	NATIONAL CENTRE FOR ACCREDITATION

MEDICAL LABORATORIES - REQUIREMENTS FOR ACCREDITATION

ACCORDING TO SM SR EN ISO 15189:2014

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CONTENT:

1. PURPOSE

The purpose of this document is to describe the requirements for accreditation of testing and calibration laboratories under SM EN ISO 15189:2013, the documents EA, ILAC, MOLDAC, applicable to this standard in order to ensure an uniform and consistent application.

2. SCOPE

This document is applicable to laboratories carrying out medical diagnosis and care of patients and who wish to obtain accreditation for part or all analyzes they practice.

Field medical tests include biochemical investigations, hematological, immunological, serological, bacteriological, virological, mycological, parasitological, histological, cytological, pathological and other types of analysis by examining isolates from humans (blood specimens, urine, CSF, secretions, tissues, etc.).

3. NORMATIVE REFERIENCES

Law 235 from 01.12.2011 on accreditation activities and of conformity assessment with subsequent changes.

SM SR EN ISO 15189:2014 Medical laboratories. Requirements for quality and competence.

SR EN ISO 15189:2013 Medical laboratories. Requirements for quality and competence.

SM SR ISO 15190:2012 Medical laboratories. Security requirements.

SM SR ISO/TR 22869:2012 Medical laboratories. Guidance on laboratory implementation of ISO 15189: 2003.

ISO/TS 22367 Medical laboratories - Reduction of error through risk management and continual improvement

SM EN ISO 17511:2014 In vitro diagnostic medical devices -- Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

SM SR EN ISO 18153:2010 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials

SM SR EN ISO/CEI 17000:2006 Conformity assessment. Vocabulary and general principles.

SM SR EN ISO/CEI 17011:2006 Conformity assessment. General requirements for accreditation bodies that accredit the conformity assessment bodies.

Rules and procedures National Accreditation Body.

Applicable Documents EA, IAF:

- EA – 4/14:2003	informative	Selection and use of reference materials
- EA – 4/16:2003	guidance	EA Guidelines on the Expression of Uncertainty in Quantitative testing
- EA – 4/17:2008	mandatory	EA Position Paper on the description of scopes of accreditation of medical laboratories
- EA – 4/18:2010	advisory	Guidance on the level and frequency of proficiency testing participation
- ILAC-P10:01/2013	mandatory (of 01.01.2014)	ILAC Policy on Traceability of Measurement Results
- ILAC G19:2014	guidance	Modules in a Forensic Science Process
- ILAC G24:2007	guidance	Guidelines for the determination of calibration intervals of measuring instruments

EA, ILAC documents can be accessed on following web-pages: www.european-accreditation.org and www.ilac.org

- MOLDAC documents published on the website www.acreditare.md.

- Policy P-02	Policy on use of PTs and ILCs and other inter laboratory comparisons in the accreditation process
- Policy P-03	Policy on traceability of measurements
- Policy P-04	Policy on handling the non-conformities
- Policy P-07	Policy on treating the objections of CAB regarding the names of team members
- Policy P-08	Policy and rules for using of accreditation symbols and references to accreditation
- RA	Accreditation Rules
- CA	General Criteria for Accreditation

4. DEFINITIONS AND ABREVIATIONS
4.1. Definitions

This document uses the terms and definitions in Chapter 3 and reference document referred to in Chapter 2 of EN ISO 15189 SR: 2013.

4.2. Abreviations

NAB –National Accreditation Body

CAB – Conformity Assessment Body

MS – Management System

LM – Medical Laboratory

CL – Calibration Laboratory

CT –Technical Committee

LAB - Laboratories

5. DESCRIPTION OF ACTIVITIES

Accreditation of Testing and Calibration Laboratories will be carried out in accordance with the SM SR EN ISO / IEC 17011:2006, the documents EA, ILAC MOLDAC applicable rules and procedures.

For making the accreditation process more explicitly and the same for all laboratories, MOLDAC approves these requirements,, that are in accordance with SM SR EN ISO 15189:2014, documents EA, ILAC.

The item numbers of this chapter correspond to the elements no. of SR EN ISO/CEI 15189:2013.

4 Management requirements

4.1 Organization and management responsibility

4.1.1 Organisation

4.1.1.1 General

4.1.1.2 Legal entity

4.1.1.3 Ethical conduct

4.1.1.4 Laboratory director

4.1.2 Management responsibility:

4.1.2.1 Management commitment

4.1.2.2 Needs of users

4.1.2.3 Quality policy

4.1.2.4 Quality objectives and planning

4.1.2.5 Responsibility, authority and interrelationships

4.1.2.6 Communication

4.1.2.7 Quality manager

Laboratory that requests accreditation according to SM SR EN ISO 15189:2014 must present identification information including at least the following:

- Full Name, under statute, short name or initials, if applicable;
- Legal status of the laboratory and/or of the organization which belongs to, Constitutive Act (by case);
- Copy of Registration Certificate;
- Head office address, telephone/ fax/ e-mail.

If the laboratory has several offices, this information has to be given for all offices that require the accreditation.

Applicable Documents showing the identification of laboratory at the request for accreditation:

- Request for Accreditation (presented by laboratory accreditation);
- Legal status of laboratory or the organisation to which it belongs, must be clearly identified (legal entity belonging to private or state) and demonstrated though relevant documents: Copy of organisation's Statute, Copy of registration Certificate, Copy of Act of incorporation;
- Status of organisation, belonging to the state, must arise from an appropriate legal document (Government Decision, law);
- If the laboratory requests accreditation as a second or third party laboratory, in the status must be clearly stated the appropriate object of activity - Technical testing and analysis activities);
- Legal Responsibility is considered to legislation of Republic of Moldova;
- At accreditation of laboratories under the jurisdiction of other states, the requirement of legal responsibility must be provided and assessed by a competent person in respective State legislation that can adequately support this requirement;
- The laboratory must have valid liability insurance except in cases when the laboratory is state is insured by State law.
- Ensuring has to be such contractual as well as civil liability.
- The insured value should be correlated with the type, field and volume of laboratory/organization activity's and should be credible being an evidence of its financial power. This must result from the liability insurance.
- If the laboratory does not have the own legal personality the obligation to ensure returns (the insurance shall cover the entire accredited field /requested for laboratory accreditation) organisation to which it belongs (parent organisation).
- Quality manual.

Management system documents must describe the functioning of the laboratory accreditation applicant stating the following elements:

- types of activities including activities other than those for requesting or for which accreditation was granted;
- locations where such activities should be presented in sufficient detail to provide a clear picture of the activities performed (if applicable);
- laboratory's technical area must be described in terms of methods and procedures used;
- laboratory's technical performance limits (measuring range, limit of detection, accuracy and precision of measurement, etc.).

Points harvesting primary samples (specimens) outside the laboratory, manned by staff of the laboratory or organization belonging to the laboratory must be mentioned in the documents SMC, in the scope of accreditation to meet and be evaluated. Organizations that

operate laboratories in several locations ,,Multi-site" ONA subject to the requirements document. The initial accreditation evaluates all locations.

When conducting activities in the temporary premises on the ground or with mobile means, there should be provision of management, technical competence and procedures for these activities.

Documents applicable:
• Quality Manual
• Organisational
• Plans / drawings and architectural site
• List of areas.

If the laboratory is part of a larger organization, but have legal personality should be provided information on relations with this organization. In addition to general information must be submitted:
• The main activities of the parent organization
• An organizational chart indicating the position of the parent organization laboratory
• All levels of the organization of the laboratory and named top management and personnel management functions.
• An evaluation of the extent to which the parent organization influences the functioning of the laboratory in terms of the quality management system, investment, human resources, procurement, etc.

