CHECKLIST FOR THE STEPWISE IMPROVEMENT PROCESS FOR STRENGTHENING LABORATORY QUALITY MANAGEMENT SYSTEMS INDICATING THE EQUIVALENCE WITH CLSI, QSE AND ISO 15189

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Index of CLSI QSE referred to in the checklist

QSE 1	- Organization	QSE 7	- Information Management
QSE 2	- Personnel	QSE 8	- Occurrence Management
QSE 3	- Equipment	QSE 9	- Assessment
QSE 4	- Purchasing and Inventory	QSE 10	- Process Improvement
QSE 5	- Process Control (Pre-Analytical, Analytical, Post-Analytical)	QSE 11	- Customer Service and Satisfaction
QSE 6	- Documents and Records	QSE 12	- Facilities and Environment

The requirements given in the checklist are not the exact clauses given in the ISO 15189:2007, however the numbering used corresponds to the relevant sections of the standard and the equivalent CLSI QSE (CLSI Guideline GP22-A2 - *Continuous Quality Improvement - Integrating Five Key Quality System Components*)

MANAGEMENT REQUIREMENTS

4.1 Organization and Management

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.1.1	1	Is the laboratory or the organization of which the laboratory is a part legally identifiable?	Company registration, articles of incorporation, license, other relevant legal documentation	X	X	X				
4.1.2	1	Is there a documented description of the laboratory services that provides for patient care and the needs of clinical personnel?	Laboratory User Manual/Guide	X	X	X				
4.1.3		Refer to 4.2.3								
4.1.4	1	Is there a written policy that addresses the declaration of conflicts of interest that could influence the creditability of laboratory activities?	Documented and approved policy on conflict of interest	X	X	X				
4.1.5 (a)	1	Are lab personnel provided with the appropriate authority and resources to carry out their duties?	Adequacy of staff, equipment and supplies to perform the volume, scope and quality of examinations required	X	X	X				
4.1.5 (b)	1	Has laboratory management identified the pressures (both internal and external) that their staff may face and defined policies to help remove or reduce the pressure?	Documented and approved policies to prevent or reduce internal and external pressures – e.g. conflict of interest, financial, commercial	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.1.5 (c)	1	Have policies and procedures for ensuring the protection of confidential information been developed and implemented?	Documented and approved policies and procedures to ensure confidentiality of information	X	X	X				
4.1.5 (d)	1	Are there policies and procedures for avoiding involvement in any activities that would diminish confidence in the competence, impartiality, judgment or operational integrity of the laboratory?	Policies and procedures to ensure the maintenance of integrity in conduct of the operations of the laboratory	X	X	X				
4.1.5 (e)	1	Has the organizational and management structure of the lab and its relationship to any other associated organizations been documented?	Documented management structure for the laboratory – including its relationship to other associated organizations (quality manual, organogram, service agreements)	X	X	X				
4.1.5 (f)	1	Have the specified responsibilities, authorities and interrelationships of all personnel been documented?	Documented organogram and documented job descriptions for all personnel	X	X	X				
4.1.5 (g)	1	Is there adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons conversant with the purpose, procedures and assessment of results of the relevant examination procedures;	Training and competency assessments for all staff and qualifications of supervisory staff REF 5.1.2		X	X				
4.1.5 (h)	1	Is there technical management with overall responsibility for technical operations and provision of resources needed to ensure quality of laboratory procedures?	Job descriptions and training records for technical management personnel REF 5.1.2	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.1.5 (i)	1	Has a quality manager been appointed and delegated responsibility and authority for compliance with the quality management system?	Individual with overall responsibility for overseeing the quality management system identified Job description and organogram	X	X	X				
4.1.5 (j)	1	Have deputies for all key functions been appointed?	Documented designation of who has primary and secondary responsibility for all key functions		X	X				
4.1.6	1	Has laboratory management ensured appropriate communication processes are established within the laboratory including regarding the quality management system?	Documentation of internal communication processes including regarding the quality management system		X	X				

4.2 Quality Management System										
ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.2.1	1	Have the documented policies, processes and procedures been communicated to, understood and implemented by all relevant personnel?	• Documented policies, processes and procedures • Evidence of communication of this information to all staff and evidence that laboratory management has ensured that all documents are understood and implemented			X				
4.2.2	1	Does the quality management system include internal quality control and participation in organized interlaboratory comparisons such as external quality assessment schemes?	• Internal quality control for all tests • EQA or interlaboratory comparison programmes for all tests	X	X X	X X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.2.3	1	Have the policies and objectives of the quality management system been defined in a quality policy statement and are they documented in a quality manual? Is the quality policy readily available to appropriate personnel? Does the quality policy include: a) the scope of service the laboratory intends to provide; b) the laboratory management's statement of the laboratory's standard of service c) the objectives of the quality management system d) a requirement that all personnel concerned with examination activities familiarize themselves with the quality documentation and implement the policies and procedures at all times e) the laboratory's commitment to good professional practice, the quality of its examinations, and compliance with the quality management system f) the laboratory management's commitment to compliance with this International Standards	• Quality policy statement documented in a quality manual. • Quality policy signed by appropriate personnel • Quality Manual	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.2.4	1	• Does the quality manual describe the quality management system and structure of the documentation used, and include or make reference to the supporting procedures including technical procedures? • Have the roles and responsibilities of technical management and the quality manager been defined in the quality manual? • Have all personnel been instructed on the use and application of the quality manual and all referenced documents, and of the requirements for their implementation? • Is the quality manual up to date?	• Document hierarchy described in the Quality manual and supporting procedures appropriately referenced • Roles and responsibilities of management and the quality manager referenced in the Quality Manual • Sign off sheet or information session records • Evidence of review and/or revision as required by document control procedure	X	X	X				
4.2.5	1	Has the laboratory established and implemented programmes that regularly monitor and demonstrate proper calibration and function of - instruments? - reagents? - analytical systems?	• Documented programme for preventive maintenance and calibration available, which at minimum follows manufacturer's recommendations • Calibration programme and records. • Preventive maintenance programme and logs		X	X				

