## INTERNATIONAL STANDARD

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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 produisant des radionucléides et des produits radiopharmaceutiques

iTeh STémetteurs de positrons REVIEW (standards.iteh.ai)

ISO 16640:2021

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#### **Foreword**

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

### 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 <sup>18</sup>F, <sup>11</sup>C, <sup>15</sup>O and <sup>13</sup>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 dirstream. 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 <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 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] Teh STANDARD PREVIEW

#### 3.6 analyser

## (standards.iteh.ai)

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

https://standards.iteh.ai/catalog/standards/sist/a94751f8-5426-405c-a65e-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 iTeh STANDARD PREVIEW

interval containing the set of true quantity values of a measurand with a stated probability, based on the information available (Standards.iteh.ai)

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

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3.15 https://standards.iteh.ai/catalog/standards/sist/a94751f8-5426-405c-a65e-

cyclotron

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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  $\alpha$ .

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]

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#### 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,  $\beta$ , 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]

## iTeh STANDARD PREVIEW

3.20 emit

3.21

## (standards.iteh.ai)

discharge contaminants into the environment

[SOURCE: ISO 2889:2010, 3.31]

3.31] <u>ISO 16640:2021</u> https://standards.iteh.ai/catalog/standards/sist/a94751f8-5426-405c-a65e-

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#### 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

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#### 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 2628abfca7cf/iso-16640-2021

[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] Teh STANDARD PREVIEW

## 3.36 representative sample

(standards.iteh.ai)

sample (3.38) with the same quality and characteristics for the material of interest as that of its source at the time of sampling https://standards.iteh.ai/catalog/standards/sist/a94751f8-5426-405c-a65e-

[SOURCE: ISO 2889:2010, 3.67] 2628abfca7cf/iso-16640-2021

#### 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]

#### 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] (standards.iteh.ai)

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https://standards.iteh.ai/catalog/standards/sist/a94751f8-5426-405c-a65etransport 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]

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#### 3.48

#### vapour

gaseous form of materials that are liquid or solids at room temperature, as distinguished from non-condensable gases

Note 1 to entry: Vapours are gases but carry the connotation of having been released or volatilised from liquids or solids.

[SOURCE: ISO 2889:2010, 3.89]

#### 3.49

#### velocity profile

distribution of the velocity values at a given cross section in a stack or duct

[SOURCE: ISO 2889:2010, 3.90]

### 4 Symbols

Symbols that are used in formulae in this document are defined below:

situation at a time  $t_0 + j \cdot \Delta t$ , in Bq·m<sup>-3</sup>;

Cross sectional area of the stack or duct, in m<sup>2</sup>; AActivity released over a period  $\Delta t_{\rm R}$ , in Bq per time;  $A_{\rm R}$ Decision threshold of the activity released over a period  $\Delta t_{\rm R}$  , in Eq. per time;  $A_{\rm R}^*$ Detection limit of the activity released over a period  $\Delta t_{\mathrm{R}}$  in Bq per time;  $A_{\rm R}^{\#}$ Lower limit of the coverage interval of the released activity over a period  $\Delta t_{
m R}$  for a given  $A_{\mathbb{R}}^{\triangleleft}$ ISO 16640:2021 probability  $(1 - \gamma)$ , in Bq per time; ards.iteh.ai/catalog/standards/sist/a94751f8-5426-405c-a65e-Upper limit of the coverage interval of the released activity over a period  $\Delta t_{
m R}$  for a given  $A_{\mathbb{R}}^{\triangleright}$ probability  $(1 - \gamma)$ , in Bq per time; Velocity-averaging correction factor for determining the flow rate in a stack or duct with a  $C_{\rm pt}$ Pitot tube from a single point reading, dimensionless; Decision threshold of the activity concentration, in Bq·m<sup>-3</sup>;  $c^*$ Detection limit of the activity concentration, in Bq·m<sup>-3</sup>;  $c^{\#}$ Gross primary measurement of the activity concentration at a time  $t_0 + i \cdot \Delta t$ , in Bq·m<sup>-3</sup>;  $C_{g,i}$ Calculated gross average activity concentration over a time interval  $m\cdot\Delta t$  at time  $t_0+i\cdot m\cdot\Delta t$ , in Bq·m<sup>-3</sup>; Calculated gross average activity concentration over a time interval  $\Delta t_{\rm R} = n \cdot m \cdot \Delta t$ , in Bq m<sup>-3</sup>;  $c_{g_{\Delta t_{\mathrm{R}}}}$ Activity concentration at a time  $t_0 + i \cdot \Delta t$ , in Bq·m<sup>-3</sup>;  $c_{i}$ Average value of  $n_{c_0}$  number of  $c_{0,i}$ , in Bq·m<sup>-3</sup>;  $c_0$ Average value of  $n_{c_0}$  number of  $\overline{c_0}_{m,im}$ , in Bq·m<sup>-3</sup>;  $c_0$ Gross primary measurement of the activity concentration which represents a background  $c_{0,j}$ 

