QA/QC to underpin the measurement cycle

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ISO/IEC 17025:2005
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 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 the results. [Control charts?]

This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) regular use of certified [???] reference materials and/or internal quality control using secondary reference materials;

b) participation in interlaboratory comparison or proficiency-testing programmes;

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

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. [What about the results already reported? Re-test the items? Inform the customers?]

4.9 Control of nonconforming testing and/or calibration work

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer.

NOTE Identification of nonconforming work or problems with the management system or with testing …. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials...

Most of the Accreditation Bodies require PT planning/participation, or other QA activities.
Replicate tests and check with the repeatability limit is cheaper than PT participation, and can be performed on a continuous basis.
We have to remember that r is defined at 95% confidence, that is the same for a z-score=2 in PTs, so 1 over 20 results "non conforming" can be a "warning" but can be accepted (so the need of control charts, in order to detect the trends).

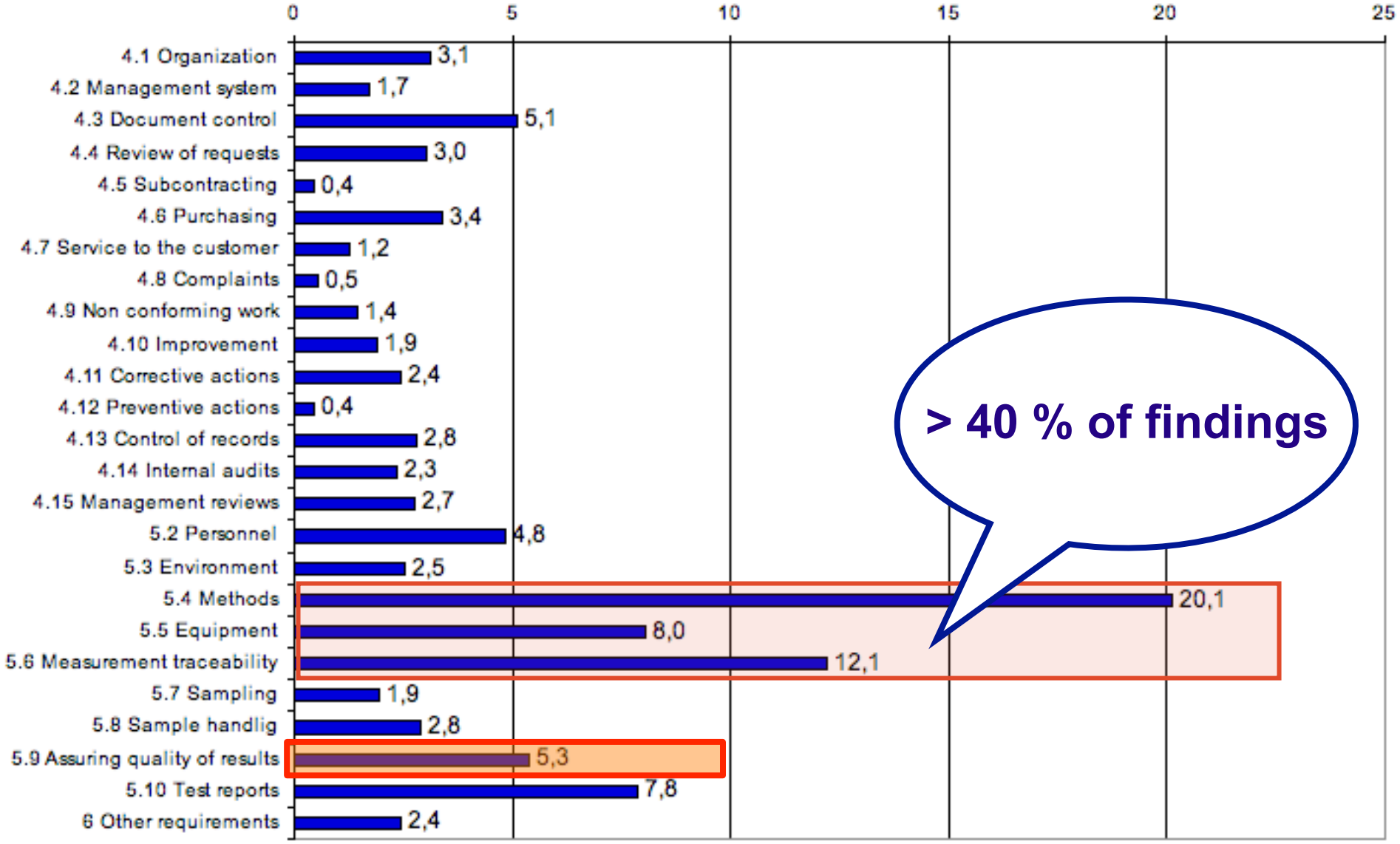
Most of the methods do not report the repeatability limit, laboratories shall calculate their own repeatability, and then check, during the time, if their results are within the limits.

