	laboratory user	Definition of 'laboratory user' added.
		3.17	management system	Definition of 'management system' added.

3.11	medical laboratory	3.20	medical laboratory	Definition of 'medical laboratory' reworded.
		3.18	measurement accuracy	Definition of 'measurement accuracy' added.
		3.19	measurement uncertainty MU	Definition of 'measurement uncertainty' added.
		3.21	patient	Definition of 'patient' added
3.12	nonconformity		-	Definition removed from the standard
3.13	point-of-care testing POCT	3.22	point-of-care testing POCT	'Point-of-care testing POCT' wording change from 'testing' to examination'
3.14	post-examination processes	3.23	post-examination processes	Slight change to wording of 'post-examination processes'.
3.15	pre-examination processes	3.24	pre-examination processes	Slight change to wording of 'pre-examination processes'.
3.16	primary sample specimen	3.25	primary sample specimen	Slight change of 'primary sample specimen' definition to add 'associated with the human body' and 'characteristics' added.
3.17	process		-	Definition removed from the standard.
3.18	quality		-	Definition removed from the standard.
3.19	quality indicator	3.26	quality indicator	-
3.20	quality management system		-	Definition removed from the standard.
3.21	quality policy		-	Definition removed from the standard.
3.22	quality objective		-	Definition removed from the standard.
3.23	referral laboratory	3.27	referral laboratory	Slight change of working to add 'data'.
3.24	sample	3.28	sample	-
		3.29	trueness measurement - trueness	Definition of 'trueness, measurement trueness' added.
3.25	turnaround time	3.30	turnaround time	-
3.26	validation	3.31	validation	Slight wording change in wording, now using the term 'plausibility'. New notes added.
3.27	verification	3.32	verification	Slight wording change to add 'of truthfulness' New examples and notes added.
4	Management requirements	4	General requirements	-
4.1	Organization and management responsibility	5	Structural and governance requirements	-
4.1.1	Organization			-
4.1.1.1	General	5.3.2	Conformance with requirements	Wording change to add 'the users, regulatory authorities and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities' and slight terminology change relating to 'associated or mobile laboratories'.
4.1.1.2	Legal entity	5.1	Legal entity	Note added regarding government laboratories.

4.1.1.3	Ethical conduct	4.1	Impartiality	Now requires that the laboratory shall be 'structured and managed to safeguard impartiality'; be committed to impartiality; be responsible for the impartiality of its laboratory; 'shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include relationships of its personnel' and 'If a threat to impartiality is identified, the effect shall be eliminated or minimized so that the impartiality is not compromised. The laboratory shall be able to demonstrate how it mitigates such threat'. Note added giving examples of risks.
4.1.1.3 e)	e) confidentiality	4.2 4.2.1	Confidentiality Management of information .	Clause 4.2.1 expanded to include 'through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory 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 information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded' as confidential.
		4.2.2 4.2.3	Release of information Personnel responsibility	New clause added regarding release of information. New clause added with more explicit requirements added regarding confidentiality.
4.1.1.4	Laboratory director	5.2	Laboratory director	Terminology changed slightly regarding the Laboratory Director, in 'however named' and 'specified qualifications added'. Responsibility for the 'implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed' added. Delegation of duties now includes delegation to 'competent' personnel and 'such delegation shall be documented'. Job duties of Laboratory director have been greatly simplified.
4.1.2	Management responsibility		-	-
4.1.2.1	Management commitment	8.2.3	Evidence of commitment	
		6 6.1	Resource requirements General	Additional clause regarding resource requirements 'The laboratory shall have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities'.
4.1.2.2	Needs of users	4.3	Requirements regarding patients	Terminology changed from 'users' to 'patients'. Wording added stating 'patients' well-being, safety and rights are the primary considerations'. Items 'a through i' added to this section.
4.1.2.3	Quality policy	5.5	Objectives and policies	Objectives and policies now merged into one clause. Additional requirement regarding 'commitment to good professional practice' and that objectives and policies are implemented 'at all' levels of the laboratory organization.

