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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 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.

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A list of all parts in the ISO 12749 series can be found on the ISO website.

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 provides terms and definitions for nuclear medicine, the medical discipline whereby radionuclides as unsealed sources are administered to patients, in order to carry out diagnostic exams, therapeutic treatments for various pathologies and to monitor the evolution of the disease.

This multidisciplinary activity is fundamentally made up of medical, radiopharmaceutical and medical physics components, although it also relies on nuclear science, biology, biochemistry, radiochemistry, nuclear chemistry, electronics, electro-mechanics, computing, metrology of ionizing radiation and dosimetry. It involves tasks relating to support, research and development as well as staff training, which are all carried out intensively in this field.

The specific areas of most relevance to nuclear medicine are oncology, cardiology, endocrinology and neurology. However, its reaches practically every medical specialty.

The professional and technical staff who work in nuclear medicine are highly specialized, carrying out their activities in highly complex facilities, using a large range of equipment, within a strict healthcare and radiological regulatory setting.

These activities produce a large amount of documentation such as reports, publications, legal documents and teaching texts, all of which require the use of precise, coherent and unambiguous terms and definitions. Therefore, it becomes essential to harmonize the terminology used by all of the above-mentioned sectors and professions.

Conceptual arrangement of terms and definitions is based on concepts systems that show corresponding relationships among nuclear medicine concepts. Such arrangement provides users with a structured view of the nuclear medicine sector and will facilitate common understanding of all related concepts, see also Annex A. Besides, concept systems and conceptual arrangement of terminological data will be helpful to any kind of user because it will promote clear, accurate and useful communication.

Nuclear energy, nuclear technologies, and radiological protection — Vocabulary —

Part 6: Nuclear medicine

1 Scope

This document contains the terms, definitions, notes to entry and examples corresponding to the frequently used concepts which apply to diagnostic and therapeutic nuclear medicine.

It comprises the minimum essential information for each nuclear medicine concept represented by a single term. It provides the reader with the information required to approach this multidisciplinary speciality, such as medical, radiopharmacy and medical physics point of view. It is intended to facilitate communication and promote common understanding.

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 Basic terms related to nuclear medicine

3.1.1
nuclear medicine
field of medicine in which unsealed radioactive sources, namely *radiopharmaceuticals* (3.4.3), are used for diagnosis or therapy

3.1.1.1
diagnostic nuclear medicine
scientific and clinical discipline in which radiopharmaceuticals, administered by different routes, are used for diagnostic purposes

Note 1 to entry: Diagnostic nuclear medicine is mainly carried out through imaging but may also be measurements of the global or regional function of an organ.

Note 2 to entry: Diagnostic nuclear medicine also includes quantitative imaging and patient monitoring for the follow-up of both the disease progression and the treatment response.

3.1.1.2
therapeutic nuclear medicine
scientific and clinical discipline in which radiopharmaceuticals are administered for therapeutic purposes

3.1.2
theranostics
theragnostics
treatment strategy based on personalized medicine, which allows selecting the most appropriate therapy according to the diagnostic images

Note 1 to entry: In nuclear medicine, the specific targeted diagnostic test and therapy can be made sequentially with the same radiolabelled molecule (i.e. radiopharmaceutical) or with the same molecule and different label radionuclides or with different molecules with similar physiological properties.

EXAMPLE Personalized treatment of a patient with a positive somatostatin receptor image (neuroendocrine tumour) by a radiopharmaceutical composed of somatostatin analogs peptide labelled with an emitter suitable for molecular radiotherapy.

3.1.3
radiopharmacy
branch of pharmacy, that deals with the preparation, characterization and quality of radioactive drugs in nuclear medicine procedures

EXAMPLE The final stage or the preparation of the pharmaceutical and/or activity dispensing is carried out from commercial products in a hospital radiopharmacy or in centralized radiopharmacies and then delivered to a hospital radiopharmacy.

