VŠB - TECHNICAL UNIVERSITY OF OSTRAVA

FACULTY OF METALLURGY AND MATERIALS ENGINEERING

TESTING AND CONFORMITY ASSESSMENT

Study support

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CONTENTS

HOW TO STUDY

You have received educational materials for combined studies of the subject Testing and Conformity Assessment for the 4th semester of Master degree program branch of study Quality Management.

PREREQUISITES

There are no prerequisites required for this course.

OBJECTIVE AND LEARNING OUTCOMES

The aim of the subject is to provide basic knowledge in the field of testing and related areas (accreditation, certification, metrology, standardization) and their common meaning in the process of removing technical barriers to trade within the functioning of the European system of conformity assessment of products and voluntary product certification.

AFTER STUDYING THE SUBJECT, STUDENTS SHOULD BE ABLE TO:

Outputs knowledge:

- *Students acquire a comprehensive overview of the:*

– *the issue of testing, testing laboratories and test methods (including the activities, status and evaluation of testing laboratories and application examples of the various elements of quality management);*

– *the principles and methods applied in the evaluation of products not only within the European Union;*

– *the development process of removing technical trade barriers for the free movement of goods within the common internal market in the integrated Europe.*

- *Students will be able to characterize concepts: testing, standardization, metrology, certification and accreditation, conformity assessment, harmonization etc.*
- *Students will be able to understand the system of voluntary and mandatory product certification within the European Union.*

Outputs skills:

- *Students will understand the structure of technical standards for test methods and manage the creation of a brief test procedure according to the standard*
- *Students will manage to evaluate the basic parameters applied in the assessment of testing laboratories within inter-laboratory tests.*
- *Students are practically acquainted with the activities of real testing laboratories and established quality management system*

IN STUDYING EACH CHAPTER, WE RECOMMEND THE FOLLOWING STEPS:

Read the text of the Lecture and re-focus on the more difficult passages, then do the additional task (in some chapters included in the Questions. More detailed information can be found in the sources listed in the paragraph References. Finally, answer the questions listed in paragraph Questions.

METHODS OF COMMUNICATION WITH TEACHERS:

At the beginning of the semester, the teacher assigns a semestral project on a given topic from the content of the subject and two projects as outputs of the practical exercises. The teacher will check the project within 14 days after its submission and the results will be sent to students by e-mail via IS EDISON.

CONSULTATIONS WILL TAKE PLACE WITH THE SUBJECT GUARANTOR OR THE LECTURER:

- *During the semester, students have the possibility of consultations with the lecturer in the form of electronic correspondence.*
- *Individual consultations are available upon request by email or telephone.*

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STRUCTURE OF CHAPTERS

The study material is divided into seven chapters. Except for the introduction, each chapter is divided into the following sections:

Time to study

Estimate of the time you will need to study the contents of the chapter.

Objective

Setting the basic objective you will get familiarized with while studying this chapter.

Lecture

The study text divided into subchapters and further division of the subchapters.

Summary of concepts

Here you will find a summary of the basic and most important concepts from the content of the chapter.

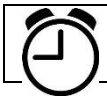
Questions

In most chapters, there are a few questions for your feedback, so that you can check whether you have understood the topic.

References

References to literary or electronic references, which the author used as sources of some information, and which can supplement the issue mentioned in this chapter.

1 INTRODUCTION



Time to study

This chapter is an introduction; it should not take you more than five minutes.

Objective

The objective of the subject „Testing and Conformity Assessment“ is to give you a comprehensive overview of the issue concerning the activities of testing laboratories and functioning of the assessment system for products, with particular emphasis on its application in the European Union and its common European market. This study support should help you acquire better understanding of the aforementioned issues.

Lecture

Examining the properties and composition of raw materials and material inputs, intermediate products in the production and characteristics of developed products have accompanied the production from time immemorial. Obviously, their form, level and intensity differed, as the organization of the production was changing in the course of history with the development of the society, products were becoming more complex and demands on their quality were increasing. With the development of industrial production, responsibility for the realization of various types of tests passed to specialized departments of manufacturing companies, which became the basis for the creation of technological testing laboratories.

Besides that, hand in hand with the development of production, market environment was developing, including efforts to protect or regulate it. The original forms of regulation reflected primarily economic and political interests of representatives of state power of the individual countries. This way to protect their own markets was realized mainly in the form of tariffs, quotas or various prohibitions that complicated or prevented the entry of foreign products on the internal market of the particular country.

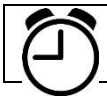
In the course of time, new forms of regulation began to apply that aimed to protect the market from the entry of dangerous or substandard products. This of course not only brought about the need to establish entities that would perform testing of the products in terms of compliance with specified requirements, but also to create a system that would ensure regulatory activities. At various levels, these regulatory systems developed initially within the countries with scope of authority within that particular country, in order to protect its internal market. With the deepening international cooperation, systems that operate on a larger geographical area, based on economics and economic integration in a certain region, were created. From our perspective, this space is naturally the European Union and its common internal market, including the countries of the European Free Trade Association (EFTA).

With regard to advancing globalization, global international cooperation plays an increasingly important role, especially in unifying the requirements for regulation and its application to remove barriers to trade, gradually and on a global level. This cooperation is reflected, for example in:

- creation of uniform rules (in the form of internationally agreed standards) applied in the area of evaluation of products,
- the existence of international organizations with a global sphere of authority, which shall assess the eligibility of bodies operating in this field, etc.

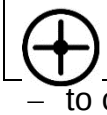
The objective of the subject “Testing and Conformity Assessment” is to give you a comprehensive overview of the issue of activities of testing laboratories and functioning of the product assessment system, with particular emphasis on its application within the European Union and its common European market. This study support should help you acquire better understanding of the aforementioned issues.

2 TESTING



Time to study

Studying the chapter will take you 1-2 hours



Objective

- to characterize the concept of testing and its development in Europe;
- to explain the basic concepts such as testing, testing laboratory, method, principle and procedure;
- to clarify the importance of validation of test methods and related concepts of traceabilty and uncertainty of a method.

Lecture

2.1 THE CONCEPT OF TESTING

It is somewhat difficult to define the concept “Testing” as in fact, this is not a scientific or technical discipline with clearly defined boundaries. On the contrary, this concept covers a wide range of activities pertaining to various technical fields, which are performed by different entities.

In this context, testing can be characterized as a set of interdependent and complementary activities and services performed by qualified and authorized entities, which constitute the basis for the cooperation needed in securing complex procedures, intended for evaluation, testing and inspection of raw materials, materials, components, or finished products. So, in accordance with these characteristics, this complex of procedures is used to ensure the specific process of conformity assessment of products.

The basis of testing, just in relation to conformity assessment of products, is primarily performing tests, i.e. the activities of testing laboratories related to the realization of

tests. In addition, it is necessary to mention other prerequisite or follow-up activities, without which the entire complex could not function successfully. These include:

- accreditation (verification of eligibility),
- certification (certification of compliance of systems, people and products),
- introducing and maintaining management systems,
- calibration and other metrological services,
- these activities are realized within the legislatively defined framework and in accordance with generally recognized or mandatory standards.

2.2 THE DEVELOPMENT OF EUROPEAN TESTING

Properly functioning testing is needed especially for the business sector, both in terms of optimization of production and production costs, as well as an objective base for supporting and documenting the safety and quality of manufactured products. The overwhelming majority of developed countries therefore supports independent testing. Since the beginning of the creation of the European economic area, much attention has also been paid to it within the member countries of the EEC, or now on the part of the governing bodies of the EU and its legislation.

2.2.1 EOTC

It is difficult to simply characterize testing as a discipline, and similarly, it is not possible to cover it with a systematic organizational structure, considering its very broad scope and effect. In the past, there were various organizations, associations or other groups on a national level that deal with and promoted the interests of partial areas of testing. Thanks to the deepening European integration, organizations of regional (European) character have been established as well. The change occurred in the late 1980s, when it effort to create a unifying platform for European testing became evident. On 25 April 1990, this resulted in the establishment of the European Organization for Testing and Certification (EOTC), involving various European organizations divided into the following five groups (sectors):

- Calibration,
- Testing,
- Certification,
- Quality Assurance,

– Inspection.

2.2.2 Distribution of competencies - management and assessment area

Relatively soon EOTC underwent some changes. In 1994, the organizations Western European Calibration Cooperation (WECC) and Western European Laboratory Accreditation Cooperation (WELAC) merged and became the organisation called the European Cooperation for Accreditation of Laboratories (EAL), devoted to the issue of accreditation of laboratories. Meanwhile, in 1991, with the assistance of CENCER, the organisation called the European Cooperation for Accreditation of Certification and Inspection Bodies (EAC) was founded, similarly engaged in the accreditation of certification and inspection people. After several years, organizations dealing with accreditation broke away from EOTC; later, in 2000, they merged into the European Cooperation for Accreditation (EA), representing the so-called “assessment area” of testing. In contrast, methodically control activity towards testing laboratories has been ensured by organizations EUROLAB and EURACHEM, and similarly, towards calibration laboratories, it was EUROMET organization. All three institutions, collectively referred to as EEE, represented the so-called “management area”. In late 1990s, two mutually separate areas of testing were formed, represented by several organizations; although they operated separately, they closely cooperated. These two areas of competence are also characteristic for contemporary European Testing.

