RISK ANALYSIS IN PHARMACY FOR PROCESS OF MASS DETERMINATION

Routine Tests in Pharmacy

RADWAG®

Content

1. Measuring instrument life cycle

Life cycle of a measuring instrument start from evaluation of operator's requirements. At this stage the operator should be familiar with production and control aspects. It is necessary to define one's expectations regarding a balance. Presently, a balance is expected to offer more than just a reliable measuring result, like cooperation with company network, compatibility in sending data to other devices.

The other important aspect is proper selection of a balance, which meets the requirements. Here, the operator should compare balance features with economic aspect, service reaction to defect, adaptation possibilities. Installation of balances with low readabilities is a job for company control department. In case of high precision balances, like microbalances, ultra-microbalances, they should be installed by authorized service of the manufacturer. This way, the parameters of a b lance will be adjusted to company profile and realized processes. This includes filter settings, and stability criteria setting. These activities are also offered and performed by RADWAG personnel as a supervision packet over a balance (technical inspection book).

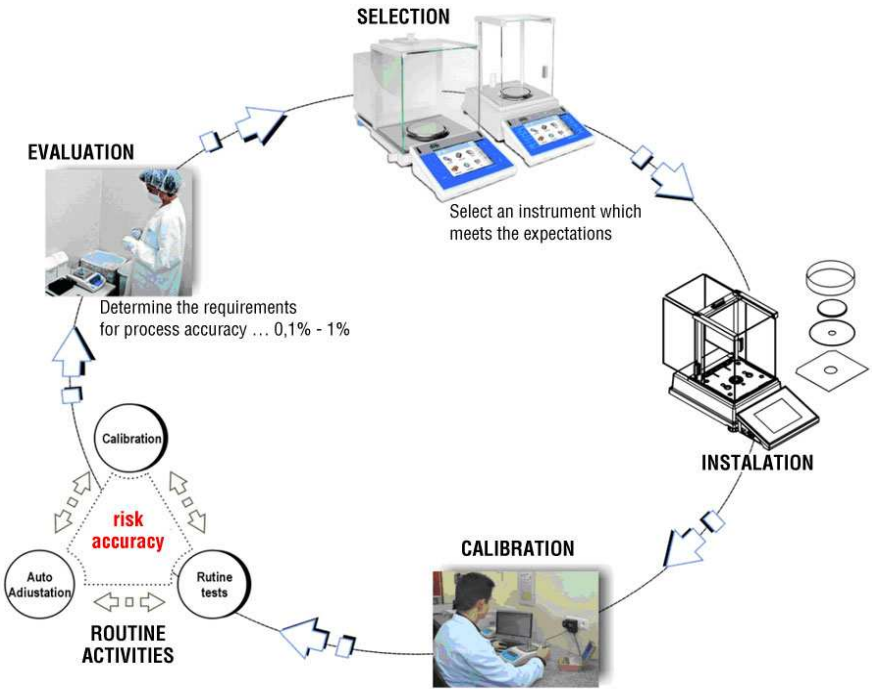

Fig. 1.Life cycle of a measuring instrument

Calibration of a balance is a inseparable part of life cycle of a measuring instrument. It determines the actual balance errors. Calibration should be connected with determination of minimal mass, if such data is necessary.

Routine activities are all the work that is performed by an operator that aims at decreasing level of risk which occurs in weighing process. Risk decreasing activities also include calibration and adjustment processes.

2. Balance routine examination

Routine tests are a means to guarantee proper accuracy of an instrument which is used for analysis , and for minimization of possible error occurrence. The basic aspect of routine examination refers to its intervals:

How often should routine texts be performed?

Routine tests can be performed according to company accepted intervals. Then, it is assumed, that between the tests, a balance operates properly, i.e. its indications are within set acceptance thresholds. In such case, it is helpful to introduce two limits for controlled parameters. The first one is cautionary limit, which exceeding does not affect balance operation.

