SADCAS POLICY – ISO 15189:2022 TRANSITION

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Table of Contents

1. INTRODUCTION

ISO 15189:2022: *Medical Laboratories – Requirements for Quality and Competence* was published on **6 December 2022**. This edition replaces the ISO 15189:2012 edition.

A resolution was endorsed at the International Laboratory Accreditation Cooperation (ILAC) General Assembly to allow a 3-year implementation period from the date of publication of the revised standard. At the end of the transition period, accreditation of a Medical Laboratory to ISO 15189:2012 will not be recognised under the ILAC Arrangement and all organisations accredited to ISO 15189:2012 must have been assessed and accredited to the latest version of the standard.

2. PURPOSE

This document defines the Transition process to be followed by Medical Laboratories to ensure successful transition to ISO 15189:2022.

3. TRANSITION TO ISO 15189:2022

3.1 General

3.1.1 For Medical Laboratories whose applications are received before **1 July 2023**; SADCAS will continue to process the applications in accordance with ISO 15189:2012 unless the Medical Laboratories explicitly request that the application will be processed in accordance with the latest version of the standard, ISO 15189:2022.

3.1.2 All new applications/extensions of scope for accreditation in accordance with ISO 15189 submitted to SADCAS after **1 July 2023** shall be based on the latest version of the standard ISO 15189:2022. It is therefore, important that Medical Laboratories intending to apply for accreditation after 1 July 2023 and have not yet implemented the new standard do so as soon as possible.

3.1.3 For all facilities accredited to ISO 15189:2012, SADCAS will continue to undertake assessments against ISO 15189:2012 up to **31 March 2024**. Medical Laboratories may however request the assessment to be undertaken against the latest version of the standard ISO 15189:2022 prior to 31 March 2024. The request shall be made 6 weeks prior to the scheduled periodic assessment.

3.1.4 From **1 April 2024**, all assessments shall be conducted in accordance with the latest version of the standard ISO 15189:2022.

3.2 Transition Plan

3.2.1 SADCAS requires Medical Laboratories to establish an action plan for implementation of this transition from ISO 15189:2012 to the latest version of the standard ISO 15189:2022.

3.2.2 Medical Laboratories that have already applied for accreditation from SADCAS based on the ISO 15189:2012 Standard whose application is progressing through the accreditation process and those already accredited to the ISO 15189: 2012 Standard shall provide SADCAS with a transition plan by **31 December 2023.**

3.2.3 The transition plan shall demonstrate that the Medical Laboratory has evaluated ISO 15189:2022 and its implication for their management system and operations and shall put in place processes to enable the Medical Laboratory to effectively implement all the changes needed to comply with ISO 15189:2022 before **5 December 2025**.

3.2.4 As a minimum the transition plan shall include:

- All specific actions to be taken to implement the changes;
- The timelines and milestones for completion of actions;
- The persons responsible for the actions; and
- Means of monitoring progress and completion of the actions.

3.3 SADCAS Assessment for Purposes of Transition

During the transition process, and after the Medical Laboratory has submitted its transition plan, SADCAS shall verify during assessments undertaken from 1 April 2024 that the Medical Laboratory is implementing actions in the transition plan in order to fully comply to the requirements of ISO 15189:2022.

3.4 Nonconformities against the New Standard ISO 15189 :2022

3.4.1 Findings raised against the requirements of ISO 15189:2022 shall be recorded as nonconformities to highlight the gap identified.

3.4.2 Nonconformities raised shall be dealt with in accordance with the SADCAS normal processes and must be cleared within the set timelines before accreditation can be granted.

3.4.3 Corrective Action Timelines per SADCAS procedures are as follows:

- 3 Months for Initial assessments; and
- 2 Months for Periodic assessments, reinstatements and re-assessments.

3.4.4 Accreditation against ISO 15189:2022 shall only be granted upon satisfactory clearance of nonconformities raised against ISO 15189:2022 standard.

3.4.5 If by **05 December 2025** SADCAS cannot confirm compliance with the latest version of the standard, ISO 15189:2022, then accreditation to ISO 15189:2012 shall be withdrawn.

