OA look at Section 6.3 on Facilities and Environmental Conditions Along with Section 6.4 on Equipment

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Option A and B as Presented in ISO/IEC 17025:2017 Along with the Management System Documentation (8.2)

- This webinar is being recorded
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Section 6.3“Facilities and Environmental Conditions”

Whether tests or calibrations are performed in the organizations well controlled fixed facility or outside its permanent control ISO/IEC 17025:2017 requires that environmental and facility conditions related requirements be met. If not, this would be considered a deviation.

Section 6.3“Facilities and Environmental Conditions”

6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

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Section 6.3“Facilities and Environmental Conditions”

6.3.2 The requirements for facilities and environmental conditions **necessary for the performance of the laboratory activities** shall be documented.

For example, within the internal procedure

- **Environmental conditions required:**
- Temperature to be within the range of 68 ºF +/- 2 ºF.
- Relative Humidity to be greater than 50 % RH
- The UUT must remain in the laboratory for a minimum of 12 hours prior to calibration to permit thermal stabilization.
- Note: Calibrations are not to be performed if the environmental conditions are outside the allowable limits stated above

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Section 6.3“Facilities and Environmental Conditions”

- **6.3.3** The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

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Section 6.3- Facilities & Environmental Conditions

6.3.4 Measures to control facilities shall be implemented, monitored and **periodically reviewed** and shall include, but not be limited to:

a) access to and use of areas affecting laboratory activities;

b) prevention of contamination, interference or adverse influences on laboratory activities;

c) effective separation between areas with incompatible laboratory activities.

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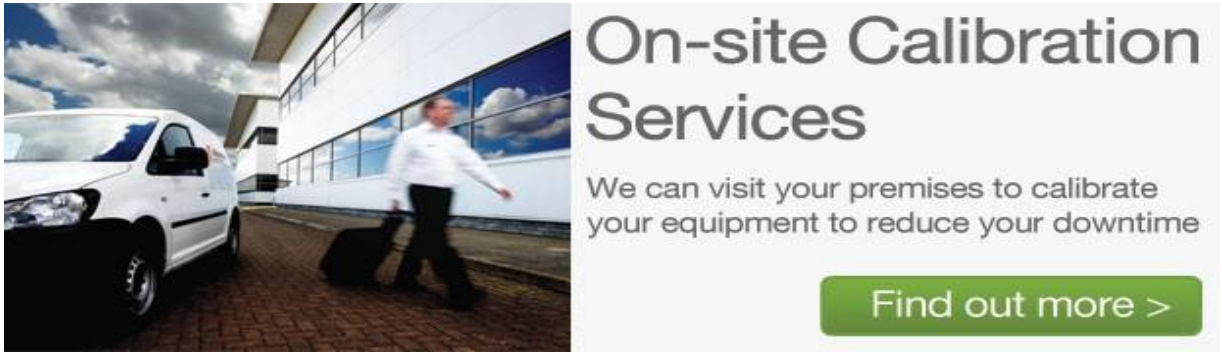
Section 6.3- Facilities & Environmental Conditions

6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.



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Section 6.3- Facilities & Environmental Conditions

What if the environmental conditions are outside specified conditions?

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See 7.4.3 – “Handling of Test or Calibration Items”

The laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

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Section 6.4 Equipment

Highlights

Standards, reference materials, reagents, and software are also considered as equipment (6.4.1).

- Conditions to calibrate equipment are set
  - ➢ if accuracy or uncertainty affect the validity of results
  - ➢ if calibration is needed to establish metrological traceability

Reference to ISO 17034 is included to emphasis the competence of reference material producers

