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Kakovost zraka - Certificiranje avtomatskih merilnih sistemov (AMS) - 1. del: Splo̧na naḷ ela

Air quality - Certification of automated measuring systems - Part 1: General principles

Luftbeschaffenheit - Zertifizierung von automatischen Messeinrichtungen - Teil 1: Grundlagen

Qualité de l'air — Certification des systemes de mesurage automatisés — Partie 1 : Principes généraux

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Air quality - Certification of automated measuring systems - Part 1: General principles

Qualité de l'air - Certification des systèmes de mesurage automatisés - Partie 1 : Principes généraux

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Foreword

This document (prEN 15267-1:2007) has been prepared by Technical Committee CEN/TC 264 “Air quality”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document is Part 1 of a series of European Standards:

— EN 15267-1, *Air quality – Certification of automated measuring systems – Part 1: General principles*

— EN 15267-2, *Air quality – Certification of automated measuring systems – Part 2: Initial assessment of the manufacturer’s quality management system and post certification surveillance for the manufacturing process*

— EN 15267-3, *Air quality – Certification of automated measuring systems – Part 3: Performance criteria and test procedures for automated measuring systems for monitoring emissions from stationary sources*

— EN 15267-4, *Air quality – Certification of automated measuring systems – Part 4: Performance specifications and test procedures for automated measuring systems for monitoring ambient air quality*

Introduction

The certification of automated measuring systems (AMS) supports the requirements of certain Directives of the European Union (EU), which require, either directly or indirectly, that AMS comply with performance criteria, maximum permissible measurement uncertainties and testing requirements. These Directives include the Directive on the limitation of emissions of certain pollutants into the air from large combustion plants [1], the Directive on the incineration of waste [2] and the Framework Directive on ambient air quality assessment and management [3] and the associated daughter directives [4], [5], [6].

The responsibility for approving AMS for monitoring ambient air quality under Directive 96/62/EC lies with the national competent authority or a body designated by the EU member state. No explicit requirement for approving AMS for monitoring emissions from stationary sources is defined in the relevant EU Directives, although the competent authorities in some EU member states have such arrangements in place.

In some EU member states the competent authority delegates the responsibility for approval of AMS to a certification body accredited to EN 45011:1998 [7] by national accreditation bodies. In some EU member states the competent authority cannot be accredited by external bodies, in others they may be. These approaches have built up over many years and reflect the different administrative and legal arrangements that exist in the EU member states. In order to recognize these different approaches, this European Standard uses the collective term “relevant body” when referring to competent authority or certification body. The terms “competent authority” and “certification body” are only used where it is necessary to be specific for the purpose of clarity in the way in which a requirement applies under the different approaches.

The European Standard EN 45011:1998 specifies general criteria that a certification body operating product certification shall follow if it is to be recognized at a national or European level as competent and reliable in the operation of a product certification system, irrespective of the sector involved. It is intended for the use of accreditation bodies concerned with recognizing the competence of certification bodies. EN 45011:1998 is identical to ISO/IEC Guide 65:1996. The document EA-6/01 [8] published by the International Accreditation

Forum (IAF) provides guidelines on the application of EN 45011:1998. The purpose of EA-6/01 is to harmonise the worldwide application of EN 45011:1998 by accreditation bodies as an important step towards mutual recognition between certification bodies under the IAF Multilateral Agreement (MLA).

EN 45011:1998 recognizes that these general criteria may have to be supplemented when applied to a particular sector. This European Standard provides guidance on the application of EN 45011:1998 to the certification of AMS for monitoring ambient air quality and emissions from stationary sources. It is Part 1 of a four part series of European Standards, which specify common requirements for the certification of AMS in EU member states.

This European Standard defines common procedures and requirements for the certification of AMS to facilitate mutual recognition by the relevant bodies and thereby minimise administrative and cost burdens on AMS manufacturers seeking certification in multiple member states. It also describes the roles and responsibilities of manufacturers, test laboratories, certification bodies (for quality management systems) and relevant bodies under these procedures.

