GUIDANCE FOR THE ACCREDITATION OF MEDICAL IMAGING LABORATORIES

ESYD G-IMAGING LAB

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Prepared by: Quality Manager of ESYD
Approved by: Chairman of ESYD

Quality Manager of ESYD **Chairman of ESYD**

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1. Introduction - Scope

The requirements and criteria presented in this document apply to medical imaging laboratories so that to develop a quality management system, to evaluate their technical competence and to confirm appropriateness of imaging services in order to be accredited according to the international standards ELOT EN ISO 15189:2012 and **ELOT EN ISO / IEC 17025:2017**, regardless of the number of their staff members and / or the extent of imaging activities.

Accreditation is the third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Imaging and interventional services include conventional radiological examinations (radiography and fluoroscopy), computed tomography (CT), magnetic resonance imaging (MRI), mammography, body composition measuring X-ray (bone density DPX, DEXA, etc.), nuclear medicine, and positron emission tomography/ computed tomography (PET and PET / CT), ultrasound and interventional radiology procedures (angiography, angioplasty, etc.).

Please note that accreditation does not exempt the laboratory from the obligation to comply with all relevant laws and regulations. Moreover, accreditation does not substitute the relevant operation licenses and certificates foreseen by national or regional legislation. In case of suspension or revocation of the special operation license and / or certificate of suitability by Greek Atomic Energy Commission (EEAE), the prerequisites for laboratory accreditation automatically are suspended.

2. Terms and definitions

Laboratory Director - The person(s) responsible and competent for the activities of the laboratory.

Laboratory Management - The person(s) who manage resources and take decisions for all laboratory activities.

Equipment - The equipment used by the laboratory, including all imaging equipment, processing, and printing hardware and software, as well as accessories.

Scientific responsible laboratory physician - The person who bears the ultimate scientific responsibility for all laboratory activities and is mentioned in the laboratory's operation license.

Staff – The term includes besides permanent personnel, trainees, interns and part-time employees.

Radiation Protection Advisor (RPA) – A medical physicist possessing the relevant license of practice and provides advice on matters of protection from ionizing and non-ionizing radiations.

Technical Competence - Documented ability to apply knowledge and skills.

Radiation Protection Officer (RPO) – A medical physicist, mentioned in the laboratory's operation license, possessing the relevant license of practice and is responsible for the implementation, supervision and control of protection measures against ionizing and non-ionizing radiation.

User of imaging laboratory services - The examined patient, the referring physician or other healthcare professional.

3. Organization and management (ELOT EN ISO 15189: 2012 §4.1, 4.15, **ELOT EN ISO / IEC 17025: 2017 §4.1, 4.2, 5, 6.1, 8.9**)

3.1 The medical imaging laboratory (hereinafter referred to as 'the laboratory'), being either an autonomous unit or part of a larger organization, must be a recognized legal entity. It is required to possess a license, a certificate of suitability by EEAE and special authorization, for all imaging systems and radiation locations, according to the regulatory framework applied for ionizing and non-ionizing radiations.

3.2 The laboratory management should illustrate all positions/jobs in an organization chart. If the laboratory is part of a parent organization, the place of the laboratory should be shown in the organizational structure of the parent organization.

3.3 The laboratory must meet the requirements of the Accreditation Standard during its operation, whether at permanent facilities, or when using mobile devices, or providing telemedicine services.

3.4 The laboratory management shall ensure the proper functioning of the laboratory and the continuous improvement of services provided.

3.5 The laboratory management must ensure that:

a) laboratory staff is not involved in any activities that would compromise confidence in its competence, impartiality and objectivity;

b) the management and staff are free from any undue commercial, financial or other pressures and influences that may adversely affect the quality of their work;

c) the confidentiality of information is maintained.

3.6 The laboratory management should be composed of individuals with necessary competence for the functions and responsibilities assigned to them.

3.7 The laboratory management shall appoint the scientifically responsible physician and the radiation consultant or radioprotection responsible person, whose activities and duties are in accordance with the regulatory framework for ionizing and non-ionizing radiations.

3.8 The duties and responsibilities of the laboratory director, the scientifically responsible physician and the radiation protection officer (hereinafter referred to as 'RPO') and/or radiation protection advisor (hereinafter referred to as 'RPA') shall be documented.

