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Radiological protection — Measurement for the clearance of waste contaminated with radioisotopes for medical application —

Part 2: Management of solid radioactive waste in nuclear medicine facilities

Radioprotection — Mesurage pour la libération des déchets contaminés par des radioisotopes lors des applications médicales —

Partie 2: Gestion des déchets radioactifs solides dans les installations de médecine nucléaire

Reference number
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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 on 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 the following URL: 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*.

A list of all the parts in the ISO 19461 series can be found on the ISO website.

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Introduction

Nuclear medicine is the branch of medicine which uses in vivo radioactive tracers, also called radiopharmaceuticals, to evaluate molecular, metabolic, physiologic or pathologic properties in human beings and animals for diagnosis, monitoring and therapeutic purposes. The use of radionuclides in medicine is a well-established practice. Their favourable physical properties allow a broad use of radionuclides in vivo, in modern medicine. As a result, a wide range of radioactive waste is produced. Most of it is considered biomedical radioactive waste. The amount and types of wastes varies depending on the scale of the nuclear medical facility, the medical applications, and the involved radionuclides.

Radioactive waste generated in nuclear medicine facilities does not present a significant long term waste management problem when compared to wastes generated from nuclear fuel cycle operations, for instance. The most important characteristics of biomedical radioactive waste produced in nuclear medicine are its short half-life and low radiotoxicity. It generally contains low-energy photon emitters (<511 keV), but also alpha and beta (β^+ and β^-) emitters. It is usually of low total and specific activity. Nevertheless, the volume of radioactive waste produced can be significant, and other associated hazards may be present, such as biological and physical risks.

The radioactive waste produced is mainly in solid or liquid form. The liquid form is associated with patient urine, since it is the main elimination mechanism of radiopharmaceuticals. Liquid waste can also be associated with the washing water of potentially contaminated material or residues of syringes, vials, etc. This liquid waste possesses a particular management problem that falls outside the scope of this document. Liquids in small quantities contained in vials and syringes are generally managed as solid waste and their management is part of this document.

When planning for the handling of radionuclides in nuclear medicine facilities, it is important to design an effective program for the overall management of the biomedical radioactive waste. This includes all steps or activities involved in the management of radioactive waste from its generation to ultimate preparation for discharge or disposal. The goal is to minimize the hazards posed by radioactive waste, including the associated biological and physical hazards.

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Radiological protection — Measurement for the clearance of waste contaminated with radioisotopes for medical application —

Part 2: Management of solid radioactive waste in nuclear medicine facilities

1 Scope

This document addresses aspects of management of solid biomedical radioactive waste from its generation in nuclear medicine facilities to final clearance and disposal, as well as the manner to establish an effective program for biomedical radioactive waste management.

Liquid and gaseous wastes are excluded from the scope of the document, but solid waste includes spent and surplus solutions of radionuclides contained in vials, tubes or syringes. Therefore, this document should be useful for any nuclear medicine facilities dealing with in vivo medical applications of radionuclides and consequently with the waste associated with such applications.

This document provides a list of the main radionuclides used in nuclear medicine facilities and their main physical characteristics, as well as the guidance to write a radioactive waste management program for their sorting, collection, packaging and labelling, radioactivity surveys and decay storage, clearance levels, and transportation, if necessary, until their ultimate disposal or discharge. This document may also be useful as guidance for regulatory bodies.

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.

ISO 19461-1, *Radiological protection — Measurement for the clearance of waste contaminated with radioisotopes for medical application — Part 1: Measurement of radioactivity*

ISO 23907-1, *Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers*

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 https://www.electropedia.org/

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3.1
activity
A
quotient of $-dN/dt$, where dN is the change in the number of radioactive nuclei, at a particular energy state and at a given time, due to spontaneous nuclear transformations in the time of interval dt

Note 1 to entry: The special name for the unit of activity in the International Systems of Units is Becquerel (Bq), where 1 Bq = 1 s^{-1}.

