

Measuring equipment in a laboratory.

Laboratory and metrology are two words that practically do not function separately. They are integrally connected to measuring equipment for tests and measurements.

Each of measuring instruments, that are present in a competent (which does not have to mean accredited, but accreditation is the best proof for laboratory competence) laboratory, undergoes various supervision processes.

Supervision over measuring equipment covers equipment in use, as well as those that are currently out of operation, and those for which there are orders placed, i.e. equipment to be present in a laboratory in short time.

Order of an equipment.

The very first activity related to start of a new measuring or testing workstation is purchase of adequate device.

Preparing a detailed specification of an order, requires taking into consideration below factors:

- kind of performed measurements, i.e. what and how the operator is going to measure,
- exploitation conditions, i.e. what ambient conditions are necessary for test room and workstation, and what are exploitation conditions needed for the equipment.
- metrological characteristics, i.e. data obtained from the manufacturer on basic metrological parameters of s specific equipment in relation to expected requirements (it may be necessary to determine additional requirement, which are not specified by the manufacturer)
- compatibility to legal regulations (if valid), i.e. whether the equipment has applicable type approval and markings, which confirm the requirements of a European Union Directive or national documents applicable in a country.
- manufacturer documentation, i.e. checking if documents supplied by the manufacturer are sufficient for laboratory purposes. Such documents are: user manuals, equipment checking documentation, calibration certificate, etc.
- other factors (service, references, price, etc.)

Equipment exploitation

Proper performance of measurements – each operator in a laboratory, who performs measurements, is to obey good laboratory practice. In different laboratories (e.g. pharmaceutical, biotechnological, analytical or any physical measurements) there are specific regulations which define good laboratory practice. In some cases, and depending on laboratory functions, some of the procedures are elaborated by specific industrial branches.

Very important aspect of measuring equipment are ambient conditions in which the equipment is to be utilized. It should be stressed, that ordered measuring instruments should be utilized according to conditions specified by the manufacturer. This condition is extremely important, as the manufacturer of an equipment can guarantee its proper functioning (i.e. metrological characteristics) only in specific ambient conditions. In most cases, it is the temperature range that is specified for proper operation of the equipment. Additionally, manufacturer can specify humidity range.

It is very important, to maintain retraceability of ambient conditions between requirements relating to measuring instruments and requirements of testing / measuring procedure.

An often error observed at workstations refers to its designing stage. It should be remembered to specify the ambient conditions that refer to measuring equipment and testing procedures at this workstation. If audited, such workstation may be incompatible, as requirements of instrument exploitation are different than testing procedures at workstation. For instance, there may be a case in which manufacturer requirements for a measuring instrument specify working temperature in range between from 18 to 25 °C, and testing procedure specifies sample storage temperature for 15 °C. In this particular case, the measuring instrument does not match correctly the workstation. It is, of course, possible to calibrate such measuring instrument in workstation conditions, and take appropriate corrections during calculations, but yet, it is necessary to thoroughly monitor instrument indications and additionally design checking timetable for this measuring instrument. Above this, laboratory should contact manufacturer of this specific instrument and ask for an opinion or test results in different temperature ranges.

Supervision over equipment is the most important aspect relating to measuring instruments. A laboratory which has quality management system compatible with ISO/IEC 17025 standard, point 5.5. is devoted to description of measuring instruments. According to this norm, a laboratory should be equipped with measuring instruments that allow for proper performance of tests and calibrations. The standard stresses here, that the equipment and its software should provide required accuracy and meet the requirements for test and calibration.

Measuring equipment should have a specific timetable for its calibration of key values and characteristic features in cases where it has big influence on obtained results. The norm also requires, that before installation on user location, complete equipment, including sampling instruments, should be calibrated or checked for its proper operation and meeting laboratory requirements, and whether it is compatible with norms and standard valid in this laboratory.

There is also another very important aspect, mentioned in section 5.5.2 of the norm, which informs, that all measuring equipment should be checked and/or calibrated before use – this text includes a reference to section 5.6, which refers to keeping measuring retraceability. In order to guarantee measuring retraceability, complete equipment used for tests and calibrations, **should be calibrated before delivering it to operator**. This also refers to including auxiliary equipment (e.g. for ambient conditions), which may have strong influence on accuracy of measurements, calibration and sampling.

