CHECKLIST FOR THE
STEPWISE IMPROVEMENT PROCESS FOR
STRENGTHENING LABORATORY QUALITY MANAGEMENT SYSTEMS
(LQMS-SIP)
TOWARDS ACCREDITATION

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

Version 1 2016

The requirements given in the checklist are not the exact clauses in the ISO 15189: 2012; however the numbering corresponds to the relevant sections of the standard. The equivalence with the CLSI Quality Systems Essentials (CLSI Guideline QMS01-A4 – Quality Management system – A Model for Laboratory Services Approved Guideline – *Fourth Edition*) is provided as a separate annex

Instructions for checklist use:

- The Stepwise Improvement Process Checklist contains 15 Management requirements and 10 Technical requirements based upon the ISO 15189 International Standard.
- In each of the main sections the requirements are separated into 3 distinct tiers, based upon relative importance/complexity.
  - Requirements noted in "black" represent Tier 1
  - Requirements noted in "blue" represent Tier 2
  - Requirements noted in "green" represent Tier 3
- Responses to all questions must be, Yes (Y), No (N) or Not applicable (N/A), to specify whether the laboratory is in compliance or not.
- All the elements of each specific requirement must be satisfactorily present to indicate "Yes".
- Provide comments for each "N/A" or "No" response

SAFETY REQUIREMENTS

The Safety requirements included are based on the ISO 15190 - Medical Laboratories - Requirements for Safety in the final section.

The results from the safety assessment do not count toward the Laboratory's final Tier classification.

NOTE: Items that include "tick lists" must receive all "yes" and/or "n/a" responses to be marked "yes" for the overarching question.

Assessors must complete the laboratory assessment using the following techniques to evaluate operations and to document findings in detail:

a) Review laboratory records to verify that the QMS and supporting documents are complete, current, accurate, and annually reviewed.

b) Observe laboratory operations including pre-analytic, analytic and post-analytic phases of laboratory testing;

c) Ask open-ended questions to clarify documentation seen and observations made.

d) Do a vertical audit of a specimen through the laboratory from collection through to reporting.

e) Review Quality Control process and records and ensure traceability of samples and results.

f) Confirm PT results and the results are reviewed and corrective action taken as required.

g) Evaluate the quality and efficiency of supporting work areas (e.g., phlebotomy, reception, drivers, cleaners, IT, etc.).

h) Talk to clinicians and staff to learn the users' perspective on the laboratory's performance.

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

LABORATORY PROFILE

Date of Assessment (dd/mm/yyyy)		
Assessor name(s)		
Laboratory Name		
Laboratory Address		
Laboratory Telephone	Fax	Email
Name of Laboratory Head (Manager or Director)		
Name of Deputy Head (Manager or Director)		
Name of Quality Manager (Officer)		
Name of Safety Officer		
Name of Consulting Pathologist:		

Print name of Lead Assessor:

Signature of Lead Assessor:

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.1 Organization and management responsibility									
4.1.1.2	Can the laboratory or the organization of which the laboratory is a part, be held legally responsible for its activities?	Company registration, articles of incorporation, license, (liability) insurance, other relevant legal documentation				x	x	x	
4.1.1.3 Ethical Conduct									
4.1.1.3	Does the laboratory have arrangements to ensure: a) No involvement in activities which would diminish confidence in laboratory's confidence, impartiality, judgement or operational integrity. b) Management and personnel are free from undue commercial, financial or other pressures c) Potential conflicts of interest are openly and appropriately declared d) Procedures are in place to ensure that human samples, tissues or remains are treated according to relevant legal requirements e) Confidentiality of information is maintained	Established code of ethics Documented and Approved staff Ethics Policy Documented and Approved Policy on declaring conflicts of interest Documented procedure about treatment and disposal of human samples, tissues or remains Confidentiality agreements signed by all staff, outlining requirements and repercussions for breeches				x	x	x	
4.1.1.4	Does a competent person(s) with medical, scientific and technical background direct the laboratory?	Job description for Laboratory Director and designees, and evidence of qualifications, continuing education and experience Records of Competency assessment for Laboratory Director, designees and Professional staff				x	x	x	
4.1.2 Management responsibility									
4.1.2.1	Has management provided evidence of commitment to the development and implementation of the QMS and its continual improvement?	Minutes of staff meetings, Management reviews and training on the QMS				x	x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.1.2.3	Has an appropriate quality policy defining the intent of the quality management system been established and documented? Does the quality policy include: a) A commitment to good professional practice, to conducting examinations fit for intended use, compliance with the requirements of the International Standard and continual improvement of the quality of laboratory services b) A framework for establishing and reviewing the quality objectives c) That it be communicated and understood within the organization d) That it be reviewed for continuing suitability	Documented and approved Quality policy statement. Quality policy signed by appropriate personnel Quality Manual				x	x	x	
4.1.2.4	Has Management established quality objectives which address the needs of the users, are consistent with the quality policy and are measureable?	Documented and approved Quality Objectives Quality Manual				x	x	x	
4.1.2.5	Has management defined, documented and communicated the responsibilities, authority and interrelationships within the organization? Have deputies for all key functions been appointed?	Documented Job descriptions and Organogram Documented designation of who has primary and secondary responsibility for all key functions				x	x	x	
4.1.2.6	Has management documented communication and meetings with staff? Has management established a communication process with stakeholders about pre-examination, examination and post examination processes and the QMS?	Minutes of staff meetings, memos to staff, Documentation of internal communication regarding the QMS, User Manual Memos, letters, press releases					x	x	
4.1.2.7	Has a quality manager been appointed, delegated responsibility and authority for development, implementation and compliance with the QMS?	Documented designation of quality manager position or responsibility Job description and organogram				x	x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.2 Quality Management System									
4.2.1	Has Management established, documented, implemented and maintained a QMS and continually improved its effectiveness in accordance with the International Standard ISO 15189?	Documented policies, processes and procedures Evidence of communication of this information to all staff Evidence that laboratory management has ensured that all documents are understood and implemented Evidence of Management reviews Data of corrective and preventive actions						x	
4.2.2 Documentation requirements									
4.2.2.1	Does the QMS documentation include procedures and records required by the International Standard ISO 15189? Does the documentation include copies of applicable regulations, standards and other normative documents?	Master list of documents SOP manuals Copies of national regulations, ISO 15189:2012, other applicable standards as referenced by the lab in its QMS, e.g. ISO 15190					x	x	
4.2.2.2 Quality Manual									
4.2.2.2	Has the laboratory established a quality manual that is accessible to and used by staff? Does the manual include all the requirements of ISO 15189:2012 Clause 4.2.2.2?	Established and documented Quality Manual Evidence of sessions to train staff on the use and applicability of the manual				x	x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
		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							

