QAL3 methods for different measurement principles from the point of view of AMS manufacturers, test houses and plant operators

Mr. Guido Baum
TÜV Rheinland Energie und Umwelt GmbH
Am Grauen Stein, 51105 Cologne
Germany
Phone: +49 221 806 2592
Guido.baum@de.tuv.com
www.qal1.de
Standard EN 14181 states the requirement of using suitability-tested AMS for monitoring official limit values.

The following Quality Assurance Levels are listed in Standard EN 14181:

- **QAL1** (Performance test)
- **QAL2** (Installation, calibration)
- **QAL3** (Ongoing device check during operation)
- **AST** (Functional test)

First Europe-wide certification procedure for automated measuring systems through implementation of QAL1 according to EN 14181 (prior legislation comprised only directives at national levels in some European countries).
EN 14181 – QA Levels for Monitoring

Suitability of AMS → Set-up Calibration Validation → QA during Operation

QAL 1 → QAL 2

QAL 3

Annual Surveillance Test
EN 14181 – Context with other Standards

EN 14181
QA AMS

QAL 1
ISO 14956
Type Approval and Certification EN 15267

QAL 2
SRM
EN xyz
Strategy EN 15259

QAL 3
Records / Charts

AST
SRM
EN xyz
Strategy EN 15259
EN 15267
QAL1 = Performance test (Type approval procedure + Audit of manufacturer‘s QM system)

Concerned are:

- The instrument manufacturer and the test house for the actual performance of type approval procedures, as well as
- Plant operators, due to their obligation to employ suitability-tested AMS for monitoring limit values.

Performance criteria for testing emission measuring system are specified in the EN 15267 directive series.

- In Germany, a notification in the Federal Gazette is required.
- A passed performance test according to EN 15267 is prerequisite for the implementation of automated measuring systems.
QAL2 = Calibration of automated measuring systems

**Concerned are:** Plant operators and test houses accredited according to § 26 of the Federal Immission Control Act (BImSchG)

The implementation of QAL2 procedures ensures that AMS in operation at plants provide measurement data of sufficient quality.

- **QAL2 procedures comprise:**
  - Installation of AMS
  - Functional test within the scope of QAL2
  - Calibration of the AMS by means of paired measurements with a standard reference method (SRM)
  - Determination of the validity range of the calibration curve
  - Determination of the variability of the AMS and verification of compliance with the specified uncertainty
  - Report.
EN 14181 QAL2 – Frequency of performance

QAL2 shall be performed:

- At least every 5 years
- At shorter intervals, if stipulated by other legal requirements
- At shorter intervals, if indicated in the notification of approval

A calibration is also necessary, if:

- The values measured are frequently outside the range of validity of the calibration curve
- The operating conditions of the plant undergo significant changes
- Any changes or repairs which will affect the results obtained are made to the AMS or any of its parts
- The AMS did not pass the AST

A period of max. 6 months is specified for the execution and implementation of QAL2 (Process concluded by report of competent authorities).
QAL3 = ongoing quality assurance during operation

**Concerned are:** Plant operators or contractors commissioned to perform maintenance works

QAL3 is a procedure designed for maintaining and demonstrating the quality of the AMS results during ongoing operation.

The requirements for execution of QAL3 tasks are specified in the performance test report:

- Frequency of performance of QAL3 is defined by maintenance interval
- Technical specifications for QAL3 implementation methodology are stated in both performance test report and manual
- The necessary equipment for execution of QAL3 (e.g. reference and auxiliary materials) is described in the performance test report. Device-specific test materials are part of the suitability-tested AMS.
EN 14181 QAL3 – Role of plant owners

- Frequent drift checks at zero and span point
- Interval is based on the maintenance interval determined during the suitability test procedure (QAL1)
- Suitable test equipment necessary
- Service can be delegated e.g. to field service of analyser manufacturers (responsible is the plant owner)
- Plant staff needs to be trained
- Responsibility needs to be defined in the quality management system of the plant operator
- Necessary actions in case of significant drift effects need to be defined:
  - Analyser adjustment
  - Analyser repair
EN 14181 QAL3 – Documentation at site

- **Control** charts
- **Follow-up** sheet
- **Responsibility / Qualification staff**
- **Process instruction** for calibration and check
- **Reports** on checks, calibration and interventions
- **Compliance** with valid calibration range
- **Ongoing Driftcheck** (≥ during maintenance interval)
The EN 14181 QAL3 procedure serves the purpose of ensuring and demonstrating the quality of the AMS through regular drift and precision checks.