A laboratory should also have a timetable and a procedure for calibration of its measuring equipment. During preparation of a timetable for calibration of measuring equipment, the standard suggests, that it covers system referring to choice, use, calibration, checking, supervision and maintenance of reference masses, reference samples used as reference masses and testing / measuring equipment used for test and calibration procedures.

Each of the measuring equipment components, should have below documentation, or at least data including:

1. identification of equipment and its software
2. manufacturer name, type marking and serial number or other individual marking
3. results from checking which denote whether the equipment is compatible with specification
4. current location of equipment, if possible,
5. user manuals supplied by the manufacturer, if accessible or data on location of such manuals,
6. dates, results and copies of reports and certificates of all calibration processes, adjustments, acceptance criteria and date of next calibration,
7. maintenance activities plan, if accessible, and report from already done maintenance activities,
8. each defect, malfunction, modifications or repairs of the equipment.

All above documentation should be stored by a laboratory in a form of documentation called „Life Cards”, „Equipment Book” or any other. With such book, person responsible for technical functioning of laboratory equipment, and auditing personnel have very much simplified view into procedure of supervision over measuring equipment.

ISO 10012:2003 norm presents simple and clear process of metrological acceptance:

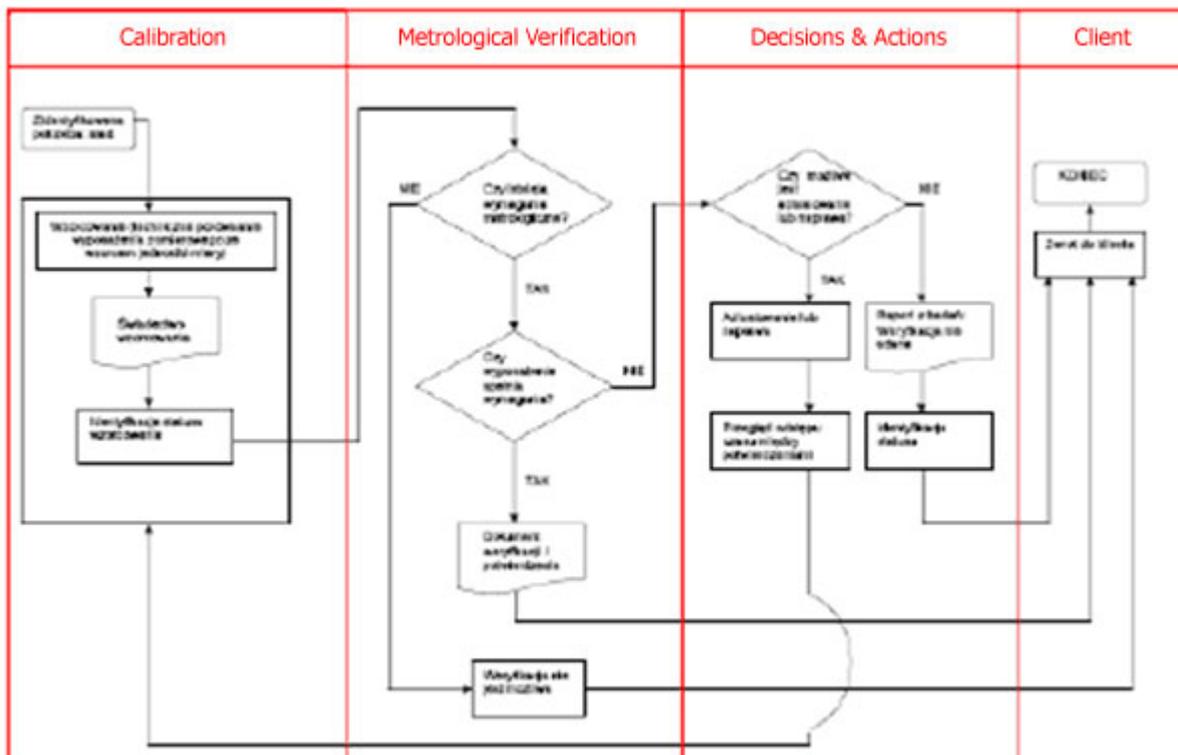


Fig 1 – process of metrological acceptance of a measuring equipment – according to ISO 10012:2003

The above process presents calibration procedure, but it may also refer to other process (for instance checking). at the beginning of the process, its purpose has to be defined.

