ISSN 2522-9818 (print)
ISSN 2524-2296 (online) Innovative technologies and scientific solutions for industries. 2020. No. 1 (11)

UDC 006.35(100)ISO DOI: https://doi.org/10.30837/2522-9818.2020.11.156

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ANALYSIS OF THE REQUIREMENTS OF INTERNATIONAL AND NATIONAL STANDARDS FOR MEASUREMENT METHODS AND METROLOGICAL EQUIPMENT

The **subject** of research in the article are methods and means of measurement and testing. The **goal** of the work is to analyze the metrological requirements of the ISO/IEC 17025:2017 standard for equipment and methods used to conduct tests in laboratories to ensure control of the metrological system processes, and to provide information on the practical application of the requirements of this standard, taking into account the provisions of other international standards. The following **tasks** are solved in the article: analysis of the position of international documents containing the requirements to the equipment and test methods for measurement in order to determine their practical implementation; analysis of ISO/IEC 17025:2017 on metrological requirements and proposed ways of implementation of these requirements. The following **methods** are used - analysis method. The following **results** have been obtained: the analysis of international requirements to the equipment, including measuring, testing (measurement) and standardization of these requirements has been carried out to implement the provisions of ISO/IEC 17025:2017. An important factor in the implementation of the standard in Ukraine is that currently there are no national standards that would regulate the general requirements for the use of measuring equipment and assess the accuracy of measurement results. This standard provides general approaches to the use of equipment and accuracy characteristics of the results obtained by appropriate methods. Fulfillment of the requirements of the methodology makes it possible to obtain a reliable result with the required accuracy. **Conclusions**: on the basis of the carried out analysis it is established that ISO/IEC 17025:2017 became a new perspective step towards application of metrological requirements to means and methods of testing and measurements defined by various other international documents in the field of metrology; the standard is a fundamental, in fact, reference book for metrologists on organization of work on assurance of reliability of measurement results and tests at the enterprise; assurance of conformity to the requirements of the international standard provides customers with confidence in the results of measurements.

Keywords: validation; verification; measurement; measuring equipment; reliability of the results; measurement technique; metrology.

Introduction

DSTU International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" [1], which sets out the general requirements for the competence of testing laboratories, known in Ukraine for many years. However, at the end of 2017, international standards organizations - ISO and IES – have announced a new version of this standard. However, in this article, the authors pay particular attention to the implementation of metrological requirements, first of all, to measurement techniques and equipment. The application of the new edition in 2018-2019 in Ukraine showed that more attention should be paid to the correct implementation of metrological requirements, because they directly affect the solution of the main task set by this standard - ensuring the reliability of the results of tests and measurements obtained in the laboratory.

SSTU International Standard ISO / IEC 17025 "General requirements for the competence of testing and calibration laboratories" [1], which sets out the general requirements for the competence of testing laboratories, known in Ukraine for many years. However, at the end of 2017, international standards organizations - ISO and IES - have announced a new version of this standard. However, in this article, the authors pay particular attention to the implementation of metrological requirements, first of all, to measurement techniques and equipment. The application of the new edition in 2018-2019 in Ukraine showed that more attention should be paid to the correct implementation of metrological requirements, because they directly affect the solution of the main task set by this standard - ensuring the reliability of the results of tests and measurements obtained in the laboratory.

In the new version of this International Standard, requirements for equipment and test methods (measurements) are different from those in previous versions. This article summarizes the results of the analysis on metrological requirements and suggests ways to implement these requirements.

Analysis of the problem and existing methods

Since the introduction of ISO / IEC 17025: 2005 [3] in Ukraine, accredited testing laboratories have focused on the fact that the measurement criterion is the measurement uncertainty. However, the new version of this standard provides for the assessment and measurement of the different quantitative characteristics provided for by other international standards for measuring accuracy. This is a significant step forward in ensuring that the measurement results are accurate because the value of measurement uncertainty in the laboratory result did not contribute to confidence in the result. This is justified by the lack of standardized methods for determining the uncertainty of the target, the absence of generally accepted equations of measurement for the given measurement task, the unproven determination of the uncertainty of type B, etc. However, there are a considerable number of international standards that describe other methods of controlling the accuracy of measurement results. Analysis of the implementation of the provisions and prospects of ISO/IEC 17025: 2017 dedicated to the work of foreign researchers [4–7].