3.5 Accreditation Certificate and Schedule

3.5.1 The accreditation certificate and schedule shall be adapted to reflect accreditation against the latest version of the standard ISO 15189:2022 after assessment against the latest version of the standard has been successfully completed and a decision has been taken to that effect by the Accreditation Approvals Committee.

3.5.2 The effective date of accreditation on the certificate shall be the date of decision to grant ISO 15189:2022 accreditation. The cycle shall remain as five years from the date that ISO 15189:2012 accreditation was initially granted or renewed.

3.5.3 The Certificate and Schedule of Accreditation shall be published as follows:

- Date of accreditation (original or renewal) i.e., date when accreditation was granted
- Effective date (Issue No./Date of Issue) i.e., date when the facility transitioned
- Expiry date (end of original accreditation cycle)

3.5.4 The Medical laboratory accreditation reference numbers shall remain the same.

3.6 End of Transition

3.6.1 The three-year transition period will conclude on **05 December 2025** and all Medical Laboratories are expected to be in full compliance with ISO 15189:2022.

3.6.2 ISO 15189:2012: Medical Laboratories – Requirements for Quality and Competence ceases to be valid as of **6 December 2025.**

APPENDIX A - Comparison between ISO 15189:2012 and ISO 15189:2022

ISO 15189:2012	ISO 15189:2022
Foreword	Foreword
Introduction	Introduction
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms and definitions3	3 Terms and definitions
4 Management requirements 4.1 Organization and management responsibility 4.1.1 Organization 4.1.1.1 General 4.1.1.3 Ethical conduct [includes confidentiality in (e)]	4. General requirements 4.1 Impartiality 4.2 Confidentiality 4.2.1 Management of information 7 Release of information Personnel responsibility
4.1.1.2 Legal entity 4.1.1.4 Laboratory director 4.1.2 Management responsibility 4.1.2.1 Management commitment	5 Structural and governance requirements 5.1 Legal Entity 5.2 Laboratory director 5.2.1 Laboratory director competence 5.2.2 Laboratory director responsibilities 5.2-3 Delegation of duties 5.3 Laboratory activities 5.3.1 General 5.3.2 Conformance with requirements 5.4.1 General 5.4.2 Quality management 8.2.3 Evidence of commitment
4.1.2.2 Needs of users	4.3 Requirements regarding patients 5.3.3 Advisory activities
4.1.2.3 Quality policy	5.5 Objectives and policies
4.1.2.4 Quality objectives and planning	53 Objectives and policies
4.1.2.5 Responsibility, authority, and interrelationships	5.4 Structure and authority
4.1.2.6 Communication	5.4.1 General b)
4.1.2.7 Quality manager	5.4.2 Quality management
4.2 Quality management system	8 Management system requirements
4.2.1 General requirements	8.1 General requirements and options
	8.1.1 General

ISO 15189:2012	ISO 15189:2022
	8.1 _ 2 Fulfilment of management requirements
	8.1.3 Management system awareness
4.2.2 Documentation requirements	8.2 Management system documentation
4.2.2.1General	8.2.1 General
4.2.2.2 Quality manual	[optional, no longer a requirement, see 8.2.1 NOTE]
4.3 Document control	8.3 Control of management system documents 8.3.1 General Management of documents
4.4 Service agreements 4.4.1 Establishment of service agreements 4.4.2 Review of service agreements	6.7 Service agreements
4.5 Examination by referral laboratories 4.5.1 Selecting and evaluating referral laboratories and consultants 4.5.2 Provision of examination results	6.8.2 Referral laboratories and consultants
4.6 External services and supplies	628 Externally provided products and services 6.8.3 Review and approval of externally provided products and services
4.7 Advisory services	5.3.3 Advisory activities
4.8 Resolution of complaints	7.7 Complaints 7.7-1 Process 7.7.2 Receipt of complaint 7.7.3 Resolution of complaint
4.9 Identification and control of nonconformities	7.5 Nonconforming work
4.10 Corrective action	8.7 Corrective action 8.7.1 Actions when nonconformity occurs 8.7.2 Corrective action effectiveness 8.7.3 Records of nonconformities

