|  |
| --- |
| **DETAILS OF ASSESSMENT** |
| **ORGANISATION** |  |
| **ADDRESS** |  |
| **LABORATORY REFERENCE NUMBER** |  |
| **ACCOMPANYING LABORATORY REPRESENTATIVE** |  |
| **DOCUMENTATION**  | **Quality Manual Procedures Manual** **Work Instructions Standard Operating Procedures****Records** |
| **TEAM LEADER**  |  |
| **SIGNATURE** |  |
| **TYPE OF ASSESSMENT** | **Preliminary Visit Initial Assessment Assessment** **Extension Extraordinary visit Re-assessment** |
| **DATE OF REVIEW** |  |
| **DATE OF VISIT** |  |

**2. MAURITAS R DOCUMENTS REQUIREMENTS**

***Assessors need to check conformance of the laboratory with respect to the requirements of MAURITAS R1, R2, R3 and R4 Regulations:***

**MAURITAS R1 – Regulations to be met by certification bodies, inspection bodies and calibration and testing laboratories**

|  |  |  |  |
| --- | --- | --- | --- |
| **Clause** | **MAURITAS R1 Requirement** | **C/NC/****NA** | **Evidence checked** |
| **7.1 d** | TL to check whether the laboratory makes reference to accreditation in such a manner so as not to bring MAURITAS into disrepute nor in a misleading manner?  |  |  |
| **7.1 g** | TL to check contracts between labs and clients.  |  |  |
| **7.1 i** | TL to check how lab ensures that its clients do not reproduce part of the test/calibration reports?  |  |  |
| **9.2** | TL to check whether there has been any changes with respect to: ‘legal, commercial or organisational status’, ‘organisation and management e.g key managerial or technical’, ‘policies or procedures’, ‘premises’, ‘equipment, facilities, working environment or other resources’, ‘technical signatories’ and ‘compliance with MAURITAS requirements’ within the organisation since the last visit of MAURITAS? Did the laboratory inform MAURITAS within 1 week of these changes?  |  |  |
| **9.3** | TL to check whether lab has been able to comply with the new Regulations and relevant criteria of competence within the deadline given by MAURITAS? |  |  |

**MAURITAS R2 – Regulations to be met by applicant and accredited CABs**

|  |  |  |  |
| --- | --- | --- | --- |
| **Clause** | **MAURITAS R2 Requirement** | **C/NC/NA** | **Evidence checked** |
| **10** | Assessment team to confirm whether all documents and access were provided during the assessment. |  |  |
| **17.6** | Assessment Team to check in case of a recent previous suspension of accreditation, whether the laboratory discontinued making any reference to accreditation with MAURITAS after suspension. |  |  |

| **CLAUSE** | **REQUIREMENTS** | **C/NC/NA** | **EVIDENCE CHECKED** |
| --- | --- | --- | --- |
| **4** | **General requirements** |  |  |
| **4.1** | **Impartiality** |  |  |
|  | Are the laboratory activities undertaken impartially?Is the laboratory structured and managed to safeguard impartiality? |  |  |
| b) | Is the laboratory management committed to impartiality? |  |  |
| c) | Is the laboratory responsible for the impartiality of its laboratory activities and does it ensure that commercial, financial or other pressures do not compromise impartiality? |  |  |
| d) | Does the laboratory monitor its activities and its relationships to identify threats to its impartiality?Does this monitoring include relationships of its personnel? |  |  |
| e) | If a threat to impartiality is identified, is the effect eliminated or minimized so that the impartiality is not compromised?Is the laboratory able to demonstrate how it mitigates such threat? |  |  |
| **4.2** | **Confidentiality** |  |  |
| **4.2.1** | **Management of information** |  |  |
|  | Is the laboratory responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities?  |  |  |
| Does the management of patient information include privacy and confidentiality? |  |  |
| Does the laboratory inform the user and/or the patient in advance, of the information it intends to place in the public domain? |  |  |
| Except for information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), are all other information considered proprietary information and regarded as confidential? |  |  |
| **4.2.2** | **Release of information** |  |  |
|  | When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is the patient concerned notified of the information released, unless prohibited by law? |  |  |
| Is information about the patient from a source other than the patient (e.g. complainant, regulator) kept confidential by the laboratory? |  |  |
| Is the identity of the source kept confidential by the laboratory and not shared with the patient, unless agreed by the source? |  |  |
| **4.2.3** | **Personnel responsibility** |  |  |
|  | Do personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory’s behalf, keep confidential all information obtained or created during the performance of laboratory activities? |  |  |
| **4.3** | **Requirements regarding patients** |  |  |
|  | Does the laboratory management ensure that patients’ well-being, safety and rights are the primary considerations? Does the laboratory establish and implement the following processes: 1. opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretations of the examination results;
 |  |  |
|  | 1. provision of patients and users with publicly available information about the examination process, including costs when applicable, and when to expect results;
 |  |  |
| 1. periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary;
 |  |  |
| 1. where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;
 |  |  |
|  | 1. treatment of patients, samples, or remains, with due care and respect;
 |  |  |
|  | 1. obtaining informed consent when required;
 |  |  |
|  | 1. ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory;
 |  |  |
|  | 1. making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;
 |  |  |
|  | 1. upholding the rights of patients to care that is free from discrimination?
