ISO 9001:2015 and Weighing
Managing Risk and Quality

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ISO 9001:2015
The changes and their implications for weighing devices

This white paper will be of interest to managers from any organization in any industry that follow ISO 9001 and use any type of weighing devices or processes in the course of their business.

The aim of this white paper is to:
1. Explain the changes in the revised standard of ISO 9001:2015 and describe the timeline associated with transition to the new version.
2. Look at the effect of these changes on weighing devices and weighing processes, as weight measurements are a critical process step which can significantly affect quality.
3. Provide guidance and recommendations on how to consider weighing devices in order to meet the process requirements and risk-based thinking approach outlined in the revised version of ISO 9001.
4. Introduce the firmly established Good Weighing Practice™ strategy which fully supports the risk-based process approach and explain how this already complies with ISO 9001:2015 and can be easily implemented into a Quality Management System.
1. **Introduction**

1.1. What is ISO 9001?

ISO 9001 is a standard that sets out the requirements for a quality management system. It helps businesses and organizations to be more efficient and improve customer satisfaction. "ISO 9001 certification is helping companies to improve their sales and costs". [1] The ISO 9001 standard is now in its fifth revision.

1.2. Why has ISO 9001 been updated?

The main reason for the current update, according to ISO, is to "respond to the latest trends and to be compatible with other quality management systems" [2, 3]. The challenges faced by business and organizations have changed significantly in the last decade. Increased globalization and reduction in trade barriers means that organizations are now trading across borders more easily. Supply chains have become more complex, and there are increased expectations from customers, with more access to information.

The Chair of the ISO subcommittee states that the revisions have been made to "adapt to a changing world" [3] and allow customers to use the standard in parallel with both their customer’s as well as applicable regulatory requirements. The standard specifies requirements for a quality system when an organization delivers products and services that meet customer and regulatory requirements and they would like to enhance customer satisfaction [4]. A revision of ISO 9001 was needed to reflect some of these changes in order for the standard to remain relevant.

1.3. What are the main changes in ISO 9001:2015?

**High-Level-Structure**

ISO 9001 has a new structure and now follows the same overall High-Level-Structure (HLS), developed within the ISO community, as other ISO management system standards. This provides consistency and makes it easier for anyone using multiple management systems (e.g. environmental management, quality management).

**Leadership and commitment**

The ISO 9001:2015 revision requires top management to demonstrate leadership and commitment to the Quality Management System (QMS). It makes management accountable for the effectiveness of the QMS, ensuring resources are available, and promoting continuous improvement. However, the use of the process approach and risk-based thinking is not just the responsibility of management. It should be everyone’s business, and should become an integral part of the organizational culture. In other words, quality becomes a company-wide practice and not solely the specific responsibility of the quality manager, or the quality department.
**Process approach**

The process approach has been an important part of ISO 9001 since 2000 and continues to be in the 2015 version. The revision has a focus on improved process performance by adopting a Plan-Do-Check-Act (PDCA) cycle to manage processes, and the interaction of those processes as a system, with an overall background of risk-based thinking. It is important to recognize that not all processes have the same impact on an organization’s ability to deliver conforming products and services. Moreover, the new changes are not prescribed, but are left to the manufacturer to evaluate based on their processes, associated risks and their customer’s expectations for high quality.

![Figure 1: Plan-Do-Check-Act (PDCA) Cycle](image)

**Risk-based thinking**

One of the key changes in the 2015 revision of ISO 9001 is a focus on risk-based thinking. Whilst risk-based thinking has always been a part of ISO 9001, the 2015 version gives it increased prominence by building it into the whole management system. In previous editions of ISO 9001, a clause on preventive action was separated from the whole. The aim is to establish a systematic approach to considering risk, rather than treating “prevention” as a separate component of a quality management system. Risk-based thinking is part of the process approach [1].

1.4. What does it mean for me?

The latest revision to standard ISO 9001:2015 was published in September 2015. There is a three year transition period to allow time for an organization to implement the changes. This means that all ISO 9001 companies must adopt the changes in the new version by September 2018 to remain certified. After September 2018, ISO 9001:2008 certificates are no longer valid. Ultimately any companies who do not make the necessary changes may lose the possibility to sell their products or services to companies who require ISO 9001 certification as a means to conduct business.

