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Testing and Certification Regulations

General terms and procedural guidelines for the certification of products according to standard EN 15267-1 from the certification body TÜV Rheinland Energy & Environment GmbH

Contents

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0. Preliminary remarks

The certification and testing body for QAL1 certifications in accordance with the EN 15267-1 standard of the certification body of TÜV Rheinland Energy & Environment GmbH (hereinafter referred to as the certification body) offers interested companies, among other things, its services for the certification of air quality monitoring equipment in accordance with the requirements of the EN 15267 series of standards as a certification body and also maintains a testing laboratory accredited in accordance with EN 17025 to carry out tests for testing air quality monitoring equipment in accordance with the above-mentioned standards as part of the QAL1 certification programme.

QAL1 certification is a European certification programme that covers air quality monitoring equipment that meets the requirements of relevant EN standards.

The obligation and assurance of independence and impartiality is ensured by the TÜV certification procedure. TÜV's existing structural and procedural organisation fulfils the criteria specified by ISO 17065. The organisation and the procedure of the certification process are detailed in the relevant quality management documents.

1. Scope and terms

These Testing and Certification Regulations govern the testing and certification of air quality monitoring equipment (AQME) on the basis of the EN 15267 series of standards, the EN 17255 series of standards, EN 14211, EN 14212, EN 14625, EN 14626, EN 16450, EN 15859, EN 12341, EN 14662-3 as well as VDI 4202-1, VDI 3950-1 and VDI 4203-1 and the *Bundeseinheitliche Praxis bei der Überwachung der Emissionen - RdSchr. d. BMUV* of 31 July 2023 - AG C I 2 - 5025/001-2023.0001. However, it should be noted that the aforementioned standardised federal practice for monitoring emissions is not in line with the requirements for certification in accordance with EN 15267-1:2023. The set of testing and certification regulations presented here are based on the current version of EN 15267-1 should any conflicts occur.

Air quality monitoring equipment (AQME) encompasses automatic measuring equipment for monitoring emissions and ambient air quality as well as long-term sampling systems and electronic data analysis systems.

The QAL1 certification is a conformity assessment procedure carried out by an accredited certification body on the basis of the above-mentioned European standards. The accreditation of a corresponding product is documented with a QAL1 certificate.

The certificate of conformity (QAL1 certificate) is issued by the certification body if it is established during the conformity assessment in accordance with the above-mentioned standards that the product complies with the provisions of the relevant standards, that the respective minimum requirements of the documented test requirements are fulfilled and that the manufacturer's quality management system complies with the requirements of EN 15267-2.

The QAL1 certificate is a document which is issued by the certification body in accordance with the rules of EN 15267-1, taking into account EN 17065, and which confirms that a product complies with the specified standards. The certificate can be issued for complete AQME measuring and evaluation systems (emission measuring devices, ambient air quality measuring devices, emission evaluation systems and long-term sampling systems).

The QAL1 test report on the technical testing of the measuring system is issued by a testing institute accredited in accordance with EN 17025 and is a documented record of the tests and assessments carried out, which requires confirmation by a certification body that the tested product complies with the specified standards.

The corresponding audit report is a document that details the results of an on-site assessment of the manufacturer's quality assurance system based on EN 15267-2 by the certification body or an organisation or person designated by the certification body in accordance with VDI 4203-1 (2017).

2. Testing and certification procedures

2.1 Conformity assessment procedure

A conformity assessment procedure is used to determine whether a product fulfils the provisions of standard EN 15267-1 in conjunction with the relevant standards and thus meets the requirements for QAL1 as defined in EN 14181.

2.2 Contract requirements

To initiate the conformity assessment procedures, the manufacturer submits an application for certification. The application must contain the following information:

- Normative requirements according to which the customer wishes to be certified. (This refers, in particular, to the type and scope of the AQME to be certified.),
- Self-disclosure letter from the customer (name, address, production locations, legal requirements, activities, resources, etc.),
- Information on outsourced processes, boundary conditions for the production of the AQME / OEM products if applicable,
- All other information required in accordance with the QAL1 certification requirements.

A form is available for preparing the application, which can also be completed with the support of the certification body if necessary.

