Requirement for proving of performance quality: use of validated methods, equipment, reagents and standards preparation and control, internal quality control in laboratory, Shewhart charts, inter-laboratory comparisons
Equipment

- General requirements for equipment are provided in the ISO 10012: 2003 (there is a respective reference in the Standard). Laboratory should have the possibility to use for performing the work connected with results receiving only the equipment (classified as measuring, testing and auxiliary equipment), whose technical and metrological characteristics are not lower than the ones specified in the respective methodologies. Requirements of the Standard cover both the laboratory equipment (own, permanently leased) and the equipment used temporarily for fulfillment of a specific order.
Suitability of equipment

- Suitability of all measuring equipment should be confirmed every reasonably established period of time, usually through periodical calibrations. In case a laboratory works within a sphere regulated by law it shall periodically submit its measuring instruments for standard calibration to the organizations designated by State Organization for Standardization in the established by those organizations periods of time (as a rule, every year or more). Sometimes a necessity to check equipment for proper functioning emerges between the standard calibrations. Such checks for proper functioning between standard calibrations enables the laboratories to decrease the risk of hidden metrological failures. Laboratory should be able to provide a documented proof of properly chosen periodicity of equipment performance checks and of those check’s results.
Maintenance of equipment

- Maintenance of equipment should be carried out in strict accordance with the established (as a rule by manufacturer) maintenance regulations and periodicity. In some cases (e.g. when non-standardized measuring instruments developed in laboratory are used) order and periodicity of maintenance could be established by the laboratory or a specially designated organization (in case the laboratory in working in the sphere regulated by law). It is sometimes feasible to check the equipment for proper functioning (including economic reasons: balance between calibration and checking of proper functioning) during the period of time between standard calibrations.
Reagents

- Materials and reagents used for equipment calibration, preparation of volumetric solutions, nutrient solutions etc.;
- Materials and reagents used in the course of analyses;
- Materials and reagents used to ensure the work of equipment, e.g. acetylene for atomic absorption, sorbents for chromatographic columns, filters etc.;
Reference standards and standard samples

- If a laboratory works in a sphere regulated by law there might be requirement to certify reference standards by specially designated laboratory. Standard samples, reference materials (SSs). Standard samples are among the most important instruments to ensure quality of measurement results, which are used for:
  - validation of methodologies;
  - calibrations;
  - estimation of uncertainty;
  - training of staff;
  - internal laboratory control;
  - inter-laboratory assessment of competence.

- Different kinds of SSs are used for different purposes (e.g. certified SSs could be used to validate methodologies, while working samples (prepared in the laboratory) – for internal laboratory control. The Standard refers to the ISO guidance of 30th series, which regulates rules of SSs choice and laboratory work with different kinds of SSs, as well as recommendations for those who prepare the SSs. Making choice on external SSs a laboratory should make sure that manufacturer is competent.
Ensure quality of testing and calibrations results

- Quality of results could be ensured by means of:
  - validation of methodologies;
  - use of respective equipment;
  - traceability of measurements;
  - compatibility with other laboratories’ results;
  - recruitment of experienced and competent staff;
  - independent proofs on the results of inter-laboratory comparisons (professional testing);
  - properly organized internal control in the laboratory;
  - involvement of a third party to confirm competence (accrediting).
Quality control charts building

- Quality control charts is one of the most important instruments to ensure quality, which has been proposed by Shewhart. This is a graph with the numbers of measurements studied under condition of repetitions along x-axis and the results of a quantitative parameter measurement along y-axis. For such a parameter the results of studies of homogenous, stable and adequate samples are usually used. In case there is a necessity to control correctness, the value of parameter to be determined in these samples should be known. Control charts are used to control stability of measurement process and to reveal the situations when the process goes outside of the statistically controlled state.
Control of analysis results stability

- Control charts are graphs:
  - Along x-axis – number of a measurement;
  - Along y-axis – results of control procedure;
  - Horizontal straight lines – different limits (regulation boundaries).

- The most important way to use the charts is their visual inspection. Visual inspection often enables us to reveal regular changes in analytical process, which can hardly be found with statistical analysis. This helps to reveal in time the situations when the process goes outside of the statistically controlled state. There are certain rules for each type of charts, which regulate under which conditions one should interfere into analytical process to ensure quality of analyses results.
Example of Schewhart control chart

Determination of Pb in soil

Result, ppm

Test number
Variations on Shewhart control charts

- Rule 1: single point beyond the control limits
- Rule 2: a shift of eight or more consecutive points above or below the centreline
- Rule 3: a trend of at least six consecutive points (up or down)
- Rule 4: two out of three consecutive points near a control limit (outer one - third)
- Rule 5: at least fifteen consecutive points "hugging" the centre line (inner one - third)
Among all the methods of internal laboratory control of chemical-analytical testing quality, which are mentioned in the Standard, one should choose (if specifics of the methodology permits) regular inter-laboratory comparisons.

The comparisons are the main instruments to assess competence of laboratory. Benefits of the comparisons are: objectiveness, coverage of entire cycle of analysis, from receiving of a sample to writing of protocol.

Inter-laboratory comparisons could be carried out for:

- validation of methodologies;
- certification of reference materials;
- assessment of competence of operators;
- study of a laboratory’s competitiveness;
- general assessment of a laboratory’s competence.