Need for traceability, uncertainty and calibration of measuring instruments in the industrial, environmental and welfare fields: 

*A reference handbook*

Professor

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Measures in Industrial and Environmental

These measures are governed by the following International Standards:

- **ISO 9001 that requires:**
  - When monitoring or measurement is used to verify the compliance of products and services with requirements, the organization must determine and make available the resources necessary to ensure valid and reliable results (measures).

- **ISO 14001 that requires:**
  - The organization must establish, implement and maintain one or more procedures to regularly monitor and measure the main characteristics of its activities and operations that may have significant environmental impact.
Measures in Welfare Applications

These measures are governed by European and International Standards:

- **For the Health in Pharmaceutical Products:**
  - For the sterilization of pharmaceutical products, working processes are required at least at 121 °C +/- 1 °C:
    - If operating at -2 °C, 25% of the bacterial flora does not die!

- **For the Well-Being of the Human People:**
  - For the measurement of human fever, thermometers with a correct indication of:
    - + 0.10 °C / - 0.15 °C are required!

✔ So in these application it is critical the measurement of the temperature that requires correct traceability and accuracy!!!
Why of the need of Traceability?

- A measurement without traceability and uncertainty is not comparable and therefore can not be compared in the global market!

- A product, process or service must always be checked with suitable equipment calibrated and confirmed metrologically at regular intervals!
What is the Traceability

• The metrological traceability of measurements according to ISO-VIM means:
  
  — “Property of a measurement results whereby the result can be related to a reference through a documented unbroken chain of calibration, each contributing to the measurement uncertainty”
Traceability in Europe and in the World

• National Calibration Laboratory in Europe

<table>
<thead>
<tr>
<th>NATION</th>
<th>INSTITUTE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>LNE</td>
<td>Laboratoire national de métrologie et d’essai</td>
</tr>
<tr>
<td>Belgium</td>
<td>SMD</td>
<td>FPS Economy, Safety, Metrology Division</td>
</tr>
<tr>
<td>Germany</td>
<td>PTB</td>
<td>Physikalisch Technische Bundesanstalt</td>
</tr>
<tr>
<td>Italy</td>
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</tr>
<tr>
<td>Netherlands</td>
<td>VSL</td>
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<tr>
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</tr>
<tr>
<td>Switzerland</td>
<td>METAS</td>
<td>Federal Institute of Metrology METAS</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>NPL</td>
<td>National Physical Laboratory</td>
</tr>
<tr>
<td>USA (America)</td>
<td>NIST</td>
<td>National Institute of Standards and Technology</td>
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• International Calibration System (ILAC)

<table>
<thead>
<tr>
<th>EA</th>
<th>Europe Accreditation</th>
</tr>
</thead>
<tbody>
<tr>
<td>APAC</td>
<td>Asian Accreditation</td>
</tr>
<tr>
<td>ARAC</td>
<td>Arab Accreditation</td>
</tr>
<tr>
<td>IAAC</td>
<td>American Accreditation</td>
</tr>
<tr>
<td>SADC</td>
<td>South Africa Accreditation</td>
</tr>
</tbody>
</table>

• National Metrological Institutes in Europe and in North America

<table>
<thead>
<tr>
<th>NATION</th>
<th>INSTITUTE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
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<td>Bulgaria</td>
<td>BAG (Bulgaria)</td>
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<td>Czech Republic</td>
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</tr>
<tr>
<td>Denmark</td>
<td>DAHAA (Denmark)</td>
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<tr>
<td>Estonia</td>
<td>EAA (Estonia)</td>
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<tr>
<td>Finland</td>
<td>FINAS (Finland)</td>
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<td></td>
</tr>
</tbody>
</table>
What is the Compatibility

• The metrological compatibility of measurements according to ISO-VIM means:
  – “Property of a set of measurement results for a specified measurand, such that the absolute value of the difference of any pair of measured quantity values from two different measurement results is smaller than some chosen multiple (usually 1) of the standard measurement uncertainty of that difference”

  Example:
  – M1 = 20,0 ± 0,1 °C
  – M2 = 20,2 ± 0,2 °C
  – M3 = 20,6 ± 0,4 °C

  Applying the Compatibility Index \( I_c \):
  \[ I_c = \left| \frac{M_1 - M_2}{U_1 + U_2} \right| \]
  where \( M_1 \) and \( M_2 \) are the measurement values, \( U_1 \) and \( U_2 \) the relative associated measurement uncertainties.

