THE INTERNATIONAL PHARMACOPOEIA

RADIOPHARMACEUTICALS: GENERAL MONOGRAPH

REVISION

(June 2013)

DRAFT FOR COMMENT

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**PROPOSED TEXT FOR THE INTERNATIONAL PHARMACOPOEIA**

**RADIOPHARMACEUTICALS: GENERAL MONOGRAPH**

**REVISION**

### Introduction

This general monograph is intended to be read in conjunction with the individual monographs on radiopharmaceutical preparations. A radiopharmaceutical preparation that is subject of an individual monograph in *The International Pharmacopoeia* complies with the general requirements stated below and with the general monograph for the relevant dosage form (most commonly that for Parenteral preparations) as modified by any of the requirements given below and by any specific instruction included in the individual monograph.

### Requirements

#### Definition

**Radiopharmaceutical preparation or radiopharmaceutical.** A radiopharmaceutical preparation or radiopharmaceutical is a medicinal product in a ready-to-use form suitable for human use that contains a radionuclide. The radionuclide is integral to the medicinal application of the preparation, making it appropriate for one or more diagnostic or therapeutic applications.

**For the purpose of this general monograph radiopharmaceuticals also cover:**

**Radionuclide generator.** A system in which a daughter radionuclide (short half-life) is separated by elution or by other means from a parent radionuclide (long half-life) and later used for production of a radiopharmaceutical preparation.

**Radionuclide precursor.** A “radionuclide precursor” means any radionuclide not being a radiopharmaceutical or generator or radionuclide kit which is produced for the radiolabelling of another substance for administration.

**Kit for radiopharmaceutical preparation.** In general a vial containing the non-radionuclide components of a radiopharmaceutical preparation, usually in the form of a sterilized, validated product to which the appropriate radionuclide is added or in which the appropriate radionuclide is diluted before medical use. In most cases the kit is a
multidose vial and production of the radiopharmaceutical preparation may require additional steps such as boiling, heating, filtration and buffering.

**Chemical precursor.** Non-radioactive substances in combination with radionuclide.

**Manufacture**

The manufacturing process for radiopharmaceutical preparations should meet the requirements of good manufacturing practice (GMP).

The manufacturer is responsible for ensuring the quality of his products and especially for examining preparations of short-lived radionuclides for long-lived impurities after a suitable period of decay. In this way, the manufacturer ensures that the manufacturing processes employed are producing materials of appropriate quality. In particular, the radionuclide composition of certain preparations is determined by the chemical and isotopic composition of the target material (see "Target materials") and pilot preparations are advisable when new batches of target material are employed.

When the size of a batch of a radiopharmaceutical preparation is limited to one or few units (for example, certain therapeutic preparations or very short-lived preparations) release of the product must rely on the process control rather than product quality control tests. Therefore validation and revalidation of manufacture process must be fully implemented as well as the product quality control tests.

**Radiation Protection.** The relevant premises and equipment must be designed, built and maintained so that they do not bear any negative impact on or represent any hazard to the product, personnel or immediate surroundings. The corresponding supporting materials are provided by various IAEA publications.¹

**Radionuclide production.** In general ways of manufacturing radionuclides for use in radiopharmaceutical preparations are:

- **Nuclear fission.** Nuclides with high atomic number are fissionable and a common reaction is the fission of uranium-235 by neutrons in a nuclear reactor. For example, iodine-131, molybdenum-99 and xenon-133 can be produced in this

way. Radionuclides from such a process must be carefully controlled in order to
minimize the radionuclidic impurities.

**Charged particle bombardment.** Radionuclides may be produced by
bombarding target materials with charged particles in particle accelerators such as
cyclotrons. The isotopic composition and purity of the target material will
influence the radionuclidic purity of irradiated target.

