ISO 15189 (2022) ASSESSMENT WORKSHEET

Self-assessment

This self-assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

4 GENERAL REQUIREMENTS

4.1 Impartiality

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.1 *NPAAC RMPS S2.4*	• Laboratory activities undertaken impartially; structured and managed to safeguard impartiality. • Laboratory management must be committed to impartiality. • Laboratory is responsible for impartiality of its activities; commercial, financial or other pressures must not compromise impartiality. • Laboratory activities and relationships of personnel are monitored to identify threats to impartiality. • Threats to impartiality are identified, and the effect is eliminated or minimized; laboratory must demonstrate how threats are mitigated.	

4.2 Confidentiality

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.2.1 *NPAAC RMPS S2.6*	Management of information Laboratory is responsible, through legally enforceable agreements: • privacy/confidentiality maintained of all patient information obtained/created during performance of laboratory activities. • user/patient informed in advance, of information to be placed in the public domain.	
4.2.2 *NPAAC RMPS S2.6*	Release of information • patient concerned is notified of the confidential information released.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• patient information obtained from a source other than the patient, is kept confidential. Identity of the source is not shared, unless agreed by the source.	
4.2.3 *NPAAC RMPS S2.6*	Personnel responsibility • all internal/external personnel with access to laboratory information, must keep confidential all information obtained/created during the performance of laboratory activities.	

4.3 Requirements regarding patients

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.3	Patients' well-being, safety and rights must be the primary considerations. Processes are established and implemented to include:	
NPAAC RMPS S2.1	• opportunities for patients/users to provide information to aid the laboratory in selection of methods, and interpretation of results;	
NPAAC RMPS S2.1	• provision of patients/users with publicly available information about examination processes, incl. costs, and when to expect results;	
	• periodic review of examinations to ensure clinically appropriate and necessary;	
NPAAC RMPS S2.2	• disclosure to patients/users, of incidents that resulted or could result in patient harm, and records of actions taken to mitigate those harms;	
NPAAC RMPS S2.3	• treatment of human samples, or remains, with due care and respect;	
NPAAC RMPS S2.5	• obtaining informed consent when required;	
NPAAC RMPS S2.7, S2.8	• ensure ongoing availability and integrity of retained patient samples and records in the event of closure, amalgamation, or merger of the laboratory;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
NPAAC RMPS S2.9 *NPAAC RMPS S2.1*	• information made available to the patient or health service provider upon request of the patient or the healthcare provider acting on the patient's behalf; • upholding the rights of patients to care that is free from discrimination.	

5 STRUCTURAL AND GOVERNANCE REQUIREMENTS

5.1 Legal entity

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.1 *NPAAC RMPS S4.2*	Is the laboratory or the organization of which the laboratory is a part, an entity that can be held legally responsible for its activities?	

5.2 Laboratory director

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.2.1 *NPAAC Supervision S1.1* *NPAAC RMPS S4.5*	Laboratory director competence • is there a person or persons (however named), with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document?	
5.2.2 *NPAAC Supervision S1.3, S1.4* *NPAAC RMPS S4.5* *NPAAC High-risk S1.1*	Laboratory director responsibilities • implementation of the management system. • application of risk management to all laboratory operations so risks to patient care and opportunities to improve are systematically identified and addressed. • are the duties/responsibilities of the laboratory director documented?	
5.2.3	Delegation of duties • if the laboratory director delegates selected duties/responsibilities to	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
NPAAC Supervision S1.1, S1.2 *NPAAC RMPS S4.3*	qualified personnel, do they maintain ultimate responsibility for operation and administration of the laboratory? • is the delegation documented?	

5.3 Laboratory activities

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.3.1 *NPAAC RMPS S4.1, S4.2*	General • the range of laboratory activities are defined and documented, incl. sites other than the main location. • only claim conformity for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.	
5.3.2 *NPAAC RMPS S4.1, S4.2*	Conformance with requirements • are laboratory activities carried out to meet the requirements of this document, the users, regulatory authorities and organisations providing recognition? • does this apply to the complete range of specified and documented laboratory activities, regardless of where the service is provided?	
5.3.3 *NPAAC RMPS S6.3, S6.4*	Advisory activities Appropriate advice and interpretation are available and meet the needs of patients and users. Arrangements for communicating with users are established, including: • advice on choice and use of examinations, incl. type of sample, clinical indications, limitations of examination methods, frequency of requesting the examination; • provide professional judgments on interpretation of results of examinations; • promote effective utilization of laboratory examinations;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• advice on scientific and logistic matters, e.g., failure of sample(s) to meet acceptance criteria.	

5.4 Structure and authority

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.4.1 *NPAAC RMPS S4.1, S4.2*	General • organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services, clearly defined? • responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities, are specified? • are procedures to ensure the consistent application of its laboratory activities and validity of the results, clearly defined?	
5.4.2 *NPAAC RMPS S5.2*	Quality management There must be personnel with authority and resources needed to carry out their duties, including: • implementation, maintenance and improvement of the management system; • identification of deviations from the management system or from the procedures for performing laboratory activities; • initiation of actions to prevent or minimize such deviations; • reporting to laboratory management on performance of the management system and any need for improvement; • ensuring the effectiveness of laboratory activities.	

5.5 Objectives and policies

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.5 *NPAAC RMPS S5.2* *NPAAC RMPS S5.4*	• Objectives and policies established and maintained for: • meeting the needs and requirements of patients/users; • committing to good professional practice; • providing examinations that fulfil their intended use; • conforming with this document. • Objectives are measurable, and consistent with policies. Objectives and policies are implemented at all levels of the laboratory organization. • Integrity of the management system is maintained when changes to the management system are planned and implemented. • Established quality indicators to monitor and evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes.	

5.6 Risk management

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.6 *NPAAC Supervision S1.4, S1.5* *NPAAC RMPS S3.1, S3.2, S3.3, S3.4, S5.1*	• Are processes established, implemented, and maintained for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement? (**See 8.5**) • Does the laboratory director ensure these processes are evaluated for effectiveness and modified, when identified as being ineffective?	

6 RESOURCE REQUIREMENTS

6.1 General

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.1 *NPAAC RMPS S6.1, S7A.2*	Are there adequate personnel, facilities, equipment, reagents, consumables, systems and support services necessary to manage and perform its activities?	

