EN 15267 – Type Approval & Certification of AMS (QAL1)

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Certification of AMS – The past (pre-EN 15267) approaches (up to 2009/2010)

**German „TUV“ - scheme:**

- Manufacturer applied for test at TUV
- TUV conducted approval test in line with German requirements (VDI 4202) as well as European requirements.
- TUV presented test report at German LAI committee for assessment.
- Positive assessment lead to publication as a type-approved AMS in the Bundesanzeiger (Federal Gazette).
- Test report has often served as a basis for English MCERTS certification

**English „MCERTS“ - scheme:**

* Used with kind permission of Sira Test and Certification Ltd.

- Manufacturer applied for certification by Sira
- Existing test data initially reviewed for acceptability
- Any gaps in evidence required additional testing - conducted at test house chosen by manufacturer
- All reports reviewed by certification committee for approval
- MCERTS certificate issued and posted on Sira website
Certification of AMS –
The present approach according to EN 15267

Content

**EN 15267-1:2009**
- General principle

**EN 15267-2:2009**
- Initial assessment of the AMS manufacturer’s quality management system and post certification surveillance of the manufacturing process

**EN 15267-3:2007**
- Performance criteria and test procedures for automated measuring systems for monitoring emissions from stationary sources

**EN 15267-4:**
- Performance criteria and test procedures for measuring ambient air quality
  - Work stopped – cancelled or on hold only?
EN 15267 part 1, General scope

**European Standard EN 15267 part 1**

specifies the general principles for the product certification of automated measuring systems (AMS) for monitoring emissions from stationary sources and ambient air quality.

**This product certification consists of the following sequential steps**

- Performance testing of an AMS
- Initial assessment of the AMS manufacturer’s quality management system
- Certification
- Surveillance

**These steps can be performed by one or different organisations.**
EN 15267 part 1,
Roles and responsibilities during certification

Manufacturer of AMS

- Initial approach for performance testing
- Submits at least two complete and identical AMS and information for testing
- Establishes, maintains and operates a quality management system according to EN 15267-2
- Ensures quality assurance and control of manufacturing such that all certified AMS continue to meet applicable performance criteria
- Controls and assesses design changes and keep detailed records on that
- Records methods and results of re-testing, if the AMS requires partial or complete re-testing
- Notifies the test laboratory and the relevant body of changes to the AMS
EN 15267 part 1, Roles and responsibilities during certification

Test Laboratory

- Holds accreditation for type approval testing according to EN ISO/IEC 17025
- Evaluates AMS conformity with performance criteria
- Advises manufacturers on suitability of AMS for different applications and measuring ranges
- Applies for the certification of the AMS at the relevant body
- Evaluates any design changes to the AMS if requested by the manufacturer,
  - if original certification is affected ⇒ notify relevant body,
  - if retesting is required ⇒ advise manufacturer and relevant body
EN 15267 part 1,
Roles and responsibilities during certification

**Relevant Body**

- Needs accreditation to EN 45011, if the relevant body is a certification body
- Has in place appropriate procedures for certification, if it is an unaccredited competent authority
- Provides guidance on arrangements and requirements for certification to manufacturer and test laboratory
- Assesses test reports and determine, whether test laboratory is appropriately accredited to carry out tests
- Verifies evidence, that manufacturer has an EN 15267-2 conform QMS
EN 15267 part 1,
Roles and responsibilities during certification

Relevant Body

- Liaises as appropriate with the relevant national competent authority
- Issues certificates with an appropriate scope of certification in either English, French or German
- Adds the AMS to official register (in Germany: www.qal1.de)
- Ensures that post certification surveillance is periodically carried out
EN 15267 part 2
QM system and audit scope

**European Standard EN 15267 part 2** specifies the requirements;

- For the QM system of the manufacturer.
- For the initial assessment of the AMS manufacturer.
- For ongoing surveillance to ensure that the AMS fulfills the minimum requirements of the approval test procedure, also after soft- or hardware modifications.
EN 15267 part 2
Modifications on the certified AMS

The manufacturer must keep records and evaluations on any modification of the certified AMS. The following three classes of changes are defined:

**Type 0:** Changes that have no measurable influence to the performance of the AMS

**Type 1:** Changes with a possible influence, but for which can be proved by tests, that the influence is non-significant

- In the annual audit, the manufacturer has to inform the relevant body
- If the auditor accepts the internal documentation no additional tests are required

**Type 2:** Changes with significant influence to the AMS

- Additional test are always required, if type 2 changes are implemented.
EN 15267 part 3
Minimum requirements and test procedures for CEMS

European Standard EN 15267 part 3
defines the performance criteria and test procedures for automated measuring systems that

- measure gases and particulate matter in respective flow of the waste gas from stationary sources.

