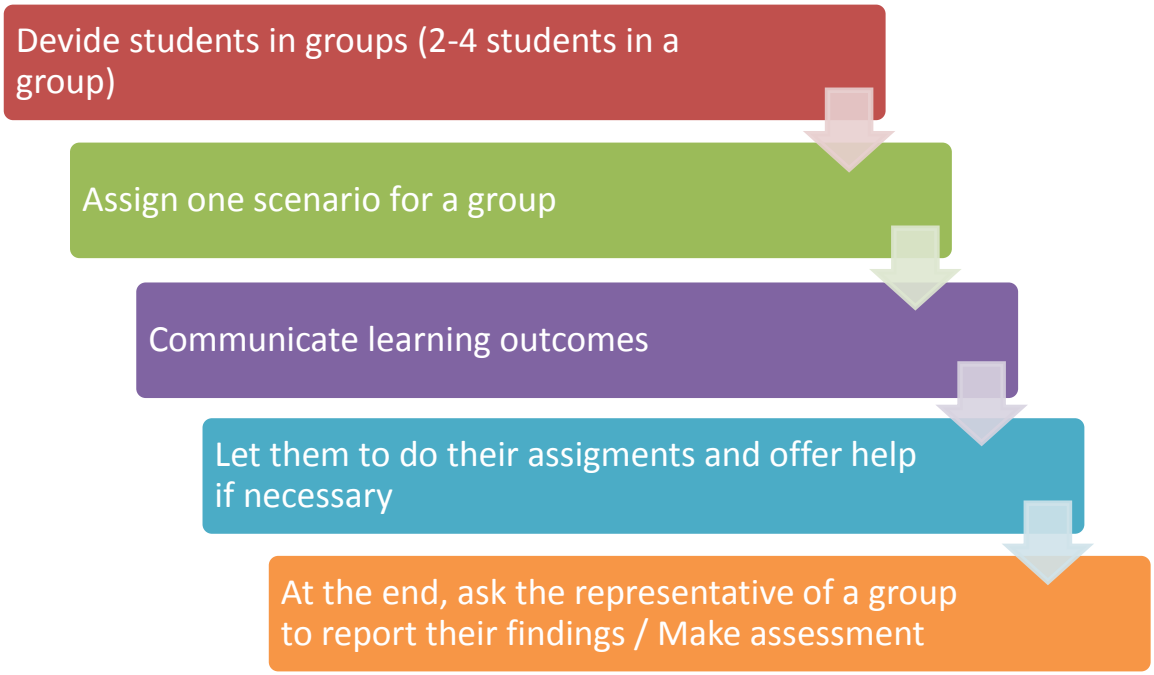
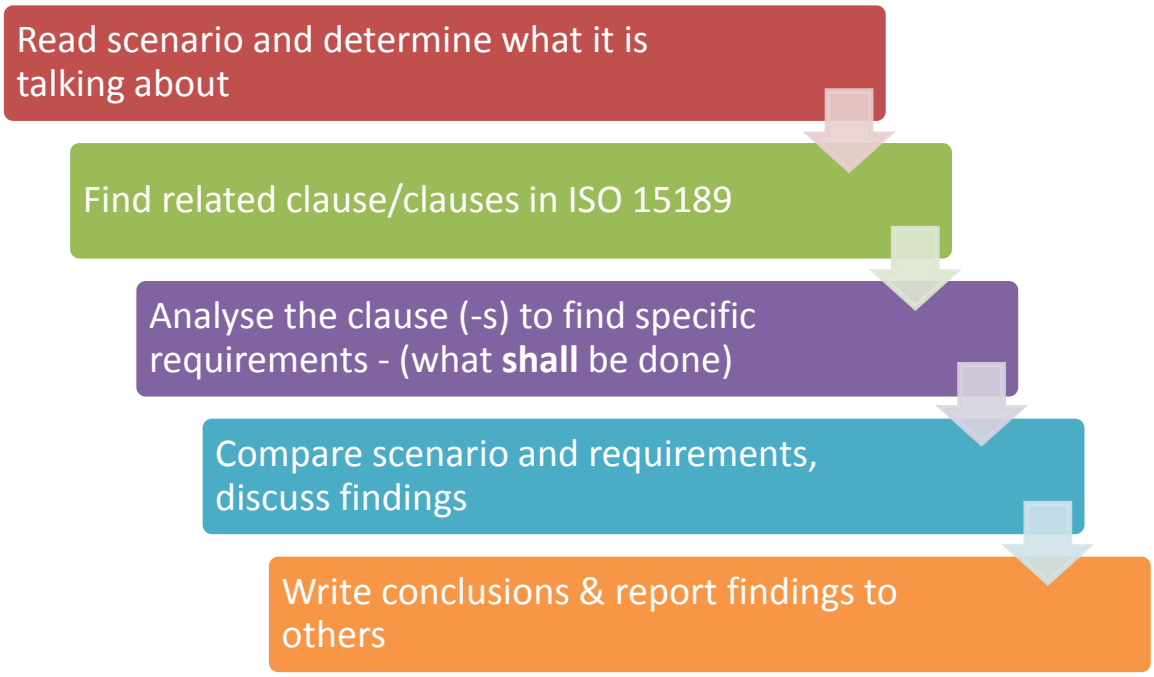
ISO 15189 CPD Exercise