1 Scope

This European Standard specifies the general principles of 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 stages:

a) performance testing of an AMS;

b) initial assessment of the AMS manufacturer's quality management system;

c) certification;

d) post-certification product-surveillance.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

prEN 15267-2, *Air Quality – Certification of automated measuring systems – Part 2: Initial assessment of the manufacturer's quality management system and post certification surveillance for the manufacturing process.*

prEN 15267-3, *Air Quality – Certification of automated measuring systems – Part 3: Performance criteria and test procedures for automated measuring systems for monitoring emissions from stationary sources.*

prEN 15267-4, *Air Quality – Certification of automated measuring systems – Part 4: Performance specifications and test procedures for automated measuring systems for monitoring ambient air quality.*

EN ISO 9001:2000, *Quality management systems – Requirements.*

EN ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories.*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
automated measuring system
AMS
entirety of all measuring instruments and additional devices for obtaining a measurement result

NOTE 1 Apart from the actual measuring device (the analyser), an AMS includes facilities for taking samples (e.g. probe, sample gas lines, flow meters and regulator, delivery pump) and for sample conditioning (e.g. dust filter, pre-separator for interferents, cooler, converter). This definition also includes testing and adjusting devices that are required for functional checks and, if applicable, for commissioning.

NOTE 2 The term “automated measuring system” (AMS) is typically used in Europe. The terms “continuous emission monitoring system” (CEM) and “continuous ambient-air-quality monitoring system” (CAM) are also typically used in the UK and USA.

3.2
relevant body
competent authority or certification body, nominated by a competent authority or EU member state, that carries out the certification of AMS

3.3
competent authority
organisation which implements the requirements of EU Directives and regulates installations, which must comply with the requirements of applicable European Standards

3.4
certification body
accredited body qualified to EN ISO/IEC 17021 for the certification of quality management systems and/or EN 45011 for the certification of products

3.5
manufacturer
organisation, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product its certification and undertakes all obligations in that connection

NOTE The term manufacturer is used instead of organisation as used in EN ISO 9001:2000. For the purpose of this standard they are interchangeable.

3.6
test laboratory
laboratory accredited to EN ISO/IEC 17025 for carrying out performance tests

3.7
product
AMS or components, which form the AMS

NOTE In the context of this European Standard product means AMS.

3.8
technical documentation
information for the operation of AMS, such as manuals

3.9
technical file
record of the reference drawings and design changes to the reference drawings

3.10
reference drawing
drawing referenced in the testing report

3.11
related drawing
drawing not referenced in the testing report

NOTE A related drawing could be used, for example, for the detailed manufacture of component parts.

3.12
certification range
range over which the AMS is tested and certified for compliance with the relevant performance criteria

NOTE 1 The lower limit is typically the detection limit of the AMS and often considered to be zero.

NOTE 2 Generally, the lower the certification range, the better the performance of the AMS. Also an AMS typically performs satisfactorily at higher values over the measurement range.

3.13
product surveillance
evaluation to determine the continued conformity of the certified product with specified requirements

[ISO/IEC Guide 2]

3.14
legislation
directives, acts, ordinances and regulations

4 Abbreviations

AMS automated measuring system

EA European Co-operation for Accreditation

EU European Union

IAF International Accreditation Forum

MLA Multilateral Agreement

5 Principles

5.1 Performance testing of the AMS

Performance testing consists of a combination of laboratory and field testing. Laboratory testing is designed to assess whether an AMS can meet, under controlled conditions, the performance criteria specified for the relevant performance characteristics. Field testing, over a minimum three month period, is designed to assess whether an AMS can continue to work and meet the relevant performance criteria in a real application. For emissions monitoring, AMS field testing is carried out on an industrial installation representative of the intended application for the AMS for which the manufacturer seeks certification. For ambient air monitoring AMS field testing is carried out at sites as specified in the Framework Directive on ambient air quality assessment and management [3] and the associated daughter directives [4], [5], [6].

An AMS is tested to evaluate its performance against criteria specified in an applicable European Standard for the performance and testing of AMS. The testing is carried out by a test laboratory accredited to EN ISO/IEC 17025 with test procedures specified in the applicable Standard.

The applicable standard for AMS for monitoring emissions from stationary sources is prEN 15267-3, and the applicable standard for AMS for monitoring ambient air is prEN 15267-4. These two standards contain performance criteria and test procedures for AMS.

5.2 Initial assessment of the AMS manufacturer's quality management system

An AMS typically undergoes design changes during its production life and it is essential to ensure that after such changes, the AMS still meets the required performance criteria. Therefore, in order to meet these performance criteria the manufacturer controls the quality assurance of production and design of the AMS using a quality management system, which meets the requirements of EN ISO 9001:2000 and the supplementary requirements specified in prEN 15267-2.

