

Avoid Serious Pitfalls when Applying Legal Metrology Rules

Legal metrology sets very strict requirements for weighing instruments used in a legal for trade application. It also sets requirements concerning the usage of these instruments. However these requirements may severely fall short of the users own process requirements and jeopardize his quality management if no complementary criteria are applied. This paper helps understand the shortcomings of legal metrology and describes complementary actions to be taken.

Introduction

Legal metrology requirements are only applicable to commercial transactions. Even if the relative regulations offer valuable information in a world where guidance is scarce, their use should be limited to their original purpose. However in their search for guidance on the correct selection and utilization of weighing instruments many users refer to the publications of the OIML and the NIST. The recommendations issued in these publications (e.g. OIML R 76-1, NIST Handbook 44) include comprehensive and important references on service approval, verification and marking. With legal for trade applications local national laws oblige the user to comply with the paragraphs found in these publications.

OIML 76-1 and Handbook 44 describe very clear rules that should finally lead to sufficiently accurate measurements for commercial transactions. Because commercial transactions are manifold, it is not possible to cover every possible application and even a complete adherence to the text may not lead to fulfill individual quality requirements. In particular, when weighing small amounts accurately, the rules specified in the referenced texts are insufficient.

Furthermore, it is important to monitor the performance of a weighing instrument continuously and the yearly or bi-yearly accredited verification of the instrument requested under local national law may not be sufficient to detect a possible drift or deterioration of the instrument's performance over time. A risk assessment should, in actual fact, set the basis of the instrument's routine verification.

This communication describes the limitations of the legal metrology approach while providing solutions to the user in search of scientific evidence that he is fulfilling his own quality requirements for accuracy, and, if relevant, also the legal for trade requirements. Additional rules and criteria (like the Minimum Weight and a Risk Analysis) to establish a sound quality management in the Laboratory and on in a production environment are presented. In the following elaborations, we will illustrate where it is necessary to use caution and which additional solutions need to be to applied.

Legal Metrology vs. Process Requirements

For commercial transactions where product is sold by weight, or weight sets the basis for a tariff, etc. it is a legal obligation that weighing equipment is approved, verified and marked as 'legal for trade'. This means that the equipment has successfully passed a stringent set of tests to ensure it is sufficiently accurate to obtain type approval.

Four accuracy classes are found in OIML R 76-1 & NIST 44. For each class several criteria are defined such as an applicable weighing range that is limited in the low end by the 'Minimum Capacity' (OIML R 76-1) or 'Minimum Load' (NIST Handbook 44) and at the upper end by the instrument's maximal capacity.

These 4 classes and their criteria help the user to select an instrument appropriate for his use. Then, after an Initial Verification, a weights and measures authorized inspector will on a regular basis inspect, test, re-certify and mark the instrument for another period of legal for trade approved usage. The test limits differ between an Initial Verification and an In-Service Verification (see below). Outside the specific scope of commercial transactions, the user has to define by himself the tolerances he needs to fulfill and he has to propose a quality management strategy that is in conformity with the regulation he has to fulfill (e.g. GMP, ISO, HACCP, etc.). Surprisingly sometimes these requirements may also include legal for trade approvals., even if the application is not part of a commercial transaction.

Legal Metrology Requirements: Limits of Accuracy

The accuracy requirements defined by OIML R 76-1 for all classes (the NIST Handbook 44 is very similar) include the definition of Maximal Permissible Errors (mpe) over the measuring range of the instrument. The measuring range is split into 3 ranges for which a different mpe will apply. The mpe and the ranges are given as multiples of 'e' (NIST HB44 uses 'd'), where 'e' (respectively 'd') is the verification scale interval of the instrument.

Two different mpe values are defined if the instrument is undergoing an Initial or an In-Service verification. An In-Service Verification allows for mpe's that are double those of an Initial Verification. Let's have a more detailed look at the In Service tolerances as they set the limits for an instrument for most of its lifespan.

Ranges	mpe
0e - 500e	+/- e
501e - 2000e	+/- 2e
2001e -	+/- 3e

In a range between 0 and 500e, the in-Service mpe is +/- e. For the next measuring range between 501e and 2000e, the in service mpe is of +/- 2e. Finally in the range starting with 2001e up to the end of the measuring range the mpe is 3e.

Let us now calculate the effective relative error an instrument should have if its verified mpe reaches the maximal limits. This would be the worst possible instrument still fulfilling the legal for trade requirements for In-Service Verification. The relative error of this instrument is calculated by dividing the In-Service mpe by the upper and lower limit of the defined range.

As example we make the calculations for a class III scale with a 3000e resolution.

$$E = \frac{3 \cdot e}{3000e} = \frac{3}{3000} = 0.1\%$$

E = Relative Error.

This means that the relative error is < 0.1% at the end of the measuring range. Repeating this calculation for the other points we obtain:

Ranges	E at Lower Limit [%]	E at upper limit [%]
e - 500e	50% → ∞	0.2%
501e – 2000e	0.4%	0.1%
2001e -	0.15%	0.1%

According to the above figures an approved instrument is very accurate in measuring ranges 2 and 3 (the relative error limits are 0.1% and 0.4% respectively) but in the measuring range 1 we detect a problem while calculating the relative error for smaller weights. The relative error follows a hyperbole and approaches infinity. To illustrate this fact we have calculated the relative error at e and not at 0. This is the reason why a Minimum Capacity (Minimum Load) needs to be considered. Typically it is set to 20e (respectively 20d) for a weighing instrument of Class III.