If the laboratory does not have legal personality accreditation contract ends with the parent organization. In this case the parent organization's management must act on behalf of the laboratory's accreditation issues. In addition the parent organization must guarantee that it will not exert any pressure on or laboratory staff and will allow full freedom in technical and scientific matters.

Use of document:
• Quality manual
• Organization chart and analysis laboratory
• Job descriptions
• Quality policy
• Management commitment

Key personnel of the organization having involvement or influence on the laboratory can be considered to consist of:
• managers subordinate laboratory which is,
• ensuring laboratory resources managers (including payment of wages)
• managers who sells laboratory services.

In small organizations, the management function which it is subordinated head of laboratory stack and responsibilities of resource allocation, service contracting anal, there must be commitment, organizational arrangements, procedures, responsibilities and records on avoiding conflicts of interest and especially on the independence of technical decision on the results of the laboratory tests.

• Personnel management should be appointed by decision stating the delegation of authority and allocation of resources necessary to accomplish tasks necessary lab work,
• management and technical staff must be listed in the job description of authority limits

especially in identifying the occurrence of deviations in quality management system and initiate corrective action, preventive action.
• The laboratory must be identified, documented resources necessary to accomplish tasks (material and human) and documented to demonstrate that they exist.

Documents applicable to demonstrate competence / requirement
• Quality manual
• Job descriptions
• Quality policy

The laboratory must declare how to ensure confidentiality and respect for property rights which should be adequate contractual clauses and agreements between him and his clients.

It is advisable to have a documented system of information classification, each class corresponding a set of protective measures. Persons authorized to possess or use documents / records classified be declared in writing and the respective documents listed. Staff can in the course of entering into possession of confidential or proprietary information, which should be treated according to the cap.4.1.1.3 of SR EN ISO 15189:2013.

Requirements relating to confidentiality should not infringing on the computer system of notifiable diseases.

Employment contracts must stipulate respecting confidentiality must be stated whether and under what conditions they can be removed from inside the lab documents and records computerized classification. System data protection must be documented.

Documents applicable:
• Quality Manual
• Security and access procedures, if not the classified information
• Code of Ethics, etc.
• Confidentiality Undertaking signed by each employee.

The organizational structure
There should be a formal establishment of the laboratory and whether it is part of a organization and an organizational chart identifying the organization's official site laboratory. Documented explanation is required responsibilities, authority and relations between laboratory functions and people.

It must be presented in a document:
• relations with the human resources department laboratory, commercial, administrative, financial, etc.
• organizational levels of the organization (if applicable)
• Limits of authority and responsibility
• The degree of centralization and delegation
• Responsibility for permanent and / or contributor

Applicable documents showing power / requirement
• Quality Manual
• Organisational
• Job descriptions

There should be a formal establishment of the laboratory and whether it is part of a

organization and an organizational chart identifying the organization's official site laboratory. Documented explanation is required responsibilities, authority and relations between laboratory functions and people.

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Applicable documents showing power / requirement
• Quality Manual
• Organisational
• Job descriptions

Requirements relating to confidentiality should not infringing on the computer system of notifiable diseases.

Employment contracts must stipulate respecting confidentiality must be stated whether and under what conditions inside the laboratory may be removed classified documents and records computerized data protection system must be documented.

Management staff should be appointed by decision stating the delegation of authority and allocation of resources necessary to accomplish tasks necessary laboratory work.

Management and technical staff must be listed in the job description of authority limits especially in identifying the occurrence of irregularities in the quality management system of and initiate preventive/corrective action.

The laboratory must be identified, documented resources necessary to accomplish tasks (material and human) and documented to demonstrate that they exist.

Organizational documenting LM:

- laboratory relations with human resources departments, commercial, administrative, etc.
- organizational levels of the organization (if applicable)
- The limits of authority and responsibility
- The degree of centralization and delegation
- Responsibilities for permanent and / or contributor.

People who provide supervision, must be identified, supervisory tasks specified in writing (job description, etc.) and must have adequate powers for good supervision.
- Supervision aims:

- monitoring maintaining technical competence of the laboratory staff
- technical monitoring of activities carried out by personnel on probation, under qualification or training, etc.

Functions that responsibility must be identifiable supervision plan. Module for supervision must be documented.

Technical management is about ensuring personal resources, knowledge, skills, methods and procedures to maintain and improve the standard of services offered by the laboratory. Qualifications and experience should be relevant to this responsibility and must be consistent with the job description.
In large organizations with multiple technical activities may be several people named as technical manager.
In this case some entities will operate separately from the other and this will have to come from the plan.
The demarcation lines between entities must be clear from the description of business entities.
Each technical manager must meet job requirements relevant to the entity.

Laboratory management must ensure that every staff member understands the role that each plays in the system and the extent to which contribute to the goals of performance.
- General objectives of LM Sheet
- Individual goals Sheet

Top management must ensure adequate circulation of information and decision in the organization and effective communication system for all aspects of the management system - description.

Documents
- Parent organization chart
- Organizational Chart LM
- Quality Manual
- Quality Policy
- Responsible formal appointment order SSM / contract.
- Officer's Job Description SSM
- The list of deputies and deputies appointment decisions.
- Job descriptions
- Statements / management Commitments

4.2 Quality management system

4.2.1 General requirements

4.2.2 Documentation requirements

4.2.2.1 General

4.2.2.2 Quality manual

Quality management system is the tool by which management can apply policy and attain its objectives.
The laboratory shall:
- Establish processes
- Determine the sequence and interaction of these processes
- Establish criteria and methods needed to ensure that both development and monitoring of these processes are effective
- The quality management system must ensure the integration of all elements in their interdependence in the process of pre-examination, examination and post-examination.

Quality management system must be updated to maintain its adequacy. The review system is necessary when there are:

- Changes in methods, regulations;
- Changes in organization and personnel;
- Activity changes or customer requirements;
- Corrective / preventive actions;

Documentation must be appropriate activity level (volume, complexity), size and organization (independent laboratory, or part of a larger organization with several entities or pubs). Excess of documentation should be avoided, in terms of content and number of copies.
The items contained in a document, should not be repeated in another document.

Quality Manual may contain or make reference to a quality policy, signed by persons with managerial function executive and the authority to set policy, organization and allocate resources that laboratory: director of the organization of which the laboratory or laboratory director if The laboratory is legal. Quality policy should indicate how the objectives are achieved.

With the exception of general and permanent objectives which are the above will set specific, measurable, mutually agreed, achievable, realistic and staggered (SMART) Documents showing power / requirements

LM management commitment to comply with SR EN ISO / IEC 15189: 2013 criteria accreditation body, to continuously improve the effectiveness of MS.

Decisions by management review, analyze their achievement.

Display in public places of the organization of the importance of fulfilling customer requirements as well as statutory and regulatory requirements.
Except for large laboratories, comprised of several entities or establishments, Quality Manual may include general procedures, through which the requirements of this standard, it ensures a greater unity and coherence.
Quality Manual may contain annexes making explicit enough: resources (including staff), organizational structure, structure system documentation (including external origin). Presentation:

- Quality manual
- MS Lists internal documents (procedures, instructions, etc.)
- The list of external documents (documents EA, ILAC, NEB Laws RM Government Decision, DN etc.).

In manual be included laboratory responsibilities of management positions (Head of Laboratory, Head of technical entities, technical manager and manager SM). Force technical personnel responsibilities are contained in documentation (procedures, instructions, programs, etc.).

