ISO 15189

ASSESSMENT

WORKSHEET

This self assessment worksheet has been designed to assist facility staff.

Facility staff can use this checklist as part of their preparation for an assessment to ISO 15189.

There is NO need to return the completed checklist to the Association.

References to the relevant clauses of the NATA Accreditation Criteria (NAC) have been provided. The Standard, the standard application document, the field application document and any relevant annexes should also be checked for further details, as this worksheet provides only a brief summary of the clauses of the Standard.

DOCUMENT REVIEW OF MANAGEMENT SYSTEM

4.1 Organisation and management responsibility

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.1.1.3	Ethical conduct • ensure there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operation integrity; • ensure management and personnel are free from any undue commercial, financial or other pressures and influences that may adversely affect the quality of their work; • potential conflicts in competing interest shall be openly and appropriately declared; • procedures are in place to ensure staff treat human samples, tissues or remains according to relevant requirements; and • confidentiality of information is maintained.			
4.1.1.4	Laboratory director (Medical Director for Cat M) • Is the laboratory director identified? • Are the duties and responsibilities of the laboratory director documented? • Is the clinical director identified? • Is the clinical input by pathologists adequate? • Are there adequate arrangements for supervision in the absence of the pathologist/ senior scientist/ medical director (Cat M facilities) in-charge? • Is there adequate supervision of after-hours staff?			

ISO 15189 Assessment worksheet

4.1.2 Management responsibility

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.1.2.1	Management commitment • Communicating to staff the importance of meeting the needs and requirements of users, regulatory and accreditation requirements;			
4.1.2.2	Needs of users/ scope of management system • Ensure management system covers activities in the laboratory's permanent facility, sites away from its permanent facilities, temporary or mobile facilities; • Is the range/ amount of testing appropriate? • Is the laboratory a specialised reference centre? • Does the laboratory reference the scope of accreditation?			
4.1.2.3	Quality policy Ensure the quality policy statement is issued under the authority of the laboratory director and includes: • is appropriate to purpose of organisation; • commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of services; • provides a framework for establishing and reviewing quality objectives; • is communicated and understood within the organisation; and • is reviewed for continuing suitability.			
4.1.2.4	Quality objectives and planning • quality objective established, measurable and consistent with quality policy; and • ensure that the integrity of the quality management system is maintained when changes are planned and implemented.			

ISO 15189 Assessment worksheet

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.1.2.5	Responsibility, authority and interrelationships • Are defined, documented and communicated; • Staff appointed which have overall responsibility for each laboratory function; • Where practical, appoint deputies for key managerial and technical personnel. • Is there an appropriate level of supervision at the main site? • Is there an appropriate level of supervision at peripheral (Cat B) sites? Document by whom, when and what is performed at supervisory visits. Refer NPAAC. • Do records detail the specific activities undertaken at supervisory visits to Cat B sites? (Refer FAD). • Do out-of-hours staff (including weekend staff) have sufficient contact with routine and supervisory staff? • Are arrangements adequate in the event of staff absences? • Are relief arrangements for all senior staff documented?			
4.1.2.6	Communication Records kept of items discussed in communications and meetings.			
4.1.2.7	Quality manager Appoint a member of staff, with direct access to senior management, as quality manager who has defined responsibility and authority for implementing and maintaining the management system.			

ISO 15189 Assessment worksheet

4.2 Quality management system

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.2.1	Document procedures as a management system to ensure quality of all work and that they are communicated, available, understood and implemented.			
4.2.2 4.2.2.1e	Documentation requirements Including copies of applicable regulations, standards and other normative documents (can be in any form, provided it is readily accessible and protected).			
4.2.2.2	Quality manual • The quality policy or reference to the quality policy; • A description of the scope of the quality management system; • A presentation of the organisation and management structure of the laboratory and its place in any parent organisation; including relationships between quality management, technical operations, support services and parent organisation (if applicable); • A description of the roles and responsibilities of the laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard; • A description of the structure and relationships of the documentation used in the quality management system (QMS); • The documented policies established for the quality management system and reference to the managerial and technical activities that support them. • All laboratory staff must have access to and be instructed on the use and application of the quality manual and the referenced documents. • Does the laboratory have a policy on the use of the NATA/RCPA logos?			