4.1.2.4	Quality objectives and planning	8.2.2	Competence and quality	Added requirement that 'The objectives and policies shall address the competence, quality and consistent operation of the laboratory'.
4.1.2.5	Responsibility, authority and interrelationships	5.4 5.4.1	Structure and authority General	Additional requirement 'define its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services; that 'lines of communication' and 'interrelationship of 'all personnel who manage, perform or verify work affecting the results of laboratory activities' are specified and that 'specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results'. Additional requirements added for POCT regarding governance and training programme.
4.1.2.6	Communication	8.1.3	Management system awareness	Requirements listed as 'a)' through 'c' added.
4.1.2.7	Quality manager	5.4.2	Quality management	Quality Manager removed, and replaced by Quality Management. The word 'improvement ' added to item a). Additional items b), c) and e) added. Note added that responsibilities can be assigned to one more persons. Additional requirement relating to POCT (a3) added regarding appointment of a person responsible for POCT quality.
4.2	Quality management system			
4.2.1	General requirements	8 8.1 8.1.1	Management system requirements General requirements General	
4.2.2 Documentation requirements				
4.2.2.1	General	8.1.1 8.2 8.2.1	(cont'd) Management system documentation General	Clause 8.1.1 Minimum requirements of the management system now required to include responsibilities; — objectives and policies (as before); documented information; actions to address risks and opportunities for improvement; continual improvement; corrective actions; evaluations and internal audits and management reviews. Requirement 8.1.2 covers the option to maintain a quality management system which meets the requirements of ISO 9001. Clause 8.2.1 Repeats clause 5.5b stating that objectives and policies are acknowledged and implemented at *all* levels of the laboratory organization. NOTE added stating that 'The management system documents can, but are not required to, be contained in a quality manual'.
4.2.2.2	Quality manual	8.2.4	Documentation	[see note above in section 8.2.1 'The management system documents can, but are not required to, be contained in a quality manual'.

		8.2.5 5.3.1	Personnel access	- Clause 5.3.1 requires that the laboratory specifies and documents the range of laboratory activities (including sites other than the main location – eg POCT or sample collection) and which ones are claimed to conform with ISO 15189.
4.3	Document control	8.3 8.3.1 8.3.2	Control of management system documents General	 Clause 8.3.1 'internal and external' documents added. Slight rewording of note to include manufacturer's instructions and that notes documents can be in any form or type of medium. Clause 8.3.2 b) adds requirement that documents are approved by personnel who 'have the expertise and competence to determine adequacy'. 8.3.2 d) adds the caveat that distribution of documents is controlled 'where necessary'. 8.3.2 f) adds a requirement that documents are 'protected from unauthorized changes and any deletion or removal'; 8.3.2 g) adds a requirement that 'documents are protected from unauthorized access'.
4.4	Service agreements			
4.4.1	Establishment of service agreements	6.7 6.7.1	Service agreements Agreements with laboratory users	 6.7.1 c) clarifies the requirement that the laboratory is required to advise the user of specific activities which are to be performed by referral laboratories or consultants, where applicable. Slight rewording of 6.7.1 regarding notification of users of changes but intent is unchanged.
		6.7.2	Agreements with POCT operators	Clause 6.7.2 added regarding agreements with POCT operators.
4.4.2	Review of service agreements			
4.5	Examination by referral laboratories			
4.5.1	Selecting and evaluating referral laboratories and consultants	6.8.2	Referral laboratories and consultants	Clause 6.8.2 focuses more on the communication of requirements to referral laboratories and consultants in terms of the procedures, examinations, reports and activities as well as the management of critical results and requirement for specific personnel qualifications.
4.5.2	Provision of examination		-	-
4.6	External services and supplies	6.8 6.8.1	Externally provided products and services General	 Clause 6.8.1 adds wording regarding the scope of suppliers of 'externally provided products and services' in sections a) through c)