 |  |  |
| **5** | **Structural and governance requirements** |  |  |
| **5.1** | **Legal entity** |  |  |
|  | 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** |  |  |
| **5.2.1** | **Laboratory director competence** |  |  |
|  | Is the laboratory directed by 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** | **Laboratory director responsibilities** |  |  |
|  | Is the laboratory director responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed? |  |  |
|  | Are the duties and responsibilities of the laboratory director documented? |  |  |
| **5.2.3** | **Delegation of duties** |  |  |
|  | Does the laboratory director delegate either selected duties or responsibilities, or both, to qualified and competent personnel and are such delegation documented? |  |  |
| However, does the laboratory director maintain the ultimate responsibility for the overall operation of the laboratory?  |  |  |
| **5.3** | **Laboratory activities** |  |  |
| **5.3.1** | **General** |  |  |
|  | Does the laboratory specify and document the range of laboratory activities, including laboratory activities performed at sites other than the main location (e.g. POCT, sample collection) for which it conforms with this document? |  |  |
|  | Does the laboratory only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis? |  |  |
| **5.3.2** | **Conformance with requirements** |  |  |
|  | Are laboratory activities carried out in such a way as to meet the requirements of this document, the users, regulatory authorities and organizations 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** | **Advisory activities** |  |  |
|  | Does laboratory management ensure that appropriate laboratory advice and interpretation are available and meets the needs of patients and users? |  |  |
|  | Does the laboratory establish arrangements for communicating with laboratory users on the following when applicable: 1. advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods, and the frequency of requesting the examination;
 |  |  |
|  | 1. providing professional judgments on the interpretation of the results of examinations;
 |  |  |
|  | 1. promoting the effective utilization of laboratory examinations;
 |  |  |
|  | 1. advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria?
 |  |  |
| **5.4** | **Structure and authority**  |  |  |
| **5.4.1** | **General** |  |  |
|  | Does the laboratory:1. define its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services;
 |  |  |
|  | 1. specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
 |  |  |
|  | 1. specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results?
 |  |  |
| **5.4.2** | **Quality management** |  |  |
|  | Does the laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:1. implementation, maintenance and improvement of the management system;
 |  |  |
| 1. identification of deviations from the management system or from the procedures for performing laboratory activities;
 |  |  |
| 1. initiation of actions to prevent or minimize such deviations;
 |  |  |
| 1. reporting to laboratory management on the performance of the management system and any need for improvement;
 |  |  |
|  | 1. ensuring the effectiveness of laboratory activities?
 |  |  |
| **5.5** | **Objectives and policies** |  |  |
| 1. **a)**
 | Does the laboratory management establish and maintain objectives and policies to:1. meet the needs and requirements of its patients and users;
2. commit to good professional practice;
3. provide examinations that fulfil their intended use;
4. conform to this document?