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The purpose of the work is to analyze the metrological requirements of the standard [1] for the equipment and methods used for testing in laboratories and to provide information on the practical application of the requirements of this standard, taking into account the provisions of other international standards.

Solving the problem

Analysis of equipment requirements by international and national standards.

Let us analyze the requirements of ISO / IEC 17025: 2017 [1] and its translation into Ukrainian [2], to equipment. The term "equipment" and not "equipment" or "equipment" used in previous revisions of ISO / IEC 17025 should be noted "and the general term by which these two types of equipment were referred to was" equipment". Which was not consistent enough.

Paragraph 6.4.1 of the standard specifies that "the laboratory must have access to the equipment (including, but not limited to, measuring instruments, software, standards, standard samples, standard reference data, reagents, supplies or accessories) required for the proper implementation of the laboratory and what may affect the results". However, the incorrect term "measuring instrument" has been used. Incorrect because the term "measuring instrument" is used in the original. When referring to the International Metrology Dictionary (VIM) [8], this term corresponds to the terms "measuring equipment means" or "measuring equipment" (see SSTU ISO 10012 [9]). Hereinafter referred to as the NAAU translation, the term "measuring equipment".

The requirement to inspect the equipment for compliance with the specified regulations before commissioning or putting it back into service complies with previous versions of the standard. However, the 2017 edition clearly states that the equipment used for the measurement must provide the measurement accuracy and / or measurement uncertainty required to ensure the accuracy of the result. And this should be understood as follows: it is recognized that measuring instruments (measuring equipment) have a basic metrological characteristic – an error. And this is confirmed by the EU directives on measuring equipment in the "essential requirements" sections, which specify the need for the manufacturer of the measuring equipment to establish the maximum permissible error. Based on the use of the term "accuracy" for measuring equipment, which is a qualitative assessment, and quantitatively for measuring equipment is characterized by its error - accuracy class or maximum permissible error.

Attention should be drawn to the definition of an "accuracy class" in the international dictionary [8], a class of measuring instruments or measuring systems that satisfies the metrological requirements necessary to maintain measurement errors or instrumental uncertainties within specified limits under specified operating conditions. The maximum permissible error sets the maximum error limits for the measuring equipment. The characteristics and designation of accuracy classes of measuring equipment by its categories are defined in the recommendation of the International Organization of Legal Metrology OIML R 34 [11].

Paragraph 6.4.6 specifies the requirement for calibration of measuring equipment. Measuring instruments must be calibrated if:

- measurement accuracy or measurement uncertainty affects the accuracy of the results obtained, and/or
- calibration of equipment is necessary to establish the metrological traceability of the obtained results.

According to Resolution 11 of the 22nd General Conference on Weights and Measures "Communication between national metrology institutes and national (recognized) accreditation bodies", FTA calibration is not a conformity assessment. The question then arises as to why calibration of measuring equipment is used in conformity assessment rather than calibration. The calibration involves the conformity of metrological characteristics of the measuring equipment with the requirements set to it, and the calibration does not provide this.

Remaining in ISO/IEC 17025: 2017 such an important requirement as metrological traceability, namely "6.5.1. The laboratory shall establish and maintain metrological traceability of the measurement results using a documented non-breaking calibration circuit, each contributing to measurement uncertainty. them with the appropriate standard ".

The revision of ISO / IEC 17025: 2017 establishes rules for handling non-measuring equipment. For such equipment (testing and auxiliary) the word "verification" was applied, which in Ukraine was carried out as attestation - verification of compliance with the equipment installed to the requirements.