  Results:
  – M1 and M2 are compatibles: \( I_c = \left| \frac{20,0 - 20,2}{0,1 + 0,2} \right| = 0,2 / 0,3 = 0,66 \)
  – M2 and M3 are compatibles: \( I_c = \left| \frac{20,2 - 20,6}{0,2 + 0,4} \right| = 0,4 / 0,6 = 0,66 \)
  – M1 and M3 are NOT compatibles: \( I_c = \left| \frac{20,0 - 20,6}{0,1 + 0,4} \right| = 0,6 / 0,5 = 1,20 \)
What is the Uncertainty

• The measurement uncertainty according to ISO-VIM (International Vocabulary Metrology: ISO Guide 99) means:
  – “Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used” (with 4 explanatory notes).

• While, the measurement uncertainty according to ISO-GUM (Guide for Uncertainty Measurement: ISO Guide 98-3) means:
  – “Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand” (with a 95% confidence level).
Sources of Uncertainty

- Generally, the combined standard uncertainty $u_c$ of a measurement process, depends on the following 5 factors, also known by the acronym E & 4M (see Figure):

**Environment & Man – Machine – Method – Material**

- Changes in environmental conditions of measurement: Environment: $u_{env}$
- Uncertainty due to the skill of the operator: Man: $u_{man}$
- Uncertainty of measurement instrumentation: Machine: $u_{mac}$
- Uncertainty due to measurement method: Method: $u_{met}$
- Incomplete sampling of measurand: Material: $u_{mat}$
Possibility to Reduce the Sources?

- **In practical calibrations of measuring instruments performed in laboratories under controlled environmental conditions and with qualified operating personnel, the 5 factors of uncertainty referred to above can essentially be reduced to 3 factors (see Figure):**
  - Uncertainty due to the reference instrument (or standard) used: \( u_{\text{ref}} \)
  - Uncertainty due to the error of indication of the instrument in calibration: \( u_{\text{ind}} \)
  - Uncertainty due to the resolution of the instrument in calibration: \( u_{\text{res}} \)

- So, in practical applications, the combined standard uncertainty \( u_c \) corresponds to the square root of a sum of the 3 individual standard uncertainty squares influencing the measurement process:

\[
 u_c = \sqrt{u_{\text{ref}}^2 + u_{\text{ind}}^2 + u_{\text{res}}^2}
\]
Why Calibrated the Measuring Instruments

- The control of measuring instruments, namely:
  - measuring equipment in the Quality Management System ISO 9001
  - surveillance equipment in the Environmental Management System ISO 14001

- provide, where necessary to ensure valid results, that measuring instruments are:
  - calibrated and verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, they must be registered with the criteria used for calibration or verification;
  - adjusted or regulated again, when necessary;

- therefore, all management systems provide the initial calibration and any periodic "metrological confirmation" (according to ISO 10012 Measurement Mgt System) of the measuring instruments to validate the various measurement processes to ensure proper traceability of measurements to the International System (SI).
Measurement Management System

- **The Measurement Management System (MMS)** provides a similar process-oriented approach to the principles laid down by ISO 9001, with the objective to manage the risk that measuring equipment and measurement processes could produce incorrect results affecting the quality of the organization's product, using methods ranging from initial and periodic verification of the equipment (i.e. Metrological Confirmation).
Measurement Management Paths

- The Metrological Confirmation can be designed, executed and implemented to ensure that the metrological characteristics of the measuring equipment satisfy the metrological requirements for the measurement process.
  - Metrological confirmation comprises measuring equipment calibration and verification!