[SOURCE: ISO 12749-1:2020, 3.1.2]

3.2
biological waste
material that possibly contains or has been contaminated by a biological agent that has the capacity to produce deleterious effects on humans or animals

Note 1 to entry: Biological waste includes, but is not limited to, Petri dishes, surgical wraps, culture tubes, syringes, needles, blood vials, absorbent material, personal protective equipment and pipette tips.

3.3
biomedical radioactive waste
waste possibly containing both radioactive and biological waste

3.4
calibration
set of operations that establish, under specific conditions, the relationship between values of a quantity and the corresponding values traceable to primary standards

[SOURCE: ISO 17665-1:2006, 3.5, modified — "indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material" was deleted.]

3.5
clearance level
value established by the competent authority, expressed in terms of *activity* (3.1), activity concentration or surface contamination (fixed and non-fixed) at or below which radioactive material or radioactive objects within authorized practice may be removed from any further regulatory control by the regulatory body

[SOURCE: ISO 19461-1:2018, 3.5]

3.6
decay
<radioactive> spontaneous nuclear transformation of one nuclide into a different nuclide or into a different energy state of the same nuclide

[SOURCE: ISO 12749-1:2020, 3.1.10]

3.7
discharge
planned and controlled release of radioactive material to the environment

[SOURCE: Adapted from IAEA: Radioactive Waste Management Glossary: 2003 Edition, Vienna]

3.8
disposal
emplacement of waste in an appropriate facility

[SOURCE: Adapted from IAEA: Radioactive Waste Management Glossary: 2003 Edition - Vienna]

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3.9
elution
process of extracting one material from another by washing with a solvent

Note 1 to entry: Process used for the production of certain radionuclides in nuclear medicine facilities, such as molybdenum-99/technetium-99m, rubidium-81/krypton-81m and germanium-68/gallium-68 generators.

3.10
fermentation
metabolic process that consumes sugar in the absence of oxygen. The products are organic acids, gases, or alcohol usually associated with enzymatic digestion by yeast and bacteria

3.11
fermentable waste
waste which ferments if not stored in an appropriate way (freezing, refrigeration)

3.12
half-life
$T_{1/2}$
time taken for the *activity* (3.1) of an amount of radionuclide to become half its initial value

Note 1 to entry: $T_{1/2} = \ln 2/\lambda$, where λ is the *decay constant* time required for the activity to decrease to half its value by a single radioactive decay process.

[SOURCE: ISO 12749-1:2020, 3.1.9]

3.13
ionizing radiation
radiation capable of displacing electrons from atoms or molecules, thereby producing ions

Note 1 to entry: Ionizing radiation includes alpha radiation, beta radiation, neutron radiation, gamma or X-ray photons, and cosmic rays.

[SOURCE: ISO 12749-1:2020, 3.1.4]

3.14
nuclear medicine
field of medicine in which *unsealed radioactive sources* (3.27), namely radiopharmaceuticals, are used for diagnosis or therapy

Note 1 to entry: The techniques in this field can be broadly divided into two categories: in vivo (nuclear medicine facilities) and in vitro applications (biological laboratory).

[SOURCE: ISO 12749-6:2020, 3.1.1, modified — Note 1 to entry was added.]

3.15
radiation
emission or transmission of energy in the form of waves or particles through space or through a material medium

[SOURCE: ISO 12749-1:2020, 3.1.3, modified — Note 1 to entry was deleted.]

3.16
radiation source
apparatus, substance or installation, that may cause radiation exposure, by emitting *ionizing radiation* (3.13)

[SOURCE: ISO 12749-1:2020, 3.1.5, modified — "or releasing radioactive substances or materials" was deleted.]