The other one is a critical limit, which exceeding causes balance recognition as defected if utilized in this specific range. In case of sensitivity control, it is necessary to consider actual balance error for loads below max capacity, like 50% Max. in such case balance error can occur as acceptable. And so, exceeding of limit no. 2 does not always result is separating a balance and recognizing it as out of order.

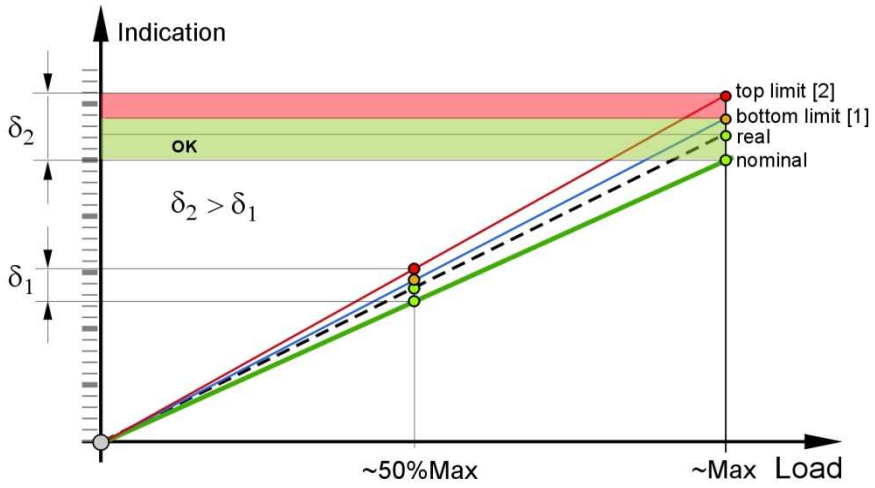

Chart. 2. Sensitivity drift – cautionary limits

Then a question emerges, on the criteria according to which a balance should be checked. Generally, it can be assumed that:

- It depends of expected weighing accuracy
- It depends on parameter which is tested
- It depends on weighing process and its acceptance within specified thresholds

The other approach is testing a balance before each measurement process. It is possible practically only if a balance is not on heavy duty (relatively low quantity of measurements, and a couple of operators). In such case it is necessary to create a specific procedure, according to which a balance will be tested. Test results should be noted down with date , time and operator code. However, application of such procedure may be a problem, as it requires very high exploitation of mass standard, and supervision over this mass standard.

Thus, is it possible to decrease test frequency?

It is recommended to decrease quantity of tests. A balance is a working device, and too frequent tests may disturb its working cycle. It is recommended to observe stability of balance parameters and with regard to their results increase or decrease quantity of tests. Analysis accuracy is the main factor here, and test frequency should be adjusted according to it. Generally, the rule is:

high risk = frequent tests

3. Low mass measurement

When a balance is used only for weighing samples of mass up to 5% balance maximal capacity, the only justified test is repeatability control. In this case, it is assumed that even if prominent tare is used, e.g. 30% of Max capacity, it is still located at the central pan point. For low mass measurement, other balance errors influence deriving from linearity, sensitivity change or eccentricity, is negligible.