2.3 TESTING AND TESTING LABORATORIES

Testing in the context of ISO 17000 standard is intended for identifying one or more characteristics of the object of conformity assessment, which is carried out according to the specified procedure of an activity or process. During testing, test method developed into test procedures are applied. The test result is presented in the form of the test report.

We usually mean testing in relation to conformity assessment of the finished product. In this case, it is verification that the product meets the properties known in advance and expected for the product. In addition, the term testing is also used in the case where unknown characteristics are found by measuring, namely in the identification and evaluation of properties of raw materials or materials. In both cases, it is a highly

professional activity carried out in test laboratories. These are conformity assessment bodies with special technical equipment and staff, which may be organizations or their sections.

2.3.1 Types of testing laboratories and their status

There are a number of testing laboratories that differ in their position, purpose, scope of tests, ranking, etc. There are also different ways to classify these laboratories. One option is to divide them into three groups as follows:

- technological testing laboratories,
- testing laboratories involved in the process of placing a product on the market,
- testing laboratories working outside the business area,

In the first case, testing laboratories perform different functions during production. They are part of the management and inspection elements of the production processes, and because they are part of the manufacturing organization, they do not fulfil the function of impartial and independent body. When assessing the conformity, these laboratories act as entities of the first party, the producer. If, however, those laboratories are accredited, in some cases, they might also participate in the process of placement of products on the market, thus fulfilling the function of the laboratories from the second group.

Testing laboratories in the second group are independent bodies with competence certificated by accreditation in accordance with the standard ISO 17025, which act in conformity assessment as typical entities of a third party. Certification bodies in certification of products, or authorized or notified entities in assessing conformity of products in the regulated sphere rely upon the activities of these testing laboratories.

Finally, the third group includes testing laboratories, operating outside the scope of activities of the first two groups. They include special testing laboratories at research institutions and universities, within the framework of supervisory organizations, but also small private testing laboratories performing specialized measurements in various areas. Even for these laboratories, it is typical to have their competence and objectivity confirmed by an accreditation.

2.3.2 Assessment of competence and performance of testing laboratories

The quality of testing laboratories can be assessed in different ways. Today, the most commonly used and almost universally recognized standard for confirming their competence is accreditation. It is a universal method of evaluation, based on an assessment of compliance with the requirements specified in ISO 17025 standard.

This option is used mainly in the case of laboratories from the second and third groups, for technological testing laboratories of the producer, it is less frequent. This is because producers use the services of these laboratories themselves within their organization, so they do not need to prove their competence to anyone. The only exception is a situation where direct participation of the accredited testing laboratory of the manufacturer is allowed in the specified conformity assessment procedures.

The requirements specified in the standard can be generally divided into two groups. This corresponds with the fact that the overall quality of testing laboratories is generally evaluated from two aspects:

- by the level of systemic provisions of quality assurance testing activities;
- by the level of technical competence in providing the required services.

This approach to evaluation is a comprehensive assessment of the quality management system (QMS) in the laboratory.

At the level of system requirements, testing laboratories are required to have:

- a clear organizational structure with clear definition of its legal status and specified scope of activity,
- accountable management with clearly defined reporting relationships and specified responsibilities and competencies of staff,
- established policy and quality objectives,
- prepared documentation of its QMS and specified functional procedures of its assessment.

From the standpoint of securing technical competence, a testing laboratory is primarily required to have:

- sufficient technical equipment matching the performed tests,
- qualified and periodically trained test staff,
- developed test procedures, including methods of their quality assurance,

– adequately ensured compliance with the metrology requirements.

Accreditation of testing laboratories is not the only possible assessment of testing laboratories. The opposite alternative, applied in the case of some technological laboratories, may be the lack of any evaluation, if it is not considered necessary by the manufacturer. In the case of technological testing laboratories, there is a relatively frequent option of their evaluation in the form of QMS certification established by the parent organization (i.e. the manufacturer). Another widely recognized way of assessing testing laboratories also used by some technological testing laboratories is verifying the performance of laboratories in proficiency testing programs, or obtaining confirmation of compliance with the criteria of successful participation.

2.3.3 The proficiency testing schemes as a tool of evaluating laboratories

Proficiency Testing Programs (Proficiency Testing - PT) are one of the form of interlaboratory comparison tests (ILCs), i.e. a peer comparison testing method, implemented at different test laboratories (the possible effects of different methods on different test results). The objectivity of such a program is guaranteed by organizers accredited as providers of proficiency testing in accordance with ISO 17043 requirements.

Participation in the ILCs programs is fully supported by accreditation bodies and successful participation in such programs is required and assessed in connection with accreditation of the laboratory. This is due to the fact that ILCs programs represent fairly objective evaluation of laboratories in view of performing certain tests in the required quality.

Proficiency testing schemes are realized in the following way: the organizer provides the registered testing laboratories with identical test samples; the laboratories measure them and submit the measurement results to the organizer, which evaluates them and compares them with predetermined criteria. The organizer then informs the individual laboratories on the evaluation, and thus on compliance or non-compliance of the criteria. The form of evaluation may be different, today; an electronic version of comments and certificates is increasingly favoured. In any case, anonymity of the participants is ensured by identifying them by codes.

2.4 TEST METHODS

Testing, or conducting tests, is practical identification of properties (characteristics) of the concerned subject by conformity assessment. In principle, it is the case of the determination of characteristic qualitative features or quantitative measurement of the subject quantities, wherein a number of different test methods elaborated into test procedures are applied. The test result is then presented in the form of the test report.

2.4.1 The principle, method, procedure

The manner, in which a particular test is performed, is called the test method. Each method is derived from a certain principle, i.e. is the sum of phenomena (physical, chemical), on which measurement is based. Selection of a particular test method for measuring a specific case depends on the type and nature of the measured quantity and on what gauge will be used. Selecting the gauge is influenced, e.g. by the working range and the values of the measured quantity, its design corresponds to the selected measuring principle. Concrete realization of the test method is described by the testing procedure that must be documented in sufficient detail to allow service staff to perform the test repeatedly and reproducibly.

In accordance with the International Vocabulary of Metrology , the following characteristics of test methods and procedures can be used:

- the method means a general description of the logical sequence of individual activities, used for the measurement;
- the procedure means a detailed description of the realization of measurement according to one or more measurement principles and the measurement method, it is based on a measurement model and includes methods of calculation required to obtain the measurement result.

2.4.2 Types of test methods

In practice, testing laboratories have a wide variety of methods used in conducting tests at their disposal. In general, we can differentiate the methods according to several aspects, such as:

- according to the nature of the measured quantity – e.g. chemical or physical;

- according to the way of detecting the measured quantity – e.g. direct and indirect, or absolute and relative.

While in direct methods, measuring the value of the concerned quantity is based on the definition of the measured quantity, in the case of indirect methods, the value of the concerned quantity is determined by calculation, using the conversion nomograms, graphs or tables from directly measured values of other quantities. In absolute method, the exact value of the measured quantity is determined in appropriate units, while in the relative method, only a change in the measured quantity compared to the selected reference value is determined.

Test methods used are different depending on the industrial sector, which includes a specific product and its production. Methods used in metallurgy differ from those applied in the construction industry, textile, or chemical industries. Specifically, for example, in metallurgy, we can differentiate between test methods:

- for chemical or physico-chemical properties,
- for the basic mechanical properties of metals,
- metallographic,
- non-destructive,
- for special properties.

For most test methods with regard to their repeated and general use and importance, there are standards that specify the particular procedure or its alternatives for conducting tests. Using methods for which there are no standards may rely on its own procedures, which must be, however, sufficiently validated. Standardized methods are validated and thus only authentication (verification) has to be performed during their acceptance and introducing in the testing laboratory practice.

2.4.3 Validation of methods

Millions of measurements are carried out daily in thousands of testing laboratories, which often play a crucial role in assessing the conformity of products. The costs of these measurements are high and other costs are related to decisions made based on these measurements. The testing laboratory and its personnel thus bear full responsibility for providing a correct measurement result, which is suitable for its

intended use. Standard ISO 17025 explicitly says that the laboratory has to use appropriate methods and procedures for all tests within its scope of activities.

Confirmation of the suitability of a test method for a specific application is done via method validation. Validation means confirmation by examination and provision of objective evidence that the requirements for a specific intended use are met. Validation is the process that is used for:

- confirmation of performance characteristics and limitations of the given method;
- identification of the conditions that could affect or change these characteristics, and to which extent;
- specification of the quantities that may be determined by the given method, in which matrixes and in the presence of which interfering components;
- determining the level of precision and accuracy of the method achievable under specified conditions.

Besides the accuracy and accuracy, one of the basic performance characteristics of the method is also its sensitivity, linearity and yield rate. Equally important characteristics of the method are also its traceability and extent of uncertainty.