 |  |  |
| 1. **b)**
 | Are objectives measurable, and consistent with policies? Does the laboratory ensure that the objectives and policies are implemented at all levels of the laboratory organization? |  |  |
| 1. **c)**
 | Does laboratory management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented? |  |  |
| 1. **d)**
 | Has the laboratory established quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives? |  |  |
| **5.6** | **Risk management** |  |  |
| 1. **a)**
 | Does laboratory management establish, implement, and maintain processes 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? |  |  |
| 1. **b)**
 | Does the laboratory director ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective? |  |  |
| **6.7** | **Service agreements** |  |  |
| **6.7.1** | **Agreements with laboratory users** |  |  |
|  | Does the laboratory have a procedure to establish and periodically review agreements for providing laboratory activities? |  |  |
|  | Does the procedure ensure that: 1. the requirements are adequately specified;
 |  |  |
|  | 1. the laboratory has the capability and resources to meet the requirements;
 |  |  |
|  | 1. when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants?
 |  |  |
|  | Are laboratory users informed of any changes to an agreement that can affect examination results? |  |  |
|  | Are records of reviews, including any significant changes, retained? |  |  |
| **6.7.2** | **Agreements with POCT operators** |  |  |
|  | Do service agreements between the laboratory and other parts of the organization using laboratory supported POCT ensure that respective responsibilities and authorities are specified and communicated? |  |  |
| **6.8** | **Externally provided products and services** |  |  |
| **6.8.1** | **General** |  |  |
|  | Does the laboratory ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are:1. intended for incorporation into the laboratory’s own activities;
 |  |  |
|  | 1. provided, in part or in full, directly to the user by the laboratory, as received from the external provider;
 |  |  |
|  | 1. used to support the operation of the laboratory?
 |  |  |
|  | Does the laboratory collaborate with other organizational departments or functions to fulfil this requirement? |  |  |
| **6.8.2** | **Referral laboratories and consultants** |  |  |
|  | Does the laboratory communicate its requirements to referral laboratories and consultants who provide interpretations and advice, for: 1. the procedures, examinations, reports and consulting activities to be provided;
 |  |  |
|  | 1. management of critical results;
 |  |  |
|  | 1. any required personnel qualifications and demonstration of competence?
 |  |  |
|  | Unless otherwise specified in the agreement, is the referring laboratory (and not the referral laboratory) responsible for ensuring that examination results of the referral laboratory are provided to the person making the request? |  |  |
|  | Is a list of all referral laboratories and consultants maintained? |  |  |
| **6.8.3** | **Review and approval of externally provided products and services** |  |  |
|  | Does the laboratory have procedures and retain records for: 1. defining, reviewing, and approving the laboratory's requirements for all externally provided products and services;
 |  |  |
|  | 1. defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers;
 |  |  |
|  | 1. referral of samples;
 |  |  |
|  | 1. ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user;
 |  |  |
|  | 1. taking any actions arising from evaluations of the performance of external providers?
 |  |  |
| **7.5** | **Nonconforming work** |  |  |
|  | Does the laboratory have a process for when any aspect of its laboratory activities or examination results do not conform to its own procedures, quality specifications, or the user requirements (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)? |  |  |
|  | Does the process ensure that:1. the responsibilities and authorities for the management of nonconforming work are specified;
 |  |  |
|  | 1. immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory;
 |  |  |
|  | 1. examinations are halted, and reports withheld when there is a risk of harm to patients;
 |  |  |
|  | 1. an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the nonconformance;
 |  |  |
|  | 1. a decision is made on the acceptability of the nonconforming work;
 |  |  |
|  | 1. when necessary, examination results are revised, and the user is notified;
 |  |  |
|  | 1. the responsibility for authorizing the resumption of work is specified?
 |  |  |
|  | Does the laboratory implement corrective action commensurate with the risk of recurrence of the nonconforming work? (see 8.7) |  |  |
|  | Does the laboratory retain records of nonconforming work and actions as specified in 7.5a) to g)? |  |  |
| **7.6** | **Control of data and information management** |  |  |
| **7.6.1** | **General** |  |  |
|  | Does the laboratory have access to the data and information needed to perform laboratory activities? |  |  |
| **7.6.2** | **Authorities and responsibilities for information management** |  |  |
|  | Does the laboratory ensure that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and modification to the information systems that can affect patient care? |  |  |
|  | Is the laboratory ultimately responsible for the laboratory information systems? |  |  |
| **7.6.3** | **Information systems management** |  |  |
|  | Is the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information:1. validated by the supplier and verified for functionality by the laboratory before introduction?

