Calibration in support of IATF16949

& differences between ISO9000 / ISO17025

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- Complex environment demands accuracy, traceability, documentation, standardization for product safety and……
- ISO 9000 - Document Management system
- IATF16949 International Automotive Task Force QM
- ISO 17025 - Calibration Laboratory: technical competency

ISO9000 family of standards

- **ISO 9000 family - Quality management system**
- Guidance and tools that products and services consistently meet requirements, and that quality is consistently improved.
- **Sector-specific applications of ISO 9001 include**
- Medical devices
  Electoral organizations at all levels of government
  Local government
  Business management system requirements for rail organizations
  Petroleum, petrochemical and natural gas industries
  Software engineering

IATF16949 is based on ISO9000

- International Automotive Task Force Quality Management System Standard for the Automotive industry.
- Incorporates structure and requirements of **ISO 9001:2015**
- Has Industry Specific requirements
- Continuous improvement
- Defect prevention
- Risk management (reduction of variability, standardization, traceability, spec)
- Management of sub-tier suppliers

Calibration in support of IATF16949

- IATF16949 requires Internal laboratory to be ISO17025 accredited
- Measurement equipment in production may be excluded
- OEM calibration is specifically allowed if no ISO accredited source available
- Traceability requirement to International Standards
- ISO9000 NOT relevant to calibration

ISO17025 requirement

7.1.5.3 Laboratory requirements

7.1.5.3.1 Internal laboratory

An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, requirements for:

a) adequacy of the laboratory technical procedures;
b) competency of the laboratory personnel;
c) testing of the product;
d) capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); when no national or international standard(s) is available, the organization shall define and implement a methodology to verify measurement system capability;
e) customer requirements, if any;
f) review of the related records.

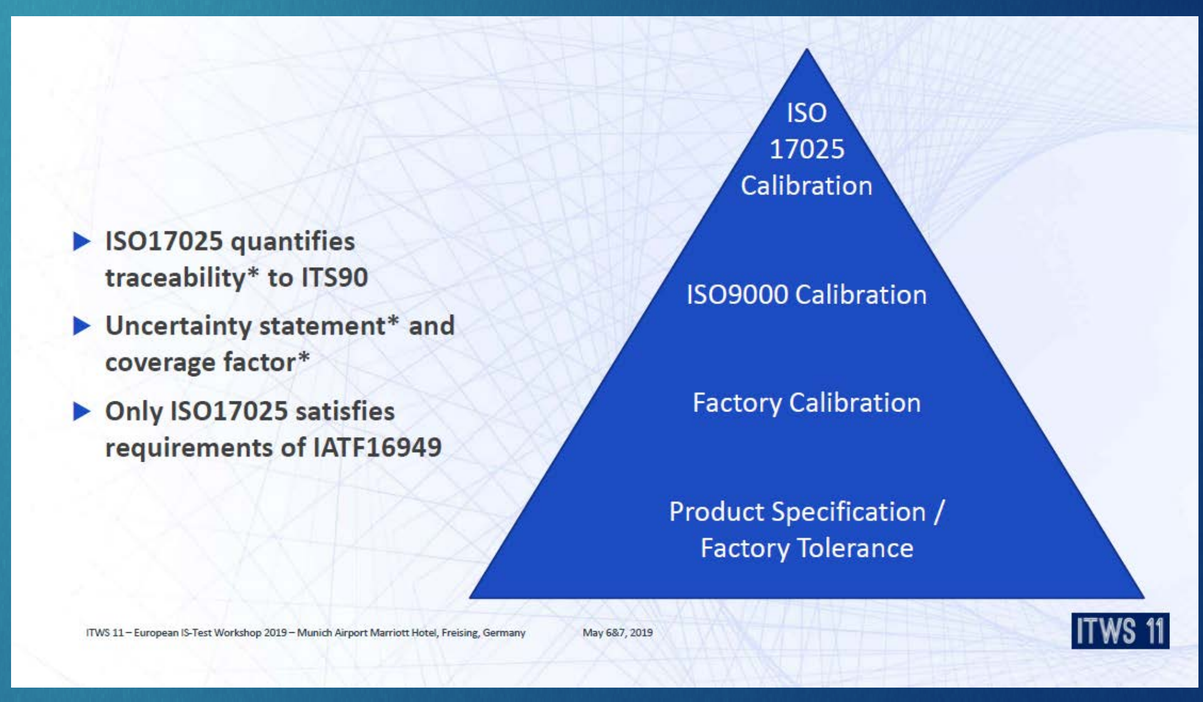
NOTE Third-party accreditation to ISO/IEC 17025 (or equivalent) may be used to demonstrate the organization's in-house laboratory conformity to this requirement.