What about uncertainty? If two results are within **r**, then $r < 2U$ shall be true.

We found that many laboratories do not verify this easy correlation! That means that their estimation of U is wrong.

One more issue is on sampling, where QA is more difficult; few, if any, PTs are available, even if we know that sampling is the most important contribution to measurement uncertainty.
Accreditation of sampling is an issue both in EA and ILAC, at the moment.

Distribution of the findings (≈8000)



EA highlighted PTs

Every year the Working Group ILC Testing of the EA Laboratory Committee selects international PTs and requires to all the Member to ask the accredited laboratories to participate, in some instances without charge.

The highlighted PTs are selected among 3 schemes:

- IMEP (IRMM)
- APLAC
- Professional PT providers (selected from the EPTIS database)

IMEP and APLAC have a limited participation (2-4 laboratories per economy), free of charge.

EA highlighted PT

The statistical evaluation is made by the EA-ILC-Testing WG on the basis of the Test Report supplied by the providers.

The results are used to:

- Promote the trust in the Mutual Recognition Agreement
- Enhance technical aspects related to methods or test techniques.
- Enhance the learning points to communicate to assessors and laboratories.

Some Learning Points

ILC	Description of the observation	Suggestions
PAH in surface water (WFD)	Some of the laboratories found too low concentrations of PAH coumpounds of high molecular weight compared with the reference values given.	This was due to the handling of the internal standard. Equilibration times lower than 24 h. In addition the kind and number of the internal standards used did not reflect the properties of the requested PAH compounds. By assessing the analysis of PAH in natural waters and soils special attention should be taken on the handling and composition of the internal standard used.
Heavy metals in toys (EN 71-3:1994)	Taking into account the dispersion of the results and the differences between the results of the reference laboratories the stated uncertainties from the laboratories seem too small. In the test report the application of the correction factor was not always stated, as required.	To be addressed in the audit: In the audit of the method should be focused on the estimation of the measurement uncertainty. Possibly the reported uncertainty is estimated from the measurement only without taking in account the sample preparation step In the test report it must be made clear if the correction factor according to EN 71-3 was applied or not when reporting the results.
All PTs asking for measurement uncertainty	Based on the reported measuring uncertainties it is evident that harmonization in the estimating of uncertainties should be continued. Some of the laboratories didn't report the uncertainty statement. EA labs should make effort to evaluate and report uncertainties.	To be addressed in the audit: Estimation and reporting of measurement uncertainty
Total arsenic, cadmium, copper, lead and mercury, as well as extractable cadmium and lead in mineral feed	- the applied technique seemed to have an influence on the results of all measurands. ICP-MS and HGAAS had the better results - Inappropriate choice of reference material - The analytical methods were not adjusted to the inorganic test material	To be addressed in the audit: - verification of the analytical methods used - reference material should be inorganic as the sample analysed -adjustment on inorganic matrix

