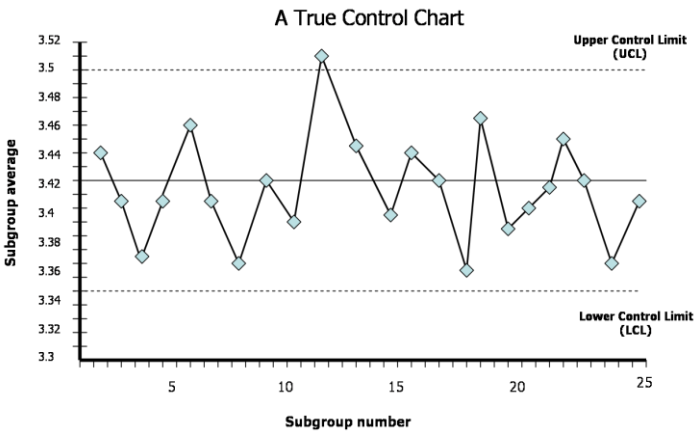
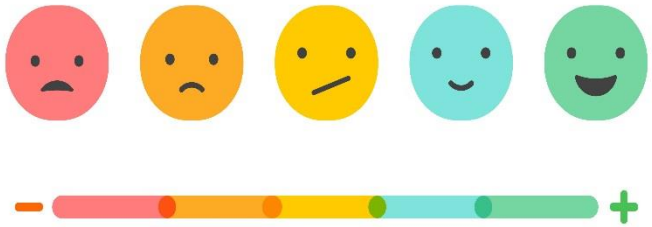
ISO/IEC 17025:2017 Section 7.10” Nonconforming Work” & Section 8.6 “Improvement”





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PJLA Calibration/Inspection Program Manager

22-November-2021

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ISO/IEC 17025:2017 Section 7.10” Nonconforming Work” & Section 8.6 “Improvement”

- This webinar is being recorded
- All PJLA webinar recordings and slides are available for download from the Past Webinars section of our website
  - https://www.pjlabs.com/training/pjla-webinars
- All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.

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Section 7.10 Nonconforming Work

Nonconforming test or calibration would occur if any aspect of the organizations testing and/or calibration work, or the result of this work, do not conform to the organizations own procedures or the agreed requirements of the customer;

Nonconforming work can be identified through customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate reviews, management reviews and internal or external audits

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Section 7.10 Nonconforming Work

A non-conformance is a deviation from an established protocol or plan, such as:

- failure of resources (i.e. personnel, equipment, facilities, work instructions) to meet performance requirements or other specified requirements;
- failure of personnel to comply with documented work instructions or operational procedures;

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Section 7.10 Nonconforming Work

- failure of test data to meet required standards due to:

1. failure (or suspected failure) to meet all conditions necessary to ensure the integrity and representatives of the sample, i.e. sample history deficiencies exist;
2. failure (or suspected failure) to comply with the test method SOP's; - failure (or suspected failure) in method performance as demonstrated by results provided by quality control samples;
3. inherent property of a sample that compromises the testing, e.g. as verified by the method of standard additions;

