Key skills for the analytical scientist: Assessing competence in the laboratory

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Overview

• Training and the measurement cycle
• Accreditation requirements
• Skills gaps
• Considerations for planning training and assessing competence
The measurement cycle

Client

Decision on result

Client issue

Data evaluation

Define issue

Report on measurement

Decision on measurement

Evaluation

Analysis

Sampling

Validated procedures

Analytical chemist

Importance of training in the measurement cycle

• ‘Human factors’ will affect all stages of the measurement cycle
  – From understanding the client’s needs, through to making the measurement and reporting the result
• Adequate training is required at every stage
• Laboratory personnel should understand the impact of their work on the measurement cycle
Certification requirements

- ISO 9001
  - Personnel ... shall be competent on the basis of appropriate education, training, skills and experience
  - determine the necessary competence for personnel
  - provide training or take other actions to achieve the necessary competence
    - evaluate the effectiveness of the actions taken
  - ensure personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives
  - maintain appropriate records of education, training, skills and experience

Accreditation requirements (1)

- ISO/IEC 17025
  - ‘human factors’ influence the reliability of tests
- 5.2 Personnel
  - ...ensure the competence of all who perform tests, evaluate results, sign reports
  - Personnel shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills
  - ...formulate goals for education, training and skills
  - ...policy and procedures for identifying training needs and providing training
  - ...effectiveness of training actions shall be evaluated
Accreditation requirements (2)

- ISO 15189
  - *adequate training* of all staff and supervision appropriate to their experience and level of responsibility by competent persons
  - Laboratory management shall provide access to *suitable educational and training opportunities* for all laboratory personnel
  - *maintain records* of the relevant educational and professional qualifications, training and experience, and competence of all personnel
  - Personnel shall have *training specific to quality assurance and quality management*
  - The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary.

Where are the skills gaps?

- Calculations/data evaluation
- Basic laboratory skills
- Understanding of quality assurance and its importance
Calculations/data evaluation

- Competence in basic calculations
  - Reagent concentrations
    - Preparation of solutions of specified concentration
  - Dilution factors
  - Calibration ranges (interpolation vs. extrapolation)
- Evaluation of data
  - Summarising and plotting data (basic statistics)
  - Importance of reviewing data
  - Identifying inconsistencies
    - What is ‘reasonable’ or ‘expected’ for a particular measurement?

Basic laboratory skills

- Weighing, volume measurements, pH
  - May not have been taught at college/university
    - Reduction in practical work
  - Equipment used at college/university may not be representative of that used in laboratories
  - Lack of understanding of the importance of these key steps
- Use of kits and ‘black box’ technology
  - Reduces understanding of processes
Understanding quality assurance

• Why is quality important?
• Understanding the ‘bigger picture’
  – Knowledge of critical points in measurement cycle that could affect results
    • Temperature, storage, sample tracking…what controls are in place and why
• What is the purpose of the QC procedures used in the laboratory
  – Why do we analyse QC materials?
  – What is the purpose of PT
  – What to do with ‘out of spec’ results
    • Don’t just record…report!
  – Importance of adhering to standard operating procedures
    • There is a time and a place for creativity!

What is ‘competence’

• ISO 15189
  – …the product of basic academic, postgraduate and continuing education, as well as training and experience of several years in a medical laboratory
• Competent to work independently
  – Individual has demonstrated that they can meet specified performance levels
  – Has gained sufficient experience to understand their strengths and limitations
The training cycle

- New staff/new procedure
- Explain
- Monitor
- Show
- Assess
- Observe

Who trains?

- The trainer must have current demonstrated competence in the technique/method being trained
  - Competence to train should be demonstrated in their training records
- Instrument/method owners
  - Designated (and demonstrated) experts responsible for carrying out training
Planning a training programme

• Assume nothing!
• Start with the basics
• Understand what the laboratory needs and plan to meet this requirement
  – What are the key steps in the laboratory’s operations
    • Sample receipt, screening, confirmation, reporting….
  – What equipment is used and for what purpose
• Explain the quality systems in place
  – Not just for the measurement procedure but for the wider (relevant) laboratory operations
    • Environmental controls, sample tracking, checking results, approval of reports

Consider the context

• The trainee needs to understand not only what to do but why
• Where does the activity being trained fit into the measurement process?
• Explain and demonstrate the work flow within the laboratory
  – Especially important where contamination can be an issue
Assessing/monitoring competence

Demonstration of competence should be based on objective evidence
• Set performance targets for equipment and methods
  – Can they be achieved?
• Analysis of previously tested samples
• Analysis of quality control materials
• Analysis of previous PT samples

• QC/batch failures and participation in PT can be used for monitoring ongoing performance

Maintaining competence

• Retrain if performance is seen to have dropped
  – Monitor – QC/batch failures
  – PT scores
• Reassess if skills have not been used for a defined period of time
• How to maintain competence for infrequently performed tests?
  – Continue to participate in PT
  – Ongoing measurement of QC materials, existing samples
Changes to methods/procedures

• If changes are made to standard operating procedures or other laboratory processes
  – Assess impact on training requirements
  – Is current competence assessment still valid?
• Minor change – does not require additional training
  – Staff document that updated procedure has been read
• Moderate change – e.g. new sample matrix, changes to standard preparation
  – Staff retrained and assessed on new section of procedure
• Major change – e.g. new extraction procedure or instrumentation introduced
  – Retrain and assess for whole procedure

Conclusions

• Effective training is an essential part of any quality management system
  – Reflected in requirements of international quality standards
• Skills gaps often relate to basic lab operations and limited understanding of QA/QC
• Training should focus not only practical skills but the wider context of the measurement process
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Highlights of outputs from E&T working group

• Guide

• Workshops
  – Internal quality control (Berlin 2012)
  – Key quality assurance challenges for analytical measurements (Moscow 2011)
  – Metrology in Chemistry: Introductory training course with practical examples (Athens 2008)
  – Quality assurance (Istanbul 2006)
  – Teaching Quality and metrology in Chemistry (Prague 2004)