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.3 Document Control									
4.3	Has the laboratory established and maintained procedures to control all documents that form part of its quality system?	Documented procedures for the control of all documents that form part of the QMS (internal and external)				x	x	x	
	Does the document control procedure include all the requirements of ISO 15189:2012 Clause 4.3?	All hard and soft copy QMS documents are reviewed and approved by authorized personnel. Quality system documents uniquely identified in accordance with the stated criteria Current master list Current authorized documents available at relevant locations Procedure for amending documents Procedure for identifying changes in documents Records of periodic review, revision and approval Obsolete documents labelled as such Specified document retention times Archived documents				x	x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.4 Service Agreements									
4.4.1	Does the laboratory have documented procedures for the establishment and review of agreements to provide services? Do these agreements take into account the request, the examination and the report including any information needed to ensure appropriate examination and result interpretation? When the laboratory enters into a service agreement does it meet all the requirements of ISO 15189:2012 Clause 4.4.1?	Documented procedure for review of service agreements that includes requirements of Clause 4.4.1. User Manual Copies of completed request forms Signed contracts or service agreements Evidence of communication about deviations from original service agreements List of referral laboratories and examinations referred						x	
4.4.2	Are records of these service agreements reviewed and any significant changes maintained? If the service agreement needs to be amended after the work commences: Is the same review process repeated? Are any amendments communicated to all parties affected?	Records of any service agreement reviews and changes agreed Records of review for service agreements amended after work commenced Records of laboratory notification of service agreement amendments to all affected parties					x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.5 Examination by Referral Laboratories									
4.5.1 Selecting and evaluating referral laboratories and consultants									
4.5.1	Does the laboratory have a documented procedure for selecting and evaluating referral laboratories and consultants? Does the procedure ensure that the laboratory meets the requirements of ISO 15189:2012 Clause 4.5.1?	Documented procedure for the selection and evaluation of referral laboratories and consultants to include all the requirements listed Clause 4.5.1 a) to e) Records of reviews of referral laboratories and consultants and Register of Referral Laboratories and / or consultants Record of requests and results for all samples referred in accordance with specified retention period					x	x	
4.5.2 Provision of Examination results									
4.5.2	Is the referring laboratory responsible for ensuring that the examination results from the referral laboratory is made available to the person making the request, unless otherwise specified? If the referring laboratory prepares the report, does it include all essential elements of the results reported, without alterations that could affect clinical interpretation? Does the report indicate which examinations were performed by the referral laboratory or consultant? Is the author of any additional information identified? Does the laboratory adopt the most appropriate means of reporting referral lab results? Are mechanisms in place to ensure that collaboration between referring and referral laboratories are not hindered by commercial or financial considerations?	Copies of referral lab/consultants reports. Copies of referring laboratory reports. Identification of personnel making addition remarks on the referral report Review of turnaround times, measurement accuracy and transcription errors Code of Ethics, Conflict of interest procedure				x	x	X	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.6 External Services and Supplies									
4.6	Does the laboratory have a procedure(s) for selection, purchasing of services, equipment, reagents and consumable supplies? Are criteria established for the selection and approval of suppliers? Is this done in collaboration with other organizational departments, where relevant? Is there a current list of approved suppliers of equipment, reagents and consumable supplies?	Procedures(s) for the selection and purchase of eternal services, equipment, reagents and supplies Criteria for selection and records of Supplier Evaluations Approved Supplier list Purchasing records with product /service specification						x	
	Does the purchasing information describe the requirements for the product and / or service? Is the supplier's performance monitored to ensure that purchased services and items consistently meet the stated criteria?								

