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| --- | --- |
| **DETAILS OF ORGANISATION *(to be filled by Laboratory)*** | |
| **ORGANISATION** |  |
| **ADDRESS** |  |
| **CONTACT PERSON** |  |
| **DATE** |  |

***NOTE: The purpose of this self-assessment is to encourage the laboratory to be well-acquainted with its management system and therefore you are kindly requested to fill in and give details with reference to the title of the document, the relevant page number and clause number the requirement has been addressed in the column highlighted in green. This duly filled in checklist needs to be submitted along with MAURITAS Application Form F 3.16 as well as application fees.***

| **CLAUSE** | **REQUIREMENTS** | **TO BE FILLED BY LABORATORY** | **FOR MAURITAS USE** | | |
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| **LABORATORY TO INDICATE WHERE THE REQUIREMENT HAS BEEN ADDRESSED (GIVING DETAILS OF DOCUMENT REFERENCE, PAGE NUMBER AND CLAUSE NUMBER)** | **COMPLIANCE** | | **MAURITAS REVIEW COMMENTS** |
| **YES** | **NO** |
| **4** | **Management requirements:** |  |  |  |  |
| **4.1** | **Organization and management** |  |  |  |  |
| **4.1.1** | **Organization:** Indicate how the following requirements are addressed/implemented. |  |  |  |  |
| **4.1.1.1** | **General:**  Does the medical laboratory (hereinafter referred to as ‘the laboratory’) meet the requirements of this International Standard when carrying out work at its permanent facilities, or in associated or mobile facilities? |  |  |  |  |
| **4.1.1.2** | **Legal entity:**  Is the laboratory or the organization of which it is part an entity that can be held legally responsible? |  |  |  |  |
| **4.1.1.3** | **Ethical conduct:**  Does the laboratory management have arrangements in place to ensure the following:   1. There is no involvement in any activities that would diminish confidence in the laboratory`s competence, impartiality, judgment or operational integrity? |  |  |  |  |
| 1. Management and personnel are free from any undue commercial, financial and other pressures and influences that may adversely affect the quality of their work? |  |  |  |  |
| 1. Where potential conflicts in competing interests may exist, they are openly and appropriately declared? |  |  |  |  |
|  | (d) There are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirement? |  |  |  |  |
|  | 1. Confidentiality of information is maintained? |  |  |  |  |
| **4.1.1.4** | **Laboratory director:**  Is the laboratory directed by a person or persons with the competence and delegated responsibility for the services provided? |  |  |  |  |
| Do the responsibilities of the laboratory director include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory? |  |  |  |  |
| If the laboratory director delegates selected duties and/or responsibilities to qualified personnel, does the ultimate responsibility for the overall operation and administration  of the laboratory remain with the director? |  |  |  |  |
| Are the duties and responsibilities of the laboratory director documented? |  |  |  |  |
| Does the laboratory director (or designated personnel for delegated duties) have the necessary competence, authority and resources in order to fulfill the requirements of this International Standard? |  |  |  |  |
| Does the laboratory director (or designate/s): Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities? |  |  |  |  |
| 1. Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community the patient population served and providers of formal agreements, when required? |  |  |  |  |
| 1. Ensure that there are appropriate number of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users? |  |  |  |  |
| 1. Ensure the implementation of the quality policy? |  |  |  |  |
| 1. Implement a safe laboratory environment in compliance with good practice and applicable requirements? |  |  |  |  |
| 1. Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate? |  |  |  |  |
| 1. Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results? |  |  |  |  |
| 1. Select and monitor laboratory supplies? |  |  |  |  |
| 1. Select referral laboratories and monitor the quality of their service? |  |  |  |  |
| 1. Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations? |  |  |  |  |
|  | 1. Define, implement and monitor standards of performance and quality improvement of the medical laboratory services? |  |  |  |  |
|  | 1. Monitor all work performed in the laboratory to determine whether clinical relevant information is being generated? |  |  |  |  |
|  | 1. Address any complaint, request or suggestion from staff and/or users of laboratory services?   (See 4.8, 4.14.3 and 4.14.4) |  |  |  |  |
|  | 1. Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable? |  |  |  |  |
| 1. Plan and direct research and development, where appropriate? |  |  |  |  |
| **4.1.2** | **Management responsibility:** Indicate how the following  requirements are addressed/ implemented. |  |  |  |  |
| **4.1.2.1** | **Management commitment:**  Does laboratory management provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:   1. Communicating to laboratory personnel the importance of meeting the needs and requirements of users (See 4.1.2.2) as well as regulatory and accreditation requirements, |  |  |  |  |
| 1. Establishing the quality policy (See 4.1.2.3), |  |  |  |  |
| 1. Ensuring that quality objectives and planning are established (See 4.1.2.4), |  |  |  |  |
| 1. Defining the responsibilities, authorities and interrelationships of all personnel (See 4.1.2.5), |  |  |  |  |
| 1. Establishing communication processes   (See 4.1.2.6), |  |  |  |  |
| 1. Appointing a quality manager (however named) (See 4.1.2.7), |  |  |  |  |
| 1. Conducting management reviews (See 4.15), |  |  |  |  |
| 1. Ensuring that all personnel are competent to perform their assigned activities (See 5.1.6), |  |  |  |  |
| 1. Ensuring availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities?   (See 5.1 – 5.7) |  |  |  |  |
| **4.1.2.2** | **Needs of users:**  Does the laboratory management ensure that laboratory services, including appropriate advisory and interpretative  services meet the needs of patients and those using the  laboratory services? (See 4.4 and 4.14.3) |  |  |  |  |
| **4.1.2.3** | **Quality policy:**  Does the laboratory management define the intent of its  quality management system in a quality policy? |  |  |  |  |
| Does the laboratory management ensure that the quality  policy:   1. Is appropriate to the purpose of the organization, |  |  |  |  |
| 1. Includes commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard and continual improvement of quality of laboratory services, |  |  |  |  |
| 1. Provides a framework for establishing and reviewing quality objectives, |  |  |  |  |
|  | 1. Is communicated and understood within the organization, |  |  |  |  |
|  | 1. Is reviewed for continuing suitability? |  |  |  |  |
| **4.1.2.4** | **Quality objectives and planning:**  Does the laboratory management establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization? |  |  |  |  |
| Are the quality objectives measurable and consistent with the quality policy? |  |  |  |  |
|  | Does the laboratory management ensure that planning of  the quality management system is carried out to meet the requirements and the quality objectives? (See 4.2) |  |  |  |  |
| Does the laboratory management ensure that the integrity of the quality management system is maintained when changes to quality management system are planned and implemented? |  |  |  |  |
| **4.1.2.5** | **Responsibility, authority and interrelationships:**  Does the laboratory management ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization? |  |  |  |  |
| Does this include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel? |  |  |  |  |
| **4.1.2.6** | **Communication:**  Does the laboratory management have effective means for communicating with staff? (See 4.14.4) |  |  |  |  |
| Are records kept of issues discussed in meetings? |  |  |  |  |
| Does the laboratory management ensure that appropriate communication processes are established between the laboratory and its stakeholders? |  |  |  |  |
| Does this communication take place regarding the effectiveness of the laboratory`s pre-examination, examination and post-examination processes and quality management system? |  |  |  |  |
| **4.1.2.7** | **Quality manager:**  Does the laboratory management appoint a quality  manager (however named) that has irrespective of other  responsibilities, delegated responsibility and authority that  includes:   1. Ensuring that processes needed for the quality management system are established, implemented and maintained, |  |  |  |  |
|  | 1. Reporting to the laboratory management of decisions made on laboratory policy, objectives, resources and on the performance of the quality management system and any need for improvement, |  |  |  |  |
|  | 1. Ensuring the promotion of users` needs and requirements throughout the laboratory organization? |  |  |  |  |
| **4.2** | **Quality management system** |  |  |  |  |
| **4.2.1** | **General:**Indicatehowthefollowingrequirementsareaddressed/implemented. |  |  |  |  |
| Does the laboratory establish, document, implement and  maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard? |  |  |  |  |
|  | Does the quality management system provide for the integration of all processes required to fulfil its quality policy and objectives and does it meet the needs and requirements of the users? |  |  |  |  |
|  | Does the laboratory:   1. Determine the processes needed for the quality management system and does it ensure their application throughout the laboratory, |  |  |  |  |
| 1. Determine the sequence and interaction of these processes, |  |  |  |  |
| 1. Determine criteria and methods needed to ensure that both operation and control of these processes are effective, |  |  |  |  |
| 1. Ensure the availability of resources and information necessary to support the operation and monitoring of these processes, |  |  |  |  |
