

RADIOPHARMACEUTICALS

Background information

Both the World Health Organization and the International Atomic Energy Agency (IAEA), a UN specialized agency, recognize that radiopharmaceuticals are unique medicinal formulations containing radioisotopes which are used in major clinical areas for diagnosis and/or therapy.

The quality of radiopharmaceuticals is important for accuracy of diagnosis and reproducibility of quantitative data from nuclear investigation. Quality is also an important determinant of safety (with respect to both pharmaceutical and radiation aspects). 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 with those governing radioactive materials. Additional regulations may apply for issues such as transportation or dispensing of radiopharmaceuticals.

During initial discussion between WHO and IAEA it was considered that what was needed by the international community was a set of individual monographs for medically relevant radiopharmaceuticals. Following consultation and discussion, it was agreed that this work would include *inter alia* revision of the general monograph in *The International Pharmacopoeia* and the preparation of monographs for individual radiopharmaceuticals.

The work has been carried out by means of consultations organized jointly by IAEA and WHO, preparation by IAEA of proposed specifications, circulation by WHO of draft texts for comment in line with the usual consultative process for monograph development followed by extensive collaboration between the WHO and IAEA secretariats and relevant experts.

The adopted texts will be published in the Fourth Edition of *The International Pharmacopoeia* as a separate section for Radiopharmaceuticals. This will comprise:

- Introduction
- General monograph
- Individual monographs
- Methods of analysis
- Supplementary information