SLOVENSKI STANDARD
oSIST prEN 15267-2:2021

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Kakovost zraka - Ocenjevanje opreme za monitoring kakovosti zraka - 2. del: Začetno ocenjevanje proizvajalčevih sistemov kakovosti in nadzor nad proizvajalčevimi procesi proizvodnje po certificiranju

Air quality - Assessment of air quality monitoring equipment - Part 2: Initial assessment of the manufacturer's quality management system and post certification surveillance for the manufacturing process

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

Ta slovenski standard je istoveten z: **prEN 15267-2**

ICS:

03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment
13.040.99	Drugi standardi v zvezi s kakovostjo zraka	Other standards related to air quality

oSIST prEN 15267-2:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 15267-2

December 2021

ICS 03.100.70; 13.040.99

Will supersede EN 15267-2:2009

English Version

Air quality - Assessment of air quality monitoring equipment - Part 2: Initial assessment of the manufacturer's quality management system and post certification surveillance for the manufacturing process

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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 264.

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.

This draft European Standard was established by CEN 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-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (prEN 15267-2:2021) 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 will supersede EN 15267-2:2009.

The main changes with respect to the previous edition are listed below:

a) The title of the revised EN 15267 series has been clarified to avoid the impression that all parts deal with the certification of automated measuring systems. The title has been generalized so that specifically Part 1 and Part 2 are also applicable to other air quality monitoring equipment.

b) The title of revised EN 15267-2 has been clarified to make it clear that Part 2 deals only with the manufacturing process as part of the certification of air quality monitoring equipment.

c) The revised EN 15267-2 is based on EN ISO 9001:2015 and is identically structured. It provides guidance on the application of EN ISO 9001:2015 with respect to AQME. It supplements EN ISO 9001:2015 by providing clarification and additional information. However, it does not re-state all the provisions of EN ISO 9001:2015 and users are reminded of the need to comply with all of the relevant criteria detailed in EN ISO 9001:2015.

d) The basic contents of EN 15267-2:2009 were largely adopted, updated and inserted into the structure of EN ISO 9001:2015.

e) The term “competent body” has been deleted and replaced throughout the text by the term “certification body”.

This document is Part 2 of a series of European Standards:

— EN 15267-1, *Air quality — Assessment of air quality monitoring equipment — Part 1: General principles of certification*

— EN 15267-2, *Air quality — Assessment of air quality monitoring equipment — Part 2: Initial assessment of the manufacturer’s quality management system and post certification surveillance for the manufacturing process*

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

— EN 15267-4, *Air quality — Assessment of air quality monitoring equipment — Part 4: Performance criteria and test procedures for portable automated measuring systems for periodic measurements of emissions from stationary sources*

Introduction

The assessment of air quality monitoring equipment (AQME) supports the requirements of certain Directives of the European Union (EU), which require, either directly or indirectly, that this equipment comply with performance criteria, maximum permissible measurement uncertainties and testing requirements. These Directives include the Directive 2010/75/EU on industrial emissions (IED), Directive (EU) 2015/2193 on medium combustion plants and the Directive 2008/50/EC on ambient air quality and cleaner air for Europe.

The assessment of AQME consists of the following sequential stages:

a) performance test;

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

c) certification;

d) surveillance for the manufacturing process.

AQME typically undergo changes during its product life. It is essential to ensure that such changes do not alter the AQME such that they no longer conform with the certified performance. In order to control such changes of AQME this document specifies the requirements for

— the manufacturer's QMS,

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

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

This document follows the structure of EN ISO 9001:2015 such that clause numbers in Clause 4 to Clause 10 coincide with those of EN ISO 9001:2015. Clause 11 provides additional requirements. This document does not preclude the use of other QMS that are compatible with the objectives of EN ISO 9001:2015.

1 Scope

This document specifies the requirements for the manufacturer's quality management system (QMS), the initial assessment of the manufacturer's production control and the continuing surveillance of the effect of subsequent changes on the performance of certified air quality monitoring equipment (AQME).

This document also serves as a reference document for auditing the manufacturer's QMS.

