

**CONFIDENTIAL**

**SINGAPORE ACCREDITATION COUNCIL**

**SINGAPORE LABORATORY ACCREDITATION SCHEME (SAC-SINGLAS)**

|  |  |  |  |
| --- | --- | --- | --- |
| **MEDICAL TESTING LABORATORY / MEDICAL IMAGING FACILITY**  **ASSESSMENT CHECKLIST [ISO 15189:2012]** | | | |
|  |  |  | |
| Type of Assessment | : | Preliminary / Initial / Renewal / Surveillance / Non-Routine / Verification | |
|  |  |  | |
| Laboratory / Facility | : |  | |
|  |  |  | |
| Address | : |  | |
|  |  |  | |
| Tel / Fax | : |  | |
|  |  |  | |
| Names of persons seen | : |  | |
|  |  |  | |
|  |  |  | |
| Field / Disciplines | : |  | |
|  |  |  | |
|  |  |  | |
| Date of visit | : |  | |
|  |  |  | |
| Technical Assessor(s) | : |  | |
|  |  |  | |
| Team Leader | : |  |  |
|  |  | Name & Signature | Date |

References

ISO 15189:2012, SAC-01, SAC-02,SAC-SINGLAS-006, PROF 001

| **Clause No** | **Description** | **Yes** | **No** | **N/A** | **Remarks** |
| --- | --- | --- | --- | --- | --- |
| **4** | **Management requirements** |  |  |  |  |
| **4.1** | **Organisation and Management responsibility** |  |  |  |  |
| 4.1.1 | Organisation |  |  |  |  |
|  | Does the laboratory management system cover work carried out in:   * permanent facilities? * associated temporary facilities? * mobile facilities ? |  |  |  |  |
| 4.1.1.2 | Legal Entity |  |  |  |  |
|  | Is the laboratory / facility or the organisation:  - legally responsible for its activities?   * ACRA/ PHMC license available? |  |  |  |  |
| 4.1.1.3 | Ethical conduct |  |  |  |  |
|  | Does the laboratory/ management have arrangements to ensure that: |  |  |  |  |
| a) | no involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity? |  |  |  |  |
| b) | its management and personnel are free from:   * any undue internal and external commercial pressure? * financial pressure? * other pressures and influences that may adversely affect the quality of work? |  |  |  |  |
| c) | Any potential conflicts of competing interests are openly and appropriately declared? |  |  |  |  |
| d) | Appropriate procedures in place to treat human samples, tissues or remains according to relevant legal requirements? |  |  |  |  |
| e) | Policies and procedures to ensure confidentiality of information? |  |  |  |  |
| 4.1.1.4 | Laboratory Director |  |  |  |  |
|  | Is the laboratory directed by a person or persons with competence and delegated responsibility for the services provide? |  |  |  |  |
|  | Does the laboratory/facility director or designees for each task have the necessary competence, authority and resources to fulfil the requirements of this International Standards? |  |  |  |  |
|  |  |  |  |  |  |
|  | Are the duties and responsibilities of the laboratory director (or designate/s) documented and include the following: |  |  |  |  |
| a) | provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities? |  |  |  |  |
| b) | relate and function effectively (including contractual arrangements, if necessary), with   * applicable accrediting and regulatory agencies, * appropriate administrative officials, * the healthcare community, * the patient population served and * Providers of formal agreements   when required? |  |  |  |  |
| c) | Ensure that there are appropriate number of staff with required education, training and competence to meet the needs of the laboratory? |  |  |  |  |
| d) | Ensure the implementation of the quality policy? |  |  |  |  |
| e) | Implement a safe laboratory/facility environment in compliance with good practice and applicable regulations? |  |  |  |  |
| f) | Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate? |  |  |  |  |
| g) | Ensure the provision of clinical advice with respect to the choice of examinations, use of service and interpretation of examination results? |  |  |  |  |
| h) | Select and monitor laboratory suppliers? |  |  |  |  |
| i) | Select referral laboratories and monitor the quality of their service? |  |  |  |  |
| j) | Provide professional development programmes for the laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations, |  |  |  |  |
| k) | Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services, |  |  |  |  |
| l) | monitor all work performed in the laboratory to determine that clinical relevant information is being generated, |  |  |  |  |
|  |  |  |  |  |  |
| m) | Address any complaint, request or suggestion from the users of the laboratory/facility, for ensuring that quality services are provided for patients. |  |  |  |  |
| n) | Design and implement a contingency plan to ensure essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.  (contingency plan should be periodically tested) |  |  |  |  |
| o) | Plan and direct research and development, where appropriate. |  |  |  |  |
|  | (The laboratory/facility director need not perform all responsibilities personally. However, it is the laboratory/facility director’s responsibility for the overall operation and administration of the laboratory/facility, for ensuring that quality services are provided for patients.) |  |  |  |  |
| 4.1.2 | Management responsibility |  |  |  |  |
|  |  |  |  |  |  |
| 4.1.2.1 | Management commitment |  |  |  |  |
|  | Does the laboratory able to provide the following evidence to show the management’s commitment to develop and implement the quality management system and to continually improve its effectiveness? |  |  |  |  |
|  | Are the importance of meeting the needs and requirement of users, regulatory and accreditation requirements communicated to the laboratory personnel? |  |  |  |  |
|  | Is there a quality policy? (see 4.1.2.3) |  |  |  |  |
|  | Is quality objectives and planning established? (see 4.1.2.4) |  |  |  |  |
|  | Specify the:   * responsibility? * authority? * Interrelationships?   of all personnel (see 4.1.2.5) |  |  |  |  |
|  | Is communication processes established?  (See 4.1.2.6) |  |  |  |  |
|  | Is a quality manager appointed? (see 4.1.2.7) |  |  |  |  |
|  | Is management review conducted? (see 4.15) |  |  |  |  |
|  | Are personnel competent to perform their assigned activities? (see 5.1.6) |  |  |  |  |
|  |  |  |  |  |  |
|  | Are adequate resources provided (see 5.1, 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities? (see 5.4, 5.5 and 5.7). |  |  |  |  |
| 4.1.2.2 | Needs of users |  |  |  |  |
|  | Does the medical laboratory / facility services, including appropriate interpretation and advisory services meet :   * the needs of patients and all personnel responsible for patient care? |  |  |  |  |
| 4.1.2.3 | Quality policy |  |  |  |  |
|  | Is the quality policy   * defined under the authority of laboratory/ facility management? * and include the following: |  |  |  |  |
| a) | Appropriate to the purpose of the organization |  |  |  |  |
| b) | The laboratory’s / facility’s commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services? |  |  |  |  |
| c) | A framework for establishing and reviewing quality objectives |  |  |  |  |
| d) | A requirement that it is communicated and understood within the organisation? |  |  |  |  |
| e) | Reviewed for continuing suitability? |  |  |  |  |
| 4.1.2.4 | Quality objectives and planning |  |  |  |  |
|  | Does the management establish quality objectives that are measurable and consistent with the quality policy? |  |  |  |  |
|  | Does it meet the needs and requirements of the users, at relevant functions and levels within the organisation? |  |  |  |  |
|  | Does the planning of the quality management system meet the requirements and the quality objectives? |  |  |  |  |
|  | Does the laboratory management ensure that integrity of the quality management system is maintained when changes to the quality management system are planned and implemented? |  |  |  |  |
|  |  |  |  |  |  |
| 4.1.2.5 | Responsibility, authority and interrelationships |  |  |  |  |
|  | Are responsibilities, authorities, interrelationships defines, documented and communicated within the laboratory organisation? |  |  |  |  |
|  | Are appointments of person(s) responsible for each laboratory function defined, documented and communicated?  Are deputies for key managerial and technical personnel appointed?  (In smaller laboratories / facilities, staff may have more than one function and it may be impractical to appoint deputies for every function.) |  |  |  |  |
| 4.1.2.6 | Communication |  |  |  |  |
|  | Are there records of items discussed in communications and meetings with the laboratory staff? Are records kept of items discussed in communications and meetings ? |  |  |  |  |
|  | Are appropriate communication processes established between the laboratory and its stakeholders in relation to laboratory’s pre-examination, examination and post-examination processes and quality management system? |  |  |  |  |
| 4.1.2.7 | Quality Manager |  |  |  |  |
|  | Is quality manager appointed? |  |  |  |  |
|  | Does the responsibilities and authority includes: |  |  |  |  |
| a) | Ensuring that processes needed for the quality management system are established, implemented and maintained, |  |  |  |  |
| b) | Reporting to the laboratory management, at a level which decision are made to laboratory policy, objectives and resources, on the performance of the quality management system and any need for improvement? |  |  |  |  |
| c) | Promoting the awareness of users’ needs and requirements throughout the laboratory organisation? |  |  |  |  |
|  |  |  |  |  |  |
| **4.2** | **Quality management system** |  |  |  |  |
| 4.2.1 | General Requirement |  |  |  |  |
|  | Does the management establish, document, implement and maintain the quality management system and continually improve its effectiveness in accordance with the requirements of this International Standards? |  |  |  |  |
| a) | Does the laboratory:  determine the processes needed for the quality management system and ensure its implementation? |  |  |  |  |
| b) | determine the sequence and interaction of these processes? |  |  |  |  |
| c) | determine criteria and methods needed to ensure that both the operation ad control of these processes are effective? |  |  |  |  |
