2. DEFINITIONS

chemical precursor for radiopharmaceutical preparation

A chemical compound or ligand used in the synthesis of the radiopharmaceutical preparation.

chemical purity

In the monographs on radiopharmaceutical preparations, chemical purity of the active ingredient is indicated and controlled by specifying limits on chemical impurities.

The chemical purity refers to the fraction of the total chemical species present in the product as the specified chemical component(s). Hence, a chemical impurity is the presence of an unwanted nonradioactive chemical. Chemical purity is important for radiopharmaceuticals, because chemical impurities may cause undesirable consequences such as chemical interactions (e.g. precipitation) and toxic biologic effects.

Chemical impurities are typically associated with production procedures and may include contaminants from raw materials, synthetic byproducts, solvents, equipment, preparative or purification columns and containers. For certain radiopharmaceuticals, chemical impurities may also be associated with generator breakthrough of resin material from the generator column (e.g. alumina) in the eluate solution.

Determination of chemical purity is generally not performed and reported as a single attribute. Rather, determinations of individual chemical impurities are performed and compared to specifications (limits) for the respective individual chemical impurities. Such determinations of chemical impurities use analytical techniques as appropriate and described in the individual radiopharmaceutical monograph.

half-life ($T_{1/2}$)

The time required for the radioactivity to decrease to half of its value by a single decay process.

isomeric transition

Where an excited state of a radionuclide decays to the de-excited state by gamma-ray emission, with no changes in atomic, mass or neutron number.

isotopes

Isotopes of an element are nuclides with the same atomic number "Z" but different mass numbers "A". They occupy the same place in the periodic table and have similar chemical properties.

isotopic carrier

An isotopic carrier is a stable isotope of the element either present in or added to the radioactive isotope of the same element. Often the radionuclides contain isotopic carriers and their content depends on the route/method followed for the production of the radionuclide.

nuclide

Species of atom characterized by its mass number "A", atomic number "Z" and nuclear energy state, provided that the mean life in that state is long enough to be observable.

period of validity or shelf-life of the radiopharmaceutical

The time during which specifications described in the monograph are complied with by the radiopharmaceutical denoting the shelf-life of the radiopharmaceutical preparation. Any radiopharmaceutical preparations including the cold kits have limited shelf-life, which needs to be clearly stated on the label as the expiry date, and if necessary, the time.

radioactive concentration

The radioactivity of a radionuclide per unit volume of the preparation.

radioactivity

The phenomenon of emission of radiation owing to the spontaneous transformation or disintegration of a radionuclide. However, the term "radioactivity" is also used to express the physical quantity (activity or strength) of this phenomenon. The radioactivity is the number of nuclear disintegrations or transformations per unit time.

radioactive decay

Radioactivity decays at an exponential rate with a particular decay constant and is a characteristic of each radionuclide.

radiochemical purity

The ratio, expressed as a percentage, of the radioactivity of the radionuclide of interest in a stated chemical form, to the total radioactivity of that radionuclide present in the preparation.

radionuclide

Nuclides containing an unstable arrangement of protons and neutrons that transform spontaneously to either a stable or another unstable combination of protons and neutrons with a constant statistical probability by emission of radiation. The initial unstable nuclide is referred to as the "parent radionuclide" and the nuclide after transformation as the "daughter radionuclide". Such a transformation is also known as "radioactive transmutation" or "radioactive disintegration" or "radioactive decay".

radionuclidic purity

The ratio, expressed as a percentage, of the radioactivity of the radionuclide of interest to the total radioactivity of the radioactive preparation. In the context of radiopharmaceuticals, the acceptable limits for the possible radionuclides are listed in the individual monographs.

specific radioactivity

The radioactivity of a radionuclide per unit mass of the element or of the chemical form of the radioactive preparation (e.g. becquerel per gram or becquerel per mole)**.**

total radioactivity

The radioactivity of the radionuclide, expressed per unit (e.g. vial, capsule, ampoule, generator and other) at the calibration time.

units of energy

Unit of energy associated with emissions of radiation is electron volt (eV). Radiopharmaceuticals typically have emission with energies in the range kilo-electron volts (keV) to mega-electron volts (MeV).

units of radioactivity

In the International System (SI), the unit of radioactivity is one nuclear transformation per second and is expressed in Becquerel (Bq). The traditional unit of radioactivity curie (Ci) is equal to 3.7×10^{10} Bq. Absolute radioactivity measurements require a specialized laboratory. Identification and measurement of radiation can be carried out by comparing with standardized preparations provided by reference laboratories recognized by international or national authorities.

With all statements involving radioactivity, it is necessary to include a reference date of measurement in case of radionuclides with a half-life less than 70 days. The time of standardization should be expressed to the nearest hour. For radionuclides with a half-life period of less than one day, a more precise statement of reference time should be given.