**Neutron bombardment.** Radionuclides may be produced by bombarding target
materials with neutrons in nuclear reactors. The rate of the nuclear reaction
depends on the energy of the incident particle, neutron flux and nuclear cross-
section. The isotopic composition and purity of the target material will influence
the radionuclidic purity of irradiated target.

**Radionuclide generator systems.** Radionuclides of short half-life may be
produced by means of a radionuclide generator system involving separation of the
daughter radionuclide from a long-lived parent by chemical or physical separation.
Care must be taken to avoid contamination of daughter radionuclide with parent
radionuclide and decay products.

**Starting materials (including chemical precursors and excipients).** In the manufacture
of radiopharmaceutical preparations, measures shall be taken to ensure that all ingredients
are of appropriate quality, including those starting materials, such as chemical precursors
for synthesis, that are produced on a small scale and supplied by specialized producers or
laboratories for use in the radiopharmaceutical industry. The actual quantity of
radioactive material compared with quantities of excipients is normally very small
therefore excipients can greatly influence the quality of the radiopharmaceutical
preparation.

**Target materials.** The composition and purity of the target material and the nature and
energy of the incident particle will determine the relative percentages of the principal
radionuclide and other potential radionuclides (radionuclidic impurities) and thus
ultimately the radionuclidic purity. Strict control of irradiation parameters such as beam
energy, intensity and duration is also essential. For very short lived radionuclides
including the ones present in most positron emission tomography (PET) tracers the
determination of radiochemical and radionuclidic purity of radiopharmaceutical
preparation before patient use is difficult. Therefore before clinical use of these
radionuclides, strict operational conditions and extensive validations are essential. Any
subsequent change in operational conditions should be revalidated.

Where applicable (e.g. cyclotron irradiation of solid targets) each new batch of target
material must be tested and validated in special production runs before its use in routine
radionuclide production and manufacture of radiopharmaceutical preparation. This will
ensure that under specified conditions, the target yields a radionuclide in the desired
quantity and quality.
Carriers. A carrier, in the form of inactive material, either isotopic with the radionuclide, or non-isotopic, but chemically similar to the radionuclide, may be added during radionuclide production and radiopharmaceutical preparation. In some situations it may be added to enhance chemical, physical or biological properties of the radiopharmaceutical preparation. The amount of carrier added must be controlled and sufficiently small for it not to cause undesirable physiological effects.

Carrier-free preparation. It is a preparation free from stable isotope of the same element as the radionuclide concerned present in the preparation in the stated chemical form or at the position of the radionuclide in the molecule concerned. When appropriate, specific radioactivity must be measured in the radiopharmaceutical preparation.

No-carrier added preparation. It is a preparation to which no stable isotopes of the same element as the radionuclide concerned are intentionally added in the stated chemical form or at the position of the radionuclide in the molecule concerned. When appropriate specific radioactivity must be measured in the radiopharmaceutical preparation.

Production of radiopharmaceutical preparation. Radiopharmaceutical preparations may contain the types of excipients permitted by the general monograph for the relevant dosage form.

Sterilization. Radiopharmaceutical preparations intended for parenteral administration are sterilized by a suitable method (see 5.8 Methods of sterilization). Whenever possible, steam sterilization is recommended.

All sterilization processes must be validated.

Addition of antimicrobial preservatives. Radiopharmaceutical injections are commonly supplied in multidose containers. The nature of the antimicrobial preservative, if present, is stated on the label or, where applicable, that no antimicrobial preservative is present.

Radiopharmaceutical injections for which the shelf-life is greater than one day and that do not contain an antimicrobial preservative should preferably be supplied in single-dose containers. If, however, such a preparation is supplied in a multidose container requirements of the general monograph for Parenteral Preparations should apply.

Radiopharmaceutical injections for which the shelf-life is greater than one day and that do contain an antimicrobial preservative may be supplied in multidose containers. After aseptic withdrawal of the first dose, the container should be stored at a temperature between 2° and 8° C and the contents used within 7 days unless otherwise specified.
Radiation protection


Identity tests

Tests for identity of the radionuclide are included in the individual monographs for radiopharmaceutical preparations. The radionuclide is generally identified by its half-life or by the nature and energy of its radiation or by both as stated in the monograph.

