MANAGEMENT REQUIREMENTS FOR MEDICAL LABORATORIES
ISO 15189:2022

Date/s of Evaluation	
Assessor/s & Observers	
Laboratory	
Area / Field of Operation	
Laboratory Representative	

This report covers the following:

Clause No		Requirement	NA	NC	C	Comments
	GENERAL ***Comment below on adequacy of how requirements have been addressed, documented and/or implemented. The order of assessment need not follow the order of the worksheet. Assessors are expected to know & have the standard and SADCAS medical laboratory requirements pertaining to the laboratory being assessed. This worksheet is designed as guidance to prompt detailed recording of the process.***					
1.		The schedule of accredited tests shall include only the tests that are performed by the Laboratory.				
2.		The relevant staff have access to SADCAS documentation				
3.		A current list of approved signatories for each discipline within the laboratory is available.				
4.	**GENERAL REQUIREMENTS**					
4.1.	**Impartiality**					
	a) Are laboratory activities undertaken impartially? How is the laboratory structured and managed to safeguard impartiality? b) What evidence is available to show management's commitment to impartiality? c) What measures are in place to ensure that the laboratory takes responsibility for the impartiality of its activities and does not allow commercial, financial or other pressures to compromise impartiality? d) Does the laboratory monitor its activities and relationships to identify threats to its impartiality? Does this monitoring include relationships of its personnel? NOTE: A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing & branding, payment of sales commission or other inducement for the referral of new laboratory users, etc? Such relationships do not necessarily present the laboratory with a threat to impartiality. e) If a threat to impartiality is identified, how does the laboratory mitigate such threats to ensure the effect is eliminated or minimized so that the impartiality is not compromised?					

4.2	**Confidentiality**				
4.2.1	**Management of Information** Is the laboratory responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities? Does the management of patient information include privacy and confidentiality? Does the laboratory 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), is all other information considered proprietary information and regarded as confidential?				
4.2.2	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, does the laboratory notify the patient concerned of the information released, unless prohibited by law? Does the laboratory keep information about the patient from a source other than the patient (e.g., complainant, regulator) confidential? Does the laboratory keep the identity of the source confidential and not share it with the patient, unless agreed by the source?				
Additional /General Comments: This space may also be used to expand on comments in specific Sections					
4.2.3	**Personnel responsibility** Do personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities?				
4.3	**Requirements regarding patients**				

	Does the laboratory management ensure that patients' well-being, safety and rights are the primary considerations? Has the laboratory established and implemented the following processes: a) opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the 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 by the laboratory to ensure they are clinically appropriate and necessary; 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; e) treatment of patients, samples, or remains, with due care and respect; f) obtaining informed consent when required; 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; 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; i) upholding the rights of patients to care that is free from discrimination?				

Additional /General Comments: This space may also be used to expand on comments in specific Sections

5.	**STRUCTURAL AND GOVERNANCE REQUIREMENTS**
5.1	**Legal Entity**
	Is the laboratory or the organization of which the laboratory is a part, an entity that can be held legally responsible for its activities? *NOTE: A government laboratory is deemed to be a legal entity on the basis of its government status.*

5.2	**Laboratory Director**				
5.2.1	**Laboratory director competence** Is the laboratory directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of ISO 15189:2022?				
5.2.2	**Laboratory director responsibilities** Is the laboratory director responsible 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? Are the duties and responsibilities of the laboratory director documented?				
5.2.3	**Delegation of duties** Has the laboratory director delegated either selected duties or responsibilities, or both, to qualified and competent personnel and is such delegation documented? Does the laboratory director maintain the ultimate responsibility for the overall operation of the laboratory?				
Additional /General Comments: This space may also be used to expand on comments in specific Sections					
5.3	**Laboratory Activities**				
5.3.1	**General** Does the laboratory 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 ISO 15189:2022ISO 15189:2022				