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.7 Advisory Services									
4.7	Has the laboratory established arrangements for communicating with users according to the requirements of ISO 15189:2012 Clause 4.7?	Minutes of meetings and consultations between laboratory director and /or consultant/specialists with clinical personnel Documented evidence of advice on individual clinical cases Records of qualifications, training and competency assessment for laboratory and associated professional staff						x	
4.8 Resolution of Complaints									
4.8	• Is there a procedure for the management of complaints or other feedback from patients, clinicians, laboratory staff and other parties? • Are there records of complaints, investigations and corrective actions?	Procedure for the management of complaints or other feedback Records of complaints, investigations and corrective actions					x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.9 Identification and Control of Non-Conformities									
4.9.1	Does the laboratory have a documented procedure to identify and manage non-conformities? Do these procedures ensure that the laboratory meets the requirements of ISO 15189 Clause 4.9.1?	Procedures for managing non-conformities that include requirements of Clause 4.9.1 a) to h) ISO 15189:2012. Records of non-conformities and investigations Reports of corrective actions taken						x	
4.10 Corrective Action									
4.10	Does the laboratory take appropriate corrective actions to eliminate the causes of nonconformities? Does the laboratory have a documented procedure for corrective actions which include all the requirements of ISO 15189:2012 Clause 4.10?	Procedure for corrective actions Records of root cause analysis and corrective actions taken						x	
4.11 Preventive action									
4.11	Does the laboratory have a documented procedure for preventive action?	Documented procedure for preventive action that include requirements of Clause 4.11 ISO 15189:2012: Records of preventive actions taken						x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.12 Continual Improvement									
4.12	Does the laboratory have a programme for continual improvement of its quality management system? Does the laboratory conduct risk assessments for the procedures that it is undertaking? Does the laboratory have documented action plans for improvement? Does the laboratory communicate improvement plans and goals to the staff?	Management review minutes Documented Quality Policy Documented Quality Objectives Risk evaluation reports Improvement action plans for priority areas Evidence that staff is informed of plans and goals e.g. correspondence with staff						x	
4.13 Control of Records									
4.13	Does the laboratory have a documented procedure for control of quality and technical records? Does the facility have suitable record storage areas?	Procedure(s) for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records Retention times of Records Review records listed in ISO 15189:2012 Clause 4.13 a) to v)				x	x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.14 Evaluation and Audits									
4.14.1	Does the laboratory plan and implement the evaluation and internal audit processes needed to ensure conformity to the QMS, improve its effectiveness and meet user needs?	Internal audit Plan, Schedule, Associated Forms and Reports				x	x	x	
4.14.2 Periodic review of requests, and suitability of procedures and sample requirements									
4.14.2	Do authorized personnel periodically review the laboratory's examinations to ensure they are clinically relevant? Does the laboratory periodically review its sample collection requirements to ensure the sample is properly collected to preserve the measurand?	Records of review of examinations by authorized personnel Records of review of sample collection and user manuals					x	x	
4.14.3 Assessment of user feedback									
4.14.3	Does the laboratory seek information from users on whether the service has met user needs? Do the methods for obtaining and using this information include cooperation with users or their representatives? Is the information obtained in a manner that ensures user confidentiality? Are records of information collected and actions taken kept?	Customer surveys and reports Records of actions taken based on customer feedback					x	X	
4.14.4 Staff suggestions									
4.14.4	Does Laboratory management encourage staff to make suggestions for the improvement of the laboratory service? Are suggestions evaluated, implemented as appropriate and feedback provided to the staff? Are records of suggestions and action taken by the management maintained?	Records of staff surveys and meetings Records of management actions based on staff feedback					x	x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.14.5 Internal audit									
4.14.5	Does the laboratory conduct internal audits at planned intervals to ascertain whether the QMS: a) Conforms to the requirements of the ISO 15189:2012 and the laboratory requirements b) Is implemented, effective, and maintained? Are personnel trained to conduct audits which assess the performance of managerial and technical processes of the QMS? Are the audit criteria, scope, frequency and methods defined and documented? Are auditors selected and audits conducted to ensure objectivity and impartiality of the audit process? Does the laboratory have a documented procedure for conducting internal audits? Are corrective actions promptly undertaken?	Audit schedule Records of auditor training Records of follow up from previous audits Documented procedure for conducting internal audits which defines the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records Documented audit criteria, scope, frequency and methods Audit reports Records of Corrective Action Plan, implementation and verification					X	x	
4.14.6 Risk Management									
4.14.6	Does the laboratory evaluate the impact of work processes and potential failures on examination results as they affect patient safety? Does the lab make modifications to processes to reduce or eliminate identified risks and document decisions and actions taken?	Risk analysis/impact assessment report(s) Record of decisions and actions taken with respect to process modifications.						x	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.14.7 Quality Indicators									
4.14.7	Does the laboratory establish quality indicators to monitor and evaluate performance? Does the laboratory have a planned process of monitoring quality indicators? Does the laboratory periodically review their indicators, to ensure their continued appropriateness? Does the laboratory, in consultation with the users, establish and monitor turnaround times?	List of quality indicators Description of process and schedule for monitoring quality indicators which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement Periodic indicator review reports Record of agreed turnaround times for each examination finalized in consultation with users Record of evaluation and report on achievement of established turnaround times					x	x	
4.14.8 Reviews by eternal organisations									
4.14.8	Does the laboratory take appropriate corrective action or preventive action when reviews by eternal organizations indicate current or potential nonconformities? Are records of reviews and corrective and preventive action maintained?	Records of the reviews by eternal organizations Records of corrective actions and preventive actions taken						X	