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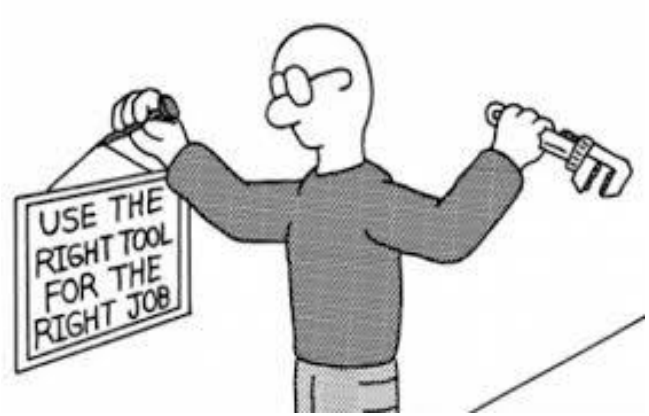
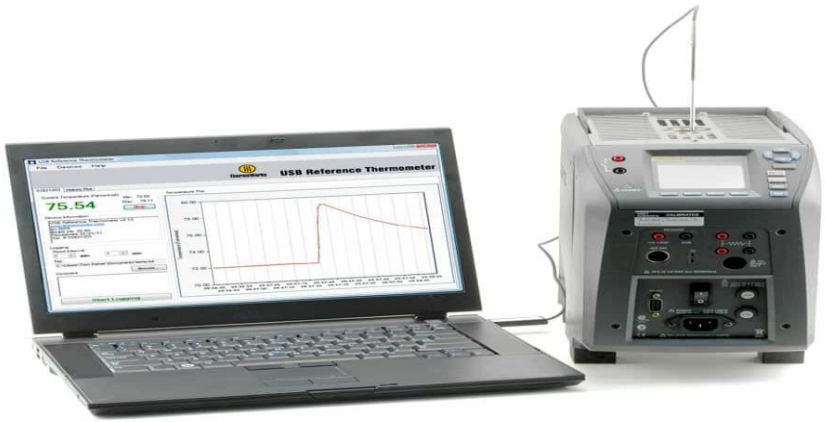
Section 6.4 Equipment

6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.





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6.4 Equipment

NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. **ISO 17034** contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability

NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.

*Basically, reference material is **a substance with a specific, defined characteristic that serves as a comparative value for analyses**. For example, for mycotoxin analysis, reference material would be a contaminated corn or wheat sample with a clearly defined mycotoxin concentration*

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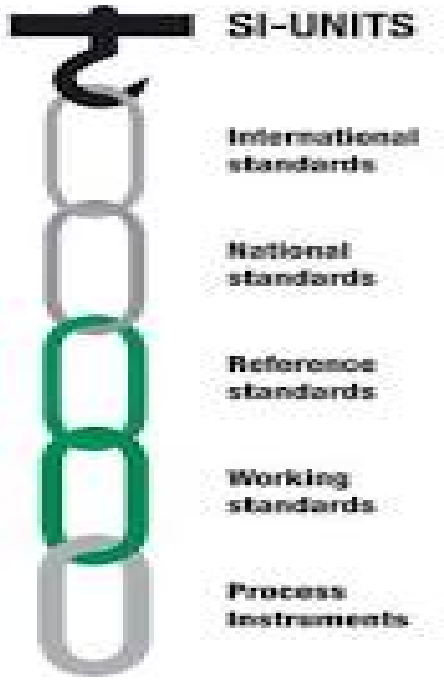
Section 6.4 Equipment

6.4.2 When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met;



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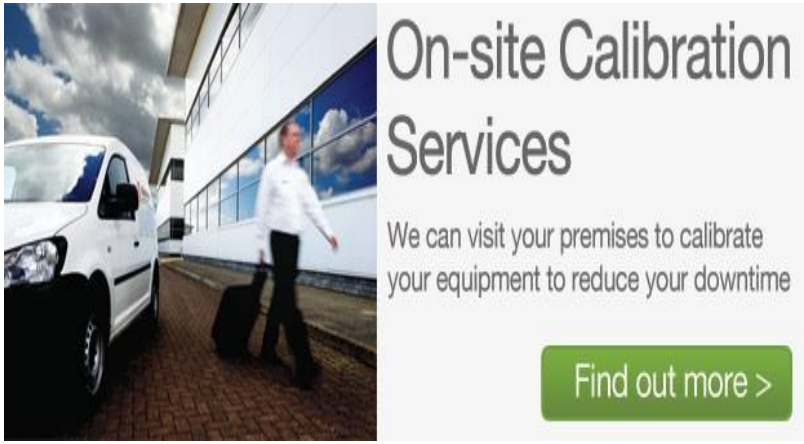
Section 6.4 Equipment