5.3.2	**Conformance with requirements** Does the laboratory carry out its activities in such a way as to meet the requirements of ISO 15189:2022, the users, regulatory authorities and organizations providing recognition? Does this apply to the complete range of specified and documented laboratory activities, regardless of where the service is provided?				
5.3.3	**Advisory activities** How does the laboratory management ensure that appropriate laboratory advice and interpretation are available, and does it meet the needs of patients and users? What arrangements has the laboratory established for communicating with laboratory users on the following when applicable: a) advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods, and the frequency of requesting the examination; b) providing professional judgments on the interpretation of the results of examinations; c) promoting the effective utilization of laboratory examinations; d) advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria.				
5.4	**Structure and Authority**				
5.4.1	**General** Has the laboratory: a) defined its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services? b) specified the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities? c) specified its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results?				
5.4.2	**Quality management** Does the laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including? 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 and any need for improvement? **e)** ensuring the effectiveness of laboratory activities**?** *NOTE These responsibilities can be assigned to one or more persons.*				
5.5	**Objectives and Policies**				
	a) Has the laboratory management established, and do they maintain objectives and policies (see 8.2) to: 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 ISO 15189:2022. b) Are objectives measurable, and consistent with policies? How does the laboratory ensure that the objectives and policies are implemented at all levels of the laboratory organization? c) How does the laboratory management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented? d) Has the laboratory established 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). *NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.*				
5.6	**Risk Management**				
	a) Has laboratory management established, implemented, and maintained processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and have actions been developed to address both risks and opportunities for improvement? (see 8.5). **b) Does the laboratory director \ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective?**				

	NOTE 1 ISO 22367 provides details for managing risk in medical laboratories. *NOTE 2 ISO 35001 provides details for laboratory biorisk management.*				
6.	**RESOURCE REQUIREMENTS**				
6.1	**General** Does the laboratory have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities?				
6.7	**Service Agreements**				
6.7.1	**Agreements with laboratory users** Does the laboratory have a procedure to establish and periodically review agreements for providing laboratory activities? Does the procedure ensure: a) the requirements are adequately specified; b) the laboratory has the capability and resources to meet the requirements; and c) when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants? Does the laboratory inform users of any changes to an agreement that can affect examination results? Are records of reviews, including any significant changes retained?				
6.7.2	**Agreements with POCT operators** Do service agreements between the laboratory and other parts of the organization using laboratory supported POCT, ensure that respective responsibilities and authorities are specified and communicated? *Established multidisciplinary POCT committees can be used to manage such service agreements as described in Annex A of ISO 15189:2022*				
6.8	**Externally provided products and services**				

6.8.1	**General** How does the laboratory ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are: 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. *It can be necessary to collaborate with other organizational departments or functions to fulfil this requirement.* *NOTE Services include, e.g. sample collection services, pipette and other calibration services, facility and equipment maintenance services, EQA programmes, referral laboratories and consultants*				
6.8.2	**Referral laboratories and consultants** Does the laboratory communicate its requirements to referral laboratories and consultants who provide interpretations and advice, for: a) the procedures, examinations, reports and consulting activities to be provided; b) management of critical results; c) any required personnel qualifications and demonstration of competence? Unless otherwise specified in the agreement, does the referring laboratory (and not the referral laboratory) maintain the responsible for ensuring that examination results of the referral laboratory are provided to the person making the request? Is a list of all referral laboratories and consultants maintained?				
6.8.3	**Review and approval of externally provided products and services.** Does the laboratory have procedures and retain records for: 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 laboratory's established requirements, or where applicable to the relevant				

	requirements of ISO 15189:2022, before they are used or directly provided to the user; e) taking any actions arising from evaluations of the performance of external providers.				
7.2	**Pre-Examination processes**				
7.2.4 7.2.4.1	**Primary sample collection and handling** **General** Does the laboratory have procedures for the collection and handling of primary samples? Is the information available to those responsible for sample collection? Is any deviation from the established collection procedures clearly recorded? Is the potential risk and impact on the patient outcome of acceptance or rejection of the sample assessed, recorded and communicated to the appropriate personnel? Does the laboratory 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?				
7.2.4.2	**Information for pre-collection activities** Does the laboratory provide information and instructions for pre- collection activities with sufficient detail to ensure that the integrity of the sample is not compromised? Does this include: 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 slides; **f)** the laboratory's criteria for acceptance and rejection of samples specific to the examinations requested.				
7.2.4.3	**Patient consent** **a)** Does the laboratory obtain the informed consent of the patient for all procedures carried out on the patient?				