Are any changes to the system, including laboratory software configuration or modifications to commercial off-the-shelf software, authorized, documented and validated before implementation? |  |  |
|  | 1. documented, and the documentation readily available to authorized users, including that for day to day functioning of the system;
 |  |  |
|  | 1. implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguard data against tampering or loss;
 |  |  |
|  | 1. 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;
 |  |  |
|  | 1. 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?
 |  |  |
|  | Are calculations and data transfers checked in an appropriate and systematic manner? |  |  |
| **7.6.4** | **Downtime plans** |  |  |
|  | Does the laboratory have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory’s activities? |  |  |
|  | Does this include automated selection and reporting of results? |  |  |
| **7.6.5** | **Off site management** |  |  |
|  | When the laboratory information system(s) are managed and maintained off-site of through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document? |  |  |
| **7.7** | **Complaints** |  |  |
| **7.7.1** | **Process** |  |  |
|  | Does the laboratory have a process for handling complaints that include at least the following:1. a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response;
 |  |  |
|  | 1. tracking and recording the complaint, including the actions undertaken to resolve it;
 |  |  |
|  | 1. ensuring appropriate action is taken?
 |  |  |
|  | Is a description of the process for handling complaints publicly available? |  |  |
| **7.7.2** | **Receipt of complaint** |  |  |
|  | Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, is the complaint resolved? (see 8.7.1) |  |  |
|  | Is the laboratory receiving the complaint responsible for gathering all necessary information to determine whether the complaint is substantiated? |  |  |
|  | Whenever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports? |  |  |
| **7.7.3** | **Resolution of complaint** |  |  |
|  | Does investigation and resolution of complaints not result in any discriminatory actions? |  |  |
|  | Is the resolution of complaints made by, or reviewed and approved by, persons not involved in the subject of the complaint in question?Where resources do not permit this, does any alternative approach not compromise impartiality? |  |  |
| **7.8** | **Continuity and emergence preparedness planning** |  |  |
|  | Does the laboratory ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption? |  |  |
|  | Are plans periodically tested and the planned response capability exercised, where practicable? |  |  |
|  | Does the laboratory:1. establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel;
 |  |  |
|  | 1. provide information and training as appropriate to relevant laboratory personnel;
 |  |  |
|  | 1. respond to actual emergency situations;
 |  |  |
|  | 1. take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact?
 |  |  |
| **8** | **Management system requirements** |  |  |
| **8.1** | **General requirements** |  |  |
| **8.1.1** | **General** |  |  |
|  | Does the laboratory establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document? |  |  |
|  | As a minimum, does the management system of the laboratory include the following:* responsibilities (8.1)
* objectives and policies (8.2)
* documented information (8.2, 8.3 and 8.4)
* actions to address risks and opportunities for improvement (8.5)
* continual improvement (8.6)
* corrective actions (8.7)
* evaluations and internal audits (8.8)
* management reviews (8.9)?
 |  |  |
| **8.1.2** | **Fulfilment of management system requirements** |  |  |
|  | Does the laboratory 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) |  |  |
|  | Does this quality management system 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** | **Management system awareness** |  |  |
|  | Does the laboratory ensure that persons doing work under the laboratory’s control are aware of:1. relevant objectives and policies;
 |  |  |
|  | 1. their contribution to the effectiveness of the management system, including the benefits of improved performance;
 |  |  |
|  | 1. the consequences of not conforming with the management system requirements?