6.4.3 The laboratory **shall have a procedure** for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.



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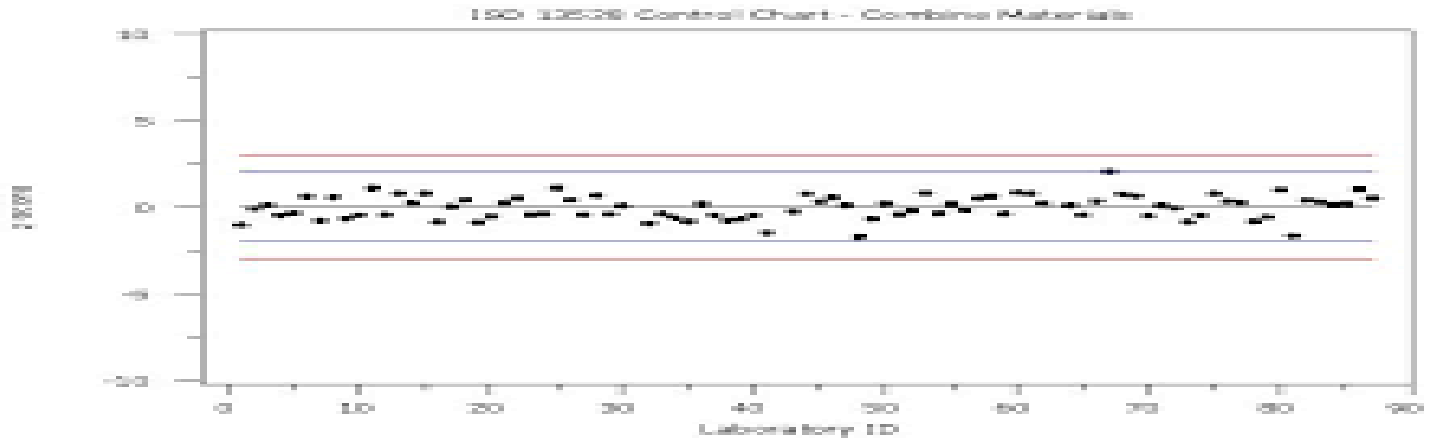
Section 6.4 Equipment

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.



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Section 6.4 Equipment

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

Temperature accuracy shall be within 0.5°C

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Thermodynamic

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Equipment to Measure Temperature and Temperature Sources [FO]	-40 °C to 700 °C	0.66 °C	J/K Thermometer with type J and type K probes
	-50 °C to 70 °C	0.65 °C	Platinum Resistance Thermometer

1. The CMC (Calibration and Measurement Capability) stated for calibrations included on this scope of accreditation represents the smallest measurement uncertainty attainable by the laboratory when performing a more or less routine calibration of a nearly ideal device under nearly ideal conditions. It is typically expressed at a confidence level of 95 % using a coverage factor *k* (usually equal to 2). The actual measurement uncertainty associated with a specific calibration performed by the laboratory will typically be larger than the CMC for the same calibration since capability and performance of the device being calibrated and the conditions related to the calibration may reasonably be expected to deviate from ideal to some degree.

2. The laboratories range of calibration capability for all disciplines for which they are accredited is the interval from the smallest calibrated standard to the largest calibrated standard used in performing the calibration. The low end of this range must be an attainable value for which the laboratory has or has access to the standard referenced. Verification of an indicated value of zero in the absence of a standard is common practice in the procedure for many calibrations but by its definition it does not constitute calibration of zero capacity.

3. The presence of a superscript FO means that the laboratory performs calibration of the indicated parameter

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6.4 Equipment

6.4.6 Measuring equipment shall be calibrated when:

— the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or

— calibration of the equipment is required to establish the metrological traceability of the reported results.

NOTE Types of equipment having an effect on the validity of the reported results can include:

— those used for the direct measurement of the measured, e.g. use of a balance to perform a mass measurement;

— those used to make corrections to the measured value, e.g. temperature measurements;

— those used to obtain a measurement result calculated from multiple quantities.