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.15 Management Review									
4.15.1	Does the laboratory management conduct a review of the quality management system at planned intervals?	Documented Procedure for Management Review to ensure its continuing suitability, adequacy and effectiveness and support of patient care					x	x	
4.15.2	Does the input to laboratory's management review include information from the results of evaluations of the requirements of ISO 15189:2012 Clause 4.15.2?	Management review meeting agenda Minutes including decisions and actions on results of at least the items listed in Clause 4.15.2 a) to o) of ISO 15189:2012						X	
4.15.3	Does the laboratory's Management review analyse the input information? Does this review include assessment of opportunities for improvement and need for changes to the QMS, and where possible, objective evaluations of appropriateness of the lab's contribution to patient care?	Records of the Management review minutes indicating items outlined in Clause 4.15.3 ISO 15189:2012.						X	
4.15.4	Is the output from the management review incorporated into a record that documents any decisions made and actions taken related to: a) Improvement of the effectiveness of the QMS its processes b) Improvement of services to users c) Resource needs? Are the findings and actions arising from management reviews recorded and reported to laboratory and other relevant staff? Does the laboratory management ensure that actions arising from management review are completed within a defined timeframe?	Minutes of Management review including a) to c) Minutes of staff meetings, emails, bulletins, memos, etc. Action and Implementation plans						X	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.1 Personnel									
5.1.1	Does the laboratory: - have a documented procedure for personnel management? - maintain records for all personnel to indicate compliance with requirements?	Documented personnel management procedure Personnel records for all staff in the organisation				x	x	x	
5.1.2 Personnel qualifications									
5.1.2	Has the laboratory management documented the personnel qualifications for each position as appropriate for the tasks to be performed?	Qualification and competency requirements				x	X	x	
5.1.3 Job Descriptions									
5.1.3	Does the laboratory have job descriptions for all personnel?	Job descriptions that describe responsibilities, authorities and tasks Organisational chart				x	X	x	
5.1.4 Personnel introduction to the organizational environment									
5.1.4	Does the laboratory have an orientation programme for new staff?	Documented orientation programme Records of staff orientation				x	X	x	
5.1.5 Training									
5.1.5	Does the laboratory provide training for all personnel inclusive of the areas listed in ISO 15189:2012 Clause 5.1.5? Are trainees supervised at all times? Is the training programme periodically reviewed for effectiveness?	Annual training plan Employee training plans Training course outlines and reports Training records Reviews of training programmes					X	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.1.6 Competence Assessment									
5.1.6	Does the laboratory assess the competence of each person to perform assigned managerial or technical tasks? Does the laboratory periodically reassess competence and retrain when necessary?	Competency assessment records Established criteria for competency of managerial and technical tasks Training Records					X	x	
5.1.7 Reviews of staff performance									
5.1.7	Do staff performance reviews consider the needs of the laboratory and the individual in order to maintain or improve the quality of service provided?	Performance reviews Evidence of reviews addressing continual improvement issues and customer service					X	x	
5.1.8 Continuing education and professional development									
5.1.8	Does the laboratory have a continuing education programme available to managerial and technical personnel? Is the programme periodically reviewed for effectiveness? Do personnel regularly participate in professional development or other professional liaison activities?	Documented continuing education programme Evidence of personnel participation in the continuing education programme Evidence of reviews of continuing education programme for effectiveness Continuing education records, certificates					X	x	
5.1.9 Personnel records									
5.1.9	Are personnel records maintained and accessible for all personnel?	Personnel records including at least requirements stated in ISO 15189:2012 Clause 5.1.9					X	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.2 Accommodation and Environmental Conditions									
5.2.1	Does the laboratory have work space that is designed to ensure the quality and efficacy of the service and the health and safety of laboratory personnel, patients and visitors? Has the laboratory evaluated the adequacy of the space allocated for its work?	Laboratory layout, space and infrastructure in accordance with international guidelines Records of evaluation					x	x	
5.2.2	Do the laboratory and office facilities provide a suitable environment that ensures the requirements of ISO 15189:2012 Clause 5.2.2	Laboratory and associated facilities layout, safety, confidentiality, and quality practices Evidence of restricted access to examination spaces Specimen collection and transport procedures Records of environmental monitoring of specimen collection and examination areas Communication Process Record of performance checks on safety devices				X	x	x	
5.2.3	Are adequate storage spaces and conditions provided? Are clinical samples and materials stored appropriately to prevent cross contamination? Are storage and disposal facilities for dangerous materials appropriate to the hazards of the materials?	Examine the conditions of storage spaces for sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results Records of monitoring of storage conditions. Methods of waste management and disposal				X	x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.2.4	Does staff have adequate access to washrooms, drinking water, storage facilities for personal protective equipment and clothing?	Examine condition of staff facilities Observe use of PPE				X	x	x	
5.2.5	When primary sample collection facilities are provided, are considerations made for accommodating patient comfort, needs and privacy? Are appropriate first aid materials for both patient and staff needs available at collection facilities?	Layout of specimen collection and accessioning area Facilities and accommodation for patients with disabilities First aid kits and emergency materials				X	x	x	
5.2.6	Are the laboratory premises maintained in a functional and reliable condition? Are work areas clean and well maintained? Does the laboratory monitor, control and record environmental conditions? Is there effective separation between neighbouring areas where incompatible activities are performed? Are appropriate measures taken to prevent cross-contamination? Is a quiet uninterrupted work environment provided?	Clean and well maintained work areas, housekeeping schedule and records Records of environmental monitoring Laboratory layout Procedure to prevent cross contamination				X	x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.3 Laboratory Equipment, reagents and consumables									
5.3.1 Equipment									
5.3.1.1	Does the laboratory have a documented procedure for the selection, purchasing and management of equipment? Is the laboratory furnished with all the items of equipment required for its services?	Procedure for selection, purchasing and management of equipment Laboratory equipment inventory list				x	x	x	
5.3.1.2 Equipment acceptance testing									
5.3.1.2	Is equipment shown to be capable of achieving the performance required and complies with specifications relevant to the examinations concerned? Is each piece of equipment uniquely labelled, marked or otherwise identified?	Equipment verification records Equipment List of with unique identifier Labels on each piece of equipment					x	x	
5.3.1.3 Equipment instructions for use									
5.3.1.3	Do only trained and authorized personnel operate equipment? Does the laboratory have procedures for safe handling, transport, storage and use of equipment to prevent its contamination/ deterioration? Are up-to-date instructions on the use and maintenance of equipment readily available to laboratory personnel?	Training and personnel records and competency assessment records Procedures for proper use of equipment Manufacturers' equipment manuals, and directions for use				X	x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.3 Laboratory Equipment, reagents and consumables									
5.3.1.4 Equipment calibration and metrological traceability									
5.3.1.4	Does the laboratory have a documented procedure for the calibration of equipment that directly or indirectly affects examination results? Does the procedure ensure that the laboratory meets the requirements of ISO 15189:2012 Clause 5.3.1.4? Is the metrological traceability to a reference material or reference procedure of the higher metrological order? Where not practical, are other methods utilised?	Documented procedure for calibration which includes requirements of Clause 5.3.1.4 a) to f) ISO 15189:2012 Calibration certificates or Calibration records Records of use of certified reference materials						x	
5.3.1.5 Equipment maintenance and repair									