6.2 Personnel

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.1 *NPAAC RMPS S6.1*	General • is there access to a sufficient number of competent persons to perform its activities? • do all personnel (internal or external), that could influence laboratory activities, act impartially, ethically, are competent and work in accordance with the laboratory's management system? • communicate to laboratory personnel the importance of meeting the needs and requirements of users, and requirements this document. • is a programme established to introduce personnel to the organization/department, incl. terms and conditions of employment, staff facilities, occupational health and safety requirements. •	
6.2.2 *NPAAC RMPS S6.1*	Competence requirements • is the competence requirements for each function influencing the results of laboratory activities, incl. education, qualification, training, retraining, technical knowledge, skills and experience specified? • laboratory must ensure all personnel have the competence to perform laboratory activities for which they are responsible	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• is there a process for managing competence of its personnel, including requirements for frequency of competence assessment? • is there documented information demonstrating competence of its personnel?	
6.2.3 *NPAAC ICT S1.3*	Authorisation Laboratory must authorize personnel to perform specific laboratory activities, including the following: • selection, development, modification, verification and validation of methods; • review, release and reporting of results; • use of laboratory information systems: accessing patient data and information, entering patient data and examination results, changing patient data or examination results. Personnel must have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations. •	
6.2.4 *NPAAC SupervisionS1.6* *NPAAC RMPS S6.1, S7A.3*	Continuing education and professional development • is a continuing education programme available to personnel who participate in managerial and technical processes? • do all personnel participate in continuing education and regular professional development? • is effectiveness of the programmes and activities reviewed periodically?	
6.2.5 *NPAAC RMPS S6.1*	Personnel records Laboratory must have procedures and retain records for: • determining the competence requirements specified in 6.2.2a); • position descriptions; • training and retraining; • authorization of personnel,	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• monitoring competence of personnel	

6.3 Facilities and environmental conditions

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.3.1 *NPAAC RMPS S7A.1, S7A.2*	General • are facilities and environmental conditions suitable for the laboratory activities? • do they adversely affect the validity of results, or the safety of patients, visitors, users, and personnel? incl: pre-examination facilities and sites other than the main laboratory, e.g., POCT. • are requirements for facilities and environmental conditions for performance of laboratory activities defined, monitored, and recorded?	
6.3.2 *NPAAC RMPS S7A.1, S7A.2*	Facility controls Processes to control facilities are implemented, recorded, monitored and periodically reviewed, and must include: • control of access, with consideration to safety, confidentiality, quality, and safeguarding medical information and patient samples; • prevention of contamination, interference, or adverse influences on laboratory activities arising from energy sources, lighting, ventilation, noise, water and waste disposal; • prevention of cross-contamination, where examination procedures pose a risk, or affected/influenced by lack of separation; • provision of safety facilities and devices, and regularly verifying their functioning;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• maintenance of laboratory facilities in a functional and reliable condition.	
6.3.3 *NPAAC RMPS S7A.1, S7A.2*	Storage facilities • adequate storage space, with conditions ensuring continuing integrity of: samples, equipment, reagents, consumables, documents and records. • patient samples and materials used in examination processes stored in a manner that prevents cross contamination and deterioration. • appropriate storage and disposal facilities for hazardous materials.	
6.3.4 *NPAAC RMPS S7A.1, S7A.2*	Personnel facilities • adequate access to toilet facilities and a supply of drinking water, and facilities for storage of personal protective equipment and clothing. • space for meetings, quiet study and rest area should be provided.	
6.3.5 *NPAAC RMPS S7A.1, S7A.2* *NPAAC Collection S1.1*	Sample collection facilities • enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of examinations; • consider privacy, comfort and needs and accommodation of accompanying persons during collection; • provide separate patient reception and collection areas; • maintain first aid materials for both patients and personnel.	

6.4 Equipment

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.4.1	General Processes for selection, procurement, installation, acceptance testing incl. Acceptability criteria, handling, transport, storage, use, maintenance, and decommissioning of equipment, to ensure proper functioning and to prevent contamination or deterioration, are established.	
6.4.2 *NPAAC RMPS S7B.5*	Equipment requirements • access to equipment required for correct performance of laboratory activities? • are requirements of this document met where equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional specification? • equipment is uniquely labelled, marked or otherwise identified and a register maintained? • equipment maintained and replaced as needed to ensure the quality of examination results?	
6.4.3 *NPAAC RMPS S7B.5*	Equipment acceptance procedure • verify equipment conforms to specified acceptability criteria before being placed or returned into service. • equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty to provide a valid result. (**see section 7.3.3 and 7.3.4 for details**).	
6.4.4 *NPAAC RMPS SB8.3*	Equipment instructions for use • appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results. • equipment is operated by trained, authorized, and competent personnel. • Instructions for use of the equipment, incl. those provided by the manufacturer, are readily available.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• equipment is used as recommended unless validated by the laboratory (**see 7.3.3**).	
6.4.5 *NPAAC RMPS S7B.5*	Equipment maintenance and repair • establish a preventive maintenance programme based on manufacturer's instructions. • deviations from the manufacturer's schedules or instructions are recorded. • equipment maintained in a safe working condition and working order, incl. electrical safety, emergency stop devices, safe handling and disposal of hazardous materials by authorized persons. • defective equipment or outside specified requirements, is taken out of service, clearly labelled/marked as being out of service (until verified to perform correctly), effect of the defect or deviation from the specified requirements is examined and initiate actions when nonconformity occurs (**see 7.5**) • where applicable, equipment is decontaminated before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.	
6.4.6 *NPAAC RMPS S7B.4*	Equipment adverse incident reporting • adverse incidents and accidents are investigated and reported to the manufacturer and/or supplier and appropriate authorities. • procedures for responding to any manufacturer's recall notice and taking actions recommended by the manufacturer.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.4.7 *NPAAC RMPS SC8.6*	Equipment records Records are maintained for each item of equipment that influences the results of laboratory activities and include, where relevant: • manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, incl. software and firmware; • dates of receipt, acceptance testing and entering into service; • evidence equipment conforms with specified acceptability criteria; • the current location; • condition when received (e.g. new, used, reconditioned); • manufacturer's instructions; • the programme for preventive maintenance; • any maintenance activities performed by the laboratory or approved external service provider; • damage to, malfunction, modification, or repair of the equipment; • equipment performance records: reports or certificates of calibrations and/or verifications, including dates, times and results; • status of the equipment: active, in-service, out-of-service, quarantined, retired or obsolete. Records are maintained and readily available for the lifespan of the equipment or longer, as specified in **8.4.3**.	

