

ISO/IEC 17025:2017 Section 8.9 Management Review Requirements



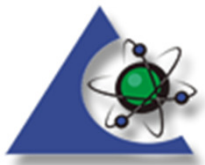
Presented by:

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Calibration Program Manager

Perry Johnson Laboratory Accreditation, Inc.

29-October-2020



Perry Johnson Laboratory Accreditation, Inc.

ISO/IEC 17025:2017 Section 8.9 Management Review Requirements

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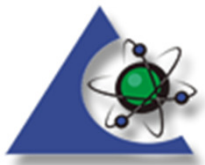
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Go to the link for recorded webinars.

Also individual slides of this and previous presentation are available.

There is a space on your screen to ask questions. Please keep question related to today's topic. At the conclusion of the webinar, received questions will be reviewed and answered.

Duration of webinar is set for one hour.



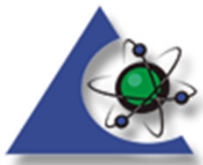
Management Review (8.9)

What is a management review?



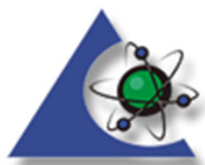
A Management Review Meeting can be described as a meeting scheduled at planned intervals to discuss the core elements of your management system.

Conducting effective management reviews is more than just gathering everyone together in a room to discuss the required standard topics so that you can generate minutes for your assessor.



Management Review

As a rule, a “management review” is a special meeting of the laboratory’s top management, called to discuss the effectiveness of the laboratory’s management system and testing and/or calibration activities, and any changes that may be needed. Usually, management reviews are timed to follow closely after each internal audit, so that the results of the audit may be discussed during the management meeting.



Management Review (8.9) Option A

Identification of changes

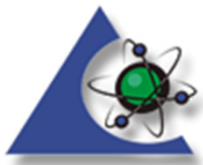
This clause has been rewritten.

The recommendation of performing the management review every 12 months has been erased.

Some inputs have been changed:

- "customer feedback" has been modified to "customer and personnel feedback"
- Instead of "recommendations for improvements", it has been modified to: "effectiveness of any implemented improvements"

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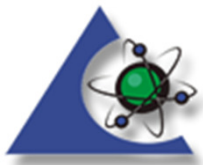
Management Review (8.9)

Some inputs have been added:

- a) changes in internal and external issues that are relevant to the laboratory;
- b) fulfilment of objectives;
- d) status of actions from previous management reviews;
- l) adequacy of resources;
- m) results of risk identification



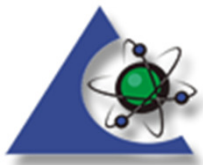
Input



Management Review (8.9)

The outputs have been detailed:

- a) the effectiveness of the management system and its processes;
- b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- c) provision of required resources;
- d) any need for change



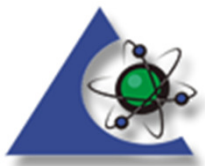
Management Review (8.9)

8.9.1 The laboratory management shall review its management system at **planned intervals**, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

The recommendation of performing the management review every 12 months has been erased

From ISO/IEC 17025:2005

NOTE 1 A typical period for conducting a management review is once every 12 months



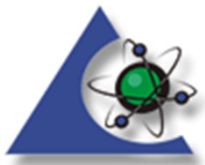
Management Review (8.9)

Who should attend? “The laboratory management “

The number of participants depends on the size of the organization. In bigger companies, a special meeting should be organized in the management circle. In smaller companies, the entire staff may be involved. The minimum however should be, the lab or technical manager and the quality manager.

Whoever falls into this category as per the structural requirement below should actively be involved:

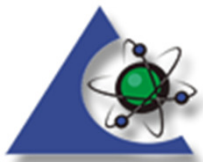
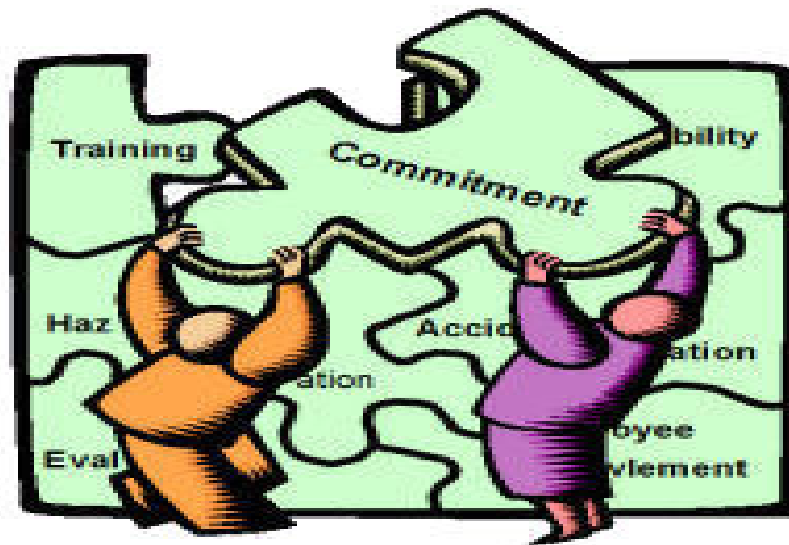
5.2 The laboratory shall identify management that has overall responsibility for the laboratory.



Management Review (8.9)

Top management being actively involved in the management review can be objective evidence to support:

8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness

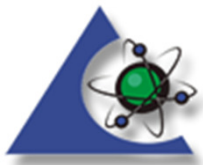


Management Review (8.9)

In preparation of the meeting and to assure the inputs and outputs requirements are captured an agenda containing those required elements can be prepared.



For compliance for ISO/IEC 17025:2017 you can always do more however those required inputs and outputs must be included.



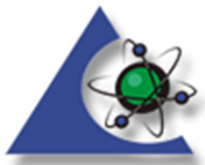
Management Review (8.9)

Ideally the management review should follow the internal audit so that the most recent internal audit can be incorporated into the management review.

Internal Audit



Management Review



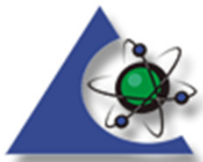
Management Review (8.9)

8.9.2 The inputs to management review shall be recorded and shall include information related to the follow;

a) changes in internal and external issues that are relevant to the laboratory;

Internal within the organizations: retirements, aging equipment, company policies:

*External; outside and not controlled by the organization.
regulations, competition, accreditation requirements, new technology*



Management Review (8.9)

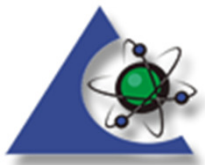
8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

b) fulfilment of objectives;

Earlier in the Standard

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization;

How did you do?



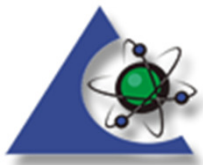
Management Review (8.9)

8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

c) suitability of policies and procedures;

Is your quality management system reflective of what that laboratory is actually doing??

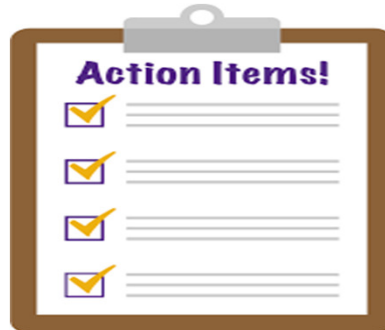
Has external documents been revised??



Management Review (8.9)

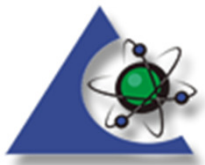
8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

d) status of actions from previous management reviews;



e) outcome of recent internal audits;

Is the process effective?



Management Review (8.9)

8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

f) corrective actions;



This should be more than stating you didn't have any or a simple reference to those implemented (both external source and internal)

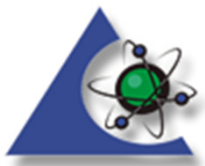
What corrective action has been implemented?

Are there any open corrective action?

Has corrective action take been monitored and been effective?

Any repeat corrective actions?

Are staff aware of the process? Anything falling between the cracks?



Management Review (8.9)

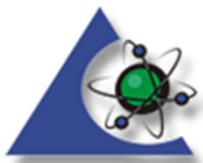
8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

g) assessments by external bodies;

By who? When? Next scheduled?

Any findings, concerns, or recommendations?

If the external body are having findings, why are they not found during the internal audit?



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Management Review (8.9)

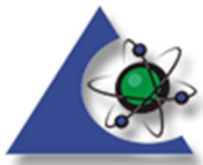
8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

h) changes in the volume and type of the work or in the range of laboratory activities;

Any trends detected ?