Quality Manual must present evidence that was developed and approved by top management that recognizes that it correctly represents intentions and knowledge and its application is mandatory for personnel.
Documents

- Quality Manual
- Lists MA refers to procedures

- Management commitment
- Quality Policy
- Objectives of LM SMART
- Obiectives SMART individual

4.3 Document control

Documents showing power / requirements

- Quality Manual
- Document control procedure including completed forms

Document control procedure which besides keeping under control the way documents with the last edition in force and its distribution shows and rules of analysis, approval, modification, responsibilities and records relating to the procedure. The procedure should define through a complete list or the list of documents (internal and external) monitored, with the latest edition (version revision) and approved their dissemination situation.

The laboratory shall ensure that:
- All documents, new or revised, are checked and approved by authorized personnel before being issued,
- Editions (versions, revisions) in place of the necessary documentation is in all places where operations,
- Changes are effective so as to ensure a correct documentation, the time for each activity and relevant function,
- Documents not available or obsolete are withdrawn and destroyed and the stored properly marked for different purposes, there is proof of their,
- It can identify the record, if known by the personal edition in force for each document,
- Unique document identification system is documented, known and applied,
- The copies are numbered and the owner identified,
- To change jobs assigned documents are withdrawn,
- It is called a person having the responsibility of using foreign documents,
- Where appropriate stakeholders are notified on the review of documents, the system applied is documented.
- Clearly documented how the identification of changes,
- It has defined authority limits on the content of the amendments made by hand.
- It documented the distribution and control of documents circulated computerized system, if the laboratory is computerized and there intranet.
- It is documented in the laboratory and controlled access from the Organization of the laboratory is a laboratory intranet.

Internal procedures, if they were written in a way that allows their use by the operational staff of the laboratory must be translated into the language of the laboratory staff (where applicable).

4.4 Service agreements

4.4.1 Establishment of service agreements

4.4.2 Review of service agreements

When this analysis is the responsibility of the head of laboratory or other manager, records of the analysis may be for simple or routine (made current), a form of decision effecting (Yes, Making, etc.) accompanied by the signature and date. In general it is necessary to draw up a contract analysis sheet.
When working on a schedule (daily, regular), written and approved by the management of the laboratory and eventually signed by the client, this program is accepted in order for executives.

Laboratory must have documented procedures for the establishment and termination of contracts for the supply of medical laboratory services.

Any request accepted by the laboratory for examination must be considered as a contract.

Conditions for service agreements:

- Be documented and understood the requirements of both parties (and users and laboratory) - harvesting, transportation, analysis, validated methods, reference
- Laboratory have adequate human and material resources
- Procedures to be adequate and meet customer requirements
- Any deviation from the contract be communicated to users
- The contract specify any reference to or consultant subcontracted
- When customers are patients' services is recommended that changes be reflected in the explanatory information and laboratory reports "
- Laboratory should not conclude financial contracts that constitute stimunlente for sending exams.
- Review service contracts must include all aspects of and be communicated to both parties.

Laboratories working for public health programs must have a document (plan, protocol) appropriated laboratory analyzes showing that we need to make, volume, frequency and capability of carrying them out.

For samples collected from third parties, the contract shall contain detailed clauses on harvesting, packaging, transportation, storage, maximum time of presentation, etc.

The laboratory must have a documented system for:
- receipt,
- recording,
- identification,
- check and analyze orders

4.5 Examination by referral laboratories

4.5.1 Selecting and evaluating referral laboratories and consultants

4.5.2 Provision of examination results

This requirement has two aspects:
1. subcontracting laboratory analyzes where the applicant has a temporary unavailability or overload for the analyzes required and
2. Refer to another laboratory for analysis or person whose outcome is not given measurement equipment but is based analyst expressed his training and experience.

Laboratory must comply with procedures related policy documents both. Policy on subcontracting laboratory must comply with MOLDAC Policy. Laboratory analysis may indicate that subcontract. In this case the requirement must be documented. MOLDAC not accredited laboratory analyzes alone can not perform to the level of said performance.

If subcontracting laboratory accredited laboratories must document and implement a procedure for the evaluation and selection of subcontractors. Records of such reviews should be available.

The laboratory should have a list of subcontractors accept. This will comprise:
- Name and address of subcontractor / contact name
- The type of analysis which was accepted / period of validity of acceptance
- Type accept or assessment based on accreditation.
- Evidence of capability for which has been selected.

Lab assumes all liability for subcontracted work and for the results obtained from analyzes carried out by a subcontractor. People who have authority and responsibility must be identifiable subcontracting. Privacy issues must be considered.
Documents
- Quality manual
- The assessment procedure subcontractors
- Subcontracting procedure.

4.6 External services and supplies

The laboratory shall:
- declare its supply policy;
- document the procedures, authority and responsibility to those who develop, analyze and approve purchasing documents;
- fully and properly document its specific requirements for each category of purchased supplies;
- consider and approve purchasing documents before launch;
- select suppliers based on their assessment of their ability to meet all specified requirements, including those relating to quality;
- ensure that the goods supplied are not used until inspected or verified and they are in accordance with the specifications drawn up;

The laboratory will have a list of supported including:
- Type of product or service supplied (training, calibration equipment, software, etc.);
- Name and address of the supplier;
- Name of contact person;
- date the period of validity was evaluated and the evaluation. The laboratory should have records of inspections at the reception.

Products that have not been inspected and verified to be separated from the found compliant. If derogate from this rule must be kept detailed records of product use.
The laboratory shall have:
- procedures for reception, storage and release of Storage Product

- instructions for checking the products in stock and inventory control
- special instructions for toxic substances, drug precursors
- spaces and special instructions for storage and handling of supplies, consumables and reagents.

Documents
- Quality manual
- Assessment Procedure suppliers
- Procedure supply
- The procedure for the sale of goods supplied
- The procedure for storage and stock control.

4.7 Advisory services

The laboratory shall document its internal customer service or overwork individuals, businesses or public authorities.

For medical analysis laboratory analyzes the prescribing doctor and the patient whose product is analyzed are Laboratory customers.
Sampling, patient training on harvesting techniques and precautions, autorecoltare, entry values in referrinţă biological analysis reports are services that must be documented and implemented.

Documents
- Quality manual

4.8 Resolution of complaints

Politics laboratory of complaint will include the principles and criteria: consideration of resource feedback and evaluation of quality of customer service by analyzing complaints, criteria for accepting complaints (written, verbal, anonymous, etc.), time to solve and answer types actions taken at the levels of authority involved.
If the complaint proves After investigating founded, for example laboratory has not acted rapid alert system, complaint handling procedure must include notification.

Policy must emphasize laboratory laboratory effort to:
- meet the applicant's requests as much as possible,
- Prevent damage the image of laboratory
- use information from complaints to correct and prevent non-compliant activities.

The procedure will describe the activities to implement this policy, including:
- Registration System,
- The forms used for records,

Documents
- Quality ,manual,
- complaint handling procedure,
- Registration for registering complaints
- records with given plaintiffs
- customer satisfaction questionnaire.

4.9 Identification and control of nonconformities

Nonconforming work includes cases occurring mistakes, losses, accidents or other deviations from procedures in assay work, using methods or procedures for measurement-

validated, incomplete validated or outdated situations of loss of control identified in the program of internal control or participation in PT schemes. They can be found in:

- complaints and feed back,
- internal audit,
- Quality control results.

Control of nonconforming testing work, must include at least:

- Works irregular correction (restoration, additions, etc.) and possibly issued documents (report, etc.)
- analysis of causes and corrective action if it finds that the nonconforming work could recur
- quality assessment prior efforts where possible.

The procedure must specify:

- How to reporting and recording of works / activities test compliant,
- The forms used for registration,
- How often are analyzed records,
- Who participate in the analysis,
- Methods used
- Who are reported test results of the analysis of non-conforming work, conclusions and corrective actions,
- Who decides on recovery attempt,
- customer who communicate test results of analyzes on the work of conformity.