6.5 Equipment calibration and metrological traceability

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.5.1	General Laboratory must specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results. Quantitative methods: specifications must include calibration and metrological traceability requirements. Qualitative methods/Quantitative methods that measure characteristics rather than discrete analytes: must specify the characteristic being assessed and such requirements necessary for reproducibility over time.	
6.5.2 *NPAAC RMPS S7B.5*	Equipment calibration Procedures are available for the calibration of equipment that directly or indirectly affects examination results and must specify: • conditions of use and manufacturer's instructions for calibration; • recording of the metrological traceability; • verification of the required measurement accuracy and functioning of the measuring system at specified intervals; • recording calibration status and date of re-calibration; • ensuring, where correction factors are used, these are updated and recorded when re- calibration occurs; • handling of situations when calibration was out of control, to minimize risk to service operation and to patients; •	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.5.3 *NPAAC RMPS S7B.5*	Metrological traceability of measurement results • establish and maintain metrological traceability of measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. • ensure measurement results are traceable to the highest possible order of traceability and as close as possible to the International System of Units (SI) through: – calibration provided by a competent laboratory – certified values of certified reference material with stated MT to the SI • if not possible, other means for providing confidence in the results are applied. • for genetic examinations, traceability to genetic reference sequences must be established. • for qualitative methods, traceability can be demonstrated by testing known material or previous samples sufficient to show consistent identification and intensity of reaction.	

6.6 Reagents and consumables

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.6.1	General Processes are established for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.6.2 *NPAAC RMPS S7B.5*	Receipt and storage • storage of reagents and consumables according to manufacturers' specifications and monitor the environmental conditions where relevant. • if the laboratory is not the receiving facility, it must verify the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.	
6.6.3 *NPAAC RMPS S7B.5*	Acceptance testing • each reagent or new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, is verified for performance before placing into use, or before release of results. • consumables that can affect the quality of examinations are verified for performance before placing into use.	
6.6.4	Inventory management • establish an inventory management system for reagents and consumables. • the system must segregate reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use.	
6.6.5 *NPAAC RMPS SB8.3*	Instructions for use • instructions for use of reagents and consumables, incl. manufacturer's instructions, are readily available. • reagents and consumables are used according to the manufacturer's specifications. Otherwise, **see 7.3.3**.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.6.6 *NPAAC RMPS S7B.4*	Adverse incident reporting Adverse incidents and accidents attributed directly to specific reagents or consumables are investigated and reported to the manufacturer and/or supplier, and appropriate authorities, as required. Procedure for responding to manufacturer's recall or other notice and taking actions recommended by the manufacturer.	
6.6.7 *NPAAC RMPS SC8.6*	Records Records are maintained for each reagent and consumable that contributes to the performance of examinations, including: • identity of the reagent or consumable; • manufacturer's information, incl. instructions, name and batch code or lot number; • date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service; • records that confirm the reagent's or consumable's initial and ongoing acceptance for use. Reagents prepared, resuspended or combined in-house - the records must also include reference to the person(s) undertaking the preparation, and the dates of preparation and expiry.	

6.7 Service agreements

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.7.1	Agreements with laboratory users Procedure to establish and periodically review agreements for providing laboratory activities must ensure: • requirements are adequately specified; • laboratory has the capability and resources to meet the requirements; • when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants. Users are informed of any changes to an agreement that can affect examination results. Records of reviews, including any significant changes, are retained.	
6.7.2	Agreements with POCT operators Service agreements between the laboratory and other parts of the organization using laboratory supported POCT, must ensure that respective responsibilities and authorities are defined and communicated.	

6.8 Externally provided products and services

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.8.1	General Ensure externally provided products and services that affect laboratory activities are suitable when such services are: • intended for incorporation into the laboratory's own activities; • provided, in part or in full, directly to the user by the laboratory, as received from the external provider; • used to support the operation of the laboratory.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.8.2 *NPAAC RMPS S9.1* *NPAAC Retention S3.1, S3.3*	Referral laboratories and consultants • communicate requirements to referral laboratories and consultants who provide interpretations and advice. • unless specified in the agreement, the referring laboratory (and not the referral laboratory) is responsible for ensuring that examination results of the referral laboratory are provided to the person making the request. • a list of all referral laboratories and consultants is maintained.	
6.8.3 *NPAAC RMPS S9.2*	Review and approval of externally provided products and services Establish procedures and retain records for: • defining, reviewing, approving the laboratory's requirements for externally provided products and services; • defining the criteria for qualification, selection, evaluation of performance and re-evaluation of the external providers; • referral of samples; • ensuring externally provided products and services conform to the laboratory's established requirements (or requirements of this document), before they are used or directly provided to the user; • taking any actions arising from evaluations of the performance of external providers.	

7 PROCESS REQUIREMENTS

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.1 *NPAAC RMPS S3.1, S3.2*	General • identify potential risks to patient care in the pre-examination, examination and post-examination processes. • risks are assessed and mitigated to the extent possible and residual risk is communicated to users as appropriate. • identified risks and effectiveness of the mitigation processes is monitored and evaluated according to the potential harm to the patient. • identify opportunities to improve patient care and develop a framework to manage these opportunities (**see 8.5**)	

7.2 Pre-examination processes

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.1 *NPAAC RMPS SA8.1*	General Procedures must be established for all pre-examination activities and make them accessible to relevant personnel.	
7.2.2 *NPAAC RMPS SA8.1, SA8.3* *NPAAC Collection S4.1*	Laboratory information for patients and users Information must be available to users and patients, and sufficiently detailed to provide users with a comprehensive understanding of the laboratory's scope of activities and requirements, including as appropriate: • location(s) of the laboratory, operating hours and contact information; • procedures for requesting and the collection of samples; • scope of activities and time for expected availability of results; • availability of advisory services; • requirements for patient consent;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• factors known to significantly impact the performance of the examination or the interpretation of the results; • laboratory complaint process.	