| 1. Monitor and evaluate these processes, |  |  |  |  |
| 1. Implement actions necessary to achieve planned results and continual improvement of these processes? |  |  |  |  |
| **4.2.2** | **Documentation requirements** |  |  |  |  |
| **4.2.2.1** | **General:**  Does the quality management system  documentation include:   1. Statements of a quality policy and quality objectives (See 4.1.2.3 and 4.1.2.4), |  |  |  |  |
| 1. A quality manual (See 4.2.2.2), |  |  |  |  |
| 1. Procedures and records required by this International Standard, |  |  |  |  |
| 1. Documents and records determined by the laboratory to ensure the effective planning, operation and control of its processes (See 4.13), |  |  |  |  |
| 1. Copies of applicable regulations, standards and other normative documents? |  |  |  |  |
| **4.2.2.2** | **Quality manual:**  Did the laboratory establish and maintain a quality manual  that includes:   1. The quality policy or makes reference to it   (See 4.1.2.3), |  |  |  |  |
| 1. A description of the scope of the quality management system, |  |  |  |  |
| 1. A presentation of the organization and management structure of the laboratory and its place in any parent organization, |  |  |  |  |
| 1. A description of the roles and responsibilities of the laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard, |  |  |  |  |
| 1. A description of the structure and relationships of the documentation used in the quality management system, |  |  |  |  |
| 1. The documented polices established for the quality management system and reference to the managerial and technical activities that support them? |  |  |  |  |
|  | Do all laboratory staff members have access to and instructed on the use and application of the quality manual and the referenced documents? |  |  |  |  |
| **4.3** | **Document Control** |  |  |  |  |
| **4.3.1** | Does the laboratory control documents required by the quality management system and ensure that unintended use of any obsolete document is prevented? |  |  |  |  |
| **4.3.2** | Does the laboratory have a documented procedure to ensure that the following conditions are met:   1. Are all documents, including those maintained in a computerized system, issued as part of the quality management system reviewed and approved by authorized personnel before issue? |  |  |  |  |
| 1. Are all documents identified to include:  * A title; * A unique identifier on each page; * The date of the current edition and/or edition number; * page number to total number of pages   ;   * Authority for issue? |  |  |  |  |
| 1. Are current authorized editions and their distribution identified by mean of a list, |  |  |  |  |
| 1. Are current and authorized editions of applicable documents only, available at points of use? |  |  |  |  |
| Where a laboratory`s document control system allows for the amendment of documents by hand, pending the re-issue of documents:   * Are procedures and authorities for such amendment defined; * Are these amendments clearly marked, initialled and dated; * Is a revised document issued within a specified time period? |  |  |  |  |
| 1. Are changes to documents identified? |  |  |  |  |
| 1. Do the documents remain legible? |  |  |  |  |
| 1. Are documents periodically reviewed and updated at a frequency that ensures that they remain fit for purpose? |  |  |  |  |
| 1. Are obsolete controlled documents dated and marked as obsolete? |  |  |  |  |
| 1. Is at least one copy of an obsolete controlled document retained for a specified time period and is it in accordance with applicable specified requirements? |  |  |  |  |
| **4.4** | **Service agreements** |  |  |  |  |
| **4.4.1** | **Establishment of service agreements:**  Does the laboratory have documented procedures for the  establishment and review of agreements for providing  medical laboratory services? |  |  |  |  |
| Is each request, accepted by the laboratory for examination(s), considered as an agreement? |  |  |  |  |
| Do agreements, to provide medical laboratory services,  take into account the request, the examination and the  report? |  |  |  |  |
| Are the following conditions met when the laboratory enters  into agreement to provide laboratory services:   1. Are the requirements of the customers, users and of the provider of the laboratory services, including the examination processes to be used defined, documented and understood, (See 5.4.2 and 5.5) |  |  |  |  |
| 1. Does the laboratory have the capability and resources to meet the requirements, |  |  |  |  |
| 1. Do the laboratory personnel have the skills and expertise necessary for the performance of the intended examinations, |  |  |  |  |
| 1. Are the examination procedures selected appropriate and able to meet the customers’ needs   (See 5.5.1), |  |  |  |  |
| 1. Are customers and users informed o deviations from the agreement that impact upon the examination results, |  |  |  |  |
| 1. Is reference made to any work referred by the laboratory to a referral laboratory or consultant? |  |  |  |  |
| **4.4.2** | **Review of service agreements:**  Do reviews of agreements to provide medical laboratory services include all aspects of the agreement? |  |  |  |  |
| Do records of these reviews include any changes to the agreement and any pertinent discussions? |  |  |  |  |
| If an agreement needs to be amended after laboratory services have commenced, is the same agreement review process repeated?  Are any amendments communicated to all affected parties? |  |  |  |  |
| **4.5** | **Examination by referral laboratories** |  |  |  |  |
| **4.5.1** | **Selecting and evaluating referral laboratories and**  **consultants:**  Does the laboratory have a documented procedure for  selecting and evaluating referral laboratories and  consultants who provide opinions as well as interpretation  for complex testing in any discipline? |  |  |  |  |
|  | Does the procedure ensure that the following conditions are  met:   1. Is the laboratory, with the advice of users of laboratory services where appropriate responsible for selecting the referral laboratory and referral consultants;   Does the laboratory monitor the quality of performance and ensure that the referral laboratories are competent to perform the requested examinations; |  |  |  |  |
| 1. Are arrangements with referral laboratories and consultants reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are being met; |  |  |  |  |
| 1. Are records of such periodic reviews maintained; |  |  |  |  |
| 1. Is a register of all referral laboratories and consultants from whom opinions are sought maintained; |  |  |  |  |
| 1. Are requests and results of all samples referred kept for a pre-defined period? |  |  |  |  |
| **4.5.2** | **Provision of examination results:**  Unless otherwise specified in the agreement, is the referring laboratory (and not the referral laboratory) responsible to ensure that the examination results of the referral laboratory are provided to the person making the request? |  |  |  |  |
| When the referring laboratory prepares the report, does it include all essential elements of the results reported by the  referral laboratory or consultant, without alterations that could affect clinical interpretation? |  |  |  |  |
| Does the report indicate which examinations were performed by a referral laboratory or consultant?  Is the author of any additional remarks clearly identified? |  |  |  |  |
| Do laboratories adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements? |  |  |  |  |
| In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, is this process hindered by commercial or financial considerations? |  |  |  |  |
| **4.6** | **External services and supplies** |  |  |  |  |
|  | Does the laboratory have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its services? (See 5.3) |  |  |  |  |
|  | Does the laboratory select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory’s requirements?  Is criteria for selection established? |  |  |  |  |
|  | Is a list of selected and approved suppliers of equipment, reagents and consumables maintained? |  |  |  |  |
|  | Does purchasing information describe the requirements for the product or service to be purchased? |  |  |  |  |
|  | Does the laboratory monitor the performance of suppliers to ensure that purchased services or items consistently meet  the stated criteria? |  |  |  |  |
| **4.7** | **Advisory services** |  |  |  |  |
|  | Does the laboratory have established arrangements for communicating with the users on the following:   1. Advising on choice of examinations and use of the services, including required type of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination, |  |  |  |  |
| 1. Advising on individual clinical cases, |  |  |  |  |
| 1. Professional judgments on the interpretation of the results of examinations (See 5.1.2 and 5.1.6), |  |  |  |  |
| 1. Promoting the effective utilization of laboratory services, |  |  |  |  |
| 1. Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria? |  |  |  |  |
| **4.8** | **Resolution of complaint** |  |  |  |  |
|  | Does the laboratory have a documented procedure for the  management of complaints or other feedback received from  clinicians, patients, laboratory staff or other parties? |  |  |  |  |
| Are records of all complaints, their investigations and the  actions taken maintained? (See 4.14.3) |  |  |  |  |
| **4.9** | **Identification and control of nonconformities** |  |  |  |  |
|  | Does the laboratory have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination,  examination or post-examination processes? |  |  |  |  |
| Does the procedure ensure that:   1. The responsibilities and authorities for handling nonconformities are designated, |  |  |  |  |
| 1. The immediate actions to be taken are defined, |  |  |  |  |
| 1. The extent of the nonconformity is determined, |  |  |  |  |
| 1. Examinations are halted and reports withheld as necessary, |  |  |  |  |
