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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **4** | **MANAGEMENT REQUIREMENTS** |  |  |  |  1. **Organisation and Management responsibility** 2. **Organisation**   Does the laboratory management system cover work carried out in:   * + Permanent facilities?   + Associated temporary facilities?   + Mobile facilities?  1. **Legal Entity**   Is the laboratory / facility or the organisation:   * + Legally responsible for its activities?   + License available?   **4.1.1.3 Ethical conduct**  Does the laboratory/ management have arrangements to ensure that:   1. No involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity? 2. 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? 3. Any potential conflicts of competing interests are openly and appropriately declared? 4. Appropriate procedures in place to treat human samples, tissues or remains according to relevant legal requirements? 5. Policies and procedures to ensure confidentiality of information? 6. **Laboratory Director**   Is the laboratory directed by a person or persons with competence and delegated responsibility for the services provide?  Do the responsibilities of the laboratory/facility director or designees include professional, scientific, consultative, advisory, organisational, administrative, and educational matters?  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:   1. Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities? 2. 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?   * 1. Ensure that there are appropriate number of staff with required education, training and competence to meet the needs of the laboratory?   2. Ensure the implementation of the quality policy?   3. Implement a safe laboratory/facility environment in compliance with good practice and applicable regulations?   4. Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate?   5. Ensure the provision of clinical advice with respect to the choice of examinations, use of service and interpretation of examination results?   6. Select and monitor laboratory suppliers?  1. Select referral laboratories and monitor the quality of their service? 2. Provide professional development programmes for the laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations,    1. Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services, 3. monitor all work performed in the laboratory to determine that clinical relevant information is being generated, 4. Address any complaint, request or suggestion from the users of the laboratory/facility, for ensuring that quality services are provided for patients. 5. 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)   1. 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.)   1. **Management responsibility** 2. **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?   1. Are the importance of meeting the needs and requirement of users, regulatory and accreditation requirements communicated to the laboratory personnel? 2. Is there a quality policy? (see 4.1.2.3) 3. Is quality objectives and planning established? (see 4.1.2.4) 4. Specify the:    * Responsibility?    * Authority?    * Interrelationships?   of all personnel (see 4.1.2.5)   1. Is communication processes established? (See 4.1.2.6)    1. Is a quality manager appointed? (see 4.1.2.7)    2. Is management review conducted? (see 4.15)    3. Are personnel competent to perform their assigned activities? (see 5.1.6)    4. 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). 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?  1. **Quality policy**   Is the quality policy   * + - Defined under the authority of laboratory/ facility management?     - and include the following:  1. Appropriate to the purpose of the organization 2. 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? 3. A framework for establishing and reviewing quality objectives 4. A requirement that it is communicated and understood within the organisation? 5. Reviewed for continuing suitability?   **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?   1. **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.)   1. **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?   1. **Quality Manager**   Is quality manager appointed?  Does the responsibilities and authority includes:   1. Ensuring that processes needed for the quality management system are established, implemented and maintained, 2. 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? 3. Promoting the awareness of users’ needs and requirements throughout the laboratory organisation? 4. **Quality management system** 5. **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?  Does the laboratory:   * 1. Determine the processes needed for the quality management system and ensure its implementation?   2. Determine the sequence and interaction of these processes?   3. Determine criteria and methods needed to ensure that both the operation ad control of these processes are effective?   4. Ensure the availability of resources and information to support the operation and monitoring of these processes?   5. Monitor and evaluate these processes?  1. Implement actions necessary to achieve planned results and continual improvement of these processes? 2. **Documentation requirements** 3. Does the quality management system documentation include: 4. Statements of quality policy and quality objectives?    1. A quality manual? (see 4.2.2.2)    2. procedures and records required by this International Standard;       1. documents and records to ensure effective planning, operation and control of its processes       2. 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)   1. **Quality Manual**   Does the quality manual includes:   1. The quality policy or makes reference to it? 2. A description of the scope of the quality management system? 3. Outlines the organisation and management structure of the laboratory/facility and its place in an parent organisation? 4. Roles and responsibilities of laboratory management for ensuring compliance with this International Standard?    * to include laboratory director and quality manager) 5. Description of the structure and relationships of the documentation used in the quality system? 6. 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?   1. **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:   * 1. Documents, including those maintained in computerized system, reviewed and approved by authorized personnel before issue?   2. documents’ identifiers to include:      + a title      + a unique identifier on each page      + the date of the current edition and/ or edition number * page number to total number of pages (e.g. “Page 1 of 5”, Page 2 of 5”) * authority for issue   (‘Edition’ can be regarded as synonymous with ‘revision’ or ‘version’)   1. A master list or an equivalent document control procedure available to identify the current revision status and distribution of documents? 2. Current authorised versions of appropriate documents are available at points of use? 3. 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?   * 1. Changes to documents are identified?   2. Documents remain legible?   3. Documents periodically reviewed, updated at a frequency to ensure that they are fit for purpose?   4. Obsolete controlled documents are dated and marked as obsolete?   