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4.3 Document Control

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.3.1	6	• Has the laboratory established and maintained procedures to control all documents that form part of its quality system? • Are these controlled documents archived for a defined retention period?	• Documented procedures for the control of all lab documents • Archived copy of all controlled documents		X	X				
4.3.2	6	Are procedures adopted to ensure that: a) documents issued to personnel reviewed and approved for use prior to issue? b) a master list or an equivalent document control procedure available to identify the current revision status and distribution of documents? c) only current authorised versions of appropriate documents are available at all relevant locations? d) documents are periodically reviewed, revised where necessary and approved by authorised personnel? e) invalid or obsolete documents are promptly removed from all points of use? f) obsolete documents appropriately identified to prevent unintended use?	a) Laboratory's documents reviewed and approved by authorized personnel prior to issue b) Up-to-date document control log that lists all the current valid revisions and location of documents c) Current documents available at relevant locations d) Records of periodic review, revision and approval as necessary by authorized personnel e) Obsolete documents not on workbenches and in manuals, dates on documents current f) Obsolete documents labelled as such		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.3.2	6	g) If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents: - Are the procedures and authorities for such amendments defined? - Are these amendments clearly marked, initialled, and dated? h) Does the laboratory have procedures for how changes in documents maintained in computerised systems are made and controlled?	g) Defined policies and procedures and authorization for amending documents by hand, if allowed Amendments clearly initialled and dated and a revised document re-issued in a timely manner h) Procedure for changes to computerized documents							
4.3.3	6	Are the quality system documents generated by the laboratory uniquely identified with: - title, date of issue, revision identification/revision number, page numbering, the total number of pages or a mark to signify the end of the document, the issuing authority(ies) and source identification?	Quality system documents uniquely identified in accordance with the stated criteria	X	X	X				

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4.4 Review of Requests and Service Agreements

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.4.1	4	Where the laboratory enters into an agreement to provide medical laboratory services it shall have documented procedures for the establishment and review of such agreements. Agreements to provide medical laboratory services shall take into account the request—including any information needed by the laboratory to ensure appropriate examination and result interpretation—the examination, and the report. Where the laboratory enters into an agreement to provide medical laboratory services the following shall take place a) The customers' and users' requirements, including the examination processes to be used, shall be defined, documented and understood. b) The laboratory shall have the capability and resources to meet the requirements. c) Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations. d) Examination procedures selected shall be appropriate and able to meet the requirements and clinical needs.	A policy and procedure established and maintained for review of service agreements that includes a, b, c, d and e		X	X				
4.4.2	4	Are records of these service agreement reviews and any significant changes maintained?	Records of any service agreement reviews and changes agreed							

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.4.3	4	Does the service agreement review cover any work referred by the laboratory?	Records of reviews conducted for work performed by referral laboratories							
4.4.4	4	Is the client (e.g. clinicians, health care providers, health insurance companies) informed of any deviation from the service agreement that could impact clinical indications or limitations of examinations?	Laboratory communication with clients re any deviations from service agreements							
4.4.5	4	If the service agreement needs to be amended after the work commences: - is the same review process repeated? - are any amendments communicated to all affected parties?	• Records of review for service agreements amended after work commenced • Records of laboratory notification of service agreement amendments to all affected parties		X	X				

4.5 Review of Requests and Service Agreements

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.5.1	4	Are documented procedures available to evaluate and select - referral laboratories? - consultants who provide second opinions for histopathology, cytology, and related disciplines? When referral laboratories or consultants are used, does laboratory management - have a procedure for monitoring the quality of referral laboratories and consultants? - ensure that the referral laboratory or consultant is competent to perform the requested examinations?	• Procedures for evaluation and selection referral laboratories and consultants who provide second opinions for histology, cytology and related disciplines • Procedures for monitoring the quality and competence of referral laboratories and consultants • Competency assessment records for referral laboratory (e.g. EQA performance, accreditation status) and consultants		X	X				
4.5.2	4	Are arrangements with referral laboratories and consultants periodically reviewed to ensure that: a) The requirements, including the pre-examination and post-examination procedures are adequately defined, documented and understood? b) The referral laboratory's capability to meet the requirements and that there are no conflicts of interest? c) Selection of examination procedures is appropriate for the intended use? d) The responsibilities for the interpretation of examination results are clearly defined? (Records of such reviews shall be maintained in accordance with local, national or regional requirements)	Records of reviews of referral laboratories and consultants that meet the listed criteria a) to d)		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.5.3	4	• Does the laboratory maintain - a register of all referral laboratories? - a register of all samples that have been referred to another laboratory? • Are the names and address of the referral laboratory given to the user? • Is a duplicate laboratory report retained in both the patient record and permanent file of the laboratory?	• List of referral laboratories • List of all samples referred to another laboratory • Copies of reports which include information on name and address of the referral laboratory • Copies of reports in both the patient record and the permanent file of the laboratory	X	X	X				
4.5.4	4	• Is the referring laboratory, and not the referral laboratory, responsible to ensure that examination results and findings are provided to the person making the request? • Does the report have all the essential elements of the results if it is reported by the referral laboratory, without alterations that could affect any clinical interpretations?	• Procedure for return of results of tests done by referral laboratory to the requesting provider • Copies of reports from referral laboratory • Copies of reports sent to requesting provider by referring laboratory containing all essential elements of the results reported by the referral laboratory, without alterations that could affect clinical interpretations	X	X	X				