| 1. The medical significance of any nonconforming examination is considered and, where appropriate, the requesting clinician or authorized individual responsible for using the results is informed, |  |  |  |  |
| 1. The results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary, |  |  |  |  |
|  | 1. The responsibility for authorization of the resumption of examinations is defined, |  |  |  |  |
|  | h) Is each episode of nonconformity documented and recorded? Are these records reviewed at regular specified intervals to detect trends and initiate corrective action? |  |  |  |  |
|  | When it is determined that nonconformities in pre- examination, examination and post-examination processes could recur or that there is doubt about the laboratory’s compliance with its own procedures, does the laboratory take action to identify, document and eliminate  the cause(s)?  Is the corrective action to be taken determined and documented? (See 4.10) |  |  |  |  |
|  | Does the laboratory define and implement procedures for the release of results in the case of nonconformities,  including the reviews of these results?  Are these events recorded? |  |  |  |  |
| **4.10** | **Corrective action** |  |  |  |  |
|  | Does the laboratory take corrective action(s) to eliminate the cause(s) of nonconformities? |  |  |  |  |
| Are corrective actions appropriate to the effects of the  nonconformities encountered? |  |  |  |  |
| Does the laboratory have a documented procedure for:   1. Reviewing nonconformities; |  |  |  |  |
| 1. Determining the root causes of nonconformities; |  |  |  |  |
| 1. Evaluating the need for corrective action to ensure that nonconformities do not recur; |  |  |  |  |
| 1. Determining and implementing corrective action(s) needed; |  |  |  |  |
| 1. Recording the results of corrective action(s) taken (See 4.13); |  |  |  |  |
| 1. Reviewing the effectiveness of the corrective action(s) taken? (See 4.14.5) |  |  |  |  |
| **4.11** | **Preventive action** |  |  |  |  |
|  | Does the laboratory determine action to eliminate the causes of potential nonconformities in order to prevent their  occurrence? |  |  |  |  |
| Are the preventive actions appropriate to the effects of the potential problems? |  |  |  |  |
| Does the laboratory have a documented procedure for:   1. Reviewing laboratory data and information to determine where potential nonconformities exist; |  |  |  |  |
| 1. Determining the root cause(s) of potential nonconformities; |  |  |  |  |
| 1. Evaluating the need for preventive action(s) to prevent the occurrence of nonconformities; |  |  |  |  |
| 1. Determining and implementing preventive action(s) needed; |  |  |  |  |
| 1. Recording the results of preventing action(s) taken (See 4.13); |  |  |  |  |
| 1. Reviewing the effectiveness of the preventive action(s) taken? |  |  |  |  |
| **4.12** | **Continual improvement** |  |  |  |  |
|  | Does the laboratory continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory’s actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives? |  |  |  |  |
| Are improvement activities directed at areas of highest priority based on risk assessments? |  |  |  |  |
| Are action plans for improvement developed, documented  and implemented, as appropriate? |  |  |  |  |
| Is the effectiveness of the actions taken determined through a focused review or audit of the area concerned?  (See 4.14.5) |  |  |  |  |
| Does the laboratory management ensure that the laboratory participates in continual improvement activities that  encompass relevant areas and outcomes of patient care? |  |  |  |  |
| When the continual improvement programme identifies opportunities for improvement, does laboratory management address them regardless of where they occur? |  |  |  |  |
| Does the laboratory management communicate improvement plans and related goals to the staff? |  |  |  |  |
| **4.13** | **Control of records** |  |  |  |  |
|  | Does the laboratory have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and  technical records? |  |  |  |  |
| Are records created concurrently with performance of each  activity that affects the quality of the examination? |  |  |  |  |
| Are the date and, where relevant, the time of amendments to records captured along with the identity of personnel making the amendments? (See 5.8.6) |  |  |  |  |
| Does the laboratory define the time period that various records pertaining to the quality management system, including pre-examination, examination and post-examination processes are retained? |  |  |  |  |
| If the length of time that records are retained varies, are  reported results retrievable for as long as medically  relevant or as required by regulation? |  |  |  |  |
| Do facilities provide a suitable environment for storage of  records to prevent damage, deterioration, loss or  unauthorized access? (See 5.2.6) |  |  |  |  |
| Do records include, at least the following:   1. Supplier selection, performance and changes to the approved supplier list; |  |  |  |  |
| 1. Staff qualifications, training and competency records; |  |  |  |  |
| 1. Request for examination; |  |  |  |  |
| 1. Records of receipt of samples in the laboratory; |  |  |  |  |
| 1. Information on reagents and materials used for examinations (e.g. lot documentation, certificate of supplies, package inserts); |  |  |  |  |
| 1. Laboratory workbooks or worksheets; |  |  |  |  |
| 1. Instrument printouts and retained data and information; |  |  |  |  |
| 1. Examination results and reports; |  |  |  |  |
|  | 1. Instrument maintenance records, including internal and external calibration records; |  |  |  |  |
| 1. Calibration functions and conversion factors; |  |  |  |  |
| 1. Quality control records; |  |  |  |  |
| 1. Incident records and action taken; |  |  |  |  |
| 1. Accidents records and action taken; |  |  |  |  |
| 1. Risk management records; |  |  |  |  |
| 1. Nonconformities identified and immediate or corrective action taken; |  |  |  |  |
| 1. Preventive action taken; |  |  |  |  |
| 1. Complaints and action taken; |  |  |  |  |
| 1. Records of internal and external audits; |  |  |  |  |
| 1. Interlaboratory comparisons of examination results; |  |  |  |  |
| 1. Records of quality improvement activities; |  |  |  |  |
| 1. Minutes of meetings that record decisions made about the laboratory’s quality management activities; |  |  |  |  |
| 1. Records of management reviews? |  |  |  |  |
| Are all of these quality and technical records available for  laboratory management review? (See 4.15) |  |  |  |  |
| **4.14** | **Evaluation and audits** |  |  |  |  |
| **4.14.1** | **General:**  Does the laboratory plan and implement the evaluation and  internal audit processes needed to:   1. Demonstrate that the pre-examination, examination, post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users; |  |  |  |  |
| 1. Ensure conformity to the quality management   System; |  |  |  |  |
| 1. Continually improve the effectiveness of the quality management system? |  |  |  |  |
| Are the results of evaluation an improvement included in  the input to the management review? (See 4.15)  . |  |  |  |  |
| **4.14.2** | **Periodic review of requests, and suitability of**  **procedures and sample requirements:**  Does authorized personnel periodically review the  examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received? |  |  |  |  |
| Does the laboratory periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand? |  |  |  |  |
| **4.14.3** | **Assessment of user feedback:**  Does the laboratory seek information relating to user perception as to whether the service has met the needs and requirements of users? |  |  |  |  |
| Do the methods for obtaining and using this Information include cooperation with users or their representatives in monitoring the laboratory’s performance, provided that the laboratory ensures confidentiality to other users? |  |  |  |  |
| Are records kept of information collected and actions  taken? |  |  |  |  |
| **4.14.4** | **Staff suggestions:**  Does laboratory management encourage staff to make  suggestions for the improvement of any aspect of the  laboratory service? |  |  |  |  |
| Are suggestions evaluated and implemented as appropriate?  Is feedback provided to the staff? |  |  |  |  |
| Are records of suggestions and action taken by the management maintained? |  |  |  |  |
| **4.14.5** | **Internal Audit:**  Does the laboratory conduct internal audits at planned  intervals to determine whether all activities in the quality  management system, including pre-examination,  examination and post-examination:   1. Conform to the requirements of this International Standard and to requirements established by the laboratory, and |  |  |  |  |
| 1. Are implemented, effective and maintained? |  |  |  |  |
| Are audits conducted by personnel trained to assess the  performance of managerial and technical processes of the  quality management system? |  |  |  |  |
| Does the audit programme take into account the status  and importance of the processes and technical and  management areas to be audited, as well as the results of  previous audits? |  |  |  |  |
| Are the audit criteria, scope, frequency and methods  defined and documented? |  |  |  |  |
| Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process? |  |  |  |  |
| Whenever resources permit, are auditors independent of the activity to be audited? |  |  |  |  |
| Does the laboratory have a documented procedure to  define the responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records? |  |  |  |  |
| Are personnel responsible for the area being audited ensured that appropriate action is promptly undertaken when nonconformities are identified?  Are corrective action taken without undue delay to eliminate the causes of the detected nonconformities? |  |  |  |  |
| **4.14.6** | **Risk Management:**  Does the laboratory evaluate the impact of work processes and potential failures on examination results as they affect patient safety? |  |  |  |  |