5.3.1.5	Does the laboratory have a documented programme of preventive maintenance? Are equipment maintained in a safe working condition and in working order? Is defective equipment taken out of service and clearly labelled? Is repaired equipment shown by verification to meet specified acceptance criteria before being placed back in operation? Does the laboratory examine the effect of defects on the previous examinations? Are reasonable measures taken to decontaminate equipment prior to service, repair or decommissioning? Does the laboratory provide suitable space for repairs and appropriate personal protective equipment? When equipment goes outside the direct control of the laboratory, is performance verified before resumption of use?	Records of preventive maintenance/service of equipment, as advised by the manufacturer Records of corrective action taken Labels on defective equipment Records of post service verification Records of review and corrective action on previous examination results Decontamination records PPE policy Records of performance verification for returned equipment					x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.3.1.6 Equipment adverse incident reporting									
5.3.1.6	Does the laboratory investigate adverse incidents and accidents that can be attributed directly to specific equipment and report this to the equipment manufacturer and appropriate authorities?	Adverse incident reports and reporting forms						x	
5.3 Laboratory Equipment, reagents and consumables									
5.3.1.7 Equipment records									
5.3.1.7	Are records maintained for each item of equipment that contributes to the performance of examinations?	Records for each piece of equipment, that include aat least the items listed in ISO 15189:2012 Clause 5.3.1.7:					x	x	
5.3.2 Reagents and consumables									
5.3.2.1	Does the laboratory have a documented procedure for management and inventory of reagents and consumables?	Procedures for reception, storage, and acceptance testing and inventory management of consumables and reagents					x	x	
5.3.2.2	Does the laboratory verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration? Are received reagents and consumables stored according to manufacturer's specifications?	Records of verification of conditions at receiving locations Examine storage conditions for reagents and consumables					x	x	
5.3.2.3	Does the laboratory verify the performance of examination kits before use?	Records of acceptance testing						x	
5.3.2.4	Does the laboratory have an inventory control system for reagents and consumables? Does the inventory control system segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use?	Inventory records Examine the storage facility for labelling and organisation Inspection Checklist					x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.3.2.5	Are the instructions for use of reagents and consumables readily available?	Reagent and Consumable instructions				x	x	x	
5.3.2.6	Does the laboratory investigate adverse incidents and accidents that can be attributed directly to specific reagents and consumables and report this to the manufacturer and appropriate authorities?	Adverse incident reports and reporting forms						x	
5.3. 2 Reagents and Consumables									
5.3.2.7	Does the laboratory maintain records for each reagent and consumable that contributes to the performance of examinations? Does the laboratory maintain records for each reagent that is prepared or completed in-house?	Records of reagents and consumables including items listed in ISO 15189:2012 Clause 5.3.2.7 Identification of persons preparing in-house reagents and date of preparation					x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.4 Pre examination Processes									
5.4.1	Are there documented procedures and information for pre-examination activities that ensure the validity of the results of examinations?	Procedure for validity of pre-examination activities User Manual				x	x	x	
5.4.2 Information for patients and users									
5.4.2	Does the lab provide appropriate information for patients and users of the laboratory services? Does the laboratory provide information for patients and users that include an explanation of the clinical procedures to be performed to facilitate informed consent?	User manual which include items listed in ISO 15189:2012 Clause 5.4.2				x	x	x	
5.4.3 Request form Information									
5.4.3	Does the laboratory have request forms?	Request forms with at least the requirements of ISO 15189:2012 Clause 5.4.3				x	x	x	
5.4.3	Does the laboratory have a documented procedure regarding verbal requests for examinations?	Procedure for verbal requests for examinations					x	x	
5.4.4 Primary sample collection and handling									
5.4.4.1	Does the laboratory have documented procedures for the collection and handling of primary samples that are available to sample collectors within and outside of the laboratory?	Procedures for the collection and handling of primary samples Distribution list				x	x	x	
5.4.4.2	Does the lab have instructions for pre-collection activities?	Instructions for pre-collection activities that include the items listed in ISO 15189:2012 Clause 5.4.4.2				x	x	x	
5.4.4.3	Does the lab have instructions for collection activities?	Instructions for collection activities that include at least the items listed in ISO 15189:2012 Clause 5.4.4.3				x	x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.4.5 Sample transportation									
5.4.5	Does the lab have instructions for post-collection activities that address requirements for packaging of samples for transportation?	Procedures (Post-Collection activities) in User Manual				x	x	x	
5.4.5	Does the laboratory have a documented procedure for monitoring the transportation of samples?	Procedures for monitoring the transportations of samples that meets the requirements of ISO 15189:2012 Clause 5.4.5					x	x	
5.4.6 Sample reception									
5.4.6	Does the laboratory have a sample reception procedure? Are all portions of the sample traceable to the original primary sample?	Sample reception procedure which ensures that the requirements of ISO 15189:2012 Clause 5.4.6 are met.					x	x	
5.4.7	Does the lab have procedures for pre-examination handling, preparation and storage?	Procedures for pre-examination handling, preparation and storage that: a) ensures security of patient samples b) prevents deterioration, loss or damage during pre-examination activities and during handling, preparation and storage c) include time limits for requesting additional examinations on the same primary sample. Examine sample storage facilities					x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.5 Examination Processes									
5.5.1 Selection, verification and validation of examination procedures									
5.5.1.1	Does the laboratory use validated examination procedures? Is the identity of persons performing activities in the examination processes recorded?	Established validated procedures appropriate for meeting the needs of users Records of persons performing examination activities					x	x	
5.5.1.2	Are validated examination procedures independently verified by the laboratory before being introduced into routine use? Has the laboratory obtained from the manufacturer/method developer information for confirming the performance characteristics? Has the laboratory confirmed through objective evidence that the performance claims for the examination procedure have been met? Are results obtained and the procedure used for verification recorded? Does staff with the appropriate authority review the verification results and record the review?	Procedures for verifying all examination processes Records of all verification procedures and results Records of review of verification results List of staff authorised to review verification results						x	
5.5 Examination Processes									
5.5.1.3	Does the laboratory validate examination procedures derived from: a) Non-standard methods? b) Lab-designed or developed methods? c) Standard methods used outside their intended scope? d) Validated methods subsequently modified? Has the laboratory confirmed through objective evidence that the performance claims for the examination procedure have been met?	Procedure for validation of examination procedures Records of all validation results Records of review of validation results List of staff authorised to review and approve validation results						x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
	Are results obtained and the procedure used for validation recorded? Does staff with the appropriate authority review the validation results and record the review? Are changes to validated examination procedures documented and are new validations performed?								
5.5.1.4 Measurement uncertainty of measured quantity values									
5.5.1.4	Has the laboratory determined measurement uncertainty for each measurement procedure in the examination phase which reports measured quantity values on patients' samples? Are performance requirements for measurement uncertainty defined and regularly reviewed? Is measurement uncertainty considered when interpreting measured quantity values and are these made available to users? Where there is no measured quantity value, does the laboratory calculate the uncertainty of the measurement step in assessing reliability of the examination procedure on the reported result?	Measurement uncertainty for each measurement procedure Measurement uncertainty performance requirements Records of review of performance requirements User communications of measurement uncertainty e.g. in reported results, User Manual, letter/email.						x	
5.5.2 Biological reference intervals or clinical decision values									
5.5.2	Are the biological reference intervals or clinical decision values: a) Defined by the laboratory? b) Documented along with the basis for them? c) Communicated to users?	SOPs, User Manual						x	
	Does the laboratory make appropriate changes if a particular reference interval is no longer appropriate for the population served? Are such changes in biological reference intervals communicated to users?	Records of investigations of biological reference intervals as necessary User communications e.g. letter/email, newsletter, User Manual.						x	