				A note is also added giving examples of services.
4.6	External services and supplies (cont'd)	6.8.3	Review and approval of externally provided products and services	Clause 6.8.3 a) strengthened to require that requirements for all externally approved products and services are 'defined, reviewed and approved'. 6.8.3 b) now includes 'qualification' and 're-evaluation of external providers'. 6.8.3 c) now added to cover 'referral of samples'. 6.8.3 d) adds a requirement to ensure that externally provided products and services conform to requirements. 6.8.3 e) adds a requirement to take action regarding evaluations of performance of external providers.
4.7	Advisory services	5.3.3	Advisory activities	Clause 5.3.3 reworded slightly to in the provision of 'appropriate' advice is provided, and communication with users 'when applicable'.
4.8	Resolution of complaints	7.7 7.7.1	Complaints Process	Clause 7.7 has been significantly expanded to align with the requirements of ISO/IEC 17025 in terms of the detail of description of the process for handing complaints (7.7.1); the receipt of complaint (7.7.2) and the resolution of complaints including impartiality (7.7.3).
4.9	Identification and control of nonconformities	7.5	Nonconforming work	7.5b adds 'long term' actions to be specified 'based on the risk analysis process established by the laboratory'. 7.5c adds that examinations reported and reports withheld 'when there is a risk of harm to patients' 7.5d adds 'impact analysis on examination results' which may be, or could have been released. 7.5e now requires that 'a decision is made on the acceptability of the nonconforming work'.
4.10	Corrective action	8.7 8.7.1 8.7.2 8.7.3	Nonconformities and corrective actions Actions when nonconformity occurs Corrective action effectiveness Records of nonconformities and corrective actions	 Clause 8.7.1 a) now requires that the laboratory 'responds to the nonconformity' and 'address the consequences, with a particular focus on patient safety including escalation to the appropriate person'. Clause 8.7.1 b) now requires that the likelihood of recurrence 'or occurrence elsewhere' is evaluated and that nonconformities are reviewed 'and analysed'. Clause 8.7.2 adds requirement that corrective actions 'shall mitigate the identified cause(s)'. Clause 8.7.3 provides more detail regarding records to be retained of nonconformities and corrective actions.
4.11	Preventive action	8.5 8.5.1	Actions to address risks and opportunities for improvement Identification of risks and opportunities for improvement	The 2012 edition of ISO 15189 on 'Preventive action' has now been effectively replaced by a new cluse 8.5 'Actions to address risks and opportunities for improvement' which requires that the laboratory is to identify risks and opportunities with a focus to minimise or eliminate risks and to enhance opportunities in a prioritized manner.

		8.5.2	Acting on risks and opportunities for improvement	
4.12	Continual improvement	7.1 8.6 8.6.1	General Improvement Continual improvement	Clause 8.6.1 b adds the requirement that 'The laboratory shall identify and select opportunities for improvement and develop, document, and implement any necessary actions'. A note has been added to this section regarding the identification of potential improvements.
4.13	*Records*	8.4 8.4.1 8.4.2 8.4. 3	Control of records Creation of records Amendment of records Retention of records	*Clause 8.4.2 has been added regarding the control of amendment to records with very specific requirements on management of changes to records.* *Clause 8.4.3a adds the requirement to implement the procedures in terms of 'changes, backup, archive, retrieval and disposal of records'.* *Clause 8.4.3d adds the requirement that 'All records shall be accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records'*.
4.14	Evaluation and audits			
4.14.1	General	8.8 8.8.1	Evaluations General	Clause 8.8.1 additionally requires that evaluations are conducted at planned intervals and cover 'management' processes.
4.14.2	Periodic review of requests, and suitability of procedures and sample requirements		7.3.1 7.2.4.1 .	
4.14.3	Assessment of user feedback	8.6.2	Laboratory patients, user, and personnel feedback	Clause 8.6.2, retitled 'Laboratory patients, user, and personnel feedback' now requires that feedback is 'analyzed and used to improve the management system, laboratory activities and services to users'. In addition, that 'Communication shall be provided to personnel on actions taken arising from their feedback'.
4.14.4	Staff suggestions	8.6.2		See above.. merged.
4.14.5	Internal audit	8.8.3 8.8.3.1 8.8.3.2	Internal audits	Additional detail has been added in clause 8.8.3.1 regarding the planning, establishment, implementation and maintenance of an internal audit programme. 8.8.3.2 a) requires that 'priority be given to risk to patients'; b) emphasises the consideration of risks; c) adds 'objectives' d) adds that auditors are required to be 'trained, qualified and authorised'; f) states that 'the results of the audits are reported to relevant personnel' and g) adds 'implementation or appropriate correction and corrective actions'. Records of audits was already covered under Clause 4.13 of ISO 15189: 2012).
4.14.6	Risk management	5.6 7.1	Risk management General	The aspect of risk management is covered in clauses 5.6, 7.1 and 8.5 of ISO 15189: 2022. *Clause 5.6 adds 'opportunities' to 'risks'*