- It can be carried out according to the table shown below according to the flow chart shown in the next figure:

<table>
<thead>
<tr>
<th>NORMAL PHASES</th>
<th>PHASES IN CASE OF ADJUSTMENT</th>
<th>PHASES IN CASE OF ADJ. IMPOSS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0. Filing equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Requirement of calibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Equipment calibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Writing of calibration document</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Calibration identification (*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. There metrological requirements??</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Conformity with the metrological req.</td>
<td>6a. Adjustment or repair</td>
<td>6b. Adjustment impossible</td>
</tr>
<tr>
<td>7. Preparing of confirmation document</td>
<td>7a. Review of confirm intervals</td>
<td>7b. Negative verification</td>
</tr>
<tr>
<td>8. Identification confirmation status</td>
<td>8a. Recalibration path from 2 to 8</td>
<td>8b. Identification status</td>
</tr>
</tbody>
</table>
Measurement Management Cycle

**CALIBRATION**

1. **Requirement need**
   - START

2. **Calibration**
   - (technical comparison of measuring equipment with a measurement standard)

3. **Calibration**
   - (Certificate/Report)

4. **Calibration**
   - (Status identification)

**METROLOGICAL VERIFICATION**

- **DO**
  - Verification is not possible
  - NOT

- **Does**
  - Verification failed
  - NOT

- **Confirmation**
  - status identification

**DECISION AND ACTIONS**

- **Is possible**
  - Adjust/Repair?
  - NOT

- **Review**
  - confirm interval

- **Adjust or Repair**

**RECALIBRATION LOOP**

- **RETURN**
  - to customer

**CUSTOMER**

- **RETURN**
  - to customer

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a) Calibration identification/labelling may be replaced by metrological confirmation identification.

b) Organization or person that receives the measuring equipment can be internal or external to the organization.
Decalogue of the Metrological Confirmation

1. Define the metrological characteristics of measuring instruments according to the use.
2. Establish an effective and documented system for confirming to ensure that the risk that a measuring instrument produces results with unacceptable errors is reduced to minimum.
3. Verify and periodically review the confirmation system to ensure that the system itself continues to be effective and take corrective action where appropriate.
4. Develop procedures for all of metrological confirmation operations with a level of detail commensurate with the complexity of the instrument in confirmation.
5. Record the successful metrological confirmation on file and confirmed the instrument using the provided label.
6. Seal the adjustment devices which can affect the performance of the instrument.
7. Maintain, handle and store the instrument in such a way as not affect its stability.
8. Refer all measures at the national or international standards consistent with the recommendations of the General Conference of Weights and Measures (CGPM) and with the International System (SI).
9. Calculate the measurement uncertainty taking into account all significant components of uncertainty identified in the measurement process, including those related to environmental factors.
10. Establish the metrological confirmation intervals of the measuring instrument at suitable intervals (usually periodic), fixed on the basis of its stability, purpose and use.
Frequency of Calibration Intervals

To determine the frequency of the confirmation is not always very easy because they affect a large number of factors, among which the most important are the following:

a) the type of instrument  
b) the manufacturer's recommendations  
c) the obtainable trends in the documents relating to previous calibrations  
d) the recording of historical information regarding maintenance and service  
e) the frequency and severity of the conditions of use  
f) the drift and stability trends  
g) the frequency of the comparisons with other instruments, in particular with the standard  
h) the frequency and the formalization for the internal calibration checks  
i) the environmental conditions (temperature, humidity, vibration, etc.)  
j) the uncertainty of the desired measures  
k) the importance of the consequences arising from correct to assume an incorrect measured value, when the instrument is out of calibration or in failure.
Definition of Calibration Intervals

• Therefore, given the variety of influential factors and practical case studies, before defining the metrological confirmation intervals of measuring instruments calibration, it is always advisable to balance these two fundamental and opposing criteria:
  – to minimize the risk that the instrument ceases to be in accordance to its metrological requirement
  – to minimize the cost of metrological confirmation operations.