![Figure 2: ISO 9001:2015 timeline](image)
2. Why is it important to adopt a process approach?

The key aim of this paper is to discuss how the new revision applies to weighing devices, because weight measurements can significantly affect the quality of a product. ISO 9001:2015 section 0.3.1 states that the purpose of the new revision is:

ISO 9001:2015*
0.3 Process approach
0.3.1 [...] promotes the adoption of a process approach [...] to enhance customer satisfaction by meeting customer requirements.

[...] The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization*.

* all grey highlighted boxes are direct quotations from the ISO 9001:2015 standard

This statement discusses what shall be achieved, but not how it will be achieved. For example, weight in a formulation can affect many characteristics of the final product, such as the appearance, taste, color, efficacy, viscosity, or concentration, to name but a few. Balance and scale users have historically chosen their weighing device either by following weights and measures specifications or by the readability/resolution listed on a specification sheet or webpage. Further to this point, many believe that: "If I can see a gram on the device's display then this must be indicative of the accuracy"; i.e., 1 gram.

Your accuracy ≠ readability or resolution

We need to go deeper to understand the implications. In these examples, users have not fully considered the "results", or weight measurements, which they would like to obtain nor have they fully considered the end customer’s expectations for high quality. You might ask then how do we choose the device that is fit for the purpose at hand?

2.1. How to define "Your Accuracy"

When YOU define the accuracy, instead of relying on external recommendations like weights and measures, or instrument manufacturer’s specifications, you align your measuring processes to enhance your customer’s satisfaction. Moreover, your accuracy becomes the foundation for continuous quality improvements because maintaining and tightening the accuracy requirements lead to further improvements in your products.

Accuracy = trueness + precision
ISO’s definition of Accuracy:
A simple ISO 5725 reference definition uses the two terms "trueness" and "precision" to describe the accuracy of a measurement method. "Trueness" refers to the closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted reference value. "Precision" refers to the closeness of agreement between test results [5].

Figure 4: Accuracy is the combination of trueness and precision

Figure 4 illustrates:

a) These results would be considered true because they are centered around the "bull's-eye" but the shots lack precision because the grouping is not tightly clustered.

b) The results are precise because they are tightly clustered and repeatable. However, they lack "trueness" because they are not clustered around the center of the target.

c) These results are both true (centered) and precise (repeatable) and can be considered accurate.

In an accurate weighing device all the results are in the center. In an accurate high-precision weighing device the results are clustered even more closely together.

Figure 5: Filling powders into bottles in the pharmaceutical industry

As an example: if you fill 1000 containers with powder, you would want to ensure that all containers contained exactly the same amount of material – not less and not more. This is where "your accuracy" is relevant, as you can specify the "fill weight" and the tolerance that you want to achieve by absolute or relative value.
Weighing tolerance = \( \frac{\text{allowed variation}}{\text{target fill weight}} \)

As an example: if your target fill weight is 100 g then an acceptable variation might be 0.1 g, which equates to a weighing tolerance of 0.1%.

Therefore, if your definition of accuracy is 0.1%, then your goal would be to fill containers with amounts ranging between 99.9 to 100.1 g.

Your accuracy = your specific measurement requirement defined as a tolerance (%)

This tolerance can now be used to define the accuracy of the measurements for each of your weighing processes, or all the measurements within one process, such as a formulation.

Under-, or over-filling a container would have consequences for image and profitability: under-filling can cause damage to your reputation and legal issues; overfilled products are basically being given away for free, as they are not paid for by the end-customer.

If you have chosen a specific readability you need to ensure that the measurement is what you think it is and can be repeated if your goal is an accurate measurement. Weights and Measures specifications, while useful in transactions between businesses and consumers, don't necessarily use tolerances that relate to YOUR business. By defining your own measurement tolerances ("Your accuracy") you take a very large step towards the enhancement of customer satisfaction. This enables you to undertake measures to ensure that the weight is always correct according to the needs of your business, consumers and your expectations for high quality. Defining "your accuracy" as a tolerance allows you to define your process requirements for each measurement. From this point you may either tighten, or loosen the tolerance until you find the perfect balance between cost and quality.
3. What is risk-based thinking?