3.9 The laboratory director, in direct communication with the laboratory management shall:

a) ensure that the necessary personnel with the required education, and technical competence is available to provide medical imaging services, which meet the needs and requirements of users of these services;

b) ensure a safe laboratory environment, in accordance with good practice and any current requirements

c) ensure the continuous implementation of safety measures and protection from ionizing and non-ionizing radiation of the patients, the staff, the public and the environment, in accordance with the regulatory framework of ionizing and non-ionizing radiation protection;

d) ensure the appropriateness of waiting and examination rooms;

e) ensure the provision of clinical advice on the choice of examinations, the use of services and evaluation of examination results;

f) evaluate and select laboratory suppliers;

g) select referral laboratories and monitor the quality of their services (where applicable);

h) enable continuous education and training for all staff;

i) seek and evaluate users feedback, in order to improve the services provided.

3.10 The laboratory must ensure the preservation of medical confidentiality and protection of personal data of all patients. Furthermore, the implementation of the appropriate examination, the safety and dignity of the patients and the security of their personal belongings, during the examination, must be ensured.

3.11 The laboratory shall ensure that patients may discuss examination options only with appropriate staff members.

3.12 The laboratory shall ensure that results are given at a specific time period.

3.13 The laboratory shall communicate with the referring physician if additional or modified examinations are needed and inform the patient.

3.14 It is the responsibility of the laboratory management to review, at least annually, the fulfillment of the requirements of accreditation with involvement of all stakeholders. The results of the review are recorded and, if necessary, corrective actions are taken and their implementation is monitored.

4. Quality Management System (ELOT EN ISO 15189: 2012 §4.2, **ELOT EN ISO / IEC 17025: 2017 §8.2, 8.9**)

4.1 The quality management system should anticipate integration of all procedures necessary for the fulfillment of the quality policy of the laboratory and its objectives, and should continuously meet the needs and requirements of users, including the provision of advice and diagnosis.

4.2 The laboratory management must undertake a policy statement on quality, which:

a) is appropriate for the purpose of the organization;

b) provides a framework for establishing and reviewing quality objectives;

c) is communicated and understood within the organization;

d) is reviewed for continuing suitability;

e) includes a commitment to comply with the requirements of Accreditation and continuous improvement of provided services;

f) is reviewed for compliance with current regulations and practices of radiation protection (national, European, international).

4.3 The laboratory management must establish quality objectives, which, through quality indicators, shall be measurable and consistent with the quality policy and document the implementation of these objectives.

4.4 The laboratory administration must designate a quality manager who, irrespective of other responsibilities, has the responsibility of maintaining and implementing the quality management system, in direct communication with the laboratory administration.

4.5 The laboratory must establish and maintain a quality manual that includes:

a) a declaration of quality policy;

b) a clear description of the scope of the quality management system;

c) presentation of the organizational and administrative structure of the laboratory and its position in any parent organization;

d) a description of the roles and responsibilities of laboratory management;

e) documented policies and procedures established for the quality management system relating to administrative and technical activities that support them.

4.6 The documentation of the quality management system should include:

a) a quality manual, quality policy and quality objectives;

b) procedures, documents and records;

c) copies of applicable radiation protection regulations, diagnostic and treatment protocols, quality control protocols of equipment and other regulatory documents.

5. Control of documents (ELOT EN ISO 15189: 2012 §4.3, **ELOT EN ISO / IEC 17025:2017 §8.3**)

5.1 The laboratory should periodically check all the documents of the quality management system of internal and external origin, in order to avoid inadvertent use of any obsolete document.

5.2 The laboratory must have a documented procedure to ensure that the following conditions are met:

a) all documents, including those in electronic form, issued as part of the quality management system, are checked and approved by authorized personnel prior to their adoption;

b) all documents are identified and have a title, a unique ID of each page, the date of the current version and /or a version number, page number out of the total number of pages, and include the names of authorship and approval;

c) current authorized versions and their distribution are recognized through a directory;

d) only current versions are available at points of use;

e) handwritten amendments must be clearly marked, initialed and dated;

f) alterations in documents should be easily visible;

g) obsolete documents are withdrawn and a copy thereof kept on file for a specified period.

5.3 The laboratory shall ensure the use and maintenance of updated versions of existing regulations, standards and other regulatory documents.

6. Service agreements (ELOT EN ISO 15189: 2012 §4.4, **ELOT EN ISO / IEC 17025:2017 §7.1**)

6.1 The laboratory shall have a policy for the formation and revision of agreements regarding the provision of medical imaging services.

6.2 Request for an examination shall be accepted only from a doctor's referral. Each examination, accepted by the laboratory, must be regarded as an agreement for the provision of medical imaging services and should include a brief case history, the medical report of the referring physician and the examination requested.

6.3 Authorized medical staff must evaluate the referral and adopt the appropriate imaging process. A copy of the referral must be kept for a certain time in a relevant file.