How to comply

- Internal laboratory
- External laboratory services
- ISO17025 calibrated equipment / OEM optional, may require customer approval in certain cases

ISO17025

- **ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories**
- Commonalities ISO 9000 , but ISO/IEC 17025 more specific in requirements for technical competence
- ISO/IEC 17025: implement quality system aimed at improving ability to consistently produce valid test results.



ISO9000 describes processes and document management

SIGMA SENSORS
Temperature Calibration Laboratory

ISO 17025 is the technical competence requirement based on ISO9000

and deals with accuracy, uncertainty, confidence and for temperature: the ITS90

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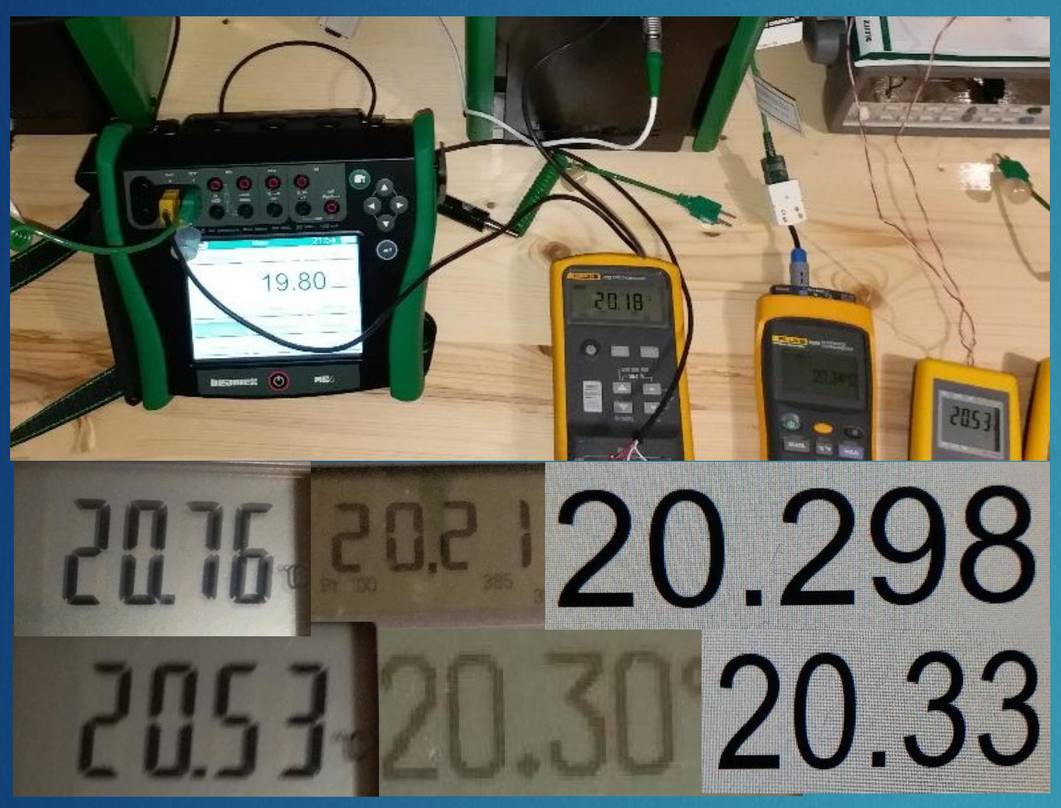
Temperature Accuracy, Certainty and Uncertainty