- This European Standard supports the requirements of particular EU Directives

- It provides the detailed procedures covering the QAL1 requirements of EN 14181

- It provides input data for QAL3 procedure described in EN 14181
EN 15267 part 4
Minimum requirements and test procedures for CAMS

European Standard EN 15267 part 4 – Not available!

- was planned to define the performance criteria and test procedures for automated measuring systems for ambient air quality for both gases and PM – work was stopped!

- Thus the underlying performance criteria and test procedures for CAMS for gases are defined in:
  - EN 14211:2005, chapter 8 for NO\textsubscript{x}
  - EN 14212:2005, chapter 8 for SO\textsubscript{2}
  - EN 14625:2005, chapter 8 for O\textsubscript{3}
  - EN 14626:2005, chapter 8 for CO
  - EN 14662-3:2005, chapter 8 for C\textsubscript{6}H\textsubscript{6}

- All the mentioned standards are currently in process of revision, but the requirements on the part “Type approval test” are not supposed to change significantly.
EN 15267 part 4
Minimum requirements and test procedures for CAMS

European Standard EN 15267 part 4- Not available!

➢ The underlying performance criteria and test procedures for CAMS for PM are currently defined in:
  - VDI 4202 Sheet 1 (September 2010) – Performance criteria
  - VDI 4203 Sheet 3 (September 2010) – Test procedures
together with
  - EN 12341:1998 for PM\textsubscript{10}
  - EN 14907:2005 for PM\textsubscript{2.5}
  - Guide to the Demonstration of Equivalence of Ambient Air Monitoring Methods GDE

➢ In future there will be only one document as basis:
  Technical specification on “Automated continuous systems for the measurement of the concentration of particulate matter (PM\textsubscript{10}; PM\textsubscript{2.5})”, developed in WG15
EN 15267

Summary

With EN 15267 for the first time in Europe an uniform and obligatory certification scheme to test and certify AMS is available

In the future, one test and one certificate in Europe is sufficient!

What has to be done in the future:

- Publication of a uniform basis standard for testing of PM monitors
- Cooperation between the relevant bodies in Europe

→ Example is the successful cooperation between UK and Germany
### Comparison of German and British System of Product Certification according to EN 15267

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<td>TÜV (reports to relevant body)</td>
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**UK:** English report, formal decision of SIRA

**Germany:** German Report, formal decision of LAI

**Mutual Information and Acceptance:**
- SIRA <-> TÜV
Possible options of certification for manufacturers:

- **The German approach:**
  EN 15267 certificate issued by TÜV and the UBA. In order to be EN 15267 compliant, the “German” certificate is issued by both UBA (representing LAI as relevant body) and TÜV. Certificates (and in case of CAMS also test reports) are published on [www.qal1.de](http://www.qal1.de)
  Status: Implemented

- **The MCERTS approach:**
  UKAS accredited certificate issued by a “certification body” (Sira) and accepted by the Environment Agency. Certificates are published on [www.siraenvironmental.com](http://www.siraenvironmental.com) or [www.mcerts.net](http://www.mcerts.net)
  Status: Implemented
Possible options of certification for manufacturers:

“Vision” for the future:

- UBA and MCERTS approval:
  One harmonized certificate issued by UK “certification body” and German relevant body, accepted by both UBA and EA. The certification work must go through both the Sira and UBA process. This implies that all relevant documents must be available in English and German language.
  **Status: Still to be developed**
Thank you for your attention
Expert Meeting on September 6th (Thursday) in Cologne
→ TÜV Rheinland Headquarter

- We kindly invite you to get:
  - first hand information on state of the art of suitability testing procedures according to standard EN 15267.
  - a complete overview throughout the history of AMS Certification presented by the Experts of the leading test house for suitability testing.
  - The presentations are held by our leading experts, leading manufacturers and endusers.
  - ......

Mr. Pletscher will provide more information for you