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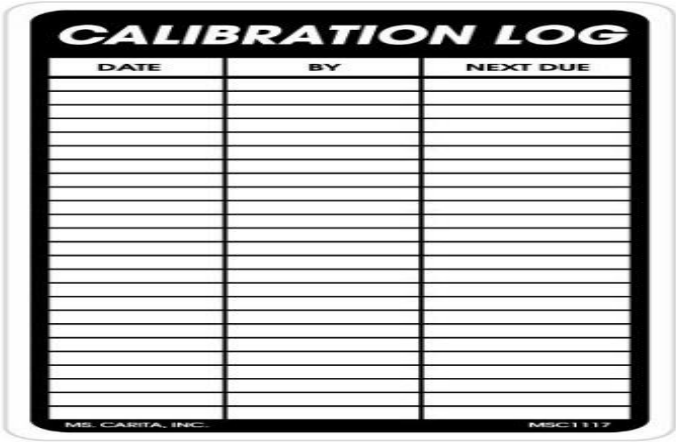
Section 6.4 Equipment

6.4.7 The laboratory shall establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.



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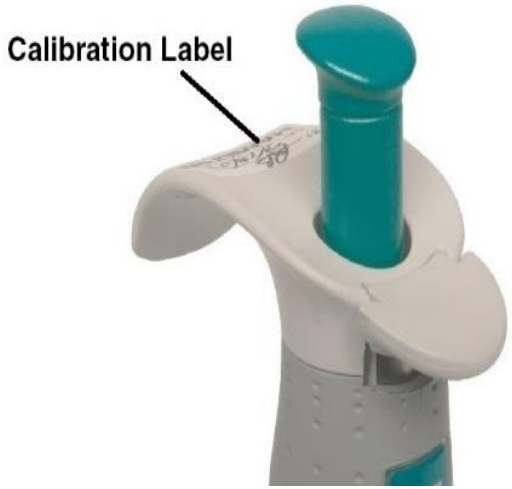
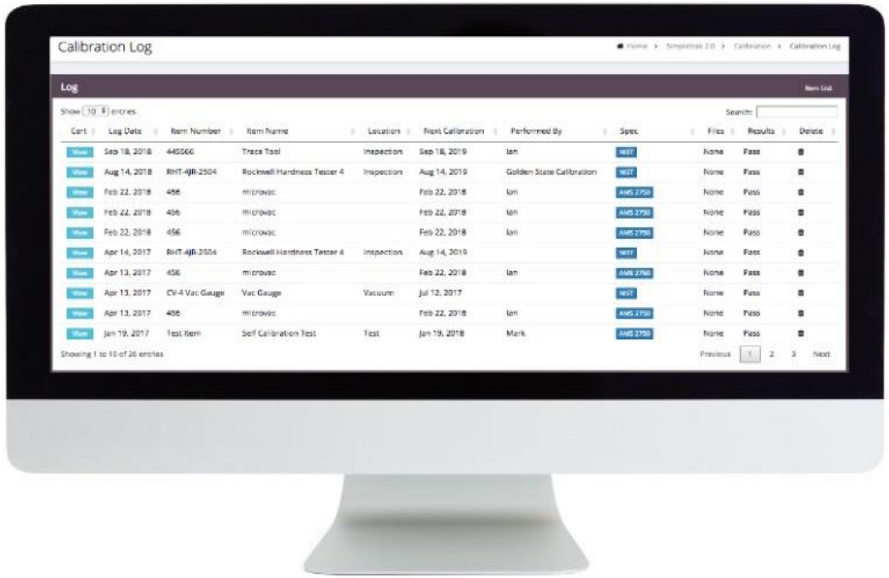
Section 6.4 Equipment

6.4.8 All equipment requiring calibration, or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to **readily identify** the status of calibration or period of validity.