			8.5 b)	Clause 7.1 also covers the assessment and 'mitigation' of risks which are to be 'monitored' and 'evaluated according to the potential harm to the patient'. Also that 'residual risk shall be communicated to users as appropriate' Specifically Clause 8.5 b) has been added stating that 'The laboratory director shall ensure that… processes are evaluated for effectiveness and modified, when identified as being ineffective'. Notes have been added referring to ISO 22367 and 35001 regarding risk management.
4.14.7 Quality indicators	.	5.5d) 8.8.2	 Quality indicators	5.5 d) The note in this section covering examples has been expanded slightly .
4.14.8	Reviews by external organizations		-	Removed from the standard
4.15	Management review	8.9	Management reviews	
4.15.1	General	8.9.1	General	Clause 8.9.1 adds the requirement that management reviews are to include 'stated policies and objectives related to the fulfilment of this document' (ie ISO 15189).
4.15.2	Review input	8.9.2	Review input	Clause 8.9.2 'Review input' has additional requirements to review: a) 'internal and external changes to the management system' and 'type of' laboratory activities; e) 'quality assurance of result validity' (only PT/EQA in the previous version; f) opportunities for improvement; and j) evaluation of POCT activities.
4.15.3	Review activities		-	Removed from the standard
4.15.4	Review output	8.9.3	Review output	Clause 8.9.3 'Review output' has additional requirement e) 'any need for change'.
5 Technical requirements				
5.1 Personnel				
5.1.1	General	6.2.1	General	Clause 6.2.1a now has the additional requirement that the laboratory shall have access to 'a sufficient number' of competent persons. Clause 6.2.1b also explicitly covers 'external' personnel and requires them to 'act impartially, ethically' and 'work in accordance with the laboratory's management system'. New note added regarding ISO/TS 22583. New requirements 6.2.1c regarding importance of personnel in meeting needs of users and systems.
5.1.2	Personnel qualifications	6.2.2	Competence requirements	
5.1.3	Job descriptions			
5.1.4	Personnel introduction to the organizational environment	6.2.1 d)		
5.1.5	Training	6.2.2 a)		

5.1.6	Competence assessment	6.2.2 a)		
5.1.7	Reviews of staff performance			
5.1.8	Continuing education and professional development	6.2.4	Continuing education and professional development	
5.1.9	Personnel records		6.2.2 6.2.5 Personnel records	
		6.2.3	Authorization	Clause 6.2.3 added which covers the authorization of personnel for specific activities.
5.2	Accommodation and environmental conditions	6.3	Facilities and environmental conditions	'Accommodation' is now 'facilities'
5.2.1	General	6.3.1	General	
5.2.2	Laboratory and office facilities	6.3.2	Facility controls	Clause 6.3.2 expanded in to state that facility controls are to be 'recorded, monitored' and 'periodically reviewed'. What was formally an (expanded) note regarding access control is now a requirement, clause 6.3.2 a) 'taking into consideration safety, confidentiality, quality and safeguarding medical information and patient samples' Clause 6.3.2 b) now covers 'prevention of contamination, interference of adverse influences on laboratory activities'. A new requirement 6.3.2 c) has been added concerning prevention of cross-contamination, Clause 6.3.2 e) added to cover maintenance of laboratory facilities.
5.2.3	Storage facilities	6.3.3	Storage facilities	Clause 6.3.3b now addressed 'deterioration' of patient samples. Clause 6.3.3 now covers biological waste and treatment in accordance with 'statutory or regulatory' requirements.
5.2.4	Staff facilities	6.3.4	Personnel facilities	
5.2.5	Patient sample collection facilities	6.3.5	Sample collection facilities	Clause 6.3.5 now includes a note referring to ISO 20658 regarding sample collection facilities.
5.2.6	Facility maintenance and environmental conditions	6.3.1		Clause 6.3.1 contains new notes on ISO 15190 for facilities and environmental conditions and examples of environmental conditions which may adversely affect results.
5.3	Laboratory equipment, reagents, and consumables	6.4 6.4.1.	Equipment	Clause 6.4.1 now additionally includes *a note to say that* 'equipment that influences the results of laboratory activities, including sample transportation systems'.
5.3.1	Equipment			