4.6 External Services and Supplies

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.6.1	4	• Does the laboratory have policies and procedure(s) for selection, purchasing of services, equipment, and consumable supplies that affect the quality of the tests and/or calibrations?	• Policies and procedures for the selection and purchase of key external services, equipment and supplies			X				
		• Do the purchased items consistently meet the laboratory's quality requirements?	• Documented specifications for acceptance of purchased items			X				
		• Do procedures exist for the inspection, acceptance/rejection and storage of consumable materials?	• Procedures for inspection, acceptance/rejection and storage of consumable materials		X	X				
4.6.2	4	Are purchased equipment/supplies/ reagents/ consumable materials inspected for compliance with standard specifications before use?	Records to verify that purchased equipment, supplies and reagents are inspected for compliance with specifications before use e.g. expiry dates, shipping conditions, equipment validation, etc.	X	X	X				
4.6.3	4	• Is there an inventory control system for all supplies?	• Records of inventory control system that include recording of lot numbers, date of receipt and date placed in service	X	X	X				
		• Are records maintained for a specified period of time for external services, supplies and purchased products?	• Records maintained for period specified in quality manual							
		• Are these quality records reviewed during the management review?	• Records of review of inventory control system during the management review e.g. management review minutes							

ISO 15189	CLSI	Requirement	What to look for	Quality Improvement	Status	Comments

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Section	QSE			Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.6.4	4	• Does the laboratory evaluate suppliers of critical consumables and supplies and services which affect the quality of testing? • Does the lab maintain approved lists and records of evaluation?	• Records of evaluations of suppliers of critical consumables, supplies and services which affect quality of testing • List of approved suppliers			X				

4.7 Advisory Services

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.7	4	Do appropriate laboratory professional staff provide advice on choice of examination, use of services, repeat frequency, required type of sample and interpretation of test results, where appropriate?	• Documented evidence of meetings and consultations between laboratory director and /or consultant/specialists with clinical personnel • Records of qualifications, training and competency assessment for laboratory and associated professional staff			X				

4.8 Resolution of Complaints

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.8	8	• Are policy and procedures available for resolution of complaints or other feedback from laboratory users? • Are records of complaints, investigations and corrective actions taken maintained by the laboratory?	• Policy and procedure for the resolution of complaints or other feedback • Records of complaints, investigations and corrective actions		X	X				

4.9 Identification and Control of Non-Conformities

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.9.1	8	• Does the laboratory have a policy and procedures to address situations when any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinician. • Do these ensure that : a) Personnel responsible for corrective actions are defined? b) Actions to be taken are defined? c) The medical significance of the nonconforming tests is considered and requesting clinician informed where appropriate? d) The examinations are halted and reports withheld as necessary? e) Corrective actions and decisions are taken immediately? f) Non-conforming test results and examinations already released are recalled? g) The responsibility for authorisation of the resumption of work is defined? h) Details of non-conformity events are documented and reviewed at regular specified intervals to detect trends and initiate preventive actions?	Policy and procedure for managing non-conformances that meet the criteria outlined in a) to h).			X				
4.9.2	8	Is there evidence of prompt implementation of procedures to address a recurrent/potential recurrent nonconforming examination and to identify, document and eliminate the root cause(s)? (See 4.10)	Records of recurrent/potential recurrent nonconforming examinations and root cause analysis and corrective actions			X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.9.3	8	Are procedures defined and implemented for the release of results in the case of nonconformities, including review of such results and are these recorded?	• Procedures for release of results and for notifying users of the service when a non-conformance is identified e.g. equipment malfunction • Records of non-conformances and actions taken • Record of review of results of examinations reported around the time of the non-conformance			X				

4.10 Continual Improvement										
ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.10.1	10	• Do the procedures for corrective actions include an investigation process to determine underlying causes of the problem? • Do the findings, where appropriate, lead to preventive actions? • Are corrective actions appropriate to the magnitude and the risk of the problem?	• Procedures for corrective actions that include root cause analysis • Records of root cause analysis being used to correct and prevent further non-conformances		X	X				
4.10.2	10	Does the management document and implement any changes required to its operational procedures resulting from corrective action investigations?	• Documented changes in procedures as indicated by the corrective action and root cause analysis investigations • Records of implementation of changes in procedures		X	X				
4.10.3	10	Are the results of corrective actions monitored to ensure their effectiveness in overcoming the identified problems?	Records that assigned personnel are reviewing records of corrective actions and monitoring the problem resolution		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.10.4	10	• Are the appropriate areas of activity audited in accordance with 4.14 when there is a doubt(s) on the laboratory's compliance? • Are the results for corrective actions submitted for laboratory management review?	• Audit reports of laboratory areas where non-compliance with policies or procedures is suspected • Records of review of corrective actions during management review e.g. meeting minutes, etc.		X	X				

4.11 Corrective Action										
ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.11.1	10	• Are the needed improvements and potential sources of non-conformances identified? • If preventive action is required, are action plans developed, implemented and monitored for effectiveness and to take advantage of the opportunities for improvement?	• Procedure by which staff actively look for potential sources of non-conformances and areas for improvement • Action plans for implementing preventive action • Records of monitoring of action plan implementation							
4.11.2	10	• Do procedures for preventive action include initiation of such actions? • Are procedures for preventive actions effective?	Procedures for preventive action including responsibility for initiation and monitoring of effectiveness of such actions							

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4.12 Preventive Action

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.12.1	10	• Are potential sources of non-conformances or other opportunities for improvement in the quality management system or technical practices identified through review at regular intervals, as defined by the management system? • If improvement is required, are action plans developed, documented and implemented?	• Documented systematic process and procedure for reviewing the quality management system and operations to identify opportunities for improvement • Action plans to guide continuous improvement as necessary • Records of implementation of continuous improvement plans							
4.12.2	10	Is the effectiveness of the actions taken evaluated through a review or audit of the area concerned?	Audit reports and/or records of review of area in which nonconformance has been addressed to determine if action taken has been successful							
4.12.3	10	Are the results of actions resulting from the review submitted to management for review and implementation of any needed changes?	Records of submission of reviews and implementation of suggested actions							
4.12.4	10	• Are quality indicators implemented to systematically monitor and evaluate the laboratory's contribution to patient care? • When improvements are identified, are these issues addressed regardless of where they occur? • Does laboratory management ensure that the laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care?	• List of quality indicators designated and monitored for evaluating the laboratory's contribution to patient care e.g. turnaround time, quality control, EQAS results, corrective actions, customer complaints • Records of implementation of improvements identified • Minutes of quality improvement meetings		X	X				
4.12.5	10	Are suitable training opportunities for all lab personnel and relevant users of the laboratory provided?	Training plans and records		X	X				