| d) | ensure the availability of resources and information to support the operation and monitoring of these processes? |  |  |  |  |
| e) | monitor and evaluate these processes? |  |  |  |  |
| f) | implement actions necessary to achieve planned results and continual improvement of these processes? |  |  |  |  |
| 4.2.2 | Documentation requirements |  |  |  |  |
| 4.2.2.1 | Does the quality management system documentation include: |  |  |  |  |
| a) | statements of quality policy and quality objectives? |  |  |  |  |
| b) | a quality manual? (see 4.2.2.2) |  |  |  |  |
| c) | procedures and records required by this International Standard; |  |  |  |  |
| d) | documents and records to ensure effective planning, operation and control of its processes |  |  |  |  |
| e) | copies of applicable regulations, standards and other normative documents |  |  |  |  |
|  | (the documentation can be in any form or type of medium, providing it is readily accessible and protected from unauthorized changes and undue deterioration) |  |  |  |  |
|  |  |  |  |  |  |
| 4.2.2.2 | Quality Manual |  |  |  |  |
|  | Does the quality manual includes: |  |  |  |  |
| a) | the quality policy or makes reference to it? |  |  |  |  |
| b) | a description of the scope of the quality management system? |  |  |  |  |
| c) | outlines the organisation and management structure of the laboratory/facility and its place in an parent organisation? |  |  |  |  |
| d) | roles and responsibilities of laboratory management for ensuring compliance with this International Standard?  - to include laboratory director and quality manager) |  |  |  |  |
| e) | description of the structure and relationships of the documentation used in the quality system? |  |  |  |  |
| f) | documented policies established for quality management system and reference to the managerial and technical activities that support them? |  |  |  |  |
|  | Are all laboratory personnel have access to and be instructed on the use and application of the quality manual and referenced documents? |  |  |  |  |
| **4.3** | Document Control |  |  |  |  |
|  | Does the laboratory/facility establish and maintain procedures to control all documents that form part of its quality system and prevent unintended use of obsolete controlled documents?  (Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration table, biological reference intervals and their origins, etc) |  |  |  |  |
|  | Are procedures documented to ensure that: |  |  |  |  |
|  | documents, including those maintained in computerized system, reviewed and approved by authorized personnel before issue? |  |  |  |  |
|  | documents’ identifiers to include:  - a title  - a unique identifier on each page  - the date of the current edition and/ or edition number  (‘Edition’ can be regarded as synonymous with ‘revision’ or ‘version’) |  |  |  |  |
|  |  |  |  |  |  |
|  | - page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”) |  |  |  |  |
|  | - authority for issue |  |  |  |  |
|  | a master list or an equivalent document control procedure available to identify the current revision status and distribution of documents? |  |  |  |  |
|  | current authorised versions of appropriate documents are available at points of use? |  |  |  |  |
|  | if the laboratory’s documentation control system allows for the amendment of documents by hand pending the re-issue of the documents:   * are the procedures for such amendments defined? * are the authorities for such amendments defined?   Are these amendments clearly:   * marked? * initialed? * dated?   Are revised document issues within a specified time period? |  |  |  |  |
|  | changes to documents are identified? |  |  |  |  |
|  | documents remain legible? |  |  |  |  |
|  | documents periodically reviewed, updated at a frequency to ensure that they are fit for purpose? |  |  |  |  |
|  | Obsolete controlled documents are dated and marked as obsolete? |  |  |  |  |
|  | Is a copy of these obsolete controlled documents retained for a specified time period or in accordance with applicable specified requirements? |  |  |  |  |
| **4.4** | **Service agreements** |  |  |  |  |
| 4.4.1 | Establishment of service agreements |  |  |  |  |
|  | Are procedures established and maintained for review of contracts?  Does the agreement include information needed on the request, the examination and the report interpretation?  (Each request accepted by the laboratory for examination(s) is considered as an agreement) |  |  |  |  |
|  |  |  |  |  |  |
|  | When the laboratory enters into an agreement to provide medical laboratory services, are the following conditions met? |  |  |  |  |
| a) | the requirements, including the examination processes to be used are:   * defined? * documented? * understood? |  |  |  |  |
| b) | the laboratory has the capability and resources meet the requirements? |  |  |  |  |
| c) | laboratory personnel have the skills and expertise for the performance of the intended examinations? |  |  |  |  |
| d) | appropriate examination procedures are selected to meet customers’ needs? |  |  |  |  |
| e) | the customer (eg clinicians, health care bodies, health insurance companies, pharmaceutical companies) are informed of any deviation from the agreement? |  |  |  |  |
| f) | reference to the referral laboratories or consultant is made? |  |  |  |  |
|  | (Where patients are customers, changes in service should be reflected in explanatory information and laboratory reports)  (Laboratories should not enter into financial arrangements with referring practitioners or funding agencies where such arrangements act as an inducement for the referral of examinations or patients or interfere with the practitioner’s independent assessment of what is best for the patient.) |  |  |  |  |
| 4.4.2 | Review of service agreements |  |  |  |  |
|  | Are records of these reviews including any changes to the agreement and any pertinent discussions maintained? |  |  |  |  |
|  | If the contract needs to be amended after the work commerce:   * is the same contract review process repeated? * are any amendments communicated to all affected parties |  |  |  |  |
|  |  |  |  |  |  |
| **4.5** | Examination by referral laboratories/facilities |  |  |  |  |
| 4.5.1 | Selecting and evaluating referral laboratories and consultants |  |  |  |  |
|  | Are documented procedures available to evaluate and select   * referral laboratories/facilities? * consultants who provide opinions as well as interpretation for complex testing in any discipline? |  |  |  |  |
|  | Does the procedure ensure that the following conditions are met? |  |  |  |  |
| a) | When referral laboratories/facilities or consultants are used,  - are the users consulted, where appropriate?  - Is laboratory management responsible for selecting and monitoring the quality of referral laboratories/facilities and consultants? |  |  |  |  |
|  | - Does the laboratory/facility ensure that the referral laboratory or consultant is competent to perform the requested examinations? |  |  |  |  |
| b) | Are arrangements with referral laboratories/ facilities and consultants periodically reviewed/ evaluate to ensure compliance to relevant parts of this International Standards? |  |  |  |  |
| c) | Are records of such periodic reviews maintained? |  |  |  |  |
| d) | Does the laboratory maintain a register of all referral laboratories/facilities and consultants from whom opinions are sought? |  |  |  |  |
| e) | Are requests and results of all samples referred kept for a pre-defined period? |  |  |  |  |
| 4.5.2 | Provision of examination results |  |  |  |  |
|  | Is the referring laboratory/facility, and not the referral laboratory/facility**,** responsible to ensure that examination results and findings are provided to the clinician making the request? |  |  |  |  |
|  | Does the report have all the essential elements of the results if it is reported by the referral laboratory/facility, without alterations that could affect any clinical interpretations?  Does the report indicate the examination performed by a referral laboratory or consultant? |  |  |  |  |
|  |  |  |  |  |  |
|  | Is the author who made any additional remarks clearly identified? |  |  |  |  |
|  | Where collaboration is required between clinicians and specialists from both referring and referral laboratories for correct interpretation of results, did the laboratory ensure that such process is not hindered by commercial or financial considerations? |  |  |  |  |
| **4.6** | **External services and supplies** |  |  |  |  |
|  | Are documented procedure(s) available for:   * selection? * purchasing of external services, equipment, reagent and consumable supplies it uses?   that affect the quality of the tests and/or calibrations. |  |  |  |  |
|  | Does the laboratory/facility maintain a list of approved suppliers of equipment, reagents and consumables? |  |  |  |  |
|  | Does the purchase 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 establish arrangements of communication with the users to: |  |  |  |  |
| a) | provide advice on   * choice of examination and use of services? * required sample type? * frequency of requesting the examinations? * clinical indications * limitation of examination? |  |  |  |  |
| b) | provide advice on individual clinical cases? |  |  |  |  |
| c) | provide professional judgments on the interpretation of results of examinations? |  |  |  |  |
| d) | promote effective utilization of laboratory services? |  |  |  |  |
| e) | provide consulting on scientific and logistic matters? |  |  |  |  |
|  |  |  |  |  |  |
| **4.8** | **Resolution of complaints** |  |  |  |  |
|  | Is a documented procedure available for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties? |  |  |  |  |
|  | Are records of complaints, investigations and corrective actions taken maintained by the laboratory/facility? |  |  |  |  |
| **4.9** | **Identification and control of non-conformities** |  |  |  |  |
| 4.9.1 | Is a documented procedure available to identify and manage nonconformities in any aspect of the quality management system? |  |  |  |  |
|  | Does the procedure ensure that : |  |  |  |  |