• A good basis to be able to deal with this dilemma is to determine the confirmation intervals through the so called "technical intuition" or comparing similar applications and experiences of the same or similar instrument, made in other companies/laboratories, taking account these factors:

  a) the manufacturer's recommendations
  b) the frequency and severity of the use
  c) the influence of the environment of use
  d) the desired measurement uncertainty
Review of Calibration Intervals

• Once established the initial confirmation intervals, it will be necessary later to a critical review of their confirmation or calibration intervals, for to minimize, according to the initial hypothesis, on the one hand the risks of non-conformity and on the other hand, the confirmation costs.

• For this purpose the International Reference Standard ISO 10012, refers to the International Document OIML D 10 (also transposed as an International Document ILAC Guide G-24) as a reference guide, which provides 5 methods for the review of confirmation intervals, while underlining that no method is ideally suitable for all instruments, but that in turn will have to be evaluated the applicability and its effectiveness:

  1) Automatic adjustment (or stair-case)
  2) Control chart (or calendar-time)
  3) Time of utilization (in use-time):
  4) Tests in service (or black-box):
  5) Other statistical approaches:
Example of Calibration Intervals Review

- **Automatic adjustment (or stair-case)**

  - **Metrological Confirmation:**
    - **Calculation**
    - **Measurement uncertainty**

  - **Uncertainty within required limits?**
    - **Increased calibration interval**
    - **Decreased calibration interval**
    - **Unchanged calibration interval**

  - **Widely**
    - With good margin
  - **Not**

  - **Unchanged calibration interval**
Example of Calibration Intervals

- *In the absence of standard and regulations in this regard the following intervals can be considered:*

<table>
<thead>
<tr>
<th>INSTRUMENT</th>
<th>ACCURACY</th>
<th>USING CONDITIONS</th>
<th>USING FREQUENCY</th>
<th>CALIBRATION FREQUENCY (MONTHS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manometers, dial</td>
<td>Classes 0.1-0.5</td>
<td>Laboratory instruments</td>
<td>Weekly</td>
<td>min 6 max 12</td>
</tr>
<tr>
<td></td>
<td>Classes 1-4</td>
<td>Field instruments</td>
<td>Continues</td>
<td>12 24</td>
</tr>
<tr>
<td>Manometers, digital</td>
<td>Lower at 0.5 %FS</td>
<td>Laboratory instruments</td>
<td>Daily</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Higher at 0.5 %FS</td>
<td>Field instruments</td>
<td>Continues</td>
<td>12 24</td>
</tr>
<tr>
<td>Pressure transmitters</td>
<td>Lower at 0.5 %FS</td>
<td>Laboratory instruments</td>
<td>Daily</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Higher at 0.5 %FS</td>
<td>Field instruments</td>
<td>Continues</td>
<td>12 24</td>
</tr>
<tr>
<td>Thermometer, glass</td>
<td>Lower at 0.2 °C</td>
<td>Laboratory instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Higher at 0.2 °C</td>
<td>Field instruments</td>
<td>Daily / continues</td>
<td>12 24</td>
</tr>
<tr>
<td>Thermoresistances (TR)</td>
<td>Lower at 0.5 °C</td>
<td>Laboratory instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Higher at 0.5 °C</td>
<td>Field instruments</td>
<td>Continues</td>
<td>12 24</td>
</tr>
<tr>
<td>Thermocouples (TC)</td>
<td>Lower at 1.0 °C</td>
<td>Laboratory instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Higher at 1.0 °C</td>
<td>Field instruments</td>
<td>Continues</td>
<td>12 24</td>
</tr>
<tr>
<td>Thermometer, digital</td>
<td>Refer also to the type of probe (TR or TC)</td>
<td>Laboratory instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Field instruments</td>
<td>Daily / continues</td>
<td>12 24</td>
<td></td>
</tr>
<tr>
<td>Standard resistor</td>
<td>Laboratory instruments</td>
<td>Field instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Field instruments</td>
<td>Daily / continues</td>
<td>24 48</td>
<td></td>
</tr>
<tr>
<td>Ammeters, voltmeters wattmeters, etc.</td>
<td>Laboratory instruments</td>
<td>Field instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Field instruments</td>
<td>Daily / continues</td>
<td>12 24</td>
<td></td>
</tr>
<tr>
<td>Digital multimeters benchtop and handheld calibrators</td>
<td>Laboratory instruments</td>
<td>Field instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
</tr>
<tr>
<td></td>
<td>Field instruments</td>
<td>Daily / continues</td>
<td>12 24</td>
<td></td>
</tr>
<tr>
<td>Digital multifunction calibrators</td>
<td>Laboratory instruments</td>
<td>Field instruments</td>
<td>10-50 times / year</td>
<td>6 12</td>
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<tr>
<td></td>
<td>Field instruments</td>
<td>Daily / continues</td>
<td>6 12</td>
<td></td>
</tr>
</tbody>
</table>
Selection of Measuring Instrument