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4.13 Quality and Technical Records

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.13.1	6	Does the laboratory establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and safe disposal of quality and technical records?	Procedures for managing storage, retention and disposal of quality and technical records		X	X				
4.13.2	6	Are all records legible and easily retrievable, stored to prevent damage or deterioration, loss, and unauthorized access?	Laboratory records and storage		X	X				
4.13.3	6	• Is retention time policy for all records established? • Is the retention time for test results defined by the nature of test and some records in accordance national, regional or local regulations?	Document and record retention policy that is consistent with any national, regional or local regulations. Records maintained may include but are not limited to: a) request forms (including the patient chart or medical record only if used as the request form), b) examination results and reports, c) instrument printouts, d) examination procedures, e) laboratory work-books or sheets, f) accession records, g) calibration functions and conversion factors, h) quality control records, i) complaints and action taken, j) records of internal and external audits, k) external quality assessment records/inter-laboratory comparisons,	X	X	X				

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.13.3	6		l) quality improvement records instrument maintenance records, including internal and external calibration records m) lot documentation, certificates of supplies, package inserts n) incident/accident records and action taken o) staff training and competency records							

4.14 Internal Audits										
ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.14.1	9	• Does the laboratory conduct self-assessment/internal audits of its system periodically and in accordance with a predetermined schedule? • Are all elements of the quality system, both managerial and technical, addressed especially, areas of critical importance to patient care?	• Reports of periodic self-assessment or internal audits • Schedule for audits (including all areas of the quality system, both technical and managerial)	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.14.2	9	• Are such audits carried out by trained and qualified personnel who are, however resources permit, independent of the activity to be audited? • Do the procedures for internal audit define the type of audits, frequencies, methodologies and other necessary information?	• Internal audit staff training record • Procedure for internal audits that ensures that personnel do not audit their own work and that defines frequency, methodology and required documentation	X	X	X				
		• When audit findings cast doubts, does the laboratory take timely corrective action?	• Documented evidence of corrective actions being undertaken as a result of audit findings		X	X				
4.14.3	9	Are the results of internal audit submitted to the laboratory management for review?	Records of review of internal audit findings by laboratory management for follow-up action		X	X				

4.15 Management Review

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.15.1	1	• Does the laboratory management conduct review that includes the laboratory's quality system, all medical services including examination and advisory activities, continuing suitability and effectiveness in support of patient care and introduces any necessary changes or improvements? • Are management reviews conducted periodically and in accordance with a predetermined schedule? • Are results of the review incorporated into a plan to include goal, objectives, and action plans for the coming year?	• Procedure for routine conduct management review that includes the stipulated aspects at least once per year • Management review meeting schedule and minutes • Action plans with goals and objectives as a result of management reviews	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.15.2	1	Does the review take account of the elements of the quality management system?	Management review meeting agenda and minutes including but not limited to: a) follow-up of previous management reviews b) status of corrective actions taken and required preventive action c) reports from managerial and supervisory personnel d) the outcome of recent internal audits e) assessment by external bodies f) the outcome of external quality assessment and other forms of interlaboratory comparison g) any changes in the volume and type of work undertaken h) feedback including complaints and other relevant factors from clinicians patients and other parties i) quality indicators for monitoring the laboratory's contribution to patient care j) nonconformities k) monitoring of turnaround time l) results of continuous improvement processes, and m) evaluation of suppliers.			X				
4.15.3	1	Is the quality and appropriateness of the laboratory's contribution to patient care monitored and evaluated objectively?	Laboratory client surveys, reports of meetings with clinical staff Records of quality indicator monitoring			X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
4.15.4	1	• Are the findings and actions from management reviews recorded? • Are laboratory staff informed of the findings and the decisions made as a result of these reviews? • Are there agreed upon time limits for actions which laboratory management achieves?	• Management review minutes • Minutes of staff meetings and memos to staff • Records of action plan monitoring		X	X				

TECHNICAL REQUIREMENTS										
5.1 Personnel										
ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.1.1	2	Does the laboratory management have an organisational plan, personnel policies and job descriptions for all personnel?	• Organogram, job descriptions REF. 4.1.5 e) and f) • Documented personnel policies	X	X	X				
5.1.2	2	Does the management maintain records of relevant educational and professional qualifications, training, experience and competence of all personnel?	Personnel records for all staff that may contain the following: a) Certification or licence, if required, b) References from previous employment, c) Job descriptions, d) Records of continuing education and achievements, e) Competency evaluations, f) Provision for untoward incident or accident reports.	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.1.3	2	Does a competent person with medical, scientific and technical background direct the laboratory?	• Job description for the Laboratory Director or 'Head' however named • Evidence of qualifications, continuing education and experience of Laboratory Director in accordance with national requirements and/or international best practice	X	X	X				
5.1.4	2	Do the responsibilities of the laboratory director or designees include professional, scientific, consultative, advisory, organisational, administrative, and educational matters? The laboratory director or designees for each task should have the appropriate training and background to be able to discharge the administrative and technical responsibilities described in the job description and the scope of service offered by the laboratory.	• Job description, quality manual, and responsibilities listed in 5.1.4 a) to o). • Records of competency assessment for Laboratory Director and professional staff • Where specific functions are designated to other persons by the Laboratory Director or "Head", record of designation		X	X				
5.1.5	2	Are staff resources adequate to carry out all the functions of the quality system?	Job descriptions, quality manual, responsibilities and performance on quality indicators.			X				
5.1.6	2	Are personnel trained specifically in quality assurance and management for services offered?	• Quality assurance and quality management training records for staff • Competency assessment records		X	X				
5.1.7	2	Does the management authorise personnel to perform particular tasks such as sampling, examination and operating particular types of equipment, including use of computers in the lab information system?	Job description and record of task authorization		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.1.8	2	Are policies and procedures established to define who operates the computer system, who may access patient data, is authorised to enter patient results, change results, correct billing and modify computer programs?	Policies and procedures to guide use of and access to the laboratory's information system		X	X				
5.1.9	2	Is continuing education program available for all levels of staff?	Documentation of staff participation in continuing education programmes		X	X				
5.1.10	2	Are employees trained to prevent or contain the effects of adverse incidents?	Records of laboratory staff training to manage adverse events that may impact on staff, clients or environment							
5.1.11	2	• Is the competency of the staff undergoing training assessed? • Is it done periodically thereafter?	• Process and procedures for checking the competency of staff undergoing training and periodically • Training plans based on competency gaps identified for retraining staff			X				
5.1.12	2	• Do the personnel making professional judgment with reference to test examination have theoretical and practical knowledge and recent experience? • Do they take part in regular professional development or other professional liaison?	SEE 5.1.4		X	X				
5.1.13	2	Do all personnel maintain confidentiality of patient information?	Policy, process and mechanism for ensuring confidentiality of client information Confidentiality agreements signed by all personnel	X	X	X				