According to ISO/IEC 17000 [10] (implemented in Ukraine as DSTU ISO/IEC 17000: 2007 "Conformity Assessment. Glossary of Terms and General Principles") a test means the determination of one or more characteristics of an object of conformity assessment in accordance with a defined procedure. During the tests the following can be applied:

- technical means having accuracy characteristics;
- technical means that do not have precise characteristics;
- measuring equipment having metrological characteristics;
- indicators - devices or substances that indicate the occurrence of a phenomenon, body or substance in the event of exceeding a specified value.

The type of technical equipment used depends on the purpose and the procedure for determining the characteristics of the conformity assessment object.

In Ukraine, experts distinguish between "test equipment" and "measuring equipment". Testing equipment is used to reproduce the test conditions, that is, technical means that in some way affect the object of research over the required time. Measuring techniques are used to perform measurements, that is, by which they implement the process of experimentally determining one or more values of a value that can reasonably be assigned to that value. The term "measuring instruments" according to ISO 10012: 2003 [9] (introduced in Ukraine as SSTU

ISSN 2522-9818 (print)
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ISO 10012: 2005 "Measurement Control Systems. Requirements for Measurement Processes and Measurement Equipment") now corresponds to the international term "measuring equipment". The term "measuring equipment" is also used in the translation of SSTU ISO/IEC 17025: 2017 [2].

Concerning the identity of the terms, then:

- according to VIM [8], the definition of "measuring instruments" indicates the following: "a device used for measurements, only one or in combination with one or more devices";

- in accordance with ISO 10012 [9], the definition of the term "measuring equipment" - measuring instrument, software, standard unit of physical quantity, standard sample, or auxiliary devices or combinations thereof necessary to perform the measurement process.

From the point of view of risk-oriented thinking, the main risk when using measuring equipment is to exceed the maximum permissible error of a particular tool or the required uncertainty of its calibration. However, at this time the issue of setting a target (regulated for a specific measurement task) measurement uncertainty is not addressed.

Clause 6.4.6 of the discussed standard [1] specifies the requirement for calibration of measuring equipment. Measuring instruments must be calibrated if:

- measurement accuracy or measurement uncertainty affects the accuracy of the results obtained, and / or

- calibration of equipment is necessary to establish the metrological traceability of the obtained results.

The estimation of measurement uncertainty during calibration is regulated in EA-4/02 [12].

The new version of the standard establishes rules for handling non-measuring equipment. For such equipment (testing and auxiliary) the word "verification" was applied, which in Ukraine was performed as a certification - a check for compliance with the established requirements for the equipment. That is, the term "testing of test equipment" can be used at this time.

Analysis of requirements for test and measurement methods according to international and national standards.

The reliability of the test results depends not only on the correct use of the equipment, but on the methods by which these tests are conducted.

Let's consider the concept of "methodology" in relation to testing and measurement. At the international level, techniques are commonly referred to as procedures. The International Metrology Dictionary [8] provides the following definition of a measurement procedure: a detailed description of measurement in accordance with one or more measurement principles and a measurement method that is based on the measurement model and contains a calculation to obtain the measurement result. This definition does not contradict the definition of "measurement technique" adopted in Ukraine: a document containing a set of operations and rules whose implementation ensures that the measurement result is obtained with established accuracy.

According to VIM [8]:

- the principle of measurement – a phenomenon that serves as a basis for measurement (a phenomenon can be physical, chemical or biological in nature);

- measurement method – a general description of the logical sequence of operations used during measurements (for example, the direct measurement method);

- measurement model – mathematical relation between all quantities that are related to measurement);

- accuracy – the closeness between the measured value of the value and the true value of the measured value.

The notion of "measurement accuracy" is not a quantity and therefore is not given in the form of a numerical value. Measurement is more accurate when it has less measurement error. More accurate measurements must be made, or it is sufficient to obtain the measurement result with less accuracy. That is, accuracy is a qualitative indicator, in quantitative terms it can be expressed by other quantitative indicators.