4.3 Document control

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	Ensure procedures to control all documentation required by the QMS are established and maintained and ensure that the unintended use of any obsolete document is prevented. Procedures must include: • Documents (including those maintained electronically) are reviewed and approved by authorised personnel before issue. • Documents are identifiable: Title, unique identifier on each page, the date of the current edition and/or edition number, page number to total number of pages, authority for issue. • Current authorised editions and their distribution are identifiable by means of a list (e.g. document register, log or master index, etc). • Only current, authorised editions are available at points of use/ staff on the bench. • Ensure if hand written amendments are allowed, defined procedures are available, which include authorities, clear marking, initialling, dating and formal re-issue. • Ensure that hand written amendments are made to all copies of the manual and brought to the attention of staff. • Changes/ amendments to documents are identified. • Documents remain legible when changes are made. • Documents are periodically reviewed and updated by the same function that performed the original review. • Obsolete controlled documents are dated and marked as obsolete. • One copy of an obsolete controlled document is retained for a specified time or in accordance with requirements. Refer FAD and NPAAC. • Obsolete documents/ superseded methods kept separate from current documents.			

4.4 Service agreements

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.4.1	Establishment of service agreements Requests accepted by the laboratory for examination is considered an agreement. Ensure policies and procedures related to service agreements are established, maintained and include: • Defining, documenting and understanding customer requirements before commencing work; • Laboratory's capability and resources; • Appropriate method selections; • Reference must be made to work that is to be subcontracted / referred to a referral laboratory or consultant.			
4.4.2	Review of service agreements • Maintain records of reviews, including pertinent discussions and/or changes to the contract. • Changes to contract communicated to users. • Ensure the same contract review process is repeated if a contract has to be amended after work has commenced and that all affected staff are advised of the amendment.			

4.5 Examination by referral laboratories

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.5.1	Selecting and evaluating referral laboratories and consultants • Procedure for selecting and evaluation referral laboratories/ consultants. • Are tests referred directly from this laboratory? • Are referral arrangements adequate? E.g. other accredited laboratories. • Arrangements with referral laboratories reviewed and evaluated with records kept. • Register of all referral laboratories and consultants maintained.			
4.5.2	Provision of examination results • The referring laboratory must provide results to the requestor (unless otherwise specified in agreement). • Are all essential elements of the referred results reported by the referral laboratory, without alterations which could affect clinical interpretation? • Is the author of any additional comments identified? • Does the report identify which results were performed by the referral laboratory? (Refer FAD) • Is there a system for tracking referred tests to ensure appropriate TAT?			

4.6 External services and supplies

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	• Procedure for the selection and purchasing of external services, equipment, reagents and consumables? • Does the procedure include the criteria required to make an appropriate selection of supplier or service? • Is there a current list of approved suppliers? • Does the purchasing information describe the requirements for the product/ service to be purchased? • Are approved suppliers monitored for adequate performance against stated criteria?			

4.7 Advisory services

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	• Is adequate information supplied to referring doctors/ collection centres on the collection, labelling, storage and handling of samples prior to dispatch to the laboratory? • Does appropriate staff provide advice or interpretation of results and/or logistical matters such as failure of samples to meet acceptance criteria to the users of the laboratory services? • Are changes to methods which result in significant changes to interpretation of results explained to users of the laboratory services in writing?			

4.8 Resolution of complaints

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	• Procedure implemented for the resolution of complaints from clinicians, patients, laboratory staff or other parties and sure records of the complaints, investigations and corrective actions (4.10) are maintained. • Are complaints closed out in an appropriate time frame? • Who is responsible for ensuring complaints are investigated and closed?			

4.9 Identification and control of nonconformities

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	Ensure that documented procedures are implemented to identify and manage nonconformities within the QMS and include: • Designated responsibilities and authorities for handling nonconformities; • Immediate actions to be taken are defined/ documented; • The extent of the nonconformity is determined; • Examinations are halted and reports withheld, as necessary. • Medical significance of nonconforming test is considered and requesting clinician informed. • Results of nonconforming or potentially nonconforming tests already released are recalled or identified as necessary. • Responsibility for authorising the resumption of testing is defined; and • Each episode of nonconformity is documented and reviewed to detect trends and initiate corrective action. Corrective action procedures must be implemented when evaluation indicates recurrence could occur or there is doubt regarding compliance of laboratory's operations with own procedures.			

4.10 Corrective action

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	Corrective action taken must eliminate the causes of nonconformities and the procedure must include: • Reviewing nonconformities; • Determining the root causes of nonconformities; • Evaluating the need for corrective action to ensure that nonconformities do not recur; • determining and implementing corrective action needed; • recording the results of corrective action taken; and • reviewing the effectiveness of the corrective action taken. Are corrective actions closed out in an appropriate time frame (relevant to the risk posed by the non-conformance)? Who is responsible for ensuring corrective actions are closed out?			

