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White Paper

July 2020

Keywords or phrases:
Legal metrology, obligation of verification, maximum permissible errors on initial verification or in service, quality requirement

Weighing in Legal Metrology

Use and testing of laboratory balances in legally regulated environments

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Abstract

Legal metrology imposes strict requirements on weighing instruments as the trueness and accuracy of their measurements is in the public interest. The legal obligation of verification serves to protect consumers and applies, among other things, to measurements in the exchange of goods – commercial transactions – and additionally in the areas of occupational safety and environmental protection as well as in medicine.

Yet the requirements set by legal metrology often do not meet the quality standards of a weighing application, especially in the case of highly accurate weighing of the smallest quantities on analytical and micro balances. This white paper describes the requirements and limits of legal metrology and identifies measures that help to ensure that the quality requirements of weighing applications are reliably met.

Use and Testing of Laboratory Balances in Legally Regulated Environments – Legal Metrology

Today, many laboratory balances are used as legal measuring instruments so users are obligated to comply with the requirements imposed by legal metrology. In many countries, only instruments that have a type approval certificate (type examination certificate) and have been tested for compliance with legal requirements (conformity assessment) may be used in weights and measures applications, also called legally relevant applications. A type approval certificate ensures that the design and metrological characteristics comply with the verification requirements in force.

Generally, type-approved balances are admitted to verification. In the process, EU directives apply to placing instruments on the market in Europe (1). Subsequent market surveillance, which determines, among other things, the intervals at which instruments must be tested and who may perform such testing, is regulated by national legislation and therefore varies from country to country.

The requirements on weighing instruments used as legal measuring equipment in regulated environments are described in Europe by NAWID (1) and transposed into national law by EN 45501 (2). This Standard is based very closely on OIML International Recommendation R 76 (3). The OIML (Organisation Internationale de Métrologie Légale) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls of its Member States. OIML R 76 describes the requirements on non-automatic weighing instruments and defines methods for testing to determine whether these values are met. The rules specified in OIML R 76 ensure that weighing instruments used in legally relevant applications deliver results of sufficient accuracy, thus protecting consumers.

When do balances need to be verified?

Harmonized directives apply within the European Union for placing verified instruments on the market. Sartorius balances with an EC type examination certificate are already verified at the factory – more accurately described as "assessed for conformity" – and can therefore be used for legally relevant applications without any further testing. In some countries, however, such instruments need to first be registered with the authorities responsible. If there is any uncertainty about this registration obligation in a country, we recommend contacting Sartorius Service or the national weights and measures authorities or the national metrology institute of that country.

Each country has its own rules for periodic verification, also called "subsequent verification." In particular, national laws differ in specifying their verification deadlines (frequency of the tests) and whom is authorized to carry out verification. As a rule, periodic verification consists of administrative examination, performance testing and stamping the instrument as approved, which involves affixing a verification mark. During such verification review and testing, it is determined whether the weighing instrument conforms to the verification requirements, particularly whether the differences in the measurements, i.e., deviations, do not exceed the maximum permissible errors on initial verification (more on this in the following sections).

In Germany, for example, verification is a task over which the government has sole sovereignty, meaning that only a government weights and measures (W&M) officer is permitted to perform verification. Sartorius Service provides support by preparing weighing instruments for verification, i.e., by previously testing balances to determine whether they meet the legally required tolerances and, if this is doubtful, by adjusting them or performing corrective maintenance to ensure that these instruments will pass testing by a W&M officer. Sartorius is also authorized to repair verified balances, without the customer experiencing the inconvenience of losing approval for use in legally relevant applications. In other countries, by contrast, such as in Belgium and Austria, verification is allowed to be performed by specially appointed service providers. Sartorius Service is officially appointed to carry out verification and related services directly in these countries, thus ensuring conformity. Moreover, it has a complete overview of local legal regulations and verification intervals. No matter which country you are in, contact your local Sartorius Service directly.

How can I tell whether a balance is a verified instrument?

Verified balances can be identified, among other things, by the labeling on their descriptive plate, also called "type plate." In Europe, besides indicating the instrument model and serial number, this label also includes the type, accuracy class and, next to the CE marking, the so-called supplementary metrology marking in the form of an M, with the adjacent last two digits identifying the year of conformity assessment. See also the example of a type plate given in Figure 1.

Figure 1: Type plate of an MCE323S-2CEU with the legally required inscriptions.

In addition to showing the scale interval (d) – also called "scale division" – on this label, verified balances are always additionally labeled with the verification scale interval (e), which is the decisive value for determining the maximum permissible errors of a verifiable or verified balance.
OIML R 76 (3) distinguishes among four accuracy classes defined by several criteria. Thus, for instance, the accuracy class determines the applicable weighing range, which is limited below by the minimum capacity (Min) and above by the maximum capacity (Max) of the instrument.
In legally relevant applications, it is not permitted to weigh objects or substances below the minimum capacity.
See also Table 1.