	Are biological reference intervals 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	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.5.3 Documentation of Examination Procedures									
5.5.3	Are all examination procedures documented in a language commonly understood by staff and available in an appropriate location? Do condensed documents correspond to the documented procedure? Are all documents associated with the performance of examinations subject to document control? In addition to document identifiers, do procedure documents contain required information? If changes are planned to an existing examination procedure such that results or their interpretations could be significantly different, are the implications explained to users after validating the procedure.	Controlled examination procedures which includes, as applicable the items listed in ISO 15189:2012 Clause 5.5.3 Document controlled job aids Records of communication to users				x	x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.6 Ensuring Quality of Examination Results									
5.6.1	Does the laboratory ensure the quality of examinations by performing them under defined conditions? Does the laboratory ensure appropriate pre- and post-examination processes are implemented? Does the laboratory ensure that no results are fabricated?	Records of environmental and equipment monitoring. Internal quality control records for every laboratory examination. Records for all aspects of testing, including specimen handling, requests, examinations and reporting				x	x	x	
5.6.2 Quality Control									
5.6.2.1	Does the laboratory design quality control procedures that verify the attainment of the intended quality of results?	Quality control procedures including: a) Frequency of conduct of internal quality control b) Methods of analysis of quality control data c) Actions to be taken in the event of quality control failure					x	x	
5.6.2.2 Quality Control Materials									
	Does the laboratory use appropriate quality control materials? Are quality control materials periodically examined to prevent erroneous results and to ensure continued suitability?	Quality control records and manufacturer's information and data e.g. package and kit inserts				x	x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.6.2.3 Quality Control Data									
	Does the laboratory have a procedure to prevent the release of patient results in the event of quality control failure? Does the laboratory reject results and re-examine patient samples when a quality control performance error is detected that indicates that examination results are likely to contain clinically significant errors? Does the laboratory evaluate the results from patient samples examined after the last successful quality control event? Does the laboratory review quality control data at regular intervals to detect trends and take preventive action as necessary?	Documented procedure for handling QC failures Quality control records Quality control corrective and preventive action records					x	x	
5.6.3 Inter-laboratory comparisons									
5.6.3.1 Participation									
5.6.3.1	Does the laboratory participate in inter-laboratory comparisons appropriate to the examination and interpretations of results? Does the laboratory monitor the results of inter-laboratory comparisons and participate in the implementation of corrective actions when performance criteria are not fulfilled? Is there a procedure for inter-laboratory comparison participation? Does the programme provide clinically relevant challenges that mimic patient samples and check the entire examination process, where possible?	Records of participation in eternal quality assessment (EQA) programmes Procedure including responsibilities and performance criteria for inter-laboratory comparison programme participation Records of monitoring of results Records of implementation of corrective actions where indicated						x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.6.3.2 Alternative approaches									
5.6.3.2	When inter-laboratory comparison programmes are not available, does the laboratory develop approaches for determining the acceptability of examination results?	Review Records such as those listed in the note under Clause 5.6.3.2 of ISO 15189:2012 Any other suitable programmes					x	x	
5.6.3.3 Analysis of inter-laboratory comparison samples									
5.6.3.3	Has the laboratory integrated inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples? Are these performed by personnel who routinely examine patient samples using routine methods? Does the laboratory avoid collaboration with other participants about sample data before the deadline for submission of the data? Does the laboratory avoid referring inter laboratory comparison samples before submission of results?	Records for handling and reporting of inter-laboratory comparison samples.					x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.6.3.4 Evaluation of laboratory performance									
	Is performance in inter-laboratory comparisons reviewed and discussed with relevant staff? When pre-determined performance criteria are not fulfilled, does staff participate in the effective implementation and recording of corrective action? Is preventive action taken where trends in returned results indicate potential nonconformities?	Records of: 1. Review of performance with relevant laboratory staff 2. Corrective action 3. Monitoring of effectiveness of corrective action 4. Preventive action.					x	x	
5.6.4 Comparability of examination results									
5.6.4	For examinations performed using same or different procedures, equipment, and/or different sites: Is there a defined means for comparing procedures, equipment and methods and establishing the comparability of results throughout the clinically appropriate intervals? Does the laboratory notify users of any differences in comparability of results and discuss implications for clinical practice? Does the laboratory document and record the results of the comparisons performed and the actions taken?	Process for periodically verifying the comparability of results when same or different procedures, equipment and/ or sites are used Records of comparisons of procedures, equipment and/or sites. User information bulletins/memos, meetings. Records of actions taken based on problems or deficiencies identified.						x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.7 Post- Examination Procedures									
5.7.1 Review of Results									
5.7.1	Does the laboratory have procedures to ensure authorized personnel review examination results before release, against internal quality control, clinical information and previous examination results?	Procedure for the review of results before they are released Records of authorization of results before release				x	x	x	
5.7.2 Storage, Retention and disposal of clinical samples									
5.7.2	Does the laboratory have a documented procedure for identification, collection, indexing, access, retention, storage, maintenance and safe disposal of samples? Does the laboratory have defined sample retention times with criteria which are based on the nature of the sample, the examination and specified requirements? Are samples disposed safely and in accordance with regulations or recommendations for waste management?	Documented procedure for sample control, retention and storage Stored samples Waste Management Regulations applied in the safe disposal of samples					x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.8 Reporting of Results									
5.8.1	Are results of each examination reported accurately, clearly, unambiguously in accordance with specific instructions in a defined format and medium? Does the laboratory have a procedure to ensure the correctness of result transcription? Is there a process for notifying requester when an examination which could compromise patient care is delayed?	Copies of issued Laboratory Reports Documented procedure for verification of transcription Process for notifying requesters when examinations are delayed Copies of requester notification					x	X	
5.8.2 Report Attributes									
5.8.2	Do the laboratory reports effectively communicate laboratory results and meet users' needs in accordance with ISO 15189:2012 Clause 5.8.2?	Copies of issued laboratory reports Feedback from users Criteria for acceptance/rejection List of critical values					x	X	
5.8 Report Content									
5.8.3	Does the laboratory have a standardized reporting format?	Laboratory reports that include the requirements of ISO 15189:2012 Clause 5.8.3				x	x	X	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.9 Release of results									
5.9.1	Does the lab have documented procedures for the release of examination results, including who may release results and to whom?	Documented procedure for release of examination results Copies of final reports with notes about sample quality Log of actions for critical results reporting Copies of original results, Copies of interim and final reports Logs for telephone and electronic results transmission, Policy for results distributed by telephone and other electronic means					x	X	
5.9.2 Automated Selection and Reporting of Results									
5.9.2	Does the laboratory have a documented procedure for automated selection and reporting of results?	Evidence will only be required if this activity is applicable to the laboratory. Documented procedure for automated selection and reporting of results Refer to requirements of ISO 15189:2012 Clause 5.9.2						x	
5.9.3 Revised Reports									
5.9.3	Does the Laboratory have written instructions regarding the revision of reports ensuring the original report is referenced, the user is notified and the action is recorded? Does the Laboratory keep records of revisions when the reporting system cannot capture amendments, changes or alterations?	Procedure for revision or alteration of reports Copies of altered reports					x	x	