2.4.4 Traceability of the method and its calibration

Traceable means any uninterrupted transfer sequence of the value of the measured quantity beginning with the standard of the highest metrological quality available for the given purpose of the measurement. This is realized by means of a chain of consecutive comparisons of this standard with lower quality standard, in which event the values of uncertainties of these comparisons are known.

This gradual transfer of the quantity value is necessary, because in practice it is not reasonably practicable to establish a direct measuring system used in the test method at the standard for the highest quality. In fact, it would assumed that all laboratories have such standards or certified reference materials (CRM) at their disposal, or they have access to them, and they have implemented and applied the relevant reference methods for transferring their values to their meters. For more details, see chapter 5.4.

Set of operations which, under specified conditions, establish the relationship between the value of the quantity realized by the standard and the value indicated by the measuring device, is referred to as calibration.

2.4.5 Uncertainty of the method

According to the definition of uncertainty in the International Vocabulry of Metrology , the measurement uncertainty is a "non-negative parameter characterizing the dispersion of the quantity values assigned to the measured quantity on the basis of information used." Apparently, the definition stated in the Guide to the Expression of Uncertainty in Measurement (GUM) is somewhat clearer. According to it, uncertainty is "a parameter associated with the result of a measurement that characterizes the degree of dispersion of the values which can be reasonably attributed to the measured quantity." In other words, uncertainty is an interval defined around the identified measurement result, in which the true value is found with the specified probability rate (typically 95 %). The method with a smaller measurement uncertainty can be considered a superior method.

Uncertainty is an integral part of each test method and its range can be evaluated by mathematical estimate of all the possible sources and covariance of their contributions. The estimation of the testing method uncertainty is an integral part of its validation. It is necessary to take into account all potential sources that influence the resulting uncertainty and evaluate their partial contributions (uncertainty components). Given the uncertainty by definition represents the degree of dispersion characterized by the standard deviation, the influence of each component is converted to its contribution to the resulting standard deviation. In the case of the component x, it is then referred to as **u(x)** and it is called the standard uncertainty of component x.

According to the procedure used to evaluate the contribution of the component, and therefore, to quantify its standard uncertainty, the components are classified in the following way:

- Type A – they are obtained on the basis of the statistical distribution of the results of a series of repeated measurements and expressed as a standard deviation of their average;

– Type B – their source is predictable systematic effects, which are calculated using the probability functions based on experience or other information (declarations), when for the given component, certain probability distribution of deviations around its value is assumed.

Typical sources of uncertainties of type B in a testing laboratory are, for example, environmental conditions and their impacts, accuracy class of the devices used or some of the declarative facts (the size of the force, dimensions of the components of test equipment).

Contributions of the individual partial standard uncertainties are then merged into the so-called combined uncertainty $\mathbf{u_c}$, which is then, to take into account the required degree of probability, multiplied (expanded) by expansion coefficient **k**. For the probability of 95%, it has the value 1.96 (after rounding, value 2). By this expansion, the combined uncertainty is converted to expanded combined uncertainty $\mathbf{U_c}$.

Uncertainty is stated in units of measurement, or in percentage as a relative uncertainty depending on how standard uncertainty of the individual components is expressed. The result of the measured quantity is then usually reported as y ± U it being understood that the stated uncertainty is calculated using the expansion coefficient k.

Summary of concepts

Based on the study of this chapter you have become familiar with the importance of testing and its relationship to the issue of conformity assessment. The basic related concepts were explained (testing, testing laboratory, competence assessment, test method, traceability of the method and measurement uncertainty).

Questions

1. Characterize the concept of “testing” and specify what constitutes its components.
2. What is EOTC and what is its significance?
3. What are the three basic types of testing laboratories?

4. How can the concept of “Testing” be defined?
5. Explain what is traceability and measurement uncertainty.

Additional tasks:

1. Familiarize yourself with the structure and content of the standard ISO 17025
2. Examine a standard for any test method

References

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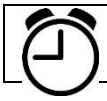
3 ACCREDITATION



Time to study

Study of this chapter will take 1-2 hours

Objective

- characterize the concept of accreditation, its importance and development;
- explain the nature and means of international cooperation in accreditation;
- explain the importance of the European accreditation system and the role of EA.

Lecture

3.1 ACCREDITATION

To make the conformity assessment constitute a highly most reliable system, it has to be carried out by authorized and adequately competent entities. Today, accreditation is considered the highest level of public inspection of the proper functioning of these entities. So that its value and credibility were not questioned, accreditation is carried out on a non-commercial basis, as the public administration service guaranteed by the state. During its application, accreditation has become a generally accepted manner, confirming that the various conformity assessment entities are sufficiently credible, impartial and independent in their decisions, and that the results of their activities can be considered reliable.

Generally, the term “accreditation” refers to official recognition that a subject of accreditation is competent to carry out specific activities. In relation to the issue of conformity assessment, the standard ISO 17000 specifies the concept of accreditation in more detail as “A*ttestation issued by a third-party related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific tasks in the field of conformity assessment”*.

A third party, i.e. the entity that carries out accreditation and recognizes the competence of the accredited body is a so-called accreditation body. There could be

numerous accreditation subjects, i.e. conformity assessment bodies, e.g. testing and calibration laboratories, certification bodies, inspection bodies, proficiency testing providers; specific tasks include testing, calibration, certification, inspection, organization of ILCs programs, etc.

Today, accreditation also applies in other areas, which are not directly related to the issues of conformity assessment, but an independent assessment of the ability of entities is also required there.

3.2 IMPORTANCE AND BENEFITS OF ACCREDITATION

If the above-mentioned basic principles of accreditation activities are complied with, the greatest benefits of accreditation can be seen in the following areas:

- accreditation primarily means increasing confidence in compliance with the required quality level of services provided by accredited bodies;
- regular supervision of the observance of accreditation criteria carried out by the accreditation body leads to the development of quality management systems with accredited entities;
- there is significant pressure to constantly improve the quality of services provided by accredited bodies, to increase the skills of their staff and to improve technical equipment of these entities;
- accreditation brings a positive economic effect, both in terms of accredited bodies and their customers, as well as from the perspective of the public interest;
- where the participation of an accredited body is not clearly stipulated, services provided by accredited and non-accredited bodies are distinguished.

3.3 THE DEVELOPMENT OF ACCREDITATION IN RELATION TO CONFORMITY ASSESSMENT

Up to now, the history of accreditation has undergone several basic stages:

- During the forties and fifties of the twentieth century, some countries created their own accreditation systems that reflected the internal needs of the state. These systems were used as a means for assessing the selected bodies operating within the state in the field of conformity assessment. Initially, it was mainly the case of testing laboratories as a means of protection of national interests. The

important role, however, was also played by the fact that there was a gradual and further development of laboratories thanks to increasing the quality of services (implementation of adequate quality control systems).

- In the sixties and seventies, accreditation was used mainly in the area of calibration laboratories, which thus became a credible means for providing measurement traceability to national and international standards and other standards of measurement, which is an indispensable foundation for the operation of testing laboratories.
- In the eighties, there was a need for the application of the GATT (General Agreement on Tariffs and Trade), which aimed to reduce technical barriers to international trade. In particular, it was the case of the practical use of accreditation as a prerequisite for obtaining an international recognition of the results of laboratories, certification bodies and inspection bodies through a system of mutual recognition agreements between national accreditation systems.

The current accreditation systems have been established based on these developments. They now provide the possibility to confirm the competence of entities operating in the field of conformity assessment, namely by an independent third party (accreditation body). These entities thus receive official recognition that their activities are in accordance with internationally established general requirements and criteria, and they therefore able to provide its customers with the required services. Currently, almost all developed but also developing countries have national accreditation bodies, which represent the core of national accreditation systems.

3.4 INTERNATIONAL COOPERATION IN ACCREDITATION

The accreditation was primarily created and still remains organized at the national level and relies on the existence of national accreditation systems. In certain geographical or geopolitical areas, however, cooperation of the national systems and their links within the regional accreditation systems was also gradually deepening. From our perspective, obviously the most important system is the European one. At present, it expresses the interests of the European Union in the field of accreditation, and it is supported by European legislation. An important role in it is played by

European cooperation for Accreditation (EA). Similarly, in other geographic areas of the world, there are organizations ensuring cooperation of accreditation bodies in the region. Their status and tasks provided may be different from region to region.

With the growing need for the mutual recognition of accreditation and with it also the related requirement to harmonize procedures for accreditation bodies worldwide, it began to be necessary to ensure cooperation on a global level. Formally, today this cooperation in the area of accreditation is provided by the existence of two organizations with a global sphere of activities: International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF).

