GAC 1.4:2019 - Rules and Procedures for Accreditation of Medical Laboratories on conformity with SST ISO 15189:2012/2015

Article 1. Scope of Application

1. The present document has been developed in accordance with international accreditation practice and represents a guiding document for accreditation of medical laboratories.
2. The present document determines specific procedures of the GAC for assessment of the conformity of medical laboratories with international standard SST ISO 15189 Medical Laboratories – Specific Requirements for Quality and Competence. Accreditation procedures are carried out in case of payment of established fee.
3. General accreditation procedures are defined in GAC 1.1:2019.
4. The international guiding documents applied in the accreditation process including documents of EA, IAF and other sectorial international organizations are published on the website of the Accreditation Center (www.gac.gov.ge) within the scope of full description of corresponding accreditation scheme with indication of the status of documents.

Article 2. Requirement for Medical laboratories

1. The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.
2. The medical lab must be independent in the range that is required with regard to the conditions under which its services in accordance with the requirements of ISO 15189.
3. Organizations performing also other activities (manufacture, sale, certification, testing, calibration etc.) have to show consistent meeting of conditions of impartiality, objectivity and non-discriminatory approach in compliance with requirements of ISO 15189, in order to be clear that these other activities do not compromise the independence and of the results. Policies and procedures the applicant must include all factors that can affect its character, impartiality and integrity (ownership relationships and interests, organizational aspects, decision-making procedures, financial affairs, personnel, etc.).
4. The applicant shall submit detailed information about the medical laboratory. Including relevant standards and test methods. Data and plan schedule in qualification tests and participation in laboratory comparison.
5. The applicant must present the procedure of taking into account the uncertainty of the measurement and its approach in the interpretation of quantitative values.

Article 3. Assessment procedure for medical laboratory

1. Applicant interested in the accreditation shall complete the appropriate official accreditation application form and submit it to GAC. The application must be accompanied by the set of documents in Georgian prepared in accordance with GAC Rules and Procedures in electronic format on CD (font type: Sylfaen). The application forms and relevant annexes are available on GAC website – "Electronic Application".

2. An applicant shall submit detailed information on its activities of laboratory including stature, personnel, corresponding standards, implemented management system, impartiality, risk management, results of internal audit da management review.
3. GAC assessment team with the coordination on the team leader will carry out review of presented management documentation, procedures in compliance with ISO 15189 standard. The aim of the team is to specify presented accreditation scope too.
4. After completion of the document review, assessment team carries out on-site assessment (see GAC1.1:2019). The aim of the on-site is to witness practical activities of the laboratory. The assessment team will conduct on-site or remote assessment methods. Using of particular method or combined evaluation techniques based on the risks identified during the assessment.
5. In order to prepare the objective and reliable assessment report, the sufficient number of fields should be assessed from the applied accreditation scope during the initial assessment.
6. If the laboratory performs in-house calibration it should ensure the traceability in accordance with SST ISO/IEC 17025 standard.
7. Laboratories should take part PT and ILC and cover accreditation scope during the accreditation cycle.
8. After granted accreditation during 4 years term of the validity of accreditation certificate GAC performs the monitoring of the accredited bodies through annual assessment. The aim of the annual assessment is to verify that the accredited bodies continue to comply with the accreditation scheme. In the framework of the annual assessment GAC will assess results of the internal audit, management review, status of appeals and complaints.
9. In the frame of the accreditation cycle (annual assessment and reassessment) on the selection bases GAC will assess working sites/branches and methods considering the laboratory requirements and volume.
10. Procedure on granting accreditation, suspension, renewal, withdrawal, extension or reduction of accreditation scope is described in GAC 1.1:2019.
11. Reassessment is planned and performed taking into consideration the information gathered from assessments performed over the accreditation cycle.
12. GAC conducts extension of accreditation scope is performed through accreditation in additional scope on the written request of the CAB. The expansion of the accreditation may include a new research materials, methods, within the scope of existing accreditation or new working area expansion of accreditation may also be included within the annual assessment.
13. GAC carries out extraordinary assessment of CAB on the basis of written augmented complaint on a specific case of violation of the accreditation requirements submitted by an administrative, civil bodies, any other bodies and person. The CAB is obliged to cooperate and assist in resolving disputes (see GAC 1.11:2019). Extraordinary assessment also is carried out on basis on written request of the CAB.
14. The accredited testing laboratories have to shell apply for a flexible scope of accreditation before the annual assessment or re-accreditation activities up to 3 months prior. Each accredited laboratory is responsible for determining its flexibility, flexible accreditation scope and flexibility according to ISO / IEC 17025 requirements. The laboratories should prove to the GAC that their approach is controlled and checked for the selected type of flexible scope is implemented in the laboratory by the management system.
15. Requirements for assessment of flexible scope of accreditation:
a) Type 1 Including of an updated standard and/or technically equivalent method/procedure.

Requirements: at least 1 year of valid accreditation status

Note 3.2: Testing/clinical laboratory may ask for this type of flexibility no sooner then 3 months before the first periodic surveillance visit and the flexibility is assessed in the course of this visit.

b) Type 2 Modification of the already accredited methods/procedures and internal developed methods/procedures and/or extension of the tested parameters provided that the measurement principle is kept.

Requirements: at least 3 years of valid accreditation status.

c) Type 3 Development of testing methods in the frame of accredited tests provided that the measurement principle is kept.

Requirements: laboratory shall show one year successful experience with flexibility of type 2.

Article 4. Sampling

1. If the lab performs sampling on place or outside of the laboratory, the lab should have a sample procedure and appropriate plan.
2. GAC will evaluate whether the described procedure and plan are in the quality management system and will make visits to the relevant sites / branches where the sampling activities is carried out.