| a) | the responsibilities and authorities for handling nonconformities are defined? |  |  |  |  |
| b) | immediate actions to be taken are defined? |  |  |  |  |
|  | extent of the nonconformity is determined? |  |  |  |  |
|  | the examinations are halted and reports withheld as necessary? |  |  |  |  |
|  | the medical significance of the non-conforming tests is considered and requesting clinician informed where appropriate? |  |  |  |  |
|  | non-conforming or potentially nonconforming examination results that are previously released are recalled or appropriately identified, as necessary? |  |  |  |  |
|  | the responsibility for authorisation of the resumption of work is defined? |  |  |  |  |
|  | details of the non-conformity are documented, recorded and reviewed at regular specified intervals to detect trends and initiate corrective action? |  |  |  |  |
|  | If evaluation of the non-conformities determine recurrence or there is doubt about the laboratory’s compliance with its own procedure, are action taken to   * identify? * document? * eliminate the cause(s)?   Corrective action to be taken shall be determined and documented. |  |  |  |  |
|  |  |  |  |  |  |
| **4.10** | **Corrective Action** |  |  |  |  |
|  | Does the laboratory take appropriate corrective action to eliminate the cause(s) of nonconformities? |  |  |  |  |
|  | Does the documented procedures include the following: |  |  |  |  |
| a) | review of nonconformities? |  |  |  |  |
| b) | determination of root causes of nonconformities? |  |  |  |  |
| c) | evaluation of corrective action to ensure non-recurrence of nonconformities? |  |  |  |  |
| d) | determination and implementation of corrective action? |  |  |  |  |
| e) | documentation of corrective action taken? |  |  |  |  |
| f) | review the effectiveness of the corrective action taken? |  |  |  |  |
|  | (Action taken at the time of the nonconformity to mitigate its immediate effects is considered as “immediate” action. Only action taken to remove the root cause of the problem is considered as “corrective” action). |  |  |  |  |
| **4.11** | **Preventive Action** |  |  |  |  |
|  | Does the laboratory determine action to eliminate the causes of potential nonconformities to prevent its occurrence? |  |  |  |  |
|  | Does the documented procedures include the following: |  |  |  |  |
| a) | review of laboratory data and information to determine potential nonconformities? |  |  |  |  |
| b) | determination of root cause(s) of potential nonconformities? |  |  |  |  |
| c) | evaluation of the need for preventive action to prevent occurrence of nonconformities? |  |  |  |  |
| d) | determination and implementation of preventive action needed? |  |  |  |  |
| e) | documentation of the results of preventive action taken? |  |  |  |  |
| f) | review the effectiveness of the preventive action taken? |  |  |  |  |
|  |  |  |  |  |  |
|  | (Preventive action is a proactive process for identifying opportunities for improvement. In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analyses and external quality assessment). |  |  |  |  |
| **4.12** | **Continual Improvement** |  |  |  |  |
|  | Does the laboratory continually improve the effectiveness of the quality management system through the use of management reviews, corrective actions and preventive actions with its intention, as stated in the quality policy and quality objectives?  Is improvement activities directed at areas of highest priority based on risk assessments? |  |  |  |  |
|  | If improvement is required, are action plans:   * developed, * documented, * implemented,   as appropriate? |  |  |  |  |
|  | Is the effectiveness of the actions evaluated through a focused review or audit of the area concerned? |  |  |  |  |
|  | Does the management ensure the following:   * the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care? |  |  |  |  |
|  | * where there are opportunities for improvement, are these issues addressed regardless of where they occur? |  |  |  |  |
|  | * improvement plans and related goals are communicated to staff? |  |  |  |  |
| **4.13** | **Control of records** |  |  |  |  |
|  | Does the laboratory/facility establish and maintain a documented procedures for:   * identification * collection * indexing * access * storage * maintenance * amendment * safe disposal of quality and technical records? |  |  |  |  |
|  |  |  |  |  |  |
|  | Are records created concurrently with performance of each activity that affects the quality of the examination?  (Records can of any form/ type of medium as long as they are readily accessible, protected from unauthorized alterations and in accordance to local, national, or regional legal requirements.) |  |  |  |  |
|  | Is the date and, where relevant, time of amendments to records captured along with the identity of personnel making the amendments? |  |  |  |  |
|  | Is retention time of all records established? Is the retention time for reported results defined to allow records to be retrievable for as long as medically relevant or as required by regulation? |  |  |  |  |
|  | Does the facilities have suitable environment for storage of records to:   * to prevent damage or deterioration? * to prevent loss? * to prevent unauthorized access? |  |  |  |  |
| 4.13.3 | Does the laboratory maintained the following records: |  |  |  |  |
| a) | supplier selection and performance, and changes to the approved supplier list |
| b) | staff qualification, training and competency records |
| c) | request forms (including the patient chart or medical record only if used as the request form), |
| d) | Records of receipt of samples in the laboratory, e.g. accession records |
| e) | Information on reagents and materials used for examination (lot documentation, certificates of supplies, package inserts) |
| f) | laboratory work-books or work sheets, |
| g) | instrument printouts and retained date and information |
| h) | examination results and reports, |
| i) | instrument maintenance records including internal and external calibration records |
| j) | calibration functions and conversion factors |
| k) | quality control records, |
|  |  |
| l) | incident records and action taken, |
| m) | accident records and action taken |
| n) | risk management records |
| o) | nonconformities identified and immediate or corrective action taken |
| p) | preventive action taken |
| q) | complaints and action taken |
| r) | records of internal and external audits |
| s) | interlaboratory comparisons of examination results |
| t) | records of quality improvement activities |
| u) | minutes of meetings that record decisions made about the laboratory’s quality management system |
| v) | records of management reviews |  |  |  |  |
|  | (All these records shall be available for laboratory management review) |  |  |  |  |
| **4.14** | **Evaluation and audits** |  |  |  |  |
| 4.14.1 | Are evaluation and internal audit processes planned and implemented to: |  |  |  |  |
| a) | demonstrate that laboratory’s processes are conducted in a manner that meets the needs and requirements of users?  (e.g users’ feedback) |  |  |  |  |
| b) | ensure conformity to the quality management system |  |  |  |  |
| c) | continually improve the effectiveness of the quality management system |  |  |  |  |
|  | Are the results of evaluation and improvement activities included as part of management review? |  |  |  |  |
| 4.14.2 | Periodic review of requests, and suitability of procedures and sample requirements |  |  |  |  |
|  | Does the laboratory management review the examinations provided by the laboratory to ensure they are clinically appropriate for the requests received? |  |  |  |  |
|  |  |  |  |  |  |
|  | Does the laboratory periodically review its pre-analytical requirements including:   * sample volume * collection device * preservative requirements for blood, urine, other body fluids, tissue and other sample types   to ensure neither insufficient nor excessive amounts of samples are collected and samples are properly collected to preserve the measurand? |  |  |  |  |
| 4.14.3 | Assessment of user feedback |  |  |  |  |
|  | Does the laboratory seek user feedback on the laboratory’s performance and whether the service has met the needs and requirements of users?  Are the records of such information and action taken retained and reviewed? |  |  |  |  |
| 4.14.4 | Staff suggestion |  |  |  |  |
|  | Does the laboratory staff make suggestions for the improvement of any aspect of the laboratory services?  Are the suggestions   * evaluated * implemented, as appropriate * feedback provided to the staff   Are the records of suggestions and action taken maintained? |  |  |  |  |
| 4.14.5 | Internal Audit |  |  |  |  |
| a)  b) | Are internal audits carried at planned intervals and covers all activities in the quality management system (including pre-examination, examination and post-examination procedures) to determine:  conformance to the requirements stated in ISO 15189, relevant SAC-SINGLAS documents and internal laboratory procedures  implementation, effectiveness and maintenance of the quality management system? |  |  |  |  |
|  | (The cycle for internal audit should be completed in one year. It is not necessary to cover all elements of the quality management system in depth. The laboratory may decide to focus on a particular activity without completely neglecting the others). |  |  |  |  |
|  |  |  |  |  |  |
|  | Are such audits carried out by personnel trained to assess the performance of managerial and technical processes of the quality management system? |  |  |  |  |
|  | How does the laboratory ensure objectivity and impartiality of the audit process? Are selected auditors, wherever resources permit, independent of the activity to be audited? |  |  |  |  |
|  | Does the audit programme include:  - the status and importance of the processes, the technical and management areas to be audited  - the results of previous audits |  |  |  |  |
|  | Do the procedures for internal audit define the criteria, scope, frequency, methodology, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining records? |  |  |  |  |