Let's assume that this purpose is calibration process, that is technical comparison of measuring equipment with reference mass. Calibration process is completed with issuing a document which in most cases is calibration certificate, including test results. The measuring instrument should also have an identification for its calibration status. The next step, according to procedure, is metrological verification. It is a checking of metrological requirements presence for a calibrated measuring instrument. If not, that such verification is not possible, and the instrument is handed to the operator. If the metrological requirements are specified, than the instrument should be verified according to such requirements. If the

instrument is compatible with all requirements, than it receives a document confirming its status (e.g. an entry to “life card” of an instrument). Following this, audit makes a decision on appointing an confirmation identification status. Then, the measuring instrument is given to the operator. If the equipment is not compatible, than decision and activities should be taken, which give an answer to question whether or not it is possible to adjust or repair the equipment which fails to meet metrological requirements. If not, than a report fro mtests should be prepared, indicating that verification is failed, identify instrument status and and return the instrument to operator. If adjustment or repair is possible, the instrument should be adjusted or repaired or handed over to personnel who can do it. On adjustment or repair, the instrument should go through complete calibration procedure.

As observed above, the process is simple and easy in introduction in an organization. It should be, however, adjusted or accomplished according to character of a specific laboratory.

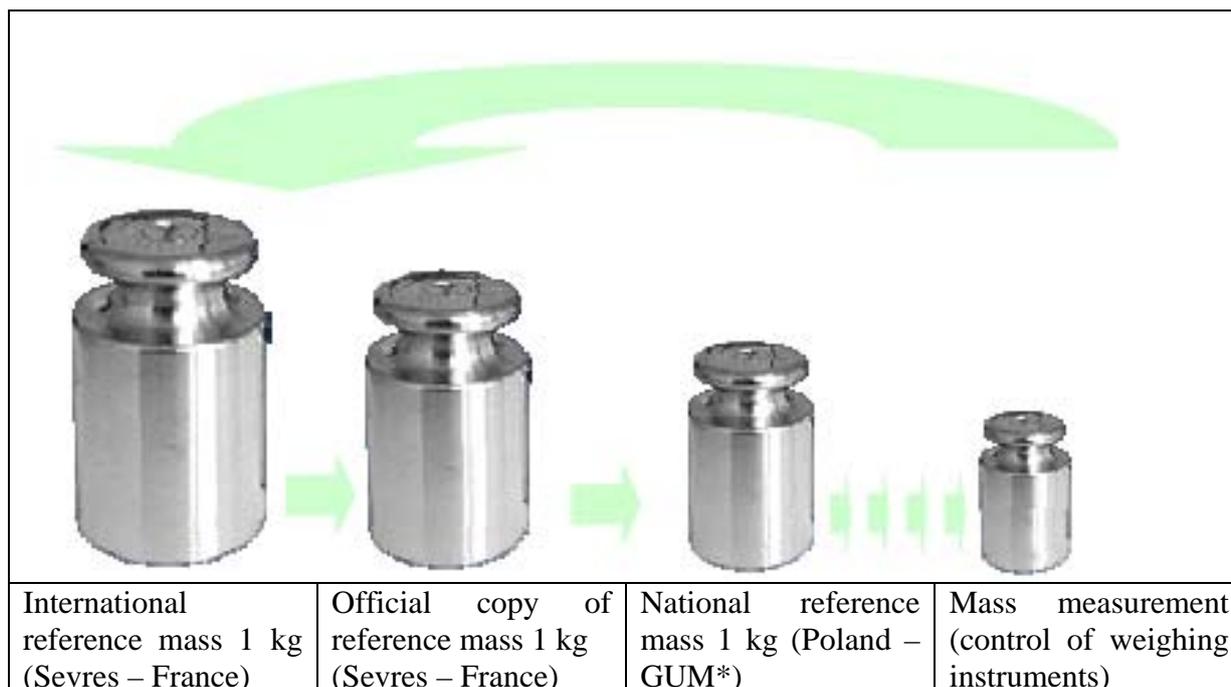
An important element that needs to be placed on an instrument on close to its location is a metrological confirmation label which clearly specifies to which instrument it refers. According to requirements specified in norm PN-ISO 10012-1:1998, which is a basis for Polish Accreditation Centre, it is possible to mark instruments with adhesive label or binding label or mark an instrument permanently.

Each label should clearly indicate date of last and next acceptance according to management system. Such label should also simplify identification of person responsible for current status of the instrument. Labels should be attached to instrument in permanent way, so that accidental or intentional damage or improper use of the label is impossible.