7.2.3 Requests for providing laboratory examinations

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.3.1 *NPAAC RMPS SA8.2, SA8.4* *NPAAC Collection S3.3*	General • each request accepted by the laboratory for examination(s) is considered an agreement. • the request must provide sufficient information to ensure: - *unequivocal traceability of the patient to the request & sample;* - *requestor identity & contact information;* - *examinations requested;* - *informed clinical & technical advice, & interpretation can be provided.* • examination request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user. • where necessary, the laboratory must communicate with users or their representatives, to clarify the user's request.	
7.2.3.2 *NPAAC RMPS SA8.4*	Oral requests Established procedure for managing oral requests for examinations that includes the provision of documented confirmation of the examination request to the laboratory, within a given time.	

7.2.4 Primary sample collection and handling

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.4.1	General • are procedures established for collection and handling of primary samples? • is this information made available to those responsible for sample collection? • are deviations from the established collection procedures clearly recorded? • potential risk and impact on patient outcome of acceptance or rejection of the sample is assessed, recorded and communicated to appropriate personnel? • periodically review requirements for sample volume, collection device and preservatives for all sample types, to ensure neither insufficient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte.	
7.2.4.2 *NPAAC RMPS, SA8.1, SA8.3, SA8.4*	Instructions for pre-collection activities Instructions must include sufficient detail to ensure that the integrity of the sample is not compromised. This must include: • preparation of the patient (e.g. patient and collector instructions); • type and amount of the primary sample to be collected, with descriptions of the containers and any necessary additives, and when relevant the order of collection samples; • special timing of collection, where relevant; • provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation,	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• sample labelling system for unequivocal identification of the patient, source and site of specimen, and labelling, when several samples from the same patient are to be collected, including multiple pieces of tissue or slides. • criteria for acceptance and rejection of samples specific to the examinations requested.	
7.2.4.3	Patient consent • is informed consent of the patient for all procedures carried out on the patient obtained? • special procedures/invasive procedures, or those with increased risk of complications, may need detailed explanations, and in some cases, consent recorded. • when obtaining consent is not possible, necessary procedures may be carried out, provided they are in the patient's best interest.	
7.2.4.4 *NPAAC RMPS SA8.5*	Instructions for collection activities Instructions are provided for safe, accurate and clinically appropriate sample collection and pre-examination storage and must include: • verification of the identity of the patient from whom a primary sample is collected; • verification the patient meets pre-examination requirements, e.g. fasting status. • collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant; • labelling of primary samples that provides an unequivocal link with patients from whom they are collected. • recording the identity of the person collecting the primary sample and collection date; and when relevant, collection time; • requirements for separating or dividing the primary sample when necessary;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• stabilisation and proper storage conditions before collected samples are delivered to the laboratory; • safe disposal of materials used in the collection.	

7.2.5 Sample transportation

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.5 *NPAAC RMPS SA8.8, SA8.9* *NPAAC Packaging & Transport*	• Instructions are provided to ensure the timely, safe and transportation of samples including: – packaging of samples for transportation; – ensuring time between collection and receipt in the laboratory is appropriate for the requested examinations; – maintaining the temperature interval specified for sample collection and handling; – any specific requirements to ensure integrity of samples, e.g. designated preservatives. • If sample integrity is compromised and there is a health risk, the organisation responsible for sample transport is notified immediately and action taken to reduce the risk and to prevent recurrence. • Laboratory must establish and periodically evaluate adequacy of sample transportation systems	

7.2.6 Sample receipt

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.6.1 *NPAAC RMPS SA8.2, SA8.6, SA8.7*	Sample receipt procedure Procedure established for sample receipt that includes: • unequivocal traceability of samples by request and labelling, to a uniquely identified patient and when applicable, the anatomical site; • criteria for acceptance and rejection of samples; • recording the date and time of receipt, when relevant; • recording the identity of the person receiving the sample, when relevant; • evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s); • instructions for samples specifically marked as urgent, incl. details of special labelling, transport, any rapid processing method, turnaround times and special reporting criteria to be followed. • ensuring all portions of the primary sample are unequivocally traceable to the original primary sample.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.6.2 *NPAAC RMPS SA8.7*	Sample acceptance exceptions Process in place that considers the best interests of the patient in receiving care, when a sample has been compromised due to: • incorrect patient or sample identification, • sample instability, e.g. delay in transport, • incorrect storage or handling temperature, • inappropriate container(s), and • insufficient sample volume. When a compromised clinically critical or irreplaceable sample is accepted, the final report must indicate the nature of the problem and where applicable, advising caution when interpreting results that could be affected.	

7.2.7 Pre-examination handling, preparation, and storage

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2.7.1 *NPAAC RMPS SA8.8, SA8.9*	Sample protection Establish procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during handling, preparation and storage.	
7.2.7.2 *NPAAC RMPS SA8.4*	Criteria for additional examination requests Procedures must include time limits for requesting additional examinations on the same sample.	
7.2.7.3 *NPAAC RMPS SA8.9*	Sample stability Considering the stability of the analyte in a primary sample, the time between sample collection and performing the examination must be specified and monitored where relevant.	

