EURACHEM WORKSHOP

Key Challenges in Internal Quality Control,

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The EA Laboratory Committee point of view of IQC activities

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Short Presentation of EA/LC

EA Laboratory Committee

EA/LC is the forum for discussion of all questions related to the assessment and accreditation of laboratories. Some of its responsibilities:

- to harmonize the implementation of the standard ISO/IEC 17011 with a view to the assessment and accreditation of laboratories against ISO/IEC 17025, ISO 15189, ISO/IEC 17043 and other relevant standards and to elaborate guidance documents where necessary
- to cooperate with relevant working parties of related European organizations, especially as far as the implementation of the standards defining technical and organizational competence of laboratories is concerned, in particular the recognised stakeholders and, if appropriate, to approve guidance documents drafted by these organizations as EA advisory documents

Membership of EA/LC

- one representative of each EA member and associate member
- the conveners of the Working Groups and Joint Working Groups and Technical Networks
- representatives from regional organizations as EUROLAB, EURACHEM, EURAMET and other Stakeholder organizations, invited by the Chair or Vice Chairperson of EA/LC or by the EA Executive Committee; representatives from other organizations invited by the Chairperson
- representatives of the recognised stakeholders

Working Groups and Technical Networks

- 3 Working Groups have been established by EA/LC to assist specific areas (**ILCs in Calibration, ILCs in testing, Health Care**)
- Technical networks (TN) are established by the LC to stimulate discussion and harmonisation in selected technical fields. The TNs operate by suitable electronic means led by a convenor and offer the EA ABs an informal platform for discussion and exchange of experience and of technical expertise and assessors. **5 TNs are currently active (Calibration, Electrical-Mechanical, Environment, Food, Forensic)**

Introduction

IQC activities when assessing a laboratory (1/2)

As for the assesment the Internal Quality Control procedure consists of:

- A major part in the process of building confidence to the competence
- A "core" requirement of the accreditation standard in order to ensure that valid results are produced

IQC activities when assessing a laboratory (2/2)

Internal Quality Control is assessed as a part of the Quality Assurance Procedures along with participation in PT schemes

Quality Assurance Procedures are assessed as a part of the overall quality system

A laboratory that performs an effective and sufficient IQC scheme, having documentation that deviations have been or will be treated accordingly , provides a reliable indication that itself can control and correct problems, thus builds confidence for its competence

ISO 17025:2005 and IQC

ISO 17025:2005 and internal quality control – Direct Reference

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

Section 5.9 Assuring the quality of test and calibration results

- *5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The results shall be recorded in such a way that trends are detectable and, where practicable statistical techniques shall be applied to the reviewing the results. ….*

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

  Regular use of CRMs and/or IQC

  Participations in ILCs or PT programs

  Replicate tests or calibrations using the same or different methods

- *5.9.2 Quality control data shall be analyzed 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 and internal quality control – Indirect Reference (1/2)

- Identification of non conforming work (4.9.1 Note)

Quality control is recognized as a potential area to identify problems

- Continuous improvement (par.4.10)

"…The laboratory shall continually improve the effectiveness of the quality system."

This would include reviewing and evaluating developments in AQC practices

- Also in par. 4.10 use of quality objectives for the monitoring of the effectiveness of the quality system: A laboratory would make use of the IQC data in the form of quality objectives in order to monitor the performance of quality assurance procedures

ISO 17025:2005 and internal quality control – Indirect Reference (2/2)

- Management Reviews (par.4.15.1)

Issues to be examined during a management review along with the results of interlaboratory comparisons and proficiency tests : "*other relevant factors such as quality control activities, resources and staff training*"

One can expect that the results of internal control procedures and if relevant, corrective actions raised from deviations are taken into consideration in order to review the performance of the laboratory

Internal Quality Control Procedures – assessing components

What a lab has to do?

In order to establish an effective IQC system, a laboratory would follow a path more or less like this:

1. Define quality goals as needed
2. Develop policies to achieve the quality goals and create a plan for the IQC
3. Establish processes and procedures to implement the IQC plan
4. Monitor and review the relevance and effectiveness of the IQC system

What an assessment team has to do?

An assessment team is assessing the IQC among other sections of the quality system.

A Technical Assessor is expected to be a competent person of a relevant experience and competence to the assessed scope.

