Section 8.9 Management Review Requirements and Utilization

Presenter: Michael Kramer
PJLA Calibration/Inspection Program Manager
28-October-2022

PJLA

ISO/IEC 17025:2017 Section 8.9 Management Review Requirements

This webinar is being recorded and will be available in it's entirely on the Perry Johnson Laboratory Accreditation Website.

www.pjlabs.com

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.

PJLA

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.

PJLA

Management Review

During the management review, laboratory's top management, shall 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.

The internal audit is an input and is a vehicle used to determine compliance.

PJLA

Management Review

Why is it important to perform management reviews other than the fact that ISO/IEC 17025:2017 requires them?

If performed effectively, the management review provides assurance to the stakeholders which would include the accreditation body that continuing suitability, adequacy, and effectiveness of the laboratory's management system, along with its stated policies and objectives are focused upon and determined if the laboratory is operating effectively. If shortcomings are identified, the provisions can be made to assure that the necessary changes are made or that the required resources are obtained.

PJLA

Management Review

The purpose of a management review is for **top management and personnel involved in the decision-making processes** to systematically evaluate the overall performance of the laboratory and its Quality Management System.

Management involvement in the management review could strengthen compliance to the following

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.

PJLA

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 can 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.

PJLA

Management Review (8.9)

In preparation of the meeting and to assure the required inputs and outputs 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.

PJLA

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.

Suitability – Are the correct process and operations included to enable and support the activities of the laboratory?

Adequacy - Evaluate if all the mandatory ISO 17025, contractual, organizational and regulatory requirements are met..

Effectiveness – Evaluate to the extent to which the management system is capable of accomplishing the purpose of producing the intended or expected result.

PJLA

Management Review (8.9)

At planned intervals

This needs to be specified within the quality management system. Ideally at least once a year.

Can be broken down into smaller segments or can be an all-encompassing management review.

PJLA

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/

PJLA

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?

PJLA

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? Does the structure and content still fill the purpose.

Has external documents been revised??

PJLA

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;

Were they assigned and accomplished. Anything outstanding.?

e) outcome of recent internal audits;

Is the process effective? What were the results?

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?

PJLA

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?

PERRY JOHNSON LABORATORY ACCREDITATION, INC. (PJLA)

FDA U.S. FOOD & DRUG ADMINISTRATION

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 or perhaps cross train

PJLA

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;**

What is your staff telling you?

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?

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”

PJLA

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

PJLA

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

PJLA

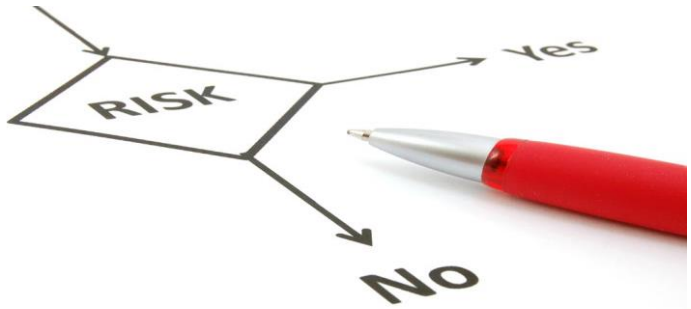
Management Review (8.9)

What risk has been identified?

Was the risk taken, mitigated, or avoided?

What was the outcome?

ISO/IEC 17025:2017 strongly emphases “risk based” thinking: ’The word “risk appears over thirty times. As per 4.1.4, risk to impartiality needs to be ongoing.



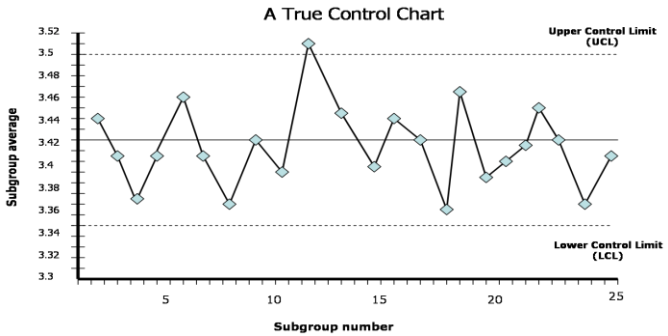
PJLA

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;

PROFICIENCY TESTING



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

PJLA

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 specifies these actions need to be recorded. These items need to be kept in mind and decisions regarding them recorded.

PJLA

Section 8.9 Management Review Requirements and Utilization

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

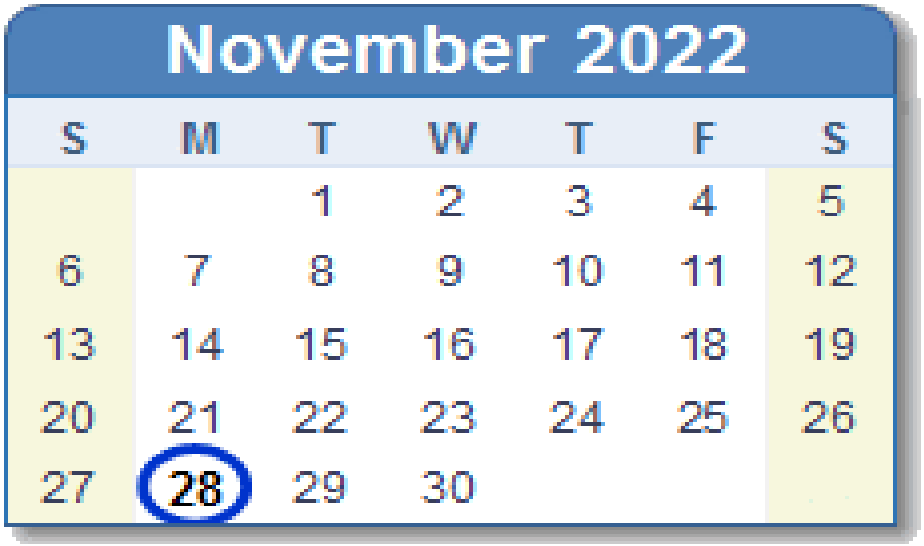
.

If a question is not answered, please submit directly to webinar@pjlabs.com

PJLA

Save the Date

Requirements for Internal Audits in ISO/IEC 17025:2017



Monday, Nov 28th 2022

PJLA