2.3 Once the application has been successfully reviewed, the certification body submits an offer to the customer for certification of the AQME concerned. If the application review leads to a negative result, the certification body will inform the customer of the reasons that led to this decision. The customer can then decide whether to rework the application, submit a new application or withdraw from certification. If a quotation for certification is prepared, it will contain, in addition to the cost details, the information required for the certification of the AQME, such as applicable standards, regulatory and other normative documents specifying the QAL1 requirements and the associated assessment methods and procedures, as well as a preliminary schedule and test plan for certification. The timeframe for the specific tasks is also included here. Testing includes activities such as documentation review, laboratory testing, field testing and report writing in accordance with the relevant standards, which are performed by an EN ISO 17025 accredited test laboratory (usually the relevant TREE test laboratory). Should the customer already have complete test documentation (test report, manual, any other applicable documents and audit report in accordance with EN 15267) from a test laboratory accredited in accordance with EN ISO/IEC 17025, the certification body shall refer to this when preparing its quotation and prepare a simplified version which includes at least the following points:

- Assessment of applications for certification
- Review and assessment of the test report
- Review and assessment of the applicable documents for the tested product
- Review and assessment of the manual
- Review and assessment of the audit report

On the basis of the offer, the manufacturer (hereinafter referred to as the customer) places a written order with the certification body of TÜV Rheinland Energy & Environment GmbH for the testing and certification of the AQME. By placing the order, the customer confirms that he/she is the owner of the rights to the draft, design and manufacture of the product commissioned for testing and that no third-party rights, in particular trade mark rights, utility model rights and/or patent rights, are infringed. The certification body is not obliged to check the correctness. If a product presented by the customer for testing is indisputably or demonstrably plagiarised, the certification body is entitled to cancel the test and charge for the costs incurred. Proof of

plagiarism can only be provided by submitting a legally binding judgement of the last instance. In addition, a contractual penalty may be imposed in accordance with point 3.15 of the Testing and Certification Regulations.

2.3.1 By accepting the certification body's quotation with the aim of certification, a Contract for Testing and Certification is automatically concluded between the customer and the certification body. These Testing and Certification Regulations form an integral part of the contract. By signing the contract, both contracting parties recognise the provisions of these Testing and Certification Regulations.

2.3.2 The test and certification orders are processed in the order in which the necessary documents and test samples are received.

2.3.3 Technical documentation

2.3.3.1 Product testing

Technical documentation, such as drawings, parts lists, images etc. in accordance with the listing below should be submitted to the certification body together with the order if possible. The technical documentation must contain the necessary criteria that enable the conformity of the product with the requirements of the standard to be assessed. They shall cover, to the extent necessary for such assessment, the design, manufacture and operation of the product and shall include the following:

- A general description of the AQME to be tested
- General drawings and, if applicable, gas flow diagrams, assembly overview and pictures of the product to be certified
- Descriptions and explanations necessary to understand the above drawings and diagrams and the operation of the product
- Test reports, assessments carried out, etc., with reference to the standards applied
- Manufacturer's declarations that the product is in compliance with all relevant European standards and/or norms (e.g. CE marking, IP protection class ...)
- Installation/ operating instructions, maintenance instructions with information on use

The documentation should be kept to a minimum but must nevertheless contain the technical characteristics for assessment. The annexes to these testing and certification regulations shall be taken into account.

At the request of the certification body, two complete test candidates (measuring systems, sampling probes if applicable, sample gas lines, data output, specific test equipment) must be submitted. If necessary, special requirements for the preparation of the test sample will be communicated. Only for the testing of DAHS in accordance with EN 17255 is the submission of one test sample sufficient.

2.3.3.2 Conformity testing

An assessment and evaluation of the documentation, such as procedural instructions, work instructions, labelling, production, testing, test equipment monitoring, management of defective products and handling of products as well as design drawings, for plausibility and conformity with the requirements of the standard is carried out as part of the assessment of the manufacturer's quality management system.

2.4 Tests/audit

2.4.1 The tests are carried out in the test laboratory specified by the certification body or on a suitable external test site or test bench or at the installation site specified by the customer, taking into account the requirements of EN 17025.

2.4.2 Partial tests can be carried out at subcontracted laboratories that have the necessary accreditation in accordance with EN ISO/IEC 17025.

In addition to the laboratory tests, the tests can also include a long-term test as a field test lasting several months. The test laboratory determines a suitable field test location with the support of the customer. The field test is also carried out by the test laboratory at a suitable installation site in accordance with the relevant standards, taking into account EN ISO/IEC 17025. The field test installation for the long-term test and, if necessary, the transport of the test candidate systems to the field test location must always be carried out by the customer or a service provider commissioned by the customer. The field test can only be started once the customer and the test laboratory have confirmed that the AQME has been installed and is functioning in accordance with the standards. The customer is also responsible for the disassembly of the test candidate systems after the field test and for the removal of the test candidate systems.