NOTE One means of demonstrating the compliance with EN ISO 9001:2000 and the requirements of prEN 15267-2 is through an initial and subsequent assessments of the manufacturer's quality management system, as carried out by a certification body accredited to EN ISO/IEC 17021.

5.3 Certification

The reports from the testing of the AMS and evidence of compliance with EN ISO 9001:2000 and prEN 15267-2 of the manufacturer's quality management system are reviewed by the relevant body for conformance with the applicable standards. If satisfactory, then the relevant body issues a certificate of conformance for the AMS.

If manufacturers, test laboratories, relevant bodies and certification bodies meet the requirements of the EN 15267 series of standards, then such compliance provides the means for mutual recognition between relevant bodies in EU member states.

The relevant body should deal with applications based on mutual recognition in ways that minimise the costs and administrative burden on the manufacturer. These should involve using simple administrative procedures to verify that all necessary details, certificates and reports have been submitted.

The relevant bodies in EU member states are recommended to establish a central register listing certified AMS. The register should provide traceable links to the original certificates and supporting information.

5.4 Post certification product surveillance

Following certification, the relevant body ensures that surveillance of the manufacturing process and performance of certified AMS is carried out periodically.

NOTE The post-certification surveillance is normally carried out by a certification body, for example, which performed the initial assessment of the manufacturer's quality management system to EN ISO 9001:2000 and to prEN 15267-2. This applies if the manufacturer chose certification of its management system as a means of demonstrating compliance with ISO 9001:2000 and prEN 15267-2.

6 Roles and responsibilities

6.1 General

The roles and responsibilities of the AMS manufacturer, the test laboratory, the certification body (for quality management systems), and the relevant body are described below.

NOTE An organisation can perform more than one role as defined in the scope of this European Standard, if it is suitably accredited. For example, a single organisation could perform all four of the stages as defined in the scope.

6.2 Roles and responsibilities of the manufacturer

The manufacturer shall

— make the initial approach to a test laboratory and/or relevant body for performance testing of an AMS,

NOTE 1 Whether a test laboratory or relevant body is approached first it is advisable that, with the agreement of the manufacturer, they inform the other so that the scope of the testing and the intended application (i.e. ambient air monitoring, type of industrial installation) for which certification is to be sought can be decided in consultation. When the scope and application have been agreed, testing can proceed.

— submit two AMS for performance testing to a test laboratory and provide all necessary information for testing,

NOTE 2 The manufacturer can submit more than two AMS of the same type, to complete the testing faster by running the laboratory and field testing in parallel.

— establish, maintain and operate a certified quality management system, meeting the requirements of EN ISO 9001:2000 and prEN 15267-2,

— provide evidence to the relevant body of continued certification of the quality management system to EN ISO 9001:2000 and the supplementary requirements of prEN 15267-2,

— ensure quality assurance and control of manufacturing such that all certified AMS continue to meet the applicable performance criteria,

— control and assess design changes, and keep detailed records of changes to the AMS within a technical file for each certified AMS in accordance with the requirements of prEN 15267-2,

NOTE 3 The assessment may include complete or partial re-testing of the changed AMS. The manufacturer may seek the advice of a test laboratory and the relevant body regarding the need for complete or partial re-testing, following design changes. Any re-testing may be carried out by the manufacturer or, at the manufacturer's request, by a test laboratory.

— record the methods and results of re-testing in the technical file, as specified in EN ISO 9001:2000, if an AMS requires partial or complete re-testing, and

— notify a test laboratory and/or the relevant body of changes to the AMS.

6.3 Roles and responsibilities of the test laboratory

The test laboratory shall

— establish, maintain and operate a management system accredited to EN ISO/IEC 17025, where the scope of accreditation includes the applicable standards for monitoring and testing,

NOTE 1 For the testing of AMS for monitoring emissions from stationary sources, the applicable standards for monitoring and testing include prEN 15267-3 and prCEN/TS (00264091) [12], which elaborates EN ISO/IEC 17025 for application to stack emission measurements, which form part of the field testing of AMS.

NOTE 2 For the testing of AMS for monitoring ambient-air quality, the applicable standards for monitoring and testing include prEN 15267-4.

— evaluate AMS conformity with the performance criteria defined in applicable European Standards, by testing in accordance with the criteria specified in those standards,

— guide the manufacturer on the suitability of the AMS for different applications (i.e. ambient air monitoring, industrial installations) and measurement ranges in accordance with the requirements defined in the applicable standard,