	NOTE For most routine laboratory procedures, consent can be inferred when the patient willingly submits to the sample collecting procedure, for example, venipuncture. b) Are special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, provide a more detailed explanation and, in some cases, recorded consent? c) If obtaining consent is not possible in emergency situations, can the laboratory carry out necessary procedures, provided they are in the patient's best interest?				
7.2.4.4	**Instructions for collection activities** To ensure safe, accurate and clinically appropriate sample collection and pre-examination storage, does the laboratory provide instructions for: 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; 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	**Sample transportation** a) To ensure the timely and safe transportation of samples, does the laboratory provide instructions for: 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 temperature interval specified for sample collection and handling;				

	4) any specific requirements to ensure integrity of samples, e.g.? use of designated preservatives. b) If the integrity of a sample has been compromised and there is a health risk, is the organization responsible for the transport of the sample notified immediately and action taken to reduce the risk and to prevent recurrence? c) Does the laboratory establish and periodically evaluate adequacy of sample transportation systems?				
7.2.6 7.2.6.1	**Sample receipt** **Sample receipt procedure** Does the laboratory have a procedure for sample receipt that includes: a) the unequivocal traceability of samples by request and labelling, to a uniquely identified patient and when applicable, the anatomical site; b) criteria for acceptance and rejection of samples; c) recording the date and time of receipt of the sample, when relevant; d) recording the identity of the person receiving the sample, when relevant; e) evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s); 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; g) ensuring that all portions of the sample shall be unequivocally traceable to the original sample?				
7.2.6.2	**Sample acceptance exceptions** a) Does the laboratory have a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to: 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, does the final report indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected?				

7.2.7 7.2.7.1	**Pre-examination handling, preparation, and storage** **Sample protection** Does the laboratory 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	**Criteria for additional examination requests** Do laboratory procedures include time limits for requesting additional examinations on the same sample				
7.2.7.3	**Sample stability** Considering the stability of the analyte in a primary sample, is the time between sample collection and performing the examination specified and monitored where relevant?				
7.5	**Nonconforming Work**				
	Does the laboratory have a process for when any aspect of its laboratory activities or 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)? Does the process ensure that: a) the responsibilities and authorities for the management of nonconforming work are specified; b) immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory; c) examinations are halted, and reports withheld when there is a risk of harm to patients; d) 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; e) a decision is made on the acceptability of the nonconforming work; f) when necessary, examination results are revised, and the user is notified; g) the responsibility for authorizing the resumption of work is specified. Does the laboratory implement corrective action commensurate with the risk of recurrence of the nonconforming work? (see 8.7). Does the laboratory retain records of nonconforming work and actions as specified in 7.5 a) to g)?				
7.6	**Control of data and information management**				
7.6.1	**General** Does the laboratory have access to the data and information needed to perform laboratory activities?				

	NOTE 1 In ISO 15189:2022, "laboratory information systems" includes the management of data and information contained in both computer and non-computerized systems? Some of the requirements can be more applicable to computer systems than to non-computerized systems. *NOTE 2 Risks associated with computerized laboratory information systems are discussed in ISO 22367:2020, A.13.* *NOTE 3 The information security controls, strategies and best practices to ensure the preservation of confidentiality, integrity and availability of information, are listed in ISO/IEC 27001:2022, Annex A Information security controls reference.*				
7.6.2	**Authorities and responsibilities for information management** Does the laboratory ensure that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and modification to the information systems that can affect patient care? Is the laboratory ultimately responsible for the laboratory information systems?				
7.6.3	**Information systems management** Are the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information: 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? *NOTE 1 Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as laboratory equipment, hospital patient administration systems and systems in primary care.* *NOTE 2 Commercial off-the-shelf software used within its designed application range can be considered sufficiently validated (e.g., word processing and spreadsheet software, and quality management software programs).* b) documented, and the documentation readily available to authorized users, including that for day-to-day functioning of the system? c) implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguard data against tampering or loss? 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 transcription? 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? Are calculations and data transfers checked in an appropriate and systematic manner?				
7.6.4	**Downtime plans** Does the laboratory have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities? Does this include automated selection and reporting of results?				
7.6.5	**Off site management** When the laboratory information system(s) are managed and maintained off-site or through an external provider, how does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of ISO 15189:2022?				
7.7	**Complaints**				
7.7.1	Does the laboratory 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 complaint, and deciding what actions shall be taken in response; *NOTE The resolution of complaints can lead to implementation of corrective actions (see 8.7) or be used as input into the improvement process (see 8.6).* b) tracking and recording the complaint, including the actions undertaken to resolve it; c) ensuring appropriate action is taken. Is a description of the process for handling complaints made publicly available?				
7.7.2	**Receipt of complaint** a) Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, does it resolve the complaint? (see 8.7.1)? b) Is the laboratory receiving the complaint responsible for gathering all necessary information to determine whether the complaint is substantiated? **c)** Whenever possible does the laboratory acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports?				
7.7.3	**Resolution of complaint** Does investigation and resolution of complaints result in any discriminatory actions?				

