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

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Presented by:

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

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

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ISO/IEC 17025:2017 Section 7.10" Nonconforming Work"

Identification of changes

This clause is more detailed, and a new item has been included that is to be taken into account in the nonconforming work procedure.

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

A novelty on the extension analysis has also been included in point c

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

ISO/IEC 17025:2017 Section 7.10” Nonconforming Work”

Nonconforming test or calibration would occur if any aspect of its 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 checking, management reviews and internal or external audits

ISO/IEC 17025:2017 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;

;

ISO/IEC 17025:2017 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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- *Equipment or standards calibrated was out of tolerance.*

As found = As used

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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

ISO/IEC 17025:2017 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;

ISO/IEC 17025:2017 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:

Acceptable, Tolerable, Undesirable, Intolerable

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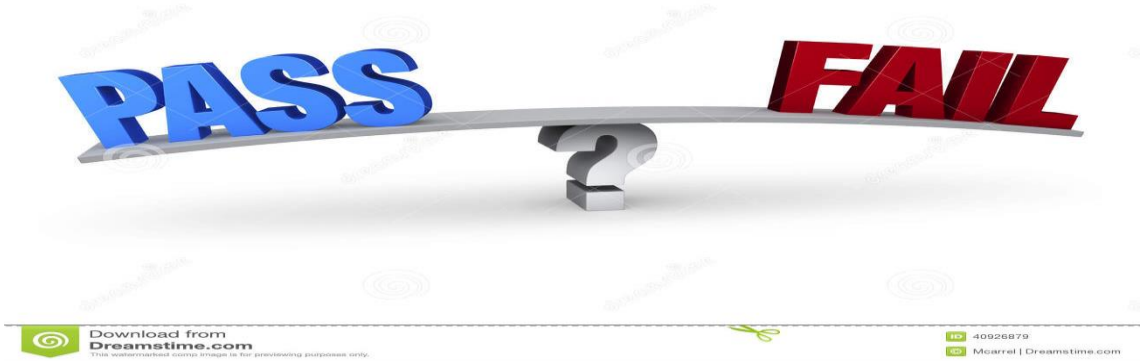
The procedure shall ensure that:

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 impact statements of compliances reported to customers? A record would need to be created to show that this investigation was performed***.**



ISO/IEC 17025:2017 Section 7.10" Nonconforming Work

The procedure shall ensure that:

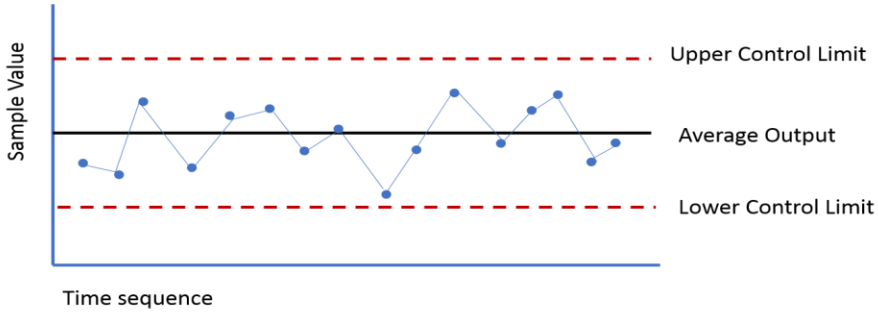
d) a decision is taken on the acceptability of the nonconforming work;

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

ISO/IEC 17025:2017 Section 7.10" Nonconforming Work

The procedure shall ensure that:

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



ISO/IEC 17025:2017 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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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.

8.6 Improvement

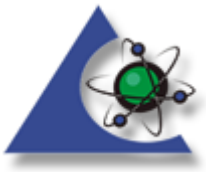
Requirements have been reduced.

From ISO/IEC 17025:2005:

The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review

From ISO/IEC 17025:2017

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



8.6 Improvement

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

The notes given provide clarification of the text, examples and guidance. They do not contain requirements

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.

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

Formerly the same requirement was captured in Section 4.7 of the 2005 Standard "Service to the Customer"

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

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

Please keep questions related to the topic covered in this webinar;

Save the Date

Next PJLA Webinar

Thursday, July 25 – 1:00pm EST

Section 5.0 "Structural Requirements" of ISO/IEC 17025:2017