SFHRAD6
Prepare prescribed radioactive and non-radioactive medicinal products from raw materials

Overview

This standard relates to the manufacture of prescribed (including unlicensed) radiopharmaceutical products for patient use, and for research purposes. It involves the preparation of products from raw materials and non standard procedures which may require further interpretation and amendment during the process due to the limitations imposed by radioactive half life. This may include preparation of highly complex positron emitting radiopharmaceuticals. This will be undertaken in a suitable containment area. This process may involve a change in chemical entity. It may include both licensed and unlicensed radionuclides and raw materials such as antibodies, peptides and drugs.

Users of this standard will need to ensure that practice reflects up to date information and policies.

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Performance criteria

You must be able to:

P1 confirm that the national guidelines for non standard procedures has been followed
P2 confirm suitability and safety of environment and equipment for producing product
P3 prepare or select radionuclide of correct identity and chemical form
P4 select sufficient starting material of suitable quality and purity
P5 conduct end process checks to confirm that activity, volume and appearance complies with specification
P6 if required, transfer aliquots of correct volume to suitable containers taking appropriate radiation protection measures
P7 ensure primary container, and secondary container where appropriate, is labelled according to approved procedures
P8 place products securely and safely in correct location for next stage of use
P9 complete relevant records accurately
P10 dispose of waste in accordance with local procedures
P11 leave work area in clean condition free from contaminants and ready for use
P12 take relevant corrective action to resolve risks, discrepancies and deficiencies in quality
P13 correctly interpret and apply relevant standard operating procedures
P14 interpret in process measurements and adjust procedure accordingly

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Knowledge and understanding

You need to know and understand:

K1 principles of Good Manufacturing Practice principles and their application
K2 regulatory requirements for the use of non licensed materials
K3 aseptic techniques and their application
K4 radiation protection guidelines and their application, including Local Rules
K5 the national guidelines for non standard procedures
K6 risks associated with the use of unlicensed raw materials
K7 the range of relevant radionuclides and their use
K8 methods for preparation of radionuclides
K9 the range of equipment and facilities, purpose and correct use
K10 radiolabelling mechanisms and their underlying chemistry
K11 your own level of responsibility relating to each part of this standard
K12 product specifications and their application
K13 requirements for storage, handling and disposal of radioactive medicinal products
K14 range of relevant standard operating procedures

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Additional Information

External links

This standard has indicative links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: HWB10 Products to meet health and wellbeing needs

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Developed by	Skills for Health
Version number	1
Date approved	June 2010
Indicative review date	June 2012
Validity	Current
Status	Original
Originating organisation	Skills for Health
Original URN	RAD6
Relevant occupations	Health, Public Services and Care; Medicine and Dentistry; Nursing and Subjects and Vocations Allied; Healthcare and Related Personal Services
Suite	Radiopharmacy
Key words	radiopharmaceuticals, radiopharmacy