- Traceability to ITS90
- Confidence in measurement

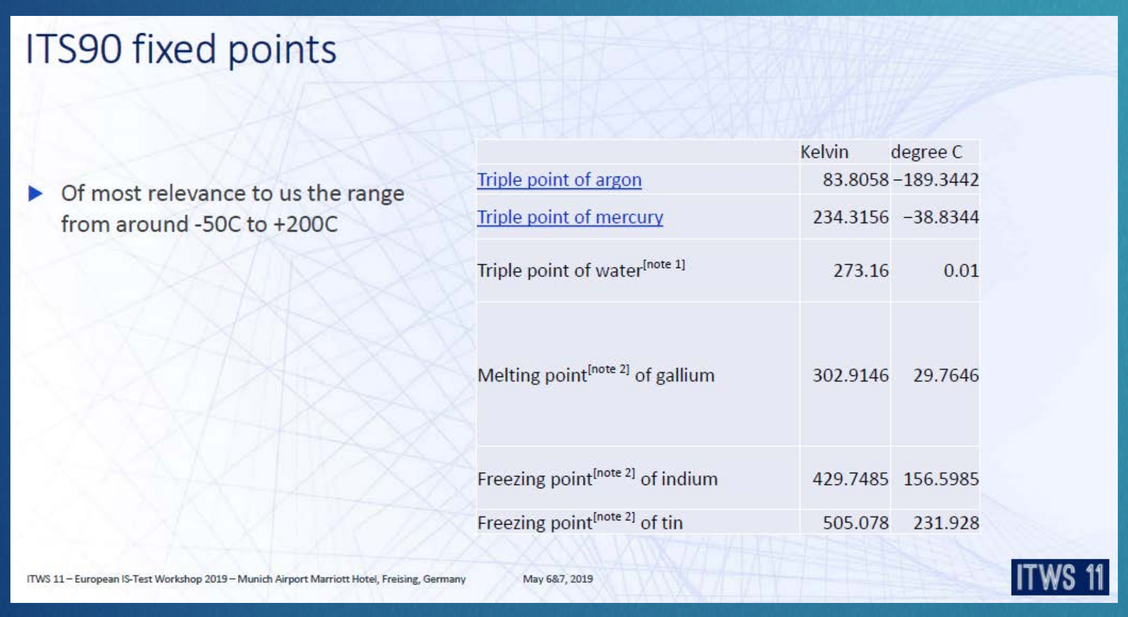


Accurate and Precise

- ISO17025 calibrated, traceable to ITS-90, Measurement uncertainty ±0.02C k=2

ITS-90

- **International Temperature Scale of 1990 (ITS-90)**
- equipment calibration standard for making measurements on the Kelvin and Celsius temperature scales.
- ITS-90 is an approximation of the thermodynamic temperature scale that facilitates the comparability and compatibility of temperature measurements internationally.
- It specifies fourteen calibration points ranging from 0.65±0 K to 1357.77±0 K (−272.50±0 °C to 1084.62±0 °C) and is subdivided into multiple temperature ranges which overlap in some instances



Uncertainty and Confidence

- Uncertainty of measurement determines accuracy
- ISO 17025 requires all uncertainties to be added in order to come up with the combined measurement uncertainty

$$u_c(y) = y \cdot \sqrt{\left(\frac{u(x_1)}{x_1}\right)^2 + \left(\frac{u(x_2)}{x_2}\right)^2 + \left(\frac{u(x_3)}{x_3}\right)^2 + \left(\frac{u(x_4)}{x_4}\right)^2}$$

- Expanded Measurement Uncertainty (Expanded Uncertainty):
  Combined standard measurement uncertainty and a factor larger than one
- Multiplying with coverage factor (i.e. k=2) we gain confidence (95%)

- **More accurate temperature measurement and control required**
- **Some customers want to see full surface characterization data, showing precision of temperature distribution and accuracy**
- **Need to satisfy requirements for IATF16949: ISO17025 calibration**

Accuracy and Precision

- Accuracy: the degree to which the result of a measurement, calculation, or specification conforms to the correct value or a standard.
- Precision: refinement in a measurement, calculation, or specification, especially as represented by the number of digits given.
- We can be precise by measuring temperature 1/1000K
- But we may not be accurate because the tolerance at 200C is +- 1C