ISO 15189 CPD Exercise

Purpose of the exercise

This simple exercise is a pilot CPD activity designed to introduce some new learning methods in adult learning process. A context for learning will be provided by solving specific problems (combination of scenario/case study and incident method).

Introduction

ISO 15189:2012 - *Medical laboratories - Requirements for quality and competence,* specifies requirements for quality and competence in medical laboratories. It can be used by medical laboratories in developing their quality management systems and assessing their own competence.

Today, non-harmonised accreditation provided by some professional or governmental bodies is replaced by an internationally accepted accreditation made by national accreditation body. This international standard is becoming a new accreditation standard for medical laboratories. It introduces several enhancements and laboratory personnel need training to get awareness of new requirements.

Who is the Exercise intended for

It is intended for everyone whose job it is to apply the ISO 15189 in their business:

- persons appointed by the laboratory management to take care of the management system in a laboratory (quality manager),
- technical managers,
- laboratory internal auditors,
- persons responsible for preparing a laboratory for accreditation,
- anyone interested in this subject.

Prior knowledge

- ✓ basic knowledge of the structure of ISO 15189

Prerequisite:

Participants need to have on disposal ISO 15189:2012.

Goals of exercise:

- ✓ Ensure participants familiarize themselves with some clauses in ISO 15189
- ✓ Give participants practical examples on how the standard relates to laboratory situations

Instructions

This exercise should be done in groups. When this is impractical, it could be done individually.

Here you can find five fictive scenarios. Your job is to:

a. define which situation represents a scenario
b. relate each scenario to a specific clause(-s) or subclause(-s) in the standard
c. read carefully the related requirements set in the standard
d. find out if the scenario conforms to the requirements
e. if not, what shall be included/how can it be improved?

Scenario 1:

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.*

Scenario 2:

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 was damaged (scratched) by improper handling. The weights were used for checking balances in the laboratory.

The laboratory took the following actions.

- *They removed the 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 new weights*
- *They checked their balances with another weights set. They found they were in tolerance so there was no risk to quality of the results issued.*

Scenario 3:

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.

Scenario 4:

The laboratory maintains procedures for the purchase, storage, and evaluation of supplies, reagents, equipment and services. The Department of procurement is responsible for purchasing. They maintain a 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 it is purchased rarely – once in a few years. Performance of suppliers of services is also not monitored as the only services they purchase are calibration and equipment maintenance.

Scenario 5:

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.