Check-list for auditors

Audit visit at candidate registered laboratories

1 Contents

2 Introduction

This document has two aims:

- to give a check-list to the auditors to be used during an audit visit
- to inform the audited laboratory of the items that will be discussed during an audit visit and of the required documentation that shall be available for examination before an audit

The audit visit by Expert group member will focus on the equipment and testing details

- For thermal conductivity curve EN 1946-1, 2 (GHP) and EN 1946-5 (pipe) and EN ISO 8497 and TS 15548 (*TC 89/WG 11doc).*
- For maximum service temperature EN 14706 and EN 14707
- For trace quantities of chloride ions EN 13468.

Documentary evidence of compliance shall be retained by the laboratory for the purposes of auditing.

Specific requirements for the individual tests are described after the general requirements valid for all/any of the tests listed above.
A laboratory may become registered for one or more of the tests as appropriate. The registration includes the listing of the temperature range for which they prove their testing capability for the thermal conductivity curve (flat and pipe testing) and the maximum service temperature (flat and pipe testing).

3 Laboratory documentation required by the standard(s), available for inspection by the auditor

The laboratory is required to have the following documentation:

- Equipment manual
  This manual shall contain:
  - equipment performance specifications
  - equipment description
  - equipment design and uncertainty analysis
  - equipment performance check complete with experimental data
- Calibration and maintenance files
  Equipment maintenance and results of calibrations shall be annotated in the calibration and maintenance files.
- Measurement procedures document
  The measurement procedures document shall contain all detailed instructions that the operator requires to perform measurements within the stated uncertainty.

Also :

- Information required in Appendix for industrial products to Quality Assurance Mark rules. (*Quality Assurance Mark is the term used for Keymark and/or VDI mark*)
  See also the annex 1 of this document.

For the determination of the thermal conductivity curve the above listed documentation is required according to EN 1946-1, EN 1946-2, and/or EN 1946-5 and in conformity with EN ISO 17025. See also annex 2 and 3 of this document.

The auditor shall be informed before the visit that this documentation will be available for inspection during the audit.

4 Items to be discussed during an audit visit

4.1. Application form and requirements for a registered laboratory

The application form filled in by the audited laboratory and sent previously to the Quality Assurance Mark Secretariat will be examined by the auditor.
This application form gives, among others things, some information about the requirements for a registered laboratory indicated in Appendix for industrial products to Quality Assurance Mark rules (see also Annex 1 of this document). These requirements will be examined in detail hence it is important to fill in the application form as fully as possible.

The following items will be discussed:

- ***Accreditation and conformity according EN ISO 17025*** :
  - Accreditation by which body?
  - Accreditation to which standards?

  - Date of last audit and details of non compliances if any?
  - …
- ***Competence of staff for testing within the Quality Assurance Mark scheme***
  - How many years of experience?
  - Comparative testings?
  - Qualifications
  - Evidence of training
  - …
- …

4.2. Equipment and testing details

The equipment used for testing within this Quality Assurance Mark scheme shall comply with the requirements of the relevant EN standards.

The following items will be considered:

- ***Validation according to the relevant EN standard(s) and uncertainty analyse(s)***
  The equipment manual will be examined with attention to the following items (Annex 2 and 3 give examples of possible tables of contents for the equipment manual for ghp and pipe tester respectively):
  - Equipment description
    (some information is available in the application form)
  - Equipment performance check
    The procedure for the equipment performance check shall be described in detail and should include experimental data.
  - Uncertainty analysis or uncertainty budget
    Detailed information shall be given of the uncertainty analysis (best measurement capability) leading to an estimate of the measurement uncertainties under different testing conditions

- ***Measurement procedures document***
  This document shall contain all detailed instructions that the operator requires to perform measurements within the stated uncertainty
  - Specimen preparation for testing
  - Testing procedures, step-by-step
  - Thickness measurement, if relevant
  - Test reporting
  - Appropriate calibration checks and maintenance actions
  - Procedure followed with samples thicker than the capability of the apparatus?
  - …

- ***Instrument calibration and status on calibration***
  - calibration of relevant elements of the equipment
  - Status on calibration?
  - Frequency?
  - Call up procedure for re-calibrations

- ***Proficiency testing***
  - Which test was performed and results?
  - Records of these tests and results?
  - History of calibration of equipment?
  - For a specific test (the auditor can pick up one report from the archive for example), is the staff able to show all results and records?
  - Details of intercomparisons and level of agreement

- ***Witness testing***
  - System for sample marking
  - Preparation of one specimen for a measurement for the individual tests ($\lambda(\vartheta)$, $\lambda(\vartheta_m)$, MST and Cl^-)
  - Identification of this specimen
  - Steps for measuring this specimen
  - Thickness, weight, length measurement, if relevant
  - Calculation sheet
  - Report
  - Checking of results before reporting

Annex 1: Requirements for registered laboratories
(quote from Appendix B for industrial products)