Trainers:



Students:


Read scenario and determine what it is talking about
Find related clause/clauses in ISO 15189
Analyse the clause (-s) to find specific requirements - (what **shall** be done)
Compare scenario and requirements, discuss findings
Write conclusions & report findings to others

Scenario 1: Management review

The Head of Department (HD) is responsible for convening management reviews with, at a minimum, the Deputy Head, Chief Technician and Quality Manager. Management review is conducted every 12 months. HD has a right to shorten this interval if he/she assesses that it is necessary. Longer periods are not allowed.

QM is responsible for collecting and reporting information from the results of evaluation of:

a) *internal audits;*
b) *risk management;*
c) *use of quality indicators ;*
d) *results of participation in PT/EQA programmes;*
e) *monitoring and resolution of complaints;*
f) *identification and control of nonconformities;*
g) *results of continual improvement including current status of corrective actions and preventive actions;*
h) *follow-up actions from previous management reviews;*
i) *changes in the volume and scope of work, personnel, and premises that could affect the quality management system;*
j) *other factors*

Management team shall analyse the input information and assess opportunities for improvement of the quality management system and revision of quality objectives, policies and procedures.

QM is responsible:

- *to record findings and actions arising from management review*
- *to report those information to laboratory staff*
- *to ensure that actions arising from management review are completed within a defined timeframe.*

Learning Objectives

Given a case scenario, the student will be able to explain:

- the process of management review
- which input information shall be reviewed
- what are the elements of the record of review output.

Answers:

Question	Answer
Define which situation represents the scenario?	**Management review**
Relate each scenario to a specific clause or subclause in the standard	4.15
Read carefully the related requirements set in the standard. Does the scenario conforms to the requirements?	No

If not, what shall be included/how can it be improved?	• Missing MR inputs:
	  ◦ the periodic review of requests, and suitability of procedures and sample requirements
	  ◦ assessment of user feedback
	  ◦ staff suggestions
	  ◦ reviews by external organizations
	  ◦ performance of suppliers
	  ◦ recommendations for improvement, including technical requirements.
	• No information that the review will analyse the input information for causes of nonconformities, trends and patterns that indicate process problems.
	• No information that the quality and appropriateness of the laboratory's contribution to patient care shall be evaluated.
	• No information that the record incorporated MR findings will consist of decisions and actions related to:
	  a) improvement of services to users
	  b) resource needs.

Performance Assessment

Only a group assessment will be made. A group shall find answers on a), b), d), e) with the help of a trainer/facilitator.

Different ideas/answers from the given could be relevant and good.

