

PRACTICAL ISSUES IN THE CONFORMITY ASSESSMENT OF NON-AUTOMATIC WEIGHING INSTRUMENTS

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Abstract. All measuring instruments used in the field of legally regulated metrology must comply with the requirements of all applicable technical regulations. Conformity with these regulations is ensured through assessment procedures defined in the respective technical regulations.

This article examines the process of obtaining certificates and ownership rights based on the results of conformity assessment procedures, using non-automatic weighing instruments as an example. It clarifies the requirements for marking and the necessary accompanying documentation for the operation of non-automatic weighing instruments in legally regulated metrology.

Additionally, the article provides information on the initial date from which the next periodic verification is calculated, following the expiration of the verification interval after the completion of conformity assessment procedures.

Keywords: Conformity assessment, Technical regulation, Non-automatic weighing instruments, Certificate, Declaration of conformity, Verification interval, Marking.

1. Introduction

Nine years ago, Ukraine’s metrology legislation [1] was updated to align with the legal framework of the European Union. These changes defined the scope of legally regulated metrology, units of measurement, requirements for national standards, measuring instruments, conformity assessment and verification procedures, and metrological supervision.

However, many questions and uncertainties still arise regarding the placement on the market and subsequent operation of measuring instruments (hereinafter referred to as MIs) and their accompanying documentation.

According to Ukraine’s current legislation, all measuring instruments used in the field of legally regulated metrology (hereinafter referred to as LRMIs), whether placed on the market, supplied to the market, or put into operation, must comply with all applicable technical regulations [1–3]. Conformity with these regulations is assessed in specific cases through procedures defined within the respective technical regulations. These procedures are primarily carried out by manufacturers. However, if the relevant technical regulations assign the manufacturers’ responsibilities to importers or distributors, then importers or distributors must fulfill these obligations.

Manufacturers of MIs frequently receive inquiries from clients, either during the ordering process or after receiving the equipment, seeking clarification on the required markings and accompanying documentation necessary for operation within the field of legally regulated metrology [4].

As an example, we will examine the results of conformity assessment procedures for LRMIs, focusing on non-automatic weighing instruments (hereinafter referred to as NAWIs). For other LRMIs, the procedures and conclusions will be similar.

2. Drawbacks

The superficial understanding among users of NAWIs regarding the required markings and accompanying documentation is due to the lack of publicly available practical information about the documentation issued following conformity assessment procedures. This issue is further exacerbated by the misuse of terms by certain unscrupulous employees of conformity assessment bodies for measuring instruments and verification laboratories.

3. Goal

The aim of this article is to clarify the process of obtaining relevant certificates, as well as the ownership and distribution rights associated with them, following conformity assessment procedures for NAWIs and other operational documentation.

4. Conformity Assessment Procedures for NAWIs

NAWIs must comply with the essential requirements of the Technical Regulation for non-automatic weighing instruments [5].

According to the Technical Regulation, compliance with these essential requirements may be confirmed, at the manufacturer’s discretion, through the following conformity assessment procedures [5]:

- Module *B* (Type Examination), with mandatory subsequent application of either Module *D* (Conformity to type based on quality assurance of the production process) or Module *F* (Conformity to type based on product verification).
- Module *G* (Conformity based on unit verification).



where

- in the supplementary metrology marking MXX,
- XX – the last two digits of the year of its affixing;
- in the identification number of the notified bodies UA.TR.YYY,
- YYY – the code of the notified body that conducted the conformity assessment procedures under module F or module D;
- B UA.TR.XXX-XXX-XX rev.X,
- UA.TR.XXX-XXX-XX – type examination certificate number,
- rev.X – certificate version.

Marking of NAWIs in accordance with the Technical Regulation

Module G is not applicable to serial production; it is used exclusively for unique, standalone NAWIs or for modified NAWIs with significant design changes that exceed the type description provided in the type examination certificate and affect the regulated metrological characteristics of the instrument.

Upon successful completion of the conformity assessment procedures, the manufacturer must affix the technical regulation conformity marking [5] and the supplementary metrology marking [6] (see Figure) to each NAWI and issue a written declaration of conformity [6].

Next, we will examine in detail the documentation specific to each module (excluding Module G from this discussion).

5. Type Examination Certificate (Module B)

During the type examination portion of the conformity assessment procedure, a designated notified body (hereinafter referred to as NB) conducts an evaluation of the technical documentation for the NAWI as well as tests and inspections of one or more representative samples provided by the manufacturer. If the results of these activities are positive, the NB issues a type examination certificate for the measuring instrument.

The type examination certificate contains information that allows for the assessment of conformity of manufactured instruments with the approved type and ensures control under operational conditions. This certificate includes technical data necessary for identifying the approved type, which may constitute the manufacturer's trade secret.

The type examination certificate is valid for 10 years, provided no significant changes are made to the NAWI's design. The certificate may be reissued, amended, withdrawn, or have restrictions applied if substantial changes are made to the approved type.

