SAMM Laboratory Forum
9 June 2009

"Common non-conformities in technical requirements for Mechanical Testing"

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1

Common non-conformities in technical requirements

- personnel (5.2)
- accommodation and environmental (5.3)
- test and calibration methods and validation (5.4)
- equipment (5.5)
- measurement traceability (5.6)
- sampling (5.7)
- handling of test/calibration items (5.8)
- assuring the quality of the test result (5.9)
- test reporting (5.10)

2

Common non-conformities in technical requirements

Personnel (5.2)

- lab is only as good as the staff (competency in doubt)
- lack understanding and training in both management and technical requirements
  - unable to conduct effective internal audit (superficial)
  - internal audit could not highlight what was found during SAMM assessment
  - staff do not have clear understanding of principles of test, MU
- records of personnel training and competency lack input from management e.g. comment on staff competency during and after training.

3

Common non-conformities in technical requirements

Personnel (5.2)

- records unable to show authorization of staff to carry out test
- training need analysis, forward training program not available
- effectiveness of training "on the staff" not documented (provides feedback to management on training requirements and staff progress)
- competency matrix to indicate level of staff competency
- competency in conducting infrequently performed test not verified

4

Training Records/Matrix

C=competent T=intraining N=training needed

Task/ Equipment	Staff			
	1	2	3	4
Test	C	C	T	C
Equipment	C	T	C	T
Calibration & Maintenance	C	T	N	N
Sampling	C	T	N	N
Internal Audit	C	T	N	N

Authorization:_____ Date:_____

5

Common non-conformities in technical requirements

Environment (5.3)

- did not ensure temperature and RH are met in the testing area e.g. - temperature mapping
- metrological traceability of environmental monitors
- stop and resume work when conditions are not met: who is responsible? record kept?

6

Common non-conformities in technical requirements

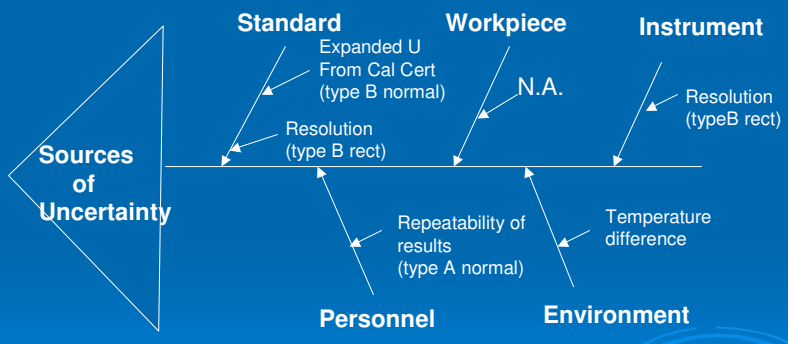
Test and calibration method (5.4)

- did not use the latest valid edition of standard (lab unaware of updates, revisions, no proper updating system)
- validate in-house method (use of CRM, ILC, MA, PT)
- initial uncertainty budget incomplete & no procedure to update uncertainty values on a regular basis
- validating of computer software programs (w*hen validating software, the laboratory must be able to demonstrate that the data generated by the software are equivalent to manually generated data across the full range of the equipment, including input and (as applicable) display and printout*
- updating of software parameters when changes are made

7

Sources of Uncertainties

S.W.I.P.E



8

Common non-conformities in technical requirements

Equipment (5.5)

- did not specify acceptance criteria (allowable tolerance) from the records in the equipment file
- records unable to show the equipment sent out for external calibration had been verified against its allowable tolerance and certified as fit for use before returning to service
- Test Accuracy Ratio (TAR or TUR) not evaluated
- record of equipment performance using SPC
- appropriateness of calibration interval not evaluated

9

Test Accuracy Ratio

Selecting Standards of Appropriate Accuracy Ratio of 3:1 between the standard and UUT (ISO 10012, clause 4.3)

E.g. Uncertainty of the standard should be no greater than 1/3 of the specified uncertainty of the UUT.

ANSI , JIS states ratio of 4:1

10

Common non-conformities in technical requirements

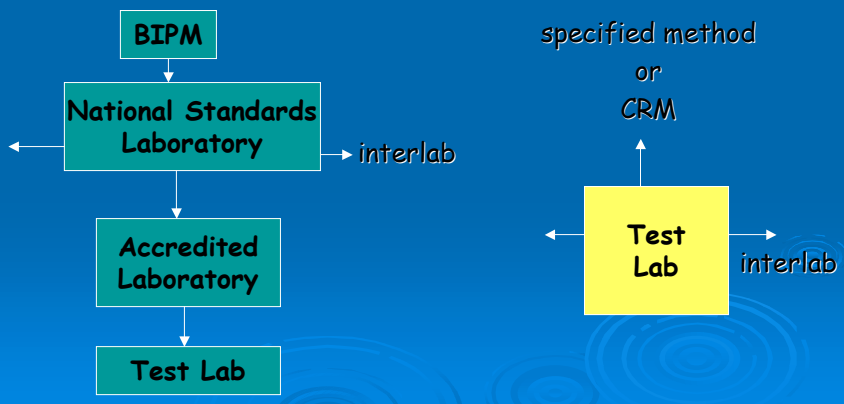
Measurement traceability (5.6)

- reference standards used for calibration or verification of testing equipment e.g. spectrophotometer is not traceable to international standards institute (use of CRM)
- expiry period of CRM or standard solution unknown
- unavailability of traceability chart of equipment and reference standards to SI unit or international standards

11

Measurement Traceability

Physical Measurement Chemical Testing



12

13

Common non-conformities in technical requirements

Sampling (5.7)

If the laboratory is not involved in the collection of samples, but rather merely tests the items as they arrive, this section on Sampling is not generally applicable.