Normally he/she will follow the same path to have a view into the level of conformity of the laboratory to the ISO/IEC 17025 requirements

1. Definition of Quality Goals

The laboratory established overall quality goals regarding the method, the application of the method, the risk for invalid results.

For this, method performance criteria defined in standard methods and/or regulatory requirements, or set by customer or required by the accreditation requirements, have to be taken into consideration

Risk factors for deviations and loss of control depending to the method and the application, the availability of resources have also to be considered

Did the laboratory take into consideration all the parameters to determine the risk level and to set the quality goals?

2. Develop policies-create IQC plan

Components

- Specific QC measures
- Consider test limitations
- Availability of control materials
- Frequency
- Design (boundaries, scope of application)

What else has to be assessed

- Technical expertise to perform the test
- Evaluating and selecting QC materials
- Selection and use of QC charts
- Selection of matrices/analytes/levels
- Selection of control/warning limits (Method? Legislation? Other requirements)

3. Implementation of the IQC plan

Components

- Detailed procedures and predefined actions
- Description into the method SOP
- Use and store of technical records
- Training
- Responsibilities for the evaluation of the IQC

To further examine…

- Knowledge and understanding of specific QC statistics
- Interpretation of QC patterns and reaction to deviations
- Reaction to out of control situations
- Log and maintain QC records and corrective actions
- Consideration of IQC results in relation to external quality control results

4. Monitor and review the relevance and effectiveness of the IQC system

Components

- IQC should reflect current laboratory conditions and requirements. Any change should be adressed
- IQC data are valuable to other sectors (method validation, quality objectives etc).

Items to be addressed

- IQC in relation to the workload/changes in the laboratory conditions, requirements
- Feedback of IQC data to other sections of the quality system

Consistency of IQC assessment

The assessment process of IQC and its consistency (1/2)

- ISO/IEC 17025 :2005 only defines outcomes in form of requirements
- It does not specify processes by which these outcomes can be achieved
- For IQC, the standard however, suggest possible options
- The laboratory, in each case as for the selection and participation in PTs, is fully responsible for the establishment of a proper IQC system and the choice of the processes to provide it
- Accreditation Bodies have to assess these processes if they satisfy the requirements of the standard

The assessment process of IQC and its consistency (2/2)

- ABs seek assessment consistency through
  - Assessment training
  - Use of technical guidance
  - Case studies, assessors meetings, reviews from assessment reports, feedback from the labs
- The IQC consists of the application of general criteria to a specific case (technical field, laboratory, application)
- Every assessment can be a different case
- It is difficult to define general requirement for each case and it is difficult to "calibrate" technical assessors for the assessment of IQC

Technical Guidance with reference to IQC

Examples of EA documents

The following EA documents and documents adopted by EA as technical guidance for the application of ISO/IEC 17025 contain, among other things, guidance for the internal quality control requirements

- **EA-4/10 G** (rev.02) Guidance Accreditation for Laboratories Performing Microbiological Testing, under revision
- **CEC TA** ISO/IEC 17025 interpretation document for CEC test methods
- **EA-4/09 G** (rev.01) Guidance Accreditation for Sensory Testing Laboratories , under revision
- **EWDTS TA** Technical / Advisory European Laboratory Guidelines for Legally Defensible Workplace Drug Testing **and** Technical Advisory Drug and Alcohol Testing in Hair, Collection and Analysis

Under development

- GMO quantitative testing: under development by ENGL with co-operation with EA LC Food Testing Technical Network

Examples of other documents

- Other documents where direct reference to internal quality control is given:
  - Antidoping testing: WADA ISL 7.0
  - Pesticide residues testing: Method Validation and Quality Control.Procedures for Pesticide Residues analysis in Food and Feed9 Document N° SANCO/12495/2011
- It also common, National Accreditation Bodies to issue guidance documents for example: water testing, metals testing, residues testing, guidance for traceability, medical laboratories accreditation, where detailed guidance and requirements for the establishment of internal quality control are referred.