Following the analysis of nonconforming activities will be carried out changes in the management system.

Documents

- Quality manual
- Procedure to deal with non-compliant activities.

4.10 Corrective action

The laboratory must declare their politics in choosing and implementing corrective actions in order:

- The client will not be affected,
- Laboratory to be as little affected
- to avoid recurrence or worsening of nonconformity,
- to prevent future non-compliance.

The laboratory should document the procedure for handling feedback and implementing corrective action whenever deviations occur from documented policies and procedures.

The procedure must specify:

- responsibilities for analyzing the causes and implications of noncompliance and corrective action choice,
- responsibility for carrying / verification,
- Methods of checking the effectiveness of corrective action,
- post-implementation monitoring corrective actions
- analysis of root causes of nonconformities,
- The results of corrective actions must be analyzed by management.

The way to solve and verify the effectiveness of corrective actions and internal audits in the areas or activities where corrective actions were taken. Often non-compliance can be treated in two stages:

- correction (immediate action),
- cause analysis and corrective action to eliminate the causes.

The laboratory must distinguish between immediate and corrective action and not be limited to immediate action.

1. immediate action (instead of correction) taken when non-compliance to solve its immediate effects.
2. solve the root cause corrective action to NC

The laboratory shall provide for the possibility of initiating corrective actions not only the result of nonconforming work, internal or external audits, management reviews, feedback from customers and staff as a result of comments.
Documents

- Quality manual,
- corrective action procedure.

4.11 Preventive action

The laboratories performing as its principal objective the prevention and treatment of not conformity. In this regard must regularly analyze laboratory quality management system operation and identify possible sources of non-compliance and potential for improvement.

- Quality manual,
- Preventive action procedure

4.12 Continual improvement

The laboratory must demonstrate continuous improvement of the functioning of its quality management system.
The laboratories performing as its principal objective the prevention and treatment of not conformity. In this regard, must regularly analyze laboratory quality management system operation and identify possible sources of non-compliance and improvement opportunities. Improvement action plans established at the meeting of the management review is completed and must always communicated to staff.

4.13 Control of records

Items activities which are reevaluated periodically (internal audits, analyzes, etc.) and shall be kept for a period of at least one cycle. Records of equipment throughout the equipment life.

Records on activities that may affect the parameters or results of the analysis (e.g. maintenance works, metrological, personnel qualification, etc.) are kept for a period of at least one accreditation cycle or during their use.

The information recorded and during storage must comply with the applicable legislation or customer requirements (if any).

The laboratory must implement a documented procedure to control records, including those on computer and submit them to the classification procedure.

Record should be created simultaneously with execution of each activity.

Records kept under control must be clearly identified (name, code, support, data), along with the location, responsibilities and shelf life.

Items activities which are revalued periodically (internal audits, analyzes, etc.) shall be kept for a period of at least one accreditation cycle.

In the case of records stored electronically will establish clear rules on prevention of unauthorized access (setting levels of access, passwords, etc.) or changes to these records.

Records on activities that may affect the parameters or test results (e.g. maintenance works, metrological, personnel qualification, etc.) are kept for a period of at least one accreditation cycle or during their use. The information recorded and shelf life must comply with applicable law.

Documents
- Quality manual,
- Procedure of control records.

4.14 Evaluation and Audits

4.14.1 General

4.14.2 Periodic review of requests, and suitability of procedures and sample requirements

4.14.3 Assessment of user feedback

4.14.4 Staff suggestions

4.14.5 Internal audit

4.14.6 Risk Management

4.14.7 Quality indicators

4.14.8 Reviews by external organizations

Management plan and implement assessment processes and internal audit. Laboratory management should periodically verify that the processes of pre-, post-examination and continues to be in compliance with the quality management system, if the requirements of users, and if it is ensured continuous improvement. Internal audits should be conducted of all system elements, both managers and technical.
Internal audits should be conducted by trained personnel having the knowledge of the business being audited, audit and reference standard requirements.

Assessment:
- Designated personnel (Head of laboratory) periodically evaluates whether the results obtained are suitable for clinical applications received.
- Check the collection and sampling to ensure that samples are not collected or insufficient amounts nor excessive amounts of sample and the sample is collected properly to preserve the measurand.
- Analyze user feedback on the performance of the laboratory (keep records).
- Analyze improvement proposals received from staff.

Internal audit is an important means of verifying the adequacy and operation of the management of the laboratory.
Each audit will check management system elements:

- Degree of suitability for laboratory activities,
- As officials,
- As documentation
- As potential for improvement,

Internal audit is performed based on annual program approved by the management of the laboratory. The frequency of internal audits may vary depending on the volume, complexity, risk level of the activities audited, on the efficacy shown by the management system and on the proven stability. It is not necessary for the internal audit to cover in each year, in depth, all the elements of the quality management system.The laboratory may choose to focus on a particular activity without completely neglecting the others.

The internal audit program for medical analysis activities will be developed so that a cycle of accreditation contains all activities in the field. In developing this program to take into account the importance of the processes and areas to be audited and the results of previous internal/external audits.

It is recommended that activities: analysis, control records and documents, complaints and control testing activities inconsistent, be audited more frequently than once a year.

It is recommended that the audit be carried out based on detailed questionnaires, documents and approved the audited known.

Any statistical techniques used in such situations, it is considered useful. The effectiveness of these audits will verify the management review.

Specific procedures must:

- The manner and criteria for designation of the audit team,
- How to make (guidelines / checklists)
- reporting module,
- the distribution of the report,
- Tracking resolve nonconformities,
- Access to records,Perioada de pastrare/ arhivare,

Documents

- Quality manual,
- internal audit procedures,
- List auditors
- Questionnaires (Checklists)
- internal audit program,
- Report of internal audit.

Risk management: According to ISO / TS 22367 "laboratory must evaluate the impact of process execution and potential errors on examination results, because they affect patient safety, and should modify processes to reduce or eliminate the identified risks and to document decisions and actions taken ".

Risk is the combination of the probability of a failure (something unacceptable) and the impact on the final outcome (severity of effect). Risk management is a process that makes the identification, analysis and evaluation of all risk.

Laboratory establish quality indicators to be monitored and reviewed regularly.

The laboratory must determine response times for each of the examinations that reflect clinical needs, to periodically evaluate whether or not they established response times.

Review by external organizations: Non-conformities that occur after external review (accreditation body, regulatory agencies and health and safety inspections), must be applied promptly and corrective and preventive actions to ensure compliance with the standard requirements.

4.15 Management review

4.15.1 General

4.15.2 Review input

4.15.3 Review activities

4.15.4 Review output

The analysis should be systematic and take into account all the quality management system components.

Laboratory management must review SMC regularly and planned. Review include all the information and analysis to predict if any alterations of SMC and quality policy.

Input data session management review include at least:
- The results of internal audits / third party,
- Performance laboratory (results PT / ILC),
- Feedback,
- The degree of achievement of individual objectives and
- adequacy management system and business plan development prospects.

The rating revisions necessary following:
- Change regulations
- Technical progress
- Customer requirements
- Change Referentials.

It is recommended that, where applicable, the processes to be monitored by specific indicators.

Proposals to improve laboratory management system, can be presented as inputs to the analysis.
Analysis is conducted as a meeting headed by executive manager who approved the policy on quality, with the participation of all laboratory personnel with responsibilities for quality. As a result of the analysis should identify:

- Solutions to improve the management system and technical competence to the requirements of regulated and clients.
- resources required material, human or training, being able to improve annual planning and establish preventive or corrective actions if necessary.