|  | 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 ?  Does the laboratory ensure that the personnel responsible for the area being audited ensure that appropriate action is promptly undertaken when non conformities are identified? Are corrective actions taken without delay to eliminate the causes of the detected non conformities? |  |  |  |  |
| 4.14.6 | Risk Management |  |  |  |  |
|  | Does the laboratory evaluate the impact of work processes and potential failures on examination results that affect patient safety?  Does the laboratory modify processes to reduce or eliminate the identified risks and document decisions and action taken? |  |  |  |  |
| 4.14.7 | Quality indicators |  |  |  |  |
|  | Does the laboratory establish quality indicators to monitor and evaluate the performance of the critical aspects of pre-examination, examination and post-examination procedures? |  |  |  |  |
|  |  |  |  |  |  |
|  | Does the procedure of monitoring the quality indicators include:  - objectives  - methodology  - interpretation  - limits  - action plan  - duration of measurement |  |  |  |  |
|  | Are the indicators periodically reviewed? |  |  |  |  |
|  | Are turnaround times for each of its examinations that reflect clinical needs established? |  |  |  |  |
|  | Does the laboratory periodically evaluate its performance to meet the established turnaround time? |  |  |  |  |
|  | (The laboratory should establish quality indicators for systematically monitoring and evaluating the laboratory’s contribution to patient care). |  |  |  |  |
| 4.14.8 | Reviews by external organisation |  |  |  |  |
|  | Does the laboratory ensure that when external organisations indicate the laboratory has non conformities or potential non conformities, the laboratory shall take appropriate immediate actions and as appropriate corrective action or preventive action to ensure continue compliance with ISO 15189:2012 ?  Does the laboratory retained records of reviews by external organizations and of the corrective actions and preventive actions taken? |  |  |  |  |
| **4.15** | **Management review** |  |  |  |  |
| 4.15.1 | Does the laboratory management review the quality management system at planned intervals to ensure continuing suitability, adequacy and effectiveness in support of patient care? |  |  |  |  |
| 4.15.2 | Review Input |  |  |  |  |
|  | Does the input to management review include: |  |  |  |  |
| a) | periodic review of requests, suitability of procedures and sample requirements |  |  |  |  |
| b) | assessment of user feedback |  |  |  |  |
| c) | staff suggestions |  |  |  |  |
| d) | the outcome of recent internal audits? |  |  |  |  |
| e) | risk management |  |  |  |  |
|  |  |  |  |  |  |
| f) | use of quality indicators |  |  |  |  |
| g) | reviews by external organizations |  |  |  |  |
| h) | interlaboratory comparison programmes (PT/ EQA) performance |  |  |  |  |
| i) | monitoring and resolution of complaints |  |  |  |  |
| j) | supplier evaluation |  |  |  |  |
| k) | identification and control of non-conformities |  |  |  |  |
| l) | results of continual improvement (including current status of corrective actions and preventive actions |  |  |  |  |
| m) | Follow-up actions from previous management reviews |  |  |  |  |
| n) | Changes in volume and scope of work, personnel and premises that could affect the quality management system |  |  |  |  |
| o) | Recommendation for improvement, including technical requirements |  |  |  |  |
| 4.15.3 | Review activities |  |  |  |  |
|  | Does the management review include the following:  - analysis of the causes of nonconformities, trends and patterns that indicate process problem?  - assessment of opportunities for improvement and the need for changes to the quality management system, including its quality policy and quality objectives?  - objective evaluation of the quality and appropriateness of the laboratory’s contribution to patient care, to the extent possible? |  |  |  |  |
| 4.15.4 | Review Output |  |  |  |  |
|  | Does the laboratory document the decisions made and action taken during management review related to: |  |  |  |  |
| a) | Improvement of the effectiveness of the quality management system and its processes |  |  |  |  |
| b) | Improvement of services to users |  |  |  |  |
|  |  |  |  |  |  |
| c) | Resource needs |  |  |  |  |
|  | Are the findings and actions arising from the management review communicated to the laboratory staff? |  |  |  |  |
|  | Are findings and actions from management reviews recorded and carried out within an appropriate and agreed timescale? |  |  |  |  |

| **Clause No** | **Description** | **Yes** | **No** | **N/A** | **Remarks** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| **5** | **Technical requirements** |  |  |  |  |
| **5.1** | Personnel |  |  |  |  |
| 5.1.1 | Does the laboratory/facility management have documented procedures for personnel management?  Does the management maintain records for all personnel to indicate compliance with requirements? |  |  |  |  |
| 5.1.2 | Personnel qualification |  |  |  |  |
|  | Does the management document personnel qualification for each position?  - Does the qualification reflect appropriate education, training, experience and demonstrated skills needed, and be appropriate for the tasks performed?  - Does the personnel making judgments 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 organisation, 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 in the following areas: |  |  |  |  |
| a) | The quality management system |  |  |  |  |
| b) | Assigned work processes and procedures |  |  |  |  |
| c) | The applicable laboratory information system |  |  |  |  |
|  |  |  |  |  |  |
| d) | health and safety, including the prevention or contamination of the effects of adverse incidents |  |  |  |  |
|  |  |  |  |  |  |
| e) | Ethics |  |  |  |  |
| f) | Confidentiality of patient information |  |  |  |  |
|  | Are personnel undergoing training supervised? |  |  |  |  |
|  | Are the effectiveness of the training programme periodically reviewed? |  |  |  |  |
| 5.1.6 | Competence assessment |  |  |  |  |
|  | Does the laboratory assess the competence of each trained person to perform assigned managerial or technical tasks according to established criteria? |  |  |  |  |
|  | Does the reassessment done periodically thereafter? |  |  |  |  |
|  | Is retraining provided, when necessary? |  |  |  |  |
|  | (competency of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:  a) direct observation of routine work processes and procedures, including all applicable safety practices  b) direct observation of equipment maintenance and function checks  c) monitoring the recording and reporting of examination results  d) review of work records  e) assessment of problem solving skills  f) examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples) |  |  |  |  |
| **5.1.7** | Reviews of Staff performance |  |  |  |  |
|  | Does the laboratory consider the needs of the laboratory and of the individual during the reviews of staff performance in order to maintain or improve the quality of service and encourage productive working relationships? |  |  |  |  |
|  |  |  |  |  |  |
| 5.1.8 | Continuing education and professional development |  |  |  |  |
|  | Is continuing education program available for personnel participating in managerial and technical processes?  Do all personnel participate 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 |  |  |  |  |
|  | Does the laboratory maintain the following records: |  |  |  |  |
| a) | educational and professional qualifications |  |  |  |  |
| b) | copy of certification or license, when applicable, |  |  |  |  |
| c) | references from previous employment, |  |  |  |  |
| d) | job descriptions, |  |  |  |  |
| e) | orientation records |  |  |  |  |
| f) | training in current job tasks |  |  |  |  |
| g) | competency assessments |  |  |  |  |
| h) | records of continuing education and achievements, |  |  |  |  |
| i) | reviews of staff performance |  |  |  |  |
| j) | records of accidents and exposure to occupational hazards |  |  |  |  |
| k) | records of immunization status (when relevant to assigned duties) |  |  |  |  |
|  | (these records are not required to be stored in the laboratory, but can be maintained in other specified locations, providing they remain accessible as needed). |  |  |  |  |
|  |  |  |  |  |  |
| **5.2** | Accommodation and environmental conditions |  |  |  |  |
| 5.2.1 | Is the laboratory/facility workspace adequate to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of the laboratory personnel, patient and visitors?  Is there evidence that the laboratory/facility director determined the adequacy of the laboratory’s space?  Where applicable, are similar provisions made for primary sample collection and examinations at sites other than the main laboratory premises, for example POCT under the management of the laboratory? |  |  |  |  |
| 5.2.2 | Does the laboratory and associated office facilities meet the following conditions: |  |  |  |  |
| a) | is access to laboratory/facility controlled? |  |  |  |  |
| b) | are medical information, patient samples, and laboratory resources safeguarded from unauthorized access? |  |  |  |  |
| c) | does the laboratory/facility for examination allow correct performance of examinations?  Example, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions. |  |  |  |  |
| d) | are the communication systems within the laboratory appropriate to the size and complexity of the facility to allow effective transfer of information? |  |  |  |  |
| e) | are safety facilities and devices provided and functioning regularly verified? |  |  |  |  |
| 5.2.3 | Storage facilities |  |  |  |  |
|  | Are storage space and conditions provided to ensure continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results? |  |  |  |  |
|  | Are clinical samples and materials stored in a manner to prevent cross contaminations? |  |  |  |  |
|  |  |  |  |  |  |
|  | Are storage and disposal facilities for dangerous materials appropriate to the hazards of the materials and as specified by applicable requirements? |  |  |  |  |