 |  |  |
| **8.2** | **Management system documentation** |  |  |
| **8.2.1** | **General** |  |  |
|  | Does the laboratory management establish, document and maintain objectives and policies for the fulfilment of the purposes of this document and ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization? |  |  |
| **8.2.2** | **Competence and quality** |  |  |
|  | Do the objectives and policies address the competence, quality and consistent operation of the laboratory? |  |  |
| **8.2.3** | **Evidence of commitment** |  |  |
|  | Does the laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? |  |  |
| **8.2.4** | **Documentation** |  |  |
|  | Are all documentation, processes, systems and records, related to the fulfilment of the requirements of this document included in, referenced from, or linked to the management system? |  |  |
| **8.2.5** | **Personal access** |  |  |
|  | Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities? |  |  |
| **8.3** | **Control of management system documents** |  |  |
| **8.3.1** | **General** |  |  |
|  | Does the laboratory control the documents (internal and external) that relate to the fulfilment of this document? |  |  |
| **8.3.2** | **Control of documents** |  |  |
|  | Does the laboratory ensure that:1. documents are uniquely identified;
 |  |  |
|  | 1. documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy;
 |  |  |
|  | 1. documents are periodically reviewed and updated as necessary;
 |  |  |
|  | 1. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
 |  |  |
|  | 1. changes and the current revision status of documents are identified;
 |  |  |
|  | 1. documents are protected from unauthorized changes and any deletion or removal;
 |  |  |
|  | 1. documents are protected from unauthorized access;
 |  |  |
|  | 1. the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose;
 |  |  |
|  | 1. 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** |  |  |
| **8.4.1** | **Creation of records** |  |  |
|  | Does the laboratory establish and retain legible records to demonstrate fulfilment of the requirements of this document? |  |  |
|  | Are records created at the time each activity that affects the quality of an examination is performed? |  |  |
| **8.4.2** | **Amendment of records** |  |  |
|  | Does the laboratory ensure that amendments to records can be traced to previous versions or to original observations? |  |  |
|  | Are both the original and amended data and files kept, including the date and where relevant, the time of alteration, an indication of the altered aspects and the personnel making the alterations? |  |  |
| **8.4.3** | **Retention of records** |  |  |
|  | Does the laboratory 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? |  |  |
|  | Are the retention times for records specified? |  |  |
|  | Are reported examination results retrievable for as long as necessary or as required? |  |  |
|  | Are all records 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** |  |  |
| **8.5.1** | **Identification of risks and opportunities for improvement** |  |  |
|  | Does the laboratory identify risks and opportunities for improvement associated with the laboratory activities to:1. prevent or reduce undesired impacts and potential failures in the laboratory activities;
 |  |  |
|  | 1. achieve improvement, by acting on opportunities;
 |  |  |
|  | 1. assure that the management system achieves its intended results;
 |  |  |
|  | 1. mitigate risks to patient care;
 |  |  |
|  | 1. help achieve the purpose and objectives of the laboratory?
 |  |  |
| **8.5.2** | **Acting on risks and opportunities for improvement** |  |  |
|  | Does the laboratory prioritize and act on identified risks? |  |  |
|  | Are actions taken to address risks proportional to the potential impact on laboratory examination results, as well as patient and personnel safety? |  |  |
|  | Does the laboratory record decisions made and actions taken on risks and opportunities? |  |  |
|  | Does the laboratory integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness? |  |  |
| **8.6** | **Improvement** |  |  |
| **8.6.1** | **Continual improvement** |  |  |
|  | Does the laboratory continually improve the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies? |  |  |
|  | Does the laboratory identify and select opportunities for improvement and develop, document and implement any necessary actions?Are improvement activities directed at areas of highest priority based on risk assessments and the opportunities identified? (see 8.5) |  |  |
|  | Does the laboratory evaluate the effectiveness of the actions taken? |  |  |
|  | Does the laboratory management ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care? |  |  |
|  | Does the laboratory management communicate to personnel its improvement plans and related goals? |  |  |
| **8.6.2** | **Laboratory patients, user and personnel feedback** |  |  |
|  | Does the laboratory seek feedback from its patients, users and personnel? |  |  |
|  | Is the feedback analyzed and used to improve the management system, laboratory activities and services to users? |  |  |
|  | Are records of feedback maintained including the actions taken? |  |  |
|  | Is communication provided to personnel on actions taken arising from their feedback? |  |  |
| **8.7** | **Nonconformities and corrective actions** |  |  |
| **8.7.1** | **Actions when nonconformity occurs** |  |  |
|  | When a nonconformity occurs, does the laboratory:1. Respond to the nonconformity and, as applicable:
2. take immediate action to control and correct the nonconformity;
3. address the consequences, with a particular focus on patient safety including escalation to the appropriate person?
 |  |  |
|  | 1. Determine the cause(s) of the nonconformity?