7.3 Examination processes

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.3.1 *NPAAC QC/QAP S6.1*	General • selection and use of examination methods have been validated for their intended use. • performance specifications for each examination method relate to the intended use of that examination and its impact on patient care. • all procedures and supporting documentation, relevant to the laboratory activities, are kept up to date and readily available (**see 8.3**). • personnel must follow established procedures; identity of persons performing significant activities in examination processes is recorded, incl PoCT operators. • authorized personnel must periodically evaluate examination methods to ensure they are clinically appropriate for the requests received.	
7.3.2 *NPAAC RMPS SB8.1, SB8.2* *NPAAC QC/QAP S6.2, S6.3, S6.4*	Verification of examination methods • procedures in place to verify the proper performance of examination methods before introducing into use, ensuring required performance, as specified by manufacturer/method can be achieved? • are performance specifications confirmed during the verification process, relevant to the intended use of the examination results? • is the extent of the verification sufficient to ensure validity of results pertinent to clinical decision making? • do personnel with appropriate authority/competence review verification results and record whether the results meet the specified requirements? • if a method is revised by the issuing body, does the laboratory repeat verification to the extent necessary?	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• are records of verification retained, incl. performance specifications, results obtained, statement of whether the performance specifications were achieved and if not, action taken?	
7.3.3 *NPAAC RMPS SB8.1, SB8.2* *NPAAC QC/QAP S6.2, S6.3, S6.4*	Validation of examination methods • Examination methods derived from the following sources must be validated: - *laboratory designed or developed methods;* - *methods used outside their intended scope;* - *validated methods subsequently modified.* • validation is extensive as necessary and confirm, through objective evidence (performance specifications), the specific requirements for the intended use of the examination have been fulfilled. • extent of validation sufficient to ensure validity of results pertinent to clinical decision making? • do personnel with appropriate authority/competence review validation results and record the review? • when changes are proposed to a validated method, is the clinical impact reviewed, and assessed whether to implement the modified method? Records of validation must be retained and include: ○ the validation procedure used; ○ specific requirements for the intended use; ○ determination of performance specifications of the method; ○ results obtained; ○ statement on the validity of the method, detailing its fitness for the intended use.	
7.3.4 *NPAAC RMPS SB8.7, SB8.8, SB8.9, SB8.10*	• Evaluation of measurement uncertainty (MU)MU of measured quantity values evaluated and maintained for its intended use? • is regularly reviewed? • if MU is not possible/relevant, is the rationale for exclusion from MU estimation documented?	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
NPAAC MU S1 *NPAAC QC/QAP S6.5*	• MU made available to laboratory users on request. • Inquiries on MU, response must consider other sources of uncertainty, e.g. biological variation; • If qualitative result relies on test which produces quantitative output data and is specified as positive/negative, based on a threshold, MU in the output quantity must be estimated using representative positive/negative samples; • Examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process; • MU should be taken into consideration when performing method verification/validation.	
7.3.5 *NPAAC RMPS SC8.1*	Biological reference intervals (RI) and clinical decision limits RI/clinical decision limits for interpretation of examination results must be defined and communicated to users. • RI/clinical decision limits defined, to reflect the patient population served by the laboratory, while considering the risk to patients? • RI/clinical decision limits periodically reviewed, and any changes communicated to users? • when changes are made to an examination or pre-examination method, impact on the associated RI/clinical decision limits is reviewed and communicated to the users. • For examinations that identify presence/absence of a characteristic, RI is the characteristic to be identified, e.g. genetic examinations.	
7.3.6 *NPAAC RMPS SB8.3*	Documentation of examination procedures • examination procedures are documented to the extent necessary, ensuring consistent application of its activities and validity of its results.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• procedures are written in a language understood by laboratory personnel and available in appropriate locations. • any abbreviated document content must correspond to the procedure. • Information from product IFU's can be incorporated into examination procedures by reference. • any validated change to an examination procedure which could affect interpretation of results, the implications of this must be explained to users. • documents associated with the examination process is subject to document control (**see 8.3**)	

7.3.7 Ensuring the validity of examination results

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.3.7.1 *NPAAC QC/QAP S4.1*	General Laboratory must have a procedure for monitoring the validity of results. The resulting data must be recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques must be applied to review the results. This monitoring must be planned and reviewed.	
7.3.7.2 *NPAAC RMPS SB8.4, SB8.6* *NPAAC QC/QAP S1.1, S2.1, S2.2*	Internal quality control (IQC) • IQC procedures are in place for monitoring ongoing validity of examination results, according to specified criteria? • IQC material selected that is fit for purpose and include: *stability; matrix match, reaction to examination method, concentrations levels at or near clinical decision points and covers the range of the examination method;* • if appropriate QC material is not available, the use of other methods for IQC is considered?	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• IQC is performed at a frequency based on the stability and robustness of the examination method and risk of harm to the patient from an erroneous result. • resulting data is recorded in a way that trends and shifts are detectable and, when applicable, statistical techniques are applied to review the results. • IQC data is reviewed with defined acceptability criteria at regular intervals, in a timeframe, which allows a meaningful indication of current performance. • lab prevents the release of patient results in the event that IQC fails defined acceptability criteria and ensures: - *When IQC criteria are not fulfilled and indicate results are likely to contain clinically significant errors, the results are rejected and relevant patient samples re-examined after the error has been corrected (**see 7.5**).* - *evaluate the results from patient samples that were examined after the last successful IQC event.*	
7.3.7.3 *NPAAC RMPS SB8.5, SB8.6* *NPAAC QC/QAP S5.1, 5.2* *NPAAC QC/QAP S5.6*	External quality assessment (EQA) • monitor the performance of its examination methods, by participation in EQA, appropriate to the examination and interpretation of examination results, incl. POCT. • establish procedure for EQA enrolment, participation and performance for examination methods, where such programs are available. • EQA are processed by personnel who routinely perform pre-examination, examination, and post examination procedures. • EQA programme(s) selected by the laboratory to the extent possible: *have the effect of checking pre-examination, examination, and post examination processes, provide clinically relevant challenges that mimic patient samples, and fulfill ISO/IEC 17034 requirements.* • when selecting EQA programme(s), consider the type of target value offered.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
NPAAC QC/QAP S5.7	• if an EQA programme is not available/suitable, an alternative approach must be used. It must justify the rationale for the chosen alternative and provide evidence of its effectiveness. • EQA data is reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance. • where EQA results fall outside specified acceptability criteria, appropriate action is taken (**see 8.7**), incl. assessment of whether it is clinically significant as it relates to patient samples. • if the impact is clinically significant: review of patient results that may have been affected; need for result amendment considered; users are advised as appropriate.	
7.3.7.4 *NPAAC RMPS SB8.2* *NPAAC QC/QAP S4.2*	Comparability of examination results • procedure for establishing comparability of results for patient samples is defined when different methods and/or equipment are used for an examination, and/or the examination is performed at a different site. • results of comparability performed, and its acceptability must be recorded. • comparability of results must be periodically reviewed. • where differences are identified, impact of the differences on RI/clinical decision limits must be evaluated and acted upon. • users are advised of any clinically significant differences in comparability of results.	