Within the management of the international accreditation organizations, whether at the global level (ILAC and IAF) or European (EA), multilateral agreements (or conventions) on mutual recognition of results of accreditation have been signed. The signatories to these agreements are member accreditation bodies or their regional associations. The result of the agreements is that each of the signatories recognizes the work of other national accreditation bodies as equivalent, and therefore considers the accreditation of the subjects within the given area of accreditation for which the agreement is concluded, as such, as if it carried out itself. Based on the mutual recognition of equivalence, the prerequisite is also created for universal use (i.e. the acceptance and recognition) of protocols and certificates issued by accreditation bodies (laboratories, certification bodies, inspection bodies, etc.). The most important multilateral agreements on mutual recognition of accreditation results are:

- **EA Multilateral agreements** in testing, calibration, certification (of products, QMS, EMS or persons), inspection and verification;
- **IAF Multilateral agreements** in QMS, EMS and product certifications;
- **ILAC Mutual recognition arrangements** in testing, calibration and inspection.

EA MLA is an European agreement through which the signatories mutually recognize granted accreditations and protocols, reports and certificates issued by entities accredited by the signatories. This agreement has covered various areas and has introduced a transparent system of regular peer evaluations. The current list of signatories to the EA MLA is available on the EA website.

ILAC MRA, or IAF MLA provides confidence in accreditation bodies and their ability to decide on the eligibility of laboratories to perform testing and calibration and

inspection bodies to carry out inspections, or eligibility of certification bodies to perform certification.

The existence of regional and global international agreements on mutual recognition of results of accreditation is also supported and welcomed by the World Trade Organization, which sees in them an important element leading to the removal of technical barriers in international trade. The Czech Republic, which is also a signatory to the agreement TBT - Agreement on Technical Barriers to Trade, is WTO member as well.

3.5 PRINCIPLES OF THE EUROPEAN ACCREDITATION SYSTEM

Conformity assessment system introduced in the EU makes full use of accreditation as a widely recognized tool used to demonstrate the competence and impartiality of conformity assessment bodies. The significance of accreditation and the need for a coherent European accreditation system were already emphasized in Council Resolution 90/C10/01 on a global approach to conformity assessment, which was adopted on 21 December 1989. Not only in relation to accreditation, the resolution stated that:

- no European supranational system will be established, but the national systems of accreditation, certification, inspection, testing, calibration, etc. will be recognized;
- accreditation bodies, certification bodies, inspection bodies and testing and calibration laboratories shall be governed by the provisions of international standards concerning accreditation;
- quality management systems introduced by the conformity assessment bodies must meet the requirements of ISO 9000 standards;
- The basis of uniform rules for accreditation required for the provision of compliance certificate are international standards and normative documents concerning accreditation, however, with regard to their generality, each national accreditation body can interpret the wording of its individual provisions, and interpretative materials of foreign organizations may also be used (ILAC, IAF, EA).

It was not until the adoption of the so-called New Legislative Frame (NLF) in July 2008 (the date of the application in January 2010) that in the European Union a comprehensive legal framework binding on all EU Member States was established for accreditation. From the legislation, which forms the NLF, the European Parliament and Council Regulation (EC) no. 765/2008 had the greatest significance for the position of accreditation within the European Accreditation System; this regulation lays down the requirements for accreditation and market surveillance relating to launching of products in the market. In this regulation, accreditation is defined as the activity of the national accreditation body attesting that the conformity assessment body meets the requirements for carrying out specific conformity assessment activities, set by harmonized standards and, where applicable, any additional requirements including those set out in relevant sectoral regulations.

In accordance with the above-mentioned regulation, it applies that:

- in connection with the conformity assessment, accreditation may be implemented on a mandatory or voluntary basis;
- in each Member State, the sole national accreditation body is appointed;
- these authorities act on a non-profit basis and in the exercise of their activities they act as public authorities of the State;
- each Member State must ensure that its national accreditation body has properly adequate financial and human resources to perform its tasks;
- a national accreditation body does not compete with other conformity assessment bodies or other national accreditation bodies of other countries;
- a national accreditation body must not offer and provide any activities and services that belong to notified bodies and no counselling;
- under specified conditions, cross-border accreditation is possible;
- Member States regularly check their national accreditation bodies to ensure that they consistently meet the demands placed on them;
- accreditation is carried out according to international standards;
- within international groups of accreditation bodies, agreements on mutual recognition of accreditation exist.

3.6 EA - EUROPEAN ACCREDITATION

Accreditation in Europe always relied on the national accreditation bodies of individual countries. However, the level of accreditation activities in different European countries sometimes quite significantly varied. For the successful development of the European system, it was needed to gradually harmonize the rules under which accreditation was carried out in different countries, and to unify the position of individual accreditation bodies in these countries.

From this perspective, an important role was played by the organization European cooperation for accreditation (abbreviated the European Accreditation – EA). The European Accreditation was formed in 2000 by merging two of the then European accreditation organizations – EAL (European cooperation for Accreditation of Laboratories) and EAC (European Accreditation of Certification). The main purpose of the EA is particularly:

- supporting the existence of a transparent and quality-focused system to evaluate the competence of conformity assessment bodies throughout Europe;
- facilitating the mutual recognition of accreditation certificates;
- promoting the general acceptance of conformity assessment results issued by accredited bodies.
- in order to ensure an equivalent level of competence of conformity assessment bodies, it is necessary that national accreditation bodies operate a rigorous and transparent peer evaluation system and regularly undergo such evaluation. That is why EA was also responsible for the evaluation of national accreditation bodies, which were among its members.
- the status of EA as a “supranational” body operating within the European accreditation system was also enshrined in the said Regulation of the European Parliament and Council Regulation (EC) No. 765/2008. Among others, it is directly specified there that within the EU:
- the individual national accreditation bodies are members of the body recognized by the Commission, which meets the requirements set out in the Annex to the Regulation;
- on the basis of an agreement with the Commission, this body is the European cooperation for accreditation (EA - European Accreditation);

- national accreditation bodies shall subject themselves to peer evaluation organized by EA.
- this regulation has been recognized by EA as a single organization, fulfilling certain functions in the European Accreditation System. Legally, it has been granted the role of the accreditation coordinator in the EU Member States, which maintains the prestige and credibility of the European accreditation system also by playing the role of the organizer of evaluation of individual national accreditation bodies.

Summary of concepts

Based on the study of this chapter you are familiar with the role of accreditation and its importance for ensuring credibility of conformity assessment processes. The chapter outlined the development of accreditation to the current state and emphasized the need for the forms of international cooperation in this field. It also clarified organization of the European accreditation system and its functioning in the context of the current European legislation.

Questions

1. Characterize the term “accreditation”.
2. What is the significance of accreditation?
3. What are multilateral agreements in the field of accreditation and what is their significance for conformity assessment processes?
4. Which conformity assessment bodies does accreditation concern?
5. What is EA, and what is its significance in the European Accreditation System?
6. What are the basic principles of the European accreditation system and how are they regulated?

Additional task:

1. Familiarize yourself with the text of the European Parliament and Council Regulation (EC) No. 765/2008 (available e.g. at http://www.eur-lex.europa.eu).

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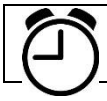
4 CERTIFICATION



Time to study

Study of this chapter will take 1.5 hours

Objective

- characterize the concept of certification and its importance for the assessment of conformity;
- specify the basic types of certification implemented in conformity assessment (certification of personnel, management systems and products);
- explain the difference between mandatory and voluntary product certification.

Lecture

4.1 CERTIFICATION

According to the definition stated in ISO 17000, certification is a certificate issued by a third party relating to products, systems or persons. To explain this brief definition, we can be characterize certification as a procedure by which a third party – certification body – provides confirmation that during the examination of the corresponding object of conformity assessment (product, system, person), it showed its compliance with specified requirements.

This definition of the concept of certification therefore implies the need for the existence of:

- a third party, i.e. a competent certification body (the first party is considered to be the supplier and the second party the customer);
- specified requirements, e.g. precise needs or expectations, which are to be assessed, which are stated either in legally binding regulations (laws and various technical regulations), or in generally accepted, however, legally binding form (standards, procedures, certification schemes etc.);

– confirmation, i.e. the statement attesting conformity, which is usually issued in the form of a written document – a certificate.

Certification is applicable in relation to all objects of conformity assessment except for conformity assessment bodies themselves, which, as was stated in the previous chapter, are accredited.

4.1.1 Certification System

The activities to be performed during the certification cannot be ensured without rules, procedures and without the cooperation and linkages to other institutions and organizations. Thus conceived, the complex is referred to as a certification system in which uniform rules for management and procedures for certification of compliance are applied both in the case of certification tied to legislative documents governing its compulsory form, as well as in the area operating on a voluntary basis. Such a certification system can exist, for example:

– at the national level, it is implemented in one single country;
– at the regional level, if involvement of the competent authorities of the countries from only one geographical, political or economic area of the world is possible;
– at the international level, if involvement of the competent authorities of all countries is possible,

4.2 MANAGEMENT SSTEM CERTIFICATION

While different forms of control systems are increasingly becoming an indispensable tool of modern organization management, their certification is becoming a strategy of managing these organizations. The aim of the certification is assure various parties outside the organization that the management system applied in the organization meets the specific requirements specified in the system standards or specifications. In the case of this type of certification, we distinguish between the following certification of systems, in which their compliance with the requirements of the relevant standards is assessed:

– Quality Management System (QMS) as per ISO 9001;
– Environmental Management System (EMS) as per ISO 14001;

- Occupational Health and Safety Management System (OHSMS) as per OHSAS 18001;
- Energy Management System as per ISO 50001;
- Information Security Management System (ISMS) as per ISO/IEC 27001;
- Food Safety Management System as per ISO 22000;
- The Quality Management System in the automotive industry according as per ISO/TS 16949;
- Production Quality Management System IVD as per ISO 13485;
- Business Continuity Management System (BCMS) as per ISO 22301.

