Preparation - additional guidance

Manufacture of radiopharmaceutical injections

Addition of antimicrobial preservatives. As noted in the general monograph radiopharmaceutical injections are commonly supplied in multidose containers. Moreover, the general monograph states that the requirement of the general monograph for Parenteral preparations that such injections should contain a suitable antimicrobial preservative in a suitable concentration does not necessarily apply to radiopharmaceutical preparations. A reason for this exemption is that many common antimicrobial preservatives (for example, benzyl alcohol) are gradually decomposed by the effect of radiation in aqueous solutions. The rate of decomposition is dependent upon a number of factors, including the nature of the radionuclide and the radioactivity concentration of the solution. It is therefore not always possible to prescribe an effective antimicrobial preservative for a radiopharmaceutical injection and for certain preparations the addition of an agent is undesirable.

Compounding

Compounded radiopharmaceuticals are not for sale and are not to be advertised. Compounding includes formulation of radiopharmaceutical reagent kits from raw ingredients for radiopharmaceuticals preparation, adding reagents to approved/unapproved commercial kits to modify or enhance performance of radiopharmaceuticals (shelf life extension, fractionation) and/or synthesis from raw materials. Compounding should follow recognized pharmacopoeial protocols whenever available; approval by institutional committee is otherwise required. The process of compounding radiopharmaceuticals must be under the supervision and responsibility of recognized nuclear physician or suitably qualified professional, ideally a radiopharmacist.

Within the radiopharmaceutical industry the range of associated risk of product failure varies from manufacturing, compounding and dispensing. Compounding is limited to clinical practice according to medical doctor’s prescription or requisition for a specific patient. Patent-protected radiopharmaceuticals should not be compounded. When, however, patented reagent kits cannot be readily obtainable from a commercial source, limited compounding shall be done to meet the urgent medical needs of an identified individual patient; in this case the prescriber shall be informed that a reagent kit will be compounded to replace the commercial product. See Operational Guidance on Hospital Radiopharmacy (IAEA, Vienna, 2008) STI/PUB/1342. Consult the IAEA web site for other current publications on Nuclear Medicine (including radiopharmaceuticals) (http://www-pub.iaea.org/MTCD/publications/SubjectAreas.asp).

Dispensing

Dispensing a radiopharmaceutical preparation is distinct from compounding in that a radiopharmaceutical preparation is prepared with the use of approved/authorized commercially available components. These usually consist of a kit for radiopharmaceutical preparation together with a radionuclide precursor or an elute from aradionuclide generator. All aspects are undertaken in accordance with the instructions provided by the manufacturers and suppliers of the components.