| Does the laboratory modify processes to reduce or eliminate the identified risks and document decisions and actions taken? |  |  |  |  |
| **4.14.7** | **Quality indicators:**  Does the laboratory establish quality indicators to monitor and evaluate performance throughout critical aspects of  pre-examination, examination and post-examination processes? |  |  |  |  |
| Is the process of monitoring quality indicators planned to  include objectives, methodology, interpretation, limits, action plan and duration of measurement? |  |  |  |  |
| Are the indicators periodically reviewed, to ensure their  continued appropriateness? |  |  |  |  |
| Does the laboratory, in consultation with the users,  establish turnaround times for each of its examinations that  reflect clinical needs? |  |  |  |  |
|  | Does the laboratory periodically evaluate whether or not it is  meeting the established turnaround times? |  |  |  |  |
| **4.14.8** | **Reviews by external organizations:**  When reviews by external organizations indicate that the  laboratory has nonconformities or potential nonconformities, does the laboratory take appropriate immediate actions and, as applicable, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard? |  |  |  |  |
| Are records kept of the reviews and of the corrective actions and preventive actions taken? |  |  |  |  |
| **4.15** | **Management review** |  |  |  |  |
| **4.15.1** | **General:**  Does the laboratory management review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care? |  |  |  |  |
| **Review input:**  Does the input to management review include information  from the results of evaluations of at least the following:   1. The periodic review of requests and suitability of procedures and sample requirements (See 4.14.2); |  |  |  |  |
| 1. Assessment of user feedback (See 4.14.3); |  |  |  |  |
| 1. Staff suggestions (See 4.14.4); |  |  |  |  |
| 1. Internal audits (See 4.14.5); |  |  |  |  |
|  | 1. Risk management (See 4.14.6); |  |  |  |  |
|  | 1. Use of quality indicators (See 4.14.7); |  |  |  |  |
|  | 1. Reviews by external organizations (See 4.14.8); |  |  |  |  |
|  | 1. Results of participation in interlaboratory comparison programmes (PT/EQA) (See 5.6.3); |  |  |  |  |
|  | 1. Monitoring and resolution of complaints (See 4.8); |  |  |  |  |
|  | 1. Performance of suppliers (See 4.6); |  |  |  |  |
|  | 1. Identification and control of nonconformities   (See 4.9); |  |  |  |  |
| 1. Results of continual improvement including current status of corrective actions and preventive actions   (See 4.10 – 4.12); |  |  |  |  |
| 1. Follow-up actions from previous management reviews; |  |  |  |  |
| 1. Changes in the volume and scope of work, personnel and premises that could affect the quality management system; |  |  |  |  |
| 1. Recommendations for improvement, including technical requirements? |  |  |  |  |
| **4.15.3** | **Review activities:**  Does the review analyse the input information for causes of nonconformities, trends and patterns that indicate process problems? |  |  |  |  |
| Does the review include assessing the opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives? |
| Is the quality and appropriateness of the laboratory’s contribution to patient care, to the extent possible, also objectively evaluated? |  |  |  |  |
| **4.15.4** | **Review output:**  Does the output from the management review incorporated  into a record that documents any decisions made and actions taken during management review relates to the:   1. Improvement of the effectiveness of the quality management system and its processes; |  |  |  |  |
| 1. Improvement of services to users; |  |  |  |  |
| 1. Resource needs? |  |  |  |  |
| Are findings and actions arising from management reviews recorded and reported to laboratory staff? |  |  |  |  |
| Does laboratory management ensure that actions arising from management review are completed within a defined  timeframe? |  |  |  |  |
| **5** | **Technical requirements** |  |  |  |  |
| **5.1** | **Personnel** |  |  |  |  |
| **5.1.1** | **General:**  Does the laboratory have a documented procedure for personnel management and maintain records for all  personnel to indicate compliance with requirements? |  |  |  |  |
| **5.1.2** | **Personnel qualifications:**  Does the laboratory management document personnel qualifications for each position? |  |  |  |  |
| Do the qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and  appropriate for the tasks performed? |  |  |  |  |
| Do the personnel making judgements with reference to examinations have the applicable theoretical and practical background and experience? |  |  |  |  |
| **5.1.3** | **Job descriptions:**  Does the laboratory have job descriptions that describe responsibilities, authorities and tasks for all personnel? |  |  |  |  |
| **5.1.4** | **Personnel introduction to the organizational**  **environment:**  Does the laboratory have a programme to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services? |  |  |  |  |
| **5.1.5** | **Training:**  Does the laboratory provide training for all personnel which includes the following areas:   1. The quality management system; |  |  |  |  |
| 1. Assigned work processes and procedures; |  |  |  |  |
| 1. The applicable laboratory information system; |  |  |  |  |
| 1. Health and safety, including the prevention or containment of the effects of adverse incidents; |  |  |  |  |
| 1. Ethics; |  |  |  |  |
| 1. Confidentially of patient? |  |  |  |  |
| Are personnel undergoing training supervised at all  times? |  |  |  |  |
| Is the effectiveness of the training programme periodically reviewed? |  |  |  |  |
| **5.1.6** | **Competence assessment:**  Following appropriate training, does the laboratory assess the competence of each person to perform assigned managerial or technical tasks according to established criteria? |  |  |  |  |
| Does reassessment take place at regular intervals? |  |  |  |  |
| Does retraining occur when necessary? |  |  |  |  |
| **5.1.7** | **Reviews of staff performance:**  In addition to the assessment of technical competence, does the laboratory ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships? |  |  |  |  |
| **5.1.8** | **Continuing education and professional development:**  Is a continuing education programme available to the personnel who participate in managerial and technical processes? |  |  |  |  |
| Do personnel take part in continuing education? |  |  |  |  |
| Is the effectiveness of the continuing education programme periodically reviewed? |  |  |  |  |
| Do personnel take part in regular professional development  or other professional liaison activities? |  |  |  |  |
| **5.1.9** | **Personnel records:**  Are records of the relevant educational and professional qualifications, training and experience and assessments of  competence of all personnel maintained? |  |  |  |  |
| Are these records readily available and do they include but not limited to:   1. Educational and professional qualifications? |  |  |  |  |
| 1. Copy of certification and professional qualifications? |  |  |  |  |
| 1. Previous work experience? |  |  |  |  |
| 1. Job descriptions? |  |  |  |  |
| 1. Introduction of new staff to the laboratory environment? |  |  |  |  |
| 1. Training in current job tasks? |  |  |  |  |
| 1. Competency assessments? |  |  |  |  |
| 1. Records of continuing education and achievements? |  |  |  |  |
| 1. Reviews of staff performance? |  |  |  |  |
| 1. Reports of accidents and exposure to occupational hazards? |  |  |  |  |
| 1. Immunisation status, when relevant to assign duties? |  |  |  |  |
| **5.2** | **Accommodation and environmental conditions** |  |  |  |  |
| **5.2.1** | **General:**  Does the laboratory have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors? |  |  |  |  |
| Does the laboratory evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work? |  |  |  |  |
|  | Where applicable, are similar provisions made for primary sample collection and examinations at sites other than the main laboratory premises, e.g. point-of-care testing (POCT) under the management of the laboratory? |  |  |  |  |
| **5.2.2** | **Laboratory and office facilities:**  Do the laboratory and associated office facilities provide  an environment suitable for the tasks to be undertaken, to  ensure that the following conditions are met:   1. Is the access to areas affecting the quality of examinations controlled; |  |  |  |  |
| 1. Are medical information, patient samples, and laboratory resources safeguarded from unauthorized access; |  |  |  |  |
| 1. Are there facilities for examination which allow for correct performance of examinations? |  |  |  |  |
| 1. Are communication systems within the laboratory appropriate to the size and complexity of the facility to ensure the efficient transfer of information? |  |  |  |  |
| 1. Are safety facilities and devices provided and their functioning verified regularly? |  |  |  |  |
| **5.2.3** | **Storage facilities:**  Are storage space and conditions provided to ensure the  continuing integrity of sample materials, documents,  equipment, reagents, consumables, records, results and of  any other items that could affect the quality of examination results? |  |  |  |  |
| Are clinical samples and materials used in examination  processes stored in a manner to prevent cross contamination? |  |  |  |  |
| Are the storage and disposal facilities for dangerous  materials appropriate to the hazards of the materials and  are they as specified by applicable requirements? |  |  |  |  |
| **5.2.4** | **Staff facilities:**  Are there adequate access to washrooms, a supply of drinking water and to facilities for storage of personal protective equipment and clothing? |  |  |  |  |
| **5.2.5** | **Patient sample collection facilities:**  Do patient sample collection facilities have separate reception/waiting and collection areas? |  |  |  |  |
| Is consideration given to the accommodation of patient privacy, comfort and needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection? |  |  |  |  |