5. Is a copy of these obsolete controlled documents retained for a specified time period or in accordance with applicable specified requirements?  1. **Service agreements** 2. **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?   1. the requirements, including the examination processes to be used are:    * Defined?    * Documented?    * Understood? 2. The laboratory has the capability and resources meet the requirements? 3. Laboratory personnel have the skills and expertise for the performance of the intended examinations? 4. Appropriate examination procedures are selected to meet customers’ needs? 5. The customer (eg clinicians, health care bodies, health insurance companies, pharmaceutical companies) are informed of any deviation from the agreement? 6. 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.)   1. **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  1. **Examination by referral laboratories/facilities** 2. **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?   1. 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? 2. Are arrangements with referral laboratories/ facilities and consultants periodically reviewed/ evaluate to ensure compliance to relevant parts of this International Standards? 3. Are records of such periodic reviews maintained? 4. Does the laboratory maintain a register of all referral laboratories/facilities and consultants from whom opinions are sought? 5. Are requests and results of all samples referred kept for a pre-defined   Period?   1. **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?   1. **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?   1. **Advisory services**   Does the laboratory establish arrangements of communication with the users to:   1. provide advice on    * Choice of examination and use of services?    * Required sample type?    * Frequency of requesting the examinations?    * clinical indications    * Limitation of examination? 2. Provide advice on individual clinical cases? 3. Provide professional judgments on the interpretation of results of examinations? 4. Promote effective utilization of laboratory services? 5. Provide consulting on scientific and logistic matters? 6. **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?   1. **Identification and control of non-conformities** 2. Is a documented procedure available to identify and manage nonconformities in any aspect of the quality management system?   Does the procedure ensure that :   * 1. The responsibilities and authorities for handling nonconformities are defined?   2. Immediate actions to be taken are defined?  1. Extent of the nonconformity is determined? 2. The examinations are halted and reports withheld as necessary? 3. The medical significance of the non-conforming tests is considered and requesting clinician informed where appropriate? 4. Non-conforming or potentially nonconforming examination results that are previously released are recalled or appropriately identified, as necessary? 5. The responsibility for authorisation of the resumption of work is defined? 6. 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.   1. **Corrective Action**   Does the laboratory take appropriate corrective action to eliminate the cause(s) of nonconformities?  Does the documented procedures include the following:   1. Review of nonconformities? 2. Determination of root causes of nonconformities? 3. Evaluation of corrective action to ensure non-recurrence of nonconformities? 4. Determination and implementation of corrective action? 5. Documentation of corrective action taken? 6. 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).   1. **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:   1. Review of laboratory data and information to determine potential nonconformities? 2. Determination of root cause(s) of potential nonconformities? 3. Evaluation of the need for preventive action to prevent occurrence of nonconformities? 4. Determination and implementation of preventive action needed? 5. Documentation of the results of preventive action taken? 6. 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).   1. **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?  1. **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?  1. **Does the laboratory maintained the following records:** 2. supplier selection and performance, and changes to the approved supplier list 3. staff qualification, training and competency records 4. request forms (including the patient chart or medical record only if used as the request form), 5. Records of receipt of samples in the laboratory, e.g. accession records 6. Information on reagents and materials used for examination (lot documentation, certificates of supplies, package inserts) 7. laboratory work-books or work sheets, 8. instrument printouts and retained date and information 9. examination results and reports, 10. instrument maintenance records including internal and external calibration records 11. calibration functions and conversion factors 12. quality control records, 13. incident records and action taken, 14. accident records and action taken 15. risk management records 16. nonconformities identified and immediate or corrective action taken 17. preventive action taken 18. complaints and action taken 19. records of internal and external audits 20. interlaboratory comparisons of examination results 21. records of quality improvement activities 22. minutes of meetings that record decisions made about the laboratory’s quality management system 23. records of management reviews   (All these records shall be available for laboratory management review)   1. **Evaluation and audits** 2. **General**   Are evaluation and internal audit processes planned and implemented to:   1. Demonstrate that laboratory’s processes are conducted in a manner that meets the needs and requirements of users?   (e.g users’ feedback)   1. ensure conformity to the quality management system 2. continually improve the effectiveness of the quality management system   Are the results of evaluation and improvement activities included as part of management review?   1. **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?   1. **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?   1. **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?   1. **Internal Audit**   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:   1. conformance to the requirements stated in ISO 15189, relevant documents and internal laboratory procedures 2. 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?   1. **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?   1. **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).   1. **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?   1. **Management review** 2. **General**   Does the laboratory management review the quality management system at planned intervals to ensure continuing suitability, adequacy and effectiveness in support of patient care?   1. **Review Input**   Does the input to management review include:   1. periodic review of requests, suitability of procedures and sample requirements 2. assessment of user feedback 3. staff suggestions 4. The outcome of recent internal audits? 5. risk management 6. use of quality indicators 7. reviews by external organizations 8. interlaboratory comparison programmes (PT/ EQA) performance 9. monitoring and resolution of complaints 10. supplier evaluation 11. identification and control of non-conformities 12. results of continual improvement (including current status of corrective actions and preventive actions 13. Follow-up actions from previous management reviews 14. Changes in volume and scope of work, personnel and premises that could affect the quality management system 15. Recommendation for improvement, including technical requirements 16. **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?  1. **Review Output**   Does the laboratory document the decisions made and action taken during management review related to:   1. Improvement of the effectiveness of the quality management system and its processes. 2. Improvement of services to users 3. 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? |  |  |  |