Risk is inherent in all aspects of a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are identified, considered and controlled throughout the design and use of the quality management system. By using risk-based thinking the consideration of risk is integral. It becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

In ISO 9001:2015 risk-based thinking needs to be considered from the beginning and throughout the system, making preventive action inherent to planning, operation, analysis, and evaluation activities.

ISO 9001:2015
0.3.3 Risk-based thinking
Risk-based thinking is essential for achieving an effective quality management system. […] To conform to the requirements […] an organization needs to plan and implement actions to address risks and opportunities.

Previously risk was implied in ISO 9001 – the 2015 revision refers to it more explicitly, emphasizing quality management standards that take steps to mitigate the risks. Risks are repeatedly referred to in the context of safety, but there are also business risks that must be considered, including:

- Quality
- Cost and profitability
- Efficiency and productivity
- Waste of materials, process goods and environmental safety
- Compliance
- Customer satisfaction and happiness – brand image

3.1. How are risk and weight related?

ISO 9001:2015
4.4 Quality management system and its processes
4.4.1 […] The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall:
(f) address the risks and opportunities […]
(g) evaluate these processes and implement any changes needed […]

Risk is defined by two parameters: the probability or likelihood that the harm will occur; and the severity or impact or the seriousness of the harm. A typical risk analysis (see Fig. 6) plots the likelihood of an incident, such as poor quality, against the impact of that incident.
For example: your customer wants your products to taste "just right" and they require that each batch of product tastes the same. However:
- Is there variation in the taste of the product due to variability in the amount of spices that are added to the mixture?
- Is this variability the result of the wrong (or improperly maintained) balance or scale being used for the process?

3.2. What risks are related to weighing?

Here is a different perspective which looks at two important sources of risk. Risk related directly to weighing and the measurement of weight can potentially have two different forms of impact (as shown in Fig. 7):

1. Impact on your business
The first form of risk relates to the impact of the measurement on your business; for example, profitability. Profitability is at risk when you give away too much product (i.e. overfilling) or when you use too much of an expensive and important component. Bad batches, or expensive time consuming adjustments, cause production inefficiencies.

2. Impact on consumers
The second important form of risk is the impact of the measurement on consumers. Could inaccurate weighing results cause injury or damage to a person or the environment? Even if a risk is discovered, sometimes at a late stage, the discovery might trigger an expensive, image damaging, product recall. In the worst case, the discovery is made by consumers who are harmed by a poorly manufactured product. If poor measurements and related quality problems could be discovered before the product leaves the facility, by a defect-detecting means, then the risk to the consumer would be lessened to the degree of confidence in the detection method.
As mentioned previously, in the traditional risk analysis, probability is plotted against impact and the means to mitigate the risk are initiated. One alternative is to assume that the probability is relatively high and substitute likelihood with accuracy. If the risk is high, then logically you can correctly assume that increasing the accuracy is a means to partially mitigate risks due to inaccurate measurements; however, this doesn’t mean that all high accuracy applications are high risk.

In Fig. 8, the tolerance is related to the qualitative description of accuracy, or weighing tolerance. The tolerance value is something that you should decide upon, either through experience or by the tolerance calculation method described in chapter 2.1. This is an initial step in the risk mitigation process; the other steps involve selecting and maintaining the weighing device, calibrating and routine testing according to both weighing tolerance (your accuracy) and risk. Combining both of these methods will give you a clear opportunity to improve your weighing processes.
Figure 9: Using accuracy (weighing tolerance) to plan risk mitigation steps

Note: the "Under Specified" category in Fig. 9 relates to "high impact processes", where the "accuracy is low". Since this is an atypical condition, a low accuracy device would not be appropriate. This situation usually arises due to selection of balances and scales based on readability instead of "your accuracy".