Overview of numbers of management system certificates issued in 2014 (and compared to 2013), presented by ISO organization, is shown in the following table:

Standard	number of certificates in 2014	number of certificates in 2013	evolution	evolution in %
ISO 9001	1 138 155	1 126 460	11 695	1 %
ISO 14001	324 148	301 622	22 526	7 %
ISO 50001	6 778	4 826	1 952	40 %
ISO/IEC 27001	23 972	22 349	1 623	7 %
ISO 22000	30 500	26 847	3 653	14 %
ISO/TS 16949	57 950	53 723	4 227	8 %
ISO 13485	27 791	25 655	2 136	8 %
ISO 22301	1 757			
TOTAL	**1 609 294**	**1 561 482**	**47 812**	**3 %**

The certification system with the longest tradition is the Quality Management System certification. QMS certification by an accredited certification body provides a guarantee that the organization that has been granted this certificate has implemented an effective quality management system in accordance with the requirements laid down in the prescribed standard. This allows it to provide products or services that not only meet the customers' needs and expectations, but also comply with applicable legal requirements. The certified management system can be regarded as one of the bases for continuous improvement. Currently, it is not only a competitive advantage, but it becomes one of the basic requirements for closing a business contract. In addition, the company has the benefit of regular impartial assessment, results of which objectively point to potential risks and vulnerabilities.

Certification of management systems is performed by certification bodies meeting the requirements of ISO/IEC 17021. Their competence in the context of meeting the requirements of this standard is verified by means of accreditation.

4.2.1 Certification of management systems internationally

QMS certification as the first of the certified management system undoubtedly has the longest tradition in Europe. In 1989, the EC Council adopted a resolution on a global approach to conformity assessment (90/C10/01) and one of the stated objectives was also evidence of the mutual recognition of conformity assessment. In this context, representatives of 18 countries of the EC and EFTA signed an agreement to create a European Committee for Quality Systems and Certification (EQS). Its primary objective was to promote:

- elimination of multiple QMS certification;
- developing confidence in the certification carried out by the competent authorities;
- harmonizing the rules for QMS certification according to relevant standards;
- joint activities of certification bodies and other initiatives for achieving mutual recognition of certificates.

Following this, eight major European certification organizations signed an agreement to create the European Network for Quality System Assessment and Certification (EQNet). Its aim was to provide organizations in the countries of the EC and EFTA comprehensive services aimed at facilitating the acquisition of QMS certificates and their mutual recognition.

In 1990, an association of IQNet was established as an international network of leading certification bodies for certification of management systems. Today, this association involves partner certification organizations from more than 35 countries around the world. Association members providing their services and assessment of management systems worldwide have issued about 350,000 certificates so far. IQNet is also involved in a number of international institutions focused on the issue of certification systems, e.g. IAF, EA, ISO/CASCO, etc.

IQNet members are signatories to the multilateral agreement IQNet MLA, ensuring mutual equivalence of certificates issued by them and their recognition by various

organizations worldwide. Among other things, the agreement makes it possible, if necessary, for any organization certified by the IQNet-partner certification authority to obtain a certificate recognized by countries of other IQNet-partners.

4.3 CERTIFICATION OF PERSONNEL

Certification of persons can be defined as an independent assessment, or evaluation of the proficiency of workers to hold a certain function in various control systems (quality, environment, occupational health and safety, etc.), or in the realization of products. Professional competence is perceived as personal ability of the evaluated worker to apply theoretical knowledge, practical experience and skills. Independence and objectivity of assessment is guaranteed mainly by the fact that the certification of persons is essentially performed by institutions which do not organize educational programs themselves, they are financially and organizationally independent on organizations where applicants for personnel certification work, and they are generally recognized for certification of people in the form of accreditation. Due to the nature of the certification process with special emphasis on independence, objectivity, depth of verification, and the ability to solve practical problems, certification of persons plays a significant role in human resource management.

In the various functions within the management systems (especially Quality Management System), certification conducted by the European Organisation for Quality (EOQ) already has had more than 20 years' tradition. As early as in 1994, it created the first so-called "Harmonized scheme for the registration and certification of personnel" (hereinafter referred to as the Scheme) in the field of quality management. This was a manifestation of the fulfilment of the part of mission EOQ that concerned strengthening European economic system by increasing the qualification of staff working in the field of quality management. Today, this Scheme was extended to define the requirements and certification procedures for other functions in the control systems of organizations, including EMS, OHSMS, etc.

Certification of persons is performed by certification bodies complying with the requirements of ISO/IEC 17024. Their competence in the context of meeting the requirements of this standard is verified by means of accreditation (in the Czech

Republic by the Czech Accreditation Institute - ČIA). At the same time, there is the possibility of extending the eligibility of the accredited certification body by the EOQ.

4.4 PRODUCT CERTIFICATION

Generally, the concept of product certification means to assess its compliance with any requirements that relate to it (either with the requirements specified by a generally binding regulation or market environment and knowledge of science and technology). The outcome of this assessment is a certificate, i.e. a declaration that the product meets specified requirements. Certification may only be performed and a certificate can only be issued by a certification authority that is authorized for this activity based on authorization or accreditation. In some cases, the issuance of a certificate is linked to the obligation to furnish the product with a mandatory certification mark, in some cases, with the granting of a license, to use other specific certification mark.

The need for assessment can be given by law or other generally binding legal regulation, or the customer requires it, or it is a response to market demands, which aims to exploit commercial benefits of certification to obtain a certain advantage over the competition. In each case, it leads to increased cost of the product.

Therefore, product certification so it can be divided into “compulsory certification”, which results from the obligation to comply with generally binding legislation, and “voluntary certification”, i.e. commercial.

4.4.1 Compulsory certification

Compulsory certification means certification of the conformity of products (in particular its safety properties) through an independent third party that is accredited for this certification and subsequently authorized, or notified. A certificate as an outcome of this certification then indicates that the product complies with all legal requirements that apply to it. This is compulsory certification, which of course implies that such all products entering the market regulated by these legal requirements have to be furnished with such a certificate.

Compulsory conformity assessment concerns so-called specified products, which are products determined by a generally binding legal regulation and the related

implementing regulations. In essence, this means that the specific basic requirements are specified for them, which the concerned products have to comply with; in addition, it is also determined whether the verification of these basic requirements must be performed by a third party, or whether it may be performed by the first party (the producer itself, or an entity designated by the producer), and also a form of certification of these requirements (issuing a certificate/without a certificate) is specified.

In the chapter Conformity Assessment further attention is focused on the development and current state of the European system of compulsory product certification.

4.4.2 Voluntary certification

To verify compliance with other requirements not specified by legal regulations, a form of so-called voluntary certification can be used in the case of all products (i.e. specified and not specified). That is again (but this time entirely voluntary) certification of the conformity of products through an independent third party, possibly the first party, which can be accredited to this certification. These properties, the product is supposed to meet, can be specified in standards or other documents, either by the customer or by the producer, for example based on the market demand. These include mainly the properties related to the utility value of the product, or complying with certain requirements of the customer. Even products certified in this regime must meet basic safety requirements that apply to them and that are specified in generally binding regulations.

Voluntary certification in terms of its use is applied almost exclusively for marketing purposes. The producer may choose itself, which properties of its product it wants to promote through a certificate, e.g. based on an analysis of latent demands of the “market”. Marketing effect can be enhanced by selecting a third party to verify the properties of the product selected by the producer and issue a certificate. Most multinational third parties offer lending their logo (brand) to the granted certificate, which, depending on the market value of the particular brand may affect the strengthening of the position of the product on the market.

Summary of concepts

Based on the study of this chapter you are familiar with the role of certification and its importance for ensuring the conformity assessment process. The chapter outlined the development of certification systems in the areas of certification of management systems, people and products together with an indication of some international organizations working in this field. Further, it clarified the role of compulsory and voluntary certification of products in relation to conformity assessment.

Questions

1. What are the basic types of certification applied for conformity assessment purposes?
2. Who is authorized to perform certification?
3. What is the significance of certification of management systems for conformity assessment?
4. Why is certification of staff performed and who is authorized to perform it?
5. Explain the difference between compulsory and voluntary product certification.

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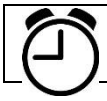
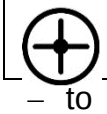
5 METROLOGY



Time to study

Study of the chapter will take 1.5 hours



Objective

- to characterize the role of metrology for the purpose of testing and conformity assessment;
- to specify metrology division into three basic categories;
- to explain the role of international cooperation in metrology and describe the international metrology system.

