SLOVENSKI STANDARD
oSIST prEN 15267-1:2021

01-december-2021

Kakovost zraka - Ocenjevanje opreme za monitoring kakovosti zraka - 1. del: Splošna načela certificiranja

Air quality - Assessment of air quality monitoring equipment - Part 1: General principles of certification

Luftbeschaffenheit - Beurteilung von Einrichtungen zur Überwachung der Luftbeschaffenheit - Teil 1: Grundlagen der Zertifizierung

Ta slovenski standard je istoveten z: **prEN 15267-1**

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 15267-1:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 15267-1

December 2021

ICS 13.040.99

Will supersede EN 15267-1:2009

English Version

Air quality - Assessment of air quality monitoring equipment - Part 1: General principles of certification

Luftbeschaffenheit - Beurteilung von Einrichtungen zur Überwachung der Luftbeschaffenheit - Teil 1: Grundlagen 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
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 15267-1:2021) 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 15267-1:2009.

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 15267-1 has been clarified to make it clear that only Part 1 deals with the basic principles of the certification of air quality monitoring equipment.

c) The revised EN15267-1 is based on EN ISO/IEC 17065:2012 and is identically structured. It provides guidance on the application of EN ISO/IEC 17065:2012 to the certification of AQME for monitoring ambient air quality and emissions from stationary sources. It supplements EN ISO/IEC 17065:2012 by providing clarification and additional information. However, it does not re-state all the provisions of EN ISO/IEC 17065:2012 and users are reminded of the need to comply with all of the relevant criteria detailed in EN ISO/IEC 17065:2012.

d) The basic contents of EN 15267-1:2009 were largely adopted, updated and inserted into the structure of EN ISO/IEC 17065:2012.

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

This document is Part 1 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 complies with performance criteria, maximum permissible measurement uncertainties and test 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.

This document is based on EN ISO/IEC 17065:2012 and defines common procedures and requirements for the certification of AQME to facilitate mutual recognition and thereby minimize administrative and cost burdens on manufacturers seeking certification in multiple member states. It also describes the roles and responsibilities of manufacturers, testing laboratories and certification bodies.

EN ISO/IEC 17065:2012 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 ISO/IEC 17065 recognizes that these general criteria may have to be supplemented when applied to a particular sector. This document provides guidance on the application of EN ISO/IEC 17065:2012 to the certification of AQME for monitoring ambient air quality and emissions from stationary sources. This document supplements EN ISO/IEC 17065:2012 by providing clarification and additional information. However, it does not re-state all the provisions of EN ISO/IEC 17065:2012 and users are reminded of the need to comply with all of the relevant criteria detailed in EN ISO/IEC 17065:2012.

Assessment and the included certification of AQME form the basis for the legal approval of this equipment. However, this document does not define the process for the legal approval of AQME. The responsibility for approving automated measuring systems (AMS) for monitoring ambient air quality under Directive 2008/50/EC lies with the national competent authority or a body designated by the EU member state. No explicit requirement for approving automated measuring systems (AMS) and data acquisition and handling systems (DAHS) 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. Additionally, the IED and its implementing measures (BAT Conclusions Decision Documents) prescribe the use of European Standards for monitoring, whilst approval schemes are a means for both suppliers and users of AQME to demonstrate compliance with the requirement of applicable European Standards.

In some EU member states the competent authority delegates the responsibility for approval of AQME to a certification body accredited to EN ISO/IEC 17065:2012 by national accreditation bodies.

1 Scope

This document specifies the general principles of certification, including common procedures and requirements, for the certification of air quality monitoring equipment (AQME).

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

This document provides for the certification of AQME according to the requirements of EN ISO/IEC 17065:2012.

This document elaborates and supplements the requirements of EN ISO/IEC 17065:2012 for bodies certifying AQME. It specifies requirements on testing laboratories as well as the manufacturer's quality management system (QMS) and the surveillance for the manufacturing process as part of the certification process.

2 Normative references

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

EN ISO 19011, *Guidelines for auditing management systems (ISO 19011)*

EN ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012)*

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*

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

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.

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.

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

3.5
product
air quality monitoring equipment

3.6
testing laboratory
laboratory carrying out the performance test

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.

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

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.

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.

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.

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]

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.

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

3.15
legislation
directives, acts, ordinances and regulations

4 General requirements

4.1 Legal and contractual matters

4.1.1 Legal responsibility

The requirements of EN ISO/IEC 17065:2012, 4.1.1, and the following apply.

The certification body shall liaise as appropriate with the relevant national competent authority.

4.1.2 Certification agreement

The requirements of EN ISO/IEC 17065:2012, 4.1.2, apply.

4.1.3 Use of license, certificates and marks of conformity

The requirements of EN ISO/IEC 17065:2012, 4.1.3, apply.

4.2 Management of impartiality

The requirements of EN ISO/IEC 17065:2012, 4.2, apply.

4.3 Liability and financing

The requirements of EN ISO/IEC 17065:2012, 4.3, apply.

4.4 Non-discriminatory conditions

The requirements of EN ISO/IEC 17065:2012, 4.4, apply.

4.5 Confidentiality

The requirements of EN ISO/IEC 17065:2012, 4.5, apply.

4.6 Publicly available information

The requirements of EN ISO/IEC 17065:2012, 4.6, and the following apply.

The certification body shall

— issue certificates with an appropriate scope of certification;

— issue certificates in at least one of the three principal CEN languages, i.e. English, French or German.

NOTE The scope of certification includes e.g. for AMS the measured components, certification ranges, process applications and any limitations of use.

5 Structural requirements

5.1 Organizational structure and top management

The requirements of EN ISO/IEC 17065:2012, 5.1, and the following apply.

The certification body shall have in place appropriate procedures for the certification of AQME in accordance with the requirements of this document.

NOTE The competence for certification of AQME in accordance with the requirements of this document can be demonstrated by an accreditation to EN ISO/IEC 17065.

5.2 Mechanism for safeguarding impartiality

The requirements of EN ISO/IEC 17065:2012, 5.2, and the following apply.

6 Resource requirements

6.1 Certification body personnel

6.1.1 General

The requirements of EN ISO/IEC 17065:2012, 6.1.1, and the following apply.

6.1.2 Management of competence for personnel involved in the certification process

The requirements of EN ISO/IEC 17065:2012, 6.1.2, and the following apply.

Personnel involved in the certification process shall know and understand the applicable European Standards for AQME.

6.1.3 Contract with the personnel

The requirements of EN ISO/IEC 17065:2012, 6.1.3, apply.

6.2 Resources for evaluation

6.2.1 Internal resources

The requirements of EN ISO/IEC 17065:2012, 6.2.1, and the following apply.

If the testing laboratory is part of the certification body, the requirements of 7.1.1.3.2 apply.

6.2.2 External resources (outsourcing)

The requirements of EN ISO/IEC 17065:2012, 6.2.2, apply.

7 Process requirements

7.1 General

7.1.1 Certification schemes

7.1.1.1 General

The requirements of EN ISO/IEC 17065:2012, 7.1.1, and the requirements specified in 7.1.1.2 and 7.1.1.3 apply.

7.1.1.2 Assessment of AQME

7.1.1.2.1 General

The assessment of AQME consists of the following sequential stages:

a) performance test;

b) initial assessment of the manufacturer's QMS;

c) certification;

d) surveillance for the manufacturing process.