As has been mentioned before, one of the main factors relating to measurements and their results is keeping measuring retraceability.

Measuring retraceability, is a feature of a measurement of reference mass, which provides a possibility to bind it with determined references, in most cases with national or international references, by means of continuous chain of comparisons, in which each element has its uncertainty values determined.

Keeping measuring retraceability is a warranty of unequivocal measuring process, allowing for its comparison to reference unit.



*- GUM – Polish Measuring Institute

Fig. 2 Visualization of measuring retraceability as in case of reference mass

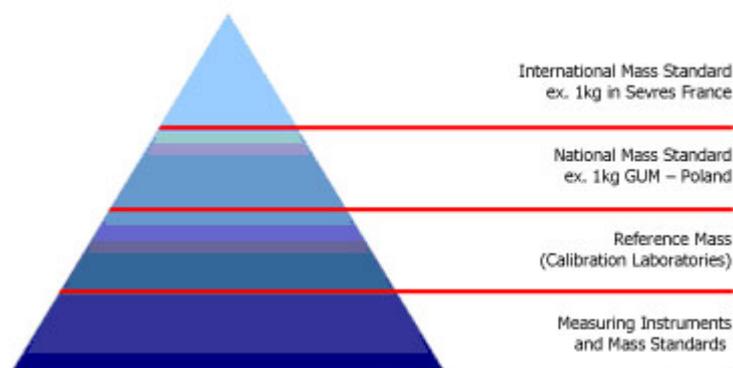


Fig. 3 Schema of measuring retraceability

In case of users of measuring instruments and reference masses, the best option for keeping measuring retraceability is to calibrate them in accredited calibration laboratories and check them according to internal calibration and checking timetable for measuring instruments.

Auditing of measuring equipment

Internal audits, as well as external ones conducted by accredited or calibration units, should include in their content sections referring directly to measuring equipment. In case of laboratories, such audit may refer to various aspects.

Thus, how to audit and where to search for documents from audit in case of measuring equipment.

The first source of information on the equipment is its documentation. Documentation can consist of:

- instrument card (called randomly by a laboratory);

An instrument card contains all data referring to product identification and data on product metrological acceptance (calibration and checking), any repairs, maintenance activities, or additional adjustment on storage location.

- user manual supplied by the manufacturer or supplier of the instrument;

Generally, instrument documentation includes original user manual, which is a source for preparation of workstation manuals and shortened versions of original user manual. It is important, as many of measuring instruments are equipped with optional functions, not utilized in a laboratory,

- calibration certificate of an instrument

- EC declaration of conformity in case of instruments covered by legal metrological control (purchased after 1st May 2004);

It is very important to store documents, as they are necessary for controls performed by national bodies and in case of second verification of an instrument after conformity evaluation (requirements of legal metrology);

- verification markings or certificate of second verification in case of instruments with legal metrological control (purchased before 1st May 2004);

Similarly to EC conformity declarations, such documents are required in case of control within legal metrology.

The second source of information during an audit is the measuring instrument itself. Directly on the measuring instrument, it is possible to identify confirmation features for its metrological status and its legibility and means of attachment. Such label should include all above specified data.

A measuring or testing workstation, one can check access to user manual (if it is required). Before that, the auditor should check the system requirements for storing and accessibility of a user manual.

Additionally, it is possible, according to auditors knowledge and possibilities, to assess general technical condition of the instrument and check authorized personnel knowledge of the instrument user manual.

Another source of information on measuring equipment, which are valid during an audit are corresponding records, which may refer to:

- maintenance, service and metrological confirmations
- weighing results during checking procedure
- calibration certificate
- authorization documents for personnel
- work safety documentation (if necessary)

The fourth source of information may be all data referring to ambient conditions on workstation. Auditor can be interested in records of specific parameters (e.g. temperature, humidity). Technical auditor can also look for means of elimination of disturbance factors (like application of an anti-vibration table).

All above are, of course, instances for the places where records from audit may be looked for, but basing on these examples, a laboratory can determine its own sources of audit information.

When discussing measuring equipment of a laboratory, it refers to control over measuring equipment, which includes calibration and periodical checking of the instruments, referring calibration and checking results to national and international reference masses and data (see section 5.6 of norm ISO/IEC 17025), as well as continuous monitoring of instruments operation. For operators of measuring instruments in laboratories, which have introduced and accredited management system, above activities are basic and fundamental.