This document elaborates and supplements the requirements of EN ISO 9001:2015.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 9001:2015, *Quality management systems - Requirements (ISO 9001:2015)*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
air quality monitoring equipment
AQME
automated measuring system or data acquisition and handling system

[SOURCE: prEN 15267-1:2021, 3.1]

3.2
automated measuring system
AMS
entirety of all measuring instruments and additional devices for obtaining a result of measurement

Note 1 to entry: The term "automated measuring system" applies to stationary and portable AMS.

Note 2 to entry: Apart from the actual measuring device (the analyser), a stationary 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 QAL3 procedures and, if applicable, for commissioning.

Note 3 to entry: 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.

[SOURCE: prEN 15267-1:2021, 3.2]

3.3
portable automated measuring system
P-AMS
automated measuring system which is in a condition or application to be moved from one to another measurement site to obtain measurement results for a short measurement period

Note 1 to entry: The measurement period is typically 8 h for a day.

Note 2 to entry: The P-AMS can be configured at the measurement site for the special application but can be also set-up in a van or mobile container. The probe and the sample gas lines are installed often just before the measurement task is started.

[SOURCE: prEN 15267-1:2021, 3.3]

3.4
data acquisition and handling system
DAHS
system, which automatically receives, processes, stores and outputs data from automated measuring systems

[SOURCE: prEN 15267-1:2021, 3.4]

3.5
product
air quality monitoring equipment

[SOURCE: prEN 15267-1:2021, 3.5]

3.6
testing laboratory
laboratory carrying out the performance tests

[SOURCE: prEN 15267-1:2021, 3.6]

3.7
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 1 to entry: The term “manufacturer” is used instead of “organisation” as used in EN ISO 9001. For the purpose of this document they are interchangeable.

[SOURCE: prEN 15267-1:2021, 3.7]

3.8
certification body
third-party conformity assessment body operating certification schemes

[SOURCE: EN ISO/IEC 17065:2012, 3.12]

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

[SOURCE: prEN 15267-1:2021, 3.9]

3.10
reference document
document that controls the manufacture and design of air quality monitoring equipment and is referenced in the test report

Note 1 to entry: Reference documents can include drawings, specifications, instructions and computer code.

[SOURCE: prEN 15267-1:2021, 3.10]

3.11
related document
document not referenced in the test report

Note 1 to entry: A related document can be used, for example, for the detailed manufacture of component parts.

[SOURCE: prEN 15267-1:2021, 3.11]

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

Note 1 to entry: The lower limit of the certification range is usually zero.

Note 2 to entry: 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.

[SOURCE: prEN 15267-1:2021, 3.12]

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

[SOURCE: EN ISO/IEC 17000:2020, 8.1]

3.14
competent authority
organisation which implements the requirements of legislation and regulates installations

[SOURCE: prEN 15267-1:2021, 3.14]

Note 1 to entry: For the purposes of this document surveillance focuses on the manufacturer's QMS to ensure that AQME continue to comply with the standard to which they are certified.

3.15
legislation
directives, acts, ordinances and regulations

[SOURCE: prEN 15267-1:2021, 3.15]

4 Context of the organization

4.1 Understanding the organization and its context

The requirements of EN ISO 9001:2015, 4.1, apply.

4.2 Understanding the needs and expectations of interested parties

The requirements of EN ISO 9001:2015, 4.2, apply.

4.3 Determining the scope of the quality management system

The requirements of EN ISO 9001:2015, 4.3, and the following apply.

The manufacturer's QMS shall ensure compliance of all AQME, of the type that has been product certified, with the performance criteria specified in the relevant certificate.

4.4 Quality management system and its processes

The requirements of EN ISO 9001:2015, 4.4, apply.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

The requirements of EN ISO 9001:2015, 5.1.1, and the following apply.

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

5.1.2 Customer focus

The requirements of EN ISO 9001:2015, 5.1.2, apply.

5.2 Policy

The requirements of EN ISO 9001:2015, 5.2, apply.

5.3 Organization roles, responsibilities and authorities

The requirements of EN ISO 9001:2015, 5.3, and the following apply.

The manufacturer shall assign the responsibility and authority for:

— the effective co-ordination of processes with respect to AQME intended for use in connection with monitoring activities which require certified products,