7.4 Post-examination processes

7.4.1 Reporting of results

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.1.1 *NPAAC RMPS SC8.1*	General • examination results are reported accurately, clearly, unambiguously, in accordance with any specific instructions in the procedure and include all information necessary for the interpretation of the results. • procedures in place to notify users when examination results are delayed, based on the impact of the delay on the patient. • all information associated with issued reports are retained in accordance with management system requirements (**see 8.4**).	
7.4.1.2	Result review and release • Results must be reviewed and authorised prior to release. • Authorized personnel review results and evaluate them against IQC, available clinical information and previous examination results. • Responsibilities and procedures for how results are released for reporting, including by whom and to whom, must be specified.	
7.4.1.3 *NPAAC RMPS SC8.3, SC8.4, SC8.5* *NPAAC RMPS S6.2* *NPAAC High-risk S2.1, S2.2, S2.3, S2.4, S2.5* *NPAAC ICT S2.3, S2.4*	Critical result reports when examination results fall within established critical decision limits: • user or other authorised person is notified as soon as relevant; • actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification; • the laboratory must have an escalation procedure for laboratory personnel when a responsible person cannot be contacted. • include clear identification of any results generated by POCT.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• identification of the person(s) reviewing the results and authorizing release of the results is readily available, if not contained in the report. •	
7.4.1.4	Special considerations for reports • results may be reported in a simplified way, if agreed. Information listed in 7.4.1.6 and 7.4.1.7 not reported is readily available; • following a preliminary report, the final report must always be forwarded to the user; • records kept of all results which are provided orally. Such results are followed by a final report; • patients given opportunity for counselling for certain examination results, e.g. genetic or certain infectious diseases. • Anonymised results don't risk patient privacy/confidentiality or legal/regulatory requirements.	
7.4.1.5 *NPAAC RMPS SC8.1*	Automated selection, review, release and reporting of results Procedures are established for automated selection, review, release and reporting of results, and must ensure: • criteria are specified, approved, readily available and understood by personnel responsible for authorizing the release of results; • criteria are validated and approved before use, regularly reviewed and verified after changes to the reporting system that can affect their proper functioning and place patient care at risk; • results selected by automated reporting system for manual review are identifiable, and as appropriate include: date and time of selection and review, identity of the reviewer; • when necessary, rapid suspension of automated selection, review, release and reporting is applied.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.1.6 *NPAAC RMPS SC8.2*	Requirements for reports Each report must include the following information, unless the laboratory has documented reasons for omitting any items: • unique patient identification, date of primary sample collection and date of issue of report, on each page of the report; • identification of the laboratory issuing the report; • name or other unique identifier of the user; • type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description); • clear, unambiguous identification of the examinations performed; • Identification of examination method used, where relevant, incl. where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle; • examination results and, where appropriate: the units of measurement, reported in SI units, units traceable to SI units, or other applicable units; • biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms supporting clinical decision limits as necessary; • identification of examinations as part of a research/development programme, for which no specific claims on measurement performance are available; • identification of any preliminary results; • indications of any critical results; unique identification that all its components are recognised as a portion of the complete report and a clear identification of the end, e.g. page number to total number of pages.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.1.7	Additional information for reports • where necessary for patient care, time of primary sample collection must be included; • time of report release, if not in report, readily available when needed • identification of all examinations or parts of examinations performed by a referral laboratory, including information provided by consultants, without alteration, as well as name of laboratory performing examinations; • when applicable, comments on: – sample quality and suitability that might compromise clinical value of examination results; – discrepancies when examinations are performed by different procedures or in different locations; – possible risk of misinterpretation when different units of measurement are in use regionally or nationally; – result trends or significant changes over time.	
	•	
7.3.1.8 *NPAAC RMPS SC8.2, SC8.3*	Amendments to reported results Procedures for the issue of amended or revised results must specify: • reason for the change is recorded and included in the report, when relevant; • revised results delivered only in the form of an additional document or data transfer, and clearly identified as having been revised. Date and patient's identity in the original report is indicated; • user is made aware of the revision; • when issuing a completely new report, this is uniquely identified and contain a reference and traceability to the original report it replaces; • when the reporting system cannot capture revisions, a record of such must be kept.	

7.4.2 Post-examination handling of samples

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.2 *NPAAC RMPS SC8.6, SC8.7* *NPAAC Retention*	The length of time samples are retained following the examination and conditions under which samples are to be stored, must be defined to ensure: • patient and source identification of the sample is maintained; • suitability of the sample for additional examination is known; • sample is stored in a manner that optimally preserves suitability for additional examination; • sample can be located and retrieved, and • sample is discarded appropriately.	

7.5 Nonconforming work

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.5 *NPAAC RMPS S3.1, S3.2, S3.4, S5.1*	Process established and implemented when any aspect of laboratory activities or examination results do not conform to procedures, quality specifications, or the user requirements. The process must ensure: • responsibilities and authorities for management of nonconforming work are specified; • immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory; • examinations are halted, and reports withheld when there is a risk of harm to patients; • evaluation is made of the clinical significance of the nonconforming work, incl. impact analysis on examination results which may have been released prior to identification of the nonconformance; • decision is made on the acceptability of the nonconforming work; • if necessary, examination results are revised, and user is notified;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• responsibility for authorizing the resumption of work is defined. Corrective action is implemented commensurate with the risk of recurrence of the nonconforming work. Records are retained of nonconforming work and actions as specified in 7.5.	

7.6 Control of data and information management

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.6.1	General Laboratory must have access to the data and information needed to perform laboratory activities.	
7.6.2 *NPAAC ICT S1.1*	Authorities and responsibilities for the management of the information systems are specified, incl. the maintenance and modification to the information systems that can affect patient care. The laboratory is ultimately responsible for the information systems.	
7.6.3 *NPAAC ICT S1.2, S1.3, S1.4, S1.5, S1.6*	Information systems management The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information must be: • validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and validated before implementation; • documented, and the documentation readily available to authorized users, including that for day to day functioning of the system; • implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguarded data against tampering or loss;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
NPAAC RMPS S7B.6	• operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; • maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions. Calculations and data transfers must be checked in an appropriate and systematic manner.	
7.6.4 *NPAAC RMPS S3.1, 3.2*	Downtime plans Laboratory must have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities. This includes automated selection and reporting of results.	
7.6.5 *NPAAC ICT S1.1*	Off site management When information system(s) are managed and maintained off-site or through an external provider, the laboratory must ensure the provider or operator of the system complies with all applicable requirements of this document.	