Other tests

Half-life measurement. The half-life is a characteristic of the radionuclide that may be used for its identification. The half-life is calculated by measuring the variation of radioactivity of a sample to be tested as a function of time. Perform the measurements in the linearity range of a calibrated instrument. Measurements should comply with the R 1.1 Detection and measurement of radioactivity. Approximate half-life can be determined over a relatively short period of time to allow release for use of radiopharmaceutical preparations. The calculated approximate half-life is within the range of the values stated in the individual monograph.

Radionuclidic purity

Radionuclidic impurities may arise during the production and decay of a radionuclide. Potential radionuclidic impurities may be mentioned in the monographs and their characteristics are described in the general monograph: Annexes: Table of physical characteristics. In most cases, to establish the radionuclidic purity of a radiopharmaceutical preparation, the identity of every radionuclide present and its radioactivity must be known.

Technical details of radionuclide identification and radionuclidic purity determination are described in R1.2 Radiation spectrometry and R1.3 Determination of radionuclidic purity. Because the level of radionuclidic impurities, expressed as a percentage of each impurity, may increase or decrease with time, the measured radioactivity of each impurity must be recalculated to the activity during the period of validity of the preparation.

The individual monographs prescribe the radionuclidic purity required and may set limits for specific radionuclidic impurities (for example, molybdenum-99 in technetium-99m). While these requirements are necessary, they are not in themselves sufficient to ensure that the radionuclidic purity of a preparation is sufficient for its clinical use. The manufacturer must examine the product in detail and especially must examine preparations of radionuclides with a short half-life for impurities with a long half-life.
after a suitable period of decay. In this way, information on the suitability of the manufacturing processes and the adequacy of the testing procedures is obtained. In cases where two or more positron-emitting radionuclides need to be identified and/or differentiated, for example the presence of 18F-impurities in 13N-preparations, half-life determinations need to be carried out in addition to gamma-ray spectrometry.

**Radiochemical purity**

A radioactive preparation may contain the radionuclide in different chemical forms other than the intended one. Therefore it is necessary to separate the different substances containing the radionuclide and determine the percentage of radioactivity due to the radionuclide concerned associated with the stated chemical form and the contribution to the total radioactivity due to the radionuclide concerned coming from other substances. For this purpose instruments for the detection and measurement of radioactivity are used in combination with a physic-chemical separation technique.

Radiochemical purity is assessed by a variety of analytical techniques such as 1.14.4 High-performance liquid chromatography, 1.14.2 Paper Chromatography, 1.14.1 Thin-layer Chromatography and 1.15 Electrophoresis combined with suitable radioactivity measurement described in R1.1 Detection and measurement of radioactivity. In all cases the radioactivity of each analyte is measured after the separation has been achieved using the stated method.

The radiochemical purity section of an individual monograph may include limits for specified radiochemical impurities, including isomers. In some cases, it is necessary to determine the physiological distribution of the radiopharmaceutical in a suitable test animal.

**Specific radioactivity.** Specific radioactivity is defined as radioactivity of a radionuclide per unit mass of the element or of the chemical form concerned. Specific radioactivity is usually calculated taking into account the radioactivity concentration and the concentration of the chemical substance being studied. Specific radioactivity changes with time. The statement of the specific radioactivity therefore includes reference to a date and, if necessary, time.

Specific radioactivity must be measured in carrier added preparations. For some non-carrier added radiopharmaceutical preparations (for example, receptor ligands) it is important to state specific radioactivity. Individual monographs might state the range of specific radioactivity.
Chemical purity

Chemical purity refers to the proportion of the preparation that is in the specified chemical form regardless of the presence of radioactivity; it may be determined by accepted methods of analysis.