| 5.2.4 | Staff facilities |  |  |  |  |
|  | Does the laboratory have adequate access to washrooms, supply of drinking water and facilities for storage of personal protective equipment and clothing?  (When possible, the laboratory should provide space for staff activities such as meeting and quiet study and rest area). |  |  |  |  |
| 5.2.5 | Patient sample collection facilities |  |  |  |  |
|  | Do the patient sample collection facilities have separate reception/ waiting and collection areas?  Are considerations made for accommodating patient disabilities, comfort, and privacy when primary sample collection facilities are provided?  Is the environment in which the primary sample collection procedures are performed suitable so that it does not invalidate the results or adversely affect the quality of the examination?  Are appropriate first aid materials available and maintained for both patient and staff at sample collection facilities? |  |  |  |  |
| 5.2.6 | Facility maintenance and environmental conditions |  |  |  |  |
|  | Is the laboratory maintained in a functional and reliable condition?  Is the work areas clean and well maintained? |  |  |  |  |
|  | Does the laboratory/facility monitor, control and record environment conditions as required by relevant specification or where they may influence the quality of sample, results and/or the health of staff?  (Due attention shall be paid to 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 as not to invalidate the results or adversely affect the required quality of examination) |  |  |  |  |
|  |  |  |  |  |  |
|  | Is there effective separation between neighbouring areas where incompatible activities are performed? |  |  |  |  |
|  | Are appropriate measures taken to prevent cross-contamination where examination procedures pose a hazard or where the work may be affected or influenced by not being separated (e.g. nucleic acid amplifications)?  Does the laboratory provide an environment conducive to quiet and uninterrupted work where it is needed? (e.g. cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing reactions and review of molecular mutation results) |  |  |  |  |
| **5.3** | **Laboratory Equipment, reagents and consumables** |  |  |  |  |
|  | Note: Instruments, reference materials, consumables, reagents, and analytical systems are included as laboratory equipment, as applicable. |  |  |  |  |
| 5.3.1 | Does the laboratory has documented procedure for  - selection  - purchasing  - management of equipment?  Is the laboratory/facility furnished with all the items of equipment required for its services (including primary sample collection, sample preparation and processing, examination and storage)? |  |  |  |  |
|  | Where the laboratory/facility needs to use equipment outside its permanent control, does the laboratory management ensure that the requirements of ISO 15189 are met?  Does the laboratory replace equipment as needed to ensure its quality of examination results? |  |  |  |  |
| 5.3.1.2 | Equipment acceptance testing |  |  |  |  |
|  | Is equipment verified upon installation and before use to shown its capability to achieve the necessary performance and compliance with requirements relevant to any examinations concerned?  (this requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory). |  |  |  |  |
|  |  |  |  |  |  |
|  | Is each item of equipment uniquely labelled, marked or otherwise identified? |  |  |  |  |
| 5.3.1.3 | Equipment instructions for use |  |  |  |  |
|  | Are equipment operated by trained and authorized personnel at all times?  Are current instructions, issued by manufacturer, on the use, safety and maintenance of equipment, including relevant manuals and directions for use, readily available?  Does the laboratory have procedures for safe handling, transport, storage and use of equipment to prevent its contamination and deterioration? |  |  |  |  |
| 5.3.1.4 | Equipment calibration and metrological traceability |  |  |  |  |
|  | Does the laboratory have documented procedure for the calibration of equipment that directly or indirectly affects examination results?  Does the procedure includes: |  |  |  |  |
| a) | reference to conditions of use and manufacturer’s instructions? |  |  |  |  |
| b) | recording of the metrological traceability of the calibration standard and traceable calibration of the item of equipment? |  |  |  |  |
| c) | verification of the required measurement accuracy and function of the measuring system at defined intervals |  |  |  |  |
| d) | recording of the calibration status and date of recalibration |  |  |  |  |
| e) | ensuring that calibration factors are correctly updated after calibration |  |  |  |  |
| f) | safeguards to prevent adjustments or tampering that might invalidate examination results. |  |  |  |  |
|  | Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.  (Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer’s examination system and calibration procedures are used without modification). |  |  |  |  |
|  |  |  |  |  |  |
|  | Where this is not possible or relevant, does the laboratory use other means for providing confidence in the results such as (but not limited to):  - 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 al parties concerned? |  |  |  |  |
| 5.3.1.5 | Equipment maintenance and repair |  |  |  |  |
|  | Is there documented programme of preventive maintenance which, at a minimum, following the recommendation from the manufacturer? |  |  |  |  |
|  | Are equipment maintained in safe working condition and in working order?  Are procedures in place to ensure examination of electrical safety, emergency stop devices, and safe handling and disposal of chemical, radioactive and biological materials by authorized persons?  Manufacturer’s specifications or instructions or both shall be used, as appropriate. |  |  |  |  |
|  | Is defective equipment taken out of service, clearly labelled and not used until it has been repaired and shown by verification to meet specified acceptance criteria? |  |  |  |  |
|  | Is the effect of this defect on previous examinations examined and institute immediate action or corrective action?  Are reasonable measures taken to decontaminate equipment prior to service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment? |  |  |  |  |
|  | When equipment goes outside the direct control of the laboratory/facility, does the laboratory ensure its performance is verified before the equipment is returned to service? |  |  |  |  |
|  |  |  |  |  |  |
| 5.3.1.6 | Equipment adverse incident reporting |  |  |  |  |
|  | Are adverse incidents and accidents that can be attributed to specific equipment investigated and reported to manufacturer and appropriate authorities, as required? |  |  |  |  |
| 5.3.1.7 | Equipment records |  |  |  |  |
|  | Are the following records of each item of equipment contributing to the performance of examinations maintained: |  |  |  |  |
| a) | identity of the equipment, |  |  |  |  |
| b) | manufacturer’s name, model, and serial number or other unique identification, |  |  |  |  |
| c) | manufacturer’s/ supplier’s contact information, |  |  |  |  |
| d) | date received and date of entered into service, |  |  |  |  |
| e) | location, |  |  |  |  |
| f) | condition when received (e.g. new, used or reconditioned), |  |  |  |  |
| g) | manufacturer’s instructions, |  |  |  |  |
| h) | records that confirmed the equipment’s initial acceptability for use when it is incorporated in the laboratory, |  |  |  |  |
| i) | maintenance carried out and the schedule for preventive maintenance, |  |  |  |  |
| j) | equipment performance records that confirm the equipment’s ongoing acceptability for use, |  |  |  |  |
| k) | damage to, or malfunction, modification or repair, of the equipment. |  |  |  |  |
|  | Does the performance records referred in j) include copies of reports/certificates of all calibrations and/or verifications including dates, time and results, adjustments, acceptance criteria and due date of next calibration and/or verification, to fulfil part or this entire requirement? |  |  |  |  |
|  | Are the records maintained and readily available for the life span of the equipment or for any time period required by national, regional and local regulations? |  |  |  |  |
|  |  |  |  |  |  |
| 5.3.2 | **Reagents and consumables** |  |  |  |  |
| 5.3.2.1 | Does the laboratory has documented procedure for  - reception  - storage  - acceptance testing  - 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 the laboratory verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration?  Is the storage of received reagents and consumables in accordance to manufacturer’s specification? |  |  |  |  |
| 5.3.2.3 | Reagents and consumables – Acceptance testing |  |  |  |  |
|  | Is new formulation of examination kits with changes in reagents or procedure, or 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 |  |  |  |  |
|  | Does the laboratory establish an inventory control system for reagents and consumables?  Does the inventory control system segregate uninspected and unacceptable reagents and consumables for those that have been accepted for use? |  |  |  |  |
| 5.3.2.5 | Reagents and consumables – Instructions for use |  |  |  |  |
|  | Are instructions for 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 to specific reagents or consumables investigated and reported to manufacturer and appropriate authorities, as required? |  |  |  |  |
| 5.3.2.7 | Reagents and consumables – Records |  |  |  |  |
|  | Are the following records (but not limited to) of each reagents and consumables contributing to the performance of examinations maintained: |  |  |  |  |
| a) | Identity of the reagent or consumable |  |  |  |  |
| b) | manufacturer’s name, and batch code/ lot number, |  |  |  |  |
| c) | manufacturer’s/ supplier’s contact information, |  |  |  |  |
| d) | date received, expiry date, and date of entering into service and, where applicable, the date the material was taken out of service, |  |  |  |  |
| e) | condition when received (e.g. accepted or damaged), |  |  |  |  |
