SLOVENSKI STANDARD
SIST EN 15267-2:2009

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Kakovost zraka - Certificiranje avtomatskih merilnih sistemov (AMS) - 2. del: Začetno ocenjevanje proizvajalčevih sistemov kakovosti za AMS in nadzor nad proizvajalčevimi procesi proizvodnje po certificiranju

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

Luftbeschaffenheit - Zertifizierung von automatischen Messeinrichtungen - Teil 2: Erstmalige Beurteilung des Qualitätsmanagementsystems des Herstellers und Überwachung des Herstellungsprozesses nach der Zertifizierung

Qualité de l'air - Certification des systemes de mesurage automatisés - Partie 2 : Evaluation initiale du systeme de gestion de la qualité des fabricants d'AMS et surveillance apres certification du procédé de fabrication

Ta slovenski standard je istoveten z: **EN 15267-2:2009**

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03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment
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EUROPEAN STANDARD

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English Version

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

Qualité de l'air - Certification des systèmes de mesurage automatisés - Partie 2 : Evaluation initiale du système de gestion de la qualité des fabricants d'AMS et surveillance après certification du procédé de fabrication

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

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 15267-2:2009) 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 2 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 product 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].

An AMS will typically undergo design changes during its product life. It is essential to ensure that such changes do not alter the AMS such that it no longer conforms with its certified performance. In order to control such design changes for the product certification of AMS this European Standard specifies the requirements for

— the manufacturer's quality management system,

— the initial assessment of an AMS manufacturer's production control, and

— the continuing surveillance of the effect on performance of certified AMS of subsequent design changes.

This European Standard follows the structure of EN ISO 9001:2000 such that clause numbers in Clauses 4 to 8 of this standard coincide with those of EN ISO 9001:2000. However, this European Standard does not preclude the use of other quality management systems that are compatible with the objectives of EN ISO 9001:2000.

1 Scope

This European Standard specifies the requirements for the manufacturer's quality management system, the initial assessment of the manufacturer's production control and the continuing surveillance of the effect of subsequent design changes on the performance of certified automated measuring systems.

This European Standard also serves as a reference document for auditing the manufacturer's quality management system.

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 ISO 9001:2000, *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)*

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 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.

[EN 15267-1:2008, 3.1]

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

[EN 15267-1:2008, 3.2]

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

[EN 15267-1:2008, 3.3]

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

[EN 15267-1:2008, 3.4]

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.

[EN 15267-1:2008, 3.5]

3.6
test laboratory
laboratory accredited to EN ISO/IEC 17025 for carrying out performance tests on automated measuring systems in accordance with applicable European Standards

[EN 15267-1:2008, 3.6]

3.7
product
automated measuring system

[EN 15267-1:2008, 3.7]

3.8
technical documentation
information for the operation of automated measuring systems, such as manuals

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

[EN 15267-1:2008, 3.8]

3.10
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.

[EN 15267-1:2008, 3.9]

3.11
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.

[EN 15267-1:2008, 3.10]

3.12
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.

[EN 15267-1:2008, 3.11]

3.13
surveillance
systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

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.

[EN 15267-1:2008, 3.12]

3.14
legislation
directives, acts, ordinances and regulations

[EN 15267-1:2008, 3.13]

4 Quality management systems

4.1 General requirements

The manufacturer's quality management system shall ensure compliance of all automated measuring systems, of the type that has been product certified, with the performance criteria specified in the relevant certificate.

4.2 Documentation requirements

4.2.1 General

The requirements specified in 4.2.1 of EN ISO 9001:2000 apply.

The manufacturer shall have methods to keep up-to-date with the requirements of legislation, standards and guidelines that are relevant to its certified AMS and AMS for which it seeks certification in accordance with the EN 15267 series of standards.

4.2.2 Quality manual

The requirements specified in 4.2.2 of EN ISO 9001:2000 apply.

The quality management system manual shall ensure that no factor (e.g. measured components, scope) defined within the AMS certificate and technical documentation (e.g. reference documents) is modified without appropriate evaluation of its impact on the performance of the AMS.

4.2.3 Control of documents

The requirements specified in 4.2.3 of EN ISO 9001:2000 apply.

Documents that control the manufacture and design of AMS are referred to as reference documents. They can include drawings, specifications, instructions and computer code.

The AMS manufacturer shall ensure that all related documents are cross-referenced to the relevant reference documents for the AMS.

Where there are common reference documents associated with more than one AMS certificate, the manufacturer shall have methods to ensure simultaneous supplementary action in the event of an amendment to such documents.

Where a manufacturer also has documents for AMS not intended for testing and certification, then the manufacturer shall have a method that enables both the related documents and reference documents to be clearly identified.

The AMS manufacturer shall either retain, or have access to any legislation and CEN standards which contains performance criteria for AMS.

4.2.4 Control of records

The requirements specified in 4.2.4 of EN ISO 9001:2000 apply.

5 Management responsibility

5.1 Management commitment

The requirements specified in 5.1 of EN ISO 9001:2000 apply.

The manufacturer shall make a commitment to know and understand the monitoring requirements and applicable performance criteria for AMS, and the impact of these requirements on instrument design, manufacturing and certification.

5.2 Customer focus

The requirements specified in 5.2 of EN ISO 9001:2000 apply.

5.3 Quality policy

The requirements specified in 5.3 of EN ISO 9001:2000 apply.

5.4 Planning

5.4.1 Quality objectives

The requirements specified in 5.4.1 of EN ISO 9001:2000 apply.

5.4.2 Quality management system planning

The requirements specified in 5.4.2 of EN ISO 9001:2000 apply.