In accordance with the requirements of the Technical Regulation [5]:

- The NB must retain a copy of the type examination certificate, its annexes and amendments, as well as the technical documentation (including documentation submitted by the manufacturer) until the certificate expires. Other NBs can obtain copies of the type examination certificate and/or its annexes upon request.

- The manufacturer must retain the type examination certificate, its annexes, and amendments along with the technical documentation for 10 years after the NAWI is placed on the market. If requested by the state market surveillance authority, the manufacturer must provide copies of these documents.

Additionally, the NB electronically submits copies of the issued type examination certificate (with annexes and amendments) to SE "UKRMETRTESTSTANDARD" for inclusion in the "Register of Approved Measuring Instrument Types" [7]. The register includes the name and designation of the instrument type, the name and location of the manufacturer, the name and identification number of the NB that issued the certificate, and the certificate's issue date and validity period.

Key Points:

- The type examination certificate (with annexes and amendments) is issued to the manufacturer and is the manufacturer's property.
- Copies of the type examination certificate must be provided upon request to designated notified bodies or state market surveillance authorities. In all other cases, such as customer requests, the decision to provide a copy is at the manufacturer's discretion. Typically, manufacturers post the first page of the certificate with general information on their website or provide it upon customer request.
- Basic information about issued type examination certificates can be found in the publicly accessible "Register of Approved Measuring Instrument Types" [6].
- Completing the type examination portion (Module B) of the conformity assessment procedure does not grant the right to place the NAWI on the market, supply it to the market, or put it into operation.

6. Certificate of Conformity (Module F)

During the conformity assessment procedure under Module F, the NB selected by the manufacturer conducts tests on each NAWI in accordance with the requirements of Section 8.3 of DSTU EN 45501 [8]. These tests verify the conformity of the NAWI with the approved type outlined in the type examination certificate and the applicable requirements of the Technical Regulation.

If the tests yield positive results, the NB issues a certificate of conformity for each tested NAWI, specifying the modification and serial number. The NB also applies its identification number (or delegates this responsibility to the manufacturer under its supervision). The manufacturer must retain the certificate of conformity for 10 years after the NAWI is placed on the market and provide a copy upon request to state market surveillance authorities. The certificate of conformity is the property of the manufacturer. However, verification laboratories often require a copy of this certificate during verification procedures.

There is no centralized registry of certificates of conformity, but many NBs maintain registers of issued certificates on their websites. For example, the NSC “Institute of Metrology” provides such a registry [9].

After receiving the certificate of conformity for a specific NAWI, the manufacturer applies the conformity marking, supplementary metrological marking, the identification number of the NB that conducted the tests (if the NB delegated this task), the type examination certificate number, and prepares a declaration of conformity. The declaration of conformity specifies the modification and serial number of the NAWI, along with information about the valid type examination certificates and certificates of conformity.

The manufacturer must retain the declaration of conformity for 10 years after the NAWI is placed on the market and provide a copy upon request to state market surveillance authorities.

In accordance with requirements of the Technical Regulation, a copy of the declaration of conformity must be accessible to relevant executive authorities upon request. Therefore, manufacturers typically provide a copy of the declaration of conformity with the NAWI.

The date of issuance of the certificate of conformity is the starting point for determining the date of the next periodic verification after the expiration of the interval between verifications, as established by Ukrainian regulations [10] – typically one year for NAWIs.

Key Points:

- The certificate of conformity is issued to the manufacturer and remains the manufacturer’s property.
- A copy of the certificate of conformity must be provided upon request to state market surveillance authorities. While the manufacturer is not obligated to provide it to customers or verification laboratories, they often do so upon request.
- After applying the combination of Modules $B+F$, all the necessary and sufficient information for placing the NAWI on the market, supplying it to the market, or putting it into operation is included on the instrument’s marking label and in the declaration of conformity.
- Information about issued certificates of conformity can be found on the websites of designated notified bodies that issued these certificates.

7. Quality Management System Approval Certificate (Module D)

During the conformity assessment procedure under Module D , the designated NB selected by the manufacturer evaluates the manufacturer’s quality management system. This assessment ensures the system’s capability to maintain the conformity of NAWI with the type described in the type examination certificate and the applicable requirements of the Technical Regulation.

If the NB’s audit team positively evaluates the quality management system, the NB issues a quality management system approval certificate for the relevant type(s) of instruments. This certificate is the manufacturer’s property, and its storage and provision requirements are similar to those for the certificate of conformity.

With this certificate, the manufacturer is authorized to:

- Apply the conformity marking, supplementary metrological marking, the NB’s identification number (responsible for the Module D assessment), and the type examination certificate number to the NAWIs tested according to the manufacturer’s quality system test program.

- Draft a written declaration of conformity for the relevant type of instrument. Unlike Module F , the declaration of conformity under Module D is a general declaration for all instruments of a particular type and does not include specific modifications or serial numbers of individual instruments. The storage and provision requirements for the declaration of conformity are the same as those under Module F .