• The instrument or equipment for measuring for the measurement processes designed, should be first choice, then calibrated and then confirmed before being inserted in the measurement process, according to the requirements prescribed in the ISO 10012.

• The initial selection must be made according to the metrological characteristics required: usually the initial calibration can be done directly from the supplier, or externally by a qualified laboratory, or even internally at the company's laboratory, but always traceable to the International System SI.

• In any case the measuring equipment must be specified at least the following elements:
  – Manufacturer
  – Type and description
  – Series or serial number
  – Measuring range
  – Measuring resolution
  – Measurement accuracy
  – Measurement uncertainty
  – Functional operating conditions
  – Environmental operating conditions
  – Stability or possible eventual drift
  – Sensitivity to any influential quantities
Selection of Reference Instrument

- **Calibration of the apparatus for measurement** (otherwise also called instrument) may be made externally or internally within the organization, with reference equipment (otherwise also called standard), having a measurement uncertainty possibly at least 3 times lower the presumed uncertainty of the instrument to be calibrated.

- **The relationship between the uncertainty of measurement between the instrument to be calibrated and reference standard** (otherwise also called TUR: Test Uncertainty Ratio), should also be possibly greater than 3, but 3 could be already sufficient given the treatment of uncertainties:
  - In fact, since the treatment of uncertainties in squaring, the individual contribution due to standard is about 1/10 compared to the contribution of any instrument errors, and therefore it increases the result of the instrument measurement uncertainty < 5%.
The recommended uncertainty ratios, unless otherwise specified from technical normatives and/or regulation are defined in the following table:

<table>
<thead>
<tr>
<th>Instrument uncertainty</th>
<th>Adequacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference uncertainty</td>
<td></td>
</tr>
<tr>
<td>&lt; 3</td>
<td>INSUFFICIENT</td>
</tr>
<tr>
<td>3</td>
<td>ACCEPTABLE</td>
</tr>
<tr>
<td>4 - 9</td>
<td>GOOD</td>
</tr>
<tr>
<td>10</td>
<td>EXCELLENT</td>
</tr>
<tr>
<td>&gt; 10</td>
<td>EXCESSIVE</td>
</tr>
</tbody>
</table>
Definition of Instrument Conformity

For "Instrument Conformity" in metrological terms, it means:

- Conformity of an instrument, device or measuring equipment, at all the metrological requirements specified.

- The "Metrological Requirements Specified" can be essentially of two types:
  - Measurement error
  - Measurement uncertainty
  whose characteristics are periodically checking through the metrological confirmation.