5.3.1.1	General	6.4.1 6.4.2	General Equipment requirements	Clause 6.4.1 now specifically requires processes for '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. Clause 6.4.2d now requires that the laboratory 'maintains' equipment in addition to the need for replacement.
5.3.1.2	Equipment acceptance testing	6.4.3	Equipment acceptance procedure	6.4.3 'Equipment acceptance procedure' reworded and now includes a new 'NOTE 2' regarding verification of equipment. 6.4.2 c) addressing equipment labelling now requires that 'a register' is maintained of each item of equipment that can influence laboratory results.
5.3.1.3	Equipment instructions for use	6.4.4	Equipment instructions for use	6.4.4 d) added, requiring that 'equipment shall be used as specified by the manufacturer, unless validated by the laboratory'.
5.3.1.4	Equipment calibration and metrological traceability	6.5 6.5.1 6.5.2 6.5.3	Equipment calibration and metrological traceability General Equipment calibration Metrological traceability of measurement results	 6.5.1 'Equipment calibration and metrological traceability = General' expanded to cover requirements for quantitative and qualitative methods including a new Note. 6.5.2 'Equipment calibration'. Procedures are now required to include e) correction factors are updated and 'recorded when recalibration occurs' and f) process to follow in the event that 'calibration is out of control to minimise risk to service operation and to patients'. Clause 6.5.3 a) regarding traceability strengthened to add 'by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference' 6.5.3 b) provides additional requirements regarding traceability to 'the highest possible level traceability and to the International System of Units (SI) through: — calibration provided by a competent laboratory' or c) 'results of reference measurement procedures' and 'accepted as providing measurement results fit for their intended use and ensured by suitable comparison' Note added referring to ISO 17511 regarding compromises in metrological traceability Clause 6.5.3 d) adds requirements for genetic examinations Clause 6.5.3 e) adds requirements for qualitative methods.
5.3.1.5	Equipment maintenance and repair	6.4.5	Equipment maintenance and repair	Clause 6.4.5a) adds a requirement to record 'deviations from manufacturer's schedules or instructions' Clause 6.4.5 c) gives an alternative option for equipment that is defective or out of specified limits can be 'marked as being out of service'. This subclause also adds the examination of 'deviation from' specified requirements in addition to defects.
5.3.1.6	Equipment adverse incident reporting	6.4.6	Equipment adverse incident reporting	Clause 6.4.6 includes notification of 'suppliers' (as appropriate) and an requirement that the laboratory is required to have procedures for 'responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer'

5.3.1.7	Equipment records	6.4.7	Equipment records	Clause 6.4.7 equipment records adds additional records to include 'software and firmware' and an additional requirement 6.4.7k to records 'status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete'.
5.3.2	Reagents and consumables			
5.3.2.1	General	6.6 6.6.1	Reagents and consumables General	 Clause 6.6.1 Note added giving examples of reagents.
5.3.2.2	Reagents and consumables — Reception and storage	6.6.2	Reagents and consumables — Receipt and storage	6.6.2 Additional requirement to 'monitor the environmental conditions where relevant'.
5.3.2.3	Reagents and consumables — Acceptance testing	6.6.3	Reagents and consumables — Acceptance testing	Clause 6.6.3 wording added 'or before release of results, as appropriate'. Notes 1 and 2 added regarding acceptance testing and verification.
5.3.2.4	Reagents and consumables — Inventory management	6.6.4	Reagents and consumables — Inventory management	
5.3.2.5	Reagents and consumables — Instructions for use	6.6.5	Reagents and consumables — Instructions for use	Clause 6.6.5 wording added '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'.
5.3.2.6	Reagents and consumables — Adverse incident reporting	6.6.6	Reagents and consumables — Adverse incident reporting	Clause 6.6.6 wording added 'The laboratory shall have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer.
5.3.2.7	Reagents and consumables — Records	6.6.7	Reagents and consumables — Records	Clause 6.6.7 c), records now require 'date of first use' Wording added to end of clause 6.6.7 to include 'resuspended or combined' as well as prepared reagents as well as adding date of 'expiry' as well as date of preparation.
5.4	Pre-examination processes			
5.4.1 l	General	7.2 7.2.1	Pre-examination processes General	 Clause 7.2.1 requires that procedures for pre-examination activities are made 'accessible to the relevant personnel' Notes added to emphasise the importance of pre-examination processes and to ISO 20658 on sample collection and transport. Note also added referring to ISO 20186 Pts 1-3, 20166, 20184, 23118 and 4307 regarding specific sources/analytes.
5.4.2	Information for patients and users	7.2.2	Laboratory information for patients and users	Clause 7.2.2 adds a requirement stating that 'information shall be sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements'.
5.4.3	Request form information	7.2.3 7.2.3.1	Requests for providing laboratory examinations	Clause 7.2.3.1b ass a requirement that the examination request provides sufficient information to ensure that 'informed clinical and technical advice… can be provided'.