In general, limits should be set for chemical impurities in preparations of radiopharmaceuticals if they are toxic or if they modify the labelling process or alter physiological uptakes that are under study or if they result in undesirable interactions (e.g. aluminium can induce flocculation of Tc-99m sulphur colloid). Special attention is necessary for impurities with a pharmacologically active or pharmacodynamic effect even for very low amounts (for example, receptor ligands). Where appropriate, the stereoisomeric purity has to be verified. In general, the type of limits for inorganic impurities such as arsenic and heavy metals that are specified in monographs for pharmaceutical substances are also valid for radiopharmaceuticals.

Characterize impurities as much as possible. Generic limits can be set for unidentified impurities. The limits has to be chosen carefully considering amounts and toxicity based upon toxicities of starting materials, precursors, possible degradation products and the final product.

pH

When required, measure the pH of non-radioactive solutions as described under 1.13 Determination of pH. For radioactive solutions the pH may be measured using a pH indicator strip R.

[Note from Secretariat:

Add pH indicator strip R to the section on Reagents using the following:

pH indicator strip. R.

Plastic or paper strip containing multiple segments of different dye-impregnated papers allowing visual determination of pH in the prescribed range by comparison with a master chart.]

Sterility

A number of monographs for radiopharmaceuticals contain the requirement that the preparation is sterile. Such preparations comply with 3.2 Test for sterility. The special difficulty arise with the radiopharmaceuticals because of the short half-life of the
radionuclide, the small size of batches and the radiation hazards. In the case that the
monograph states that the preparation can be released for use before completion of the
test for sterility, the sterility test must be started as soon as practically possible in relation
to the radiation. If not started immediately, samples are stored under conditions that are
shown to be appropriate in order to prevent false negative result.

When the size of the batch of a radiopharmaceutical is limited to one or few samples (e.g.
therapeutic or very short-lived radiopharmaceutical preparations), sampling the batch
may not be possible. In this case reliance is on process control rather than the final
product control.

**Bacterial endotoxins/pyrogens**

Where appropriate, an individual monograph for a radiopharmaceutical preparation
requires compliance with 3.4 Test for bacterial endotoxins. Validation of the test is
necessary to exclude any interference or artefact due to the nature of the
radiopharmaceutical. The pH of some radiopharmaceutical preparations will require to be
adjusted to pH 6.5–7.5 to achieve optimal results.

Where it is not possible to eliminate interference with the test for bacterial endotoxins
due to the nature of the radiopharmaceutical, compliance with 3.5 Test for pyrogens may
be specified.

**Labelling**

Every radiopharmaceutical preparation must comply with the labelling requirements
established under GMP.

[Note from Secretariat: Check that the text is consistent with current GMP text needs to
be undertaken in final version.]

The label on the primary container should include:

- a statement that the product is radioactive or the international symbol for
  radioactivity;
- the name of the radiopharmaceutical preparation;
- where appropriate, that the preparation is for diagnostic or for therapeutic use;
- the route of administration;
- the total radioactivity present at a stated date and, where necessary, time; for
  solutions, a statement of the radioactivity in a suitable volume (for example, in
  MBq per ml of the solution) may be given instead;
- the expiry date and, where necessary, time;
• the batch (lot) number assigned by the manufacturer;
• for solutions, the total volume.

The label on the outer package should include:

• a statement that the product is radioactive or the international symbol for radioactivity;
• the name of the radiopharmaceutical preparation;
• where appropriate, that the preparation is for diagnostic or for therapeutic use;
• the route of administration;
• the total radioactivity present at a stated date and, where necessary, time; for solutions, a statement of the radioactivity in a suitable volume (for example, in MBq per ml of the solution) may be given instead;
• the expiry date and, where necessary, time;
• the batch (lot) number assigned by the manufacturer;
• for solutions, the total volume;
• any special storage requirements with respect to temperature and light;
• where applicable, the name and concentration of any added microbial preservatives or, where necessary, that no antimicrobial preservative has been added.

