



SLOVENSKI STANDARD
oSIST prEN ISO 16640:2022

01-oktober-2022

Nadzorovanje radioaktivnih plinov v odpadnih vodah iz obratov, ki proizvajajo pozitronske radionuklide in radiofarmacevtske izdelke (ISO 16640:2021)

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

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

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

*Surveillance des gaz radioactifs dans les effluents des installations
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ISO 16640:2021(E)

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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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.

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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]

ISO 16640:2021(E)**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]

ISO 16640:2021(E)**3.17****detection limit**

smallest true value of the measurand which ensures a specified probability of being detectable by the measurement procedure

Note 1 to entry: With the decision threshold, the detection limit is the smallest true value of the measurand for which the probability of wrongly deciding that the true value of the measurand is zero is equal to a specified value, β , when, in fact, the true value of the measurand is not zero. The probability of being detectable is consequently $(1 - \beta)$.

[SOURCE: ISO 11929-1:2019, 3.13]

3.18**effluent**

waste stream flowing away from a process, plant, or facility to the environment

Note 1 to entry: In this document, the focus is on effluent air that is discharged to the atmosphere through stacks, vents and ducts.

[SOURCE: ISO 2889:2010, 3.29]

3.19**emission**

contaminants that are discharged into the environment

[SOURCE: ISO 2889:2010, 3.30]

3.20**emit**

discharge contaminants into the environment

[SOURCE: ISO 2889:2010, 3.31]

3.21**flow rate**

rate at which a mass or volume of gas (air) crosses an imaginary cross-sectional area in either a sampling system tube or a stack or duct

Note 1 to entry: The rate at which the volume crosses the imaginary area is called the volumetric flow rate; and the rate at which the mass crosses the imaginary area is called either the mass flow rate or the volumetric flow rate at standard conditions.

[SOURCE: ISO 2889:2010, 3.33]

3.22**hydraulic diameter**

type of equivalent duct diameter for ducts that do not have a round cross section

Note 1 to entry: Generally, it is four times the cross-sectional area divided by the perimeter.

[SOURCE: ISO 2889:2010, 3.38]

3.23**in-line system**

system where the detector assembly is adjacent to, or immersed in, the *effluent* (3.18)

3.24**limits of the coverage interval**

values which define a coverage interval

Note 1 to entry: It is characterized in this document by a specified probability $(1 - \gamma)$, e.g., 95 %, and $(1 - \gamma)$ represents the probability for the coverage interval of the measurand.

Note 2 to entry: The definition of a coverage interval is ambiguous without further stipulations. In ISO 11929-1 two alternatives, namely the probabilistically symmetric and the shortest coverage interval, are used. In this document only the probabilistically symmetric is used.

Note 3 to entry: The probabilistically symmetric coverage interval is the coverage interval for a quantity such that the probability that the quantity is less than the smallest value in the interval is equal to the probability that the quantity is greater than the largest value in the interval

[SOURCE: ISO 11929-1:2019, 3.16]

3.25

mixing element

device placed in a stack or duct that is used to augment mixing of both contaminant mass and fluid

[SOURCE: ISO 2889:2010, 3.47]

3.26

monitoring

continual measurement of a quantity (e.g. activity concentration) of the airborne radioactive constituent or the gross content of radioactive material continuously, at a frequency that permits an evaluation of the value of that quantity in near real-time, or at intervals that comply with regulatory requirements

[SOURCE: ISO 2889:2010, 3.48]

3.27

normal conditions

limits (or range) of use or operation under which a program or activity is able to meet its objectives and without significant changes that would impair this ability

3.28

nozzle

device used to extract a *sample* (3.38) from a stream of the gaseous *effluent* (3.18) and to transfer the sample to a transport line or a collector

[SOURCE: ISO 2889:2010, 3.49]

3.29

off-normal conditions

conditions that are unplanned and which present a gap with normal conditions

Note 1 to entry: Examples are accidents and equipment failure.