Assessment criteria

Responsibility: trainer/facilitator

Observation of the group work discussion		
	Criteria	Assessment
Group understands the process of management review.	Yes	
Group recognises which input information shall be reviewed.	Yes	
Group recognises the elements of the record of review output.	Yes	
Group work report		
	Criteria	Assessment
Group finds missing input information.	50 %	
Group finds missing elements of the output record.	50 %	

Scenario 2: Calibration Non-Conformance

A laboratory got an out-of-specification report for its weights that were sent out to an external accredited laboratory for its scheduled recalibration. In the accompanying letter the calibration laboratory described that the surface of weights were damaged (scratched) by improper handling. The weights were used for checking balances in the laboratory.

The laboratory took the following actions.

- *They removed previous calibration label from the weight box*
- *They attached label "do not use" and removed weights from service.*
- *They logged the failure of the weights in their log*
- *They required purchase of the new weights*
- *They checked their balances with the other weights set. They found they were in tolerance so there was no risk to quality of the results issued.*

Learning Objectives

Given a case scenario, the student will be able to explain:

- what shall be done when equipment is found to be defective
- when corrective actions shall be applied
- what are the basic elements of the CA process.

Answers:

Question	Answer
Define which situation represents the scenario?	**Calibration Non-Conformance**
Relate each scenario to a specific clause or subclause in the standard	**5.3.1.5, 4.9 and 4.10**
Read carefully the related requirements set in the standard. Does the scenario conforms to the requirements?	It mostly does, but as this nonconformity could recur, (*the surface of weights were damaged (scratched) by **improper handling***) corrective actions (CA) are necessary (4.10)
If not, what shall be included/how can it be improved?	c) Find out why the weights were damaged (root causes) d) Determine and implement CA e) Review the effectiveness of the CA taken.

Performance Assessment

Only a group assessment will be made. A group shall find answers on a), b), d), e) with the help of a trainer/facilitator.

Different ideas/answers from the given could be relevant and good.

Assessment criteria

Responsibility: trainer/facilitator

Observation of the group work discussion		
	Criteria	Assessment
Group understands the process of dealing with equipment non-conformance in ISO 15189.	Yes	
Group understands the purpose of corrective action.	Yes	
Group recognises the elements of corrective action process (4.10 a) to f)).	Yes	
Group work report		
	Criteria	Assessment
Group finds missing actions.	2 out of 3	

Scenario: Measurement uncertainty

The head of a biochemical laboratory said that they determined measurement uncertainty for each of their accredited measurement procedures. They found that the most significant contributors to measurement uncertainty of their routine measurement procedures were: imprecision and the uncertainty of calibrator-assign values. For imprecision they used estimates of the long-term within-laboratory precision for two concentration levels. Uncertainties of calibrator-assign values are estimated assuming uniform (rectangular) probability distribution.

Control charts had been used to monitor long-term within-laboratory precision. For this purpose pooled patient samples and reference materials were used. They were not able to monitor instrument bias directly as their control material was not a trueness control material (Certified reference material or a reference material with a traceable assign value and stated uncertainty). They analysed PT/EQA results regularly and didn't find any evidence that their results were biased.

They made their estimates of measurement uncertainty available to laboratory users through their web site. They didn't consider MU when interpreting measured quantity values as they found this as inappropriate.

Learning Objectives

Given a case scenario, the student will be able to explain:

- what shall be done regarding measurement uncertainty (what are requirements in ISO 15189)
- what are the typical sources of the measurement uncertainty in a routine examination method
- how can those sources be quantified

Answers:

Question	Answer
Define which situation represents the scenario?	**Measurement uncertainty**
Relate each scenario to a specific clause or subclause in the standard	5.5.1.4
Read carefully the related requirements set in the standard. Does the scenario conforms to the requirements?	No
If not, what shall be included/how can it be improved?	1. They do not consider MU when interpreting measured quantity values. 2. They do not regularly review estimates of measurement uncertainty.

Performance Assessment

Only a group assessment will be made. A group shall find answers on a), b), d), e) with the help of a trainer/facilitator.