7.7 Complaints

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.7.1 *NPAAC RMPS S5.4*	Process There must be a process for handling complaints that include the following: • description of the process for receiving, substantiating and investigating the complaint, and deciding what actions must be taken in response; • tracking and recording the complaint, including the actions undertaken to resolve it;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• ensuring appropriate action is taken. A description of the process for handling complaints must be publicly available.	
7.7.2 *NPAAC RMPS S5.4*	Receipt of complaint • upon receipt, it must be confirmed whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, must resolve the complaint. • the laboratory receiving the complaint must be responsible for gathering all necessary information to determine whether the complaint is substantiated. • whenever possible, the laboratory must acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.	
7.7.3 *NPAAC RMPS S5.4*	Resolution of complaint • investigation and resolution of complaints must not result in any discriminatory actions. • resolution of complaints must be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach must not compromise impartiality.	

7.8 Continuity and emergency preparedness planning

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.8 *NPAAC RMPS S3.1, 3.2*	Risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, must be identified. A coordinated strategy that involves plans, procedures, and technical measures to enable continued operations after a disruption must be in place. Plans must be periodically tested and the planned response capability exercised, where practicable. The laboratory must: • establish a planned response to emergency situations, taking into account needs/capabilities of all relevant laboratory personnel; • provide information and training as appropriate to relevant personnel; • respond to actual emergency situations; • take action to prevent/mitigate the consequences of emergency situations; •	

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 General requirements and options

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.1.1 *NPAAC RMPS S5.1*	General Laboratory must establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document. As a minimum, the management system of the laboratory must include: • objectives and policies (8.2) • responsibilities (8.1) • management reviews (8.9) • evaluations and internal audits (8.8) • corrective actions (8.7) • actions to address risks and opportunities for improvement (8.5); • documented information (8.2, 8.3 and 8.4)) • continual improvement (8.6).	
8.1.2	Fulfilment of management system requirements The laboratory may meet 8.1.1 by establishing, implementing, and maintaining a quality management system (e.g., in accordance with the requirements of ISO 9001) (**see Table B.1**). The quality management system must support and demonstrate the consistent fulfilment of the requirements of **Clauses 4 to 7** and the requirements specified in **8.2 to 8.9.**	
8.1.3 *NPAAC RMPS S5.2*	Management system awareness The laboratory must ensure persons doing work under the laboratory's control are aware of: • relevant objectives and policies; • their contribution to the effectiveness of the management system, incl. the benefits of improved performance; • consequences of not conforming with the management system requirements.	

8.2 Management system documentation

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.2.1 *NPAAC RMPS S5.2*	General Laboratory management must establish, document, and maintain objectives and policies for the fulfilment of the purposes of this document and must ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization.	
8.2.2 *NPAAC RMPS S5.2*	Competence and quality Objectives and policies must address the competence, quality, and consistent operation of the laboratory.	
8.2.3 *NPAAC RMPS S5.2*	Evidence of commitment Laboratory management must provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.	
8.2.4 *NPAAC RMPS S5.1*	Documentation Documentation, processes, systems, and records, related to the fulfilment of the requirements of this document must be included in, referenced from, or linked to the management system.	
8.2.5 *NPAAC RMPS S5.2*	Personnel access Personnel involved in laboratory activities must have access to parts of the management system documentation and related information that are applicable to their responsibilities.	

8.3 Control of management system documents

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.3.1 *NPAAC RMPS S5.1*	General The laboratory must control the documents (internal and external) that relate to the fulfilment of this document.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.3.2 *NPAAC RMPS S5.1*	Control of documents • documents are uniquely identified; • documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy; • documents are periodically reviewed and updated as necessary; • relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; • changes and the current revision status of documents are identified; • documents are protected from unauthorized changes and any deletion or removal; • documents are protected from unauthorized access; • the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose; • at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.	

8.4 Control of records

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.4.1 *NPAAC RMPS S5.1*	Creation of records • establish and retain legible records to demonstrate fulfilment of the requirements of this document. • records are created at the time each activity that affects the quality of the examination is performed.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.4.2 *NPAAC RMPS S5.1*	Amendment of records • ensure amendments to records can be traced to previous versions or to original observations. both original and amended data and files are kept, including date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations.	
8.4.3 *NPAAC RMPS SC8.6* *NPAAC Retention*	Retention of records • implement the procedures needed for the identification, storage, protection from unauthorized access and changes, back-up, archive, retrieval, retention time, and disposal of its records. • retention times for records are specified. • reported examination results are retrievable for as long as necessary or as required. • records are accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review (**see 8.9**).	

8.5 Actions to address risks and opportunities for improvement

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.5.1 *NPAAC RMPS S3.1, S3.2, S3.4* *NPAAC SupervisionS1.5*	Identification of risks and opportunities for improvement Laboratory must identify risks and opportunities for improvement associated with the laboratory activities to: • prevent or reduce undesired impacts and potential failures in the laboratory activities; • achieve improvement, by acting on opportunities; • assure that the management system achieves its intended results; • mitigate risks to patient care;	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	• help achieve the purpose and objectives of the laboratory.	
8.5.2 *NPAAC RMPS S3.1, S3.2, S3.4* *NPAAC SupervisionS1.5*	Acting on risks and opportunities for improvement • identified risks must be acted upon. • actions taken to address risks must be proportional to potential impact on laboratory examination results, as well as patient and personnel safety. • decisions made and actions taken on risks and opportunities are recorded. • integrate and implement actions on identified risks and improvement opportunities into the management system and evaluate their effectiveness.	

8.6 Improvement

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.6.1 *NPAAC RMPS S3.1, S3.2, S5.1*	Continual improvement • continually improve the effectiveness of the management system, incl. pre-examination, examination and post-examination processes as stated in the objectives and policies. • identify and select opportunities for improvement and develop, document, and implement any necessary actions. Improvement activities must be directed at areas of highest priority based on risk assessments and the opportunities identified (**see 8.5**) • evaluate effectiveness of the actions taken. • ensure laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. • communicate to personnel its improvement plans and related goals.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.6.2 *NPAAC RMPS S5.4*	Laboratory patients, user, and personnel feedback • seek feedback from patients, users, and personnel. • feedback is analysed and used to improve the management system, laboratory activities and services to users. • records of feedback are maintained incl. action taken. • communication is provided to personnel on actions taken arising from their feedback.	