Registration analysis must be clear and explicit elements and terms of output (planning, responsibility, deadlines) and should be sent to persons responsible for carrying out activities / measures set.

Specific procedures must:
- Responsibilities
- mode of implementation, frequency,
- reporting module,
- The distribution of the report,
- Access to records,
- period of storage / archiving,
- The planning and implementation of improvements.

Documents
- Quality manual,
- management review procedure.

5 Technical requirements
5.1 Personnel

4.1.2 General

4.1.3 Personnel qualifications

4.1.4 Job descriptions

4.1.5 Personnel introduction to the organizational environment

4.1.6 Training

4.1.7 Competence assessment

4.1.8 Reviews of staff performance

4.1.9 Continuing education and professional development

4.1.10 Personnel records

The remuneration shall not be a direct correlation between the volume of tests or their results and salary.

Laboratory must have documented procedures and records for all staff, stating qualifications (education, experience and skills).

Medical analysis laboratory staff must meet the following criteria of competence:
• **studies:** graduates of medicine, biology, chemistry, biochemistry, pharmacy,
•**Qualification:** Laboratory medicine residency for physicians; postgraduate studies in laboratory analysis for biologists, chemists, biochemists; college or specialty school proficiency certified laboratory assistant, lab,

• Experienced according to assigned responsibilities, ex.minimum two years for bacteriology

• **Training:** Training needs identified according to each person to busy work,

• **Skills:** adequate specific activity,
• in some cases are very useful references from previous employers.

Personnel issues opinions and interpretations have theoretical and practical knowledge in the field, to be in accordance with the opinions of regulations and guides professional societies.

Was there a job description, responsibilities, authorities and tasks for each person. Be a program for the introduction of new staff in the organization, department or area: employment conditions, facilities, health and safety requirements (rules of labor protection and labor health service).

If there are requirements of the law, other regulations or technical customer on certification or other proof of competence, staff performing these analyzes must have certification or attestation required (ex. - Cytology).

Staff responsible for the opinions and interpretations included in the analysis report shall be the primary physician or laboratory medicine or other person educated in the field of medical analyzes.

Head of laboratory quality manager and responsible for the analysis must be permanent staff (part time or full time).

The medical laboratory must document and implement biosafety rules, universal precautions and post-exposure measures in accordance with ISO 15190 SM SR: 2012.

The laboratory must establish a documented training system to ensure that each person is trained in technical and management, and knowledge are maintained and updated in accordance with policy.

The training program will be developed for training and categories according to the type of activity and responsibility / authority attributed to the person.
➢ For new staff training program will:
- study period and adaptation
¬ active probation under supervision
¬ continuous training.

This applies to personnel who was transferred and assigned a new activity (which requires a higher qualification). Staff competence and training needs will be evaluated permanently.

The laboratory must conduct an assessment of the efficiency of training and competence of each person through:
- Direct observation of processes, equipment maintenance,
- By monitoring records,
- Problem solving skills assessment,
- Examining samples provided specifically (which were analyzed).

Besides the technical performance is an assessment of professional performance. Staff needs to be trained, evidence on:
- SMC
- Work processes and procedures,
- SIL,
- Health and safety,
- Ethics and confidentiality.

Staff in training must constantly supervised by forming stage to make an assessment by the chief supervisor.

The laboratory shall have requirements (job) and records (personal records) on training, experience and knowledge of staff, including one authorized to formulate opinions or recommendations.
Head of laboratory quality management system manager and responsible for the analysis must be permanently employed staff.

In particular, duties and responsibilities of temporary staff and / or trainees must be defined in relation to other members of the laboratory. Supervision of such personnel must be ensured throughout to ensure that temporary staff and / or trainees working under laboratory procedures. The laboratory must evaluate temporary or probationary staff competence and keep records.

The provisions relating to skills acquisition for particular tasks can be applied. If necessary, staff training can be adapted to the distributed nature of such staff.

1) Using staff who provide activities for several employers.

When using such a personal laboratory, he must identify employers and potential conflicts of interest and ensure confidentiality of information that personnel has access vis-a-vis its other employers.

2) Replenishment (replacements), (4.1.5. J).

The absence of any deputies for certain functions must be compatible with the service level shown by the laboratory. For example, if the laboratory is committed to realize its benefits within the deadline, he must have resources to meet this commitment and therefore have without persons holding proxies.

Sitters should be able to replace the holders of the qualification level expected: it is for the laboratory to provide oversight and maintenance of their qualification.

A permit may cover multiple tasks simultaneously, such as signature validation The results and analysis reports.

Authorization must be regularly reviewed and confirmed skills. When there is objective evidence daily of learning tasks (e.g. use of reference materials for each series of analyzes or participation in inter-laboratory comparisons), these elements justify maintaining competence and skills.

The laboratory must provide confirmation of approval of a person for a task after a certain period without achieving pregnancy. Need confirmation of competence is based on the

length of inactivity, the technical competence required load and possible changes that took place before the last time the person has performed the task.

3.) The person appointed to validate and signing Analysis reports.

Analysis reports signatory is the person who takes responsibility for this issue and implicitly certifies that the quality requirements analysis results in accordance with SM. It is a personal responsibility that has authorization and validation of results or has received authorization from the Directorate laboratory for this activity.

When ballots include results validated by different persons it is necessary that signatory bulletin have appropriate knowledge and experience to analyze and correlate the results with each patient test report.

The job description should include:
- Name and mail (function)
- Job position in the organization,
- Contents (activities, tasks)
- minimum conditions of employment (education, experience, competence, skills)
- Responsibility and authority,
- relationship of subordination / coordination / collaboration / representation.

A single job description for staff can be reached with the same function, especially in small laboratories.
There should be instructions for maintaining personnel files. They must document:
- Who, where and how your files,
- How and when updated,
- Access to personnel records.

In small laboratories or similar competent staff that all staff can be authorized by the job description to perform all analyzes.

In laboratories carrying out analysis with a high degree of specialization or risk must authorize staff do the sampling, sample prepared at working with different equipment makes statistical processing, issues analysis report, comments or interpretations of results.
There must be records of this meeting criteria for personal jurisdiction.

Documents
- Quality manual
- Procedures for selection, evaluation and retraining staff
- Procedures for permanent employment or temporary staff
- Procedures for training
- Procedures for completing personnel files
- sheets for posts in laboratory
- Rules for authorization, authorization list (where applicable).

5.2 Accommodation and environmental conditions

5.2.1 General

5.2.2 Laboratory and office facilities

5.2.3 Storage facilities

5.2.4 Staff facilities

5.2.5 Patient sample collection facilities

5.2.6 Facility maintenance and environmental conditions

Operational site laboratory to be located in the protected pollutant chemical and biologigi that could influence the results of analyzes and safety of staff.
The area and room volumes must conform to regulatory requirements (Rules established by the Ministry of Health).

Laboratory space and must be sufficiently designed so that:
- Does not compromise quality of care,
- Ensuring the safety of staff, patients and visitors,
- To prevent cross-contamination.

Access to areas affecting the quality of examinations to be controlled.

Laboratory staff provide areas:

- There are storage space for equipment and personal stuff,
- Access to toilets and safe drinking water,
- If possible, it is recommended study space, meeting and resting.

Location of different activities must pursue a one-way circuit work properly, so that samples circuit not cross the waste stream.

Sector working with patients should be completely separated from other sectors working of the laboratory.

The finishing floors and walls must be perfectly smooth (smooth), washable and disinfection of surfaces InBin round (without corners) and with as few bumps the accumulating dust.

The laboratory must have the appropriate attachments and function spaces volume number personal and specific activities (storage, dressing rooms, toilets, lounge, dining, reading, etc.)