A laboratory shall fulfil the following requirements in order to be accepted by the Quality Assurance Committee as a registered laboratory:

1. The laboratory shall be accredited against EN ISO 17025 (EA accreditation). In particular, the laboratory shall be able to demonstrate participation in inter-laboratory comparative testing for the relevant test methods [1].
2. The laboratory shall be notified within the frame of the CPD for insulation products.
3. The laboratory shall have recent experience with test procedures (conditioning, ageing and measuring according to product specifications) according to the specific product standards.
4. The competence of staff and fitness for purpose of the equipment used for testing within the Quality Assurance Mark scheme shall comply with the requirements of relevant European standards:
   - For thermal conductivity curve EN 1946-1, 2 (GHP) and 5 (pipe) and EN ISO 8497 and TS 15548 (*TC 89/WG 11doc).*
   - For maximum service temperature EN 14706 and EN 14707
   - For trace quantities of chloride ions EN 13468.

   Documentary evidence of compliance shall be retained by the laboratory for the purposes of auditing.
5. Measurements shall be carried out with registered test equipment.
6. Results shall be in agreement with the European levels of conformity requirements for the three tests as follows:

- For thermal conductivity curve, $\lambda(\vartheta)$	a) ± 3 % for temperature range from -180 ºC up to 500 ºC b) ± 5 % for temperatures above 500 ºC
- For thermal conductivity curve, $\lambda(\vartheta_m)$	a) ± 3 % for temperature range from -70 ºC up to 300 ºC
- For maximum service temperature, MST	± 0,5 % deformation at a chosen temperature (equipment verification in comparative testing)
- For chloride content, Cl^-	± 1.5 ppm.

The listed values are provisional.
This shall be demonstrated by the laboratory's participation in a programme of comparative testing every third year.

NOTE 1 A laboratory may become registered for one or more of the test methods (the thermal conductivity curve, maximum service temperature and chloride content measurements)

NOTE 2 Where a registered laboratory is contracted by a manufacturer to conduct testing for the manufacturer's own factory production control, the acceptance of that registered laboratory to conduct testing for a Certification Body for the Quality Assurance Mark scheme, will be at the discretion of the Certification Body. In such a case the certification body shall inform the Quality Assurance Committee.

Annex 2: Example of a table of content for an equipment manual Guarded hot plate apparatus (according to EN 1946-2)

Annex 3: Example of a table of content for an equipment manual Pipe tester (according to EN 1946-5 and EN ISO 8497)

Annex 4: Example of a table of content for an equipment manual Maximum service temperature equipment (flat or pipe)

Annex 5: General experience/rules for audits, additional information for candidate registered laboratories and the auditor

There is a limit to the length of time that discussions with a candidate can continue. Clear time schedules shall be agreed between parties. If no actions are taken by the candidate for more than 18 months after the audit all actions need to be repeated (audit and comparative testing).
An important element for candidates is that the EN ISO 17025 accreditation shall be in place before a laboratory can apply.

Confidentiality is taken very seriously, and e.g. detailed discussions in the expert group on the individually candidates will not be in the minutes of the expert group meetings and will not be discussed with anyone outside the group.

The individual experts are responsible for follow up on actions agreed and at expert group meetings an item on the agenda will be to report on progress of these actions. The draft minutes of expert group meetings shall reflect actions to be taken and can be used by auditors when checking updates on the individual candidates.

When a candidate laboratory believes it is ready for the audit and guidance has been given by the auditor, a mutually convenient date will be arranged for the audit to take place.

If laboratories want Quality Assurance Mark approval for more than one equipment for each test method, all such equipment shall be subject to comparative testing, except for pipe tester where selected diameters will be chosen (both for thermal conductivity and for MST).
Only those equipment can be used for Quality Assurance Mark testing. In addition internal calibration procedures shall be documented and used in all registered laboratories.

In general the required documentation shall be forwarded to the auditor before the audit. The check list for audits (scheme rules appendix C, i.e. this document) will be made available to the applicants to help them prepare for the audits.
The basis for the auditing will be that candidate registered laboratories are accredited by an appropriate national body. That work shall not be repeated, but spot checks on technical details related to testing shall be made. Special emphasis shall be given to the EN 1946 technical assessment.
Observations will be made during the audit, and based upon the reporting of the auditor, the laboratory group will make their decision. The Laboratory group secretariat will inform the candidate registered laboratory of the final conclusion.
All communication with the candidate will be handled by the secretariat with full information copied to the Laboratory group. Full confidentiality is essential here and shall be respected by all Expert group members.
If a surveillance audit is needed the price will be 1000 EURO with the addition of the travelling costs for the auditor.
The format of the audit reports will follow the check list (scheme rules appendix C, i.e. this document).
An audit might not be needed if the candidate laboratory has been assessed in the normal accreditation process by one of the expert group auditors and this auditor can confirm that the elements of the Quality Assurance Mark rules appendix for industrial products requirements was covered during the audit. This will be judged case by case by the auditor.