3.1.4
administered activity
activity (in MBq) of radiopharmaceutical that has been administred to the patient for diagnostic or therapeutic purposes

3.1.5
uptake
accumulation of administered activity to a particular organ or tissue at a particular time after administration

[SOURCE: NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS. NCRP Composite Glossary. NCRP, Bethesda, 2011]

3.2 Terms related to diagnostic nuclear medicine

3.2.1
diagnostic nuclear medicine
(See 3.1.1.1)

3.2.2
nuclear medicine imaging
imaging performed after administration of a radiopharmaceutical

Note 1 to entry: Imaging is considered a non-invasive diagnostic technique, as opposed to a biopsy or exploratory surgery.

Note 2 to entry: PET and SPECT are the main type of nuclear medicine imaging, providing information about how certain tissues and organs are functioning. It is complementary to anatomical imaging, such as X-ray imaging.

3.2.3
molecular imaging
MI
imaging allowing the visualization, characterization, and measurement of biological processes at the molecular and cellular levels in humans and other living systems

Note 1 to entry: *Nuclear medicine imaging* (3.2.2) is one of the modalities of molecular imaging.

[SOURCE: Mankoff DA. A definition of molecular imaging. J. Nucl. Med. 2007 Jun;48(6):18N, 21N, modified.]

3.2.4
quantitative imaging
extraction and use of numerical/statistical features from medical images

Note 1 to entry: The chief method used in quantitative imaging is to delineate a region of interest on the image and determine the mean uptake in this region, but many other features can be extracted.

[SOURCE: Abramson RG, Burton KR, Yu JP, et al. Methods and challenges in quantitative imaging biomarker development. Academic Radiology 2015 Jan, 22(1):25-32].

3.2.5
diagnostic reference level
DRL
level used in medical imaging to indicate whether, in routine conditions, the activity of a radiopharmaceutical administered in a specified radiological procedure is unusually high or unusually low for that procedure

Note 1 to entry: In diagnostic nuclear medicine, DRL is a level of activity for typical examinations for groups of standardized patients.

[SOURCE: IAEA SAFETY STANDARDS SERIES No. GSR Part 3 (2014), modified.]

3.2.6
standard uptake value
SUV
value equal to the radio of the image derived radioactivity concentration (in kBq/ml) to the whole body concentration (in kBq/kg)

Note 1 to entry: Mainly used in PET imaging, but also in SPECT imaging.

Note 2 to entry: There are other definitions of the SUV when substituting the body weight with the lean body weight or the body surface area. In addition, from a region of interest, several SUV values can be extracted (such as the maximum, the mean SUV-value, etc.).

3.3 Terms related to therapeutic nuclear medicine

3.3.1
therapeutic nuclear medicine
(See 3.1.1.2)

3.3.2
radiotherapy
radiation therapy
therapy that uses ionizing radiation to kill cells and shrink pathological tissues

Note 1 to entry: Radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (brachytherapy) or from radiopharmaceutical administered to the patient (molecular radiotherapy).

3.3.3
molecular radiotherapy
radiation therapy that uses a radiopharmaceutical to kill pathological cells and tissues by the effect of ionizing radiation

3.3.3.1
metabolic radiotherapy
molecular radiotherapy using selective irradiation of a target zone by a radiopharmaceutical administered to the patient and that participates in the metabolism of tumour cells

EXAMPLE The most widely used form of molecular radiotherapy is for the treatment of thyroid pathologies (thyroid cancer and hyperthyroidism). Called radioiodine therapy, this treatment consists of an oral administration of iodine-131, which will primarily concentrate in the thyroid to kill diseased cells.

3.3.3.2
radioimmunotherapy
RIT
molecular radiotherapy based on a personalized cancer treatment that combines radiation therapy with the precise targeting ability of immunotherapy

Note 1 to entry: In immunotherapy, scientists create monoclonal antibodies in a laboratory that mimic cellular activity in the body's immune system and are designed to recognize and bind to the antigen of a specific cancer cell.