Calculated gross average activity concentration over a time interval  $m \cdot \Delta t$ , which represents  $c_{0\,m,jm}$ a background situation at time  $t_0 + j \cdot m \cdot \Delta t$ , in Bq·m<sup>-3</sup>;  $d_t$ Tube diameter, in m;  $F_{\mathbf{k}}$ Fluctuation constant, dimensionless: NOTE 1 This is set at 1 for a meter whose readings do not fluctuate. If there are fluctuations, the parameter is set taken to be the average number of scales unit above and below the mean indicated value. Gross current of the compensating detector at time  $t_0 + i \cdot \Delta t$ , in A;  $I_{g,cd,i}$  $I_{g,i}$ Gross current of the measuring detector at time  $t_0 + i \cdot \Delta t$ , in A;  $I_{\min}$ Minimum amount of current registered by the measuring detector with  $I_{\min} = \frac{Q_{\min}}{t_{n}}$ , in A; Background current of the compensating detector at a time  $t_0 + j \cdot \Delta t$ , in A;  $I_{0,\mathrm{cd},i}$ Background current of the measuring detector at a time  $t_0 + j \cdot \Delta t$ , in A;  $I_{0,i}$ k Quantile of a standard normal distribution, if  $k_{1-\alpha} = k_{1-\beta}$ , dimensionless; NOTE 2 The value of k is 1,96 for a coverage interval of 95 %. Quantile of a standard normal distribution for a probability  $(1 - \alpha)$ , dimensionless;  $k_{1-\alpha}$ Quantile of a standard normal distribution for a probability  $(1 - \beta)$ , dimensionless;  $k_{1-\beta}$ Quantile of a standard normal distribution for a probability  $\left(1\frac{\gamma}{2}\right)$ , dimensionless; Number of times  $\Delta t$  to calculate  $c_{{\rm g}_{m,im}}$  and  $c_{0_{m,jm}}$  from archived data; m Number of times  $m \cdot \Delta t$  to calculate  $cg_{\Delta t_{\mathrm{R}}}$  from archived data; n Number of measurements of  $\mathbf{c}_{0,j}$  to determine  $\overline{c_0}$  , dimensionless; Number of measurements of  $\overline{c_0}_{m,jm}$  to determine  $\overline{c_0}$  , dimensionless; Р Penetration, dimensionless: NOTE 3 Penetration is the ratio between the activity concentration at the sampling system exit, including transport lines, and the activity concentration in the ventilation duct. Pressure, in Pa; р Standard pressure, equal to 101 325 Pa;  $p_{\rm std}$ Minimum amount of electric charge that induces a pulse registered by the measuring detector, in C;  $Q_{\min}$ Total volume of gas (air) sampled, in m<sup>3</sup>;  $Q_{\mathrm{T}}$ Volumetric flow rate, in m<sup>3</sup>⋅s<sup>-1</sup>; q Volumetric flow rate in the ventilation duct, in m<sup>3</sup>·s<sup>-1</sup>;  $q_{\rm D}$ 

 $q_{\rm std}$ 

Volumetric flow rate at standard conditions, in m<sup>3</sup>·s<sup>-1</sup>;