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5.2 Facilities and Safety

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.2.1	12	• Is the laboratory workspace adequate to carry out quality work, quality control procedures, and safety of personnel and patient care services? • Has the laboratory director determined the adequacy of the laboratory's space? • Are laboratory resources maintained in a functional and reliable condition?	Laboratory layout, space and infrastructure in accordance with national regulations	X	X	X				
5.2.2	12	• Is the laboratory designed for efficiency of its operation to optimise the comfort of its occupants and to minimise the risk of injury and occupational illness? • Are patients, employees and visitors protected from recognised hazards?	Laboratory layout and hazard control practices	X	X	X				
5.2.3	12	Are considerations made for accommodating patient disabilities, comfort, and privacy when primary sample collection facilities are provided?	• Layout of specimen collection and accessioning area • Procedure for facilitating patients with disabilities	X	X	X				
5.2.4	12	• Is the laboratory design and environment suitable for the tasks carried out? • Is the environment in which the primary sample collection and/or examinations undertaken is suitable and monitored so that it does not invalidate the results or adversely affect the required quality of any measurements?	• Laboratory layout and specimen collection and transport procedures • Records of monitoring of environment of specimen collection and examinations areas e.g. temperature records	X	X	X				
5.2.5	12	Does the laboratory monitor, control and record environment conditions as required by relevant specification or where they may influence the quality of results?	Records of monitoring of environmental conditions that may affect test results e,g temperatures, dust, humidity, mould, air flows, etc?		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.2.6	12	Is there effective separation between neighbouring areas where incompatible activities are performed? Are appropriate measures taken to prevent cross-contamination?	• Laboratory layout and activities performed • Process and procedure to prevent cross-contamination	X	X	X				
5.2.7	12	Is access to laboratory controlled?	Signs restricting access, swipe cards, ID badges, or security locks, etc.	X	X	X				
5.2.8	12	Are the communication systems within the laboratory efficient to the size and complexity of the facility and the efficient transfer of messages?	Communication systems e.g. phone, PA, email, memos, where necessary			X				
5.2.9	12	Are relevant storage space and conditions provided to ensure continuing integrity of samples, slides and histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies and records and results?	• Storage space for all of the items listed e.g temperature controlled fridges & freezers, UPS units for equipment, locked cupboards • Records of monitoring of storage conditions e.g temperature, moisture etc	X	X	X				
5.2.10	12	• Are the work areas kept clean and well maintained? • Are the dangerous materials stored and disposed as specified by relevant regulations? • Are measures taken to ensure good housekeeping in the laboratory? • Are special procedures and training for personnel provided when necessary?	• Housekeeping schedule and records. • Procedures for storage and disposal of dangerous materials according to the approved specifications • Storage facilities for dangerous materials • Proce dures and training records for handling of dangerous materials	X	X X X X	X X X X				