May need to shift resources (financial and human)

May need to train additional human resources



Management Review (8.9)

8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

i) customer and **personnel feedback**;

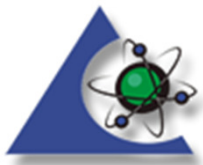
-personnel feedback is an addition;

Earlier in the standard under “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.

Well?

Customer Feedback



Management Review (8.9)

8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

j) complaints;

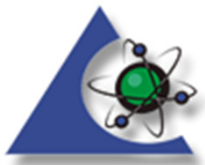
Beyond if you received any:

Any Trends?

Any Corrective Action taken as a result;

Are they being processed accordingly (**7.9 Complaints**)?

Are complaints being directed to proper personnel “awareness”



Management Review (8.9)

8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

k) effectiveness of any implemented improvements;

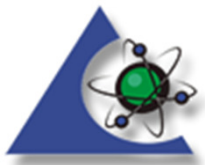
Earlier in the Standard “Improvement”

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

-This could also include any preventive action;

l) adequacy of resources;

-equipment, human resources, facilities



Management Review (8.9)

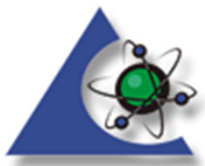
8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

m) results of risk identification; - new

Earlier in the Standard “Actions to Address Risk and Opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results; b) enhance opportunities to achieve the purpose and objectives of the laboratory; c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; d) achieve improvement



Management Review (8.9)

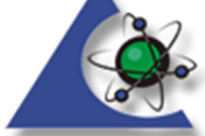
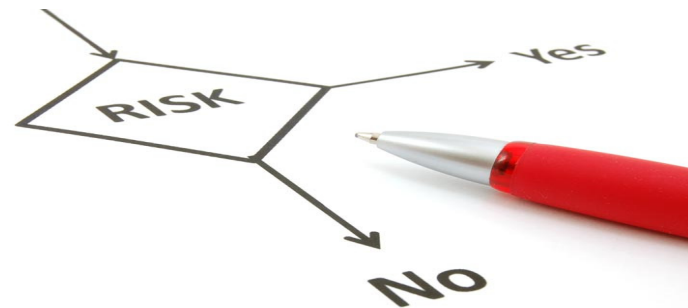
What risk has been identified?

Was the risk taken, mitigated, or avoided?

What was the outcome?

ISO/IEC 17025:2017 strongly emphasizes “risk based” thinking:

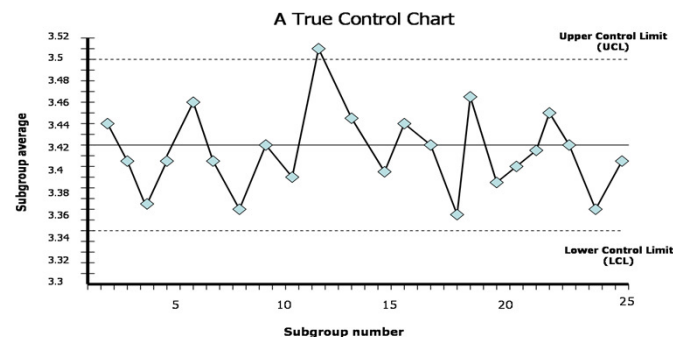
’The word “risk appears over thirty times in the document compared to only four appearances in the 2005 Standard



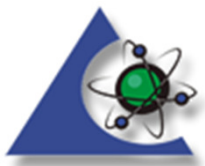
Management Review (8.9)

8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

n) outcomes of the assurance of the validity of results;



o) other relevant factors, such as monitoring activities and training.

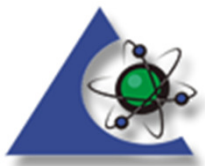


Management Review (8.9)

8.9.3 The outputs from the management review **shall record** all decisions and actions related to at least:

- a) the effectiveness of the management system and its processes;
- b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- c) provision of required resources;
Are they being supplied????
- d) any need for change.

--The standard now specifies these actions need to be recorded.



ISO/IEC 17025:2017 Section 8.9 Management Review Requirements



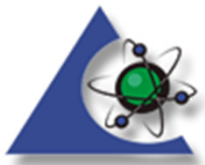
Thank You

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 not answered, please submit directly to
webinar@pjlabs.com*



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Save the Date

Next scheduled webinar is set for 23 November 2020
. ISO/IEC 17025:2017 and Section 8.8 on Internal Audits

November 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	20	21
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29	30					

Monday, Nov 23rd 2020