Different ideas/answers from the given could be relevant and good.

Assessment criteria

Responsibility: trainer/facilitator

Observation of the group work discussion		
	Criteria	Assessment
Group recognises the requirements on measurement uncertainty in ISO 15189.	Yes	
Group recognises the sources of measurement uncertainty in the scenario.	Yes	
Group understands how those sources were quantified.	Yes	
Group work report		
	Criteria	Assessment
Group finds missing elements.	50 %	

Scenario: Purchasing

The laboratory maintains procedures for the purchase, storage, and evaluation of supplies, reagents, equipment and services. For purchasing responsible is the Department for procurement. They maintain the list of the suppliers of supplies and reagents used. Performance of those suppliers is monitored. Typical performance metrics are supplier's on-time delivery; percentage of claims and product returns, responsiveness and payment terms. This process doesn't include suppliers of laboratory equipment as they are purchased rarely – ones in few years. Performance of suppliers of services is also not monitored as the only services they purchase are calibration and equipment maintenance.

Learning Objectives

Given a case scenario, the student will be able to explain:

- what shall be done regarding purchasing according to the requirements of ISO 15189

Answers:

Question	Answer
Define which situation represents the scenario?	Purchasing
Relate each scenario to a specific clause or subclause in the standard	4.6 External services and supplies
Read carefully the related requirements set in the standard. Does the scenario conforms to the requirements?	No
If not, what shall be included/how can it be improved?	1. Criteria for selection of suppliers shall be established 2. List of selected and approved suppliers shall be maintained (not only used) 3. Suppliers of equipment and services shall also be on the list 4. Monitoring of performance of suppliers of equipment and services shall be included.

Performance Assessment

Only a group assessment will be made. A group shall find answers on a), b), d), e) with the help of a trainer/facilitator.

Different ideas/answers from the given could be relevant and good.

Assessment criteria

Responsibility: trainer/facilitator

Observation of the group work discussion		
	Criteria	Assessment
Group recognises the requirements on purchasing in ISO 15189.	Yes	
Group work report		
	Criteria	Assessment
Group finds missing elements.	50 %	

Scenario: Resolution of complaints

The laboratory established documented procedure for the receipt, resolution, and maintenance of records of complaints and other feedback regarding laboratory activities. Complaints can result from clinicians and laboratory staff.

Complaints may be lodged by various means in writing, electronically through e-mail, by telephone, web application, and in person. Staff who receive a complaint documents it on the Complaint Feedback form. It includes:

the name of the person and organization who lodged the complaint,
the date when the complaint was received, and
the nature of the complaint.

If the person receiving the complaint can determine the cause and the corrective action, they should take the corrective measures, complete the complaint form and forward it to the Head of the Laboratory.

If the cause and corrective action cannot be determined by the person receiving the complaint, submission of the complaint is made directly to the Head of the Laboratory.

When the corrective action has been completed, the complaint is closed. The Complaint Feedback form and corrective action form are submitted to the Quality manager who monitors the complaints received for trends, resolutions and corrective action.

Learning Objectives

Given a case scenario, the student will be able to explain:

- what shall be done regarding management of complaints (what are requirements in ISO 15189)

Answers:

Question	Answer
Define which situation represents the scenario?	**Resolution of complaints**
Relate each scenario to a specific clause or subclause in the standard	4.8
Read carefully the related requirements set in the standard. Does the scenario conforms to the requirements?	No
If not, what shall be included/how can it be improved?	1. Complaints shall result also from patients and others (assessors, accreditation body or other relevant bodies).

Performance Assessment

Only a group assessment will be made. A group shall find answers on a), b), d), e) with the help of a trainer/facilitator.

Different ideas/answers from the given could be relevant and good.

Assessment criteria

Responsibility: trainer/facilitator

Observation of the group work discussion		
	Criteria	Assessment
Group recognises the requirements on management of complaints in ISO 15189.	Yes	
Group work report		
	Criteria	Assessment
Group finds missing element.	1 out of 1	