TECHNICAL REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
5.10 Laboratory information management									
5.10.1	Does the Laboratory have a documented procedure to ensure the confidentiality of patient information is maintained at all times?	Documented procedure on confidentiality of paper based and/or computer data					x	x	
5.10.2 Authorities and Responsibilities									
5.10.2	Has the laboratory defined the authorities and responsibilities for the management of the information system, including maintenance and modification affecting patient care? Has the laboratory defined the authorities and responsibilities of the personnel who use the Information Management System?	Job Descriptions List of authorities for Information Management system according to requirements of ISO 15189:2012 Clause 5.10.2 IT user manual					x	x	
5.10.3 Information system management									
5.10.3	Is there evidence that the Laboratory information system meets the requirements of ISO 15189 Clause 5.10.3? Does the laboratory have a documented contingency plan for maintenance of services in the event of an information system failure or downtime which affects the laboratory's ability to provide service?	Validation and verification data and records including system training checklist LIS User manual and SOPs Copy of national or international requirements for data protection List of authorized users Copy of LIS Contingency plan Corrective Action Reports						x	

SAFETY REQUIREMENTS

Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
Section 1: Safety Officer, Safety Manual, Safety Programme										
6.1		Is there an appointed Biosafety Officer (BSO)?	Job description, letter of appointment				x	x	X	
6.2		Has the BSO been trained to perform their duties?	Training records					x	X	
6.3	**7.2, 7.4, 8**	Is a safety manual specific for the laboratory's needs readily available to all employees?	Safety manual to include (but not be limited to): *a) fire prevention, electrical safety* *b) accidents/incidents* *c) chemical, radiation and biohazards* *d) hazardous material identification, labelling, storage, spill clean up and waste disposal, use of MSDS sheets* *e) detailed instructions for evacuation* *f) health and safety committee*					x	X	
		Is there evidence that employees have read the manual?	Sign-off sheets							
6.4	**7.2, 7.4, 8, 17.1**	Are there instructions regarding job hazards that describe how to carry out tasks safely and what to do if an incident occurs?	Documented procedure/instructions - Use of BSC, Spills, Needle stick injuries, Blood, Equipment (Centrifuge, Autoclave)					x	x	
6.5	**7.2, 7.4**	Are other essential safety-related procedures, policies (aside from the safety manual) available in the laboratory?	Documents, binders, texts - E.g., MSDS on all chemical and biological agents					x	x	
6.6	**7.3.1, 7.5.3**	Is the safety program reviewed annually?	Safety program review report to include the following documents and records: a) safety and health policy b) written procedures that include safe work practices c) education and training						x	

SAFETY REQUIREMENTS

Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
			d) reports of physical inspections e) hazardous materials and substances f) health surveillance g) first aid services and equipment h) investigation of accidents and illnesses							
6.7	**7.3.2**	Is there evidence that work areas are inspected annually for safety?	Safety inspection report covering the following: (a) fire emergency apparatus, alarms and evacuation processes, ready and functioning (b) hazardous spillage containment procedures and materials or necessary equipment, available and in good working order (c) proper storage of flammable and combustible materials (d) proper decontamination and disposal processes				x	X	x	
6.8	**8**	Are hazardous areas and the presence of certain hazards (e.g., flammable) identified?	Conspicuously posted signs/notices and labels for hazardous materials				x	x	x	
6.9	**8**	Are visitors, non-permanent staff and other workers made aware of hazards in the laboratory?	Records of visitor briefing				X	x	x	
6.10		Has the laboratory performed a risk assessment to determine which procedures require the use of a biological safety cabinet?	SOP for Risk Assessment Reports of risk assessment					x	x	
Section 2: Reporting of Incidents, Accidents and Occupational Illness										
6.11	**7.5.2, 9**	Is there a program for reporting safety-related accidents/incidents?	Procedure and reporting forms Accident/incident Reports					X	x	

SAFETY REQUIREMENTS

Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
6.12	**7.5.2, 9**	Are detailed reports filed for all incidents/accidents?	Detailed Reports giving persons involved, time and place, identification of the cause, and recommendations for prevention and actions).					x	x	
6.13	**9**	Are the accident/incident reports reviewed by laboratory management to ensure that remedial action(s) is taken to avoid recurrence?	Evidence of review and associated remedial actions					X	x	
6.14	**7.5.2**	Is there a procedure and process (e.g., vaccination where applicable) regarding occupational exposure to Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and tuberculosis?	Documented procedure on control occupational exposure				X	x	X	
Section 3: Training										
6.15	**5.2, 7.5.2, 9**	Is there evidence that a safety training program is in place?	Manuals and training records of at least the following areas: *a) staff orientation and periodic retraining* *b) fire prevention and preparedness* *c) chemical and radiation safety* *d) biological hazards* *e) standard/universal precautions* *f) infection prevention/available immunization* *g) emergency procedures* *h) transportation of Dangerous Goods* *i) personal protective equipment and clothing*					x	X	
6.16	**9, 14.1**	Is there evidence that all staff have been trained in the safe handling, use and disposal of sharp instruments and devices?	Training Records				x	x	x	
6.17	**9, 14.1, 15**	Is there evidence that staff are trained to be aware of the hazards associated with the handling of body fluids?	Training Records				X	x	x	

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Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
6.18		Are lab employees trained to ensure that all applicable regulations are followed when transporting or offering for transport biological material and dangerous goods?	Records of staff trained in dangerous goods transport.					x	x	
Section 4: Personnel Responsibilities and Safe Work Practices										
6.19	**5.2, 14.1, 14.2, 15**	Do staff consistently practice standard precautions to ensure the protection of themselves, co-workers, patients, and the public from exposure to sources of danger?	Direct observation				X	x	x	
6.20		Are all samples, control materials, biologically sourced calibrators, cultures and waste assumed to contain viable pathogens and handled in a safe manner?	SOP for safe handling of pathogens				x	x	x	
6.21	**11.1**	Are food and drink prohibited in the laboratory where specimens are stored and handled and from specimen/reagent refrigerators?	Signs and policy on handling food and drink in the lab, direct observation				X	x	x	
6.22		Is the use of cell phones prohibited in the lab (unless authorized)?	Signs and policy on cellular telephone use in the lab				x	x	x	
6.23	**11.1**	Is smoking prohibited in the laboratory?	Lab policy prohibiting smoking in the lab				X	x	x	
6.24	**11.1**	Is there evidence that the application of cosmetics and the handling of contact lenses are prohibited in the laboratory?	Signs and policy on cosmetic use and contact lenses in the lab				x	x	x	
6.25	**11.1**	Are arrangements in place to warn of hair, beards, loose clothing and jewellery being caught in equipment or contaminated by infectious substances?	Lab policy on safety precautions for long hair, beards, loose clothing and jewellery				X	x	x	
6.26	**11.4**	Is personal property stored where it cannot become contaminated?	Direct observation				x	x	x	