6.4 The agreement for the provision of medical imaging services requires the implementation of the following:

a) the laboratory has the technical competence and resources to meet the needs of the users;

b) laboratory staff possesses the skills and experience needed to carry out the required examinations;

c) the selected examination procedures are appropriate and sufficient to meet the needs of the patients;

d) the examination procedures using ionizing and non-ionizing radiation take into consideration the radiation protection and safety of the patients, carers, and staff;

e) referees are informed of deviations from the agreement which may affect the test results;

f) a written consent regarding side effects must exist (e.g., MRI exams, use of contrast media or anesthesia etc.) after the patient is relatively informed.

6.5 The laboratory must keep a record of the relevant conventions, agreements and referrals in a proper way (i.e. printed, electronic, entry in the information system of the laboratory) in order to ensure traceability of the laboratory work.

7. External supplies and services (ELOT EN ISO 15189: 2012 §4.6**, ELOT EN ISO / IEC 17025: 2017 §6.6**)

7.1 The laboratory must have a documented procedure for the evaluation and selection of services, equipment, drugs, contrast media and consumable materials that affect the quality of its services and to maintain an updated list of approved suppliers.

7.2 The laboratory must determine the specifications and criteria used for the selection and approval of its suppliers. However, it may be necessary to cooperate with other departments of the organization in order to fulfill this requirement.

8. Consulting services (ELOT EN ISO 15189: 2012 §4.7, **ELOT EN ISO / IEC 17025: 2017 §7.1, 8.6**)

The laboratory should establish arrangements for communicating with the users of its services for the following:

a) advise on the choice of examinations and use of services, including the indicated examination, clinical indications and limitations of an examination and frequency of a reexamination, especially those using ionizing radiation;

b) specific advice and guidance of patients who are administered radiopharmaceuticals for nuclear medicine examinations, their companions and members of their family;

c) evaluation and interpretation of examination results;

e) information on examination cases that do not meet the acceptance criteria.

9. Resolution of complaints (ELOT EN ISO 15189: 2012 §4.8, **ELOT EN ISO / IEC 17025: 2017 §7.9**)

The laboratory must manage any complaint or other comments received from users of its services. Record should be kept of all complaints and their investigation and the actions taken. The management of complaints must be in accordance with the provisions of record keeping and at the completion of the investigation the complainant must be informed.

10. Identification and control of non-conformities (ELOT EN ISO 15189: 2012 §4.9, 4.10, 4.11, **ELOT EN ISO / IEC 17025: 2017 §7.10, 8.5, 8.7**)

The laboratory shall have a documented procedure for the identification and management of non-conformities, in every aspect of the quality management system, including quality control, internal audits, and examination procedures, reporting results, imaging equipment, radiation protection, security and administrative issues. This procedure should ensure that:

b) the required corrective actions are defined;

c) the medical importance of the nonconformity is examined and where appropriate, the referring physician is informed;

d) the results of nonconforming examinations, already released, are recalled or appropriately identified, if necessary;

e) any non-compliance is recorded and archived. The implementation of the corrective action is monitored and its effectiveness is verified. Files of non-conformities and corrective actions are reviewed at regular intervals by the laboratory management in order to detect trends and take preventive actions.

11. Record keeping (ELOT EN ISO 15189: 2012 §4.13, **ELOT EN ISO / IEC 17025: 2017 §7.5, 7.11, 8.4**)

11.1 For the documentation of the quality management system, the laboratory shall maintain records, in printed or electronic form as anticipated and required by accreditation standards and other regulations.

11.2 All quality records and technical records must be available for review by the management of the laboratory.

11.3 Quality records should be created and updated simultaneously with the execution of the relevant activity. The date of the modifications of the files must be visible, as well as the identity of the authorized personnel making those modifications.

11.4 The laboratory shall determine the time duration that records, related to the quality management system, should be kept. However, the examination results must be kept and be retrievable as long as required by medical practice, regardless of the determined period.

11.5 The laboratory facilities should provide a suitable and safe environment for storing all the files. It is recommended that computer files are also stored with alternate means, outside the laboratory.

12. Quality control (ELOT EN ISO 15189: 2012 §4.14, 5.6, **ELOT EN ISO / IEC 17025: 2017 §8.8, 7.7**)

12.1 The laboratory should plan and implement internal quality control procedures, including internal audits, to ensure:

a) examinations are conducted in a way that meet the needs and requirements of the patients and the referring physician;

b) compliance and continuous improvement of the quality management system.

For documentation of quality audits, the laboratory shall keep, inter alia, referrals and exams, examination protocols, inspection files of radiation protection / hazards, plans for prevention and safety measures of staff and the public, a file of measurements and quality control, of radiation protection and safe operation of the equipment.