After the certificate has been issued or otherwise granted, the submitted test candidates are scrapped by the certification body, stored securely or returned to the customer for further use or disposal, depending on the agreement. The certification body decides whether it is necessary to store a sample securely for the duration of the storage of the technical documentation. In such cases, the sample is taken into safekeeping by the certification body or signed off and handed over to the customer for safekeeping.

In all cases, test candidate systems are secured by means of documentation and, if necessary, temporary sample securing at the operating site of the tested product is agreed.

Agreements are made with the customer on a case-by-case basis regarding the location of test candidates whose testing has not resulted in a certificate. The certification body or test laboratory is not liable for damage to the test candidate samples caused by the test or by burglary, theft, fire or water. It must exercise the same care that it applies in similar matters of its own (§690 BGB).

The customer shall bear the costs associated with the transport, storage or scrapping of test candidate samples.

2.4.3 The results of the tests/audit are documented in a written and confidential test report/audit report, which the customer receives. If the testing procedure did not give rise to any issues, the test report and the associated technical documentation are forwarded to the certification body.

2.4.4 The certification body reserves the right to publish the final test report (not the audit report) as well as the QAL1 certificate on the ‘qal1.de’ website should the certification decision be favourable.

2.5 Carrying out the production site inspection (audit)

To audit the QM system and the manufacturing process, the manufacturer must first submit the quality management manual and supplementary documented QM procedures. These documents should preferably be available in German or English. Other languages will only be accepted after prior consultation and written confirmation. To check the effectiveness of the QM system in the production process, audits are carried out on the manufacturer's premises in one or more stages. In addition to checking the relevant points of the QM system, random checks of manufactured products (for conformity with the approved design) and the manufacturing processes (to ensure consistent quality), including exemplary routine tests, may also be carried out.

3. Issue of certificate and utilisation

3.1 The certification body checks the results of the conformity test for completeness and technical correctness.

3.1.1 A certificate is only issued in accordance with the EN 15267-1 standard if the tests have not revealed any non-compliances with regard to the requirements to be taken into account or any relevant defects. Any solution that varies from the standard must be described, tested and accepted and must not have any relevant design flaws.

3.1.2 A QAL1 certificate is only issued if the tests have not revealed any non-compliances with regard to the minimum requirements to be taken into account. However, there may be non-compliances that restrict the area of application of a measuring system. These are then shown on the certificate and certification can be achieved if relevant applications exist in which the measuring system can be operated without the influence of these restrictions.

3.1.3 The TREE certification body is only accredited to issue QAL1 certificates in accordance with the requirements of the EN 15267-1 standard. QAL1 certification is linked to the performance of regular annual production centre inspections.

3.2 Certificates that can be issued depending on conformity assessment procedures

3.2.1 The EN 15267-1 standard can only issue the following certificate:

- QAL1 certificates

3.3 The authorisation to use the certificate by the customer only applies to the complete product as tested and named in the certificate and for which the certificate holder holds all rights. A product may be taken apart for shipping as far as is needed. The terms must be specified in the assembly or operating instructions.
The customer must ensure through its quality management system that the products from ongoing production continue to fulfil the product requirements of the applicable test standards. This is also checked as part of the annual surveillance audit. To this end, the customer shall make arrangements to ensure that the performance of testing and monitoring, including consideration of the review of documentation and records, access to the relevant equipment, site(s), area(s) and personnel, and the customer's subcontractors and complaint investigation is assured to the extent required by the standard. Failure to comply with this can lead to the loss of certification. In addition, the participation of observers in the testing and monitoring activities should be allowed if necessary.

3.4 The certification body may demand a contractual penalty if violations of the Testing and Certification Regulations are detected, in particular in the event of unlawful use of a mark or certificate. It reserves the right to assert further recourse claims in court against the customer or the abusive user of the mark. If the order is cancelled by the contractor due to unlawful use, the services rendered and agreed shall be remunerated as agreed in the order. In addition, remuneration shall be paid for the services not yet rendered and cancelled in accordance with the agreed remuneration as per the contract. Unlawful use also exists if a product is placed on the market with the certification body's mark before the certificate applied for is granted or if unauthorised advertising is carried out with it.

3.5 A certificate can only be transferred to a third party by the certification body with the consent of the customer. A contract must first be concluded with the third party after the application has been submitted. The identification number or name of the product must be changed in such a way that the product origin can be distinguished.

