# 1. INTRODUCTION

Radiopharmaceuticals are unique medicinal formulations containing radioisotopes which are used in major clinical areas for diagnosis and/or therapy. The facilities and procedures for the production, use and storage of radiopharmaceuticals are subject to licensing by national and/or regional authorities. This licensing includes compliance both with regulations governing pharmaceutical preparations and those governing radioactive materials. Additional regulations may apply to particular issues such as transportation or dispensing of radiopharmaceuticals.

Each producer or user must be thoroughly cognizant of the national requirements pertaining to the articles concerned.

Regulations concerning the quality of pharmaceutical preparations include the application of Good Manufacturing Practices (GMP). For the current WHO recommendations, consult the website WHO Guidelines: Norms and Standards of Pharmaceuticals.

Regulations governing radioactive materials include those on safe handling and production of radioisotopes. See *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (IAEA, Vienna, 2003, CD-ROM Edition),Safety Series No. 115/CD, *Radiological Protection for Medical Exposure to Ionizing Radiation Safety Guide* (International Atomic Energy Agency (IAEA), Vienna, 2002); *Radiation Protection and Safety in Medical Uses of Ionizing Radiation* (IAEA, Vienna, 2018), Safety Standard Series No. RS-G-1.5 and the *Operational Guidance on Hospital Radiopharmacy: A Safe and Effective Approach* (IAEA, Vienna, 2008, Operational Guidance on Hospital Radiopharmacy | IAEA. Consult the IAEA website for the current Safety Standards and publications (http://www-ns.iaea.org/standards/).

Annex 1 and Annex 2 lists the relevant information for radiological safety considerations and dose limits of medically important radionuclides.

Radiopharmaceuticals can be divided into four categories:

**Radiopharmaceutical preparation**

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

**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.

**Radiopharmaceutical precursor**

A radionuclide produced for the radiolabelling process with a resultant radiopharmaceutical preparation.

**Kit for radiopharmaceutical preparation**

Any preparation to be reconstituted and/or combined with radionuclides to form the final radiopharmaceutical preparation, usually shortly before its administration. 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.

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.