

SLOVENSKI STANDARD

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Kakovost zraka - Certificiranje avtomatskih merilnih sistemov (AMS) - 1. del: Splošna načela

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 systèmes de mesurage automatisés - Partie 1 :
Principes généraux

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EUROPEAN STANDARD
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EUROPÄISCHE NORM

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English Version

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

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

Luftbeschaffenheit - Zertifizierung von automatischen
Messeinrichtungen - Teil 1: Grundlagen

This European Standard was approved by CEN on 14 February 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN 15267-1:2009) has been prepared by Technical Committee CEN/TC 264 "Air quality", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by September 2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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 AMS 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*

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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] and [7].

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 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 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 is identical to ISO/IEC Guide 65. The document EA-6/01 [8] published by the International Accreditation Forum (IAF) provides guidelines on the application of EN 45011. The purpose of EA-6/01 is to harmonise the worldwide application of EN 45011 by accreditation bodies as an important step towards mutual recognition between certification bodies under the IAF Multilateral Agreement (MLA).

EN 45011 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 to the certification of AMS for monitoring ambient air quality and emissions from stationary sources. It is Part 1 of a three 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, including common procedures and requirements, for the product certification of automated measuring systems (AMS) for monitoring ambient air quality and emissions from stationary sources. This product certification consists of the following sequential stages:

- a) performance testing of an automated measuring system;
- b) initial assessment of the AMS manufacturer's quality management system;
- c) certification;
- d) surveillance.

This European Standard applies to the certification of all AMS for monitoring ambient air quality and emissions from stationary sources for which performance criteria and test procedures are available in European Standards.

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.

EN 14211, *Ambient air quality — Standard method for the measurement of the concentration of nitrogen dioxide and nitrogen monoxide by chemiluminescence*

EN 14212, *Ambient air quality — Standard method for the measurement of the concentration of sulphur dioxide by ultraviolet fluorescence*

EN 14625, *Ambient air quality — Standard method for the measurement of the concentration of ozone by ultraviolet photometry*

EN 14626, *Ambient air quality — Standard method for the measurement of the concentration of carbon monoxide by nondispersive infrared spectroscopy*

EN 14662-3, *Ambient air quality — Standard method for measurement of benzene concentrations — Part 3: Automated pumped sampling with in situ gas chromatography*

EN 15267-2, *Air quality — Certification of automated measuring systems — Part 2: Initial assessment of the AMS 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 45011, *General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)*

EN ISO 9001, *Quality management systems — Requirements (ISO 9001:2000)*

EN ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2006)*

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

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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 result of measurement

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 interferences, 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 automated measuring systems

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

any body operating a product certification system or any body accredited to EN ISO/IEC 17021 for the certification of quality management systems

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 and its certification, and undertakes all obligations in that connection

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

3.6

test laboratory

laboratory accredited to EN ISO/IEC 17025 for carrying out the performance tests on automated measuring systems in accordance with applicable European Standards

3.7

product

automated measuring system

3.8

technical file

record of the reference documents and design changes to the reference documents

3.9

reference document

document that controls the manufacture and design of an AMS and is referenced in the test report

NOTE Reference documents can include drawings, specifications, instructions and computer code.

3.10

related document

document not referenced in the test report

NOTE A related document can be used, for example, for the detailed manufacture of component parts.

3.11

certification range

range over which the automated measuring system 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.

3.12

surveillance

systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

[EN ISO/IEC 17000:2004, 6.1]

NOTE For the purposes of this European Standard surveillance focuses on the manufacturer's quality management system to ensure that automated measuring systems continue to comply with the standard to which they are certified.

3.13

legislation

directives, acts, ordinances and regulations

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4 Abbreviations

AMS	automated measuring system
EA	European Co-operation for Accreditation
EU	European Union
IAF	International Accreditation Forum
MLA	Multilateral Agreement
QMS	quality management system

5 Principles

5.1 Performance testing of the automated measuring system

Performance testing consists of a combination of laboratory and field testing. Laboratory testing is designed to assess whether an automated measuring system (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

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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] and [7] as well as in the corresponding European Standards.

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 standards include:

- EN 15267-3 for AMS for monitoring emissions from stationary sources,
- EN 14211, EN 14212, EN 14625, EN 14626 and EN 14662-3 for AMS for monitoring ambient air quality, and
- other European Standards currently under preparation that specify performance criteria and test procedures for AMS for monitoring emissions from stationary sources or monitoring ambient air quality.

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 production and design of the AMS using a quality management system, which meets the requirements specified in EN 15267-2.

Compliance with the requirements of EN 15267-2 is determined by an initial assessment of the manufacturer's quality management system. This initial assessment can be carried out by the relevant body, or a party acting on behalf of the relevant body, or by a certification body accredited to EN ISO/IEC 17021 if the requirements of EN 15267-2 have been incorporated into a certified quality management system (e.g. EN ISO 9001). In the latter case, the initial assessment can focus only on the additional requirements of EN 15267-2.

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5.3 Certification

The reports from the testing of the AMS and the initial assessment 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, and relevant 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 Surveillance

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

This post-certification surveillance is normally carried out by the organisation which performed the initial assessment of the manufacturer's quality management system to EN 15267-2 as described in 5.2.