			General	Clause 7.2.3.1c was a 'note' but is now a requirement. Clause 7.3.2.1d requires that, 'where necessary for patient care, the laboratory shall communicate with users or their representatives, to clarify the user's request'.
		7.2.3.2	Oral requests	
5.4.4	Primary sample collection and handling			
5.4.4.1	General	7.2.4 7.2.4.1 7.2.4.3	Primary sample collection and handling General Patient consent	Clause 7.2.4.1 adds a requirement regarding deviations that 'rejection of the sample shall be assessed, recorded..' Clause 7.2.4.3 adds a requirement requiring the laboratory 'shall obtain the informed consent of the patient for all procedures carried out on the patient'.
5.4.4.2	Instructions for pre-collection activities		7.2.4.2 Information for pre-collection activities	Clause 7.2.4.2 adds the requirement that the information and instructions for pre-collection activities provide 'sufficient detail to ensure that the integrity of the sample is not compromised'. Clause 7.2.4.2b adds 'where relevant the order of collecting samples' Additional subclauses 7.2.4.2e and f added covering sample labelling and identification of patient, source and site of sampling and criteria for acceptance/rejection of samples.
5.4.4.3	Instructions for collection activities	7.2.4.4	Instructions for collection activities	Clause 7.2.4.4. The words 'To ensure safe, accurate and clinically appropriate sample collection and pre-examination storage' added. 7.2.4.4c. 'as well as the order of sample collection, where relevant' added. New sub-clause 7.2.4.4f. 'requirements for separating or dividing the primary sample when necessary' added. 7.2.4.4g 'stabilization' added to storage conditions prior to sample delivery.
5.4.5	Sample transportation	7.2.5	Sample transportation	Clause 7.2.5 a) The words 'To ensure the timely and safe transportation of samples' added. Clause 7.2.5 a) 1)'Packaging of samples for transportation' added New subclause 7.2.5 b) added regarding situations where the sample integrity has been compromised added. New subclause 7.2.5 c) added requiring the laboratory to 'establish and periodically evaluate adequacy of sample transportation systems'.
5.4.6	Sample reception	7.2.6 7.2.6.1	Sample receipt Sample receipt procedure	7.2.6.1 c) the words 'where relevant' added regarding date and time of sample receipt. 7.2.6.1 d) the identity of the person receiving the sample shall be identified 'when relevant' (previously read 'where possible')

		7.2.6.2	Sample acceptance exceptions	Clause 7.2.6.2 'Sample acceptance exceptions' now requires a 'process that considers the best interests of the patient in receiving care, when a sample has been compromised'
5.4.7	Pre-examination handling, preparation and storage	7.2.7 7.2.7.1 7.2.7.2 7.2.7.3	Pre-examination handling, preparation, and storage Sample protection Criteria for additional examination requests. Sample stability	 New clause 7.2.7.3 added concerning sample stability
5.5	Examination processes	7.3	Examination processes	
5.5.1	Selection, verification and validation of examination procedures			
5.5.1.1 General	,	7.3.1	General	Clause 7.3.1 a) the words 'to assure the clinical accuracy of the examination for patient testing' have been added. Clause 7.3.1 b) the words 'and its impact on patient care' have been added. New subclause 7.3.1 c) added to ensure that instructions, standards, manuals and reference data are up to date and readily available to personnel.
5.5.1.2	Verification of examination procedures	7.3.2	Verification of examination methods	Clause 7.3.2 a) now requires 'a procedure' for verification that it can properly perform work. New subclause 7.3.2 c) concerning the extent of verification of methods. New subclause 7.3.2 e) added concerning verification when methods are revised. New subclause 7.3.2 f) added detailing verification records that are required to be retained.
5.5.1.3	Validation of examination procedures	7.3.3	Validation of examination methods	Clause 7.3.3 a 2) now provides examples of methods used outside their 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)'; Clause 7.3.3 b) adds the requirement that 'extent of validation of an examination method is sufficient to ensure the validity of results pertinent to clinical decision making' Clause 7.3.3 c) adds the requirement to record whether 'the results meet the specified requirements' Clause 7.3.3 d) now requires that 'a decision made as to whether to implement the modified method' New subclause 7.3.3 e) added regarding validation records.