The test also applies the concept of "test accuracy". In this case, accuracy is characterized by an accuracy characteristic or an established tolerance for the test result. Accurate test performance is, for example, an error in setting the temperature in a drying cabinet or the tolerance to the value of the relevant product parameter being tested..

The requirements of the standard [1,2] for the methods are set out in section 7.2 "Selection, verification and validation of methods".

The laboratory should use acceptable methods and procedures to carry out the entire activity (ie measurements and tests in the field of activity). The text of this standard defines that the term "method" as used in the original of this document may be considered synonymous with the term "measurement procedure" (i.e. test/measurement technique) as defined in the dictionary. [8].

The status of test/measurement techniques in ISO / IEC 17025: 2017 Section 7.2 is as follows:

(1) all methods, procedures and supporting documentation, such as instructions, standards, guidelines and background data related to the activities of the laboratory, should be kept up-to-date and accessible to staff;

2) the laboratory must ensure that it uses the latest valid version of the method, except where it is inappropriate or impossible;

3) where necessary, the application of the method should be supplemented by additional information to ensure consistent application;

4) techniques developed by the laboratory.

Unfortunately, in ISO / IEC 17025: 2017 the term "standardized methodology" does not apply in clause 7.2.1.4, but hereinafter it is used. However, it is confirmed that techniques published in international, regional or national standards, or published by reputable technical organizations, or published in relevant scientific literature or journals, or those specified by the manufacturer of the equipment, are recommended (ie standardized). It has also been confirmed that techniques developed and modified by the laboratory can also be used.

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A positive aspect of the new version of the standard is the clear definition of the application of the terms "verification" and "validation" to test and measurement methods. Verification means providing objective evidence that an entity meets the above requirements. As for the test facility, both the measurement method and the test method are subject.

Verifications are subject to standardized (recommended) techniques that apply to their scope. The laboratory should check that its specialists can properly perform the methods before their introduction by demonstrating that the desired performance can be achieved - the reliability of the measurement (test) result. Records of verification of methodologies should be kept in the laboratory. The verification procedure for standardized methods should be performed by all testing (measuring) laboratories, and not only by accredited ones, as this is evidence of the quality assurance of the laboratory work.

The laboratory should validate:

- non-standard methods;
- techniques developed by the laboratory;
- standardized techniques that are used other than as provided or modified.

Validation is the verification that these requirements are appropriate for the intended use. Thus, during the validation of the methodology, the laboratory confirms its suitability for use.

Validation should be as extensive as is necessary to meet the needs of the application or scope. The techniques used to validate the method can be one or a combination of the following:

- measurement bias and precision estimation using standard samples;
- systematic evaluation of the factors that influence the result;
- checking the stability of the method by changing adjustable parameters such as incubator temperature, dose volume;
- comparison with results obtained by other validated methods;
- interlaboratory comparisons;
- estimation of uncertainty of measurement results on the basis of understanding of theoretical principles of method and practical experience of work on sampling or test method.

The laboratory must determine the accuracy of the measurements. However, not only accuracy is estimated by uncertainty. The measurement uncertainty requirement is defined where appropriate. It is very important from the point of view of practical application of the techniques that the main requirement for the performance characteristics of the validated methods is compliance with the needs of the customers and compatibility with certain requirements. This means that not only uncertainty can characterize measurement accuracy, as defined in previous versions of the standard, and is contrary to many other international standards that govern measurement accuracy requirements.

International standard [1] provides that performance may include, but is not limited to, measurement range, measurement error, measurement uncertainty, detection limit, quantification limit, method selectivity, linearity, repeatability or reproducibility, resistance to external influences, or cross-sensitivity to the influence of the sample matrix or test object and measurement offset.

Therefore, when developing techniques in the laboratory, those performance characteristics that are appropriate to its scope can be selected.

