Requirements in Section 6.4 “Equipment”

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October 26, 2023

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” Requirements in Section 6.4 “Equipment”

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Requirements in Section 6.4 “Equipment”

Equipment that is performing well and properly maintained is a prerequisite for the ongoing accuracy of test and calibration results. This section deals with the capabilty and quality of equipment. The whole idea is to make sure that the instrument is suitable for performing selected tests/calibrations and is well characterized, calibrated, and maintained.

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Requirements in 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 which is required for the correct performance of laboratory activities, and which can influence the result.

Notes are added clarifying reference material and also : ISO Guide 33 as a resource for selection and use of reference materials and ISO Guide 80 to produce in house quality control materials.

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Requirements in Section 6.4 “Equipment”

6.4.2 In those cases where the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

This includes when it has been sent out for calibration. A check per a defined procedure should be made. The check needs to incorporate both the function and calibration of equipment and determines if it is shown to be satisfactory upon return.

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Requirements in Section 6.4 “Equipment”

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

This could reference manufactures protocol however additional procedures may be necessary when equipment is used outside the permanent laboratory for tests, calibrations or sampling.

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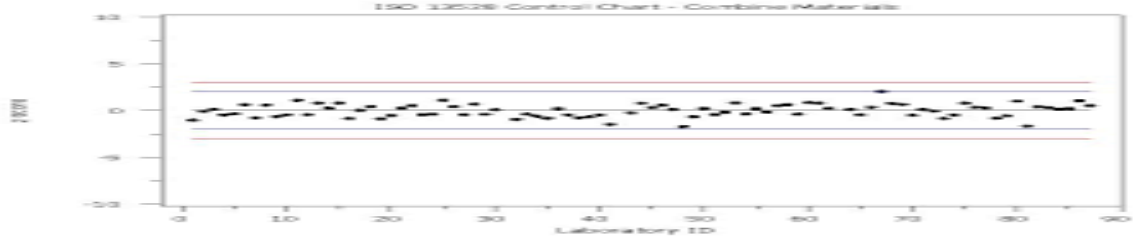
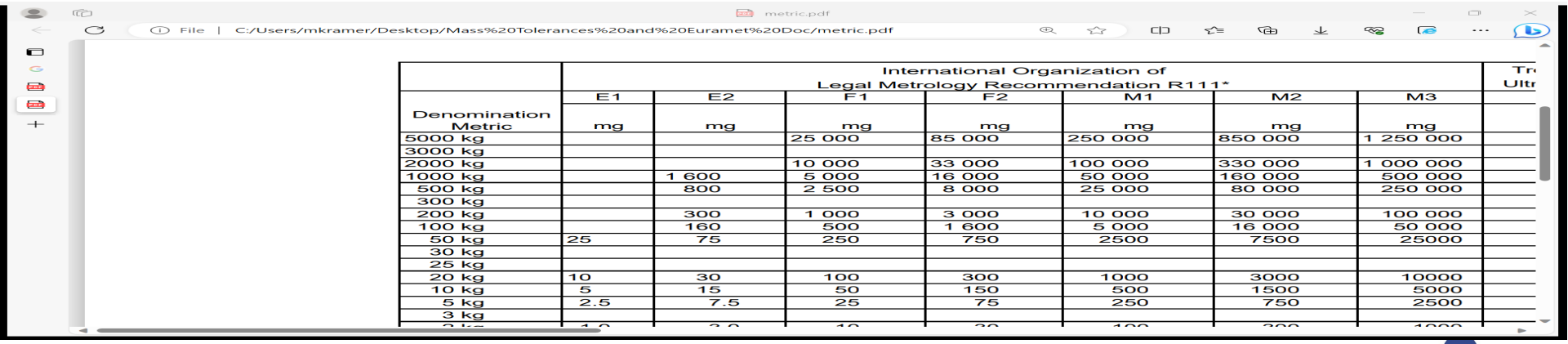
Section 6.4 Equipment

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



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.



metric.pdf

File | C:/Users/mkramer/Desktop/Mass%20Tolerances%20and%20Euramet%20Doc/metric.pdf

Denomination Metric	International Organization of Legal Metrology Recommendation R111* E1 mg	E2 mg	F1 mg	F2 mg	M1 mg	M2 mg	M3 mg	Tr Ultr
5000 kg			25 000	85 000	250 000	850 000	1 250 000	
3000 kg								
2000 kg			10 000	33 000	100 000	330 000	1 000 000	
1000 kg		1 600	5 000	16 000	50 000	160 000	500 000	
500 kg		800	2 500	8 000	25 000	80 000	250 000	
300 kg								
200 kg		300	1 000	3 000	10 000	30 000	100 000	
100 kg		160	500	1 600	5 000	16 000	50 000	
50 kg	25	75	250	750	2500	7500	25000	
30 kg								
25 kg								
20 kg	10	30	100	300	1000	3000	10000	
10 kg	5	15	50	150	500	1500	5000	
5 kg	2.5	7.5	25	75	250	750	2500	
3 kg								

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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.