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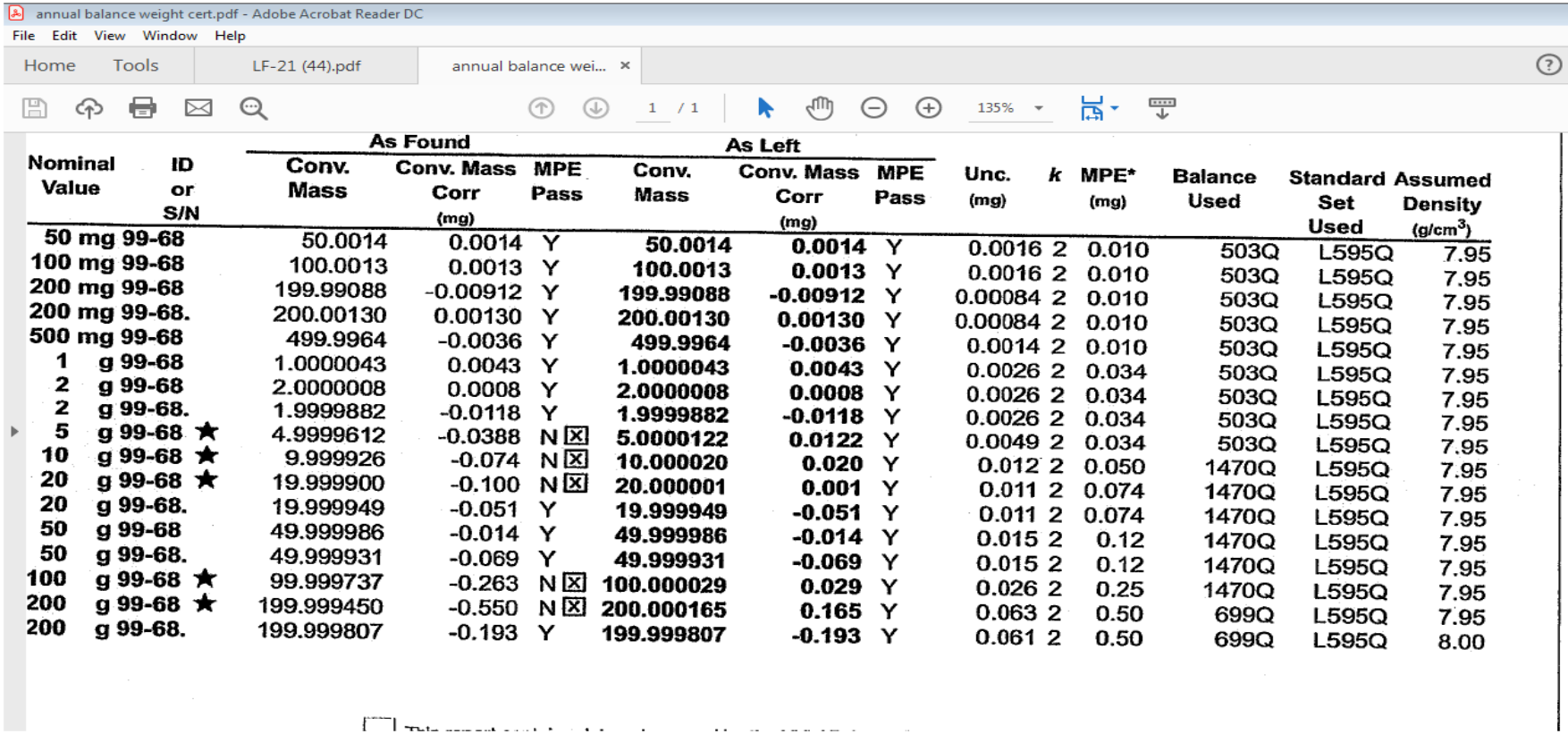
Section 7.10 Nonconforming Work

- Equipment or standards calibrated was out of tolerance.