| Do the facilities at which patient sample collection procedures are performed (e.g. phlebotomy) enable the sample collection to be undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination? |  |  |  |  |
|  | Do sample collection facilities have and maintain appropriate first aid materials for both patient and staff needs? |  |  |  |  |
| **5.2.6** | **Facility maintenance and environmental conditions:**  Is the laboratory premises maintained in a functional and reliable condition? |  |  |  |  |
| Are work areas clean and well maintained? |  |  |  |  |
| Does the laboratory monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results, and/or the health of staff? |  |  |  |  |
| Is attention paid to factors such as light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of any examination? |  |  |  |  |
| Is there effective separation between laboratory sections in which there are incompatible activities? |  |  |  |  |
| Are procedures in place to prevent cross- contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated? |  |  |  |  |
| Does the laboratory provide a quiet and uninterrupted work environment where it is needed? |  |  |  |  |
| **5.3** | **Laboratory equipment, reagents and consumables** |  |  |  |  |
| **5.3.1** | **Equipment** |  |  |  |  |
| **5.3.1.1** | **General:**  Does the laboratory have a documented procedure for the selection, purchasing and management of equipment? |  |  |  |  |
| Is the laboratory furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage)? |  |  |  |  |
| In cases where the laboratory needs to use equipment outside its permanent control, does the laboratory management ensure that the requirements of ISO 15189:2012 standard met? |  |  |  |  |
| Does the laboratory replace equipment as needed to ensure the quality of examination results? |  |  |  |  |
| **5.3.1.2** | **Equipment acceptance testing:**  Does the laboratory verify upon installation and before use  that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned? (see 5.5.1) |  |  |  |  |
| Is each item of equipment uniquely labelled, marked or otherwise identified? |  |  |  |  |
| **5.3.1.3** | **Equipment instructions for use:**  Are equipment operated at all times by trained and authorized personnel? |  |  |  |  |
| Are current instructions on the use, safety and maintenance  of equipment, including any relevant manuals and directions  for use provided by the manufacturer of the equipment, readily available? |  |  |  |  |
| Does the laboratory have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration? |  |  |  |  |
| **5.3.1.4** | **Equipment calibration and metrological traceability**  Does the laboratory have a documented procedure for the calibration of equipment that directly or indirectly affects  examination results? |  |  |  |  |
| Does this procedure include:   1. Taking into account conditions of use and the manufacturer`s instructions; |  |  |  |  |
| 1. Recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment; |  |  |  |  |
| 1. Verifying the required measurement accuracy and the functioning of the measuring system at defined intervals; |  |  |  |  |
| 1. Recording the calibration status and date of recalibration; |  |  |  |  |
| 1. Ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated; |  |  |  |  |
| 1. Safeguards to prevent adjustments or tampering that might invalidate examination results? |  |  |  |  |
| Is metrological traceability to a reference material or  reference procedure of the higher metrological order  available? |  |  |  |  |
| Where this is not possible, are other means for providing  confidence in the results applied?  Do these include the following:   * Use of certified reference materials; |  |  |  |  |
| * Examination or calibration by another procedure; |  |  |  |  |
|  | * Mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned? |  |  |  |  |
| **5.3.1.5** | **Equipment maintenance and repair:**  Does the laboratory have a documented programme of  preventive maintenance which, at a minimum, follows the  manufacturer’s instructions? |  |  |  |  |
| Is equipment maintained in a safe working condition and  in working order?  Does this include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, are manufacturer’s schedules or instructions, or both used? |  |  |  |  |
| Whenever an equipment is found to be defective, is it taken  out of service and clearly labelled? |  |  |  |  |
| Does the laboratory ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria? |  |  |  |  |
|  | Does the laboratory examine the effect of any defects on  previous examinations and does it institute immediate action or corrective action? (see 4.10) |  |  |  |  |
| Does the laboratory take reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and  provide appropriate personal protective equipment? |  |  |  |  |
| When equipment is removed from the direct control of the laboratory, does the laboratory ensure that its performance is verified before being returned to laboratory use? |  |  |  |  |
| **5.3.1.6** | **Equipment adverse incident reporting:**  Are adverse incidents and accidents that can be attributed directly to specific equipment investigated and reported to the manufacturer and appropriate authorities, as required? |  |  |  |  |
| **5.3.1.7** | **Equipment records:**  Are records maintained for each item of equipment that contributes to the performance of examinations? |  |  |  |  |
| Do these equipment records include, but are not limited to  the following:   1. Identity of the equipment; |  |  |  |  |
| 1. Manufacturer’s name, model and serial number or other unique identification; |  |  |  |  |
| 1. Contact information for the supplier or the manufacturer; |  |  |  |  |
| 1. Date of receiving and date of entering into service; |  |  |  |  |
| 1. Location; |  |  |  |  |
| 1. Condition when received (e.g. new, used or reconditioned); |  |  |  |  |
| 1. Manufacturer’s instructions; |  |  |  |  |
| 1. Records that confirmed the equipment’s initial acceptability for use when equipment is incorporated in the laboratory; |  |  |  |  |
|  | 1. Maintenance carried out and the schedule for preventive maintenance; |  |  |  |  |
| 1. Equipment performance records that confirm the equipment’s ongoing acceptability for use; |  |  |  |  |
| 1. Damage to, or malfunction, modification, or repair of the equipment? |  |  |  |  |
| Do the performance records referred to in (j) include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all of this requirement? |  |  |  |  |
| Are these records maintained and readily available for the lifespan of the equipment or longer, as specified in the laboratory’s Control of Records procedure? (see 4.13) |  |  |  |  |
| **5.3.2** | **Reagents and consumables** |  |  |  |  |
| **5.3.2.1** | **General:**  Does the laboratory have a documented procedure for the  reception, storage, acceptance testing and inventory  management of reagents and consumables? |  |  |  |  |
| **5.3.2.2** | **Reagents and consumables – Reception and storage:**  Where the laboratory is not the receiving facility, does it  verify that the receiving location has adequate storage  and handling capabilities to maintain purchased items in a  manner that prevents damage or deterioration? |  |  |  |  |
| Does the laboratory store received reagents and  consumables according to manufacturer’s specifications? |  |  |  |  |
| **5.3.2.3** | **Reagents and consumables – Acceptance testing:**  Is each new formulation of examination kits with changes in  reagents or procedure, or a new lot or shipment, verified for  performance before use in examinations? |  |  |  |  |
| Are consumables that can affect the quality of examinations  verified for performance before use in examinations? |  |  |  |  |
| **5.3.2.4** | **Reagents and consumables – Inventory management:**  Has the laboratory established an inventory control system  for reagents and consumables? |  |  |  |  |
| Does the system for inventory control segregate  uninspected and unacceptable reagents and consumables  from those that have been accepted for use? |  |  |  |  |
| **5.3.2.5** | **Reagents and consumables – instructions for use:**  Are instructions for the use of reagents and consumables,  including those provided by the manufacturers, readily  available? |  |  |  |  |
| **5.3.2.6** | **Reagents and consumables – Adverse incident**  **reporting:**  Are adverse incidents and accidents that can be attributed  directly to specific reagents or consumables investigated  and reported to the manufacturer and appropriate  authorities, as required? |  |  |  |  |
| **5.3.2.7** | **Reagents and consumables – Records**  Are records maintained for each reagent and consumable  that contributes to the performance of examinations? |  |  |  |  |
| Do these record include but are not limited to the following:   1. Identity of the reagent or consumable; |  |  |  |  |
| 1. Manufacturer’s name and batch code or lot number; |  |  |  |  |
|  | 1. Contact information for the supplier or the manufacturer; |  |  |  |  |
| 1. Date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service; |  |  |  |  |
| 1. Condition when received (e.g. acceptable or damaged); |  |  |  |  |
| 1. Manufacturer`s instructions; |  |  |  |  |
| 1. Records that confirmed the reagent`s or consumable`s initial acceptance for use; |  |  |  |  |
| 1. Performance records that confirm the reagent`s or consumable`s ongoing acceptance for use? |  |  |  |  |
| Where the laboratory uses reagents prepared or completed  in-house, do the records include, in addition to the  relevant information above, reference to the person or  persons undertaking their preparation and the date of  preparation? |  |  |  |  |
| **5.4** | **Pre-examination processes** |  |  |  |  |
| **5.4.1** | **General:**  Does the laboratory have documented procedures and  information for pre-examination activities to ensure the  validity of the results of examinations? |  |  |  |  |