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Section 6.4 Equipment

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

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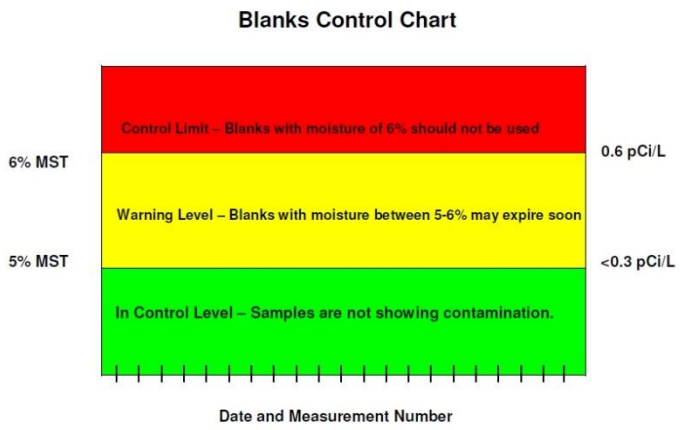
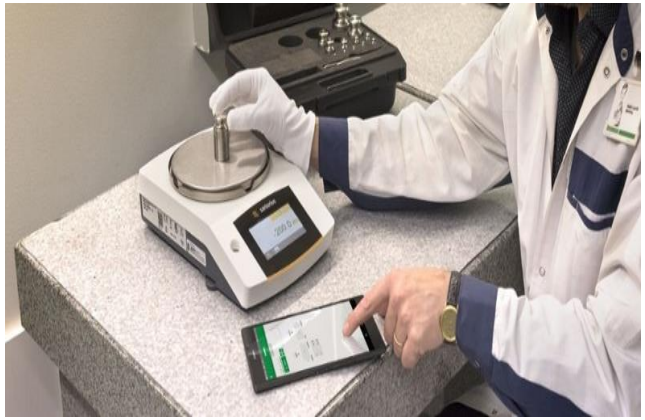
Section 6.4 Equipment

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.





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Section 6.4 Equipment

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements

Consider a calibration certificate reporting corrections

Instrument reading (units)	**Correction (units)**
100	-0.2
110	-0.3
120	-0.3

The result of a measurement in which the instrument gave a reading of 110 units is obtained by adding the correction to the reading

- corrected result = 110 + (-0.3) = 109.7 units

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6.4 Equipment

6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

- Calibration Mode

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Section 6.4 Equipment

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, **where applicable**:

a) the identity of equipment, including software and firmware version;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) evidence of verification that equipment conforms with specified requirements

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Section 6.4 Equipment

d) the current location;

e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;

h) details of any damage, malfunction, modification to, or repair of, the equipment.

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This time is allocated for questions. You should have a space provided for submitting questions.

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If a question is not answered, please submit directly to webinar@pjlabs.com

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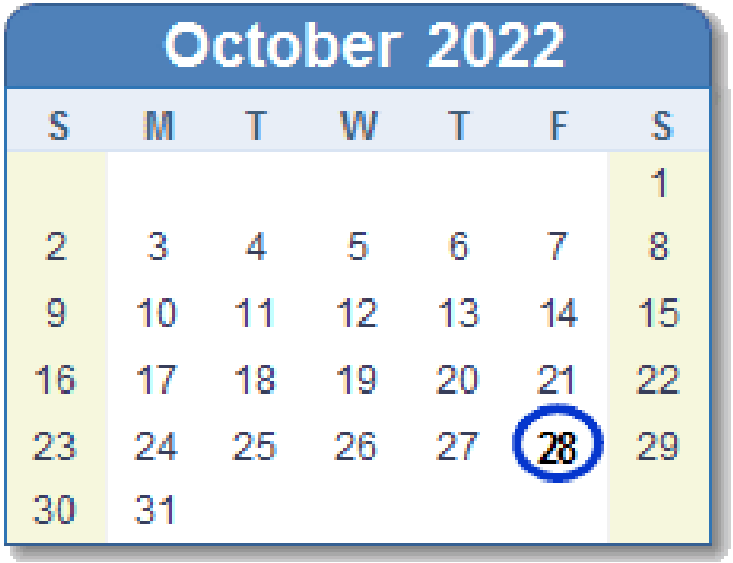
Save the Date

ISO/IEC 17025:2017 Section 8.9 Management Review Requirements and Utilization



Friday, Oct 28th 2022

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