  As found = As used



Nominal Value	ID or S/N	As Found Conv. Mass	As Found Conv. Mass Corr (mg)	As Found MPE Pass	As Left Conv. Mass	As Left Conv. Mass Corr (mg)	As Left MPE Pass	Unc. (mg)	k	MPE* (mg)	Balance Used	Standard Set Used	Assumed Density (g/cm³)
50 mg	99-68	50.0014	0.0014	Y	50.0014	0.0014	Y	0.0016	2	0.010	503Q	L595Q	7.95
100 mg	99-68	100.0013	0.0013	Y	100.0013	0.0013	Y	0.0016	2	0.010	503Q	L595Q	7.95
200 mg	99-68	199.99088	-0.00912	Y	199.99088	-0.00912	Y	0.00084	2	0.010	503Q	L595Q	7.95
200 mg	99-68.	200.00130	0.00130	Y	200.00130	0.00130	Y	0.00084	2	0.010	503Q	L595Q	7.95
500 mg	99-68	499.9964	-0.0036	Y	499.9964	-0.0036	Y	0.0014	2	0.010	503Q	L595Q	7.95
1 g	99-68	1.0000043	0.0043	Y	1.0000043	0.0043	Y	0.0026	2	0.034	503Q	L595Q	7.95
2 g	99-68	2.0000008	0.0008	Y	2.0000008	0.0008	Y	0.0026	2	0.034	503Q	L595Q	7.95
2 g	99-68.	1.9999882	-0.0118	Y	1.9999882	-0.0118	Y	0.0026	2	0.034	503Q	L595Q	7.95
5 g	99-68 ★	4.9999612	-0.0388	N ☒	5.0000122	0.0122	Y	0.0049	2	0.034	503Q	L595Q	7.95
10 g	99-68 ★	9.999926	-0.074	N ☒	10.000020	0.020	Y	0.012	2	0.050	1470Q	L595Q	7.95
20 g	99-68 ★	19.999900	-0.100	N ☒	20.000001	0.001	Y	0.011	2	0.074	1470Q	L595Q	7.95
20 g	99-68.	19.999949	-0.051	Y	19.999949	-0.051	Y	0.011	2	0.074	1470Q	L595Q	7.95
50 g	99-68	49.999986	-0.014	Y	49.999986	-0.014	Y	0.015	2	0.12	1470Q	L595Q	7.95
50 g	99-68.	49.999931	-0.069	Y	49.999931	-0.069	Y	0.015	2	0.12	1470Q	L595Q	7.95
100 g	99-68 ★	99.999737	-0.263	N ☒	100.000029	0.029	Y	0.026	2	0.25	1470Q	L595Q	7.95
200 g	99-68 ★	199.999450	-0.550	N ☒	200.000165	0.165	Y	0.063	2	0.50	699Q	L595Q	7.95
200 g	99-68.	199.999807	-0.193	Y	199.999807	-0.193	Y	0.061	2	0.50	699Q	L595Q	8.00

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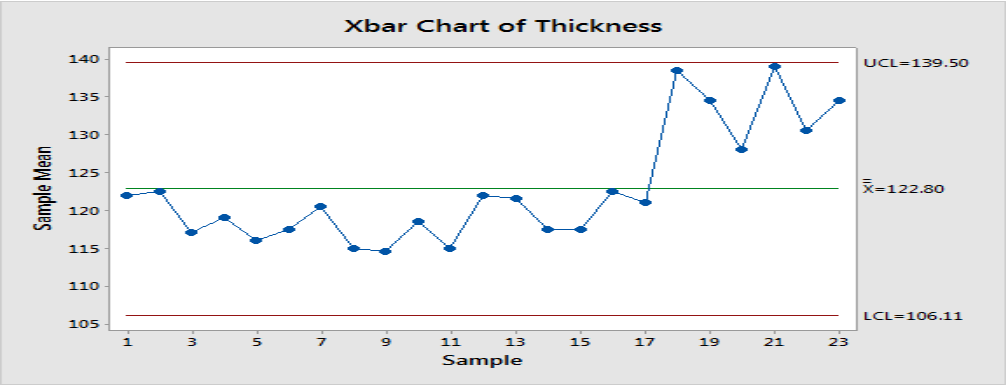
Section 7.10 Nonconforming Work

Out of tolerance conditions from calibration reports need to be evaluated as per the requirements in this section. These conditions need to be investigated as to any impact on testing or calibration work produced for your clients. Ideally a good system of intermediate checks on equipment may provide supporting data as to when the equipment was out of tolerance. With no system of intermediate checks in place, for all you know it could of drifted out of tolerance the day the instrument was received back from the previous calibration or the day before it was sent out for this calibration.



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Section 7.10 Nonconforming Work

7.10.1 The laboratory **shall have a procedure** that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

- a) the responsibilities and authorities for the management of nonconforming work are defined;

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Section 7.10 Nonconforming Work

The procedure shall ensure that:

- b) actions (including halting or repeating of work and withholding of reports, as necessary) **are based upon the risk levels established by the laboratory**

The laboratory should adapt its procedure of nonconforming work handling to include different levels of risk with the most severe having direct adverse effect on customers reported results:

For example: Acceptable, Tolerable, Undesirable, Intolerable

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Section 7.10 Nonconforming Work

The procedure shall ensure that:

c) an evaluation is made of the significance of the nonconforming work, including **an impact analysis on previous results**

For example did the out of tolerance condition on as found data impact statements of compliances reported to customers? A record would need to be created to show that this investigation was performed.