For example: you notice that you have an unused scale in inventory with a readability that is similar to your smallest sample size. Without specific knowledge relating to "your accuracy" this scale should not be moved into production. First, the scale would need to be calibrated first to discover its measurement uncertainty at the point of use before ascertaining if the scale is suitable for this application.
4. Lifecycle Planning – an ideal strategy for risk mitigation

Every measuring device should be calibrated and adjusted when deviations are found. It is important to perform some type of testing between calibration intervals, in order to ensure accurate measurement performance is being maintained. This is recommended in the new wording of ISO 9001:2015:

ISO 9001:2015
9.1 Monitoring, measurement, analysis and evaluation
9.1.1 General
The organization shall determine:
(b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
(c) when the monitoring and measuring shall be performed;
9.1.3 Analysis and evaluation
[...] The results of analysis shall be used to evaluate:
(e) the effectiveness of actions taken to address risks and opportunities

However, this extract from ISO 9001:2015 does not give specific recommendations regarding the actual use and care of weighing devices. Therefore, we suggest that the most effective method to care and maintain your weighing devices is to schedule the following activities at intervals based on risk:

- Preventative maintenance (PM)
- Routine testing (RT)
- Calibration (CAL)
- Adjustment (ADJ)

In simple terms, if a measurement is considered low risk then PM, RT and CAL can be carried out less frequently. Whereas, weighing devices performing high risk measurements will require more frequent PM, RT and CAL. However, these frequencies should be increased in situations where the weighing devices are subject to harsh conditions such as rough handling, wash-down, frequent use (> 200 measurements per day) and accumulated materials. Ultimately, it is the responsibility of the user, in discussion with the instrument supplier, to decide what service intervals are necessary for a particular application.

A brief definition of these terms:

<table>
<thead>
<tr>
<th>Service Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive Maintenance (PM)</td>
<td>Measures undertaken by your staff to ensure that devices continue to deliver accurate results. For example, remove anything which would prevent free movement of the weighing mechanism.</td>
</tr>
<tr>
<td>Routine Testing (RT)</td>
<td>Measures undertaken by your staff or service provider identify potential problems between calibrations. They consist of trueness (sensitivity, or error of indication) testing, repeatability (precision) testing and eccentricity testing, using appropriate test weights to manufacturer’s specified tolerances (called warning and control limits). These tolerances (limits) act as an early warning that indicates that your device may be drifting out of specification.</td>
</tr>
<tr>
<td>Calibration (CAL)</td>
<td>Activities performed by a qualified service provider to confirm the device’s performance and to establish the measurement uncertainty of the device.</td>
</tr>
<tr>
<td>Adjustment (ADJ)</td>
<td>Sometimes also mistakenly called “calibration”. Adjustment is a set of operations that are performed when the device’s sensitivity (trueness) or eccentricity is out of the specification or predefined tolerances. A typical adjustment is always followed by a calibration to ensure that the adjustment was correct. The result of the new calibration is a new statement of measurement uncertainty for that device.</td>
</tr>
</tbody>
</table>

Table 1: Definition of service activities undertaken to reduce weighing errors
4.1. Mitigating the likelihood of inaccurate results

Inaccurate weighing results can have a significant impact on the quality of a final product, but it is up to you to determine the potential effect. Only when the potential risk of inaccurate weighing has been established, can you then establish mitigation steps. Let’s refer back to ISO:

ISO 9001:2015
4.4 Quality management system and its processes
4.4.1 […] The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall:
(f) address the risks and opportunities […]
(g) evaluate these processes and implement any changes needed […]

As previously explained, routine testing should be performed either by your staff or by a third party (service provider). The ideal strategy would be to carry out routine testing between calibration intervals to confirm that your devices are still performing according to your requirements. This will ensure continuous high quality.

ISO 9001:2015
7.1.5.2 Measurement Traceability
When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:
a) calibrated or verified, or both, at specified intervals, or prior to use […]

Fig. 10 shows an example of how calibration and routine testing are planned. The black line represents a change or drift of the measurement value from the initial calibration. Routine testing occurs more frequently as a means to mitigate risk when the adjusted values in a scale or balance have changed over time.

A good example of such an occurrence is when a device is operating at a different temperature than the temperature at which it was calibrated and adjusted. If the device does not have an automatic adjustment system (FACT*) to compensate for the impact of temperature changes on a measurement, then the weight value could affect the quality of your product. A routine test will discover such a situation. If the weight value is beyond the control limit then a calibration is performed, followed by an adjustment to bring the device back into proper operating status.

* FACT, Fully Automatic Calibration Technology – included in selected Mettler Toledo devices.
4.2. How many calibration and routine testing cycles are necessary for my process?

This is where risk analysis can be useful in your planning. Low risk, low accuracy devices can be calibrated annually and routine testing should be carried out on a semi-annual basis. However, high risk, high accuracy devices should be calibrated and tested more frequently to mitigate these more significant risks.