5.5.1.4	Measurement uncertainty of measured quantity values	7.3.4	Evaluation of measurement uncertainty (MU)	Clause 7.3.4 a) now requires that the measurement uncertainty is 'maintained for its intended use, where relevant' New subclause 7.3.4 c) added dealing with the situation where evaluation of Measurement Uncertainty is not possible and rational for exclusion. New subclauses 7.3.4 e) through h) added regarding user enquiries, qualitative results based upon quantitative data, uncertainties in intermediate steps and consideration of uncertainties when conducting verification or validation.
5.5.2	Biological reference intervals or clinical decision values	7.3.5	Biological reference intervals and clinical decision limits	New note added to clause 7.3.5 a) regarding the use of biological reference values. New requirement 7.3.5 b) stating that biological reference intervals and clinical decision limits should be periodically reviewed New requirement 7.3.5 d) concerning identification of presence or absence of a characteristic.
5.5.3	Documentation of examination procedures	7.3.6	Documentation of examination procedures	Subclause 7.3.6 a) now states that examination procedures should be 'to the extent necessary to ensure the consistent application of its activities and the validity of its results' Note in this section slightly modified to include 'flow process diagrams' Subclause 7.3.6 d) regarding product instructions has been added (was originally a note)
5.6	Ensuring quality of examination results	7.3.7	Ensuring the validity of examination results	
5.6.1	General			
5.6.2	Quality control			
5.6.2.1	General	7.3.7.1	General	Clause 7.3.7.1 adds a requirement concerning the monitoring of validity of results that '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'.
5.6.2.2	Quality control materials	7.3.7.2	Internal quality control (IQC)	Subclause 7.3.7.2 a New note added regarding peer review. New subclauses 7.3.7.2 b) through e) have been added regarding IQC material and data.
5.6.2.3	Quality control data	7.3.7.2 7.3.7.1	Internal quality control (IQC) General	Clause 7.3.7.1 now requires 'statistical techniques shall be applied to review the results' of Internal Quality Control (was previously a note).
5.6.3	Interlaboratory comparisons			
5.6.3.1	Participation	7.3.7.3	External quality assessment (EQA)	Subclause 7.3.7.3 d) 3) now requires that EQA programmes 'fulfill ISO/IEC 17043 requirements' (was a note) Additional subclause 7.3.7.3 e) added concerning selection of EQA programmes. Notes 1 and 2 also added to this section.
5.6.3.2	Alternative approaches	7.3.7.3	External quality assessment (EQA)	7.3.7.3 f) adds the consideration that an EQA programme is 'not suitable' and that the 'the rationale for the chosen alternative and provide evidence of its effectiveness' is to be justified.