4.11 Preventative action

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	Ensure needed improvements and potential sources of nonconformities are identified and action plans developed, implemented and monitored, using control to ensure they are effective and that the documented procedure includes: • review information to determine potential nonconformities; • determine the rout cause; • elevate the need for preventative action; • implement preventative action; • recording results/ outcome of preventative action taken; and • reviewing the effectiveness of preventative action taken.			

4.12 Continual improvement

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	• Continually improve the effectiveness of the QMS through the review of procedures, action plans, evaluation and implementation. • Does the laboratory participate in continual improvement activities? • What do these activities involve?			

ISO 15189 Assessment worksheet

4.13 Control of records

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	Ensure a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records are implemented: • legible; • readily retrievable; • maintained in a suitable environment; • retained for established time? (Refer NPAAC) • held secure and in confidence.			
	Technical records: • original test observations, calculations and derived data • sufficient information to establish an audit trail • calibration records • staff records • copy of test reports • identity of personnel responsible for critical steps in the examination process • identity of the person reviewing QC results • Are all data transcriptions and manual calculations checked?			
	ensure any changes to the original records (including electronic) are made so that: • original record is not obscured • correct value entered alongside • alterations signed or initialled by the person making the correction • equivalent measures must be taken for records stored electronically			

ISO 15189 Assessment worksheet

4.14 Evaluation and audits

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.14.1	Does the evaluation process: ▪ demonstrate the laboratories activities meet the needs and requirements of users ▪ ensure conformity to the QMS ▪ continually improve the effectiveness of the QMS ▪ Are the results of these activities included in management review (4.15.2)			
4.14.2	Periodic review of requests, and suitability or procedures and sample requirements • Are methods/ examinations reviewed by authorised staff to ensure methods are clinical appropriate? • Are sample volume, collection device and preservative requirements periodically reviewed?			
4.14.3	Assessment of user feedback Does the organisation seek information on whether the service provided meets users' requirements?			
4.14.4	Staff suggestions Are staff encouraged to make suggestions for the improvement of the service?			
4.14.5	Internal audit • Is there a predetermined audit program? • Is there a documented procedure defining the responsibilities and requirements for planning and conducting audits, and for reporting and maintaining records? • Are audits conducted by staff trained to assess the managerial and/or technical processes of QMS? • Is the outcome of previous audits included, where necessary? • Are the audit criteria, scope, frequency and method defined and documented?			

ISO 15189 Assessment worksheet

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.14.5 (Continue)	• Are staff objective and impartial? • Where resources permit are auditors independent of the activity to be audited? • Is prompt appropriate action taken to nonconformities identified? • Does the action eliminate the causes of the nonconformities?			
4.14.6	Risk management • Does the organisation evaluate the impact of work processes and potential nonconformities in relation to the risk posed to patient safety? • Are actions taken and decisions regarding risk management documented?			
4.14.7	Quality indicators Have appropriate quality indicators been establish to cover critical aspects of: • Pre-examination/ analytical • Examination / analytical • Post examination / analytical Have quality indicators been establish which meet clinical needs and are these periodically reviewed to ensure continued appropriateness? • Have TAT been established in consultation with requestors? • Are TAT appropriate and are they being achieved?			
4.14.8	Reviews by external organisations • Have reviews by external organisations been included in the evaluation process?			

4.15 Management review

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
4.15.1	Management must conduct an annual review (Refer FAD) of the QMS to ensure continuing suitability, adequacy, effectiveness and support of patient care. How often are the reviews planned to occur? Does the organisation meet its own planning schedules?			
4.15.2	Review input • Requests, procedures and sample requirements; • User feedback and staff suggestions; • Risk management; • Quality indicators; • Reviews by external organisations; • QAP/EQA; • Complaints and Nonconformities; • Supplier performance; • Continual improvement; • Follow-up actions from previous management reviews; • Changes in volume, scope, staff, and premises; and • Recommendations for improvement (including technical requirements).			
4.15.3	Review activities • How does the review evaluate the laboratory's contribution to patient care? • What activities occur to ensure effective QM review occurs?			
4.15.4	Review output • Are records of the review documented? • Are decisions and actions taken to improve effectiveness of the QMS? • Improve service to users? • Assess resource needs? • Are findings reported to laboratory staff, if so how? • Ensure actions arising are completed within a defined timeframe			