However, if the laboratory uses the results of their testing to make a statement about a population, then Sampling does apply

When a laboratory performs sub-sampling from a larger, client-supplied test item, Section 5.7 applies

14

Common non-conformities in technical requirements

Handling of test/calibration items (5.8)

- Provisions to protect the integrity of test or calibration item and interests of the customer
- System for identifying and tracking the test or calibration item
- Examination upon receipt to assess the condition of the item and suitability for test or calibration
- Appropriate facilities to avoid deterioration or loss during storage, handling, and preparation

15

Common non-conformities in technical requirements

Assuring the quality of the test result (5.9)

- lack of initiative to conduct QC checks such as ILC. It is expected that accredited laboratories will take every opportunity to confirm the technical validity of the test results being produced by them.
- SPC plots to show consistency of results
- correlation of results using other test methods
- PT to be conducted at least once in 4 years for each test (requirements of international MRA)
- evaluation of QC results using En and z-score

16

Common non-conformities in technical requirements

Assuring the quality of the test result (5.9)

- The use of reference materials/standards provides for the monitoring of accuracy performance.
- Replicate testing of duplicate test items and repeated measurements provides for the monitoring of precision performance.
- The retention and re-rest of test items may be specified in response to questionable results or complaints.
- Evaluation of interrelated characteristics of individual test items can aid in detecting errors.

17

Proficiency Testing - Measurement Audit

***Evaluation of Results**: A* laboratory's participation in a given measurement audit is usually evaluated based on the following equation:

$$En = \frac{|Lab - Ref|}{\sqrt{(U_{95}Lab)^2 + (U_{95}Ref)^2}}$$

where Lab and Ref indicate the laboratory and reference measurement values respectively for the attribute in question and U_{95}Lab and U_{95}Ref represent the expanded uncertainties expressed at the 95% confidence level for the laboratory and reference laboratory respectively.

En values greater than 1 indicate that a laboratory's measurement result and associated uncertainty deviate significantly from the reference measurement result and associated reference uncertainty.

18

Proficiency Testing – Z score

In all proficiency tests (PT) is the use of a performance indicator to quantify the analytical performance of each participant. The z score is frequently used. The z score is a measure of the deviation of the result from the assigned value for that determinant and is calculated as:

$$z = \frac{(x - \bar{x})}{s}$$

where s is a standard deviation which is chosen either as an estimate of the actual variation between results encountered in a particular round of the scheme, x is the score and x bar the mean of the round.

Assuming the individual z scores will have a Gaussian or normal distribution with a mean of zero and a standard deviation of one.

$z < 2$ is considered Satisfactory

$2 \leq z \leq 3$ is considered Questionable

$z > 3$ is considered Unsatisfactory

19

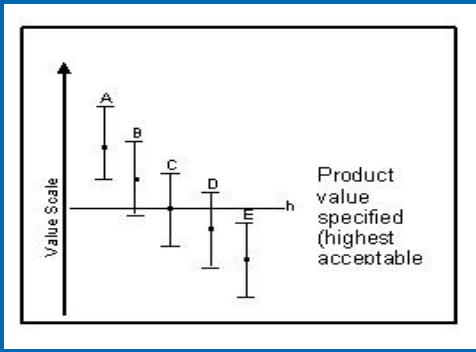
Common non-conformities in technical requirements

Test reporting (5.10)

- all information in a test report must be supported by the records pertaining to the test
- should include all information to allow repeating of test results and obtain a comparable result (includes diagrams and sketches)
- use of measurement uncertainties where a statement of compliance is required. (compliance cannot be established in some cases)
- confidentiality concerns, test reports converted to a non- editable format that can also be encrypted. An example would be to use Adobe PDF format and then a lab password to prevent changing or editing the document. An additional customer password would then be used to open the document

20

Example of applying the confidence interval to test results



- Test result A indicates there is more than 95% confidence that the product failed the specification.
- Test result E at 95% confidence indicates an acceptable product.
- For test results B, C and D, one cannot say with 95% confidence whether the product passed or failed.
- For test result C, one is 50% confident that the product passed and 50% confident that it failed.
- For result B, one is somewhere between 50% and 95% confident that the product failed. For result D, one is somewhere between 50 and 95% confident that the product passed. The laboratory can calculate the percentage of confidence that result B is a fail and result D is a pass.

21