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3.17
shielding
radiation shield
materiel interposed between a source of radiation and persons, equipment or other objects, in order to reduce the radiation

[SOURCE: ISO 12749-1:2020, 3.1.7]

3.18
radioactivity
stochastic process whereby nuclei undergo spontaneous disintegration, usually accompanied by the emission of subatomic particles, or photons

[SOURCE: ISO 12749-1:2020, 3.1.1]

3.19
radioactive waste
material for which no further use is foreseen that contains or is contaminated with radionuclides at *activity* (3.1) greater than *clearance levels* (3.5) as established by regulatory body

[SOURCE: ISO 12749-1:2020, 3.5.1, modified — Note 1 to entry was deleted.]

3.20
radioactive waste management
all administrative and operational activities involved in the handling, conditioning, transport, radioactive material storage, and disposal of *radioactive waste* (3.19)

[SOURCE: ISO 12749-1:2020, 3.5.7, modified — "pre-treatment and treatment" were deleted from the definition.]

3.21
radioisotope
unstable isotope of an element that decays or disintegrates spontaneously, thereby emitting radiation

[SOURCE: ISO 19461-1:2018, 3.9, modified — Note 1 to entry was deleted.]

3.22
radionuclide
unstable isotope of an element that decays or converts spontaneously into another isotope or different energy state, emitting radiation

[SOURCE: ISO 16640:2021, 3.34]

3.23
radiopharmaceutical
radioactive drug used for diagnostic or therapeutic purposes

Note 1 to entry: The radiopharmaceutical is a radiotracer approved by regulatory authorities for routine human use.

Note 2 to entry: The radiopharmaceutical has two components: a radioactive part (radionuclide) that defines the physical parameters such as physical half-life and type of radiation for the medical procedure, and non-radioactive part (tracer, chemical and /or biological part) that defines the biological parameters such as biological half-life and specificity.

[SOURCE: ISO 12749-6: 2020, 3.4.3, modified — Note 1 to entry was added.]

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3.24
radiopharmaceutical kit
preparation to be reconstructed or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration

[SOURCE: ISO 11616: 2017, 3.1.29, modified — Note 1 to entry was deleted.]

3.25
sealed radioactive source
radioactive material sealed in a capsule or associated with a material to which it is closely bonded, this capsule or bonding material being strong enough to maintain tightness of the sealed source under the conditions of use and wear for which it was designed

[SOURCE: ISO 12749-2:2013, 6.3]

3.26
sharps waste
form of waste composed of used "sharps", which includes any device or object used to puncture or lacerate the skin. Sharps waste is classified as hazardous waste

Note 1 to entry: Common medical materials treated as sharps waste are needles, syringes, lancets, scalpels, blades, and contaminated glass.

3.27
unsealed radioactive source
radioactive source which is not sealed into a capsule

Note 1 to entry: In nuclear medicine, unsealed radioactive sources allow the fractionation of radioactivity for the preparation of radiopharmaceuticals, which may also be responsible for a dispersion of radioactivity.

[SOURCE: ISO 5576:1997, 2.123, modified — The word "radioactive" was added in the term and the Note 1 to entry added.]

3.28
waste
any residue of a production operation, transformation, or use, any substance, material, product that its holder intends for disposal

[SOURCE: ISO 22716:2007, 2.36]

4 Fundamentals

4.1 Characteristics of radionuclides used in nuclear medicine facilities

4.1.1 General

The principle of in vivo nuclear medicine is to administer a radiopharmaceutical, usually injected into the bloodstream, inhaled or swallowed, to target a physiological function for diagnostic, monitoring or therapeutic purposes. These radiopharmaceuticals are unsealed radioactive sources. They are either ready-to-use preparations or derived from radiopharmaceutical kits. Some radionuclides are produced in nuclear medicine facilities using a generator such as molybdenum-99/technetium-99m generators. Sealed sources are also used for anatomical marking, quality control and calibration of medical devices. The list of the main radionuclides used in nuclear medicine facilities and their medical applications are given in Tables 1, 2 and 3.

4.1.2 Diagnosis and patient monitoring

The main application of in vivo nuclear medicine is diagnostic imaging. The principle is to administer a radiopharmaceutical, which consists of a radionuclide linked to a chemical compound. The chemical

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