

Monitoring radioactive gases in effluents from facilities producing positron emitting radionuclides and radiopharmaceuticals (ISO 16640:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 16640:2022 sisaldab Euroopa standardi EN ISO 16640:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 16640:2022 consists of the English text of the European standard EN ISO 16640:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.12.2022.	Date of Availability of the European standard is 21.12.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 13.030.30, 13.280

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis-ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis-ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

**Monitoring radioactive gases in effluents from facilities
producing positron emitting radionuclides and
radiopharmaceuticals (ISO 16640:2021)**

Surveillance des gaz radioactifs dans les effluents des
installations produisant des radionucléides et des
produits radiopharmaceutiques émetteurs de
positrons (ISO 16640:2021)

This European Standard was approved by CEN on 18 December 2022.

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.

CEN members are the national standards bodies of 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 United Kingdom.



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

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

European foreword

The text of ISO 16640:2021 has been prepared by Technical Committee ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 16640:2022 by Technical Committee CEN/TC 430 "Nuclear energy, nuclear technologies, and radiological protection" the secretariat of which is held by AFNOR.

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 June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.

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.

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 organizations 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.

Endorsement notice

The text of ISO 16640:2021 has been approved by CEN as EN ISO 16640:2022 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Symbols	8
5 Factors impacting the design of the monitoring system	11
6 Types of monitoring systems	11
7 General monitoring system requirements	12
7.1 General	12
7.2 Detection range	12
7.3 Detector location	12
7.3.1 Background	12
7.3.2 Ease of accessibility for maintenance	13
7.3.3 Environmental conditions	13
7.4 Emission stream flow measurement	13
8 Requirements specific to bypass systems	13
8.1 General	13
8.2 Sample extraction locations	13
8.3 Condensation	14
8.4 Maintenance	14
8.5 Leak checks	15
9 Requirements specific to in-line systems	15
9.1 General	15
9.2 Location of the probe or detector	15
9.3 Environmental conditions	15
10 Evaluation and upgrading of existing systems	15
11 Quality assurance and quality control	16
Annex A (informative) Factors impacting the monitoring system design	18
Annex B (informative) Evaluating uncertainty of effluent measurement	31
Annex C (informative) Quality assurance	41
Annex D (informative) Mixing demonstration and sampling system performance verification	45
Annex E (informative) Techniques for measurement of flow rate through a stack or duct	49
Bibliography	51

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*, Subcommittee SC 2, *Radiological protection*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document focuses on monitoring the activity concentrations of radioactive gases. They allow the calculation of activity releases in the gaseous effluent discharge from facilities producing positron emitting radionuclides and radiopharmaceuticals. Such facilities produce short-lived radionuclides used for medical purposes or research. They include accelerators, radiopharmacies, hospitals and universities. This document provides performance-based criteria for the use of air monitoring equipment including probes, transport lines, sample monitoring instruments, and gas flow measuring methods. It also provides information covering monitoring program objectives, quality assurance, developing air monitoring control action levels, system optimisation, and system performance verification.

The goal of achieving an accurate measurement of radioactive gases, which are well mixed in the airstream, is accomplished either by direct (in-line) measurement within the exhaust stream or by extraction (bypass) from the exhaust stream for measurement remote from the duct. This document sets forth performance criteria and recommendations to assist in obtaining valid measurements.

Monitoring radioactive gases in effluents from facilities producing positron emitting radionuclides and radiopharmaceuticals

1 Scope

This document focuses on monitoring the activity concentrations of radioactive gases. They allow the calculation of the activity releases, in the gaseous effluent discharge from facilities producing positron emitting radionuclides and radiopharmaceuticals. Such facilities produce short-lived radionuclides used for medical purposes or research and can release gases typically including, but not limited to ^{18}F , ^{11}C , ^{15}O and ^{13}N . These facilities include accelerators, radiopharmacies, hospitals and universities. This document provides performance-based criteria for the design and use of air monitoring equipment including probes, transport lines, sample monitoring instruments, and gas flow measuring methods. This document also provides information on monitoring program objectives, quality assurance, development of air monitoring control action levels, system optimisation and system performance verification.

The goal of achieving an unbiased measurement is accomplished either by direct (in-line) measurement on the exhaust stream or with samples extracted from the exhaust stream (bypass), provided that the radioactive gases are well mixed in the airstream. This document sets forth performance criteria and recommendations to assist in obtaining valid measurements.

NOTE 1 The criteria and recommendations of this document are aimed at monitoring which is conducted for regulatory compliance and system control. If existing air monitoring systems were not designed according to the performance criteria and recommendations of this document, an evaluation of the performance of the system is advised. If deficiencies are discovered based on a performance evaluation, a determination of the need for a system retrofit is to be made and corrective actions adopted where practicable.

NOTE 2 The criteria and recommendations of this document apply under both normal and off-normal operating conditions, provided that these conditions do not include production of aerosols or vapours. If the normal and/or off-normal conditions produce aerosols and vapours, then the aerosol collection principles of ISO 2889 also apply.

2 Normative references

There are no normative references in this document.

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 <http://www.electropedia.org/>

3.1

abatement equipment

apparatus used to reduce contaminant concentration in the airflow exhausted through a stack or duct

[SOURCE: ISO 2889:2010, 3.1]