



The UKAS approach to assessing quality control and ensuring consistency

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BS EN ISO/IEC 17025:2005

- General requirements for the competence of testing and calibration laboratories
- Applied to a wide range of laboratories – not specifically for water microbiology.
- Sets out requirements for a laboratory quality system which includes technical and quality requirements



Quality assurance systems

- Verification of method performance
- Participation in proficiency testing schemes
- Internal quality control processes



BS EN ISO/IEC 17025:2005

The standard contains 59 clauses, of which 2 directly address internal quality control requirements

Contained in section 5.9 - Assuring the quality of test and calibration results

(Other clauses cover requirements for method validation and Proficiency scheme participation)



ISO17025 Requirements for AQC

Clause 5.9.1 states:

The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of results.



ISO17025:2005

Clause 5.9.1 continues...

The monitoring shall be planned and reviewed and may include, but is not limited to, the following

regular use of CRMs and/or IQC

participation in ILCs or PT programmes

replicate tests or calibrations using the same or different methods.

Note: the selected methods should be appropriate for the type and volume of work undertaken



ISO17025:2005

Clause 5.9.2

Quality control data shall be analysed and where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.



ISO 17025:2005

- Quality assurance requirements
- Procedures in place to monitor the validity of tests and results.
- Analysis of data to identify trends and non conforming results.
- Investigate identified failures and trends.
- Prevent incorrect results being reported.
- Standard gives some indication of the type of procedures which could be used.



Other guidance documents

- EA – 4/10 revision 02 (2002)
- UKAS publication LAB 37 edition 2 (2009)
- Other technical guidance documents



Guidance document EA – 4/10

EA - 4/10 . *Accreditation in Microbiological Laboratories*

This document has been produced by a joint EA/EURACHEM Working Group. It supplements ISO/IEC 17025 and provides specific guidance on the accreditation of laboratories performing microbiological testing.

ISO/IEC 17025 remains the authoritative document against which findings are raised.

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Guidance document EA – 4/10

- Contains specific guidance for both laboratories and assessors, which includes requirements for...
- Method validation.
- Traceability of reference strains.
- Internal quality control.
- External Quality Assessment.



Guidance document EA – 4/10

12.1.2 A programme of periodic checks is necessary to demonstrate that variability (i.e. between analysts and between equipment or materials etc.) is under control. All tests included in the laboratory's scope of accreditation need to be covered.

The programme may involve:

- the use of spiked samples
- the use of reference materials (including proficiency testing scheme materials)
- replicate testing
- replicate evaluation of test results



Drinking Water Testing Specification

UKAS publication Lab 37 ed.2 (2009) Accreditation Requirements for Sampling and Testing in Accordance with the Drinking Water Testing Specification (DWTS).

Prepared by UKAS in collaboration with the Regulators, ie the Drinking Water Inspectorate of England and Wales (DWI), the Drinking Water Quality Regulator for Scotland, and the Drinking Water Inspectorate for Northern Ireland.

It sets out how the requirements of ISO 17025 and the UKAS Agreement shall be interpreted when applied to organisations undertaking sampling and/or testing of drinking water.

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Lab 37 ed.2 (2009)

Provides specific guidance which includes Quality Assurance.

References *SCA Microbiology of Drinking Water* (2002)

Which contains detailed guidance on quality assurance, in the form of a range of options



The Assessment process

ISO 17025:2005 defines outcomes,

It does not specify the processes by which these are to be achieved.

It does however, for internal quality control suggest a number of possible options.



The Assessment process

AQC systems are assessed as part of the quality system

The assessment team has to evaluate whether the AQC procedures adopted by a laboratory meet the requirements of the standard (or standards) and deliver the required outcomes.



Assessment of AQC systems

The Quality system must include:-

Internal quality assurance systems for all accredited parameters

Analysis of AQC data to identify non conforming results and trends

The systems adopted are fit for purpose – deliver the required outcomes.

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Assessment of AQC

Assessment of AQC systems is not done in isolation, also examine:-

- Data from method re-verification
- Uncertainty of measurement calculations
- Proficiency scheme results



Continuous improvement

Clause 4.10

The laboratory shall continually improve the effectiveness of its quality system.....

This would include reviewing and evaluating developments in microbiological AQC practices



Consistency

UKAS needs to be consistent in its approach to assessment whilst allowing laboratories the flexibility to develop quality systems which meet the requirements of the standard and is appropriate to the type and volume of work undertaken

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Consistency

UKAS strives for consistency through:-

- Careful selection of assessors and assessment managers
- Comprehensive training systems
- Reviews of individual assessor performance and feedback
- Annual assessor training events
- Annual meetings with water sector stakeholders

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Consistency

Standardisation of methods and procedures lead to
More consistent assessment

eg.

The analytical methods documented in
The Microbiology of Drinking Water (2002)

The DWI Cryptosporium methodology

UKAS representation on SCA Microbiology WG2



Conclusions

- AQC is assessed as part of the overall quality system
- The laboratory is responsible for the choice of processes used to provide AQC
- UKAS is responsible for assessing whether these procedures satisfy the requirements of ISO 17025 and where applicable DWTS.



Conclusions

- UKAS has a range of procedures in place to encourage consistency within the assessment process.
- This process would be aided by developing more specific technical guidance within UK / Europe



Questions ?

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