When Module D is applied, individual testing of each NAWI to confirm conformity with the approved type and applicable requirements of the Technical Regulation is carried out by the manufacturer rather than the NB. Authorized specialists at the manufacturer’s enterprise conduct acceptance testing of each NAWI during production based on the approved quality management system. They prepare test protocols in accordance with Section 8.3 of DSTU EN 45501 [8]. The manufacturer then completes the acceptance / release certificate in the operational documentation (e.g., user manual or passport), specifying the release date and certifying it with the manufacturer’s stamp.

The release date indicated in the operational documentation is used to calculate the next periodic verification date.

Key Points:

- The quality management system approval certificate is issued to the manufacturer and remains their property.
- A copy of the quality management system approval certificate must be provided upon request to state

market surveillance authorities. While not obligated, the manufacturer may provide a copy to customers or verification laboratories upon request.

- After applying the combination of modules $B+D$, all necessary and sufficient information for placing the NAWI on the market, making it available, or putting it into operation is included on the instrument's marking label and in the declaration of conformity. The declaration is issued for the type of instruments, not individual ones.
- The operational documentation (manual or passport) specifies the release date, which determines the date of the next periodic verification.

8. Conclusions

Only those non-automatic weighing instruments (NAWIs) that have passed the conformity assessment procedure using the combination of modules $B+F$ or $B+D$, bear the appropriate marking, and have a written declaration of conformity may be placed on the market, put into circulation, or put into operation.

NAWIs in operation must undergo periodic verification one year after completing the conformity assessment procedures in accordance with the requirements of the Technical Regulations.

The verification interval is determined as follows:

- For modules $B+F$: from the date of issuance of the certificate of conformity for the device.
- For modules $B+D$: from the date of acceptance / release of the device, as specified by the manufacturer in the operational documentation.

Before conducting verification, verification laboratories must check for the presence of the required marking and declaration of conformity to ensure that the NAWI has undergone the necessary conformity assessment procedures. If there are any doubts, the laboratory may request a copy of the relevant supporting certificates.

If incorrect marking is found or if supporting documents confirming the completion of all required conformity assessment procedures are missing (e. g., only module B has been conducted), the verification laboratory must refuse to perform the verification. In some cases, unscrupulous personnel in verification laboratories neglect their responsibilities and issue a verification certificate for an instrument that does not meet the requirements. However, this does not exempt the NAWI user from liability for the improper use of the device [4].

Conflict of Interest

The authors state that there are no financial or other potential conflicts regarding this work.

References

- [1] On Metrology and Metrological Activity: Law of Ukraine [adopted by the Verkhovna Rada of Ukraine on 05 June 2014, No. 1314-VII]. Available: <http://zakon5.rada.gov.ua/laws/show/1314-18>.
- [2] On Technical Regulations and Conformity Assessment: Law of Ukraine [adopted by the Verkhovna Rada of Ukraine on 15 January 2015, No. 124-VIII]. Available: <http://zakon2.rada.gov.ua/laws/show/124-19>.
- [3] T. Ilnytska, Kr. Vasylykha, "The Means of Measuring Equipment Related to the Measurement of Mass in and Outside the Area of Legally Regulated Metrology", *Metrology and Instrument*, No. 4(78), pp. 55–61, 2019.
- [4] T. Ilnytska, O. Dvornyk, "Manufacturer's Perspective on the Conformity Assessment of Non-Automated Weighing Instruments", *II International Scientific and Practical Conference "Information and Measuring Technologies IVT-2024": PROCEEDINGS*, Lviv: Lviv Polytech. Publ., Ukraine, 2024, pp. 22–23. Available: <https://science.lpnu.ua/ivt-2024/proceedings>
- [5] Technical Regulations on non-automatic weighing devices: Resolution [adopted by the Cabinet of Ministers of Ukraine on 16 December 2015, No. 1062]. Available: <http://zakon3.rada.gov.ua/laws/show/1062-2015-%D0%BF>.
- [6] On Approval of the Form, Description of the Mark of Conformity with Technical Regulations, Rules and Conditions for its Application: Resolution [adopted by the Cabinet of Ministers of Ukraine on 30 December 2015, No. 1184]. Available: <https://zakon.rada.gov.ua/laws/show/1184-2015-%D0%BF>.
- [7] Register of information on the approved type of measuring instruments [Online]. Available: <https://legalzvt.kiev.ua/search>
- [8] DSTU EN 45501:2016 Metrological aspects of non-automatic weighing instruments (EN 45501:2015, IDT).
- [9] Register of certificates of conformity in the NSC "Institute of Metrology" [Online]. Available: <http://www.metrology.kharkov.ua/index.php?id=978&L=0>.
- [10] On approval of calibration intervals of legally regulated measuring instruments in operation by categories: Order [adopted by the Ministry of Economic Development and Trade on 13 October 2016, No. 1747]. Available: <http://zakon5.rada.gov.ua/laws/show/z1417-16>.