For example: a freight scale can be calibrated less frequently because its accuracy requirements are low. The consequences of an out-of-tolerance situation are less significant and the back charge penalties incurred are relatively small – as compared with a high risk situation that could cause risk to both the company and the consumer, such as an active ingredient in a batch.

Following a risk-based plan ensures that you perform the relevant testing at appropriate intervals for your process. This allows you to improve your quality and save time, whilst maintaining full compliance to national and international standards.

4.3. Test weights used for routine tests

Routine testing weights (standards) are an important contributor to the traceability because the "closeness of agreement between the test result and accepted reference" is the ISO definition of accuracy. There are two sources of standards for these reference standards:

- **OIML R 111-1 [6]**
  OIML concentrates only on SI units (metric) and is recognized as the international standard.
- **ASTM 617-13 [7]**
  ASTM weights cover both SI (metric) and pounds and is considered a national standard.

A calibration certificate following Euramet cg-18 includes the weight tolerances, defined as maximum permissible errors (MPE), in the calculation of measurement uncertainty. The larger the MPE of the weight, the larger the uncertainty described in a calibration certificate. The class of weights is normally selected based on "your accuracy" requirements.
4.4. Which standards should be used?

Should I use *my accuracy* or other standards? Let’s refer to ISO 9001:2015:

**ISO 9001:2015**

7.1.5.2 Measurement Traceability [...] measuring equipment shall be:

(a) calibrated or verified [...] against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

In effect, there are no national or international weighing standards specific to weight measurement in industry except those specific to legal metrology, e.g., protection of the consumer against fraud. They do not address the need for continuous improvement so responsible users (or applied metrologists) must consider using their own accuracy requirements to improve quality as described in chapter 2.1: How to define *"Your accuracy"*? By defining and adhering to your own tolerances you have a very strong methodology to stabilize and improve your products. In most cases, you will far exceed the legal tolerances.

![Figure 11: Standards and their benefits](image)

Good measurements fall within acceptable limits when your process weighing tolerance is greater than the determined measurement uncertainty of your device [8].

**Process weighing tolerance > device’s measurement uncertainty**

This measurement uncertainty is determined through calibration. The determination of measurement uncertainty follows the international standard Euramet cg-18 [9]. With the statement of measurement uncertainty it is possible to compare your weighing device to *"your accuracy"* defined as your tolerance. This is what can be referred to as *"verification"* in the standard. If you use a safety factor in combination with your process weighing tolerance you will see marked improvement in the reliability of your measurements.
4.5. What is a safety factor and why should I use one?

A safety factor is a method to compensate for all influences on weighing that haven’t been considered in your planning, such as environmental influences (temperature changes, slight vibration, light breezes, etc.) in the immediate vicinity of the workplace, or variability in user technique [10]. It is important to use a safety factor when choosing and using balances or scales, because it minimizes the risk of the weighing measurement falling outside of the expected parameters and ensures the results will be accurate. This safety factor is assigned to the weighing tolerance. If you haven’t yet chosen a safety factor, please consider the method described in Fig. 11.

<table>
<thead>
<tr>
<th>Process weighing tolerance ÷ safety factor &gt; device's measurement uncertainty</th>
</tr>
</thead>
</table>

### Rule of Thumb

A safety factor ensures reliable measurements

<table>
<thead>
<tr>
<th>Your Considerations for Safe Weighing</th>
<th>Safety Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>No considerations for variations in the device, operators or environment. High potential for Out of Specification (OOS) results.</td>
<td>1</td>
</tr>
<tr>
<td>Devices are installed in an ideal environment. Not recommended due to statistical variations. Potential for OOS results.</td>
<td>1.5</td>
</tr>
<tr>
<td><em>Laboratory conditions</em>, insignificant environmental influences, one or two operators.</td>
<td>2</td>
</tr>
<tr>
<td><em>Production conditions</em> - accounting for one or two low-magnitude influences such as temperature variation or low-frequency vibration, several operators.</td>
<td>3</td>
</tr>
<tr>
<td>Increasing levels of safety consideration accounting for many low-magnitude environmental influences, several operators, heavy usage or accumulated debris, varying tare containers. Portable scales.</td>
<td>4-10</td>
</tr>
</tbody>
</table>

Note: Higher-magnitude variations in environmental conditions (temperature, vibration, wind) must be eliminated. In these cases, increasing the safety factor will not bring the desired results.