This also indicates that different performance characteristics can be applied in standardized methods. And then there is the question - what is the need to evaluate measurement uncertainty if the reliability of the result is provided by other characteristics of the accuracy of the result.

For the evaluation of many of the characteristics proposed in the standard [1, 2], the provisions of ISO 5725 [13–18] should be used. The authors of the article [19] described in detail the working characteristics of the methods.

It is advisable to clarify what characteristics quantify the notion of "measurement accuracy" in test and measurement methods:

- measurement error – normalized maximum permissible error; attributed an error at a confidence probability of 0.95;
- measurement uncertainty – target (set maximum allowed value); laboratory definitive (own) measurement uncertainty;
- correctness – systematic error, offset from the reference value;

Precision – random error, repeatability and reproducibility.

For practical use in testing laboratories, it is advisable to use the characteristics of techniques such as the limit of tolerance of the results of two measurements, carried out in parallel or quickly in succession, in repeatability and reproducibility conditions (see SSTU GOST ISO 5725-6 [18]). To determine these characteristics, it is necessary to conduct experimental studies, namely n independent observations, which should be at least 10. Based on the obtained values to determine the experimental mean-square deviation of the mean by the formula (1):

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}\left(x_i - x_{ar}\right)^2}{n\left(n-1\right)}}, \qquad (1)$$

where x_i – results of n independent observations; x_{ar} – arithmetic mean of n independent observations.

It should be noted that the results of the experimental studies and the determined experimental mean-square deviation of the mean can be determined:

- standard uncertainty of measurements according to type A by formula (1);
- the random component of the measurement error according to the formula (1);
- the margin of tolerance of the results of two measurements, carried out in parallel or carried out rapidly in series, in terms of the repetition of the formula (2):

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ISSN 2524-2296 (online) Innovative technologies and scientific solutions for industries. 2020. No. 1 (11)

$$r = 2{,}77\,\sigma, \qquad (2)$$

where σ – experimental mean squared deviation of the mean determined by the formula (1).

The coefficient 2.8 can be used instead of the coefficient 2.77. The concept of "fast sequentially performed in repeatability" is interpreted as conducting independent observations over a time during which the measured value will not change compared to its condition at the first observation.

Determination for the test and measurement methods of the limit of tolerance of the results of two measurements in the conditions of repeatability enables the laboratory to control the reliability of the obtained result during measurements and tests.

Conclusions

Based on the analysis, it should be noted that:

- ISO / IEC 17025: 2017 has become a new promising step towards the application of metrological requirements to the means and test and measurement methods identified by various other international metrology documents;

- this standard is fundamental, essentially a guide for metrologists to organize work to ensure the accuracy of measurements and tests at the enterprise;

- ensuring compliance with the requirements of the international standard gives the customers confidence in the results obtained in the laboratory.

Currently, the ISO / IEC 17025: 2017 metrological requirements confirm the variety of means and methods for ensuring the reliability of results, so practicals-metrologists, based on analyzing these requirements and professionally determining the feasibility of applying them to a specific measurement task, can ensure the quality control of product parameters at all stages its production.

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Received 14.02.2020

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АНАЛІЗ ВИМОГ МІЖНАРОДНИХ ТА НАЦІОНАЛЬНИХ СТАНДАРТІВ ДО МЕТОДИК ВИМІРЮВАННЯ ТА МЕТРОЛОГІЧНОГО ОБЛАДНАННЯ