REVIEW OF TECHNICAL ACTIVITIES

5. Technical requirements

5.1 Personnel

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.1.2	Personnel qualifications • Have qualifications been documented for each position? • Are they appropriate to the tasks to be performed?			
5.1.3	Job descriptions • Do job descriptions describe the responsibility, authorities and tasks for all personnel?			
5.1.4	Personnel introduction to the organisation • Is there an induction programme for new staff?			
5.1.5	Training Staff undergoing training must be supervised and does training include: • QMS and work procedures; • LIS; • Health and safety; • Ethics and Confidentiality. Are the effectiveness of the training programme periodically reviewed?			
5.1.6	Competence assessment • How is the competence of staff assessed after training? • Have defined criteria been established to assess competence? • How often does competence evaluation take place? • Refresher training where staff are expected to work in areas other than those in which they normally work (e.g. weekends or on-call) • On-going training for dedicated out-of-hours and/or weekend staff			
5.1.7	Reviews of staff performance • Does staff performance reviews consider the needs of the laboratory and the individual to maintain or improve the quality of service?			

ISO 15189 Assessment worksheet

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.1.8	Continuing education and professional development • Does all staff involved with managerial and technical processes partake in continuing education activities (In-house and/or external)? • And are records of these activities kept? • Are staff encouraged to attend professional society meetings? • Is there support for conference attendance?			
5.1.9	Personnel records • Are records of relevant educational, professional qualifications, training, experience and assessment of competence maintained for staff? The following records must be maintained (not necessarily by the laboratory): • Educational and professional qualifications; • Copy of certification/ license, when applicable; • Pervious work experience; • Job descriptions; • Introduction of new staff; • Training in current tasks; • Competency assessments; • Continuing education and achievements; • Staff performance reviews; • Reports of accidents and exposure to occupational hazards; and • Immunisation status, where relevant.			

ISO 15189 Assessment worksheet

5.2 Accommodation and environmental conditions

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.2.1	Laboratory and office facilities • access to areas affecting testing is controlled • medical information, patient samples and laboratory resources are safeguarded from unauthorised access • environmental conditions allow for correct performance of examinations • communication systems are appropriate to size and complexity of facility • safety devices are functioning and regularly verified			
5.2.3	Storage facilities Ensure adequate storage space and suitable conditions to prevent cross contamination?			
5.2.4	Staff facilities Appropriate staff facilities (access to washrooms, drinking water and storage of personal protective equipment).			
5.2.5	Patient sample collection facilities • Separate reception/ waiting and collection area; • Patient privacy, comfort and needs considered; • Facilities do not invalidate the result or adversely affect the quality of the examination; and • Appropriate first aid materials.			
5.2.6	Facilities maintenance and environmental conditions • Facilities maintained in a functional and reliable condition? • Environmental conditions monitored, controlled and recorded where they may influence the quality of the sample/ results. • Effective separation between incompatible activities. • Procedures in place to prevent cross-contamination where testing can be influenced by not being separated. • Provide quiet and uninterrupted work environment where needed.			

5.3 Laboratory equipment, reagents and consumables

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.3.1.1	Equipment • Ensure a documented procedure for the selection, purchasing and management of equipment. • Ensure all equipment and its software is available for use.			
5.3.1.2	Equipment acceptance testing Is new equipment (including reagents and consumables) verified prior to patient testing?			
5.3.1.3	Equipment instructions for use • Are trained and authorised staff operating equipment? • Are there up-to-date instructions on the use and maintenance of equipment, including safe handling, transport, storage and use of equipment to prevent deterioration? • Are operating manuals readily available?			
5.3.1.4	Equipment calibration and metrological traceability Ensure procedures for the calibration of equipment includes the following: • Complies with conditions of use and manufacturer instructions; • Has calibration programs been established with key quantities or values; • Is checked and/or calibrated before use with records kept of the calibration standard used; • Is capable of achieving required accuracy; • Record of calibration status and date of recalibration; • Are there records of correction factors used and have these been correctly updated? • Safeguarded to prevent adjustments or tampering.			