Lecture

The results from well-conducted testing, which means results that are reliable, comparable and internationally recognized, are essential for the successful functioning of today's global economy. Metrology is the scientific discipline that provides the basis for the comparability of test results, especially by defining the units of measurement and by providing metrological traceability with the declared uncertainty of the measurement results. The condition that prevents test results from creating technical barriers to trade is widely used and strong metrological infrastructure based on international cooperation.

Metrology as a science of measurement performs these three main tasks:

1. Defining internationally accepted units of measurement (for example metre).
2. The realization of units of measurement by scientific methods, such as the realization of a metre using laser beams.
3. The establishment of traceability chains by determining and documenting the value and accuracy of the measurement and transmission of such data, e.g.

the documented relationship between the micrometre screw in a precision engineering workshop and a primary laboratory for optical length metrology.

5.1 CATEGORIES OF METROLOGY

Metrology is divided into three categories with different levels of complexity and accuracy:

1. Scientific (also referred to as fundamental) metrology deals with the organization and development of measurement standards and with their maintenance (the highest level).
2. Industrial metrology has to ensure the adequate functioning of measurement instruments used in industry and in production and testing processes, for ensuring quality of life for citizens and for academic research.
3. Legal metrology is concerned with measurements where the measurement influences the transparency of economic transactions, particularly where there is a requirement for legal verification of meters.

Scientific metrology is the basis of the entire metrology system. It has the character of scientific research and deals with:

- examining quantities, **units of measurement** and their **systems**,
- development, realization, and maintenance of their **standards** of the highest metrological quality,
- a set of physical **constants**,
- research of measurement principles and development of measurement methods.

Legal metrology is an internationally coordinated activity that aims to provide public assurance of safety and appropriate measurement accuracy and thus protect against the consequences of bad measurements. It uses various technical and legal rules for determining the legal units of measurement and legislative requirements for measuring devices, methods of measurement and testing. Organization and performance of legal metrology is an important part of the national metrology systems. It is ensured by organizations responsible for metrology designated by the state (usually the national metrology institutes or institutions).

Industrial (applied) metrology provides uniform and accurate measurements in practice, i.e. at the level of manufacturing companies, testing laboratories, services and other entities. At this level, it realizes:

- measurement traceability
- selecting the proper measurement methods and procedures
- the correct use of appropriate measuring instruments

This category includes metrology activities associated with calibration of standards and working measuring instruments used in general practice.

5.2 INTERNATIONAL PROVINCE OF METROLOGY

5.2.1 The metric convention

In 1875 in Paris, a diplomatic conference on the meter was held, where 17 governments signed the treaty called “the Metre Convention”. The signatories to this agreement had decided to establish and financially secure a permanent expert body – “the International Bureau of Weights and Measures” (BIPM). The convention was signed by the then Austria-Hungary, since 1922, by then Czechoslovakia. In 2008, the Metre Convention had 51 full members and 27 associate members.

Today, the main purpose of the activities of the BIPM is the administration of the SI international system of units. Representatives of the governments of the Member States meet every four years at the General Conference on Weights and Measures (CGPM - Conference Generale des Poids et Mesures). The CGPM discusses and examines the work of individual national metrology institutes and the BIPM, and makes recommendations on new fundamental metrological determinations and all major issues of concern in connection with the BIPM. CGPM elects up to 18 representatives of the International Committee for Weights and Measures (Comite International des Poids et Mesures - CIPM), which meets every year. The CIPM on behalf GCPM supervises the BIPM and cooperates with other international metrology organizations. The CIPM is supported by 10 consultative committees. To perform specific tasks, a number of joint committees of the BIPM and other international organizations were established.

5.2.2 The CIPM Agreement on Mutual Recognition – CIPM MRA

In 1999, an agreement was signed between the National Metrology Institutes (NMIs), a significant document prepared by the CIPM committee called the Agreement on Mutual Recognition of National Standards, Calibration and Certificates issued by NMIs abbreviated CIPM MRA. This arrangement was important to create an open, transparent and comprehensive scheme of comparability of national metrology services as an expression of the efforts to create a basis for mutual trust and the removal of technical barriers to trade. The aim of the CIPM MRA was:

- to establish the degree of equivalence of national standards, held in the NMI;
- to ensure mutual recognition of output documents on calibration and measurements issued by the NMI;
- to provide governments and other parties with a secure technical foundation for wider agreements related to international trade, market and to administrative and regulatory matters.

5.2.3 The National Metrology Institutes - NMIs

The NMI is an institution whose purpose is, based on the decision of the state, among other things, to develop and maintain the national (state) standards (measurement standards) of quantities. The NMI represents the particular country internationally in relation to the national metrology institutes of other countries, regional metrological organizations, and in relation to the BIPM. The NMIs are the backbone of the organization for international cooperation in metrology.

For the NMIs it is typical that in the context of the national metrology system of the particular country, they are also responsible for the transmission of SI units downwards, i.e. to the accredited calibration laboratories, industry, research institutions, regulatory authorities, etc.

5.2.4 Cooperation in metrology at the global and regional level

The CIPM MRA agreement produces one of the foundations of the functioning of the global system of measurements based on:

- comparability of national standards, maintained at the NMI level, with provable traceability to SI units and with their recognition in accordance with the CIPM MRA;
- ensuring effective follow-up within the national metrology systems where meters are traceable to national standards;
- harmony between the measures taken by national authorities working in the field of legal metrology;
- the existence of internationally recognized specifications, standards and regulatory requirements regarding metrology.

Besides the stated cooperation at the global level, close cooperation at the regional level is crucial to ensure optimal functioning of metrology. The cooperation of the national metrology organizations is coordinated by the regional metrology organizations.

5.2.5 European cooperation in metrology

From the point of view of ensuring European cooperation in metrology, the vital role is played by the organization “European Association of National Metrology Institutes” (EURAMET e.V). Until 1 July 2007, this function was fulfilled by the organization EUROMET. The EURAMET members are 37 European metrology institutes and the Institute for Reference Materials and Measurements of the European Commission (IRMM). In addition, EURAMET has several associate members and so-called designated institutes.

EURAMET coordinates cooperation of the European NMIs especially from the viewpoint of metrology research, ensuring measurement traceability to SI units, and international recognition of national standards, and it manages metrology projects of interest to the EU in terms of ensuring the functioning of the common market. EURAMET is a body of the European Commission and has responsibility for the development and implementation of the European Metrology Research Program (EMRP).

5.2.6 OIML – The International Organization of Legal Metrology

The OIML is an intergovernmental organization founded in 1955. Its purpose is to promote the global harmonization of legal metrology procedures. During its existence, the OIML has developed a worldwide technical oriented system that provides its members with metrological implementing regulations and guidelines for drafting national and regional requirements concerning the manufacture and use of measuring instruments for legal metrology. The OIML issues international recommendations that provide the members with an internationally agreed basis for the application of national legislation on various categories of measuring instruments.

Some international and regional institutions and organizations also participate in these activities on a consultative basis. Between the OIML and bodies such as the ISO or IEC, agreements are concluded with the aim of avoiding the determination of conflicting requirements.

5.2.7 WELMEC – European Cooperation in Legal Metrology

This organization was founded in 1990 based on the Memorandum of Understanding signed by 15 of the EC Member States and three EFTA countries. The acronym WELMEC reflects the original name of the organization – “Western European Legal Metrology Cooperation”, which was changed to the current “European Cooperation in Legal Metrology” in 1995; the original acronym has been maintained. The WELLMEC members are the national metrology regulatory authorities of the EU Member States and EFTA countries, working in the field of legal metrology.

The aim of the WELMEC is:

- harmonization of activities in the field of legal metrology;
- developing mutual trust between the regulatory bodies in the field of legal metrology in Europe;
- strengthening information exchange between the competent authorities.

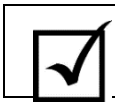
The WELMEC also provides advice to the European Commission and the Council regarding the use and further development of directives in legal metrology – e.g. the Measuring Instruments Directive and the Directive on Non-Automatic Weighing Instruments.

5.3 TRACEABILITY AND CALIBRATION OF MEASURING INSTRUMENTS

Traceability of a measuring instrument means its inclusion in an unbroken sequence of transfer of a quantity value beginning with the standard of the highest metrological quality for the given purpose. Figuratively, measurement traceability results from this as a quality of the measurement result, which can be used to determine its relationship to the stated references (usually national or international standards) through an unbroken chain of comparisons, where uncertainty is known for every article of this chain.

It is understood that for routine measurements it is not possible to use primary standards, embodying the given unit of the measured quantity, nor standards on lower levels. For these measurements, measuring devices (gauges) are used, for which the need arises to ensure their traceability to standards of higher level. The end user obtains traceability to the highest international level either directly through the national metrology institute or through a secondary calibration laboratory, usually an accredited one.