Note 2 to entry: In RIT, the monoclonal antibody is paired with a radioactive material. When injected into the patient's bloodstream, the antibody travels to and binds to the cancer cells, allowing a high dose of radiation to be delivered to the tumour.

Note 3 to entry: The antibodies are designed to attach only very specific types of cells, consequently, radioimmunotherapy maximizes the radiation that can be delivered to the diseased tissue and minimizes the amount of radiation to which healthy tissue is exposed.

[SOURCE: Glossary of Molecular Imaging Terms, web SNMMI, 2017, modified.]

3.3.3.3
peptide receptor radionuclide therapy
molecular radiotherapy that is targeted towards peptide receptors

Note 1 to entry: The peptide receptor radionuclide therapy is used to overexpress peptide receptors in the treatment of neuroendocrine tumours.

3.3.4
selective internal radiotherapy
SIRT
radioembolization
cancer treatment that uses radioactive glass or resin beads, called microspheres, which are injected in the tumour blood supply

Note 1 to entry: The selective internal radiation therapy is mainly used for treatment of liver tumours.

3.4 Terms related to radiopharmacy

3.4.1
radiopharmacy
(See 3.1.2)

3.4.2
tracer
chemical compound used to trace the course of a biological process

3.4.2.1
radiotracer
tracer labelled by a radionuclide

3.4.3
radiopharmaceutical
radioactive drug used for diagnostic or therapeutic purposes

Note 1 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.

3.4.4
radiochemical purity
percentage of activity of a radionuclide in the specified chemical form in relation to the total activity of the sample

3.4.5
radionuclide purity
quantity of desired radionuclide in relation to unwanted (impurity) radionuclides, typically expressed as a percentage purity or percentage impurity content

Note 1 to entry: Suppliers may state 'minimum' purity values rather than measured values.

3.4.6
compounding
formulation of radiopharmaceutical reagent kits from raw ingredients for the preparation of radiopharmaceuticals by the addition of radionuclides, adding reagents to commercial kits to modify or enhance the performance of radiopharmaceuticals, shelf life extension, fractionation, and/or synthesis from raw materials

3.4.7
radiopharmaceutical reagent kit
sterile and pyrogen-free reaction vial(s) containing non-radioactive starting material that is required to compound or produce a specific radiopharmaceutical

3.4.8
radionuclide generator
device that is based on the principle of the decay-growth relationship to produce a short-lived radionuclide product from its long-lived parent

Note 1 to entry: A long-lived parent nuclide is needed to decay to its short-lived daughter nuclide and the latter is then chemically separated.

Note 2 to entry: The most frequently used radionuclide ^{99m}Tc to form a radiopharmaceuticals produced in a Technetium 99m generator from parent nuclide ^{99}Mo.

3.5 Terms related to medical equipment

3.5.1
medical equipment
device that is used to aid in the diagnosis of patients

3.5.1.1
imaging device
device used to produce detailed images of the inside of the body for diagnostic or therapeutic purposes

Note 1 to entry: In nuclear medicine imaging, examples of these devices include the gamma camera and PET scanner.

[SOURCE: Glossary of Molecular Imaging Terms, web SNMMI, 2017, modified.]

3.5.1.1.1
gamma camera
imaging device used in diagnostic nuclear medicine, which is capable of detecting the gamma radiation from photon emitters

Note 1 to entry: The gamma camera creates two-dimensional pictures of the inside of the body from different angles. If it is a SPECT camera it can also produce 3D images.

EXAMPLE Mapping the 2D or 3D distribution of the radiopharmaceutical administered to the patient.

3.5.1.1.1.1
single photon emission computed tomography scanner
SPECT scanner
specialized gamma camera used in diagnostic nuclear medicine, which is capable of mapping the 3D distribution of the radiopharmaceutical administered to the patient