The laboratory must be provided with all necessary utilities (water, sewerage system, electricity, heat, gas, ventilation, access roads, telephone, e-mail, etc.).
The furniture in the laboratory work area must be perfectly smooth and resistant SUBSTANCE corrosive, offer the possibility of cleaning the floor under the furniture, cabinets as may be suspended on the wall.

Medical analysis laboratories which have compartmentalized structure of bacteriology, mycology, parasitology, virology, molecular diagnosis should be supplied to the mandatory class biological safety hood appropriate microbiological risk group they belong manipulated microorganisms falling under Guide national medical laboratory biosafety.

Sampling points are subject to the same rules of organization and functioning.

5.3 Laboratory equipment, reagents and consumables

5.3.1 Equipment

5.3.1.1 General

5.3.1.2 Equipment acceptance testing

5.3.1.3 Equipment instructions for use

5.3.1.4 Equipment calibration and matrological traceability

5.3.1.5 Equipment maintenance and repair

5.3.1.6 Equipment adverse incident reporting

5.3.1.7 Equipment records

5.3.2 Reagents and consumables

5.3.2.1 General

5.3.2.2 Reagents and consumables – Reception and storage

5.3.2.3 Reagents and consumables – Acceptance testing

5.3.2.4 Reagents and consumables – Inventory management

5.3.2.5 Reagents and consumables – Instructions for use

5.3.2.6 Reagents and consumables – Advers incident reporting

5.3.2.7 Reagents and consumables - Records

The laboratory must have all the necessary equipment (their list).

Installation and before using laboratory must verify equipment performance, this requirement applies "equipment used in laboratory equipment used equipment borrowed or mobile locations by others associated or authorized"

The laboratory must document each equipment Instructions for use
- Be trained and authorized personnel,
- Summer use instructions and manuals to be easily accessible,
- Procedures for the handling, transport, storage and use of equipment to prevent contamination or damage.

The laboratory must declare its policy on assuring traceability and document how to maintain and check equipment condition (calibration). The laboratory's policy on traceablity must comply with the MOLDAC policy "Politica privind trasabilitatea măsurărilor conform ILAC P10", code P-3.
The laboratory must have a documented procedure for calibration of equipment with influence on the final outcome, which include:
- The manufacturer's instructions,
- Metrological traceability of calibrator (certificate of traceability)
- Registration curve (ratio) calibration
- The date of recalibration,
- Updating correction factors previously established,
- Safeguards against eventual adjustments.

"Metrological Traceability must be reported in a reference material or a reference procedure available for higher metrological order." Supplied by the manufacturer. "The equipment produced and marketed under the regulations requiring traceability (e.g. IVD (In Vitro Diagnostics) European Directive (Directive 98/79 / EC)) is judged to meet the traceability requirements of this policy. Statements concerning traceability documentation should be available in the laboratory. "

When this is not possible, ensure traceability laboratory by:

- Use of certified reference materials,
- Examination or calibration by another procedure,
- Standards or methods agreed by mutual agreement of the parties.

Lab to ensure that the equipment to be used safely:

- Electro,
- Stopping in emergency,
- Disposal of chemical, radioactive and biological authorized persons.

Manufacturer's instructions to be used:

- Have a documented procedure for maintenance in compliance with the manufacturer's recommendations,
- Defective equipment labeled and stored in a safe way
- Considering the possible effect of defects on previous results and decide on the failure of immediate corrective action
- Before use after repair, equipment must be decontaminated and checked.

Incidents and accidents attributable to an equipment manufacturer should be analyzed and reported immediately.

Equipment and reagents used in medical analysis laboratory must be approved and registered as medical devices. They will only be purchased equipment and reagents that meet the requirements for establishing the conditions for marketing and commissioning of medical devices establishing the conditions for marketing and use of in vitro diagnostic medical devices.

For metering equipment and where appropriate for their parts it is advisable to validation before use, usually with reference materials. The interval between calibrations depend on the characteristics of the metrological reliability means that measuring the intensity and conditions of use. For metering equipment is required to obtain log book sites.

Except by the measurement apparatus covered by legal metrology and to be calibrated or verified persons (laboratories) authorized by the legal metrology, the rest of the program can be calibrated devices based on internal calibration procedures. The laboratory shall keep, if necessary, documents concerning: commissioning of measuring instruments, repairs them or calibration before each use.

These activities should be carried out by qualified personnel using standards or certified reference materials and records must be kept especially the estimated measurement uncertainty.

The laboratory should check (intermediate) at appropriate intervals between calibrations maintaining their ability to control the measurement determined in calibration. These checks must be performed by an appropriate, documented and maintained records of the results. These checks can be made using prepared laboratory standards and metrology adequately confirmed. When selecting certified reference materials laboratory should be guided by EA document 4/14.

Operating technical books and manuals of the equipment, it is advisable to be translated in full or in extract form comprising instructions for use and maintenance.

Each device must be uniquely identified by: type, serial number and year of manufacture and if this requirement is not met by a unique identifier (code number) assigned to the laboratory and recorded.

The laboratory must have a documented procedure for receiving, warehousing, inventory management and acceptance testing of reagents and consumables:

- Reagents and supplies to be stored in cf. manufacturer's specifications,
- If the location is different than the laboratory, to ensure that prevents the destruction or damage
- Each new lot or transport of reagents and supplies to be checked before use,
- To have an inventory control system, consumables and reagents to separate uninspected since the unsupported or supported for use,
- Instructions for use (and those of the producer) to be easily accessible
- Incidents and accidents attributable reagents and consumables, to be investigated and reported to the manufacturer.

Note: If the laboratory reagent or consumable preparations used in your location, store data about the person's identity, date and time of preparation.

5.4 Pre-examination processes

5.4.1 General

5.4.2 Information for patients and users

5.4.3 Request form information

5.4.4 Primary sample collection and handling

5.4.4.1 General

5.4.4.2 Instructions for pre-collection activities

5.4.4.3 Instructions for collections activities

5.4.5 Sample transportation

5.4.6 Sample reception

5.4.7 Pre-examination handling, preparation and storage

Laboratory application form prescribed by the regulations of CNAS and MS must meet SM SR EN ISO 15189:2014.

For patients that speak directly to the laboratory must provide the appropriate request form analyze. When recording directly into the computer, application personnel must be trained

and how the information should be obtained.

Primary Sampling Points external (outside the laboratory), served by laboratory staff / organization belongs laboratorulu must meet 5.4 points. from SM SR EN ISO 15189:2014.

The laboratory must display in a visible place for patients and users information on:
- Based laboratory
- The work program,
- The list of services, including sublets,
- Required sample volume required special precautions, response time, biological reference intervals, clinical decision values,
- Instructions for samples collected from the patient,
- Instructions for patient preparation,
- Instructions for sample transport,
- "Any patient consent requirements (eg, consent to disclose clinical and family history of relevant health care professionals"
- Criteria for acceptance / rejection samples,
- List of known factors that could significantly affect the interpretation of results,
- Availability of counseling clinic
- Laboratory policy regarding the protection of personal data,
- Complaints procedure.

Information for patients and users include an explanation of the clinical procedure (ex.flebotomia) to be performed to enable informed consent.

The application form, on paper or electronically, include:

- Patient identification (name, date of birth, contact information and unique identification (no. Of hospitals and no. Provided)
- Name physician or other person authorized to request analysis, contacts,
- Type of primary sample and where relevant, place of origin,
- Examination requested
- Clinical information about the patient to interpret the results,
- (Family history, travel, diseases, etc)
- Date and where relevant, time collection esationului primary
- Date and time of reception in the laboratory,
- Be a verbal request form.

