

# Ochrana ovzdušia Hodnotenie zariadení na monitorovanie kvality ovzdušia

Časť 2: Začiatočné posudzovanie systému manažérstva kvality výrobcu a dohľad nad výrobným procesom po certifikácii STN EN 15267-2

83 4106

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

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/23

Obsahuje: EN 15267-2:2023

Oznámením tejto normy sa ruší STN EN 15267-2 (83 4106) z novembra 2009

#### 137383

# EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 15267-2

July 2023

ICS 03.100.70; 13.040.99

Supersedes 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

Qualité de l'air - Évaluation des équipements de surveillance de la qualité de l'air - Partie 2 : Évaluation initiale du système de management de la qualité du fabricant et surveillance après certification du procédé de fabrication Luftbeschaffenheit - Beurteilung von Einrichtungen zur Überwachung der Luftbeschaffenheit - Teil 2: Erstmalige Beurteilung des Qualitätsmanagementsystems des Herstellers und Überwachung des Herstellungsprozesses nach der Zertifizierung

This European Standard was approved by CEN on 24 April 2023.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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# EN 15267-2:2023 (E)

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# **European foreword**

This document (EN 15267-2:2023) 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 January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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

This document supersedes 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 restate 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

#### EN 15267-2:2023 (E)

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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

## 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. This document can also be applied e.g. in the context of other national legislation.

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 is based on EN ISO 9001 and supplements the requirements of EN ISO 9001 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 changes on the performance of certified AQME. This document does not preclude the use of other QMS that are compatible with the objectives of EN ISO 9001.

#### EN 15267-2:2023 (E)

## 1 Scope

This document specifies requirements for the manufacturer's quality management system (QMS). Furthermore, it specifies requirements for 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 applies only in combination with EN ISO 9001.

#### 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~15267-1:2023, Air~Quality~-~Assessment~of~air~quality~monitoring~equipment~-~Part~1:~General~principle~of~certification

koniec náhľadu – text ďalej pokračuje v platenej verzii STN