Note: The shipment of radioactive substances is subject to special national and international\(^2\) regulations as regards to their packaging and outer labelling.

Storage

Radiopharmaceuticals should be kept in well-closed containers and stored in an area assigned for the purpose. The storage conditions should be such that the maximum radiation dose rate to which persons may be exposed is reduced to an acceptable level. Care should be taken to comply with national regulations for protection against ionizing radiation.

Radiopharmaceutical preparations that are intended for parenteral use should be kept in a glass vial, ampoule or syringe that is sufficiently transparent to permit the visual inspection of the contents. Glass containers may darken under the effect of radiation.

ANNEXES: TERMINOLOGY

Biological half-life

The biological half-life \( (T_{1/2b}) \) of a radiopharmaceutical is the time taken for the concentration of the pharmaceutical to be reduced 50% of its maximum concentration in a given tissue, organ or whole body, not considering radioactive decay.

Critical organ

The critical organ is the organ or tissue which is the most vulnerable to radiation damage. This may not be the target tissue or the tissue that receives the highest dose and therefore the dose to the critical organ will determine the maximum safe dose which can be administered.

Effective half-life

The effective half-life \( (T_{1/2e}) \) is the actual half-life of a radiopharmaceutical in a given tissue, organ or whole body and is determined by a relationship including both the physical half-life and biological half-lives. The effective half-life is important in calculation of the optimal dose of radiopharmaceutical to be administered and in monitoring the amount of radiation exposure. It can be calculated from the formula:

\[
T_{1/2e} = \frac{T_{1/2p} \cdot T_{1/2b}}{T_{1/2p} + T_{1/2b}}
\]

Where \( T_{1/2p} \) and \( T_{1/2b} \) are the physical and biological half-lives respectively.

Half-life

The time in which the radioactivity decreases to one-half its original value.

EXPLANATORY NOTE. The rate of radioactive decay is constant and characteristic for each individual radionuclide. The exponential decay curve is described mathematically by the equation:

\[
N = N_0 e^{-\lambda t}
\]

where \( N \) is the number of atoms at elapsed time \( t \), \( N_0 \) is the number of atoms when \( t = 0 \), and \( \lambda \) is the disintegration constant characteristic of each individual radionuclide. The half-life period is related to the disintegration constant by the equation:
Radioactive decay corrections are calculated from the exponential equation, or from decay tables, or are obtained from a decay curve plotted for the particular radionuclide involved (see Figure 1).

\[ T_1 = \frac{0.693}{\lambda} \]

FIGURE 1. MASTER DECAY CHART
Isotopes

Atoms of the same element with different atomic mass numbers are called isotopes.

Nuclide

Nuclide is defined as species of atom as characterized by the number of protons, the number of neutrons, and the energy state of the nucleus.

Radioactive concentration

The radioactive concentration of a solution refers to the amount radioactivity per unit volume of the solution. As with all statements involving radioactivity, it is necessary to include a reference date and time of standardization. For radionuclides with a half-life of less than one day, a more precise statement of the reference time is required.

Units for radioactive concentration are megaBecquerels per millilitre (MBq/ml).

Since the radioactive concentration will change with time due to decrease in the nuclide radioactivity it is always necessary to provide a reference time. For short-lived radionuclides the reference time will be more precise including time of day in addition to date.

Radioactive decay

The property of unstable nuclides during which they undergo a spontaneous transformation within the nucleus. This change results in the emission of energetic particles or electromagnetic energy from the atoms and the production of an altered nucleus.

EXPLANATORY NOTE. The term “disintegration” is widely used as an alternative to the term “transformation”. Transformation is preferred as it includes, without semantic difficulties, those processes in which no particles are emitted from the nucleus.