[SOURCE: ISO 2889:2010, 3.54]

3.30

positron emission tomography

PET

imaging technique that uses radioactive substances to reveal the operating function and metabolism of tissues and organs and allows the observation of malignant tissues

Note 1 to entry: The technic involves injection of a radioactive drug with the radionuclide being a positron emitter. Upon annihilation of the positron, two 511 keV photons are produced at 180° angle. These photons are used in the scanner to determine the point of annihilation and to develop an image.

3.31

probe

sometimes used colloquially to refer to the equipment inserted into a stack or duct for measurement of volumetric flow or amount of activity present

ISO 16640:2021(E)**3.32****profile**

distribution of gas velocity over the cross-sectional area of the stack or duct

[SOURCE: ISO 2889:2010, 3.62]

3.33**quality assurance**

planned and systematic actions necessary to provide confidence that a system or component performs satisfactorily in service and that the results are both correct and traceable

[SOURCE: ISO 2889:2010, 3.63]

3.34**radionuclide**

unstable isotope of an element that decays or converts spontaneously into another isotope or different energy state, emitting radiation

[SOURCE: ISO 2889:2010, 3.64]

3.35**reference method**

apparatus and instructions for providing results against which other approaches may be compared

Note 1 to entry: Application of a reference method is assumed to define correct results.

[SOURCE: ISO 2889:2010, 3.66]

3.36**representative sample**

sample (3.38) with the same quality and characteristics for the material of interest as that of its source at the time of sampling

[SOURCE: ISO 2889:2010, 3.67]

3.37**response time**

time required after a step variation in the measured quantity for the output signal variation to reach a given percentage for the first time, usually 90 %, of its final value

[SOURCE: IEC 60761-1:2002, 3.15]

3.38**sample**

portion of an air stream of interest, or one or more separated constituents from a portion of an air stream

[SOURCE: ISO 2889:2010, 3.68]

3.39**sample extraction location**

location of extraction of a *sample* (3.38) from the *bulk stream* (3.8), also known as sampling location

[SOURCE: ISO 2889:2010, 3.69, modified — definition was reworded.]

3.40**sampling**

process of removing a *sample* (3.38) from the *bulk stream* (3.8) and transporting it to a monitor

[SOURCE: ISO 2889:2010, 3.72]

3.41**sampling plane**

cross sectional area where the *sample* (3.38) is extracted from the airflow

[SOURCE: ISO 2889:2010, 3.75]

3.42**sampling system**

system consisting of an inlet, a transport line, a flow monitoring system and a monitor

[SOURCE: ISO 2889:2010, 3.76]

3.43**sensitivity**

change in indication of a mechanical, nuclear, optical or electronic instrument as affected by changes in the variable quantity being sensed by the instrument

Note 1 to entry: The slope of a calibration curve of an instrument, where a calibration curve shows output values of an instrument as a function of input values.

[SOURCE: ISO 2889:2010, 3.78]

3.44**standard conditions**

temperature of 25 °C and pressure of 101 325 Pa

Note 1 to entry: Used to convert air densities to a common basis. Other temperature and pressure conditions may be used and should be applied consistently.

[SOURCE: ISO 2889:2010, 3.82]

3.45**transport line**

part of a *bypass system* (3.9) between the outlet plane of the *nozzle* (3.28) and the inlet plane of a detector chamber or a vessel

[SOURCE: ISO 2889:2010, 3.84]

3.46**turbulent flow**

flow regime characterized by bulk mixing of fluid properties

Note 1 to entry: For example, in a tube, the flow is turbulent if the Reynolds number is greater than about 3 000 and laminar if the Reynolds number is below about 2 200. There is little mixing in the laminar flow regime.

[SOURCE: ISO 2889:2010, 3.86]

3.47**uncertainty**

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

Note 1 to entry: An analysis of uncertainty is a procedure for estimating the overall impact of estimated uncertainties in independent variables on the accuracy or precision of a dependent variable.

[SOURCE: ISO 11929-1:2019, 3.10]