8.7 Corrective Action

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.7.1 *NPAAC RMPS S5.1* *NPAAC SupervisionS1.5* *NPAAC RMPS S4.4*	Actions when nonconformity occurs When a nonconformity occurs, the laboratory must: • respond to the nonconformity and, as applicable: - *take immediate action to control and correct the nonconformity;* - *address the consequences, with a focus on patient safety including escalation to appropriate person.* • determine the cause(s) of the nonconformity; • evaluate need for corrective action to eliminate cause(s) of the nonconformity, to reduce likelihood of recurrence or occurrence elsewhere, by: - *reviewing and analyzing the nonconformity;* - *determining whether similar nonconformities exist, or could potentially occur;* - *assessing the potential risk(s) and effect(s) if the nonconformity recurs.* • implement any action needed; • review/evaluate effectiveness of any corrective action taken; • update risks/opportunities, as needed; • make changes to the management system, if necessary.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.7.2	Corrective action effectiveness Corrective actions must be appropriate to the effects of the nonconformities encountered and must mitigate the identified cause(s).	
8.7.3 *NPAAC RMPS S5.1*	Records of nonconformities and corrective actions The laboratory must retain records as evidence: • nature of the nonconformities, cause(s) and any subsequent actions taken; • evaluation of the effectiveness of any corrective action.	

8.8 Evaluations

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.8.1 *NPAAC RMPS S5.4*	General Laboratory must conduct evaluations at planned intervals to demonstrate the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients/users; and to ensure conformity to the requirements of this document.	
8.8.2 *NPAAC RMPS S5.4*	Quality indicators • process of monitoring quality indicators (**see 5.5**) are planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring. • indicators are periodically reviewed, to ensure their continued appropriateness.	

8.8.3 Internal audits

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.8.3.1 *NPAAC RMPS S5.3*	Laboratory must conduct internal audits at planned intervals to provide information on whether the management system conforms to: • laboratory's own requirements for its management system, incl. laboratory activities; • the requirements of this document; and • is effectively implemented and maintained.	
8.8.3.2 *NPAAC RMPS S5.3*	Laboratory must plan, establish, implement and maintain an internal audit programme that includes: • priority given to risk to patients from laboratory activities; • a schedule which takes into consideration identified risks, outcomes of external evaluations and previous internal audits, occurrence of nonconformities, incidents, and complaints, and changes affecting the laboratory activities; • specified audit objectives, criteria and scope for each audit; • selection of auditors trained and qualified/authorized to assess performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited; • ensuring objectivity and impartiality of the audit process; • ensuring the results of the audits are reported to relevant personnel; • implementation of appropriate correction and corrective actions without undue delay; retention of records as evidence of the implementation of the audit programme and audit results.	

8.9 Management reviews

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.1	General Laboratory management must review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness including the stated policies and objectives related to the fulfilment of this document.	
8.9.2 *NPAAC RMPS S5.4*	Review input The inputs to management review must be recorded and include: • status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources; • fulfilment of objectives and suitability of policies and procedures; • outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions and assessments by external bodies; • patient, user and personnel feedback and complaints; • quality assurance of result validity; • effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement; • performance of external providers; • results of participation in interlaboratory comparison programmes (EQA/PT); • evaluation of POCT activities; • other relevant factors, such as monitoring activities and training.	

Clause No.	Activities	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.3 *NPAAC RMPS S5.4*	Review output Outputs from management review must record all decisions and actions related to: • effectiveness of the management system and its processes; • improvement of the laboratory activities related to the fulfilment of the requirements of this document; • provision of required resources; • improvement of services to patients/users; • any need for change. Laboratory management must ensure actions arising from management review are completed within a specified timeframe. Conclusions and actions arising from management reviews are communicated to laboratory personnel.	

ISO 15189 (2022) ASSESSMENT WORKSHEET

Self-assessment

If the management system is certified by a certification body that is signatory to the IAF MLA

Where 1) to 6) below are confirmed, a document review of the laboratory's management system does not need to be formally performed. A limited review of records at assessment is to be performed to specifically confirm 6) e.g. management review, an internal audit, example of corrective action etc.

The required extent of assessment will be dependent on the evidence provided in 3) and 4) below.

Where nonconformities are identified, these are to be raised against clause 8.1.2.

Where 1) to 6) cannot be confirmed, then assessment of the laboratory's management system shall be against clauses 8.2 to 8.9 of ISO 15189:2022.

Certified management system	Evidence
1) evidence the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA).	
2) evidence that the CB's accreditation covers ISO/IEC 17021 Parts 1 and 3. If Part 3 is not specifically listed in the CB's scope of accreditation, then it must be clear that its accreditation covers the certification of Quality Management Systems (QMS) to ISO 9001 (which may be included in the scope of accreditation or other documentation provided by the accreditation body signatory to the IAF MLA).	
3) copies of the most recent certification audit report(s) issued by the CB covering the laboratory's management system in full.	
4) confirmation from the CB of the close out of any nonconformities raised during certification audits.	
5) evidence the certification of the management system covers the laboratory activities covered by its NATA scope of accreditation.	
6) supports the facility fulfilling consistently the requirements of ISO 15189:2022 to assure the quality of results.	

Annex A

Additional requirements for Point-of-Care Testing (POCT)	Evidence
A.2 Governance The governing body of the organisation must be ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organisation. Service agreements between the laboratory and all locations using laboratory supported POCT must ensure that respective responsibilities and authorities are specified and communicated within the organisation. These agreements must have clinical approval, and where applicable, financial approval. These service agreements must be with POCT areas and may be managed via a health professional grouping.	
A.3 Quality assurance programme The laboratory must appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of this document as related to POCT.	
A.4 Training programme A person with appropriate training and experience must be appointed to manage training and competency assessment of personnel performing POCT. The trainer must develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel.	