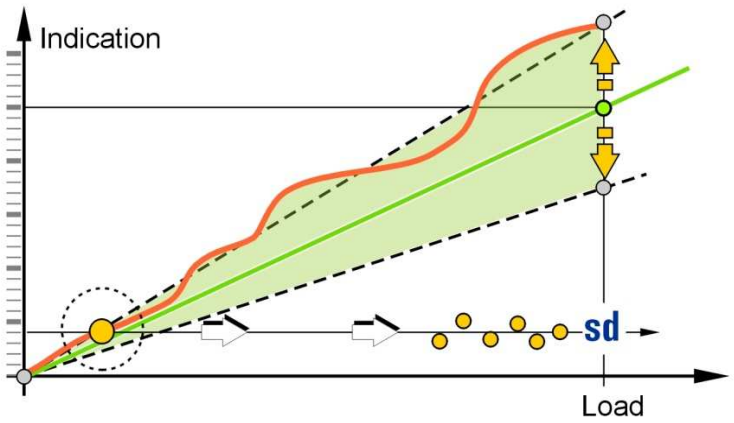

Fig.3 Low mass measurement – parameter checking

4. All-purpose balance

Optimal solution for balances is their utilization at 100% which in practice means good measurement ability for light and heavy loads. In case of such balance, sensitivity drift should be checked more often.

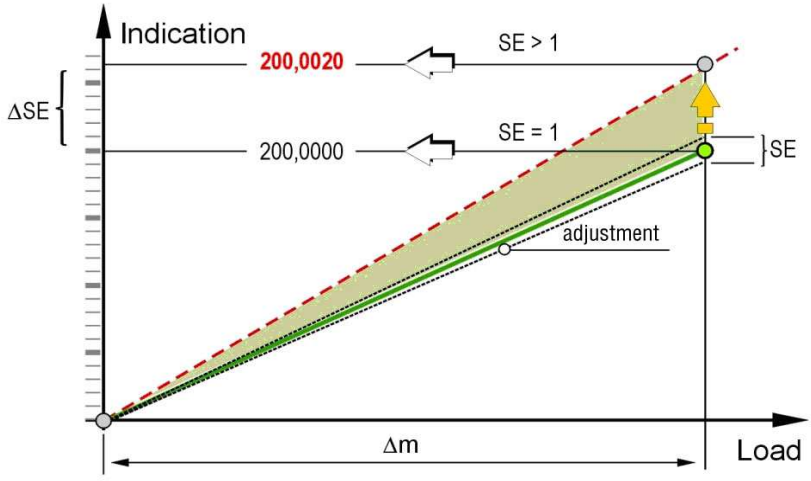

Fig. 4 Sensitivity change test – balance adjustment

Sensitivity drift can occur even though most balances are equipped with self-adjustment system. It can be caused by device drift as a result of ambient conditions change. If it occurs, than situation from drawing no.4 takes place.

As practice shows, most organizations test only adjustment effectiveness, and balance accuracy is controlled after adjustment with mass standard with precisely specified weight. Balance indication

is not checked according to elapsing time from last performed calibration. In such case the result would show stability of balance indications in time, which is stability of sensitivity.

According to good measuring practice, before taking a measurement, an operator is to perform adjusting procedure. Then all errors connected with sensitivity changes are leveled. After the operation, error-free value should not be expected, because adjustment process relates to mass weighing, and has been already said, there are not ideal measurements.

5. Summary

1. Sensitivity change test should be performed only in case of heavy loads weighing.

2. Repeatability test should be performed mainly during low mass measurement, as it is main source of errors. It does not mean, that this parameters should be neglected if heavy loads are weighed. Heavy loads measuring process creates a risk of stroke if a load hits a weighing pan and damages precise mechanism of a balance.

3. Eccentricity should be checked if weighed loads have big dimensions or untypical shapes. In such cases the load may not have central position on the weighing pan. Errors resulting from eccentricity may be avoided if special holders for weighed object are applied.

4. Non-linearity – does not refer to low mass measurements. This parameter is stable in whole measuring range of a balance, and its share in error budget is relatively low. In most cases non-linearity error results from not repeatable operation of a balance.

5. Intervals defining balance testing should take into account: range of jobs performed on a balance, their intensity, balance stability in time and expected weighing process measurement precision. Assuming that external conditions are stable, following balance parameters control periods can be fixed:

   - calibration annually
   - repeatability monthly
   - centricity monthly
   - sensitivity change weekly
   - adjustment daily

Above specified parameters for balance control are not obligatory. Each metrological unit should establish the requirements and specifications for balance operation.