| **5 TECHNICAL REQUIREMENTS**   1. **Personnel** 2. **General**   Does the laboratory/facility management have documented procedures for personnel management?  Does the management maintain records for all personnel to indicate compliance with requirements?   1. **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?   1. **Job descriptions**   Does the laboratory have job descriptions that describe responsibilities, authorities and tasks for all personnel?   1. **Personnel introduction to the organizational environment**   Does the laboratory has 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?   1. **Training**   Does the laboratory provide training for all personnel in the following areas:   1. The quality management system 2. Assigned work processes and procedures 3. The applicable laboratory information system 4. health and safety, including the prevention or contamination of the effects of adverse incidents 5. Ethics 6. Confidentiality of patient information   Are personnel undergoing training supervised?  Are the effectiveness of the training programme periodically reviewed?   1. **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:   * 1. direct observation of routine work processes and procedures, including all applicable safety practices   2. direct observation of equipment maintenance and function checks   3. monitoring the recording and reporting of examination results   4. review of work records   5. assessment of problem solving skills   6. examination of specially provided samples, such as previously examined samples,   interlaboratory comparison materials, or split samples)   1. **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?   1. **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?   1. **Personnel records**   Does the laboratory maintain the following records:   1. educational and professional qualifications 2. copy of certification or license, when applicable, 3. references from previous employment, 4. job descriptions, 5. orientation records 6. training in current job tasks 7. competency assessments 8. records of continuing education and achievements, 9. reviews of staff performance 10. records of accidents and exposure to occupational hazards 11. 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). |  |  |  |
| 1. **Reporting of results** 2. **General**   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 is notified when an examination is delayed that could compromise patient care?  1. **Report attributes**   Does the laboratory ensure that:   1. comments on sample quality that might compromise examination results, 2. comments regarding sample suitability with respect to acceptance/ rejection criteria, 3. critical results, where applicable and 4. 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?   1. **Report content**   The report should include but not limited to:   1. Clear unambiguous identification of the examination including, where appropriate, the examination procedure? 2. The identification of the laboratory/facility that issued the report? 3. Identification of all examinations that have been performed by a referral laboratory? 4. Identification and location of the patient on each page? 5. Name or other unique identifier of the requester and the requester’s contact details? 6. Date of primary sample collection and time where available and relevant to patient care? 7. source and system (or primary sample type), 8. Measurement procedure, where appropriate? 9. Results of the examination including SI units or units traceable to SI units, or other applicable units? 10. Biological reference intervals, clinical decision values, or diagrams 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).   1. Interpretations of results, where appropriate? 2. 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)? 3. Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available? 4. 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)? 5. Date and time of release of report, if not on the report, shall be readily accessible when needed? 6. page number to total number of pages (e.g. “Page 1 of 5”) |  |  |  |
| 1. **Release of results** 2. **General**   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:   1. When quality of the primary sample received is unsuitable for examination, or could have compromised the result, it is indicated in the report? 2. 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? 3. Results are legible, without mistakes in transcription, and reported to persons authorised to receive and use the information? 4. When results are transmitted as an interim report, the final report is always forwarded to the requester? 5. 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?   1. **Automated selection and reporting of results**   For automated selection and reporting of results, is there a documented procedure to ensure that :   1. 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).   1. Criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning? 2. 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 3. A process to incorporate analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate? 4. Results selected for automated reporting are identifiable at the time of review before release and that date and time of selection are included? 5. A process for rapid suspension of automated selection and reporting is in place? 6. **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? |  |  |  |
| 1. **Laboratory information management** 2. **General**   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).   1. **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:   1. Who can access patient data and information? 2. Who can enter patient data and examination results? 3. Who can change patient data or examination results? 4. Who is authorise to release examination results and reports? 5. **Information system management**   Are the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information:   1. 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).   1. Documented to include day to day functioning of the system and be readily available to authorised users? 2. protected from unauthorised access 3. safeguarded against tampering or loss 4. operated in an environment that complies with supplier specifications or provides conditions which safeguard the accuracy of manual recording and transcription 5. 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, 6. 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?  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. |  |  |  |