| **5.4.2** | **Information for patients and users:**  Does the laboratory have information available for patients  and users of the laboratory services? |  |  |  |  |
| Does this information include, as appropriate:   1. The location of the laboratory; |  |  |  |  |
| 1. Types of clinical services offered by the laboratory including examinations referred to other laboratories; |  |  |  |  |
| 1. Opening hours of the laboratory; |  |  |  |  |
| 1. The examinations offered by the laboratory including, as appropriate, information concerning samples required, primary samples volumes, special precautions, turnaround time (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values; |  |  |  |  |
| 1. Instructions for completion of the request form; |  |  |  |  |
| 1. Instruction for preparation of the patient; |  |  |  |  |
| 1. Instructions for patient-collected samples; |  |  |  |  |
| 1. Instructions for transportation of samples, including any special handling needs; |  |  |  |  |
| 1. Any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed); |  |  |  |  |
| 1. The laboratory`s criteria for accepting and rejecting samples; |  |  |  |  |
| 1. A list of factors known to significantly affect the performance of the examination or the interpretation of the results; |  |  |  |  |
|  | 1. Availability of clinical advice on ordering of examinations and on the interpretation of examination results; |  |  |  |  |
| 1. The laboratory`s policy on protection of personal information; |  |  |  |  |
| 1. The laboratory`s complaint procedure? |  |  |  |  |
| Does the laboratory have information available for patients  and users that includes an explanation of the clinical  procedure to be performed to enable informed consent? |  |  |  |  |
| Is importance of provision of patient and family information,  where relevant (e.g. for interpreting genetic examination  results), explained to the patient and user? |  |  |  |  |
| **5.4.3** | **Request form information:**  Does the request form or an electronic equivalent allow  space for the inclusion of, but are not limited to the  following:   1. Patient identification, including gender, date of birth and the location/contact details of the patient, and a unique identifier; |  |  |  |  |
| 1. Name or other unique identifier of clinician, healthcare provider or other person legally authorized to request examinations or use of medical information together with the destination for the report and contact details; |  |  |  |  |
| 1. Type of primary sample and where relevant the anatomic site of origin; |  |  |  |  |
| 1. Examinations requested; |  |  |  |  |
| 1. Clinically relevant information about the patient and the request, for examination performance and result interpretation purposes; |  |  |  |  |
| 1. Date and where relevant, time of primary sample collection; |  |  |  |  |
| 1. Date and time of sample receipt? |  |  |  |  |
| Does the laboratory have a documented procedure  concerning verbal requests for examinations that includes  providing confirmation by request form or electronic  equivalent within a given time? |  |  |  |  |
| Is the laboratory willing to cooperate with users or their  representatives in clarifying the user’s request? |  |  |  |  |
| **5.4.4** | **Primary sample collection and handling** |  |  |  |  |
| **5.4.4.1** | **General:**  Does the laboratory have documented procedures for the  proper collection and handling of primary samples? |  |  |  |  |
|  | Are the documented procedures available to those  responsible for primary sample collection whether or not the  collectors are laboratory staff? |  |  |  |  |
| Where the user requires deviations and exclusions from, or  additions to, the documented collection procedure, are  these recorded and included in all documents containing  examination results and are these communicated to the  appropriate personnel? |  |  |  |  |
| Do special procedures, including more invasive procedures,  or those with an increased risk of complications to the  procedure need a more detailed explanation and a written  consent? |  |  |  |  |
| In emergency situations, where consent might not be  possible, is it acceptable to carry out necessary  procedures, provided they are in the patient`s best interest? |  |  |  |  |
| **5.4.4.2** | **Instruction for pre-collection activities:**  Does the laboratory’s instructions for pre-collection  activities include the following:   1. Completion of request form or electronic request; |  |  |  |  |
| 1. Preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients); |  |  |  |  |
| 1. Type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives; |  |  |  |  |
| 1. Special timing of collection, where needed; |  |  |  |  |
| 1. Clinical information relevant to or affecting sample collection, examination performance or result interpretation? |  |  |  |  |
| **5.4.4.3** | **Instructions for collection activities:**  Does the laboratory’s instructions for collection activities  include the following:   1. Determination of the identity of the patient from whom a primary sample is collected; |  |  |  |  |
| 1. Verification that the patient meets pre- examination requirements; |  |  |  |  |
| 1. Instructions for collection of primary blood and   non-blood samples, with descriptions of the primary sample containers and any necessary additives; |  |  |  |  |
| 1. Information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions determined and communicated to the appropriate clinical staff, in situations where the primary sample is collected as part of clinical practice; |  |  |  |  |
| 1. Instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected; |  |  |  |  |
|  | 1. Recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time; |  |  |  |  |
| 1. Instructions for proper storage conditions before collected samples are delivered to the laboratory; |  |  |  |  |
| 1. Safe disposal of materials used in the collection? |  |  |  |  |
| **5.4.5** | **Sample transportation:**  Do the laboratory’s instructions for post-collection activities  include packaging of samples for transportation? |  |  |  |  |
| Does the laboratory have a documented procedure for  monitoring the transportations of samples to ensure they  are transported:   1. Within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned; |  |  |  |  |
| 1. Within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples; |  |  |  |  |
| 1. In a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements? |  |  |  |  |
| **5.4.6** | **Sample reception:**  Does the laboratory’s procedure for sample reception  ensure that the following conditions are met:   1. Are the samples unequivocally traceable by request and labelling to an identified patient or site; |  |  |  |  |
| 1. Are laboratory-developed and documented criteria for acceptance or rejection of samples applied; |  |  |  |  |
| 1. Where there are problems with the patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, does the final report indicate the nature of the problem and where applicable, that caution is required when interpreting the result; |  |  |  |  |
| 1. Are all samples received recorded in an accession book, worksheet, computer or other comparable system;   Are the date and time of receipt and/or registration of samples recordedand whenever possible, is the identity of the person receiving the sample also recorded; |  |  |  |  |
| 1. Do the authorized personnel evaluate received samples to ensure that they meet the acceptance criteria for the requested examination(s); |  |  |  |  |
|  | 1. Where relevant, are instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent;   Do these instructions include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed? |  |  |  |  |
| Are all portions of the primary sample unequivocally  traceable to the original primary sample? |  |  |  |  |
| **5.4.7** | **Pre-examination handling, preparation and storage:**  Does the laboratory have procedures and appropriate  facilities for securing patient samples and avoiding  deterioration, loss or damage during pre-examination  activities and during handling, preparation and storage? |  |  |  |  |
| Do laboratory procedures include time limits for requesting  additional examinations or further examinations on the  same primary sample? |  |  |  |  |
| **5.5** | **Examination process** |  |  |  |  |
| **5.5.1** | **Selection, verification and validation of examination**  **procedures** |  |  |  |  |
| **5.5.1.2** | **General:**  Does the laboratory select examination procedures which  have been validated for their intended use? |  |  |  |  |
| Are the identities of the persons performing activities in  examination processes recorded? |  |  |  |  |
| Are the specified requirements (performance specifications)  for each examination procedure related to the intended use  of that examination? |  |  |  |  |
| **5.5.1.2** | **Verification of examination procedures:**  Are validated examination procedures, used without  modification, subject to independent verification by the  laboratory before being introduced into routine use? |  |  |  |  |
| Does the laboratory obtain information from the  manufacturer/ method developer for confirming the  performance characteristics of the procedure? |  |  |  |  |
| Does the independent verification by the laboratory confirm,  through obtaining objective evidence (in the form of  performance characteristics) that the performance claims  for the examination procedures have been met? |  |  |  |  |
| Are the performance claims for the examination procedure  confirmed during the verification process those relevant to  the intended use of the examination results? |  |  |  |  |
| Does the laboratory document the procedure used for the  verification and record the results obtained? |  |  |  |  |
| Does staff with the appropriate authority review verification  results and record the review? |  |  |  |  |
| **5.5.1.3** | **Validation of examination procedures:**  Does the laboratory validate examination procedures  derived from the following sources:   1. Non-standard methods; |  |  |  |  |