Предметом дослідження в статті є методи та засоби вимірювання та випробувань. **Мета** роботи – проведення аналізу метрологічних вимог стандарту ISO/IEC 17025:2017 до обладнання та методик, за якими проводяться випробування в лабораторіях для забезпечення управління процесами метрологічної системи, та надання інформації щодо застосування на практиці вимог цього стандарту із урахуванням положень інших міжнародних стандартів. В статті вирішуються наступні **завдання:** аналіз положення міжнародних документів, які містять вимоги до обладнання та методик випробувань до проведення вимірювань з метою визначення їх доцільної практичної реалізації; аналіз ISO/IEC 17025:2017 щодо метрологічних вимог та запропонування шляхів реалізації цих вимог. Використовуються такі **методи:** метод аналізу. Отримано наступні **результати:** проведено аналіз міжнародних вимог до обладнання, у тому числі до вимірювального, методик випробувань (вимірювань) та нормування цих вимог з метою реалізації положень ISO/IEC 17025:2017. Важливим фактором впровадження стандарту в Україні є те, що на цей час відсутні національні стандарти, які б регламентували загальні вимоги до використання засобів вимірювальної техніки та оцінки точності результатів вимірювання. В стандарті, що розглядається, надані загальні підходи до використання обладнання та характеристик точності результатів, одержаних за відповідними методиками. Виконання вимог методики дає можливість одержати достовірний результат з необхідною точністю. **Висновки:** на підставі проведеного аналізу визначено, що ISO/IEC 17025:2017 став новим перспективним кроком до застосування метрологічних вимог до засобів та методик випробувань та вимірювань, визначених різними іншими міжнародними документами в галузі метрології; стандарт є основоположним, по суті довідником для метрологів щодо організації роботи із забезпечення достовірності результатів вимірювань та випробувань на підприємстві; забезпечення відповідності вимогам міжнародного стандарту надає замовникам довіри до результатів, одержаних у лабораторії.

Ключові слова: валідація; верифікація; вимірювання; вимірювальне обладнання; достовірність результатів; методики вимірювань; метрологія.

ISSN 2522-9818 (print)
ISSN 2524-2296 (online) Innovative technologies and scientific solutions for industries. 2020. No. 1 (11)

АНАЛИЗ ТРЕБОВАНИЙ МЕЖДУНАРОДНЫХ И НАЦИОНАЛЬНЫХ СТАНДАРТОВ К МЕТОДИКАМ ИЗМЕРЕНИЯ И МЕТРОЛОГИЧЕСКОГО ОБОРУДОВАНИЯ

Предметом исследования в статье являются методы и средства измерения и испытаний. **Цель** работы – проведение анализа метрологических требований стандарта ISO/IEC 17025:2017 к оборудованию и методик, по которым проводятся испытания в лабораториях для обеспечения управления процессами метрологической системы, и предоставление информации по применению на практике требований этого стандарта с учетом положений других международных стандартов. В статье решаются следующие **задачи:** анализ положения международных документов, содержащих требования к оборудованию и методик испытаний к проведению измерений с целью определения их целесообразной практической реализации; анализ ISO/IEC 17025:2017 по метрологическим требованиям и предлагаемых путей реализации этих требований. Используются следующие **методы**: метод системного анализа. Получены следующие **результаты**: проведен анализ международных требований к оборудованию, в том числе к измерительному, методик испытаний (измерений) и нормирования этих требований с целью реализации положений ISO/IEC 17025:2017. Важным фактором внедрения стандарта в Украине является то, что в настоящее время отсутствуют национальные стандарты, которые бы регламентировали общие требования к использованию средств измерительной техники и оценки точности результатов измерения. В рассматриваемом стандарте предоставлены общие подходы к использованию оборудования и характеристик точности результатов, полученных по соответствующим методикам. Выполнение требований методики дает возможность получить достоверный результат с требуемой точностью. **Выводы**: на основании проведенного анализа установлено, что ISO/IEC 17025:2017 стал новым перспективным шагом к применению метрологических требований к средствам и методик испытаний и измерений, определенных различными другими международными документами в области метрологии; стандарт является основополагающим, по сути справочником для метрологов по организации работы по обеспечению достоверности результатов измерений и испытаний на предприятии; обеспечение соответствия требованиям международного стандарта предоставляет заказчикам доверия к результатам, полученных в лаборатории.

Ключевые слова: валидация; верификация; измерения; измерительное оборудование; достоверность результатов; методики измерений; метрология.

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