Table 1: Minimum capacity depending on the accuracy class and on the verification scale interval according to OIML R 76-1:2006.

Accuracy class	Verification scale interval e	Number of verification scale intervals n = Max/e	Minimum capacity Min
I Special	0.001 g ≤ e	50 000 ≤ n[1]	100 · d
II High	0.001 g ≤ e ≤ 0.05 g 0.1 g ≤ e	100 ≤ n ≤ 100 000 5 000 ≤ n ≤ 100 000	20 · d 50 · d
III Medium	0.1 g ≤ e ≤ 2 g 5 g ≤ e	100 ≤ n ≤ 10 000 500 ≤ n ≤ 10 000	20 · d 50 · d
IIII Ordinary	5 g ≤ e	100 ≤ n ≤ 1 000	10 · d

[1] For weighing instruments with d < 0.1 mg, n is permitted to be < 50 000.

Table 2: Maximum permissible errors for conformity-assessed weighing instruments depending on accuracy class and load according to OIML R 76 1:2006.

Load m, expressed as a multiple of the verification scale interval e				Maximum permissible error (mpe)
Class I	Class II	Class III	Class IIII	
m ≤ 50 000	m ≤ 5 000	m ≤ 500	m ≤ 50	± 0.5 e
50 000 < m ≤ 200 000	5 000 < m ≤ 20 000	500 < m ≤ 2 000	50 < m ≤ 200	± 1.0 e
200 000 < m	20 000 < m ≤ 100 000	2 000 < m ≤ 10 000	200 < m ≤ 1 000	± 1.5 e

Figure 2: Laboratory balances are often used in legal metrology applications.

Maximum Permissible Errors

Besides establishing the minimum capacity and maximum capacity, the accuracy class of a conformity-assessed balance also defines the maximum permissible error, mpe, and expresses this as a multiple of "e." These errors are provided in Table 2 for all accuracy classes.

For conformity assessment as part of initial placement on the market of a weighing instrument, the error of the value displayed may not exceed the maximum permissible error given in Table 2. When the weighing instrument is operated, the maximum permissible errors in service apply. These are double the maximum permissible errors mentioned above. The following Figures provide examples of the associated maximum permissible errors on initial verification for three different balances of the Sartorius Cubis® II series.

Example 1:
The first example shows a precision balance frequently encountered in laboratories. Imagine the following situation that can often occur for verification of this balance as a legal measuring instrument.

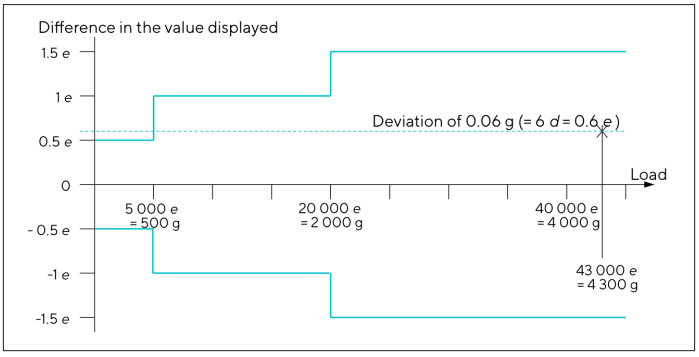

Figure 3: Maximum permissible errors for MCE8202S-2CEU (Max 8 200 g, Min 0.5 g, *e* = 0.1 g, *d* = 0.01 g), accuracy class II

The display of the balance loaded with 4 300 g shows 4 300.06 g. Is that OK? Yes, because such a difference is legally permitted for loads above 500 g.

Example 2:
Here is an example of a high-capacity precision balance:

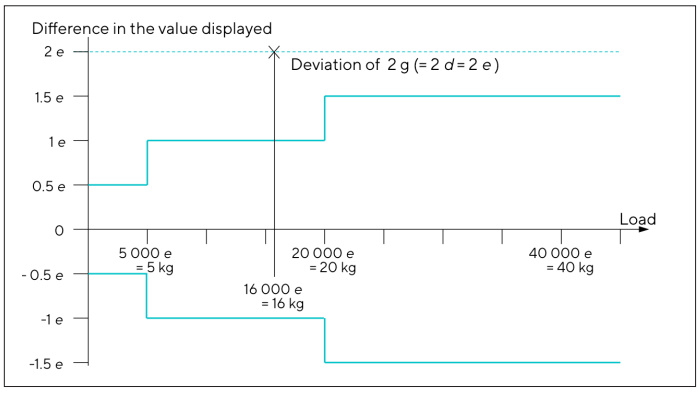

Figure 4: Maximum permissible errors for MCA36200S-2CEU (Max 36.2 kg, Min 50 g, *e* = *d* = 1 g), accuracy class II

This balance displays 16.002 kg for a load of 16 kg. Is this OK? No, because a deviation of 2 g is not within the range of the maximum permissible errors at any of the loads. Differences of 1 g (in this case, one digit) are allowed only for loads greater than 5 kg.

