



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

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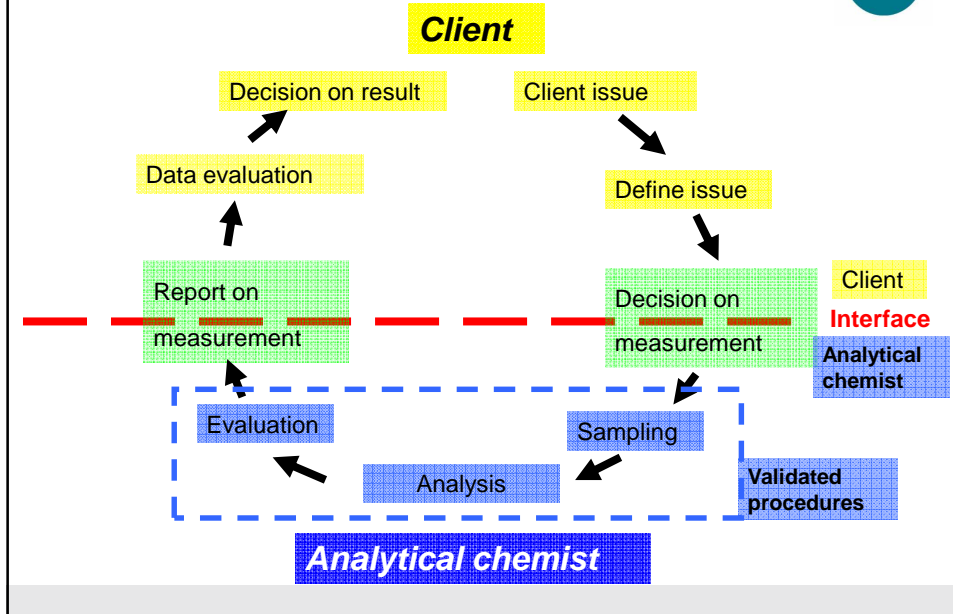
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Overview

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

The measurement cycle



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)

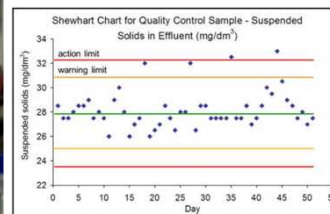
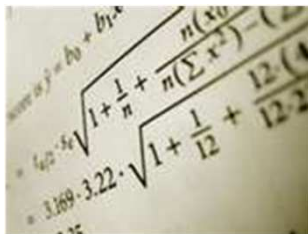


- ISO 15189
 - ...adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons
 - Laboratory management shall provide access to suitable educational and training opportunities for all laboratory personnel
 - ...maintain records of the 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



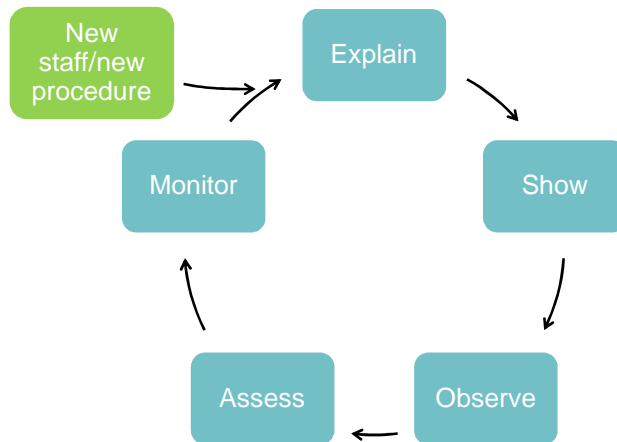
- Why is quality important?
- Understanding the 'bigger picture'
 - Knowledge of critical points in measurement cycle that could affect results
 - Temperature, storage, sample tracking...what controls are in place and why
- What is the purpose of the QC procedures used in the laboratory
 - Why do we 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



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
 - Terminology in Analytical Measurement: Introduction to VIM 3 (2011)
- 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)