				The note in this section as be expanded to cover additional possibilities for consideration.
5.6.3.3	Analysis of interlaboratory comparison samples			
5.6.3.4	Evaluation of laboratory performance	7.3.7.3	External quality assessment (EQA)	Subclause 7.3.7.3 g) adds the requirement that EQA data is reviewed 'at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance' Subclause 7.3.7.3 h) adds the requirement that where EQA results are outside acceptance criteria, consideration is given to 'an assessment of whether the non-conformance is clinically significant as it relates to patient samples' New subclause 7.3.7.3i) added regarding impact of results of EQA being outside limits.
5.6.4	Comparability of examination results.	7.3.7.4	Comparability of examination results	7.3.7.4 a) New note added regarding comparability of examination results 7.3.7.4 b) requires that the results of comparability are performed as well as 'its acceptability' New subclauses 7.3.7.4 c) and d) added regarding the review of comparability results and concerning the impact of differences on biological reference intervals/clinical decision limits.
5.7	Post-examination processes	7.4	Post-examination processes	
5.7.1	Review of results	7.4.1.2	Result review and release	Clause 7.4.1.2 now requires that 'Responsibilities and procedures for how examination results are released for reporting, including by whom and to whom, shall be specified'
5.7.2	Storage, retention and disposal of clinical samples	7.4.2	Post-examination handling of samples	Clause 7.4.2 contains additional requirements to be ensured after the examination, listed as items a) through e)
5.8.1	General	7.4.1 7.4.1.1	Reporting of results General	Subclause 7.4.1.1 b) now requires a 'procedure' to cover notification of users when the results are delayed. New Subclause 7.4.1.1 c) added concerning retention of information associated with issued reports.
5.8.2	Report attributes			
5.8.2	Report attributes	7.4.1.6	Requirements for reports	7.4.1.6 'requirements for reports' requires information to be included 'unless the laboratory has documented reasons for omitting any items'. 7.4.1.6 e) new note added concerning codings 7.4.1.6 a) the word 'unique' added to patient identification and that date of primary sample collection and date of issue of the report is required on 'each page of the report' (it must be noted that the grammatical structure of this requirement is not quite clear) 7.4.1.6 d) requires that in addition to the type of primary sample 'any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description)' is included. 7.4.1.6 f) requires that, in addition to the examination method 'where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle;

				7.4.1.6 h) adds 'likelihood ratios' 7.4.1.6 k) and l) added concerning any results considered to be preliminary and indications of any critical results respectively
		7.4.1.7	Additional information for reports	7.4.1.7 c) now refers to information 'provided by consultants' in addition to identification of results from referral laboratories. The name of the laboratory performing the examination is now also required. Subclause 7.4.1.7 d) also adds additional requirements 2) through 4) relating to discrepancies, risk of misinterpretation and result trends/changes.
5.9	Release of results			
5.9.1	General	7.4.1.3	Critical result reports	Subclause 7.4.1.3 c) requires an escalation procedure in the event that a responsible person is not available. Clause 7.4.1.4 a) now addresses simplified reports. 7.4.1.4 c) concerning oral transmission of results now includes 'details of verification of accuracy of communication' Subclauses 7.4.1.4 d) and e) have been added regarding special counselling and anonymisation of data respectively (these were formerly notes).
5.9.2	Automated selection and reporting of results	7.4.1.5	Automated selection, review, release and reporting of results	Subclause 7.4.1.5 a) now includes criteria for 'review and release' of results Subclause 7.4.1.5 b) now requires that criteria are 'approved' and 'regularly reviewed' Subclause 7.4.1.5 c) now includes 'as appropriate' date and time of selection 'and review, as well as identity of the reviewer'. Subclause 7.4.1.5 d) now includes 'review, release' in relation to rapid suspension of results.
5.9.3	Revised reports	7.4.1.8	Amendments to reported results	7.4.1.8 has been reworded in regard to amendment to reports, stating '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 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 original report that it replaces.
5.10	Laboratory information management			
5.10.1	General	7.6 7.6.1	Control of data and information management General	
5.10.2	Authorities and responsibilities	7.6.2	Authorities and responsibilities for	7.6.2 A requirement has been added stating that 'The laboratory is ultimately responsible for the laboratory information systems'.

			information management	
5.10.3	Information system management	7.6.3	Information systems management	Subclause 7.6.3 a) now requires that changes to the system 'including laboratory software configuration or modifications to commercial off-the-shelf software' are authorised. Subclause 7.6.3 c) now addresses 'cybersecurity' Subclause 7.6.3 e) adds the requirement that 'Calculations and data transfers shall be checked in an appropriate and systematic manner'.
		7.6.4	Downtime plans	7.6.4 is now termed 'downtime plans' (cf contingency plans) but has been expanded to specifically cover 'automated selection and reporting of results'.
		7.8	Continuity and emergency preparedness planning	New clause 7.8 Continuity and emergency preparedness planning has been added.
		7.6.5	Off site management	

Annexes to the 2022 edition:

Annex A (normative) Additional requirements for Point-of-Care Testing (POCT) – (*Incorporated into the above comparison)*

Annex B

Table B1: Comparison between ISO 9001:2015 and ISO 15189:2022

Table B2: Comparison between ISO/IEC 17025:2017 and ISO 15189:2022

Annex B

Table C1: Comparison between ISO 15189:2012 and ISO 15189:2022 *(broadly in line with the comparison given above)*

Bibliography