SLOVENSKI STANDARD
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Kakovost zraka - Certificiranje avtomatskih merilnih sistemov (AMS) - 2. del: Zaļ etno ocenjevanje proizvajalļ evih sistemov kakovosti za AMS in nadzor nad proizvajalļ evimi procesi 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

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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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If this draft becomes a European Standard, 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.

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Foreword

This document (prEN 15267-2:2007) 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 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*

— 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].

This standard defines the requirements for:

— the manufacturer’s quality management system;

— the initial assessment of an AMS manufacturer’s production control;

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

The clauses of this standard supplement those of EN ISO 9001:2000. The additional requirements to EN ISO 9001:2000 cover specific provisions that apply to the control of design and manufacturing of AMS.

AMS typically undergo design changes during their design lives and it is essential to ensure that such changes do not change the performance of the AMS such that it no longer meets the required performance criteria.

1 Scope

This European Standard covers the supplementary requirements for an AMS manufacturer's management system to EN ISO 9001:2000, for the control of design and manufacturing of AMS. This European Standard also serves as a reference document for auditing the AMS manufacturer's 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.*

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 regulate 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 test 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
legislation
directives, acts, ordinances and regulations

4 Quality management systems

4.1 General requirements

The manufacturer's quality management system shall meet the requirements of EN ISO 9001:2000 and the supplementary requirements described in this European Standard.

NOTE The clause numbers in this standard coincide with those of EN ISO 9001:2000.

4.2 Documentation requirements

4.2.1 General

The manufacturer shall have methods to both access and keep up-to-date with the requirements of relevant international legislation, international standards and guidelines, which include performance criteria for AMS.

4.2.2 Management system manual

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

4.2.3 Control of documents

The AMS manufacturer shall have a method to refer to all related drawings to the relevant reference drawings for the AMS.

Where there are common reference drawings 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 drawings.

Where a manufacturer also has drawings for AMS not intended for testing and certification, then the manufacturer shall have a method that enables both the related drawings and reference drawings 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

No supplementary requirements to EN ISO 9001:2000.

5 Management responsibility

5.1 Management commitment

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

No supplementary requirements to EN ISO 9001:2000.

5.3 Quality policy

No supplementary requirements to EN ISO 9001:2000.

5.4 Planning

5.4.1 Quality objectives

No supplementary requirements to EN ISO 9001:2000.

5.4.2 Quality management system planning

No supplementary requirements to EN ISO 9001:2000.

5.5 Responsibility, authority and communication

No supplementary requirements to EN ISO 9001:2000.

5.5.1 Responsibility and authority

The manufacturer shall have methods for

a) the effective co-ordination of processes with respect to AMS intended for use at installations and monitoring activities which require certified products,

b) determining the need to liaise with the testing laboratories and relevant bodies responsible for AMS testing and certification, with respect to any proposed change to the design defined in the AMS certificate and the technical documentation, and

c) authorising initial approval and changes to related reference-drawings, where appropriate.

5.5.2 Management representative

The manufacturer shall have a representative who has overall responsibility for assuring that the certified AMS meets the applicable performance criteria. The representative shall also have overall responsibility for design changes to the certified AMS.

5.5.3 Internal communication

No supplementary requirements to EN ISO 9001:2000.

5.6 Management review

5.6.1 General

The maximum interval between management reviews, normally every 12 months, has to be defined by the manufacturer to assure an appropriate, adapted and efficient management system.

The person(s) responsible for the activities as detailed in 5.5.1 shall participate in the review.

The requirements of this European Standard for management review shall be incorporated within the management review for the EN ISO 9001:2000 management system.

5.6.2 Review input

The review shall include the overall effectiveness of the management system with respect to AMS intended for use at installations requiring certified products.

A review of AMS conformity shall be used as an indicator of the effectiveness of the management system.

5.6.3 Review output

No supplementary requirements to EN ISO 9001:2000.

6 Resource management

6.1 Provision of resources

No supplementary requirements to EN ISO 9001:2000.

6.2 Human resources

6.2.1 General

No supplementary requirements to EN ISO 9001:2000.

6.2.2 Competence, awareness and training

Appropriate staff shall be trained in the requirements of the applicable European standards for monitoring and measurement, and AMS performance criteria.

6.3 Infrastructure

No supplementary requirements to EN ISO 9001:2000.

6.4 Work environment

No supplementary requirements to EN ISO 9001:2000.

7 Product realisation

7.1 Planning of AMS realisation

No supplementary requirements to EN ISO 9001:2000.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the AMS

The manufacturer shall

a) determine the type of AMS and its application,

b) identify the performance criteria for each measured component and the site conditions, which affect AMS performance, and

c) identify any special conditions, which could impact upon the AMS's ability to meet the applicable performance criteria.

7.2.2 Review of requirements related to the AMS

No supplementary requirements to EN ISO 9001:2000.

7.2.3 Customer communication

No supplementary requirements to EN ISO 9001:2000.

7.3 Design and development

7.3.1 Design and development planning

No supplementary requirements to EN ISO 9001:2000.