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5.3 Laboratory Equipment

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.3.1	3	• Is the laboratory furnished with all the items of equipment required for its services (including primary sample collection, sample preparation and processing, examination and storage)?	• Laboratory equipment inventory, list of services	X	X	X				
		• Where the laboratory needs to use equipment outside its permanent control, does the laboratory management ensure that the requirements of ISO 15189 are met?	• Documented procedure for monitoring calibration, validation and preventive maintenance records for equipment used							
5.3.2	3	• Is equipment shown to be capable of achieving the performance required and complies with specifications relevant to the examinations concerned?	• Equipment validation records		X	X				
		• Is a programme established to regularly monitor and demonstrates proper calibration and function of instruments, reagents and analytical systems?			X	X				
		• Is there documentation of preventive maintenance, at a minimum, following the recommendation from the manufacturer?	• Documented preventive maintenance programme that monitors calibration and function of instruments, reagents and analytical systems according to the manufacturer's instructions where applicable		X	X				
5.3.3	3	Is each piece of equipment uniquely labelled, marked or otherwise identified?	List of equipment with unique identifier on each piece of equipment		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.3.4	3	Are the following records of each item of equipment contributing to the performance of examinations maintained: Are these records maintained and readily available for the life span of the equipment or for any time period required by law or regulation?	Laboratory equipment records that contain the information: a) identity of the equipment; b) manufacturer's name, type identification and serial number or other unique identification; c) manufacturer's contact person and telephone number, as appropriate; d) date of receiving and date of putting into service; e) current location, where appropriate; f) condition when received (e.g. new, used or reconditioned); g) manufacturer's instructions, if available, or reference to their retention; h) equipment performance records that confirm the equipment's suitability for use; i) maintenance carried out and that planned for the future; j) damage to, or malfunction, modification or repair, of the equipment; k) predicted replacement date, if possible. Records maintained for life span of equipment or in accordance with any relevant country regulations or laws?		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.3.5	3	• Are the equipment operated by authorised personnel only? • Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) readily available to laboratory personnel?	• Training records and competency assessment records • Manufacturers' equipment manuals	X	X	X				
5.3.6	3	• Are equipment maintained in a safe working condition? • Are procedures in place to ensure examination of electrical safety, emergency stop devices and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons?	• Records of safety checks on laboratory equipment, electricals and chemicals as advised by the manufacturer • Records of corrective action taken		X	X				
5.3.7	3	• Is defective equipment taken out of service, clearly labelled and appropriately stored until it has been repaired?	• Defective equipment labelled and removed where necessary		X	X				
		• Is repaired equipment shown by calibration, verification or testing to meet specified acceptance criteria before being placed back in operation?	• Documented procedure and records for ensuring by calibration or testing that the equipment is in good working order before returning it to service • Records of examination to determine the possible effect that malfunctioning equipment may have had on previous exams REF 4.9			X				
		• Are reasonable measures taken to decontaminate equipment prior to service, repair or decommissioning?	• Procedure and records of decontamination of equipment prior to servicing, repair or decommissioning		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.3.8	3	• Is a list of the measures taken to reduce contamination given to the person working on the equipment? • Does the laboratory provide suitable space for repairs and appropriate personal protective equipment?	• Procedure for decontamination and sign-off by repair personnel • PPE for repair personnel		X	X				
5.3.9	3	Are the equipment labelled or otherwise coded to indicate the status of calibration or verification and the date when recalibration or reverification is due?	Label of calibration status and date for re-calibration		X	X				
5.3.10	3	When equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?	Records of calibration or testing that the equipment is in good working order before returning it to service			X				
5.3.11		Does the laboratory ensure when computers or automated examination equipment are used for collection, processing, recording, reporting, storage or retrieval of examination data?	• Validation records for computer software • Procedures and records for protecting integrity of data • Manufacturer's specifications and environmental monitoring records • Procedures for restricting access to computers to specific levels of authority			X X X X				
5.3.12		Are procedures available for safe handling, transport, storage, and use of equipment to prevent its contamination or deterioration?	Procedures for safe handling, transport, storage and use of equipment		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.3.13	3	Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies of prior correction factors are correctly updated?	Procedures for ensuring that calibration correction factors are correctly updated when necessary			X				
5.3.14	3	Are equipment including both hardware and software, reference materials, consumables, reagents and analytical systems safeguarded from adjustments or tampering that might invalidate examination results?	Procedure on the use and adjustment of equipment such as who uses specific equipment, who is authorized to adjust , calibrate, etc.			X				

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5.4 Pre-Examination Procedures

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.4.1	5	Does the request form contain sufficient information to identify the patient and authorised requester and provides pertinent clinical data?	Request forms including space for the inclusion of, but not limited to: a) unique identification of the patient; b) name or other unique identifier of physician or other person legally authorized together with the destination for the report. c) type of primary sample and the anatomic site of origin, where appropriate; d) examinations requested; e) clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes; f) date and time of primary sample collection; g) date and time of receipt of samples by the laboratory.	X	X	X				
5.4.2	5	• Are specific instructions for the proper collection and handling of primary samples documented, implemented and made available to those responsible for primary sample collection • Are these instructions contained in a primary sample collection manual?	• User Manual that contains instructions for collection and handling of primary samples • Records that User Manual has been made available to relevant personnel		X	X				
5.4.3	5	Does the primary sample collection manual include the information listed in Clause 5.4.3 a) to d)?	User Manual/primary sample collection manual containing the information as detailed in Clause 5.4.3 a) to d)	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.4.4	5	Is the primary sample collection manual part of the document control system?	User Manual with identifier and is it updated as required by the document control system		X	X				
5.4.5	5	• Are primary samples traceable to an identified individual normally by a request form? • Are primary samples lacking proper identification rejected by the laboratory?	• Requisition forms matched to samples • Sample acceptance/rejection criteria and log	X	X	X				
5.4.6	5	Does the laboratory monitor how the samples are transported to the laboratory?	User manual, records of monitoring the time, temperature and safety conditions for samples transported to the lab in accordance with Clause 5.4.6 a) to c)	X	X	X				
5.4.7	5	• Are all the primary samples recorded in an accession book, worksheet, computer or other comparable system upon receipt? • Is date and time of receipt of samples and identity of the receiving officer recorded?	Records of samples received, either manually or in a computer including date, time and identity of the person receiving the sample	X	X	X				
5.4.8	5	Are criteria developed and documented for acceptance or rejection of primary samples? If compromised samples are accepted, does the final report indicate the nature of the problem and, if applicable, that caution is required when interpreting the results?	• Specimen acceptance/rejection criteria • Reports indicating the problem and advising caution in interpretation of results when applicable	X	X	X				
5.4.9	5	Does the laboratory periodically review its sample volume requirements for phlebotomy (and other sample such as cerebrospinal fluid) to ensure that - neither insufficient nor excessive amounts of sample are collected?	Procedure for periodic review of sample volume requirements			X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.4.10	5	Is there systematic review of requests and samples by the authorised personnel to decide which examinations are to be performed and the methods used to perform them?	Procedure for review of test requests and samples by authorized personnel to determine examinations to be performed and methods to be used			X				
5.4.11	5	Is there a documented procedure for the receipt, labelling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent?	Procedure for handling samples marked as urgent that include the required details as listed in Clause 5.4.11	X	X	X				
5.4.12	5	Are the sample portions traceable to original primary sample?	Accessioning procedure that maintains correct patient identity when samples are separated or aliquoted into a secondary container(s)	X	X	X				
5.4.13	5	Are written polices available concerning verbal requests for sample examinations?	Policy for management of verbal requests			X				
5.4.14	5	Are samples stored for a specified time under conditions ensuring the stability of sample preparations to enable repetition of the examinations after reporting of the result or for additional examinations?	Sample storage and retention policy (SEE Clause 5.4.3 d)) and records		X	X				