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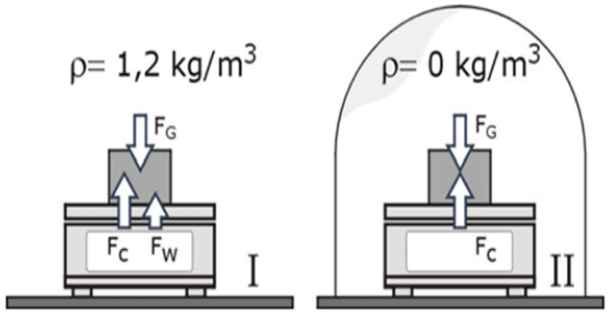
Noted is ISO/IEC 17025:2017 Types of equipment having an effect on the validity of the reported results can include:

— those used for the direct measurement of the measurand, 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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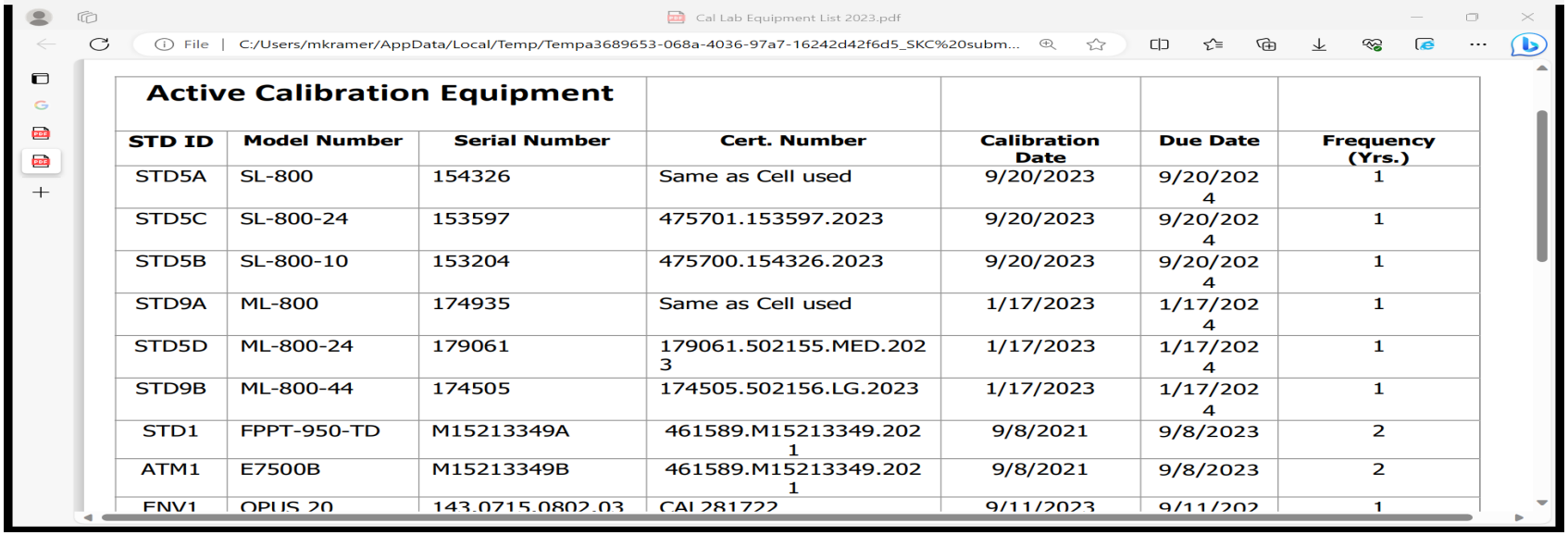
Section 6.4 Equipment

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



Active Calibration Equipment

STD ID	Model Number	Serial Number	Cert. Number	Calibration Date	Due Date	Frequency (Yrs.)
STD5A	SL-800	154326	Same as Cell used	9/20/2023	9/20/2024	1
STD5C	SL-800-24	153597	475701.153597.2023	9/20/2023	9/20/2024	1
STD5B	SL-800-10	153204	475700.154326.2023	9/20/2023	9/20/2024	1
STD9A	ML-800	174935	Same as Cell used	1/17/2023	1/17/2024	1
STD5D	ML-800-24	179061	179061.502155.MED.2023	1/17/2023	1/17/2024	1
STD9B	ML-800-44	174505	174505.502156.LG.2023	1/17/2023	1/17/2024	1
STD1	FPPT-950-TD	M15213349A	461589.M15213349.2021	9/8/2021	9/8/2023	2
ATM1	E7500B	M15213349B	461589.M15213349.2021	9/8/2021	9/8/2023	2
ENV1	OPUS 20	143.0715.0802.03	CAL 281722	9/11/2023	9/11/202	1

Calibration should not be a one-time event and risk should be considered when selecting calibration intervals.

See Section 7.10 Nonconforming work

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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 labeled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

- Needs to be able to readily identify

There are extenuating circumstances rendering labeling. Such reasons might include:

- Labeling the equipment would compromise the results or accuracy
- The equipment exists in a harsh environment in which a label would not survive
- The size of the equipment is not sufficient for labeling or coding.

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6.4 Equipment

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, 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 labeled 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.

Often with testing this is incorporated with the testing procedure with the use of spikes, blanks, or known reference materials.

For calibration control chart are often utilized. Testing a balance with a known test weights prior to proceeding with a pipette calibration would be an intermediate check assuring that the display in indicating within predefined limits of acceptance.

Again risk should be considered when determining how often intermediate checks are needed.

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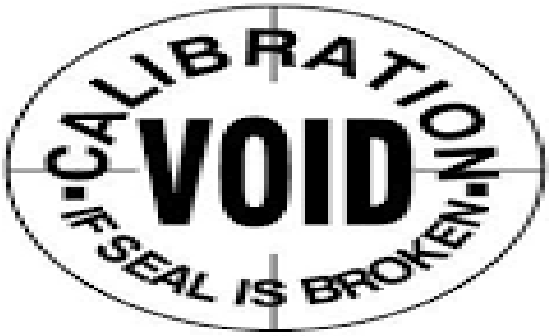
6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.



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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;

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;

• Continued next slide

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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.

- These records do not need to be maintained in one location

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Section 6.4 Equipment

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

Understanding The PJLA Flexible Scope Policy for Testing Labs, RMPs and PTPs

Presented by:
Matthew Sica, PJLA Technical Program Manager

October 31, 2023, 1:00 PM - 2:00 PM EST

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