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.3.1.5	Equipment maintenance and repair Does the laboratory follow manufacturer instructions on maintenance of equipment? Ensure equipment subjected to overloading or mishandling, giving suspect results, or shown to be defective or outside specified limits is taken out of service, and is: • isolated or clearly labelled or marked as being out of service; • examined for the effect of the defect or departure from specified limits on previous tests and/or calibrations; • addressed under the "Control of nonconforming work" procedure (4.9). • Ensure that equipment removed from the direct control of the laboratory is verified prior to patient testing.			
5.3.1.6	Equipment adverse incident reporting Adverse incidents are investigated and reported to the manufacturer and appropriate authorities.			
5.3.1.7 5.3.2.7	Equipment and Reagent and consumables records • Identity of equipment, reagent/ consumable and equipment software; • Manufacture's name, model and serial number/ batch code or other unique identification; • Contact information for the supplier or manufacturer; • Date of receiving equipment and date of placing into service; • Date of receiving consumables/ reagents, the expiry date, date placed into use and where applicable the date taken out of use; • Evidence that the equipment complies with the accuracy requirements and with specification relevant to the tests or calibrations; • Current location of equipment, where appropriate;			

ISO 15189 Assessment worksheet

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.3.1.7 5.3.2.7 Continued	• Condition when received and initial acceptance records; • Equipment calibration history and due date of next calibration; • Equipment maintenance records and schedule of preventative maintenance; • Equipment damage, malfunction, modification or repair to equipment; • Reagent and consumable performance records that confirm ongoing acceptance for use. • Environmental monitoring records (where appropriate), e.g. temperature records, humidity, positive pressure/ flow, anaerobic conditions, etc.			
5.3.2	Reagents and consumables • Procedure for the reception, storage, acceptance testing and inventory of reagents and consumable. • Reagents and consumables are stored according to manufacturer instructions. • Verify new kit lot/ batch numbers for performance prior to patient testing (including changes in reagents and methods). • Inventory control system must segregate uninspected and unacceptable reagents and consumable from those accepted for use. • Instructions for use available. • Adverse incidents reported. • For in-house prepared reagents a record of the identity of the person and date of preparation must be kept.			

5.4 Pre-examination processes

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.4.1	• Are there document pre-examination procedures?			
5.4.2	Information for patients and users • Location, services offered and opening hours; • Instructions for self-collect and/or pre-collection requirements;			
5.4.3	Request form information • Patient identification, including gender, date of birth, patient contact details and a unique identifier; • Are three identifiers used on the request form? (Refer NPAAC) • Name or other unique identification of the requestor, including contact details; • Type of primary sample, and where relevant anatomic site of origin; • Tests requested; • Clinically relevant information; • Date and where relevant time of primary sample collection; • Date and time of sample receipt.			
5.4.4	Primary sample collection and handling • Are patients positively identified at collection, e.g. 'What is your name'? • Verification that patient meets pre-examination requirements, e.g. fasting. • Is there an 'order of draw'? • Are samples labelled after collection, in the presence of the patient? • Are the patients full name and either date of birth or medical record number recorded on the specimen collection label? • Identity of the collector, collection date and where needed collection time. • Instructions for storage before collected samples are delivered to the laboratory; and • Safe disposal of materials used in collection.			

ISO 15189 Assessment worksheet

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.4.5	Sample transportation • Are suitable containers used to transport samples? • Are transport times appropriate and are these monitored?			
5.4.6	Sample reception • Are samples, request forms and other records uniquely identified during all stages of testing? • Are there documented sample reception procedures? • Are there documented sample acceptance or rejection criteria? • Where a sample does not meet the acceptance criteria, but is processed, is a comment included in the final report? • Are samples recorded in a LIS or workbook at reception? • Is the date and time of receipt into the laboratory recorded? Including the identity of the person receiving the sample. • Is a unique identification number (laboratory number) given to samples? • Is there a procedure for processing urgent samples? • Is there a procedure for processing samples received out-of-hours? • Does the laboratory have a procedure for verbal requests? • Are portions of the primary sample unequivocally traceable to the original primary sample?			
5.4.7	Pre-examination handling, preparation and storage • Are samples stored securely and in such a way to prevent deterioration?			

5.5 Examination processes

Where new methods have been introduced, developed or deviations have been made to standard methods, records of verification and/or validation shall be requested and referred for review according to field / program procedures. Where a scope extension is requested, a DTV or VAR shall be arranged as necessary.

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.5.1	Selection, verification and validation of examination procedures • Are methods in use appropriate and validated for their intended use? • Is the source of method reference? • Where a test is performed by more than one method, are criteria available for method selection? • Are consumables, e.g. reagents, kits, antibodies, verified prior to use with patient testing? • Are records maintained for validation/ verification of new methods and changes to existing methods? • Do these records show evidence of review and authorisation? • Are appropriate staff involved in method review? • Has MU been estimated for all relevant test procedures? • Have all relevant uncertainties been considered in the MU estimation (analytical processes only)?			
5.5.2	Biological reference intervals or clinical decision values • Are the sources of biological reference intervals recorded? (Refer FAD) • Are biological reference intervals reviewed when a method is changed?			
5.5.3	Documentation of examination procedures • Are documented methods clear and unambiguous? • Do staff demonstrate adequate expertise/ understanding of methods?			