ISO 15189:2012	ISO 15189:2022
4.11 Preventive action	8.5 Actions to address risks and opportunities for improvement 8.5.1 Identification of risks and opportunities for improvement 8.5.2 Acting on risks and opportunities for improvement
4.12 Continual improvement	8.6 Improvement 8.6.1 Continual improvement 8.6.2 Laboratory patients, user and personnel feedback
4.13 Control of records	8.4 Control of records 8.4.1 Creation of records 8.4.2 Amendment of records 8.4.3 Retention of records
4.14 Evaluation and audits 4.14.1 General	8.8 Evaluations 8.8.1 General 8.8.2 Quality indicators 8.8.3 Internal audits
4.14.2 Periodic review of requests, and suitability of procedures, and sample requirements	7.2.3 Requests for providing laboratory examinations 7.2.3.1 General 7.2.4.1 General 7.3 Examination processes 7.3.1 General e)
4.14.3 Assessment of user feedback 4.14.4 Staff suggestions	8 6.2 Laboratory user and personnel feedback
4.14.5 Internal audit	8.8.3 Internal audits
4.14.6 Risk management	5.6 Risk management 8.5 Actions to address risks and opportunities for improvement 8.5.1 Identifications of risks and actions taken 8.5.2 Acting on risks and opportunities for improvement
4.14.7 Quality indicators	5.5 Objectives and policies d) 8.8.2 Quality indicators
4.14.8 Reviews by external organizations	8.7 Nonconformities and corrective action
4.15 Management review	8.9 Management review

ISO 15189:2012	ISO 15189:2022
4.15.1 General	8 9.1 General
4.15.2 Review input	8.9.2 Review input
4.15.3 Review activities	[not specified]
4.15.4 Review output	8.9.3 Review output
5 Technical requirements	6 Resource requirements
5.1 Personnel 5.1.1 General 5.1.2 Personnel qualifications 5.1.3 Job descriptions 5.1.4 Personnel introduction to the organizational environment 5.1.5 Training 5.1.6 Competence assessment 5.1.7 Review of staff performance 5.1.8 Continuing education and professional development 5.1.9 Personnel records	6.2 Personnel 6.2.1 General 6.2.2 Competence requirements 6.2.3 Authorization 6.2.4 Continuing education and professional development 6.2.5 Personnel records
5.2 Accommodation and environmental conditions 5.2.1 General 5.2.2 Laboratory and office facilities 5.2.3 Storage facilities 5.2.4 Staff facilities 5.2.5 Patient sample collection facilities 5.2.6 Facility maintenance and environmental conditions	6.3 Facilities and environmental conditions 6.3.1 General 6.3.3 Storage facilities 6.3.4 Personnel facilities 6.3.5 Sample collection facilities 6.3.2 Facility controls
5.3 Laboratory equipment, reagents, and consumables	6.4 Equipment and 6.6 Reagents and consumables

ISO 15189:2012	ISO 15189:2022
5.3.1 Equipment 5.3.1.1 General 5.3.1.2 Equipment acceptance testing 5.3.1.3 Equipment instructions for use 5.3.1.4 Equipment calibration and metrological traceability 5.3.1.5 Equipment maintenance and repair 5.3.1.6 Equipment adverse incident reporting 5.3.1.7 Equipment records	6.4 Equipment 6.4.1 General 6.4.2 Equipment requirements 6.4.3 Equipment acceptance procedure 6.4.4 Equipment instructions for use 6.4.5 Equipment maintenance and repair 6.4.6 Equipment adverse incident reporting 6.4.7 Equipment records 6.5 Equipment calibration and metrological traceability 6.5.1 General 6.5.2 Equipment calibration 6.5.3 Metrological traceability of measurement results
5.3.2 Reagents and consumables 5.3.2.1 General 5.3.2.2 Reagents and consumables— reception and storage 5.3.2.3 Reagents and consumables acceptance testing 5.3.2.4 Reagents and consumables and inventory management 5.3.2.5 Reagents and consumables instructions for use 5.3.2.6 Reagents and consumables — adverse incident reporting 5.3.2.7 Reagents and consumables records	6.6 Reagents and consumables 6.6.1 Reagents and consumables — General 6 6.2 Reagents and consumables - Receipt and storage 6.6.3 Reagents and consumables - Acceptance testing 6.6.4 Reagents and consumables— Inventory management 6 6.5 Reagents and consumables - Instructions for use 6.6.6 Reagents and consumables Adverse incident reporting 6.6.7 Reagents and consumables - Records