Drift and precision controls shall be achieved by the use of control charts:

**Shewhart control charts** or **CUSUM control charts, manual evaluation** is permitted in exceptional cases.
Manufacturer needs to deliver suitable analysers for the measuring task
Test equipment for QAL3 tests (zero and span check) and for functional test (AST) needs to be available for a QAL1 tested analyser

- **AST: zero standard and in minimum 3 to 4 over the range evenly spread reference materials necessary**

For some analysers device-specific test equipment is required (e.g. for particulate matter analysers)

- **Analyser manufacturer has to provide suitable test devices**

Test equipment has to be tested and qualified during the type approval procedure (QAL1)

- **Development of test equipment is an important step in the development of the analyser**

- **Test equipment needs to be available at the beginning of the QAL1 certification process**
Test materials for performing QAL3

The manufacturer is obliged to carry out regular zero and span point checks as part of QAL3 testing.

**Critical components for QAL3:**

**Gaseous components:**

When testing components H$_2$O, HCl, HF, NH$_3$ and Hg, the production of test gas through evaporation of appropriate test solutions is necessary for some AMS.

- Plant operators often have no test gas generator and commission the manufacturers to perform the checks as part of maintenance works
- The application of wet test gases is performed with the same method used for dry test gases, i.e. feeding the gases over the entire sampling system.
- Condensations of test gas behind the evaporator must be avoided in any case. If necessary, the gas supply line to the sampling probe shall be heated.
Different AMS require device-specific test materials.

**Dust measuring systems:**
- Reference materials for zero and span point checks, e.g. grey glass filters, grid filters or scattered light bodies for optical measurement methods, test standards for simulation of the span point in triboelectric measuring devices.
- Auxiliary materials for zero and span point checks, e.g. mounting racks and zero tubes

**In-situ measuring systems:**
- External measuring cells are requisite for testing gas analysers. If necessary, these shall be heated

The test materials used for QAL3 must undergo testing as part of the performance test of the AMS followed by a notification of their suitability.
EN 14181 QAL3 – Role of test institutes

**At the customer site:**
- Check the necessary documentation during the annual functional test (AST)
  - Documentation of drift checks, „History of AMS“, Training…
- Test institutes need suitable test equipment to perform AST

**During the type approval:**
- Qualification of device-specific test equipment during the type approval procedure
  - Suitability during the laboratory and field test
  - Stability during the field test
  - Comparison with other standards
  - Description of the procedure for conducting functional tests in QAL1 report
  - List of the necessary test and auxiliary materials
The terminology of Directive EN 15267 states that only a complete measuring system and not just the analyser can apply for certification. A complete measuring system consists of:

- Analyser unit (may be integrated in the measurement cabinet)
- Sample gas processing equipment comprising sampling probe, solid filtering device, sampling line, gas conditioning device / gas drying device
- Measurement data processing and output unit
- Suitability-tested software version
- Technical documentation, manual
- If required, test materials for performing AST and QAL3 according to EN 14181
- Performance test report / Certificate
- “History of the AMS” after installation: maintenance log, QAL3 records
List of suitability tested analysers:

- **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 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*
Summary

Instrument manufacturer:
- Production and distribution of measuring systems in technical conformity with the type approved version (hardware / software).
- Development of suitable (device-specific) test equipment for QAL3 and AST

Plant operator:
- Performance, evaluation and documentation of QAL3 tests
- Qualification of the operator staff by training
- Fix responsibilities and implement necessary actions for QAL3 procedure

Test institute:
- Check of the QAL3 documentation and “analyser history” of the plant owner during the annual AST
- Use of suitable, device specific reference materials and test procedures
- Qualification of QAL3 procedures and materials during the type approval
Thank you for your kind attention