At 20e, the relative error limit reaches a maximum value of 5%. Measuring below the limit of 20e is only permissible in presence of the customer. So a class III instrument provides a measurement uncertainty limit comprising of between 0.1% (end of ranges) and 5% (Minimum Capacity resp. Minimum Load).

We can proceed similarly with the other classes defined under OIML 76-1 and NIST Handbook 44 with similar findings.

Process Tolerances

For purposes of quality assurance, a company needs to define process tolerances that must be fulfilled at all times. Typical tolerances are:

- 0.10% for materials to be accurately measured according to the United States Pharmacopoeia (USP) General Chapter 41
- 0.1% - 1% for the Pharmaceutical, Cosmetics and Nutraceuticals Industries
- 0.5 – 2% for the Food Industry and other Manufacturing Industries.

In practice the most frequently applied process tolerance is 1%, meaning that a measurement is considered accurate if the effective quantity of material on the weighing pan is within +/-1% of the indicated value.

It is obvious that most of the time these process tolerances may not be achieved when small quantities are weighed under strict application of the requirements of OIML R-76 1 or NIST Handbook 44. Measurements in the upper weighing range are mostly unproblematic except when the USP is considered. It is obvious that a class III instrument would never systematically fulfill the requirements of the USP. Considering that smaller ingredients of a formulation are normally the critical ones, it becomes obvious that additional criteria to those of legal metrology need to be introduced.

Process Tolerances and Minimum Weight

The concept of Minimum Weight results from the consideration that the relative measurement uncertainty of a weighing instrument follows a hyperbole and approaches infinity when small amounts are weighed. There is therefore a lower limit for which the required process tolerance is justly fulfilled. This limit is referred to as the Minimum Weight. Below this limit the measurement uncertainty of the instrument is such that it is superior to the required process tolerance. More information on how to derive the Minimum Weight can be obtained from the following source: ► www.mt.com/gwp-library

The Minimum Weight is calculated as follows:

$$M_w = \frac{U}{A}$$

Where:

- U is the expanded measurement uncertainty of the instrument at a given weight
- A is the required accuracy (process tolerance).

The Minimum Weight is the absolute lowest measuring point where the process tolerance is still achieved. During routine use, weighing at this lower limit is however not necessarily valid for routine purposes because of the variability of the environment and its influence on the weighing process. It is therefore recommended to include a safety factor (a multiple) at this lower limit. Typically a Safety Factor of >2 is considered a good value. Practically this means that the smallest net sample weight to be weighed should not be lower than the verified minimum weight x 2.

We have now 2 applicable criteria to limit the measuring range of a scale or a balance: The Minimum Capacity (respectively the Minimum Load) and the Minimum Weight.

Both have different purposes and both must be fulfilled at the same time when a legal for trade approval is required and additional quality requirements are defined.

The Minimum Capacity (Minimum Load) assures compliance to legal for trade requirements while the Minimum Weight assures that quality relevant accuracy is fulfilled at all times.

Monitoring of Accuracy via Routine Testing

It is common knowledge that the performance of a weighing instrument will change over time (wear and tear, dirt, accidents, etc.). The changes can be such that the measurement uncertainty of the instrument doesn't fulfill the requirements for process tolerances anymore. A monitoring strategy is therefore required. This is referred to as routine testing of a weighing instrument.

Legal for trade requires that the instrument is verified by a qualified inspector once every year or every second year (depending on the local national regulations). This is most of the time not sufficient for a user who looks to achieve consistent process tolerances.

A sound approach is to derive the routine testing strategy from a risk analysis. Depending on the level of risk and on the process tolerance required a different frequency of verification will be applied. The rule is that for processes where inaccuracy leads to a high impact (severe negative consequences) a higher frequency of verification is required and vice versa. The probability that a wide tolerance is not achieved by a given instrument because of drifting is lower than for a narrow tolerance. Therefore the frequency of verification increases when the process tolerance gets narrower. The combination of the impact and the process tolerance assessment are the building blocks of the risk analysis.

Determining the frequency of testing is not the only task a user has to consider. He also has to select which test will lead to clear decision criteria, which weights to use for conducting the tests, which warning and control limits to apply and how to correctly execute the tests. The reader can refer to the following source for more information about this subject.

► www.mt.com/gwp-library

Conclusion

Before selecting weighing equipment a user shall determine precisely his needs. If he has to comply with legal for trade requirements, he has no choice than to select an instrument that has been approved for such a usage. But before final selection it is imperative to consider the quality requirements and assure that the instrument can also achieve these requirements (e.g. process tolerance and measuring range).

A risk analysis is essential to assess the criticality of the weighing process in order to determine what kind of routine testing will be required and with which frequency. Consequently standard operating procedures can thus be defined.

The procedures described in this document will therefore help to fulfill both legal and quality requirements when evaluating and selecting the optimum weighing instrument for specific purposes.

Find more technical references on

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