

# ISO/IEC 17025:2017 - 7.9 “Complaints”

## *ISO/IEC 17025:2017 - 7.9 Complaints: Overview of New Requirements*



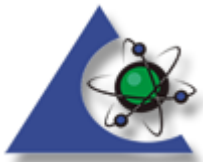
*Presented by:*

*Michael Kramer*

*Calibration Program Manager*

*Perry Johnson Laboratory Accreditation, Inc.*

*19-March-2020*



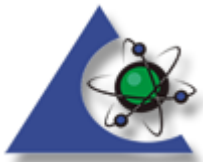
# ISO/IEC 17025:2017 - 7.9 “Complaints”

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*Go to the link for recorded webinars.*

*Duration of webinar is set for a maximum time of 1 hour*

*You should have a space provided for questions. You can type questions directly into the designated area. At the end of the presentation I will review and answer the submitted questions. Please keep questions related to todays topic.*



# ISO/IEC 17025:2017 - 7.9 “Complaints”

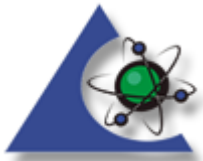
**From ISO/IEC 17025:2005**

## **4.8 Complaints**

The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

ISO/IEC/17025:2017 places more emphasis on this section

7.9.1 – 7.9.7

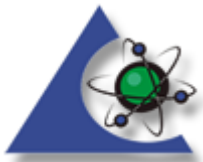


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*Complaint is one of nine new definitions in ISO/IEC 17025:2017*

## **3.2 complaint**

Expression of dissatisfaction by any person or organization to a *laboratory* (3.6), relating to the activities or results of that laboratory, where a response is expected;



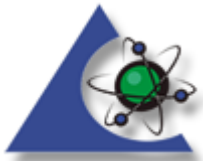
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**7.9.1** The laboratory shall have a documented process to receive, evaluate and make decisions on complaints

*A documented process outlines the steps necessary to complete a task or process*

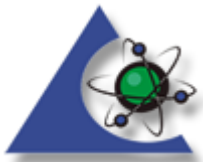
*Ways to document a process may include: flow charts, swim lane diagrams, standard operating procedures or , manually, in Excel, or through automated software,*

*If you currently have a documented procedure that can still be used however may need to be revised.*



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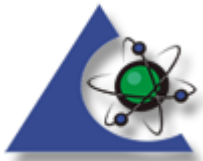
**7.9.2** A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.



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**7.9.3** The process for handling complaints **shall** include at least the following elements and methods:

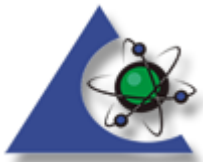
- a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
- b) tracking and recording complaints, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken;



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**7.9.4** The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

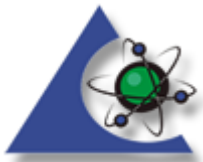
*In other words the lab needs to assure information received is accurate.*





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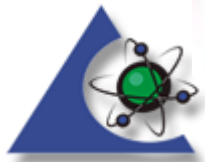
**7.9.5** Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.



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**7.9.6** The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

NOTE This can be performed by external personnel

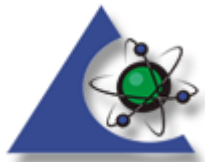


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**7.9.7** Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

What about confidentiality ??

Section 4.2 Confidentiality is in regards to all laboratory activities.



# *ISO/IEC 17025:2017 - 7.9*



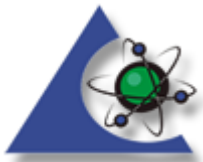
Thank You

Any Questions?

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

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*If a question is unanswered please submit directly to [webinar@pjlabs.com](mailto:webinar@pjlabs.com)*



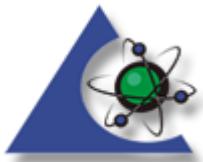
# *ISO/IEC 17025:2017 - 7.9*

*Next scheduled webinar is set for 20-April-2020 1:00 pm Eastern Time*

*Topic: A look at the ISO/IEC 17025:2017 requirements concerning Document Control and Control of Records.*

April 2020						
S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	<b>20</b>	21	22	23	24	25
26	27	28	29	30		

**Monday, Apr 20th 2020**



# Webinar: What to Expect in Your Initial ISO/IEC 17025 Assessment

March 25 @ 2:00 pm - 3:00 pm EDT

We understand that laboratories seeking accreditation for the first time face many challenges regarding how to implement the standard and the expectations of your accreditation body assessor.

These questions are magnified if this is your first experience in a regulated laboratory setting and with ISO/IEC 17025 in particular. This webinar is intended to help you understand what to expect in that initial audit.

We will be joined by Tracy Szerszen, president and operations manager of Perry Johnson Laboratory Accreditation (PJLA), who will help you answer questions as you prepare for your assessment.

For additional information and to register go to? [www.pjlabs.com](http://www.pjlabs.com)