Example 3:
The last example shows a micro balance typically used in a laboratory.

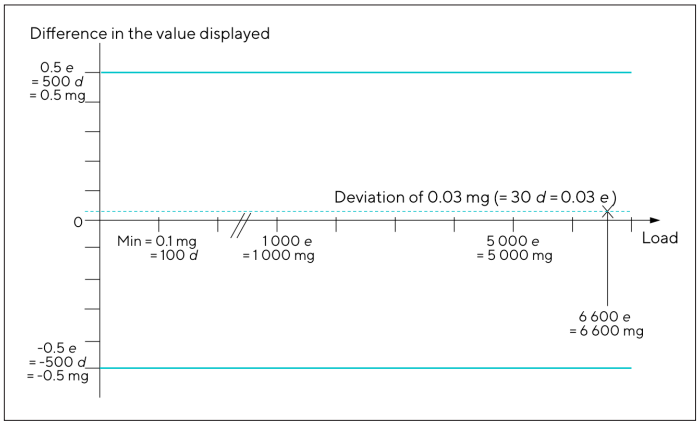

Figure 5: Maximum permissible errors for MCA10.6S-2CEU (Max 10.1 g, Min 0.1 mg, *e* = 1 mg, *d* = 1 µg), accuracy class I

This balance displays "6600.03 mg" mg for a load of 6.6 g. Is this OK? Yes, for balances that have such a high resolution, the minimum requirements of legal metrology do not represent any meaningful acceptance criteria. The reason is that in legally regulated environments, only verification scale intervals of $e \geq 1$ mg apply and, hence, there are no maximum permissible error tolerances of less than 0.5 mg.

Limitations of Legal Metrology

For very high-resolution balances, particularly analytical and micro balances, the maximum permissible errors defined in OIML R 76 (3) are frequently insufficient for meeting a customer's individual quality requirements, as shown in Example 3. The same is often true of the testing intervals governed by (national) weights and measures legislation for verification of highly accurate weighing instruments used to weigh the smallest quantities.

The reasons are two-fold: For one, the technical possibilities have outpaced legal requirements and, for another, the basic idea of legal metrology for creating generally applicable rules to ensure minimum standards is a limitation in itself. Moreover, measurement uncertainties occurring in legal metrological testing are not considered separately. The metrological requirements, such as the definition of the smallest possible verification scale interval or the lowest possible test point and the choice of maximum permissible errors already allow for such factors. For this reason, it is understandable that individual considerations of a weighing process usually result in a better assessment.

In this respect, test intervals and acceptable maximum permissible errors for meeting the criticality of a specific weighing application should be established on the basis of risk assessment for verified balances as well. Such a risk assessment usually results in the necessity of performing interim tests in addition to the legally prescribed verification testing.

These interim tests can range from daily checks done by trained staff to regular calibration performed by external service providers.

The basis for risk assessment that should be conducted individually for each instrument is to evaluate the various factors that cause a change in the weighing result. Among such factors are external influences, such as accumulation of fine particles or other contaminants on the balance, and fluctuations in the environmental conditions, as well as effects caused by the balance user. The test tolerances and intervals resulting from this evaluation should be selected to allow meaningful weighing while ensuring the reliability of the results obtained. For more information, see the respective white papers of this series (4).

Sartorius Recommendations

- Ask about which laws and requirements apply in your country: For which applications do you need an approved balance? Do approved balances need to be registered? Are there any defined intervals for verification testing? For convenient information and support, just contact your local Sartorius Service directly.
- Be sure to comply with the deadlines of legally required testing, i.e., "periodic verifications," for your balance. As a user, you are responsible that verification of your balance is still valid each time you use it (see the verification mark) and that this instrument complies with the defined maximum permissible errors in service.
- Besides complying with the defined legal requirements, establish suitable test requirements (tolerances, intervals) tailored to your weighing processes and document these and the results of your tests as well.

Literature

1. NAWID: Directive 2014|31|EU of the European Parliament and of the Council on 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments
2. EN 45501:2015 Metrological aspects of non-automatic weighing instruments
3. OIML R 76-1:2006 Non-automatic weighing instruments: Metrological and technical requirements – Tests
4. Sartorius White Paper: Test Intervals and Tolerances (How are test intervals and tolerances defined in a practical and risk-based manner?), 2020 (planned publication).

This white paper is part of our series of white papers "Best Practice Guide: Lab Weighing." Each of these are assigned a version number to allow updates and revisions to be added when periodically issued and, at the same time, to enable users to reference these as clearly as possible to maintain fully traceable quality management documents, for instance.

Version History

Version	Date	Changes
1.0	July 2020	Initial Version

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