3.6 QAL1 certificates are always valid for a maximum of five years. The respective certificate can be extended after the expiry date under the conditions of this document.

3.7 A certificate expires if

- the customer renounces the certificate,
- the Contract on Testing and Certification is terminated by one of the contracting parties in compliance with the notice periods,
- the customer goes bankrupt or an application to open bankruptcy proceedings against the customer in question is rejected for lack of assets, or
- the terms and conditions on which the certificate is based have been amended or other terms and conditions are applicable, e.g. due to a change in use.

3.8 A certificate may be withdrawn by the certification body if

- hidden defects are subsequently discovered in the product,
- an inspection of the product labelled with the identification number of the certification body reveals serious defects,
- misleading or otherwise unauthorised advertising is carried out in connection with the certificate,
- the customer refuses or does not enable production monitoring and does not have it carried out despite a written request from the certification body,
- facts and circumstances that could not be recognised at the time the certificate was issued become known,
- the certificate or attestation should not have been issued or the formulated conditions have not been fulfilled within a reasonable or set period, or
- a final, legally binding court judgement is available to prove plagiarism in court.

3.9 The certification body publishes the expiry or withdrawal of certificates on QAL1.de.

3.10 The certification body is authorised to inform the supervisory authorities, the accreditation bodies, the notified bodies and the approval authorities about the granting, expiry or withdrawal of certificates.

3.11 The certification body shall not be liable for any disadvantages suffered by the customer as a result of the non-issue, cancellation or withdrawal of a certificate.

3.12 If a certificate is withdrawn, the customer is obliged to remove the test mark from all products of the type in question that are accessible to the customer and to enable the certification body or the body commissioned by it to carry out a corresponding inspection. Any resulting costs shall be borne by the customer.

3.13 After expiry of the validity of a certificate, it is permitted to place on the market the product in stock existing at that time for a reasonable period of time, but not exceeding two years. Stocks of products bearing the identification number of the certification body must be made known to the certification body on request. The contractual provisions between the parties shall remain valid for the temporary period of bringing to the market. A distribution authorisation shall not be granted if the certificate has been declared invalid.

3.14 The certification body is entitled to claim a contractual penalty of 25,000 euros in the event that a test order is cancelled due to the existence of demonstrable plagiarism (see 2.2.1).

4. Inspection of production and assembly

4.1 To ensure consistent product quality, the certification body may, in accordance with the requirements of EN 15267-2, carry out or arrange for regular inspections of the production and testing facilities at the expense of the certificate holder.

4.2 The holder of the certificate shall receive a written report on the results of any such inspections.

If issues are found during the inspection that make a repeat inspection necessary, the holder of the QAL1 certificate shall bear the costs incurred for this.

5. Obligations of the certification body

5.1 The TÜV certification organisation and the members of the certification body undertake to treat all information made available to them about the customer's company as confidential and to use it only for the agreed purpose. Documents made available will not be passed on to third parties without the customer's permission. The customer may release the certification body from its duty of confidentiality under certain circumstances.

5.2 Should the customer seek further certification from another certification body on the basis of the QAL1 certification of TÜV Rheinland Energy & Environment GmbH, the customer must authorise the transfer of the documents when placing the order.

5.3 The certification body shall only be liable to the customer or third parties to the extent prescribed by law in cases of wilful intent or gross negligence. Any further claims are excluded.

5.4 The head of the certification body is obliged, as far as possible, to ensure the correct representation of the certification in marketing activities by the customer.

6. Obligations of the customer

6.1 The customer shall take all necessary measures to ensure that the production and manufacturing process fulfils the requirements documented in the relevant standards and that conformity with the technical documentation is guaranteed.

6.2 The customer is obliged to continuously monitor the production of the certified products for conformity with the certified type and compliance with the minimum requirements. A test carried out with a final certificate does not release the customer from its statutory product liability.

6.3 The customer shall notify the certification body of all changes made to the product compared to the version certified on the basis of the test sample or planned or implemented changes to the product. All changes to the certified product must be documented in the technical file of the product and this documentation must be submitted to the certification body at least 2 weeks before the annual surveillance audit. Changes to the certified product must always be assessed and categorised in accordance with the requirements of EN 15267-2 before being brought to the market. The following obligations arise for the customer depending on the categorisation of the changes:

Type 0 changes: Type 0 changes in accordance with EN 15267-2 may be introduced and placed on the market without consulting the certification body. If the changes affect the appearance or the identifiability of the certified product or if the software of the measuring system is affected by the change, the certification body must be informed immediately.