Working Backwards !

reverse traceability

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Section 7.10 Nonconforming Work

The procedure shall ensure that:

d) a decision is taken on the acceptability of the nonconforming work;

- e) where necessary, the customer is notified and work is recalled;

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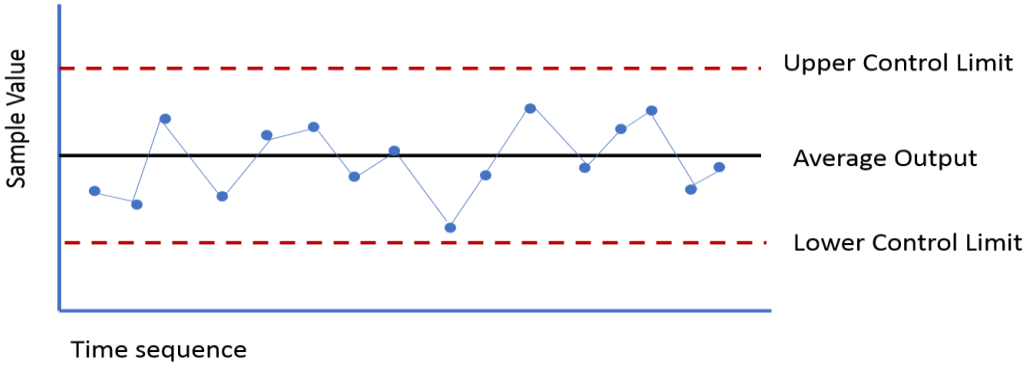
Section 7.10 Nonconforming Work

The procedure shall ensure that:

- f) the responsibility for authorizing the resumption of work is defined.



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Section 7.10 Nonconforming Work

7.10.2 The laboratory shall **retain records** of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

Needs to show that it has been done

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Section 7.10 Nonconforming Work

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

Section 8.7 

should be implemented therefore establishing the causes of the nonconforming work and preventing reoccurrence.

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8.6 Improvement

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results

These areas given in the note above are all incorporated into the requirements of ISO/IEC 17025:2017. Ideally besides meeting any specified requirements, they will provide benefits to the organization and provide opportunities which can be identified

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8.6 Improvement

8.6.2 The laboratory **shall seek** feedback, both positive and negative, from its customers. The feedback **shall be analyzed** and used to improve the management system, laboratory activities and customer service

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers;

Make it work for you. If you send 200 surveys out and only get 2 back chances are it is not providing any benefit.

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Thank You

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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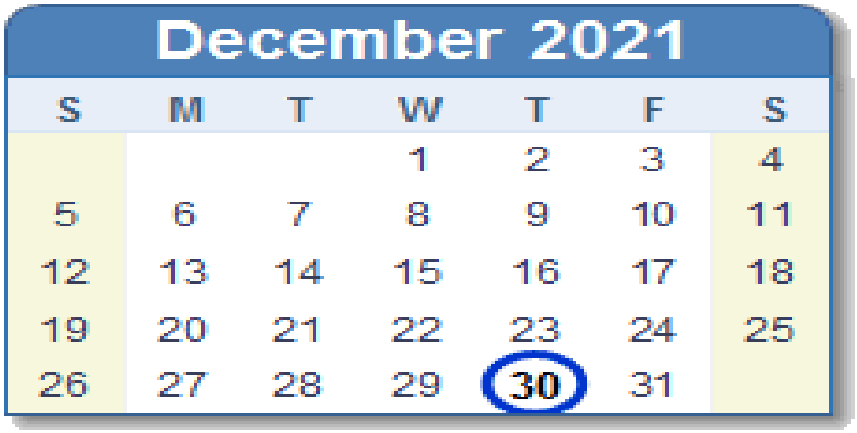
Save the Date

Section 5.0 Structural Requirements of ISO/IEC 17025:2017



Thursday, Dec 30th 2021

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