EA HIGHLIGHTED PTs 2014 PLANNING

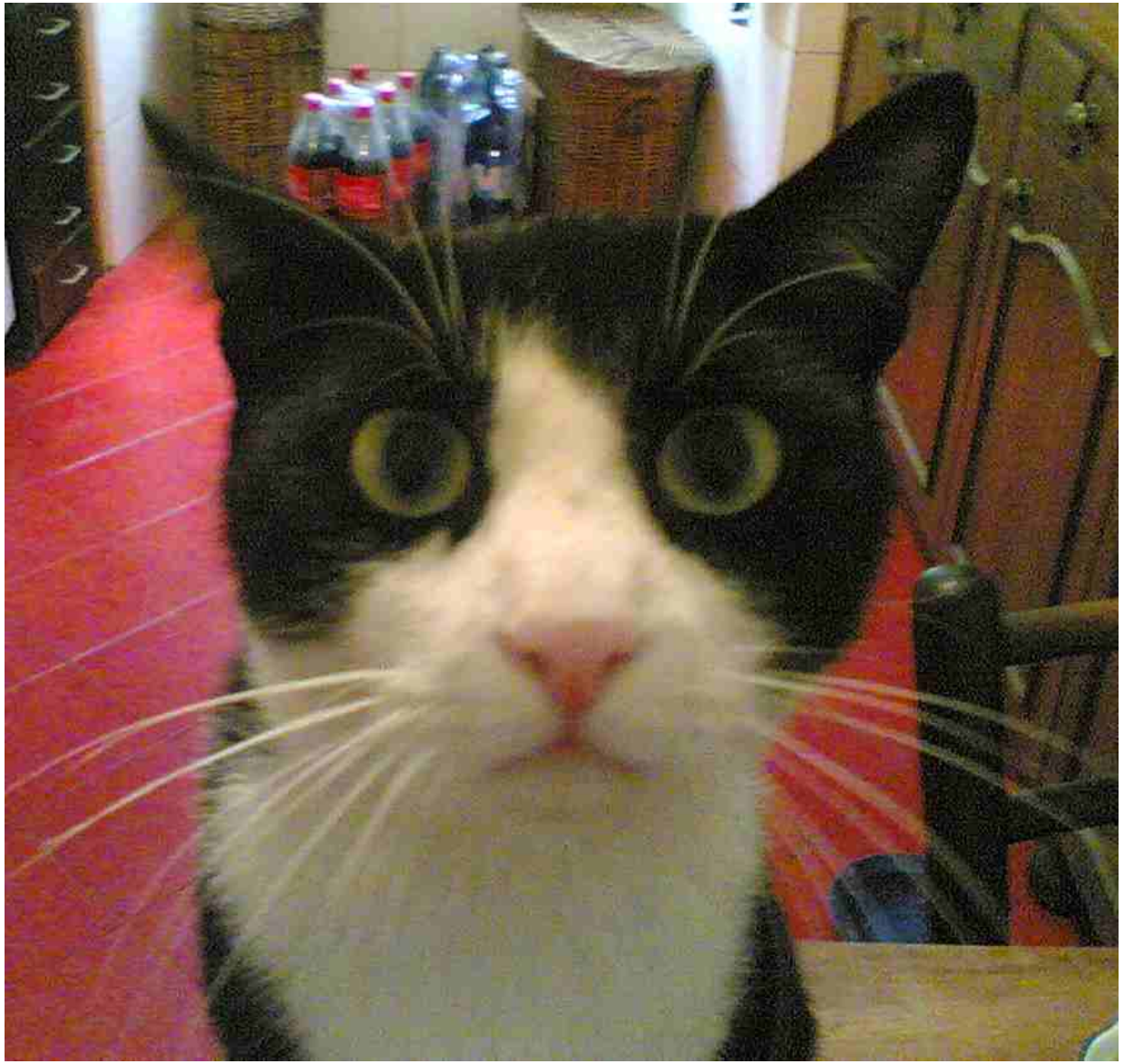
IMEP - APLAC

IMEP 40	Heavy metals in seawater
IMEP 41	Heavy metals in canned food
IMEP 42	Heavy metals in vegetable food
APLAC ?	Analysis of Lubricants (plan: announcement March 2014, Registration April 2014)
APLAC T090	Analysis of coal (sent on January 10th 2014)

EA HIGHLIGHTED PTs 2014 PLANNING

Professional Providers

Field	Scheme	PT provider	Remark
Pharmaceutical/medical	Therapeutic drugs scheme (TDM)	LGC, UK	Web: http://www.lgcpt.com/productviewnarrow.aspx?SchemeID=162
Mechanical	Charpy Impact testing (proficiency test metal)	Ifep, Germany	Web: http://proficiencytest.eu/english/newproficiencytests.aspx
Medical	Low molecular weight heparine	ECAT, The Netherlands	Web: http://www.ecat.nl/wp-content/uploads/2013/12/Quality-Programme-Manual-2014.pdf
Medical	HIV1 RNA quantification	UK Neqas, UK	This scheme was already highlighted in 2011. Most of the information should be readily available. Web : http://www.ukneqasmicro.org.uk/images/pdf/DOC.0401.pdf
Veterinary Drugs residue	Drugs	FAPAS, UK	We may only request the information on the number of laboratories accredited for this test and use results of previous rounds. This should be clarified during our next meeting in March 2014 Web : http://fapas.com/proficiency-testing-schemes/fapas/
Foodstuffs	Migration in Ceramics	GCSL, Greece	A survey will be conducted in order to ensure that there should be sufficient EA participation, before formally proposing this scheme. Web: http://www.gcsl.gr/index.asp?a_id=372
Water Framework Directive - PBDE	Flame retardants	AQS Baden-Württemberg, University of Stuttgart	The registration deadline for this scheme is September 2014. Web: http://www.iswa.uni-stuttgart.de/ch/aqs/pdf/Ringversuche2014.en.pdf



Thank you for your attention