Type 1 changes: Type 1 changes in accordance with EN 15267-2 may be introduced and placed on the market without consultation with the certification body if the investigations and tests carried out by the customer have shown that the changes have no significant influence on the performance of the certified product. The investigations and tests carried out by the customer must be documented and presented at the next surveillance audit. It is recommended to submit the documentation to the certification body for verification before placing the product with the type 1 change on the market or to wait until after the next surveillance audit before placing the product on the market in order to avoid any necessary retests or recalls.

Type 2 changes: Type 2 changes in accordance with EN 15267-2 may not be introduced without the approval of the certification body and may not be placed on the market without the approval of the certification body. Type 2 changes always require technical testing by an independent testing institute accredited in accordance with EN 17025. The results of this testing must be submitted to the certification body for evaluation and assessment.

6.4 The continued validity of certificates issued depends on the customer's proof of compliance with the standard requirements or on a supplementary test. Supplementary tests to the original certificate can be carried out, which amend or extend certain properties or application conditions of the certified product. If the documented properties of the certified product are changed as part of the supplementary test, a new certificate must be issued.

6.5 The customer shall notify the certification body in good time of any intended relocation of audited production facilities or the intended transfer of ownership of the company to another company or another company owner.

6.6 The customer is obliged to notify the certification body of any damage or accidents caused by tested products.

6.7 The customer must record and archive all complaints relating to their certified product. At the request of the certification body, these documents must be made available and information must be provided detailing the measures taken to rectify justified complaints.

6.8 The customer is obliged to immediately remedy any defects in products that subsequently become apparent and to take appropriate measures to minimize any damage in the market. In any case, the customer must immediately stop placing the labelled products on the market and inform the certification body.

6.9 The customer is obliged to archive certificates, attestations, documents or samples that have been handed over to him for safekeeping for a period of ten years after production of the product has ceased or for a period of ten years after the product has been placed on the market and to make them available to the certification body free of charge on request. Additional requirements from other regulations remain unaffected

6.10 The customer may only pass on or publish test reports and certificates in full.

6.11 The customer may use the QAL1 certification mark in accordance with the instructions published on the certificate.

6.12 In the event of suspension, withdrawal or termination of certification, the customer shall cease the use of all promotional materials containing any reference to the certification and shall take all measures required by these Testing and Certification Regulations.

6.13 The customer shall not use the product certification in a way that could bring the certification body into disrepute, nor make any statements about its product certification that the certification body could consider misleading or unauthorised.

6.14 When referring to its product certification in communication media, such as documents, brochures or promotional materials, the customer shall fulfil the requirements of the certification body in accordance with the certification agreement and this document.

6.15 The customer shall keep records of all complaints made known to the customer in relation to compliance with the certification requirements and make these records available to the certification body on request, e.g. as part of the audit or upon request; and take appropriate action in relation to such complaints and any defects discovered in the products that affect compliance with the certification requirements. The measures taken for this purpose must be documented.

6.16 In addition, the customer must inform the certification body immediately of any changes that could affect its ability to fulfil the certification requirements.

7. Appeals process

7.1 The customer may lodge an objection or complaint with the certification body against unsatisfactory decisions by the certification body within the framework of the certification procedure carried out. The certification body must then provide the complainant with detailed reasons for its decision.

7.2 If the reasons given by the certification body are not acceptable to the complainant, the complainant may lodge an appeal with the steering committee of the certification body. The steering committee must reach a definitive decision.

8. Transfer of certification results

QAL1 certificates are also issued by other certification bodies with different restrictions or additional requirements in different countries. In addition, national authorities in Europe have the option of defining independent procedures for the national recognition of AQMEs. Prior to state approval, AQMEs must first fulfil the minimum requirements in accordance with the relevant standards. In addition, the requirements for the manufacturer's quality management system must be fulfilled. On behalf of the customer, the relevant data regarding the QAL1 certification process at TÜV Rheinland Energy & Environment GmbH can be transferred to a state certification body to obtain state approval. In addition, the certification body of TÜV Rheinland Energy & Environment can provide the necessary technical and administrative support for state approval of an AQME at the customer's request.

9. Enactment and amendment

9.1 The Testing and Certification Regulations come into force on 22 May 2025.

9.2 They apply in principle to all certificates issued during the period of validity.

9.3 Future amendments to the Testing and Certification Regulations may be applied to existing certificates by written agreement with the holders.