 |  |  |
|  | 1. Evaluate the need for corrective actions to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere, by:
2. reviewing and analyzing the nonconformity;
3. determining whether similar nonconformities exist, or could potentially occur;
4. assessing the potential risk(s) and effect(s) if the nonconformity recurs?
 |  |  |
|  | 1. Implement any action needed?
 |  |  |
|  | 1. Review and evaluate the effectiveness of any corrective action taken?
 |  |  |
|  | 1. Update risks and opportunities for improvement, as needed?
 |  |  |
|  | 1. Make changes to the management system, if necessary?
 |  |  |
| **8.7.2** | **Corrective action effectiveness** |  |  |
|  | Are corrective actions appropriate to the effects of the nonconformities encountered and do they mitigate the identified cause(s)? |  |  |
| **8.7.3** | **Records of nonconformities and corrective actions** |  |  |
|  | Does the laboratory retain records as evidence of the:1. nature of the nonconformities, cause(s) and any subsequent actions taken, and
 |  |  |
|  | 1. evaluation of the effectiveness of any corrective action?
 |  |  |
| **8.8** | **Evaluations** |  |  |
| **8.8.1** | **General** |  |  |
|  | Does the laboratory conduct evaluations at planned intervals to demonstrate that the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document? |  |  |
| **8.8.2** | **Quality indicators** |  |  |
|  | Is the process of monitoring quality indicators (see 5.5d) planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring?Are the indicators periodically reviewed, to ensure continued appropriateness? |  |  |
| **8.8.3** | **Internal audits** |  |  |
| 8.8.3.1 | Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system:1. conforms to the laboratory’s own requirements for its management system, including the laboratory activities,
 |  |  |
|  | 1. conforms to the requirements of this document, and
 |  |  |
|  | 1. is effectively implemented and maintained?
 |  |  |
| 8.8.3.2 | Does the laboratory plan, establish, implement and maintain an internal audit programme that includes:1. priority given to risk to patients from laboratory activities;
 |  |  |
|  | 1. a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities;
 |  |  |
|  | 1. specified audit objectives, criteria and scope for each audit;
 |  |  |
|  | 1. selection of auditors who are trained, qualified and authorized to assess the performance of the laboratory’s management system, and whenever resources permit, are independent of the activity to be audited;
 |  |  |
|  | 1. ensuring objectivity and impartiality of the audit process;
 |  |  |
|  | 1. ensuring that the results of the audits are reported to relevant personnel;
 |  |  |
|  | 1. implementation of appropriate correction and corrective actions without undue delay;
 |  |  |
|  | 1. retention of records as evidence of the implementation of the audit programme and audit results?
 |  |  |
| **8.9** | **Management reviews** |  |  |
| **8.9.1** | **General** |  |  |
|  | Does laboratory management 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** | **Review input** |  |  |
|  | Are the inputs to management review recorded and include evaluations of at least the following: 1. 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;
 |  |  |
|  | 1. fulfilment of objectives and suitability of policies and procedures;
 |  |  |
|  | 1. outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies;
 |  |  |
|  | 1. patient, user and personnel feedback and complaints;
 |  |  |
|  | 1. quality assurance of result validity;
 |  |  |
|  | 1. effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;
 |  |  |
|  | 1. performance of external providers;
 |  |  |
|  | 1. results of participation in interlaboratory comparison programmes;
 |  |  |
|  | 1. evaluation of POCT activities;
 |  |  |
|  | 1. other relevant factors, such as monitoring activities and training?
 |  |  |
| **8.9.3** | **Review output** |  |  |
|  | Does the output from the management review record the decisions and actions related to at least:1. the effectiveness of the management system and its processes;
 |  |  |
|  | 1. improvement of the laboratory activities related to the fulfilment of the requirements of this document;
 |  |  |
|  | 1. provision of required resources;
 |  |  |
|  | 1. improvement of services to patients and users;
 |  |  |
|  | 1. any need for change?
 |  |  |
|  | Does laboratory management ensure that actions arising from management review are completed within a specified time frame? |  |  |
|  | Are conclusions and actions arising from management reviews communicated to laboratory personnel? |  |  |

🗆**The Team Leader has performed review of the documentation of the laboratory prior to the assessment.**

**Verified by: Name:………………………………. Signature:……………………………… Date:…………………**