Issues defined for the assessment of IQC

"Indirect" use of IQC data in the quality system

- Evaluation of technical competence of the personnel (par.5.1.1)
- Evaluation of the effectiveness of a training activity (par. 5.2.2)
- Update of validation, uncertainty data

Other issues (1/2)

- Frequency of IQC
- Use of control limits as regulatory requirements (for example SANCO document requirements)
- Use of IQC as a tool (along with participation in PTs) in order to keep an inactive method (no samples) in the accreditation scope

Other issues (2/2)

- Review of cases of corrective actions related to deviations/problems identified through IQC
- The flexible scope and the IQC

Laboratories develop flexibility in their accreditation also need to establish an IQC system capable to follow the extension of the accredited activities within the flexible scope boundaries

Survey among EA-ABs

- Conducted in the framework of EA/LC, last meeting, Oslo
- 9 common finding in the assessment of IQC
- Relative Rating regarding occurrence and significance
- 8 ABs have already responded (AAB,ACCREDIA,COFRAC, DAkkS, DANAK, ESYD, FINAS, NA)

Rate on Significance of the findings

Findings related to the ISO/IEC 17025:2005 requirements for internal quality control as described in par. 5.9 or relative ones	**SCORE on the significance**
The IQC scheme concluded to the identification of a deviation, but the laboratory didn't start a corrective action	22
Internal Quality Control samples/materials are not proper for the method	18
The established scheme for internal quality control does not fully cover the scope of application of the method. (for example matrices/analytes/concentration levels)	17
The criteria set for the IQC are not conformed to those defined in the method/or in regulatory requirements/or in other requirements, for example accreditation guidance	16
The laboratory has not predefined actions in case of deviations from internal quality control	16
The IQC patterns have not been interpreted correctly (for example trends in QC charts have not been identified)	13
The frequency of internal quality control is not assuring its effectiveness	13
QC data have not been reviewed in order to update the validation/verification data of the method.	13
QC charts have not been constructed the right way	10

Rate on the Occurrence of the findings

Findings related to the ISO/IEC 17025:2005 requirements for internal quality control as described in par. 5.9 or relative ones	SCORE on the occurrence
The IQC scheme concluded to the identification of a deviation, but the laboratory didn't start a corrective action	42
QC data have not been reviewed in order to update the validation/verification data of the method.	39
The IQC patterns have not been interpreted correctly (for example trends in QC charts have not been identified)	35
The laboratory has not predefined actions in case of deviations from internal quality control	32
The criteria set for the IQC are not conformed to those defined in the method/or in regulatory requirements/or in other requirements, for example accreditation guidance	32
The established scheme for internal quality control does not fully cover the scope of application of the method. (for example matrices/analytes/concentration levels)	32
Internal Quality Control samples/materials are not proper for the method	29
The frequency of internal quality control is not assuring its effectiveness	28
QC charts have not been constructed the right way	26

Other findings proposed by the ABs

- **assessment by the laboratory on the significance of out-of-control-situation is missing**
- **estimated values showing out-of-control are not registered in the control chart (test is repeated until value is well within control)**
- **No certified reference materials are used for IQC, even if available**

Total Score of the findings

Findings related to the ISO/IEC 17025:2005 requirements for internal quality control as described in par. 5.9 or relative ones	SCORE of COMBINED EFFECT : occurrence x significance
The IQC scheme concluded to the identification of a deviation, but the laboratory didn't start a corrective action	117
Internal Quality Control samples/materials are not proper for the method	65
The laboratory has not predefined actions in case of deviations from internal quality control	63
The criteria set for the IQC are not conformed to those defined in the method/or in regulatory requirements/or in other requirements, for example accreditation guidance	61
The established scheme for internal quality control does not fully cover the scope of application of the method. (for example matrices/analytes/concentration levels)	59
The IQC patterns have not been interpreted correctly (for example trends in QC charts have not been identified)	58
QC data have not been reviewed in order to update the validation/verification data of the method.	57
The frequency of internal quality control is not assuring its effectiveness	46
QC charts have not been constructed the right way	40

Conclusions

Most common findings

- The IQC scheme concluded to the identification of a deviation, but the laboratory didn't start a corrective action
- QC data have not been reviewed in order to update the validation/verification data of the method.
- The IQC patterns have not been interpreted correctly (for example trends in QC charts have not been identified)

Most significant and common findings

- The IQC scheme concluded to the identification of a deviation, but the laboratory didn't start a corrective action
- Internal Quality Control samples/materials are not proper for the method
- The laboratory has not predefined actions in case of deviations from internal quality control

One could find satisfactory the consistency among the different ABs regarding the occurrence and significance of the findings