Therefore, the basic means of ensuring traceability of measurement is calibration of standards and measuring instruments. It is a set of operations under specified conditions establishing the relationship between values of quantities indicated by a measuring instrument or measuring system, and the corresponding values that are implemented by standards. Using comparisons with standards, metrological characteristics of the meter are determined. By calibration of the measuring instrument, it is achieved that either values of measured quantities are connected to the indicated values, or corrections to the indicated values are determined.



Summary of concepts

Based on the study of this chapter you are familiar with the role of metrology to ensure the quality of test results. The chapter specified three basic categories of metrology and their role. It outlined the development of the international metrology system together with an indication of some international organizations in this field. It also clarified the meaning of terms “traceability of measurement and calibration”.

Questions

1. What is the primary role of metrology?
2. What are the three basic categories of metrology?
3. What is the Metre Convention and the CIPM MRA Agreement?
4. Explain the concept of “Traceability of measuring instruments” and explain the manner of its provision.

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2. Terminology in the field of metrology; Proceedings of technical standardization, ÚNMZ 2010
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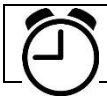
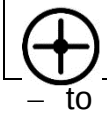
6 TECHNICAL STANDARDISATION



Time to study

Study of this chapter will take 1 hour



Objective

- to characterize the role of technical standardization for the purposes of testing and conformity assessment;
- to specify metrology division and its three basic categories;
- to explain the role of international cooperation in metrology and describe the international metrology system.

Lecture

Technical standardization is an important activity engaged in the development of technical regulations - standards. In the field of inspection and testing methods, the term standard means a compulsory and precise description of a test method, preparation of appropriate test procedures, devices, and conditions for testing and final evaluation. Standardized test methods are the basis for monitoring the properties of products when buying and selling them, in the determination and inspection of acceptance terms in domestic and foreign trade, but also in product assessment by authorized laboratories. Standards thus play an important role in the relationship between production and technical sphere on the one hand, and trade and economic sphere on the other hand.

However, the subject of standardization activities are not only testing methods. The standards cover a wide range of other areas, where they determine unify, simplify and generalize the numbers of types of products and their kinds, the main parameters and product characteristics, quality indicators for raw materials, materials and products, methods of calculation, signs, symbols, names, units of measurement, quantities or management system requirements or conformity assessment, etc.

Generally speaking, the standards are designed to serve as a means of communication between partners, as an instrument of unification and unambiguous interpretation in technical practice. When developing national standards, the peculiarities of the particular country and instrumentation are taken into account, as well as the standards of other countries. Otherwise, it would not be possible to compare the properties of the individual materials, which would be an obstacle to the mutual development and trade.

6.1 INTERNATIONAL STANDARDIZATION

The structure of the current system of technical standards consists of three levels: international, European and national. The pillar of technical standardization are international standardization bodies. International standards emerging at this level form the basis of technical specifications, which are within the principles of technical harmonization subsequently disseminated within the system of technical standardization at the European and national level.

6.1.1 International Level

The international level is represented by three standards bodies:

- ISO - International Organization for Standardization,
- IEC - International Electrotechnical Commission,
- ITU - International Telecommunication Union

International Organization for Standardization ISO is a worldwide federation of national standards bodies based in Geneva. The ISO was founded in 1947. Its main activity is the creation of international ISO standards and other documents in all areas of standardization except electrical engineering.

The ISO members are the national standards bodies representing normalization in the particular country. The ISO has currently has 162 members, of which 105 are full members, 47 correspondent members and 10 candidates for membership.

The basic duties of the members include the obligation to inform the authorities and organizations in their country on new standardization activities, to provide a unanimous standpoint on the various documents on behalf of the given country, and financially support the activities of the ISO. The ISO full members are entitled to

participate in activities of any technical committee and exercise all voting rights, they may be elected to the ISO Council, and they are represented at the ISO General Assembly. The correspondent members are usually organizations in a country where the national standards activity is not fully developed. The corresponding member does not actively participate in the technical and strategic work, but it may be informed. Candidates for membership are mainly countries with very small economy.

6.1.2 European level

The European level is also represented by three standards bodies:

- CEN - European Committee for Standardization,
- CENELEC - European Committee for Electrotechnical Standardization,
- ETSI - European Telecommunications Standards Institute.

The CEN, or CENELEC works in parallel with the ISO, or IEC and tries to take over the international standards (IS) and transpose them into European standards (EN) under the Vienna Agreement between the CEN and the ISO (revised in 2001) and Lugano agreement between the CENELEC and IEC (Dresden Revised Agreement of 1996).

6.1.3 European technical standardization system

The existing system of standardization within the EU is determined by European Parliament and Council Directive 98/34/EC on the provision of information in the field of standards and technical regulations (amendment of Directive 98/48/EC). The directive establishes a basic framework for European standardization based on the common European standardization system. It consists of the three European standardization bodies, together with national standardization bodies of the EU Member States at the national level of the European standardization system. The common objective is to create a system of harmonized European standards.

6.1.4 National standards bodies in the European standardization system

The European standardization bodies CEN, CENELEC and ETSI manage the development of European standards, but they do not issue the standards. It is the task of the national members, which issue them as part of their national systems of

standards. European standards are approved in the three official languages – English, French and German.

Obligations of the EU Member States in the European standardization system are as follows:

- agreed and approved text of an EN standard must be introduced by the national members into their national standards within six months;
- all national members are obliged to introduce all the EN standards;
- all conflicting national standards must be invalidated when an EN standard is transformed into the national system;
- when work begin on a new European standard, all work at the national level on the same subject must be stopped (standstill), if they have not reached the stage of public comments.

Summary of concepts

Based on the study of this chapter, you are familiar with the role of standardization to ensure proper function of testing. The chapter described the structure of international cooperation in issuing standards (world and European), including the introduction of some international organizations in this field. Attention was paid to the European Standardisation System.

Questions

1. What is the purpose of a standard and what are the types of standards?
2. What organizations are active in international and European standardization system?
3. On what principles does the European standardization system function?

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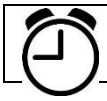
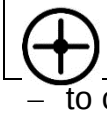
7 ASSESSMENT OF CONFORMITY



Time to study

Study of this chapter will take 1.5 hours



Objective

- to characterize the concept of “conformity assessment”;
- to describe the development of the European conformity assessment system;
- to explain the concept of technical regulation (regulated and unregulated area);
- to explain the concept of technical harmonization and its stages (old and new approach, NLF – New Legislative Framework).

Lecture

7.1 EXPLAINING THE CONCEPT OF “CONFORMITY ASSESSMENT“

“Conformity assessment” or “conformity evaluation” can generally mean any activity concerned with determining the extent of meeting specified requirements. This interpretation is very broad and covers a wide range of situations where it is determined whether something is in conformity with specified requirements. For the area of testing, it is more appropriate to use the definition referred to in ISO 17000: *”Conformity Assessment is a demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”.* In the context of this definition, conformity assessment is connected with performing tests, inspections, certification, or accreditation of conformity assessment bodies, i.e. bodies that perform services in the field of conformity assessment – testing laboratories, inspection bodies and certification bodies (certification of products, management systems and people).

However, there is a certain ambiguity of this term. In relation to the evaluation of products, the term “conformity assessment” refers to a specific system of compulsory certification of products falling within the so-called regulated sphere, which is

implemented in the current EU under its legislation. In this sense, this term is also applied in the following text of this chapter.

7.2 THE DEVELOPMENT OF THE EUROPEAN CONFORMITY ASSESSMENT SYSTEM

In the past and today, the various countries have somehow regulated their internal market and product placement on it. The intention has been both to protect their own inhabitants and environment, but often also to protect their own economic interests. The level of regulation and practical form of legal regulations that governed it were often different in different countries and corresponded to the political and economic conditions of a particular state.

Obviously, the same situation was in the 1950s in the countries of Western Europe, when the process of European integration was launched. From the beginning, it was clear that the key condition for the creation of the united market would be elimination of material, fiscal and technical barriers to trade. Technical hurdles were represented by different conditions in regulating the access of products to the markets of individual countries resulting from differences between compulsory technical regulations specifying the requirements for products, as well as the different rules governing the procedures for attestation of conformity.

The general aim was to modify the regulation within the EC in a uniform manner to make it acceptable in all the Member States. As the best way to start the functioning of the internal market, the EC Commission selected harmonization of different national technical regulations. Besides, various measures of deregulatory nature invalidating superfluous legal regulations the Member States were also adopted. It concerned the rules governing technical requirements for products, or preventing products from entering the market, discriminating entities operating in the market or restricting their competitiveness.

7.2.1 Technical regulation

In terms of applying technical regulation, products can be divided into two groups according to whether regulation concerns them or not. Products can thus be classified into so-called regulated or unregulated sector (area).

Unregulated sector

This group includes those products, use of which essentially poses no danger or risk, so there is no need to restrict their properties by specifying special requirements. These products must meet the general requirements for their safety that are within the current European legislation regulated by Directive of the European Parliament and the Council No. 2001/95/EC on the general product safety.