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5.5 Examination Procedures

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.5.1	5	• Is the laboratory using appropriate examination procedures for selecting or taking sample portions, meeting the needs of the users of the laboratory services and appropriate for the examinations? • Is the laboratory selecting appropriate methods published from established/authorative textbooks, peer-reviewed texts, journals, international, regional, national guidelines? • If in-house procedures are used, are they appropriately validated for their intended use and fully documented?	Established procedures appropriate for meeting the needs of users		X X	X X X				
5.5.2	5	• Are validated procedures used for confirming that the examination procedures are suitable for the intended use? • Are the validations as extensive as necessary to meet the needs in the given application or field of application? • Are results obtained and the procedure used for validation recorded? • Are the methods and procedures evaluated for satisfactory results before implementation? • Does the laboratory director or designate review these procedures initially and at defined intervals (normally annual review)? • Are these reviews documented?	• Procedure for validating all examination procedures before implementation and use • Records of all validation procedures and results • • Records of laboratory director or designate review of validation results and authorization of all procedures prior to implementation and periodically			X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.5.3	5	Are all documented test procedures available at the workstation? Is it available in a commonly understood language?	• Current and authorized standard operating procedures (SOPs) for all examinations performed in the lab readily available to staff in a language that is understood • Card files or other job aids referenced back to a written SOP and maintained as controlled documents • SOPs consistent with manufacturers' instructions for use with deviations documented and reviewed as necessary • Documented, reviewed and authorized deviations from written SOPs • Records of performance verifications on all new versions of kits that have major changes in reagents or SOPs • SOPs consistent with the documentation as listed in Clause 5.5.3 a) to q)	X	X	X				
5.5.4	5	Do the performance specifications for each procedure used in an examination relate to the intended use of that procedure?	• List of performance specifications • Kits inserts and SOPs			X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.5.5	5	• Are the biological reference intervals periodically reviewed?	• SOPs	X	X	X				
		• Does the laboratory undertake investigations if the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population?	• Records of investigations of biological reference intervals as necessary							
		• Are necessary follow-ups made as corrective action?	• Records of corrective actions as necessary	X	X	X				
		• Are biological reference intervals also reviewed, if appropriate, when the laboratory changes an examination procedure or pre-examination procedure?	• Records of review of biological reference intervals when SOPs are changed, if necessary	X	X	X				
5.5.6	5	Does the laboratory make list of its current examination procedures, including primary sample requirements and relevant performance specification and requirements, available to laboratory users upon request?	• User manual • List of performance specifications	X	X	X				
5.5.7	5	When the laboratory changes an examination procedure so that results or their interpretations may be significantly different, are the implications explained to users in writing prior to the introduction of the change?	Written information to users	X	X	X				

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5.6 Assuring the Quality of Examination Procedures										
ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.6.1	5	Does the laboratory design systems that verify the attainment of the intended quality of results is achieved? This includes a) the procedure for control analysis b) the type of control material used, the acceptable tolerance limits for each analyte and a plan of action to follow when control results exceed tolerance limits including when to notify a supervisor and how to document.	a) Internal quality control procedures for every laboratory examination b) Quality control system and records for all aspects of testing, including specimen handling, requests, examinations and reporting	X	X	X				
5.6.2	5	• Does the laboratory determine the uncertainty of its measurements, where relevant and possible? • Are the uncertainty components which are of importance taken into account such as sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, conditions of the sample and changes in the operator, etc.	• Documentation of uncertainty of results where relevant and possible. • Procedures – to include identification of the variables that may impact the quality of a test in every SOP e.g. temperature, dust, the patient's biological factors etc.			X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.6.3	5	• Is a programme designed for calibration of measuring systems and verification of trueness designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference? • Where the laboratory is using external calibration services, is traceability of measurement assured by these external calibration laboratories? • Where none of these are possible or relevant, other means for providing confidence in the results shall be applied.	• Documentation that calibration materials are traceable. • Records of, but not limited to, the requirements listed in Clause 5.6.3 a) to f).		X	X				
5.6.4	5	• Does the laboratory participate in inter-laboratory comparisons such as those organised by external quality assessment schemes? • Does the laboratory monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled?	• Records of participation in external quality assessment (EQA) programmes for all examinations • Procedure and records for monitoring the results of EQA and conducting corrective actions where indicated		X	X				
5.6.5	5	• When proficiency or inter-laboratory comparison programmes are not available, does the laboratory develop mechanisms for deciding the acceptability of procedures not otherwise evaluated? • Does the laboratory monitor the results in the above programmes and participate in the implementation and recording of corrective actions?	• Records of participation in informal inter-laboratory comparisons such as exchanges of samples with other labs when it can't access formal EQA programmes • Procedure and records for monitoring the results of interlaboratory comparisons and conducting corrective actions where indicated		X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.6.6	5	• For examinations performed using different procedures, different equipment, or different sites, does the laboratory have a defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals? • Are such verifications performed at defined periods of time appropriate to the characteristics of the procedure or instrument?	Procedure for periodically verifying the comparability of results when different methods and/or equipment are used			X				
5.6.7	5	• Does the laboratory document, record the results of the comparisons performed in 5.6.6 appropriately? • Does the laboratory expeditiously act upon results from the comparisons? • Are the problems or deficiencies identified and rectified and records of actions retained?	• Records of method/equipment comparability data • Procedure for taking and recording corrective action on problems identified when comparisons are made • Records of corrective actions taken			X				

5.7 Post- Examination Procedures

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.7.1	5	Do authorised personnel systematically review the results of examinations and evaluate them in conformity with the clinical information available regarding the patient and authorise the release of the results?	• Procedure for the review of results by competent personnel before they are released • Records of authorization of results before release	X	X	X				