| f) | manufacturer’s instructions, |  |  |  |  |
| g) | records that confirmed the reagent’s or consumable’s initial acceptability for use, |  |  |  |  |
| h) | performance records that confirm the reagent’s or consumable’s ongoing acceptance of use. |  |  |  |  |
|  | Where the laboratory uses reagents prepared or completed in-house, does the records also include reference to the persons or persons undertaking their preparation and the date of preparation? |  |  |  |  |
| **5.4** | Pre-examination Process |  |  |  |  |
| 5.4.1 | Does the laboratory has 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 |  |  |  |  |
|  | Are the following information available for patients and users of the laboratory services: |  |  |  |  |
| a) | location of the laboratory |  |  |  |  |
|  |  |  |  |  |  |
| b) | types of clinical services offered by the laboratory including examinations referred to other laboratories |  |  |  |  |
| c) | opening hours of the laboratory |  |  |  |  |
| d) | examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample 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, |  |  |  |  |
| e) | Instruction for completion of request form |  |  |  |  |
| f) | Instruction for preparation of the patient |  |  |  |  |
| g) | Instruction for patient-collected samples |  |  |  |  |
| h) | Instruction for transportation of samples, including any special handling needs, |  |  |  |  |
| i) | any requirement for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed |  |  |  |  |
| j) | the laboratory’s criteria for accepting and rejecting samples, |  |  |  |  |
| k) | a list of factors known to significantly affect the performance of examination or the interpretation of the results |  |  |  |  |
| l) | availability of clinical advice on ordering of examinations and on interpretation of examination results, |  |  |  |  |
| m) | the laboratory’s policy on protection of personal information, |  |  |  |  |
| n) | the laboratory’s complaint procedure |  |  |  |  |
|  | Is information that includes an explanation of the clinical procedure to be performed available for patients and users to enable informed consent?  Are 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 electronic equivalent allow space for the inclusion of, but not limited to: |  |  |  |  |
| a) | unique identification of the patient; |  |  |  |  |
| b) | name or other unique identifier of physician or other person legally authorised to order examinations or use medical information together with the destination for the report. If the requesting clinician’s address provided as part of the request form information; |  |  |  |  |
| c) | type of primary sample and the anatomic site of origin, where relevant; |  |  |  |  |
| d) | examinations requested; |  |  |  |  |
| e) | clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes; |  |  |  |  |
| f) | date and time of primary sample collection; and |  |  |  |  |
| g) | date and time of receipt of samples by the laboratory.  The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the user of laboratory services. |  |  |  |  |
|  | Does the laboratory has a documented procedure to handle 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? |  |  |  |  |
| 5.4.2. | Are specific instructions for the proper collection and handling of primary samples   * documented? * implemented? * made available to those responsible for primary sample collection   Are these instructions contained in a primary sample collection manual? |  |  |  |  |
|  |  |  |  |  |  |
| 5.4.4 | Primary sample collection and handling |  |  |  |  |
| 5.4.4.1 | Does the laboratory have documented procedures for proper collection and handling of primary samples?  Is the procedure(s) available to those responsible for primary sample collection regardless if the collectors are laboratory staff? |  |  |  |  |
|  | Where the user requires deviations, exclusions from or additions to, the documented collection procedure, are the deviations recorded and included in all documents containing examination results and communicated to the appropriate personnel?  (All procedures carried out on a patient need the informed consent of the patient) |  |  |  |  |
|  | Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.  In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures; provided they are in patient’s best interest. |  |  |  |  |
|  | (Adequate privacy during reception and sampling should be available and appropriate to the type of information being requested and primary sample being collected). |  |  |  |  |
| 5.4.4.2 | Instructions for pre-collection activities |  |  |  |  |
|  | Does the laboratory have instructions to include the following: |  |  |  |  |
| a) | completion of request form or electronic requests; |  |  |  |  |
| b) | preparation of the patient (e.g. instructions to caregivers and phlebotomists)?  identifications of primary sample? |  |  |  |  |
| c) | type and amount of primary sample to be collected (e.g., phlebotomy, skin puncture, blood, urine and other body fluids) with descriptions of the primary sample containers and any necessary additives? |  |  |  |  |
| d) | special timing of collection, if required? |  |  |  |  |
|  |  |  |  |  |  |
| e) | clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs)? |  |  |  |  |
| 5.4.4.3 | Instructions for collection activities |  |  |  |  |
|  | Does the instructions for collection activities include the following: |  |  |  |  |
| a) | positive identification in detail of the patient from whom a primary sample is collected? |  |  |  |  |
| b) | verification that patient meets pre-examination requirements [e.g. fasting status, medication status, sample collection at predetermined time or time intervals, etc.]? |  |  |  |  |
| c) | instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives? |  |  |  |  |
| d) | where primary sample is collected as part of clinical practice, determination and communication to appropriate clinical staff on the information and instructions for primary sample containers, any necessary additives and sample transport conditions? |  |  |  |  |
| e) | instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected. |  |  |  |  |
| f) | identification of the collector and collection date, and when needed, recording of the collection time |  |  |  |  |
| g) | instructions for proper storage conditions before collected samples are delivered to the laboratory |  |  |  |  |
| h) | 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 monitor how the samples are transported to the laboratory for the following: |  |  |  |  |
| a) | within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned? |  |  |  |  |
|  |  |  |  |  |  |
| b) | within a temperature range specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples? |  |  |  |  |
| c) | in a manner that ensures the integrity of the samples and safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements? |  |  |  |  |
|  | (A laboratory which is not involved in primary sample collection and transportation is considered to have satisfied clause 5.4.5c) above when, upon receipt of a sample whose integrity was compromised or which could have jeopardized the safety of the carrier or the general public, the sender is contacted immediately and informed about measures to be taken to eliminate recurrence). |  |  |  |  |
| 5.4.6 | Sample reception |  |  |  |  |
|  | Does the laboratory’s procedure for sample reception ensure that the following conditions are met:  Is the primary sample collection manual part of the document control system? |  |  |  |  |
| a) | Are primary samples unequivocally traceable, by request and labelling, to an identified patient or site? |  |  |  |  |
| b) | Are laboratory-developed and documented criteria for acceptance or rejection of samples applied? |  |  |  |  |
| c) | Where there is uncertainty in the identification of the primary sample, or 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? |  |  |  |  |
| d) | Are all sample received recorded in an accession book, worksheet, computer or other comparable system and include:   * date and time of receipt and/ or registration of samples * identity of person receiving the sample, whenever possible |  |  |  |  |
|  |  |  |  |  |  |
| e) | Are received samples evaluated by the authorised personnel to ensure that they meet the acceptance criteria relevant for the requested examination? |  |  |  |  |
| f) | Where relevant, are there instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent?  Do the instructions include:   * details of special handling of the request form and the primary sample? * mechanism of transfer of the primary sample to be examination area of the laboratory? * any rapid processing mode to be used? * 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 to :  - secure patient samples  - prevent deterioration, loss or damage during pre-examination activities, and during handling, preparation and storage  Is time limits established for request of additional examinations or further examinations on the same primary sample? |  |  |  |  |
| **5.5** | **Examination procedures** |  |  |  |  |
| 5.5.1 | Selection, verification and validation of examination procedures |  |  |  |  |
| 5.5.1.1 | Does the laboratory select examination procedures which have been validated for their intended use?  Is the identity of persons performing activities in examination processes recorded?  Does the specified requirements (performance specifications) for each examination procedure relate to the intended use of that examination.  (Preferred procedures are those specified in the instructions of use of *in vitro* medical devices or those published in established/ authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines or regional and national regulations). |  |  |  |  |
|  |  |  |  |  |  |
| **5.5.1.2** | Verification of examination procedures |  |  |  |  |
