SLOVENSKI STANDARD
SIST EN ISO 16640:2023

01-marec-2023

Nadzorovanje radioaktivnih plinov v iztokih iz obratov, ki proizvajajo radionuklide in radiofarmacevtske izdelke, ki oddajajo pozitrone (ISO 16640:2021)

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)

Ta slovenski standard je istoveten z: **EN ISO 16640:2022**

ICS:

13.030.30	Posebni odpadki	Special wastes
13.060.25	Voda za industrijsko uporabo	Water for industrial use
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN ISO 16640:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16640

December 2022

ICS 13.030.30; 13.280

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.

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

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

Ref. No. EN ISO 16640:2022 E

Contents

Page

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of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.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.

INTERNATIONAL STANDARD

ISO 16640

First edition
2021-01

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

Surveillance des gaz radioactifs dans les effluents des installations produisant des radionucléides et des produits radiopharmaceutiques émetteurs de positrons

Reference number
ISO 16640:2021(E)

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Published in Switzerland

Contents

Page

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).

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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]

3.2
accident (conditions)
any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety

3.3
accuracy
closeness of agreement between a measured quantity and the true quantity of the measurand

[SOURCE: ISO 2889:2010, 3.4]

3.4
action level
threshold concentration of an effluent contaminant at which it is necessary to perform an appropriate action

[SOURCE: ISO 2889:2010, 3.5]

3.5
aerosol
dispersion of solid or liquid particles in air or other gas

Note 1 to entry: An aerosol is not only the aerosol particles.

[SOURCE: ISO 2889:2010, 3.8]

3.6
analyser
device that provides for near real-time data on radiological characteristics of the gas (air) flow in a sampling system or duct

Note 1 to entry: Usually, an analyser evaluates the concentration of radionuclides in a sampled air stream; however, some analysers are mounted directly within or just outside a stack or duct.

[SOURCE: ISO 2889:2010, 3.12]

3.7
bend
gradual change in direction of a *sample* (3.38) transport line

[SOURCE: ISO 2889:2010, 3.14]

3.8
bulk stream
air flow in a stack or duct, as opposed to the *sample* (3.38) flow rate

[SOURCE: ISO 2889:2010, 3.15]

3.9
bypass system
system whereby a *sample* (3.38) is withdrawn from the effluent stream and analysed at a location that is remote from the region where the extraction takes place

3.10
calibration
operation that, under specified conditions, in a first step establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

3.11
coefficient of variation
C_V
quantity that is the ratio of the standard deviation of a variable to the mean value of that variable

Note 1 to entry: It is usually expressed as a percentage.

[SOURCE: ISO 2889:2010, 3.18]

3.12
continuous air monitor
CAM
near real-time sampler and associated detector that provide data on radionuclides (e.g. concentration of alpha-emitting aerosol particles) in a sample stream

Note 1 to entry: A CAM is used for monitoring and detecting radioactive gases.

[SOURCE: ISO 2889:2010, 3.21]

3.13
continuous monitoring
continuous near real-time measurements of one or more sampling characteristics

[SOURCE: ISO 2889:2010, 3.22]

3.14
coverage interval
interval containing the set of true quantity values of a measurand with a stated probability, based on the information available

[SOURCE: ISO 11929-1:2019, 3.4]

3.15
cyclotron
particle accelerator that is commonly used in nuclear medicine to produce positron emitting radionuclides

Note 1 to entry: Charged particles (e.g. protons or deuterons) are accelerated along a spiral path from the centre outward to an appropriate target.

3.16
decision threshold
value of the estimator of the measurand, which, when exceeded by the result of an actual measurement using a given measurement procedure of a measurand quantifying a physical effect, is used to decide that the physical effect is present

Note 1 to entry: The decision threshold is defined such that in cases where the measurement result exceeds the decision threshold, the probability of a wrong decision, namely that the true value of the measurand is not zero if in fact it is zero, is less or equal to a chosen probability α.

Note 2 to entry: If the result is below the decision threshold, it is decided to conclude that the result cannot be attributed to the physical effect; nevertheless, it cannot be concluded that it is absent.

[SOURCE: ISO 11929-1:2019, 3.12]