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ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.7.2	5	Are primary samples and other laboratory samples stored in accordance with approved policy?	• Sample retention and storage policy (REF 5.4.14) • Stored samples	X	X	X				
5.7.3	5	Are samples that are no longer required for examination disposed safely and in accordance with regulations or recommendations for waste management?	Procedure for waste disposal in accordance with national and/or recommended universal specifications	X	X	X				

5.8 Reporting of Results

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.8.1	5	Is the laboratory responsible for formatting reports in collaboration with users?	• Records of review of laboratory reporting format • Report format			X				
5.8.2	5	Does the laboratory management share responsibility with the requester to ensure that the reports are received by the appropriate individual within the agreed-upon time interval?	• Process and procedures for monitoring return of result and turnaround time for reports • Records of receipt of results and corrective action as necessary		X	X				
5.8.3	5	Are the test results legible, without mistakes in transcription and reported to persons authorised to receive and use medical information?	• Copies of laboratory results • Procedure for report verification REF 5.7.1 • Laboratory reports include the elements listed in Clause 5.8.3 a) to n).	X	X	X				

CHECKLIST FOR THE STEPWISE IMPROVEMENT PROCESS FOR STRENGTHENING LABORATORY QUALITY MANAGEMENT SYSTEMS INDICATING THE EQUIVALENCE WITH CLSI, QSE AND ISO 15189

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.8.4	5	Does the description of examinations performed and their results follow the vocabulary and syntax recommended by one or more internationally recognized organizations, as appropriate?	Reports (standard units and reference intervals)	X	X	X				
5.8.5	5	If the quality of the primary sample received was unsuitable for examination or could have compromised the result, are these indicated in the report?	• Criteria for acceptance/rejection REF 5.4.8 • Reports indicating inappropriate samples as required	X	X	X				
5.8.6	5	• Are copies or files of reported results retained by the laboratory such that prompt retrieval of the information is possible? • Are reported results retained for a period - as long as medically relevant or - as required by the regulatory requirements?	• Stored and easily retrievable copies of reports and/or records of results • Quality and technical records - record retention policy REF 4.13.1 to 4.13.3	X	X	X				
5.8.7	5	• Does the laboratory have procedures for immediate notification of physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established “alert” or “critical” intervals? • Does the above also include samples sent to referral laboratories for examination?	• Procedure for critical value reporting and action • Documented critical values for immediate reporting	X	X	X				
5.8.8	5	• Does the laboratory determine the critical properties and their “alert/critical” intervals in agreement with the clinicians who use the laboratory? • Does the above apply to all examinations including both nominal and ordinal properties?	• Consultation with clinician users (memos, meeting minutes, etc.)			X				

CHECKLIST FOR THE STEPWISE IMPROVEMENT PROCESS FOR STRENGTHENING LABORATORY QUALITY MANAGEMENT SYSTEMS INDICATING THE EQUIVALENCE WITH CLSI, QSE AND ISO 15189

ISO 15189 Section	CLSI QSE	Requirement	What to look for	Quality Improvement			Status			Comments
				Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.8.9	5	For results transmitted as an interim report, is the original report always forwarded to the requester?	Copies of interim and final reports	X	X	X				
5.8.10	5	• Are records maintained of actions taken in response to results in the critical intervals? • Do these records include date, time, responsible laboratory staff member, person notified, examination results, any difficulty encountered in meeting this requirement? • Are such records reviewed during the audits?	• Records of critical values reported that include date, time, responsible lab staff, person notified, the results transmitted and any difficulty encountered • Audits reports	X	X	X				
5.8.11	5	• Does the laboratory in consultation with the requesters, establish turnaround times for each of its examinations? • Does the turnaround time reflect the clinical needs? • Is there a policy available for notifying requester when an examination is delayed? • Are the turnaround times as well as any feedback from clinicians regarding turnaround times monitored, recorded, reviewed and where necessary, corrective actions identified to address any problems?	• Procedure for establishing turnaround times in consultation with clinician users • Policy for notifying requesters when examinations are delayed and could compromise patient care • Records of turnaround times (TAT), monitoring and review of TAT and corrective action taken when necessary (See quality indicators – 4.12.4)		X	X				
5.8.12	5	When examination results from referral laboratory need to be transcribed by the referring laboratory, are there procedures available to verify the correctness of all transcriptions?	Procedure for reporting results of referred out examinations REF 5.8.3 and 5.7.1	X	X	X				

ISO 15189	CLSI	Requirement	What to look for	Quality Improvement	Status	Comments

CHECKLIST FOR THE STEPWISE IMPROVEMENT PROCESS FOR STRENGTHENING LABORATORY QUALITY MANAGEMENT SYSTEMS INDICATING THE EQUIVALENCE WITH CLSI, QSE AND ISO 15189

Section	QSE			Tier 1	Tier 2	Tier 3	Y	N	N/A	
5.8.13	5	• Does the laboratory have clearly documented procedures for release of examination results including details of who may release results and to whom? • Do the procedures also include guidelines for the release of results directly to patients?	Procedure for the release of examination results REF 5.8.3 and 5.7.1	X	X	X				
5.8.14	5	• Does the laboratory establish policies and practices to ensure that the results distributed by telephone or other electronic means only reach authorised receivers? • Are results provided verbally followed by a properly recorded report?	Policy and procedures for results distributed by telephone and other electronic means REF 5.8.3, 5.7.1, 5.8.9, 5.8.2	X	X	X				
5.8.15	5	• Does the laboratory have written policies and procedures regarding the alteration of reports? • Are original entries legible when alterations are made? • Are original electronic records retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration?	• Policy and procedure for alteration of reports that ensures that the original entry remains legible and shows the time, date and name of person responsible for the change • Copies of altered reports	X	X	X				
5.8.16	5	• Are results that have been available for clinical decision-making revised and retained in subsequent cumulative reports and clearly identified as having been revised? • If the reporting system cannot capture amendments, changes, or alterations, is an audit log used?	Cumulative results or logs showing reports that have been revised			X				