Radioactivity

Generally the term “radioactivity” is used both to describe the phenomenon of radioactive decay and to express the physical quantity of this phenomenon. The radioactivity of a preparation is the number of nuclear disintegrations or transformations per unit time. In the International System (SI), the term “activity” is used, which corresponds to radioactivity in the context of this general monograph.
It is expressed in becquerel (Bq), which is 1 nuclear transformation per second.

EXPLANATORY NOTE. The term “disintegration” is widely used as an alternative to the term “transformation”. Transformation is preferred as it includes, without semantic difficulties, those processes in which no particles are emitted from the nucleus.

Radiochemical purity

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

Relevant potential radiochemical impurities are listed with their limits in the individual monographs. (Note: Source of information: European Pharmacopoeia.)

As radiochemical purity may change with time, mainly because of radiolysis or chemical decomposition, the result of the radiochemical purity test should be started at given date and if necessary hour indicating when the test was carried out. The radiochemical purity limit should be valid during the whole shelf-life.

Radionuclidic purity

The radionuclidic purity is the ratio expressed as a percentage of radioactivity of the radionuclide concerned to the total radioactivity of the radiopharmaceutical preparation.

The relevant potential radionuclidic impurities are listed with their limits in their individual monographs.

Specific radioactivity

The specific radioactivity of a radionuclide corresponds to the SI term “specific activity” in the context of this monograph and is defined as radioactivity of radionuclide per unit mass of the element or of the chemical form concerned, e.g. Bq/g or Bq/mole.

The term employed in radiochemical work is “specific activity”. As the word “activity” has other connotations in a pharmacopoeia, the term should, where necessary, be modified to “specific radioactivity” to avoid ambiguity.

Units of radioactivity

The activity of a quantity of radioactive material is expressed in terms of the number of spontaneous nuclear transformations taking place in unit time. The SI unit of activity is the becquerel (Bq), a special name for the reciprocal second (s⁻¹). The expression of
activity in terms of the becquerel therefore indicates the number of transformations per second.

The historical unit of activity is the curie. The curie (Ci) is equivalent to $3.7 \times 10^{10}$ Bq. The conversion factors between becquerel and curie and its submultiples are given in Table 1.

Table 1. Units of radioactivity commonly encountered with radiopharmaceuticals and the conversions between SI units and historical units

<table>
<thead>
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<th>Number of atoms transforming per second</th>
<th>SI unit: becquerel (Bq)</th>
<th>historical unit: curie (Ci)</th>
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</thead>
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<tr>
<td>1</td>
<td>1 Bq</td>
<td>27 picocurie (pCi)</td>
</tr>
<tr>
<td>1000</td>
<td>1 kilobecquerel (kBq)</td>
<td>27 nanocurie (nCi)</td>
</tr>
<tr>
<td>$1 \times 10^6$</td>
<td>1 megabecquerel (MBq)</td>
<td>27 microcurie (µCi)</td>
</tr>
<tr>
<td>$1 \times 10^9$</td>
<td>1 gigabecquerel (GBq)</td>
<td>27 millicurie (mCi)</td>
</tr>
<tr>
<td>37</td>
<td>37 Bq</td>
<td>1 (nCi)</td>
</tr>
<tr>
<td>37,000</td>
<td>37 kBq</td>
<td>1 (µCi)</td>
</tr>
<tr>
<td>$3.7 \times 10^7$</td>
<td>37 MBq</td>
<td>1 (mCi)</td>
</tr>
<tr>
<td>$3.7 \times 10^{10}$</td>
<td>37 GBq</td>
<td>1 Ci</td>
</tr>
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ANNEXES: TABLE OF PHYSICAL CHARACTERISTICS

Physical characteristics of clinically relevant radionuclides

Information on the physical characteristics of key radionuclide used in nuclear medicine is provided in the following Table 2.

*Note from Secretariat: This table will be updated by IAEA.*

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