The laboratory shall document and implement documented procedures (manual harvesting) for primary sample collection and handling, available to those responsible, including those who are not part of the laboratory staff.
All procedures on a patient require the informed consent thereof.
Submission of an application form and willingly assume it is subjected to venipuncture.
Hospital patients have the opportunity to refuse, but some require more invasive procedures written consent.

In emergencies, if the patient can be dropped in the interest of getting consimtamnatului.
The laboratory must document:

1. Instructions for pre-collection activities on:

- Completing the application form,
- Patient preparation,
- Primary sample type (type of container, additive)
- Instructions on the order of harvesting containers, if any,
- The necessary clinical information (eg. The history of administration of drugs).

2. Instructions for collection activities on:
- Establish the identity of the patient from whom a primary sample is collected
- Checking that the patient meets the pre-examination (job status, medication, time d ela last dose, etc.)
- Instructions for collecting blood samples and non-primary blood, with descriptions of the primary receptacles and any additives necessary
- If the collection of evidence is done in the clinic, to be instructions regarding transport of samples
- Labeling instructions to avoid non identification (mixture of patients with previous labels)
- Recording the identity of the person who collects the date and time
- Instructions for sample storage before being delivered to the lab.
- Instructions for safe disposal of materials used

3. Instructions for transportation primary sample (specimen) on:
- Packaging samples,
- The time they arrive in the laboratory for analytical stability
- Respect and discipline laboratory
- Suitable preservatives temperature and sample integrity,
- Sample safety, the carrier, the general public and the laboratory.

4. Instructions for receiving primary samples (specimens).
- Samples to be drawn based on demand and labeling to a patient and the location of collection,
- Applied laboratory criteria for acceptance / rejection
- If the sample does not meet the acceptance criteria and the lab. decide to process it, buletuinul analysis must indicate the nature of the problem and thus recommend caution in interpretation of the result,
- Samples are recorded (register, PC), time and date reception, the person who received samples,
- Instructions for treating samples to be marked as urgent.

5. Instructions for handling, preparation and storage of examination, which provide for procedures to avoid loss, damage or destruction of samples during pre-examination.

Laboratory Procedures include deadlines for requesting additional examinations on the same primary sample.

5.5 Examination processes

5.5.1 Selection, verification and validation of examination procedures

5.5.1.1 General

5.5.1.2 Verification of examination procedures

5.5.1.3 Validation of examination procedures

5.5.1.4 Measurement uncertainty of measured quantity values

5.5.2 Biological reference intervals or clinical decision values

5.5.3 Documentation of examination procedures

Methods for medical tests published in books, guides, straightening, etc. They are considered validated, provided that these methods are recognized by professional associations and relevant authorities, domestic and international.
Medical analysis laboratories using automated analyzers and methods imposed by Kitt's and methods published in books, guides, straightening, etc. They must ensure that they are suitable for the purpose for which they are used.

Laboratories must be selected to ensure that those procedures recommended in the instructions used and / or published in specialized manuals. The procedures selected should be appropriate to the purpose. It must be registered identity of persons who select procedures.

Checking examination procedure:
- The examination procedures validated and used without any modification must be checked before use.
- To keep records proving that obtained in laboratory performance meets specified requirements (comparable with those of validator method) and demonstrate fitness for purpose.
The head of the laboratory to have an emergency plan in case of unavailability of laboratory examination process.

The laboratory must calculate at least the following parameters:
- Lower detection limit,
- The limits of the measuring range,
- Precision (repeatability / reproducibility)
- Accuracy (accuracy)
- Measurement uncertainty.

It validates the laboratory:
- Non-standard methods,
- Methods designed and developed in the laboratory,
- Validated methods used outside purpose,
- Validated, modified.

Validation should be as extensive as necessary and provide proof of performance for fitness for purpose. Validation should be done by a competent person documented procedures and analyze the results validation.

The laboratory shall document and estimate the measurement uncertainty for quantitative measurements:
- Defining performance requirements for each method in part A (towards ETA)

- UM has re-estimated regularly,
- To use the data in internal control that include as many changes routine
- Uncertainty components relevant proecesele need to consider the pre-examination and postexaminare,
- In interpreting a patient measured values must take into account estimated UM,
- User demand, these estimates are provided to the laboratory on the UM.

Biological reference intervals and clinical decision values:
- Laboratory should justify these intervals and communicate them to users.
- If a biological reference interval does not correspond to underserved populations, have made the appropriate adjustments communicated to the users.
- Biological reference intervals should be checked whenever a change pre- and examination procedure.

Documentation Examination procedures:

- Laboratory examination procedures must have documented, in a language understood by all staff in an accessible place.
- Work instructions or any other information -rezumat are acceptable for use "provided a complete procedure documentation is available".

Written procedures must include:
- Purpose of the examination;
Principles and methods used for examination proceedings;
- Performance characteristics
- Type of sample (eg plasma, serum, urine);
- Preparation of the patient;
- Type of container and additives;
- Necessary equipment and reagents;
- Environmental controls and security;
- Calibration procedures (metrological traceability);
- Procedural stages;
- Quality control procedures;
- interference
- Calculation procedure
- Estimated measurement uncertainty
- Biological reference intervals and clinical decision values
- Reportable interval of examination results
- Instructions for determining the values when a result is not in -measuring interval (dilution)
- Alert values, where applicable
- Interpretation of clinical laboratory
- Potential sources of variation
- References
Any change in procedure must be communicated to users after its validation.

5.6 Ensuring quality of examination results

5.6.1 General

5.6.2 Quality control

5.6.2.1 General

5.6.2.2 Quality control materials

5.6.2.3 Quality control data

5.6.3 Interlaboratory comparisons

5.6.3.1 Participation

5.6.3.2 Alternative approaches

5.6.3.3 Analysis of interlaboratory comparison samples

5.6.3.4 Evaluation of laboratory performance

5.6.4 Comparability of examination results

The laboratory shall document and implement procedures to ensure the quality of results, processes, appropriate pre- and post-examination must be implemented.

The laboratory does not have to invent any results. Quality assurance must consider internal control and external quality control.

Quality control: Laboratory documentary and implemented procedures for quality control checks achieving quality intended outcomes (TEA), ie to ensure that the total error in the lab (CV% and Bias%) is always less than the total error allowed (TEA).

Control materials must:
- Be of human origin, to react to the measuring system in a manner dissimilar samples,
- Frequency of use into account the stability to the proceedings and the risk daunarii patient
- Concentration of control materials to be close to the clinical decision,
It is recommended to control the use of third party materials, in addition to those recommended by the producers of reagents and instruments.

Data requirements for quality control:
- Have a control procedure to prevent release rezulattelor in case of failure of control
- If the control criteria are violated results to be rejected and re examined samples likely errors
- Control analysis must lead to preventive actions in case the trends show measuring system problems

The laboratory shall document its policies and procedures to ensure and quality control results generated laboratory Policy on ILC / PT must comply with Policy on use of PTs and ILCs and other inter laboratory comparisons in the accreditation process comply the ILAC P9, EA-2/14 şi EA-4/18, cod P-02

The laboratory should have a documented procedure for participation in inter-comparisons with:

- Responsibilities,
- Instructions for participation and
- Performance criteria (other than the supplier).

The laboratory must participate in programs) inter-recommended suppliers meeting the requirements further ISO/CEI 17043:2010 and must:
- Monitor results,
- Apply appropriate corrective and preventive actions,
- Suppliers to provide evidence that mimic patient samples and can check the pre processes, examination and post-examination.

Alternative approaches:
If not available on the market an inter-scheme to provide confidence in results, the laboratory must find alternatives. (Eg. Use of MRC or exchange of samples with other laboratories, etc).

