Change management of certified AMS according to EN 15267 (QAL1)

Carsten Röllig
TÜV Rheinland Energie und Umwelt GmbH
Am Grauen Stein, 51105 Cologne
Germany
Phone: ++49 221 806 2422
roellig@de.tuv.com
www.qal1.de
Topics to be Covered

• Auditing process according to EN 15267-2
• Requirements for the quality management system of the manufacturer of an AMS
• Change process according to the requirements of EN 15267
• Publication of certified AMS in Germany
• Certification of OEM products
• Maintenance of the certificate
Performance Criteria

EN 15267 part 2 establishes performance criteria for

- The manufacturer’s quality management system,
- the initial assessment of the manufacturer’s production monitoring,
- monitoring influences caused by design changes to hard or software that might affect performance of a certified measuring system.

✅ It complements EN ISO 9001:2000
Types of Changes

DIN EN 15267-2 defines 3 types of changes

**Type 0:** changes that have no measurable influence on the performance of the AMS;

**Type 1:** changes that can have an influence on the performance of the AMS, but where internal tests prove that such changes do not have a significant influence;

- During the annual audit, documentation of the assessment has to be presented and evidence has to be plausible.
- If the auditor disagrees with the assessment, further action is required.

**Type 2:** changes that have a significant influence on the performance of the AMS.

- Re-assessment / Complementary tests are required.

Regardless of the type of change as defined in DIN EN 15267-2, reporting requirements of the design change may apply in Germany. Further details are given in the annual audit.
Possible consequences for changes which have not been communicated:

- No installation certificate for new installations is issued.
- In-built systems will be discovered during QAL2 and AST.
- Certificate and publication are withdrawn.
Documentation of Design Changes

- Each change has to be documented in an auditable manner.
- Changes need to be documented in the technical file.
- Assessment of the change needs to be evident from the change documents.
- Test results for the assessment of changes have to be documented in the same manner.
- Reporting requirements equally apply to changes in hardware, electronics or software.
- Bills of materials and technical drawings need to be updated (as the case may be).
- A list of all on-going changes to an AMS may make sense.
- A list of components which are critical for performance may help the manufacturer to assess changes, it does not, however, rid him of his obligation to document all changes made to the AMS.
Type 0 Changes

• Changes that have no measurable influence on the performance of the AMS

  *Examples: introduction of a new language to the software of a measuring system, minor hardware changes without influence to analyser function of the AMS, new colour of the housing.*

• All type 0 changes have to be documented.

• Documentation needs to include at least a description and an assessment of the change.

• The point in time at which the change is implemented in the production should be clear.

• Clearance procedures for changes need to be defined unambiguously.
Type 1 Changes

- Changes that can have an influence on the performance of the AMS, but where subsequent tests prove that such changes do not have a significant influence. 

  *Examples: Installation of a new power supply, changes to the housing of an AMS, changes to the software which might affect the display of measured values, for example.*

- Any type 1 change is to be documented.
- Documentation needs to include at least a description and an assessment of the change.
- The point in time at which the change is implemented in the production should be clear.
- Clearance procedures for changes need to be defined unambiguously.
- All tests which serve to determine the effects of design changes shall be documented.
- All type 1 changes have to be included in audit reports.
Type 2 Changes

- Changes that have a significant influence on the performance of the AMS
  
  *Examples: Changes to critical parts of the AMS (light sources, cuvettes), Software changes which affect the formation of measured values, substantial changes to evaluation electronics.*

- Any type 2 change is to be documented.
- Documentation needs to include at least a description and an assessment of the change.
- Before they are implemented in production, type 2 changes have to be presented to the test institute and the competent authority as the case may be. The further course of action and the test program which may be required will then be agreed.
- Results of such tests will be documented in the form of a position statement or a complementary test report by the test institute and will be published by the competent authority after thorough examination.
Publication of Changes in Germany

• In Germany, every suitability-tested AMS is published by UBA in the Federal Gazette “BAnz” (formerly GMBI.) (list available on UBA web site and on QAL1.de).

• This list also serves as a source of information for local test houses notified according to the Federal Immissions Control Act, article 26 for performing QAL2 and AST.

• A local test house in acc. with article 26 shall be capable of identifying an approved AMS. To this effect the performance test report accompanying the AMS is available (TÜV Rheinland’s suggestion: publish report on QAL1.de).

• Changes to the AMS have to be made public in order to identify approved measuring systems on site beyond any doubt.

Changes are published by UBA notifications in the FG, Any type of change which complicates identification of approved systems for the local test house may be liable to publication.
Auditing in the 15267 Process

• The EN 15267 standard requires AMS performance and the manufacturer‘s quality management system to meet specific criteria:
• Prior to certification, ensure that the manufacturer’s QMS meets DIN EN 15267-2 requirements (initial audit).
• After certification of the AMS, monitor the manufacturing process and performance of the certified AMS at the manufacturer’s premises regularly (annual audit).
Initial Audit

• The initial audit of the AMS manufacturer’s QMS takes place at the manufacturer’s premises.

• Compliance of the QMS with the requirements of EN 15267 is verified. The manufacturer usually maintains a QMS certified in accordance with ISO 9001 requirements. In this case, the audit focusses on the additional requirements of DIN EN 15267-2.

  ➡️ ISO 9001 is no pre-requisite for an EN 15267 certification.