Table 2: Considerations in choosing a safety factor for weighing
5. How do I identify and safeguard my weighing equipment?

During the process of calibration and verification of a weighing device, the minimum recommended limit of the balance or scale will be identified. This should be included in the device status and easily seen by the operator.

ISO 9001:2015
7.1.5.2 Measurement Traceability [...] measuring equipment shall be:
  b) identified in order to determine their status;

A recommendation compliant with this requirement is shown in Figure 12.

Figure 12: Sample Smallest Net Weight sticker

It shows a Smallest Net Weight label that can be stuck on to the balance or scale’s display to alert operators of the lowest limit of the safe weighing range. Weighing below this smallest recommended net weight can yield measurement results with high measurement uncertainty, which may lead to out-of-specification results.

ISO 9001:2015
7.1.5.2 Measurement Traceability [...] measuring equipment shall be:
  c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The following recommendations will help fulfill the requirement to safeguard the device against deterioration:

- Routine testing is a widely accepted method to early detect potential out-of-tolerance conditions. It will reduce the risk of incorrect measurements in-between calibrations before any consequential harm is done. Frequent routine testing is mandatory when using multi-celled analog load cells because sensitivity errors, due to a failed load cell, are not apparent to a typical operator. Frequent routine testing is necessary in environments where a scale could be damaged by a forklift or accumulated debris from the production process.

- Calibration must be performed every time the scale is moved. If the scale is intended to be portable then testing of sensitivity and repeatability are recommended after each move by qualified members of your company who are trained on how to conduct proper balance and scale testing.

- Automatic features, such as FACT*, should be enabled. FACT automatically compensates for the sensitivity when significant temperature changes occur to keep the results stable under changing conditions.

* FACT, Fully Automatic Calibration Technology – included in selected Mettler Toledo devices.
6. Using Good Weighing Practice™ (GWP®) to apply PDCA

The Plan-Do-Check-Act cycle (shown in Fig. 1) is described in the revised version of ISO 9001:2015:

**ISO 9001:2015**

**0.3.2 Plan-Do-Check-Act Cycle**

The PDCA cycle can be applied to all processes and to the quality management system as a whole. The PDCA cycle can be briefly described as follows:

- **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;
- **Do**: implement what was planned;
- **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;
- **Act**: take actions to improve performance, as necessary.

This strategy can easily be applied to weighing devices and weighing processes by introducing the risk-based Good Weighing Practice (GWP) approach.

### 6.1. What is Good Weighing Practice?

Good Weighing Practice™ (or GWP®), is the global standard that can be applied to new or existing weighing equipment from any manufacturer in any industry and workplace [11]. Established in 2007 by METTLER TOLEDO, GWP is a standardized scientific methodology for secure selection, calibration and operation of weighing equipment. It uses a risk-based approach to selecting the correct weighing equipment for a purpose and managing the devices through their lifecycle. GWP assists in compliance with regulations and significant improvement in quality by allowing you to define the accuracy relevant to each weighing process.

GWP provides the documented evidence for reproducible weighing results in harmony with all current quality standards in laboratory and manufacturing. Users who focus on stable processes, constant product quality, lean manufacturing or regulatory compliance, can use GWP as the benchmark to select and calibrate their weighing equipment.
The GWP risk-based methodology covers the entire life cycle of a weighing device in five steps:

<table>
<thead>
<tr>
<th>GWP® Recommendation – the right scale for every process</th>
<th>GWP® Verification – the accurate weighing process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Evaluation</td>
<td>2. Selection</td>
</tr>
<tr>
<td>Understand your weighing process and evaluate your requirements.</td>
<td>Advice on selection of the right balance or scales for your weighing requirements.</td>
</tr>
<tr>
<td>3. Installation</td>
<td>4. Calibration</td>
</tr>
<tr>
<td>Professional installation, qualification and configuration with in-depth user training.</td>
<td>Confidence in your results with documented measurement uncertainty and minimum weight of your weighing equipment on-site.</td>
</tr>
<tr>
<td>5. Routine Operation</td>
<td></td>
</tr>
<tr>
<td>An optimized risk-based testing program to minimize risk and avoid unnecessary cost.</td>
<td></td>
</tr>
</tbody>
</table>

### 6.2. How can GWP be applied to a PDCA cycle?

The GWP program is completely aligned with PDCA and meets all the requirements relating to risk-based weighing when using balances and scales.