Analysis of samples from interlaboratory comparisons:
- They must be processed in the normal flow of Lab., Under the same conditions as patient samples, the same people with the same procedures,
- Do not provide information about other participants sample.

Performance Evaluation Laboratory
- The results to be analyzed with all staff,
- If not met the performance requirements to apply corrective actions to be monitored.

Comparability results of exams:
- Laboratory must make an analysis of the results obtained by the method and / or equipment used with other methods or equipment laboratory (in raporului data from manufacturer)
- Notify users in case of differences from other groups stating their system measurement range of measurement.

NOTE - in the case of the measurement results metrological traceability are of the same reference, the results are described as having provided comutabilităţii metrological comparability calibrators.

The laboratory shall participate in interlaboratory comparison schemes at least 2 times a year. The results must be within the organizer's expectations and laboratory criteria.

The results demonstrate that the laboratory must obtain a performance comparable to laboratory group with the comparator.

The laboratory must systematically analyze the results, identify the reasons for the results that do not comply with the criteria and implement effective AC.

5.7 Post-examination processes

5.7.1 Review of results

5.7.2 Storage, retention and disposal of clinical samples

The laboratory shall document and implement a procedure for verifying and validating results before release.

The laboratory must appoint authorized persons (chief laboratory responsible for analyzing) to review, validate and sign before releasing results. The validation is done by reference to internal quality control of the day and, if appropriate, by collaborating clinical information available and the results of previous examinations.

If the revision procedure sets the automatic allocation "should be established to approve and documented evaluation criteria.

The laboratory must have a documented procedure for the identification, collection, preservation, indexing, access, storage, maintenance and safe disposal of clinical samples.

Retention of samples is determined based on the sample, the nature of the examination and other requirements specified.
Removing samples shall respect the regulations.

NOTE - The legal liability concerns certain types of procedures (eg histology examinations, genetic examinations, pediatric examinations), which may require the keeping of samples for much longer periods than for other samples.

Depending on the policy laboratory samples Primary storage is done on a time and under conditions that ensure the stability of the parameters that would be reviewed.

Storage, decontamination and removal of hazardous materials must be made according to regulations. The laboratory must keep for the decontamination and disposal in accordance with regulations infectogene MS.

5.8 Reporting of results

5.8.1 General

5.8.2 Report attributes

5.8.3 Report content

The laboratory must have a documented procedure for preparing the analysis report results on a bulletin that the results be reported accurately, clearly, unambiguously.

The laboratory should establish and support Report format (paper or electronic) and how it is communicated. The report must contain sufficient information for analysis and for late succeed, to have a process for notifying the applicant.

Analysis report must:

- Contain comments on sample quality
- If the sample observation is consistent / inconsistent with the acceptance criteria
- Critical results, if necessary

Contents of the analysis must include the following:
- Clear identification of laboratory transmitter
- Clear identification of the examination, including the method,
- Identification of examinations conducted by lab.subcontractat,
- Patient identification on each page,
- Name and contact details of the applicant (doctor, insurance company,
- Primary sample collection date and hour when relevant,
- Primary sample type,
- Measurement procedure, where appropriate,
- Examination results reported in SI units, units traceable to SI units or other applicable units,
- Biological reference intervals, clinical decision values, or
- Charts / nomograms supporting clinical decision values, if any,
- Interpretation of results, where appropriate.

NOTE - full interpretation of the results require the context of clinical data, which may not be available in the laboratory.

- Other reviews, such as reminders or explanation (eg, results / interpretations of the laboratories contracted)

- Identification examinations carried out as part of a research program, or development and not available for specific requirements performance measurement,

- Identify the person (s) revising (reviewing)
- Results and those authorizing the release of the report,
- Date and time of release,
- Page number of total pages.

The laboratory must document, in case of positive findings notifiable communicable diseases and the application of the Rapid Alert legislation.
When elaborating the analysis report laboratories should respect the MOLDAC policy cocerning the usage of accreditation symbols and references to accreditation, code P-08.

5.9 Release of results

5.9.1 General

5.9.2 Automated selection and reporting of results

5.9.3 Revised reports

Laboratory must have documented procedures for the issuance of who and whose release results?

The laboratory must ensure that stated the report state primary sample if the report no data alert is immediately notify your doctor, recording the time, the person notified and outcome of the examination, the person who submitted and any difficulties encountered in transmitting to ensure that results are legible, without mistakes, if you release a report part, will always issue a final report, to ensure a process of transmitting telephone outcomes (certainly results only reach recipients certified) be a evidence of the results transmitted

orally and they are followed by the issuance of a written report.

NOTE 1 - For results of examinations (eg certain genetic diseases or infectious examinations) may require special counseling. The laboratory should endeavor to see that results with serious implications not be communicated directly to the patient without proper counseling possibility ness.

The results that were removed patient identification data can be used for statistical purposes epidemiology, demography or other statistical analyzes.

Selection and automated reporting results: to have a procedure in which the selection criteria and automated reporting to be defined, agreed, immediately accessible and comprehensible for staff, who decide how to modify the absurd, improbable or critical if there is a process that shows the presence of interference (hemolysis, lipemia, etc.) selected for automatic reporting results should be identifiable in its review before release and selection include the date and time, if determined to suspend the rapid selection and automatic reporting.

Reports reviewed:
- A revised report must be clearly identified as a revision and includes reference to the date and the identity of the patient in the initial report;
- User is aware Review
- Revised record shows time and date change and name of the person responsible for change;
- Registration entries remain in the original report when revisions are made.

The results were made available for clinical decision making and review this clinical decisions should be retained in subsequent cumulative reports and be clearly identified as revised.

5.10 Laboratory information management

5.10.1 General
5.10.2 Authorities and responsibilities
5.10.3 Information system management

The laboratory must have a procedure in place that describes how to permanently maintain the confidentiality of patient information.

NOTE - In this International Standard, "systems" include both data management and information contained in the computer and non-computer systems. Some of the requirements may be more appropriate computerized calculation systems than non-computerized systems. Computer systems may include those integrated equipment functional laboratory and standalone systems that use general software, such as applications for word processing, spreadsheets and databases that generate, collate, report and archive patient information and reports.

Authorities and Responsibilities:

The laboratory must define authority and responsibility for the use, maintenance and modification of computer systems, authority and responsibility for all people:

- Accessing data and patient information;
- Enter patient data and examination results;
- Modify patient data and examination results;
- Authorize the release of examination results and reports.

Management Information System: Information system for acquiring, processing, recording, reporting, storage and recovery of data and information examination must be:
- Validated by the supplier and
- Laboratory tested before use.

NOTE - Validation and verification include, where appropriate, the proper functioning of interfaces between the laboratory information system and other systems, such as laboratory instruments, systems management inpatient and primary care systems.

The information system must be documented and the documentation is accesbila authorized users. This procedure must provide:

- Protection against unauthorized access,
- Safeguard against forgery or loss,
- Use with the specifications of the supplier,
- Maintaining in a way that ensures data integrity, system errors also include recording and immediate and appropriate corrective actions.

In accordance with national and international requirements on data protection, the laboratory must ensure that the results of the information and all associated comments are reproduced accurately and electronically and on paper.
The laboratory shall ensure that the laboratory external information (computers, fax machines, electronic mail, web, etc.) are sent directly and correctly.

The laboratory shall document the emergency plans in case of failure or service interruption information systems.

If the computer system is operated and maintained outside space laboratory or subcontracted, the laboratory is responsible if the operator meets all requirements of this standard. If non computerized systems, to ensure the accuracy of registration and manual transcription.

6. SYNTHESIS OF MODIFICATION

Changes were made on pages: 4,38.