Competency

Are your staff adequately trained?

NRL Asian Workshop on Quality

Hanoi, Vietnam
4 March 2019
Outline

- ISO 15189 requirements
- Initial training
- Options for assessing staff competency
  - Direct observation
  - Monitoring
  - Review of records
  - Assessment of problem solving skills
  - Testing a sample panel
- Establish a track record of competency
5.1.6 Competence Assessment

“Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria.”

- Reassessment shall take place at regular intervals
- Retraining shall occur when necessary
ISO 15189: Staff competency

Competence of laboratory staff can be assessed by any combination of the following approaches under the same conditions as the general working environment:

1. Direct observation of routine work
   - Including safety procedures and equipment maintenance
2. Monitoring the recording & reporting of results
3. Review of work records
4. Assessment of problem solving skills
5. Examination of specially provided samples
ISO 15189: Staff competency

Competence assessment for professional judgement should be designed as specific and fit for purpose.
Initial training

The laboratory shall provide training for all personnel that includes:

- QMS, assigned work processes, safety, ethics, confidentiality of patient information

Training Checklists

- Ensures that everyone gets trained in the same way
- Acts as a reminder for the trainer on the key messages of the training
- Once completed, becomes a personnel record of evidence of training
Training checklists

Completed TCLs become a record in the laboratory QMS

- Should contain the document control elements as the other forms in the QMS
- Name of trainee and trainer
- Date of training
- References to documents
- Tasks
- Comments
- Final sign off
**TRAINING CHECKLIST FOR BATCH RELEASE**

Trainee Name: ________________________________

Type of training (circle one):  Initial  Update  Refresher

Reference Documents:

<table>
<thead>
<tr>
<th>Task Element</th>
<th>Demonstration to trainee</th>
<th>Observation of trainee</th>
<th>Final Observation of trainee</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trainer Initial</td>
<td>Date</td>
<td>Trainer Initial</td>
</tr>
<tr>
<td>Understand when batch release is required</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vail results of kit controls and external QC with new batch</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Affix completed green label to kits/reagents/consumables</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Affix white label to reagents prepared in house</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check the details entered in the LIS are correct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record the “First used date” in the LIS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:

| Task Training complete |                         |                         |                             |
|------------------------|--------------------------|--------------------------|
|                         | Trainer signature | Trainee signature | Date |

NRL Science of Quality
Options for assessing staff competency

1. Direct observation of routine work
   - Can use a TCL to ensure all critical tasks are observed
   - Include comments on whether performance is satisfactory
   - Indicate whether retraining is required
Options for assessing staff competency

2. Monitoring the recording & reporting of results
   - Double-checking of data entry
     - Error rates in laboratory notebooks / data collection forms / LIS
   - Authorisation of laboratory reports
     - Tracking corrections needed
   - Need to document findings and, if necessary, corrective actions
Options for assessing staff competency

3. Review of work records
   - Internal audit
     - Reviewer should be independent of the work records they audit
     - Determine exactly what data will be collected (scope)
     - Document findings (audit checklist)
Options for assessing staff competency

4. Assessment of problem solving skills
   - Quiz or Exam
   - Training Assessment Presentation (TAP)
     - Power Point Presentation
     - Series of slides containing information and multiple choice questions
     - Reader chooses answer to question
       - If correct, presentation proceeds
       - If incorrect, reader is asked to choose again
     - On completion an email is sent to provider
Biological and Chemical Spill Training

TAP-0708
Version 5.D, 09/05/2016

Next Slide
Class I Biological Cabinet
Question 1

Do Class I Biological Safety Cabinets provide personnel and environmental protection?

A. No
B. Yes
Sorry

This is incorrect - Try Again
Correct – Congratulations!

- The Class I Biological Safety Cabinet will provide personnel and environmental protection, but NOT product protection

- These cabinets have unrecirculated airflow away from the operator that is discharged to the atmosphere after filtration through a HEPA (High Efficiency Particulate Air) filter

- Open front negative pressure cabinet, that do NOT require UV cleaning

Go to Next Question
Options for assessing staff competency

5. Examination of specially provided samples

- Competency panel
  - Set of specimens with known reactivity
  - Staff member performs testing and submits results for review
  - Specific for laboratory assays
Establish a track record of competency

EXAMPLE of staff competency schedule

- **Technical tasks**
  - Test an EQAS panel: 1 time per year *(EQAS report)*
  - Direct observation: 3 times per year *(TCL)*
  - Review of records / data entry: Every month *(Track as QI)*

- **Safety and QMS**
  - Training Assessment Presentation: Every month *(Email record)*
  - Multiple choice quiz: 2 times per year *(Personnel file)*

- **Key functions of the laboratory**
  - Internal audit: annual review of each function *(Audit checklist)*
Establish a track record of competency

Follow-up action is vital!

- If the staff member meets requirements
  - Document details (name, date, method used….)
- If the staff member does not meet requirements
  - Document details
  - Initiate corrective action
  - Gather evidence that corrective action has been effective

Establishing staff competency is an element in the continual improvement of the laboratory
Establish a track record of competency

PDCA cycle
Summary

- Decide on the appropriate combination of assessments to establish staff competency
  - May be different for the various staff positions
  - Develop a QMS procedure
- Create an appropriate schedule
- Document in a consistent way
  - Store records
- Initiate follow-up action as required