Measuring instruments in industry.

Measuring instruments that are present in any branch of industry, are subject to different levels of supervision, like in case of laboratories.

Supervision relates to those instruments that are in continuous use, and such which are out of operation or such those ordered by a customer for future operation.

Organizations, that have implemented and certified quality management systems based on various standards, should have corresponding manuals and procedures which specify activities performed on instruments for measuring and monitoring.

Norms and documentation on measuring instruments specify numerous references which can be found either in specific sections referring directly to measuring instruments, or they can be found in other documents which refer to measuring procedures.

For instance, the most popular norm on management systems, i.e. ISO 9001 contains section 7.6 which covers equipment for monitoring and measurements. A norm requires that an organization determines monitoring and measurements that have to be performed, and equipment for monitoring and measurements that is needed for providing compatibility of a product with the requirements. An organization should determine the requirements that are specified by a customer, and which refer to delivery and post-delivery activities, any requirements not specified by a customer, which are indispensable for intended use of a product, if such id defined. It also covers any legal requirements and norms referring to a product and any additional internal requirements of an organization.

Requirements of systematic norms, similarly to a „laboratory" norm (which is described in no. 5 of Laboratorium magazine), provide regulation for measuring retraceability. An organization should establish processes which check and verify whether monitoring and processes are performed in a way that is retraceable to requirements on monitoring and measurements.

Monitoring, is in other words an activity, which covers observation and supervision with utilization of instruments for monitoring, like supervising questionnaire which give non-quantity results. When mentioning measurements, one bears in mind activities which aim at determining quantity, volumes or dimensions measured with measuring instruments. Such activities are for instance measuring a substance or counting pieces on an electronic balance. Result of both measuring processes is a definite physical data.

Bearing in mind the above specified data, if there is a need to ensure reliable results, than measuring instruments should be:

- calibrated or checked in specific time intervals and before use with standard units that have their references in national or international equivalents. Calibration process should be performed by a competent calibration laboratory for specific physical volume. If possible, such laboratory should be accredited. List of accredited calibration laboratories is accessible on internet website of Polish Accreditation Centre www.pca.gov.pl; Calibration is a process of comparing of measuring instrument with their reference equivalents. It is aimed at specifying the accuracy and compatibility with measuring processes and regulations supervising this measuring process. Calibration processes should be performed with scheduled frequency, in set time intervals.
- adjust or re-adjust an instrument if it is necessary. Adjustment process can be perforemed by an operator in measuring laboratory, if there are sufficient technical conditions in the laboratory. If not, than adjustment should be performed by authorized service point of instrument supplier;
- identify for the purpose of calibration status. Requirements on means of instrument identification are listed in norm ISO 10012;
- protect an instrument against adjustments that could make measuring process invalid. In most cases the protections take form of stickers offered by manufacturers and suppliers, or by metrological services from a specific organization;
- protect an instrument from damage or deterioration on transport, storage and maintenace. Act according to user manual recommendations, workstantion manuals and good professional proactice.

Every time a verification of an instrument is defined as incompatible with the requirements, an organization should determine and record reliability of previous measuring results. Thus, an organization should undertake activities which aim at specific measuring instrument and any other equipment which might have been influenced by the incompatibility. Any activities relating to this process should be documented in a form of notes.

It should also be remembered, that normalization, i.e. certification for compatibility with requirements of system norms is voluntary. However, if this process is introduced, than it should be obeyed. Thus, this conditions should be born in mind while utilizing a measuring instrument.

The situation is different in case of pharmaceutical companies, which are governed by Health Ministry Regulation of 2nd October 2006 on Good Manufacturing Practice.

The attachment to the regulation, chapter 3, point 3.41 includes a note, that instruments designed for measuring, weighing, keeping records and control should be calibrated and checked with specific methods and in specific time intervals. Records from these activities should be stored. Paragraph 3, point 2 of the Regulation gives a definition of calibration process – it is an process which aims at denoting, that a specific instrument or equipment gives results in a defined range. The range is determined by its comparison with reference substances or comparison with identifiable standards in a specific measuring range. This definition is compatible with definition of CALIBRATION from International Vocabulary of Basic and General Terms in Metrology.
When analysing this record, and records from other system norms, it is visible, that requirements from random area have been transformed to regulated area. Thus, it is visible that aspects relating to measuring equipment are very important.

Ordering an instrument.
Pthe first activity related to ordering an instrument is proper preparation of order specification. In order to make such specification of an instrument, the operator should take into account below factors:
- kind of performed measurements, i.e. what and how a product / substance is measured,
- exploitation conditions, i.e. what conditions are necessary for in a weighing room or workstation, and what are exploitation conditions of an instrument.
- metrological characteristics, i.e. data obtained from a manufacturer on basic metrological parameters of a specific measuring instrument which refer to operator's requirements (there may be a need to define some additional parameters, which are not defined by a manufacturer as standard).
- compatibility with legal requirements (if valid), i.e. whether an instrument has applicable type approval and corresponding marking, which is a confirmation for compatibility with requirements of European Union Directives or countries of specific legal regulations
- manufacturer documentation, i.e. checking whether documentation supplied by a manufacturer is sufficient for the present requirements. Such documentation includes: user manual, instrument checking documentation, calibration certificate, etc.
- other factors (service, references, price, etc.)

Instrument exploitation

Measurements should be performed in a specified and defined way – each operator should obey rules of good professional practice. Any kind of industrial plants or service points performs measurements (for instance, building construction, ceramics, motorization, food processing, pharmaceutical, etc.) have norms which are determined by documents on good practice. Depending on performed activity, norms are prepared for each specific industry.

Very important aspect of measuring instrument exploitation refers to ambient conditions in which the instrument will be utilized. An operator should remember, that an ordered instrument should be utilized in conditions that are defined by a manufacturer. Obeying this condition is extremely important, as the manufacturer can guarantee proper operation) of an instrument (functioning according to declared metrological characteristics) only in specified ambient conditions. Most often such data s specification of working temperature and humidity in which an instrument operates as intended.

An operator should always remember to keep retraceability between ambient conditions as required by an instrument and those referring to specific testing or measuring procedure.

Supervision over an instrument is the most important aspect relating to measuring instruments. Companies that have introduced management system compatible with standard like ISO 9001 should focus on point 7.6, which refers to measuring instruments.

Each item from measuring equipment should have its records with specific information on its characteristics, like:

1.identification of a measuring instrument, and its software

2. manufacturer name, type marking and serial number or other individual marking

3. checking procedure results, which denote instrument compatibility with its specification

4. current storage place of an instrument, if such is definable,

5. user manual supplied by a manufacturer, if they are accessible, or data on their storage location,

6. dates, results and copies of statements and certificates from every calibration, adjustment, acceptance criteria and date of next calibration process,

7. maintenance activities plan, if applicable, and list of maintenance activities which were already performed,

8. any defect, malfunctioning, modification or repair of an instrument.

The above list is stored by an organization in a form of documentation named “life cards”. With such life cards, a person responsible for metrological supervision or an auditor has simplified access to supervision procedures over a measuring instrument.

Internal audits – measuring equipment

Internal audits are performed by internal auditors according to scheduled calibration intervals and measuring instrument checking timetable. Internal auditors should include points that refer directly to measuring instruments. Below there is a description of a way an audit should be performed and where proof from an audit of a measuring instrument should be searched for.

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 of 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 at a workstation,

- 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 instances of places where records from audit may be looked for, but basing on these examples, an organization can determine its own sources of audit information.

When discussing measuring equipment in industrial area, than similarly to 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 (point 7.6 of norm ISO 9001) as well as continuous monitoring of instrument operation.