**Plan**
- Smallest net weight
- Largest gross weight
- Desired accuracy in tolerance %
- Safety factor
- Risks

**Do**
- Installation and installation qualification

**Check**
- Performance qualification
- Calibration to national and international standards with measurement uncertainty
- Risk-based testing plan, calibration, routine tests weights and test tolerances

**Act**
- Confirm/reposition device
- Acquire new devices to fill gaps
- Adjust SOP’s for best practice

**GWP® Recommendation**
- Device is pre-qualified

**GWP® Verification**
- Installation Pacs
- CalibrationCert. & GWP Verification
- Device qualification proves that devices are fit for purpose

**Consulting**
  - Training
  - SOP Writing

Figure 14: Applying PDCA cycle to weighing processes according to Good Weighing Practice
If you are planning to follow this new ISO revision and your processes include weighing devices, you should consider the advice in Table 3:

| 1. Plan | Ensure that your measurement processes are planned in terms of expected results; this is expressed as a target measurement with tolerances. When there is a range of measurements, the smallest and the largest weights are proposed to be used in a GWP Recommendation. The Recommendation ensures that the measurement uncertainty of a new proposed weighing device is below your desired accuracy expressed as tolerance and safety factor. If the risk analysis is completed at this point you are presented with correct class of test weights with warning and control limits to use once your process is on-line. Simple SOP’s can be used to check the scale to ensure continued good measurements. |
| 2. Do | Acquisition and installation of equipment according to professional installation packages. The correct selection, installation and calibration ensure that the following steps will meet the customer’s processes. |
| 3. Check | A qualified calibration (including statement of measurement uncertainty) and GWP Verification allows you to confirm that the weighing instruments actually meet your accuracy requirements according to your process tolerances and quality expectations at the place of use. GWP Verification uses the previously described risk-based analysis, which means that you are advised of the appropriate routine testing and calibration frequencies, as well as weights and tolerances (expressed as warning and control limits). Warning limits indicate when a device is nearing an out-of-specification condition. Control limits alert you to when the device needs calibration and adjustment. |
| 4. Act | Routine testing and calibration cycles are presented and adjusted to ensure continued reliable and accurate measurements. |

Table 3: Recommended PDCA actions for weighing processes

During all four of these PDCA phases, documents are generated to provide evidence that robust processes were followed to appease critical auditors - whether they are from your customer or from an external regulatory body. An accuracy calibration certificate with a clear statement of measurement uncertainty and a GWP annex mathematically confirms that the weighing device meets your process requirements. Consulting, training and SOP writing help you maximize your potential meet regulatory requirements and maximize your customer satisfaction.
7. Conclusion and Recommendations

The latest revision to standard ISO 9001:2015 was published in September 2015. ISO 9001 companies have until September 2018 to adopt the new standard.

The changes focus on risk-based thinking and a process approach. The process approach involves managing processes using Plan-Do-Check-Act (PDCA) and managing interaction of those processes as a system, with an overall background of risk-based thinking.

A systematic approach to risk should be established so that risk-based thinking is considered from the beginning and throughout the system. This makes preventive action inherent to planning, operation, analysis, and evaluation activities, rather than treating “prevention” as a separate component of a QMS.

For weighing devices, measurements and calibration, METTLER TOLEDO can support you with the changes in the new ISO update. The PDCA approach described in ISO 9001:2015 can be implemented easily by using the well-established Good Weighing Practice (GWP) approach. GWP is a risk-based program to selecting correct weighing equipment for the purpose and managing the devices through their full lifecycles. This program helps you determine whether your new or existing balances and scales (from any manufacturer) are fit for purpose according to all national and international standards, such as NTEP Handbook 44 or OIML. GWP delivers exactly what you need to know in order to improve your weight-based measurements without significant change or cost to your organization.
8. References


Additional Sources of Information:

- General Information on Good Weighing Practice™: www.mt.com/gwp
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