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Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
6.27	**6.2, 12.7, 14.2**	Are workers and visitors required to wash their hands immediately after contact with infectious substances, patients or when leaving the lab?	Lab policy on handwashing and hygiene				X	x	x	
6.28	**6.2, 12.9e**	Are dedicated hand-washing sinks available and located in areas where biological materials are handled or close to exits?	Sinks with appropriate signage				x	x	x	
6.29	**14.1**	Is there evidence that mouth pipetting is prohibited?	Lab Policies on mouth pipetting and direct observation				X	x	x	
6.30	**14.1, 23**	Has the laboratory management determined and implemented a procedure for handling sharps, including use of puncture-resistant containers?	Procedure for handling and disposal of sharps and direct observation of WHO approved sharps containers				x	x	x	
6.31	**15**	Are samples centrifuged safely?	Written instructions for use and safety with centrifuges to include lockable lids, rotor cover, bucket covers				X	x	x	
Section 5: Personal Protective Clothing and Equipment										
6.32	**12.1, 12.3, 14.2, 17.1**	Is PPE provided to staff, visitors, and patients as required?	Procedure for distribution and use of PPE				X	x	x	
6.33	**12.1, 12.2**	Is PPE changed when necessary and removed when leaving the lab?	Protective clothing changed when necessary and immediately if contaminated with hazardous materials - direct observation				X	x	x	
6.34	**12.1**	Has the laboratory management determined and implemented the criteria for the transport and washing of contaminated clothing?	Procedure for transport and washing of contaminated PPE/clothing				x	x	x	
6.35	**12.4**	Has the laboratory management provided appropriate gloves for those staff that suffer from allergies or reactions?	Direct observation, Policy on handling latex allergies				X	x	x	

SAFETY REQUIREMENTS

Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
6.36	**12.5**	Is there evidence that shoes with open toes are prohibited in the laboratory?	Direct observation, Policy on lab approved footwear				x	x	x	
Section 6: First Aid and Emergency Practices										
6.37	**12.9f**	Are appropriately trained personnel and appropriate equipment available to provide first aid, if required?	Training Records and procedure on administering first aid					x	x	
6.38	**20**	Is there a plan for emergency evacuation?	Documented emergency plan					x	x	
Section 7: Good Housekeeping										
6.39	**13**	Are laboratory work areas tidy and uncluttered, exits, aisles and corridors unobstructed?	Direct observation of areas clean, trash disposed				X	x	x	
6.40	**6.3.1, 6.3.7**	Are there exit signs and adequate lighting at the point of exit from the laboratory?	Appropriate signage				x	x	x	
6.41	**13**	Is there documented evidence that work surfaces and equipment are cleaned and disinfected when required (whenever spills or contaminations occur) and laboratory benches disinfected at the end of each shift?	Decontamination logs, Records of spills and actions taken, Procedure for decontamination				X	x	x	
6.42	**13,23**	Is a person designated to oversee good housekeeping practices?	Duty roster, Terms of reference				X	x	x	
Section 8: Biological Hazard Containment										
6.43	**16**	Have biological safety cabinets been certified by a qualified person before being placed into service, when HEPA filters are changed, when moved or after maintenance, and at least annually to ensure that they function as designed?	Certificates of inspection (Class I and II), maintenance log					X	x	

SAFETY REQUIREMENTS

Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
6.44		Does the laboratory employ an appropriate containment level for their operational practice and are staff familiar with required operational guidelines?	Training records, Procedure for operation in BSL 2,3 or higher					x	x	
Section 9: Chemical Safety (Including Gases and Liquid Nitrogen)										
6.45	**17.1**	Are hazardous liquids and gas cylinders appropriately stored?	Proper (Appropriate storage) cabinets, restraints for gas cylinders					X	x	
6.46	**12.1, 17.2**	Does the lab have eye wash stations?	Eye wash station(s), maintenance log					X	x	
6.47	**12.11, 17.2**	Are emergency showers available where needed, are they tested periodically and is documentation kept?	operational Shower and documentation of inspection					X	x	
6.48	**13, 17.2, 19.4**	Are chemical spill kits available?	Spill kits, checklist of items included					X	x	
6.49	**13, 17.3**	Is there a process defined for the disposal of chemicals?	Procedure for disposal of chemicals					x	x	
Section 10: Electrical and Fire Safety										
6.50	**21**	Is there evidence that power cords and plugs are regularly inspected for damage and fraying?	Records of electrical inspection and procedure for checking electrical safety					X	x	
6.51	**20**	Is there a complete fire safety plan?	Fire safety plan						x	
6.52	**19.7**	Are portable fire extinguishers visible and accessible, and do they have the correct rating for the hazards present?	Fire extinguishers, guidance on use of Class A,B,C,D extinguisher for different fires					x	x	
6.53	**19.6, 19.7, 20**	Is there evidence that all personnel participate in an annual fire drill or other emergency evacuation training?	Records of fire drill, evacuation training					X	x	
6.54	**19.5**	Are containers for flammable liquids as small as possible, appropriately stored and closed when not in use and are they transported in safety containers?	Appropriate safety containers, SOP for transport, use and disposal of flammable liquids				x	x	x	

SAFETY REQUIREMENTS

Section numbers	ref to ISO 15190	Requirement	What to look for	Status			Quality Improvement Levels			Comments
				Y	N	NA	Tier 1	Tier 2	Tier 3	
6.55	**19.4**	Are areas well-ventilated where flammable gases and liquids are used?	Direct observation, Policy on use of flammable gases and liquids				X	x	x	
6.56	**19.4**	Are flammable gases and liquids kept away from sources of heat or ignition including electric motors and direct sunlight?	Procedure for storage of flammable liquids				x	x	x	
Section 11: Waste Disposal										
6.57	**18.3, 23**	Are staff familiar with the requirements for the handling and disposal of hazardous waste?	Training Records				X	x	x	
6.58	**23**	Is waste disposed of on a regular basis and not allowed to accumulate?	Procedure for disposal of hazardous wastes				x	x	x	

General comments:

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