|  | 1. Laboratory designed or developed methods; |  |  |  |  |
| 1. Standard methods used outside their intended scope; |  |  |  |  |
| 1. Validated methods subsequently modified? |  |  |  |  |
| Is the validation as extensive as necessary and does it  confirm, through the provision of objective evidence  (in the form of performance characteristics), that the  specific requirements for the intended use of the  examination have been fulfilled? |  |  |  |  |
|  | Does the laboratory document the procedure used for the  validation and record the results obtained? |  |  |  |  |
|  | Does staff with the authority review the validation results  and record the review? |  |  |  |  |
|  | When changes are made to a validated examination  procedure, is the influence of such changes documented  and, when appropriate, is a new validation carried out? |  |  |  |  |
| **5.5.1.4** | **Measurement uncertainty of measured quantity**  **values:**  Does the laboratory determine measurement uncertainty  for each measurement procedure in the examination phase  used to report measured quantity values on patients’  samples? |  |  |  |  |
| Does the laboratory define the performance requirements  for the measurement uncertainty of each measurement  procedure and does it regularly review estimates of  measurement uncertainty? |  |  |  |  |
| Does the laboratory consider measurement uncertainty  when interpreting measured quantity values? |  |  |  |  |
|  | Upon request, does the laboratory make its estimates of  measurement uncertainty available to laboratory users? |  |  |  |  |
| Where examinations include a measurement step but do  not report a measured quantity value, does the laboratory  calculate the uncertainty of the measurement step where it  has utility in assessing the reliability of the examination  procedure or has influence on the reported result? |  |  |  |  |
| **5.5.2** | **Biological reference intervals or clinical decision**  **values:**  Does the laboratory define the biological reference intervals  or clinical decision values, document the basis for the  reference intervals or decision values and communicate this  information to users? |  |  |  |  |
| When a particular biological reference interval or decision  value is no longer relevant for the population served, are  appropriate changes made and communicated to the  users? |  |  |  |  |
| When the laboratory changes an examination procedure or  pre-examination procedure, does the laboratory review  associated reference intervals and clinical decision values,  as applicable? |  |  |  |  |
| **5.5.3** | **Documentation of examination procedures:**  Are examination procedures documented? |  |  |  |  |
| Are they written in a language commonly understood by the  staff in the laboratory and available in appropriate locations? |  |  |  |  |
| Does any condensed document format (e.g. card files or  similarly used systems) correspond to the documented  procedure?  . |  |  |  |  |
| Are all documents associated with the performance of  examinations including procedures, summary documents,  condensed document format and product instructions for  use, subject to document control? |  |  |  |  |
| In addition to document control identifiers, does  documentation include, when applicable to the examination  procedure, the following:   1. Purpose of the examination; |  |  |  |  |
| 1. Principle and method of the procedure used for examinations; |  |  |  |  |
| 1. Performance characteristics(see 5.5.1.2 and 5.5.1.3); |  |  |  |  |
| 1. Type of sample; |  |  |  |  |
| 1. Patient preparation; |  |  |  |  |
| 1. Type of container and additives; |  |  |  |  |
| 1. Required equipment and reagents; |  |  |  |  |
| 1. Environmental and safety controls; |  |  |  |  |
|  | 1. Calibration procedures (metrological traceability); |  |  |  |  |
| 1. Procedural steps; |  |  |  |  |
| 1. Quality control procedures; |  |  |  |  |
| 1. Interferences and cross reactions; |  |  |  |  |
| 1. Principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values; |  |  |  |  |
| 1. Biological reference intervals or clinical decision values; |  |  |  |  |
| 1. Reportable interval of examination results; |  |  |  |  |
| 1. Instructions for determining quantitative results when a result is not within the measurement interval; |  |  |  |  |
| 1. Alert/critical values, where appropriate; |  |  |  |  |
| 1. Laboratory clinical interpretation; |  |  |  |  |
| 1. Potential sources of variation; |  |  |  |  |
| 1. References; |  |  |  |  |
| If the laboratory intends to change an existing examination  procedure such that results or their interpretations could be  significantly different, are the implications explained to  users of the laboratory services after validating the  procedure? |  |  |  |  |
| **5.6** | **Ensuring quality of examination results** |  |  |  |  |
| **5.6.1** | **General:**  Does the laboratory ensure the quality of examinations  by performing them under defined conditions? |  |  |  |  |
| Are appropriate pre and post-examination processes  implemented? (see 4.14.7, 5.4, 5.7 and 5.8) |  |  |  |  |
| **5.6.2** | **Quality control** |  |  |  |  |
| **5.6.2.1** | **General:**  Does the laboratory design quality control procedures  that verify the attainment of the intended quality of results? |  |  |  |  |
| **5.6.2.2** | **Quality control materials:**  Does the laboratory use quality control materials that react  to the examining system in a manner as close as possible  to patient`s samples? |  |  |  |  |
|  | Are quality control materials periodically examined with a  frequency that is based on the stability of the procedure  and the risk of harm to the patient from an erroneous  result? |  |  |  |  |
| **5.6.2.3** | **Quality control data:**  Does the laboratory have a procedure to prevent the  release of patient results in the event of quality control  failure? |  |  |  |  |
| When the quality control rules are violated and indicate that  examination results are likely to contain clinically significant  errors, are the results rejected and relevant patient samples  re-examined after the error condition has been corrected  and within-specification performance is verified? |  |  |  |  |
| Does the laboratory also evaluate the results from patient  samples that were examined after the last successful  quality control event? |  |  |  |  |
| Is Quality control data reviewed at regular intervals to detect  trends in examination performance that may indicate  problems in the examination system?  When such trends are noted, are preventive actions taken  and recorded? |  |  |  |  |
| **5.6.3** | **Interlaboratory comparisons** |  |  |  |  |
| **5.6.3.1** | **Participation:**  Does the laboratory participate in an interlaboratory  comparison programme(s) (such as an external quality  assessment programme or proficiency testing programme)  appropriate to the examination and interpretations of  examination results? |  |  |  |  |
| Does the laboratory monitor the results of the  interlaboratory comparison programme(s) and participate in  the implementation of corrective actions when  predetermined performance criteria are not fulfilled? |  |  |  |  |
| Does the laboratory establish a documented procedure for  interlaboratory comparison participation that includes  defined responsibilities and instructions for participation,  and any performance criteria that differ from the criteria  used in the interlaboratory comparison programme? |  |  |  |  |
| Does the interlaboratory comparison programme(s) chosen  by the laboratory, as far as possible, provide clinically  relevant challenges that mimic patient samples and does it  have the effect of checking the entire examination process,  including pre- examination procedures, and post-  examination procedures, where possible? |  |  |  |  |
| **5.6.3.2** | **Alternative approaches:**  Whenever an interlaboratory comparison is not available,  does the laboratory develop other approaches and provide  objective evidence for determining the acceptability of  examination results?  Whenever possible, does this mechanism utilize  appropriate materials?  . |  |  |  |  |
| **5.6.3.3** | **Analysis of interlaboratory comparison samples:**  Does the laboratory integrate interlaboratory comparison  samples into the routine workflow in a manner that follows,  as much as possible, the handling of patient samples? |  |  |  |  |
| Are interlaboratory comparison samples examined by  personnel who routinely examine patient samples using  the same procedures as those used for patient samples? |  |  |  |  |
| Does the laboratory communicate with other participants in  the interlaboratory comparison programme about sample  data until after the date for submission of the data? |  |  |  |  |
| Does the laboratory refer to interlaboratory comparison  samples for confirmatory examinations before submission  of the data, although this would routinely be done with  patient samples? |  |  |  |  |
| **5.6.3.4** | **Evaluation of laboratory performance:**  Is the performance in interlaboratory comparisons  reviewed and discussed with relevant staff? |  |  |  |  |
| When predetermined performance criteria are not fulfilled  (i.e. nonconformities are present), does the staff participate  in the implementation and recording of corrective action? |  |  |  |  |
| Is the effectiveness of corrective action monitored?  Are the returned results evaluated for trends that indicate  potential nonconformities and are preventive actions taken? |  |  |  |  |
| **5.6.4** | **Comparability of examination results:**  Is there a defined means of comparing procedures, equipment and methods used and for establishing the comparability of results for patient samples throughout the  clinically appropriate intervals? |  |  |  |  |
| Is this applicable to the same or different procedures, equipment, different sites, or all of these? |  |  |  |  |
| Does the laboratory notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand and when examination methods are changed? |  |  |  |  |