	Is the resolution of complaints made by, or reviewed and approved by, persons not involved in the subject of the complaint in question? Where resources do not permit this, does the laboratory ensure that any alternative approach does not compromise impartiality?				
7.8	**Continuity and Emerging preparedness planning**				
	Does the laboratory 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? Are plans periodically tested and the planned response capability exercised, where practicable? Does the laboratory: 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.	**MANAGEMENT SYSTEM REQUIREMENTS**				
8.1	**General Requirements**				
8.1.1	Does the laboratory establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of ISO 15189:2022? As a minimum, does the management system of the laboratory include the following: — responsibilities (8.1) — objectives and policies (8.2) — documented information (8.2, 8.3 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	**Fulfilment of management system requirements** 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 consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9.				

8.1.3	**Management system awareness** Does the laboratory ensure that persons doing work under the laboratory's control are aware of: 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	**General** Did laboratory management establish, document, and maintain objectives and policies for the fulfilment of the purposes of ISO 15189:2022ISO 15189:2022 and did they ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization? *NOTE The management system documents can, but are not required to, be contained in a quality manual*				
8.2.2	**Competence and quality** Do the objectives and policies address the competence, quality and consistent operation of the laboratory				
8.2.3	**Evidence of commitment** How does laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?				
8.2.4	**Documentation** Are all documentation, processes, systems, and records, related to the fulfilment of the requirements of ISO 15189:2022ISO 15189:2022 included in, referenced from, or linked to the management system?				
8.2.5	**Personnel access** Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities.				
8.3	**Controls of Management System Documents**				
8.3.1	**General** Does the laboratory control the documents (internal and external) that relate to the fulfilment of ISO 15189:2022ISO 15189:2022? *NOTE In this context, "document" can be policy statements, procedures and related job aids, flow charts, instructions for use, specifications, manufacturer's instructions, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as laws, regulations, standards and textbooks from which examination methods are taken, documents describing personnel qualifications (such as job descriptions), etc? These can be in any form or type of medium, such as hard copy or digital.*				

8.3.2	**Control of documents** Does the laboratory ensure that: 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; f) documents are protected from unauthorized changes and any deletion or removal; g) documents are protected from unauthorized access; h) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose; 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.				
8.4	**Control of Records**				
8.4.1	**Creation of records** Does the laboratory establish and retain legible records to demonstrate fulfilment of the requirements of ISO 15189:2022ISO 15189:2022? Are records created at the time each activity that affects the quality of an examination is performed? *NOTE Records can be in any form or type of medium.*				
8.4.2	**Amendment of records** Does the laboratory ensure that amendments to records can be traced to previous versions or to original observations? Are both the original and amended data and files 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	**Retention of records** a) Does the laboratory 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) Are the retention times for records specified?				

	NOTE 1 In addition to requirements, retention times can be chosen based on identified risks. c) Are reported examination results retrievable for as long as necessary or as required? d) Are all records accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review (see 8.9)? NOTE 2 Legal liability concerns regarding certain types of procedures (e.g.? histology examinations, genetic examinations, pediatric examinations) can require the retention of certain records for much longer times than for other records.				
8.5	**Actions to address risks and opportunities for improvement**				
8.5.1	**Identification of risks and opportunities for improvement** Does the laboratory identify risks and opportunities for improvement associated with the laboratory activities to: a) prevent or reduce undesired impacts and potential failures in the laboratory activities; b) assure that the management system achieves its intended results; c) mitigate risks to patient care; and d) help achieve the purpose and objectives of the laboratory?				
8.5.2	**Acting on risks and opportunities for improvement** Does the laboratory prioritize and act on identified risks? Are actions taken to address risks proportional to the potential impact on laboratory examination results, as well as patient and personnel safety? Does the laboratory record decisions made and actions taken on risks and opportunities? Does the laboratory integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness? NOTE 1 Options to address risks can include identifying and avoiding threats, eliminating a risk source, reducing the likelihood or consequences of a risk, transferring a risk, taking a risk in order to pursue an opportunity for improvement, or accepting risk by informed decision. NOTE 2 Although ISO 15189:2022ISO 15189:2022 requires that the laboratory identifies and addresses risks, there is no requirement for any particular risk management method? Laboratories can use ISO 22367 and ISO 35001 for guidance. NOTE 3 Opportunities for improvement can lead to expanding the scope of the laboratory activities, applying new technology, or creating other possibilities to fulfil patient and user needs				