|  | Does the laboratory performed independent verification for validated examination procedures before being introduced into routine use?  Is information from the manufacturer/ method developer obtained for confirming the performance characteristics of the procedure?  Does the independent verification by the laboratory, through obtaining of objective evidence, confirm that the performance claims for the examination procedure have been met and relevant to the intended use?  Are the verification procedure and results obtained documented?  Are the verification results reviewed by appropriate authority and is the review documented? |  |  |  |  |
| 5.5.1.3 | Does the laboratory validate the examination procedures derived from: |  |  |  |  |
| a) | non-standard methods, |  |  |  |  |
| b) | laboratory designed or developed methods |  |  |  |  |
| c) | standard methods used outside their intended scope |  |  |  |  |
| d) | validated methods subsequently modified |  |  |  |  |
|  | The validations shall be as extensive as necessary and confirm, through provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled. |  |  |  |  |
|  | (Performance characteristics of an examination procedure should include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substance, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and sensitivity). |  |  |  |  |
|  | Are the validation procedure and results obtained documented? |  |  |  |  |
|  | Are the validation results reviewed by appropriate authority and is the review documented? |  |  |  |  |
|  |  |  |  |  |  |
|  | When changes are made to a validated examination procedure, are the impact of the changes documented and, when appropriate, a new validation shall be carried out. |  |  |  |  |
| 5.5.1.4 | Measurement uncertainty of measured quantity values |  |  |  |  |
|  | Does the laboratory determine measurement uncertainty for each measurement procedure used to report measured quantity values on patient’s samples?  Is the performance requirements for the measurement uncertainty of each measurement procedure defined regularly reviewed?  The laboratory shall consider measurement uncertainty when interpreting measured quantity values.  Upon request, does the laboratory make its estimation of measurement uncertainty available to laboratory users? |  |  |  |  |
|  | Where examinations include a measurement step but do not report a measured quantity value, the laboratory should 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 |  |  |  |  |
|  | Are the biological reference intervals or clinical decision values, defined and basis of which, documented and communicated to users?  Are appropriate changes made, when a particular biological reference interval or decision value is no longer relevant for the population served? Are the changes communicated to the users?  When the laboratory changes an examination procedure or pre-examination procedure, are the associated reference intervals and clinical decision values reviewed? |  |  |  |  |
|  |  |  |  |  |  |
| 5.5.3 | Documentation of examination procedures |  |  |  |  |
|  | Are examination procedures documented and written in a language commonly understood by the staff in the laboratory? Ire they available in appropriate locations?    Any condensed document format (e.g. card files or similar used systems) shall correspond to the documented procedure.    (Information from product instructions for use may be incorporated into examination procedures by reference).  Are all documents associated with the performance of examinations, including procedures, summary documents, condensed documents format and product instructions for use, subjected to document control? |  |  |  |  |
|  | In addition to document control identifiers, does documentation include, when applicable, the following: |  |  |  |  |
| a) | purpose of the examination |  |  |  |  |
| b) | principle and method of the procedure used for examinations |  |  |  |  |
| c) | performance characteristics (see 5.5.1.2 and 5.5.1.3) |  |  |  |  |
| d) | type of sample (e.g. plasma, serum, urine) |  |  |  |  |
| e) | patient preparation |  |  |  |  |
| f) | type of container and additive |  |  |  |  |
| g) | required equipment and reagents |  |  |  |  |
| h) | environmental and safety controls |  |  |  |  |
| i) | calibration procedures (metrological traceability) |  |  |  |  |
| j) | procedural steps |  |  |  |  |
| k) | quality control procedures |  |  |  |  |
| l) | interferences (e.g., lipaemia, haemolysis, bilirubinemia) and cross reaction |  |  |  |  |
| m) | principle of procedure for calculating results, including, where relevant, measurement uncertainty of measured quantity values |  |  |  |  |
|  |  |  |  |  |  |
| n) | biological reference intervals or clinical decision values |  |  |  |  |
| o) | reportable interval of examination results |  |  |  |  |
| p) | instructions for determining quantitative results when results is not within the measurement interval |  |  |  |  |
| q) | alert/critical values, where appropriate |  |  |  |  |
| r) | laboratory clinical interpretation |  |  |  |  |
| s) | potential sources of variation |  |  |  |  |
| t) | References |  |  |  |  |
|  | If the laboratory intends to change to an existing examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services after validating the procedure. |  |  |  |  |
|  | (This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include directed mailings, laboratory/facility newsletters, or part of the examination report itself.) |  |  |  |  |
| **5.6** | **Ensuring quality of examination results** |  |  |  |  |
| 5.6.1 | The laboratory shall ensure that quality of examinations by performing them under defined conditions. Appropriate pre- and post- examination processes shall be implemented (see 4.14.7, 5.4, 5.7 and 5.8).  The laboratory shall not fabricate any results. |  |  |  |  |
| 5.6.2 | Quality control |  |  |  |  |
| 5.6.2.1 | Does the laboratory/facility design internal quality control systems that verify the attainment of the intended quality of results? |  |  |  |  |
| 5.6.2.2 | Quality control material |  |  |  |  |
|  | Does the laboratory use quality control materials that react to the examination system in a manner as close as possible to patient 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? |  |  |  |  |
|  |  |  |  |  |  |
|  | (The laboratory should choose concentration of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made).  (Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer). |  |  |  |  |
| 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, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified.  Does the laboratory evaluate the results from patient samples that were examined after the last successful quality control event?  Are quality control data reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system?  Are preventive actions taken when such trends are noted and the actions recorded? |  |  |  |  |
| 5.6.3 | Interlaboratory comparisons |  |  |  |  |
| 5.6.3.1 | Participation |  |  |  |  |
|  | Does the laboratory participate in inter-laboratory comparison programme(s) appropriate to the examination and interpretations of examination results?  Does the laboratory   * monitor the results of the interlaboratory comparison programme(s)? * participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled? |  |  |  |  |
|  |  |  |  |  |  |
|  | Is there a documented procedure for interlaboratory comparison participation that include:  - defined responsibilities and instructions for participation?  - performance criteria that differs from the criteria used in the interlaboratory comparison programme?  Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process including pre- and post-examination procedures, where possible. |  |  |  |  |
| 5.6.3.2 | Alternative approaches |  |  |  |  |
|  | Whenever interlaboratory comparison is not available, does the laboratory develop other approaches and provide objective evidence for determining the acceptability of examination results?  Wherever possible, this mechanism shall utilise appropriate materials. |  |  |  |  |
| 5.6.3.3 | Analysis of interlaboratory comparison samples |  |  |  |  |
|  | The laboratory shall integrate interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. |  |  |  |  |
|  | Does the laboratory ensure that: |  |  |  |  |
|  | - interlaboratory comparison samples are examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples? |  |  |  |  |
|  | - no communication with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data. |  |  |  |  |
|  | - interlaboratory comparison samples are not sent 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, does the laboratory:  - involved the staff in the implementation and recording of corrective actions?  - monitored the effectiveness of the corrective action?  - evaluated the returned results for trends that indicate potential nonconformities and take appropriate preventive action? |  |  |  |  |
| 5.6.4 | Comparability of examination results |  |  |  |  |
|  | Is there a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals?  This is applicable to the same or different procedures, equipment, different sites, or all of these.  (In the particular case of measurement results that are metrologically traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable). |  |  |  |  |
|  | 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 above comparisons?  Are the problems or deficiencies identified and rectified and records of actions retained? |  |  |  |  |
| **5.7** | **Post-examination process** |  |  |  |  |
| 5.7.1 | Review of results |  |  |  |  |
|  | Do authorised personnel review the results of examinations and evaluate them against internal quality control, available clinical information and previous examination results before the release of the results? |  |  |  |  |
|  |  |  |  |  |  |
|  | Are review criteria established, approved and documented for procedure that involves automatic selection and reporting (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  - safe disposal of clinical samples |  |  |  |  |
|  | Does the laboratory define the retention time of clinical samples? Does the retention time take into consideration:  - nature of sample  - the examination  - any applicable requirements/ regulation? |  |  |  |  |
