Guidance for the accreditation of clinical laboratories according to ELOT EN ISO 15189
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Guidance for the accreditation of clinical laboratories to ELOT EN ISO 15189

Scope of the international standard ELOT EN ISO 15189 is to specify requirements for quality and technical competence particular to medical laboratories.

1. Terminology

- Biological Variation: reference interval
- Examination: set of operations having the object of determining the value or characteristics of a property.
- Medical laboratory: clinical laboratory
- Pre-examination procedures: preanalytical phase
- Post-examination procedures: postanalytical phase
- Referral laboratory: similar laboratory for a supplementary or confirmatory examination procedure and report

2. Chapter 4 “Quality Management Requirements”

4.1.1 Legal substance of the laboratory
For the clinical laboratories authorisation of operation is required according to the following legal regime:

B) Private laboratories: Two licences required, authorisation of foundation and authorisation of operation, according to presidential decree Nr 84/2000.

For more information visit web page of “Athens Medical Association” (www.isathens.gr)

4.1.5 Ethics
Annex C of the standard gives particular accent to the Ethics of a medical laboratory.

4.2.4 Quality manual
Elements which require particular attention:
k) Safety
i) Environmental aspects (for example transport and management of waste)
u) Communications and other interactions with patients, health professionals, referral laboratories and suppliers.
w) Ethics (Annex C)

4.5 Examination by referral laboratory
The laboratory shall have an effective documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology and related disciplines.
Particular requirements:
A) List of referral laboratories
B) Record of all the samples that have been referred to another laboratory
C) Notification of the relevant elements (name and address) of the referral laboratory to the person making the request
The referring laboratory is responsible for providing the applicant with the results and findings of the referral laboratory. If the referring laboratory prepares the report of the results, it should mention all the essential elements of the results reported by the referral laboratory, without alterations that could affect clinical interpretation.

The referring laboratory director may elect to add interpretative remarks to those, if any, of the referral laboratory (the author should be clearly identified).

(*) Referral laboratories are not reported in subcontractors.

4.7 Advisory services
Appropriate laboratory professional staff shall provide advice on choice of examinations and use of the services, including repeat frequency, required type of sample and interpretation of the results, when is asked. The laboratory should establish criteria of appropriateness of personnel as well as criteria of effectiveness of education of personnel.

In case of hospitals, there should be regular meetings of professional staff of the laboratory with the clinical doctors, regarding the use of the laboratory services and the purpose of consultation on scientific matters. Furthermore, staff of the laboratory should participate in clinical rounds.

4.15.2 1, 1 Management review
A testing laboratory should adopt quality indicators for monitoring the laboratory’s contribution to patient care and continuous improvement indicators.

3. Chapter 5 “Technical requirements”

5.1 Personnel

5.1.1 Job descriptions, duties and responsibilities (one copy to each worker)
Files that should be kept are:
   a) Organizational plan
   b) Vacation schedule
   c) Personnel files including:
      • Personal information
      • Certification or license, if required
      • conditions of work
      • Education, professional qualifications, experience
      • File of accidents-exposure to occupational hazards
      • File of medical follow-up (vaccinations etc)
   d) Laboratory meetings
   e) Evaluation of personnel
   f) Training schedule for the personnel:
      • Theoretical (attendance of seminars of scientific companies, congresses etc)
      • Practical (training on the job) for technicians

5.1.4 c, 3,4 Qualification of laboratory director
Director’s qualifications are evaluated according to the legislation.

5.1.10 Employees shall be trained to prevent or contain the effects of adverse incidents
5.1.13 Confidentiality of information regarding patients shall be maintained by all personnel. Statement of confidentiality.

5.2 Accommodation and environmental conditions
The laboratory should apply the existing legislation.

5.2.2 Protection of personnel from injury and occupational illness
Application of provisions Η.Π. 37591/2031 FEK 1419/τ. β/1-10-2003 for the management of medical waste.

5.2.3 Accommodation and environmental conditions for different kinds of sampling
When primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimization of collection conditions.