8.6	**Improvement**				
8.6.1	**Continual improvement** a) Does the laboratory 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) Does the laboratory identify and select opportunities for improvement and develop, document, and implement any necessary actions? Are improvement activities directed at areas of highest priority based on risk assessments and the opportunities identified (see 8.5)? *NOTE Opportunities for improvement can be identified through risk assessment, use of the policies, review of the operational procedures, overall objectives, external evaluation reports, internal audit findings, complaints, corrective actions, management reviews, suggestions from personnel, suggestions or feedback from patients and users, analysis of data and EQA results.* c) Does the laboratory evaluate the effectiveness of the actions taken? d) Does laboratory management ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care? e) Does laboratory management communicate to personnel its improvement plans and related goals?				
8.6.2	**Laboratory patients, user, and personnel feedback** Does the laboratory seek feedback from its patients, users, and personnel? Is the feedback analysed and used to improve the management system, laboratory activities and services to users? Are records of feedback maintained including the actions taken? Is communication provided to personnel on actions taken arising from their feedback?				
8.7	**Nonconformities and corrective actions**				
8.7.1	**Actions when nonconformity occurs** When a nonconformity occurs, does the laboratory: a) Respond to the nonconformity and, as applicable: 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 order to reduce the likelihood of recurrence or occurrence elsewhere, by: 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	**Corrective action effectiveness** Are corrective actions appropriate to the effects of the nonconformities encountered and shall mitigate the identified cause(s)?				
8.7.3	**Records of nonconformities and corrective actions** Does the laboratory retain records as evidence of the: a) nature of the nonconformities, cause(s) and any subsequent actions taken, and b) evaluation of the effectiveness of any corrective action?				
8.8	**Evaluations**				
8.8.1	**General** Does the laboratory 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 ISO 15189:2022ISO 15189:2022?				
8.8.2	**Quality indicators** Is the process of monitoring quality indicators [see 5.5 d)] planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring? Are the indicators periodically reviewed, to ensure continued appropriateness?				
8.8.3 8.8.3.1	**Internal audits** Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system a) conforms to the laboratory's own requirements for its management system, including the laboratory activities,				

	b) conforms to the requirements of ISO 15189:2022ISO 15189:2022 and c) is effectively implemented and maintained?				
8.8.3.2	Does the laboratory plan, establish, implement and maintain an internal audit programme that includes: a) priority given to risk to patients from laboratory activities? b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities? c) specified audit objectives, criteria and scope for each audit? 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? e) ensuring objectivity and impartiality of the audit process? f) ensuring that the results of the audits are reported to relevant personnel? g) implementation of appropriate correction and corrective actions without undue delay? h) retention of records as evidence of the implementation of the audit programme and audit results? *NOTE ISO 19011 provides guidance for auditing management systems.*				
8.9	**Management Reviews**				
8.9.1	**General** Does laboratory management 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 ISO 15189:2022				
8.9.2	**Review input** Are the inputs to management review recorded and does it include evaluations of at least the following: 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 of non-conformities, corrective actions, assessments by external bodies; d) patient, user and personnel feedback and complaints; e) quality assurance of result validity; f) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement; g) performance of external providers; h) results of participation in interlaboratory comparison programmes; i) evaluation of POCT activities; j) other relevant factors, such as monitoring activities and training.				
8.9.3	**Review output** Is the output from the management review a record of decisions and actions related to at least: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of ISO 15189:2022ISO 15189:2022; c) provision of required resources; d) improvement of services to patients and users; e) any need for change. Does laboratory management ensure that actions arising from management review are completed within a specified time frame? Are conclusions and actions arising from management reviews communicated to laboratory personnel				
	Additional requirements for Point-of-Care Testing (POCT)				
A.2	**Governance** Is the governing body of the organization ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organization? Do service agreements between the laboratory and all locations using laboratory supported POCT ensure that respective responsibilities and authorities are specified and communicated within the organization? Do these agreements have clinical approval, and where applicable, financial approval?				

	Are these service agreements with POCT areas and can they be managed via a health professional grouping (e.g. medical advisory committee)?				
A.3	**Quality assurance programme** Did the laboratory appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of ISO 15189:2022ISO 15189:2022 as related to POCT?				
A.4	**Training programme** Is a person with appropriate training and experience appointed to manage training and competency assessment of personnel performing POCT? Does the trainer develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel?				

Additional /General Comments: This space may also be used to expand on comments in specific Sections

Team Leader/ Technical Assessor	**Name:**	**Signature:**	**Date:**