• If the manufacturer does not maintain a QMS certified to ISO 9001, all requirements of the DIN EN 15267 will have to be audited.

• The approach of the initial audit is primarily a systematic one. It serves to examine the QMS of the manufacturing process.

• The report on the initial audit of the QMS of an AMS manufacturer is presented to the competent authority along with the test report for certification.
Initial Audit

Important requirements of EN 15267-2 which exceed those of ISO 9001.

• The manufacturer knows the basic requirements for air quality control in Europe.
• The manufacturer defines responsibilities for AMS monitoring.
• The manufacturer is obliged to keep a technical file.
• The manufacturer has a procedure for design changes in place which complies with the standard.
• Additional requirements to control the purchasing process.
• Requirements for testing and controlling manufactured AMS.
• Specific requirements with regard to traceability of manufactured AMS.
• Specific information requirements for the control of non-conforming products.
• Performance of annual surveillance.
Annual Surveillance Audit

According to DIN EN 15267-1 an annual audit of the manufacturing process and the AMS performance shall take place (exceptions are only possible in clearly specified individual cases).

- Emphasis during annual audits is placed on examining the product and changes to the product in the course of the past year.
  
  Contrary to the initial audit, the annual audit focusses on the product. Aspects of the QMS are only randomly checked, save the manufacturer does not maintain a certified QMS.

- Related documentation and any assessment of changes to the AMS is examined.
- Documentation relating to changes is prepared in cooperation with the manufacturer in order to notify the competent body as are all necessary official steps (notification, complementary testing if required).
- Random hands-on tests of the certified system may also be possible.
Certification of OEM Products

- Pursuant to a resolution made by the competent authority in Germany, distributors of OEM products shall also be included in annual surveillance procedures.
- A complete record of measured values in accordance with EN 15267-3 has to be available for the OEM product.
- Subject to any changes that the distributor may make to the measuring system, certification is possible on the basis of the original test report.
- The distributor of an OEM product shall also undergo an initial audit.
- In addition to general requirements, particular attention shall be directed to the flow of information between the manufacturer and the OEM distributor.
- The OEM distributor assumes responsibility as outlined in EN 15267 for all certified AMS distributed under his name.
- It has to be ensured that the distributor is fully informed about any changes to the AMS by the manufacturer.
Audit Report

• A report on all results obtained during the audit is produced.
• The report is presented to the competent authority as proof of the audit.
• The report contains an overview of the most important aspects of the manufacturer’s QMS with regard to DIN EN 15267 requirements.
• In addition, reports on surveillance audits contain an overview of the most important changes made to the AMS in the assessment period.
• In particular, all type 1 changes and those which have to be communicated are listed in the report.
• Type 2 changes are also listed in the report. They cannot be admitted to the production until clearance is given by the test institute and the competent authority. In this case additional documentation may be required (complementary test report).
• The audit report makes a recommendation on maintaining the certificate (the final decision is taken by the competent authority).
Individual Approval

In exceptional cases, the manufacturer may need to deliver products which differ from the performance-tested version of the AMS. The manufacturer has to inform his customer and, in the event of official measurements, the local authority as well as the test institute about this fact.

- In individual cases the local test house (in acc. with article 26) may issue an installation certificate after specific testing.
- This is an exceptional case which has to be coordinated with the competent authority at any rate.
- This procedure should only be made use of if the performance-tested solution is not (yet) available for the intended application.
Maintenance of the Certificate

In the event of non-compliance with the requirements of EN 15267 the competent authority may withdraw the certificate.

Reasons for withdrawal include:

- Implementation of changes to the AMS without sufficient documentation.
- Implementation of changes to the AMS without having notified the test institute or the competent authority.
- Changes to the manufacturer’s QMS which compromise compliance of the AMS manufacturing process.
- Failure to conduct the annual surveillance audit.
Experience Drawn from Past Audits

- Manufacturers with a solid QMS according to ISO 9001 usually meet the general requirements of DIN EN 15267, too.
- Quality of the QMS varies greatly among the different manufacturers.
- Frequently, there is a need for training with regard to air quality monitoring.
- Many manufacturers thoroughly assess design changes and do so in compliance with the standard.
- In some instances, issues arise with regard to documentation of type 0 changes.
- A list of critical parts may help (required by SIRA).
- In most cases traceability of manufactured AMS is excellent.
- Chronological documentation in particular is sometimes difficult to generate from the systems although it is required.
Conclusion 1

- EN 15267 procedures entirely implemented since 2009.
- Requirements are largely well implemented by manufacturers in question.
- Documenting and assessing design changes to certified AMS is among the core issues raised in the DIN EN 15267-2 standard.
- Under an appropriate quality management system, the manufacturer can make changes to certified measuring systems as part of product maintenance.
- DIN EN 15267 provides an assessment scheme to classify design changes.
- During annual audits at the manufacturer’s site, the QMS as well as any changes made to the AMS are assessed.
• The change procedure according to EN 15267 allows considerable leeway for manufacturers to implement production-related changes and improvements to certified AMS.
• In addition, reporting requirements for design changes as part of publication procedures need to be considered.
• Annual audits improve communication between the test institute, competent authority and manufacturers.
• According to EN 15267, the manufacturer receives a high-quality, internationally recognised certificate which certifies performance of his AMS.
• Mutual recognition of certificates in Europe has made good progress, but there is still room for improvement.
Thank you for your kind attention