ISO 15189:2012	ISO 15189:2022
5.4 Pre-examination processes 5.4.1 General 5.4.2 Information for patients and users 5.4.3 Request form information 5.4.4 Primary sample collection and handling 5.4.4.1 General 5.4.4.2 Instructions for pre-collection activities 5.4.4.3 Instructions for collection activities 5.4.5 Sample transportation 5.4.6 Sample reception 5.4.7 Pre-examination handling, preparation, and storage	7.2 Pre-examination processes 7.2.1 General 7.2.2 Laboratory information for patients and users 7.2.3 Requests for providing laboratory examinations 7.2.3.1 General 7.2.3.2 Oral requests 7.2.4 Primary sample collection and handling 7.2.4.1 General 7.2.4.2 Information for pre-collection activities 7.2.4.3 Patient consent 7.2.4.4 Instructions for collection activities 7.2.5 Sample transportation 7.2.6 Sample receipt 7.2.6.1 Sample receipt procedure 7.2.6.2 Sample receipt exceptions 7.2.7 Pre-examination handling, preparation and storage 7.2.7.1 Sample protection 7.2.7.2 Criteria for additional examination requests 7.2.7.3 Sample stability
5.5 Examination processes	7.3 Examination processes
5.5.1 Selection, verification, and validation of examination procedures	7.3.1 General
5.5.1.2 Verification of examination procedures	7.3.2 Verification of examination procedures
5.5.1.3 Validation of examination procedures	7.3.3 Validation of examination methods
5.5.1.4 Measurement uncertainty of measured quantity values	7.3.4 Evaluation of measurement uncertainty
5.5.2 Biological reference intervals or clinical decision values	7.3.5 Biological reference intervals and clinical decision limits
5.5.3 Documentation of examination procedures	7.3.6 Documentation of examination procedures
5.6 Ensuring quality of examination results 5.6.1 General	7.3.7 Ensuring the validity of examination results 7.3.7.1 General
5.6.2 Quality control 5.6.2.1 General 5.6.2.2 Quality control materials 5.6.2.3 Quality control data	7.3.7.2 Internal quality control (IQC)

ISO 15189:2012	ISO 15189:2022
5.6.3 Interlaboratory comparisons 5.6.3.1 Participation 5.6.3.2 Alternative approaches 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)
5.6.4 Comparability of examination results	7.3.7.4 Comparability of examination results
5.7 Post-examination processes	7.4 Post-examination processes
5.7.1 Review of results	7.4.1.2 Result review and release 7.4.1.3 Critical result reports
5.7.2 Storage, retention, and disposal of clinical samples	7.4.2 Post-examination handling of samples
5.8 Reporting of results 5.8.1 General 5.8.2 Report attributes 5.8.3 Report content	7.4.1 Result reporting 7.4.1.1 General 7.4.1.4 Special consideration for result reports 7.4.1.6 Requirements for reports 7.4.1.7 Additional information for reports
5.9 Release of results	7.4.1.2 Result review and release
5.9.1 General	7.4.1.1 General
5.9.2 Automated selection and reporting of results	7.4.1.5 Automated selection, review, release and reporting of results
5.9.3 Revised reports	7.4.1.8 Amendments to results reported
5.10 Laboratory information management 5.10.1 General 5.10.2 Authorities and responsibilities 5.10.3 Information system management	7.6 Control of data and information management 7.6.1 General 7.6.2 Authorities and responsibilities for information management 7.6.3 Information systems management 7.6.4 Downtime plans 7.6.5 Off site management 7.8 Continuity and emergency preparedness planning

APPENDIX B– AMENDMENT RECORD

Revision status	Change			Approved by	Effective Date
	Page No.	Clause	Description of change		
Issue no.1	-	-	-	CEO	2023-02-21