Regulated sector

Products from regulated sector represent an increased threat to the legitimate interest, therefore, regulatory measures relate to them. This means that they must be assessed for compliance with the technical requirements that are set for them in the relevant legislation. These products are also referred to as “specified products”.

Harmonization of technical requirements for products within the EC was solved through technical harmonization. Those harmonized requirements applied uniformly throughout the European Economic Area represent so-called harmonized area. However, there are also some product groups, for which the technical requirements were not specified by the individual EC Member States, or the EU. Within the regulated sector, these products fall within the so-called non-harmonized area in which rules of so-called mutual recognition are applied. According to this principle, it is not possible for a Member State to limit on its territory the sale of products that were legally marketed in another Member State.

In order to avoid possible conflicts between the non-harmonized and harmonized technical regulations, a process of so-called notification of technical regulations of the Member States is applied in the EU, in accordance with the current rules and principles laid down in Directive 98/34/EC on the provision of information in the field of technical standards and regulations.

7.2.2 Technical harmonization

Since the beginning of its implementation, harmonization has undergone several stages of development. The initial, the so-called “Old Approach” to technical harmonization was in the mid-eighties supplemented with the “New Approach”, which

is currently followed by its revision known as the “New Legislative Framework” of the EU for the area of technical regulation and harmonization.

The Old Approach

The first method of removing technical barriers, which EEC began to apply, is now known as the so-called “Old Approach”. It was applied mainly until 1985, but for certain categories of products posing a higher degree of risk, it is still used.

The „Old Approach” to harmonization is characterized by adopting harmonization technical regulations in the form of directives directly laying down technical specifications of products. These directives are very detailed, extensive and very professional. Their character is therefore closer to a technical standard rather than a legal regulation. This approach entails a number of problems. The detail and extensiveness does not make it possible to cover all individual requirements for each product category. Moreover, the technical specifications and solutions quickly become outdated with the progress and development of technologies, and these detailed rules have to be updated more frequently to maintain their application. Even their creation represented a lengthy legislative process. It often took many years before the adoption of a solution acceptable to all concerned. To strengthen the harmonization and development of the internal market, it was therefore necessary to create a new system that would ensure quicker and more efficient process and better respond to the dynamics of technological development.

The New Approach

In the mid-eighties of the 20th century, a new system was introduced in the EC, known as the “New Approach”. Its aim was to create a more dynamic process of harmonization, which would simplify the adoption of harmonization technical regulations and eliminate the disadvantages of the “Old Approach”. The basic document, from which the application of the “New Approach” proceeds, is the resolution of the Council No. 85/C/136/1.

The resolution declared the four principles, on which the “New Approach” to technical harmonization and standardization is based:

- harmonization of legal regulations is limited to establishing the essential safety requirements (or other requirements in the public interest) through directives,

which marketed products must meet in order to benefit from freedom of movement within the EC;

- the task of drawing up the technical specifications needed for the production and marketing of products in compliance with the essential requirements set out by directives is assigned to the organizations responsible for the area of standardization;
- the above mentioned technical specifications are not generally binding and retain their status of voluntary standards;
- declaration of so-called presumption of conformity, which is derived from the obligation of national authorities to recognize that products manufactured in accordance with harmonized standards (or temporarily according to national standards) are regarded as meeting the essential requirements of the Directive.

The aim of the “New Approach” was to simplify the EC harmonization technical regulations. Directives issued under this approach therefore contained only general product requirements and specifications of conformity assessment procedures used to assess their fulfilment. Product requirements relate primarily to ensure the safety of persons, domestic animals or property, or protection of public interests (especially health, consumers or the environment). Accurate and more detailed technical specifications and characteristics of the products were defined by technical standards (primarily by harmonized European standards, in the case of their absence, by national standards). This lead to fundamental interconnection of harmonization at the level of legislation and harmonization in the field of standardization, i.e. the creation and revision of technical standards. Adoption of European standards was subject to approval by the European standardization bodies (CEN, CENELEC, or ETSI).

Therefore, the directives of the “New Approach” are much better suited to the nature of the legal regulations, which should preferably be short, clear and concise. This simplified the way to search for compromises in adopting directives, and the legislative process was accelerated.

Introducing the “New Approach” thus lead to an acceleration of the whole harmonization process, it was basically divided into two closely interrelated but separate branches. Nearly a quarter-century of use safely tested and confirmed its quality and significance. Even after this time, no “post-new” approach was introduced,

there were only revisions, completions and extensions of the existing “New Approach”.

The New Legislative Framework

In 2003, i.e. at the time before the planned enlargement of the EU, the EC Commission decided to revise the “New Approach”. The process of the review was completed on 9 July 2008 by adoption of three regulations of the European Parliament and the Council, together known as the so-called “New Legislative Framework”. Specifically, they were Regulations No. 764/2008/EC and No. 765/2008/EC supplemented by Decision No. 768/2008/ES.

The purpose of the Regulation No. 764/2008/EC was to support the functioning of the EU internal market, especially in the area of non-harmonized regulated sector. One of the objectives of the regulation is to strengthen the principle of mutual recognition in relation to products from this sector. The regulation sets out the rules and procedures applied in adopting administrative decisions that cause the ban to market the product or ordering the product recall. Another aim of the regulation was to simplify access to information on technical requirements for non-harmonized products accepted in different Member States. In accordance with the regulation, Product Contact Points (ProCoP) were established in all the Member States, whose primary task is to collect information about technical requirements on individual non-harmonized products in their Member State. They provide the Commission, each other, and other applicants with this information.

The objective of Regulation No. 765/2008/EC is to improve the functioning of the EU common internal market, which is reflected in three aspects. The first is creating a comprehensive framework for accreditation and laying down uniform principles for the functioning and organization of accreditation at the European level. Within the EU, accreditation is considered as a priority way for verifying the competence of conformity assessment bodies, both in the regulated sector (harmonized and non-harmonized areas), as well as in the unregulated sector. Its activities are secured by the sole national accreditation body demonstrably functioning as a non-profit organization. The regulation also includes the procedures applied in the inspection of the professional level of national accreditation bodies.

The second aspect is the functioning of bodies for market surveillance and checking products entering the internal market from non-member states. Thorough implementation of both of these activities ensures adequate security of products that move in the single market, and prevents abuse of the benefits provided by the single market. One of the tasks of surveillance is to check whether all the products on the market within the regulated sphere have undergone all compulsory procedures. Similarly, the task of checking products entering the market is to check that the product has met all the requirements necessary for its entry into the single European market. The regulation also regulates the exchange of information on market surveillance authorities and on individual cases of non-compliance with the harmonized legislation.

The last aspect, which Regulation No. 765/2008/EC focuses on, is the use and placement of the CE mark. This mark symbolizes the product's compliance with all requirements of relevant harmonization legislation and its placement on the product means that it meets the applicable safety requirements, and risks associated with its use are minimal. The regulation laid down rules for the CE marking and established entities entitled for granting the mark and thus bearing responsibility that this mark for granted justifiably. The only entitled entities are the manufacturer or its authorized representative. By using the mark for the product, the manufacturer proclaims its responsibility for conformity of the product with the relevant requirements. The regulation also pays attention to the penalties for non-fulfilment or improper use of CE marking.

The third document, which is a part of the "New Legislative Framework", is the Decision No. 768/2008/EC. This decision establishes a common framework of general principles and reference provisions for the drawing of EU legislation affecting harmonization of technical requirements for products. It was adopted in order to unify the terminology and content of harmonization legal regulations, in other words, to ensure their own harmonization. The decision sets out definitions, general obligations of economic entities and the various procedures (modules) for conformity assessment. The decision includes three annexes containing relevant reference provisions:

Annex I presents a glossary containing definitions of terms and phenomena related to the area of conformity assessment.

Annex II describes the typical conformity assessment procedures and provides basic modules (and their modifications) for these activities. Each module represents a specific way of demonstrating the product conformity with the requirements set out for it. Modules are available for legislators so that they could use them to specify the degree of difficulty and checking the fulfilment of specified requirements with respect to risk level of the products. The modules make it possible to divide, quickly and clearly, the entities that may perform conformity assessment for the given kinds of products, and to establish the conditions that must be observed. In this part, the decision replaces the previous Council Decision No. 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures. It complements it and elaborates it in more detail, while preserving the original number of basic modules (i.e. 8 designated A, B, C to H), including their focus.

Annex III sets out the form of the certificate “EC declaration of conformity” including specifying the required information, which this statement should include.

Summary of concepts

Based on the study of this chapter, you are familiar with the principles of the release of products on the single European market, both within the unregulated sector and within the sector where regulation is applied. You have become familiarized with the development of technical harmonization and legislative regulations valid in the EU.

Questions

1. Explain the concept of conformity assessment.
2. What are regulated and unregulated sector of products?
3. Characterize the development stages of technical harmonization.
4. What is the new legislative framework and what does it include?

Additional task:

1. Familiarize yourself with the various conformity assessment modules listed in Annex II of text of the Decision of the European Parliament and Council Regulation (EC) no. 768/2008 (available e.g. at http://www.eur-lex.europa.eu).

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