12.2 The audits must be carried out by appropriately trained and authorized personnel. The audit program takes into account the status and importance of the processes, techniques and management areas to be audited, and the results of previous audits. The audit criteria, scope, frequency and methods must be established and documented and be in accordance with the regulatory framework of ionizing and non-ionizing radiation.

12.3 Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. The auditors, where resources allow, should be independent of the activity to be audited.

12.4 The laboratory should have a documented procedure defining responsibilities and requirements for planning and conducting audits, and for reporting results and compliance with the relevant records.

12.5 If during the internal audit non-conformities are identified, the relevant procedures for appropriate corrective actions are implemented.

12.6 When external quality control programs are available, the laboratory must establish a participation program, which is based on the availability of these programs for the techniques used in the laboratory, at least once every four years.

13. Risk management (ELOT EN ISO 15189: 2012 §4.14.6, **ELOT EN ISO / IEC 17025: 2017 §8.5**)

13.1 The laboratory shall evaluate the operating methods for eventual failures of the examination results that affect the patients' health and appropriately modifies the relevant procedures.

13.2 The laboratory shall ensure the recognition and management of patients who are at risk of adverse reactions to certain drugs and contrast media, and complications from the execution of the required examination (e.g. MRI).

13.3 The laboratory shall ensure appropriate management of risks associated with invasive examinations and shall document procedures for unforeseen emergency cases.

13.4 For pediatric examinations optimized processes are required, in order to ensure that specific clinical needs are met and to reduce exposure to ionizing radiation.

13.5 The laboratory should inquire for possible pregnancy, before an examination with ionizing and non-ionizing radiation, and should implement appropriate procedures when examining pregnant women with ionizing and non-ionizing radiation.

14. Staff (ELOT EN ISO 15189: 2012 §5.1, **ELOT EN ISO / IEC 17025: 2017 §6.2**)

14.1 The laboratory should have a procedure for the management of staff. The laboratory shall have job descriptions, which describe the qualifications and responsibilities for each position. For all employees, including laboratory management, records should be kept to document the qualifications of each person (diplomas, certificates of education, training, experience and skills required, retraining after a long absence, continuing education, etc.).

14.2 The medical staff that makes diagnoses shall have the appropriate theoretical and practical background and experience.

14.3 All staff shall receive training, covering at least the laboratory's quality management system.

14.4 The integration of new staff or staff absent for some time should be done with a proper procedure in the area of its employment.

14.5 Personnel under training shall be supervised constantly. The effectiveness of the training program should be reviewed periodically. Education should include specific procedures for children, pregnant women, and people with disabilities.

Retraining of staff is performed when deemed necessary (e.g. after replacement, expansion or installation of new equipment).

14.6 Personnel should take part in continuing education programs. The effectiveness of the continuing education program should be reviewed periodically.

15. Facilities and environmental conditions (ELOT EN ISO 15189: 2012 §5.2, **ELOT EN ISO / IEC 17025: 2017 §6.3**)

15.1 The laboratory shall have adequate facilities, sufficiently accommodated and controlled to ensure the quality and effectiveness of services provided, as well as hygiene, safety and radiation protection of the patients, the staff, the public and the environment.

15.2 The laboratory shall ensure that:

a) access is controlled to areas that affect the quality of examinations;

b) medical information and examination results are protected from unauthorized access;

c) facilities allow proper execution of the examinations (indicatively are mentioned : radiation protection, energy sources, lighting, ventilation, water supply, waste disposal etc.);

d) communication systems in the laboratory are appropriate to the size and complexity of the installation, to ensure an effective transfer of information;

e) auxiliary equipment (e.g. wheelchairs, stretchers) are available and maintained.

15.3 The space and storage conditions shall ensure the continued integrity of drugs, contrast media, documents, equipment, supplies, records, referrals, images and reports.

15.4 Storage and disposal of hazardous (toxic, infectious, radioactive, etc.) materials should be appropriate and consistent with the relevant regulations.

15.5 There should be sufficient access to toilets, drinking water and facilities for storage of personal protective equipment and clothing.

15.6 There shall be effective separation of laboratory sections with incompatible activities.

15.7 The management of the laboratory shall ensure regular monitoring of the laboratory safety regarding fire safety, electrical installations , mechanical equipment, oxygen systems and where else deemed necessary, in accordance with applicable laws. The results of the inspection and checks shall be kept in appropriate files.