- In fact, the "Metrological Confirmation" is formally defined in ISO 10012:
  “Set of operations required to ensure that measuring equipment conforms to the requirements for its intended use”.
Verification of Instrument Conformity

- The conformity assessment of measuring instruments installed in the field on production processes, to control a specified parameter, it can be implemented in three ways:

1. Practical method, by means of verification of the Maximum Tolerated Error (MTE):
   without determining the actual uncertainty of measurement given normal low uncertainty influence of the measurement reference standard used.

2. Analytical method, by means of verification of the Maximum Tolerated Uncertainty (MTU):
   determining the actual uncertainty of measurement given the not always scarce influence of the uncertainty of the measurement reference standard used.

3. Precautionary method, by checking the Zone Secure Conformity (ZSC):
   determining the area of secure conformity respect the specific zone required and tolerated
1st Practical Verification Conformity

• This first practical method, evaluate the conformity of the instruments in the field by checking only that the Maximum Relieved Error (MRE) during the metrological confirmation process, is less than or equal to the Maximum Tolerated Error (MTE) specified for the instrument, or:
  ➢ MRE ≤ MTE

• This method is applied by default when the reference standard used for the calibration of the instrument to be verified, has an error or measurement uncertainty negligible respect that of the field instruments to be verified (typically ≤ 1/3).

• In fact if the reference standard has a lower measurement uncertainty Uref equal or maximum 1/3 of the maximum tolerated error the instrument in calibrations Uins, it is demonstrable that the total budget of the calibration uncertainty U, is equal to the square root of the squaring sum of the individual uncertainties of the instrument and the reference standard:

\[
U = \sqrt{(U_{\text{ins}})^2 + (U_{\text{ref}})^2}
\]

• If Uins = 1 and Uref = 1/3, result:

\[
U = \sqrt{(1)^2 + (1/3)^2} = 1,05 \approx 1
\]
  ➢ Therefore the uncertainty of the measuring instrument in calibration does not vary!
2\textsuperscript{nd} Analytical Verification Conformity

- This second analytical method, evaluate instead the conformity of the instruments in the field by checking that the \textbf{Maximum Relieved Uncertainty (MRU)} during the metrological confirmation process, is less than or equal to the \textbf{Maximum Tolerated Uncertainty (MTU)} specified for the measurement process, or:
  - $\text{MRU} \leq \text{MTU}$

- This method is applied in case when the reference standard used for the calibration of the instrument to be verified, has an error or measurement uncertainty not negligible respect that of the of the instruments to be verified (typically $> 1/3$).

- In this cases, the measurement relieved uncertainty resulting from the calibration or confirmation $U$ (i.e. MRU), takes into account more than the maximum relieved error on the instrument $E_{\text{max}}$ and the relative resolution error $E_{\text{res}}$, also the measurement uncertainty of the reference standard $U_{\text{ref}}$, and it is given by the following formula (seen previously):

$$U = 2 \cdot \sqrt{\left( \frac{U_{\text{ref}}}{2} \right)^2 + \left( \frac{E_{\text{max}}}{\sqrt{3}} \right)^2 + \left( \frac{E_{\text{res}}}{2\sqrt{3}} \right)^2}$$

- It is better because consider also the uncertainty of the reference (standard).
3rd Precautionary Verification Conformity

- This third method, as an alternative to the methods described above, evaluate the conformity of field instruments with the metrological requirements specified and required, always if the measurement uncertainty of the reference standard is not negligible, and it is implemented according to the ISO 14253 which starts from the following assumptions:
  - If at project level and performing of a measurement process are defined the tolerances in the technical specifications, are easy to locate the zones of secure conformity and nonconformity as shown in Figure.

  ➢ It is the best one because it does not consider the sum of the reference uncertainty \( U \) in squaring, but subtracts it from the tolerance zone and therefore the verification it is more precautionary!
Evidence of Conformity

- Following confirmation metrology conduct and the basis used to verify the conformity of the measuring instrument, the objective evidence for the conformity of the intended use of the instrument is given from the confirmation label affixed on the instrument, or if not feasible, by means of label holder, or even on the box or instrument case.