| Does the laboratory document, record and, as appropriate,  expeditiously act upon results from the comparisons  performed? |  |  |  |  |
| Are problems or deficiencies identified acted upon and  records of actions retained? |  |  |  |  |
| **5.7** | **Post-examination processes** |  |  |  |  |
| **5.7.1** | **Review of results:**  Does the laboratory have procedures to ensure that  authorized personnel review the results of examinations  before release and to evaluate them against internal quality  control and, as appropriate, available clinical information  and previous examination results? |  |  |  |  |
| When the procedure for reviewing results involves  automatic selection and reporting, are review criteria  established, approved and documented? (see 5.9.1) |  |  |  |  |
| **5.7.2** | **Storage, retention and disposal of clinical samples:**  Does the laboratory have a documented procedure for  identification, collection, retention, indexing, access,  storage, maintenance and safe disposal of clinical  samples? |  |  |  |  |
| Does the laboratory define the length of time clinical  samples are to be retained? |  |  |  |  |
| Is this retention time defined by the nature of the sample,  the examination and any applicable requirements?  . |  |  |  |  |
| Are safe disposal of samples carried out in accordance with  local regulations or recommendations for waste  management? |  |  |  |  |
| **5.8** | **Reporting of results** |  |  |  |  |
| **5.8.1** | **General:**  Are the results of each examination reported accurately,  clearly, unambiguously and in accordance with any  specific instructions in the examination procedures? |  |  |  |  |
| Does the laboratory define the format and medium of the  report (i.e. electronic or paper) and the manner in which it  is to be communicated from the laboratory? |  |  |  |  |
| Does the laboratory have a procedure to ensure the  correctness of transcription of laboratory results? |  |  |  |  |
| Do reports include the information necessary for the  interpretation of the examination results? |  |  |  |  |
| Does the laboratory have a process for notifying the  requester when an examination is delayed that could  compromise patient care? |  |  |  |  |
| **5.8.2** | **Report attributes:**  Does the laboratory ensure that the following report  attributes effectively communicate laboratory results and  meet the users’ needs:   1. Comments on sample quality that might compromise examination results; |  |  |  |  |
| 1. Comments regarding sample suitability with respect to acceptance/rejection criteria; |  |  |  |  |
| 1. Critical results, where applicable; |  |  |  |  |
|  | 1. Interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results in the final report (see 5.9.1); |  |  |  |  |
| **5.8.3** | **Report content:**  Does the report include, but not be limited to, the following:   1. A clear, unambiguous identification of the examination including, where appropriate, the examination procedure; |  |  |  |  |
| 1. The identification of the laboratory that issued the report; |  |  |  |  |
| 1. Identification of all examinations that have been performed by a referral laboratory; |  |  |  |  |
| 1. Patient identification and patient location on each page; |  |  |  |  |
| 1. Name or other unique identifier of the requester and the requester’s contact details; |  |  |  |  |
| 1. Date of primary sample collection (and time, when available and relevant to patient care); |  |  |  |  |
| 1. Type of primary sample; |  |  |  |  |
| 1. Measurement procedure, where appropriate; |  |  |  |  |
| 1. Examination results reported in SI units, units traceable to SI units, or other applicable units; |  |  |  |  |
| 1. Biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable; |  |  |  |  |
| 1. Interpretation of results, where appropriate; |  |  |  |  |
| 1. Other comments such as cautionary or explanatory notes; |  |  |  |  |
| 1. Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available; |  |  |  |  |
| 1. Identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed); |  |  |  |  |
| 1. Date of the report and time of release (if not contained in the report, readily available when needed); |  |  |  |  |
| 1. Page number to total number of pages? |  |  |  |  |
| **CLAUSE** | **REQUIREMENTS** | **TO BE FILLED BY LABORATORY** | **FOR MAURITAS USE** | | |
| **LABORATORY TO INDICATE WHERE THE REQUIREMENT HAS BEEN ADDRESSED (GIVING DETAILS OF DOCUMENT REFERENCE, PAGE NUMBER AND CLAUSE NUMBER)** | **COMPLIANCE** | | **MAURITAS REVIEW COMMENTS** |
| **YES** | **NO** |
| **5.9** | **Release of results** |  |  |  |  |
| **5.9.1** | **General** |  |  |  |  |
|  | Does the laboratory establish documented procedures for the release of examination results, including details of who may release results and to who? |  |  |  |  |
| Does the procedures ensure that the following are met:   1. When the quality of the primary sample received is unsuitable for examination, or could have compromised the results, is it indicated in the report; |  |  |  |  |
| 1. When examination results fall within established “alert” or “Critical” intervals:  * Is a physician (or other authorized health professional) immediately notified; * Are records of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications maintained; |  |  |  |  |
| 1. Are results legible, without mistakes in transcription, and reported to persons authorized to receive and use the information; |  |  |  |  |
|  | 1. When results are transmitted as an interim of report, is the final report always forwarded to the requester; |  |  |  |  |
| 1. Are results provided orally followed by a written report, and is there a record for all oral results provided? |  |  |  |  |
| **5.9.2** | **Automated selection and reporting or results** |  |  |  |  |
|  | If the laboratory implements a system for automated selection and reporting of results, does it establish a documented procedure to ensure that: |  |  |  |  |
| 1. The criteria for automated selection and reporting are defined, approved, readily available and understood by the staff; |  |  |  |  |
| 1. The criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning; |  |  |  |  |
| 1. There is a process for indicating the presence of sample interferences that may alter the results; |  |  |  |  |
| 1. There is a process for incorporating analytical warning messages from the instrument into the automated selection and reporting criteria, when appropriate; |  |  |  |  |
|  | 1. Results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection; |  |  |  |  |
| 1. There is a process for rapid suspension of automated selection and reporting? |  |  |  |  |
| **5.9.3** | **Revised reports** |  |  |  |  |
|  | When an original report is revised, are there written instructions regarding the revision so that: |  |  |  |  |
| 1. The revised report is clearly identified as a revision and includes reference to the date and patient’s identity in the original report; |  |  |  |  |
| 1. The user is made aware of the revision; |  |  |  |  |
| 1. The revised record shows the time and date of the change and the name of the person responsible for the change; |  |  |  |  |
| 1. The original report entries remain in the record when revisions are made? |  |  |  |  |
| Are results that have been made available for clinical decision making and revised, retained in subsequent cumulative reports and are clearly identified as having been revised? |  |  |  |  |
|  | When the reporting system cannot capture amendments, changes or alterations, are such records kept? |  |  |  |  |
| **5.10** | **Laboratory Information Management** |  |  |  |  |
| **5.10.1** | **General** |  |  |  |  |
|  | Does the laboratory have access to the data and information needed to provide a service which meets the needs and requirements of the user? |  |  |  |  |
| Does the laboratory have a documented procedure to ensure that the confidentiality of patient information is maintained at all times? |  |  |  |  |
| **5.10.2** | **Authorities and Responsibilities** |  |  |  |  |
|  | Does the laboratory ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care? |  |  |  |  |
| Does the laboratory define the authorities and responsibilitiesof all personnel who use the system in particular those who:   1. Access patient data and information; |  |  |  |  |
| 1. Enter patient data and examination results; |  |  |  |  |
| 1. Change patient data or examination results; |  |  |  |  |
|  | 1. Authorize the release of examination results and reports? |  |  |  |  |
| **5.10.3** | **Information System Management** |  |  |  |  |
|  | Are the system(s) used for collection, processing, recording, reporting, storage or retrieval of examination data and information:   1. Validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation; |  |  |  |  |
| 1. Documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users; |  |  |  |  |
| 1. Protected from unauthorized access; |  |  |  |  |
| 1. Safeguarded against tampering or loss; |  |  |  |  |
| 1. Operated in an environment that complies with supplier specifications or, in the case of non-computerized systems failures and the appropriate immediate and corrective actions; |  |  |  |  |
| 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; |  |  |  |  |
|  | 1. In compliance with national or international requirements regarding data protection? |  |  |  |  |
| Does the laboratory verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information? |  |  |  |  |
| When a new examination or automated comments are implemented, does the laboratory verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory? |  |  |  |  |
| Does the laboratory have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory’s ability to provide service? |  |  |  |
| When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, is the laboratory management responsible for ensuring that the provider or operator of the system complies with all applicable requirements of ISO/IEC 15189:2012 standard? |  |  |  |  |