16. Radiation protection (ELOT EN ISO 15189: 2012 §5.2, **ELOT EN ISO / IEC 17025: 2017 §6.3, 6.4**)

16.1 The laboratory shall ensure the issuance and regular renewal of the special operation license and the certificate of suitability by EEAE which certify protection from radiation of personnel, patients, public and environment from the laboratory activities with ionizing and non-ionizing radiation.

16.2 The RPO or RPA determines specific measures to optimize the exposure of patients to ionizing and non-ionizing radiation in accordance with the regulatory framework which must be applied by the laboratory in medical imaging examinations.

16.3 To document radiation protection, the laboratory must keep relevant records.

17. Equipment (ELOT EN ISO 15189: 2012 §5.3, **ELOT EN ISO / IEC 17025: 2017 §6.4**)

17.1 The laboratory must be equipped with the necessary equipment to provide the required imaging services.

17.2 The laboratory should have a documented procedure for quality control of equipment that directly or indirectly may affect the examination results and the protection of the patients.

17.3 The laboratory should have a documented preventive maintenance program, which, at a minimum, follows the manufacturer's instructions.

17.4 The laboratory should renew its equipment when required to ensure the quality of examination results or when it is required by legislation.

17.5 Each item of equipment shall be uniquely labeled or otherwise identifiable and included on a list of equipment.

17.6 Records of the equipment used to perform the examinations should include, among others:

a) Identification of the equipment (manufacturer, model, serial number, date of construction or reconstruction, etc.);

b) manuals of use and repairs;

c) acceptance records of equipment, date of receipt and date of initial operation;

d) maintenance program and quality controls;

e) records of equipment performance and quality controls (log books);

f) failures or malfunctions, modifications or repairs of the equipment.

17.7 The operation of the equipment should only be performed by trained and authorized personnel.

17.8 The laboratory must verify, by appropriate controls that the equipment meets specific criteria of acceptance and verify their performance before assigned for clinical use.

17.9 Defective equipment should be set out of use, be clearly identified and should not be used until repaired. The laboratory examines the impact of any defects or failures in previous examinations and takes direct action or corrective actions.

17.10 If equipment is removed from the direct control of the laboratory, for repair, replacement of a part or for any other technical work, the operator or the radiation consultant should verify its performance before being return to laboratory use.

17.11 When computers or IT systems are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory must ensure the continued protection of information integrity.

18. Examination procedures (ELOT EN ISO 15189: 2012 §5.4, 5.5, **ELOT EN ISO / IEC 17025: 2017 §7.2**)

18.1 The laboratory should have working protocols for all exams.

18.2 The laboratory should provide each patient with adequate information of the required preparation before an examination. The consensus of the patient (or the attendant for

children) is indispensable for the administration of contrast substances or anesthesia, and especially in cases where certain factors determine whether to execute or not an examination (e.g. the existence of a pacemaker in a patient for magnetic tomography).

18.3 The laboratory, in order to perform an examination, requires the existence of a request by a physician, where the need of the examination is justified. Examinations with ionizing radiation are performed when alternative non-ionizing examinations are excluded or relevant data of the patient are taken into account.

18.4 The laboratory should provide the patient with necessary information relevant to the clinical procedure of the examination.

19. Reporting of results (ELOT EN ISO 15189: 2012 §5.8, 5.9, **ELOT EN ISO / IEC 17025: 2017 §7.8**)

19.1. The results of each examination (medical report) must be reported accurately with clarity, according to the indications of the examination.

19.2. The laboratory determines the form and means for recording the examination (e.g., print or electronic).

19.3 The report shall be signed by the physician who evaluates the results and issues the diagnosis.

19.4 When an initial diagnosis is revised, the data of the prior examination is indicated, and the patient and the referring physician are informed. The results should be delivered in a determined time after the performance of the examination, reflecting clinical needs.

20. Bibliography

ELOT EN ISO 15189:2012 ‘Medical Laboratories - Requirements for quality and competence’.

ELOT EN ISO / IEC 17025:2017 ‘General requirements for the competence of testing and calibration laboratories’.

Radiation Protection Regulations, PhD. Min. No. 1014 (FOR) 94 / 6.3.2001 (GG / B / 216).

Regulations on "Licensing laboratories MRI scanners - radiation Receivables from non-ionizing radiation, when using magnetic resonance imaging system," Draft Joint Ministerial Decision.

Diagnostic and Therapeutic Protocols to Radiology, Greek Radiological Society, Athens, 2011.

Protocols Oncology imaging, Greek Radiological Society, Athens, 2012.

Guidelines screening Greek Nuclear Medicine Society of Nuclear Medicine and Molecular Imaging, Athens 2012.