- In case of positive metrological confirmation, the label should contain at least these items:
  - Instrument denomination and/or identification
  - Confirmation report
  - Confirmation date
  - Next confirmation date
- as shown in the left Figure, otherwise put in the instrument the negative label as shown in the right Figure.
Calibration and Metrological Confirmation

• The Calibration and Metrological Confirmation it must be carried out initially and then periodically on the instruments in order to verify and maintain over time their measurement accuracy characteristics required by the production process or the monitoring service.

• Therefore a procedure should be provided for the various types of the measuring instruments to verify the correct measurement accuracy with the two main methods previously reported, or:
  
  – verifying that max relieved error (MRE) of the instrument is ≤ max tolerated error (MTE): generally recommended using references with uncertainty ≤ 1/3 of that of the instrument to be calibrated;  

  – verifying that max relieved uncertainty (MRU) of the instrument is ≤ max tolerated uncertainty (MTU): particularly recommended using references with uncertainty > 1/3 of that of the instrument to be calibrated;  

  obviously, always in compliance with any applicable related normatives!
The Calibration Handbook

• The book is written mainly for operators who verify and calibrate measuring instruments used in several ambient system:
  – Quality Management Systems ISO 9001,
  – Environment Applications ISO 14001,
  – Automotive Industry ISO 16949,
  – Aviation Industry EN 9100.

• It is a practical consultation manual that deals with all topics useful for ensuring and managing the measurement of industrial and environmental processes in quality.
Handbook Arguments

• The Handbook describes the general concepts for managing measurement equipment according to ISO 10012, concerning the management system of instruments and measurements:
  
  – The instrument's suitability to perform accurate measurements and control the drift to maintain the quality of the measurement process.
  
  – The criteria and procedures for accepting, managing, and verifying the calibration of the main industrial measuring instruments.
  
  – The provisions of law and regulations for production, European marking CE of metrological instruments used in commercial transaction and for their periodic verification.
Handbook  General Topics

• **General references for calibration:**
  - the International System of units (SI)
  - and their conversions to other units
  - the International, European and National calibration Services (ILAC, EA and Others)
  - the metrological & performance requirements
  - or the measurement instruments
  - the criteria for determination the traceability
  - and for evaluation measurement uncertainty
  - the technical regulatory and legal requirements
  - relating to the mgt. instruments and measures
Handbook Specific Topics

- **Metrological verification and confirmation of instruments for the following quantities:**
  - **Physical:**
    - pressure, flow, level, temperature, humidity, mass, ...
  - **Chemical:**
    - pH, conductivity, chromatography, spectrometry, ...
  - **Mechanical:**
    - length, couple, force, vibration, noise, ...
  - **Electrical and Electronic:**
    - current, tension, multimeters, oscilloscopes, ....
Handbook Procedure Index

Procedure index for calibration every measuring instrument:

1. Scope and purpose
2. Identification and classification
3. Normative references
4. Ambient conditions
5. Initial checks
6. Calibration method
7. Calibration verification
8. Calibration results
9. Metrological confirmation
Procedure Example

The procedure details:

- **Main reference normatives**
  - International, Regional or National

- **Main calibration methods**
  - in relation to the measurement uncertainty of the instrument in the calibration

- **The calibration verification cycles and measuring points**

- **The conformity of the instrument**
  - evaluated according two methods:
    1°: **Practical method:**
      - Max Relieved Error ≤ Max Tolerate Error
    2°: **Analytical method:**
      - Max Rel. Uncertainty ≤ Max Tol. Uncertainty
Card Example

- For each family of instruments it is proposed:
  - Calibration & metrological procedures of the main measuring instruments
  - Collection cards and the data processing suitable for recording and drafting the related...
  - Calibration report & metrological confirmation manually or automatically with the CD

Calibration cards & Spreadsheets reported on CD
Practical Spreadsheets for the compilation of Calibration Reports
Handbook Information

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International Society of Automation
or

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Thanks for Your Attention!!!