ISO 15189 Assessment worksheet

5.6 Ensuring quality of examination results (QC and QAP)

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.6.2	Quality control • Are appropriate QC procedures documented and implemented? • Are results recorded and reviewed? • Does the laboratory have a system of long term monitoring of QC results which assesses method performance? • If relevant, have acceptable limits of imprecision and inaccuracy been fixed? • Is there an appropriate documented procedure to be followed when control results fall outside the acceptable limits? • Are records kept of corrective action taken to non-conforming QC results?			
5.6.3	Interlaboratory comparison (QAP) Does the laboratory participate in external quality assurance programs (QAPs) covering its full range of testing? Please consult briefing notes and detail any discrepancies. • Are QAP results satisfactory? • Are QAP results submitted to the organisers on time? • Do records show evidence of review and by whom? • Are the results of the QAPs and the available educational material discussed with staff? • Are records kept of corrective action taken to non-conforming QAP results? • Where a formal QAP is unavailable is there a mechanism for determining the acceptability of procedures e.g. sample exchange? • Where more than one method or analyser is used to perform a test, is the degree of correlation established and records of this kept?			

5.7 Post-examination processes

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
	• Is result release/validation limited to trained and qualified staff? • Are samples stored as per NPAAC retention requirements? • Are samples stored under appropriate conditions?			

5.8 Reporting of results

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.8.1	• Correctness of transcribed results; • Requestor to be notified of delayed results;			
5.8.3	Report content • Name of the test; • Identification of the laboratory issuing the report; • Identification of tests performed by a referral laboratory; • Patient identification and patient location on each page; • Name of the requestor and contact details; • Date of primary sample collection; • Type of primary sample; • Method used, where appropriate; • Units of measurement, SI units, where applicable; • Are biological reference intervals quoted on reports relevant to patient age and sex? • Interpretation of results; • other comments (e.g. method being validated, unlabelled sample) • identification of the person reviewing the results and authorising the release of the report (if not contained in the report, readily available when needed); • Date of the report and time of release (if not contained in the report, readily available when needed); • Page number to total number of pages; • Accreditation number; • Test sample number; • Where relevant, corrected and original results;			

5.9 Release of results

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.9.1	• Does the laboratory have a policy for releasing results including who may release results and to whom? • Is a comment included in the report when the quality of the sample may compromise the test results, eg haemolysis, lipaemia, icterus? • NOTE: 'compromised' samples do not include mislabelled or inadequately labelled samples. • Does the laboratory have a procedure for notification of critical results? • Are critical limits available and appropriate? • Are records maintained to document the date, time, staff member, person notified and results conveyed when results fall within critical intervals? Does the laboratory have a documented protocol for telephoning results? Are appropriate records maintained? • date and time of release • who received report • issuing person			
5.9.2	Automated selection and reporting of results • If interim reports are accessible electronically, is the interim status evident to the enquirer? • Is there a documented procedure for the automated release of reports which meets 5.9.2?			
5.9.3	Revised reports • Where results have been available for clinical-decision making and subsequently amended, are the amendments identifiable from the original results?			

ISO 15189 Assessment worksheet

5.10 Laboratory information management

Clause No.	Activities	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
			Yes	No
5.10.1	• Is access to LIS restricted to authorised users? • Does the laboratory ensure confidentiality of patient information?			
5.10.2	Authorities and responsibilities • Defined responsibilities for the management of the LIS, including maintenance and modification to the system; Defined responsibilities for: • Access patient data and information; • Enter patient data and examination results; • Change patient data or examination results; • Authorise the release of the examination results and reports.			
5.10.3	Information system management • Validated by supplier; • Verified for functioning by laboratory before introduction (including interfaces); • Changes to the system authorised, documented and verified before implementation (including interfaces); • Procedure for day to day operation; • Protected from unauthorised access; • Safeguarded against tampering or loss; • Verify that results, including calculations and new tests, are accurately reproduced, electronically and in hard copy, by systems external to the laboratory (e.g. electronic report/ download by a requestor); • Record of system failure and corrective action taken; • Sub-contracted suppliers comply with requirements; • Contingency plan to maintain service in event of failure or downtime.			