| 5.7.3 | Are samples that are no longer required for examination disposed safely and in accordance with regulations or recommendations for waste management? |  |  |  |  |
| **5.8** | **Reporting of results** |  |  |  |  |
| 5.8.1 | The results of each examination shall be 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 (electronic or paper) and the manner in which it is to be communicated from the laboratory? |  |  |  |  |
|  | Are procedures in place to ensure  - the correctness of transcription of laboratory results?  - the reports have the necessary information for the interpretation of the examination results  - requester are notified when an examination is delayed that could compromise patient care? |  |  |  |  |
|  |  |  |  |  |  |
| 5.8.2 | Report attributes |  |  |  |  |
|  | Does the laboratory ensure that: |  |  |  |  |
| a) | comments on sample quality that might compromise examination results, |  |  |  |  |
| b) | comments regarding sample suitability with respect to acceptance/ rejection criteria, |  |  |  |  |
| c) | critical results, where applicable and |  |  |  |  |
| d) | interpretative comments on results, where applicable, which may include the verification of the interpretation or automatically selected and reported results (see 5.9.1) in the final report  are effectively communicated and meet the users' needs? |  |  |  |  |
| 5.8.3 | Report content |  |  |  |  |
|  | The report should include but not limited to: |  |  |  |  |
| a) | clear unambiguous identification of the examination including, where appropriate, the examination procedure? |  |  |  |  |
| b) | the identification of the laboratory/facility that issued the report? |  |  |  |  |
| c) | Identification of all examinations that have been performed by a referral laboratory? |  |  |  |  |
| d) | identification and location of the patient on each page? |  |  |  |  |
| e) | name or other unique identifier of the requester and the requester’s contact details? |  |  |  |  |
| f) | date of primary sample collection, and time where available and relevant to patient care? |  |  |  |  |
| g) | source and system (or primary sample type), |  |  |  |  |
| h) | measurement procedure, where appropriate? |  |  |  |  |
| i) | results of the examination including SI units or units traceable to SI units, or other applicable units? |  |  |  |  |
| i) | biological reference intervals, clinical decision values, or diagrams/ nomograms supporting clinical decision values, where applicable?  (Under some circumstances, it may be appropriate to distribute lists or tables of biological reference intervals to all users and sites where reports are received). |  |  |  |  |
|  |  |  |  |  |  |
| k) | interpretations of results, where appropriate? |  |  |  |  |
| l) | other comments such as cautionary or explanatory notes (e.g., quality or adequacy of primary sample, which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure)? |  |  |  |  |
| m) | Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available? |  |  |  |  |
| n) | identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available when needed)? |  |  |  |  |
| o) | date and time of release of report, if not on the report, shall be readily accessible when needed? |  |  |  |  |
| p) | page number to total number of pages (e.g. “Page 1 of 5”) |  |  |  |  |
| **5.9** | **Release of results** |  |  |  |  |
| 5.9.1 | Does the laboratory/facility have documented procedures for the release of examination results, including details of who may release results and to whom? |  |  |  |  |
|  | Does the procedures ensure the following conditions are met: |  |  |  |  |
| a) | When quality of the primary sample received is unsuitable for examination, or could have compromised the result, it is indicated in the report? |  |  |  |  |
| b) | When examination results fall within established “alert” or “critical” intervals,  - immediate notification of physician (or other clinical personnel responsible for patient care) including referral laboratories’ results?  - maintenance of records of actions taken in including   * date and time? * responsible laboratory staff member? * person notified? * examination results conveyed? * any difficulty encountered in meeting this requirement? |  |  |  |  |
|  |  |  |  |  |  |
| c) | results are legible, without mistakes in transcription, and reported to persons authorised to receive and use the information? |  |  |  |  |
| d) | When results are transmitted as an interim report, the final report is always forwarded to the requester? |  |  |  |  |
| e) | Does the laboratory/facility establish policies and practices to ensure that the results distributed by telephone or other electronic means only reach authorised receivers? |  |  |  |  |
|  | Are results provided verbally followed by a properly recorded report?  Are records of all oral results documented? |  |  |  |  |
| 5.9.2 | Automated selection and reporting of results |  |  |  |  |
|  | For automated selection and reporting of results, is there a documented procedure to ensure that : |  |  |  |  |
| a) | criteria for automated selection and reporting are defined, approved, readily available and understood by the staff?  (Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values). |  |  |  |  |
| b) | criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning? |  |  |  |  |
| c) | a process is in place to indicate the presence of sample interferences (e.g. haemolysis, iceterus, lipaemia) that may alter the results of the examination |  |  |  |  |
| d) | a process to incorporate analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate? |  |  |  |  |
| e) | results selected for automated reporting are identifiable at the time of review before release and that date and time of selection are included? |  |  |  |  |
| f) | a process for rapid suspension of automated selection and reporting is in place? |  |  |  |  |
|  |  |  |  |  |  |
| 5.9.3 | Revised reports |  |  |  |  |
|  | Does the laboratory/facility have written instructions regarding the alteration of reports? |  |  |  |  |
|  | Do the instructions include:   * clear identification of the revised report and includes reference to the date and patient’s identity in the original report? * notification to user regarding the revision? * clear indication of the time and date of change and the name of person responsible for the change on the revised record? * retention of the original report entries in the record when revisions are made? |  |  |  |  |
|  | Are results used for clinical decision-making revised and retained in subsequent cumulative reports and clearly identified as having been revised?  When the reporting system cannot capture amendments, changes or alterations, is a record of such/ audit log retained? |  |  |  |  |
| **5.10** | **Laboratory information management** |  |  |  |  |
| 5.10.1 | Does the laboratory/facility have access to the data and information needed to provide a service which meets the needs and requirements of the users?  Is there a documented procedure to ensure confidentiality of patient information is maintained at all times?  (“Information systems” includes the management of data and information contained in both computer and non-computerised systems. Computerised systems can include those integral to the functioning of laboratory equipment and stand alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports). |  |  |  |  |
| 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 defined authorities and responsibilities of all personnel who use the system include: |  |  |  |  |
| a) | who can access patient data and information? |  |  |  |  |
|  |  |  |  |  |  |
| b) | who can enter patient data and examination results? |  |  |  |  |
| c) | who can change patient data or examination results? |  |  |  |  |
| d) | who is authorise to release examination results and reports? |  |  |  |  |
| 5.10.3 | Information system management |  |  |  |  |
|  | Are the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information: |  |  |  |  |
| a) | validated by supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorised, documented and verified before implementation?  (Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation, hospital patient administration systems and systems in primary care). |  |  |  |  |
| b) | documented to include day to day functioning of the system and be readily available to authorised users? |  |  |  |  |
| c) | protected from unauthorised access |  |  |  |  |
| d) | safeguarded against tampering or loss |  |  |  |  |
| e) | operated in an environment that complies with supplier specifications or provides conditions which safeguard the accuracy of manual recording and transcription |  |  |  |  |
| f) | 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, |  |  |  |  |
| g) | 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?  e.g. clinics’ computer systems, fax machines, e-mail, personal web devices or websites |  |  |  |  |
|  |  |  |  |  |  |
|  | When new examination or automated comments are implemented, is the same verification process performed? |  |  |  |  |
|  | Are documented contingency plans available to maintain services in the event of failure or downtime in information systems that affects the laboratory’s ability to provide service? |  |  |  |  |
| 5.3.14 | When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, the laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard. |  |  |  |  |
| **SAC-SINGLAS Requirements** | | | | | |
| **A.** | **Key Personnel** |  |  |  |  |
| 1. | Do the key personnel still occupy appropriate positions in the staff structure to be responsible for the adequacy of test results? |  |  |  |  |
| 2. | Do the key personnel still retain sufficient contact time with testing procedures to maintain the ability for critical evaluation of results? |  |  |  |  |
| **B.** | **SAC-SINGLAS Accredited Reports and Use of Mark** |  |  |  |  |
| 1. | Does the laboratory / facility comply with the terms and conditions for SAC-SINGLAS endorsed report as stipulated in SAC 02? |  |  |  |  |
|  |  |  |  |  |  |

|  |  |
| --- | --- |
| **C.** | **Follow up on last year findings** |
| **D.** | **Other Observation and Comments**  Safety |