ISO/IEC 17025-2006 requirements. General matters of quality system, requirements for documentation and the list of the documents required for a quality system package: quality policy, quality manual, quality procedures
ISO/IEC 17025-2006

ISO 17025 is the main standard (hereinafter – the standard) used by measuring and calibration laboratories. It was initially issued by the International Organization for Standardization in 1999. Though ISO 17025 is similar to ISO 9000, it comprises at the same time a notion of competence, which is directly relevant for the results of testing and calibration. The standard establishes general requirements for competence required to perform testing and / or calibration, as well as sampling. The standard covers testing and calibration carried out using both standard and non-standard methods, as well as methods developed by the laboratory. The standard is applicable for all the first, second and third party laboratories that do testing and / or calibration.
Content of the ISO/IEC 17025-2006

• Sphere of application
• Regulatory documents
• Terms and determinations
• Management requirements
• Technical requirements
Sphere of application

• Requirements to laboratories
• Correspondence of laboratory activities to safety requirements and other compulsory requirements
• Correspondence to this standard provides fulfillment of the ISO 9001: 2000 requirements
Regulatory documents

• ISO 9001: 2000 quality management systems

• ISO / IEC Guide 2: General terms and their determinations pertaining to standardization

• VIM: International Vocabulary of basic and general terms in metrology
Management requirements

- processes of quality system planning, analysis and improvement;
- documentation and data management processes;
- resources management processes;
- processes connected with consumer;
- development and elaboration processes;
- purchasing processes;
- production and implementation processes;
- processes of monitoring and measurement of products and processes
Technical requirements

- General
- Staff
- Premises and environmental conditions
- Selection of methodologies for determination
- Methodologies of testing and calibration, as well as assessment of methodologies suitability
- Equipment
- Traceability of measurements
- Reference materials and standard samples
- Handling of testing and calibration objects
- Ensuring of quality of testing and calibration results
Benefits of the ISO 17025:2005 for testing and calibration laboratories

- acknowledgement of technical competence;
- increasing of performance efficiency;
- marketing benefits;
- international recognition of laboratory;
- possibility to participate in international certification, comparison and control tests.
Quality assurance

Comprises:

- Development of “Quality Manual” in each laboratory participating in monitoring programmes.
- Provision of required conditions in laboratory premises and attestation of working places.
- Preparation of standard operation procedures (SOPs) for each kind of observation.
- Establishing of characteristics of method (correctness, precision, detection limits) and their documentation.
- Regular checks of instruments and equipment by Gosstandard (State Organization for Standardization) bodies.
- Organization and introduction into regular practice of quality control system.
- Procedure of documentation maintenance and reporting all over the sample testing analysis (from sampling, preservation and storage to final measurement and giving out of results).
- Observation data management.
- Professional training to upgrade qualification of laboratory staff.
- Participation in inter-laboratory comparisons on regular basis.
Quality control

Is performed using:

- **Calibration standards** are the solution with known concentrations of substances used to calibrate analytical instruments. The standards are prepared by specially designated organizations and called DZSU (State Standard Sample of Ukraine), have specific numbers and certificates.
- **Control standards** are similar to the DZSU, but they are of different origin. For example, a laboratory uses the DZSU prepared by Odessa Institute of Physics and Chemistry and the other (control) standard is bought from another manufacturer based in Kharkiv. Control standards are used to prove precision of calibration standards.
- **Checking standards** are the standards of one concentration (usually mid-range) used to build the calibration curve and are analyzed to check the curve.
- **Internal standards** are the artificial compounds similar to the studies analyte. Internal standard of known concentration is added to the sample analyzed and passes all the stages of the sample processing (extraction, elution, detection). The received result of internal standard concentration measurement in the analyzed sample gives the percent of recovery (extraction), from which the real concentrations of other determined substances are calculated.
- **Spiked samples** (or matrix form) is and aliquot of sample to which a measured amount of analyte of known concentration is added. Undetermined aliquot of the same sample is to be analyzed (this is matrix). This quality control sample is to be processed the same way as the real samples. Concentration of spiked sample minus concentration of undetermined aliquot should give the quantity of the analyte added.
- **Certified reference materials (SRMs)** are the samples of dry powdered material (soil, bottom sediment, hydrobionts etc.), whose one or more properties values are certified with proper procedure and shown in respective certificate.
Scheme of professional level testing

- Scheme of professional level testing (or inter-laboratory comparisons) is an activity comprising measurement of concentration of parameters in a sample distributed to different laboratories, which do not know the real values of those parameters. The results of tests or measurements are sent to the coordinating organization, which considers the data received and sends a confidential assessment to each participant.

- Organizers and coordinators of international inter-laboratory comparison in the European Union are the Marine Environment Laboratory of IAEA (Monaco) and the European Centre QUASIMEME in the Netherlands.