5.2.7 Controlled access
Appropriate measures shall be taken to safeguard samples and resources from unauthorized access.

5.2.10 Storage and disposal of dangerous materials shall be those specified by relevant regulations.

5.4 Pre-examination procedure

5.4.1 Patient's request form should contain:
- One-track identification of patient
- Elements of referring doctor
- Type of sample and the anatomic site of origin
- Examinations requested
- Clinical information relevant to the patient (sex, date of birth, medication etc)
- Date and time of primary sample collection
- Date and time of receipt of samples by the laboratory

5.4.2 Specific instructions for the proper collection and handling of primary shall be documented and implemented by laboratory management and distributed free of charge to the medical and nursing personnel or to the patients.

The primary collection manual shall include the following:
- Preparation of the patient
- Special timing of collection, if required
- Collecting tubes
- Labeling of primary samples
- Storage of the sample till examination
- Any special handling needed between time of collection and time received by the laboratory
- Date and time of primary sample collection
- Date and time of receipt of samples by the laboratory
- τρόπος και τόπος φύλαξης του δείγµατος εάν δεν αναλυθεί αµέσως.
- Storage of the sample for further examination
5.4.5 Primary samples shall be traceable to an identified individual. Primary samples lacking proper identification shall not be accepted or processed by the laboratory.  
* In cases however where the sample is critical or irreplaceable (biopsy, encephalospinal liquid) it can be received and analyzed but without releasing the results until the primary sample identification. If this is impossible, the name of person in charge is marked in the report.

5.4.6. c) Transportation of the sample should be in a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with national, regional or local regulatory requirements.

5.4.8 The laboratory should develop and apply documented criteria of acceptance or rejection of sample or receipt under terms and that these are recorded in the report of result.

5.4.9 Periodical review of the appropriateness of the required sample volume is necessary to ensure that the collected amounts are neither insufficient nor excessive. Relative standard procedures shall exist.

5.4.11 Each laboratory shall have a thoroughly documented procedure, for each stage (receipt, labeling, processing and reporting) of the handling of those received samples, which are specifically marked as urgent, so that the latter are easily and rapidly identified. The personnel shall be trained, in order to identify samples, which are characterized as urgent (e.g., bone-marrow, blood cultivation, etc).

5.4.13 The laboratory shall have a written policy concerning verbal requests for sample examinations. For that purpose, the laboratory shall keep files for the detailed documentation of those requests.

5.5.5 Biological reference intervals shall be periodically reviewed. A review of biological reference intervals shall also take place when the laboratory changes an examination or pre-examination procedure.

5.5.7 If the laboratory intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services in writing, prior to the introduction of the change.

5.7 Post-examination procedures

5.7.1 Authorized personnel shall systematically review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorize the release of the results.

5.7.3 The laboratory shall apply local regulations or recommendations for medical waste management.

5.8.3 i) Examination reports shall include biological reference intervals, where applicable. For instance, according to the laboratory estimation, the drug doses could be recorded.
5.8.4 The examination results should follow the vocabulary and syntax recommended by International Organizations.

5.8.7 The laboratory shall determine the critical properties and their “alert/critical” intervals and notify anyone involved in the examination or post-examination stage, so that he would be able to react immediately in case of exceedance.

5.8.16 Results available for clinical decision-making and revised afterwards shall be retained in subsequent cumulative reports.

ANNEX C
Ethics in laboratory medicine

The general principle of healthcare ethics is that the patient’s welfare is paramount and that the laboratory should handle all patients in the same manner without discriminations.

According to the aforementioned:

a) As far as the information collection is concerned, in order to ensure precise sample identification, correct results evaluation and protection of the employees, the patient could be asked to provide general or personal details, for which the laboratory shall give proper explanations if requested.

b) Prior to sampling procedure, the patient shall be informed on the utilized sampling technique and, if necessary, requested to provide a signed consent. The patient has the right to deny the sampling procedure, despite the prescription of the attendant doctor.

During the sampling procedure, the personnel shall take into consideration and respect social, cultural or religious particularities of the patients. In urgent situations, the patient’s welfare is paramount. Moreover, the existence of appropriate places for sample collection shall be checked (e.g., blood collection, vaginal fluid, seminal fluid, etc).

c) For sample volume, which arrives at the laboratory in an inappropriate condition, the attendant doctor shall be informed before the sample being rejected.

d) Each laboratory, depending on its specialty, shall have patient information policy on the requested examination (e.g., genetic), as well as attendant doctor information policy (e.g., result evaluation or complementary examinations).

e) Counterfeiting of laboratory results, as well as any financial transaction with attendant doctors or commercial firms, is strictly forbidden.