

## SFHRAD4

### Prepare radioactive and non-radioactive medicinal products



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#### Overview

This standard relates to the manufacture of radiopharmaceuticals according to validated standard operating procedures, which may include the following: It will be undertaken in a suitable containment area.

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 select radionuclide of correct identity and chemical form matched to requested product type and method of administration, or handle and operate radionuclide generator in accordance with manufacturer's instructions and applying correct aseptic techniques if required
- P2 select correct kit for manufacture, if appropriate
- P3 reconstitute or dilute, where required, in accordance with relevant standard operating procedure
- P4 conduct end process checks to confirm product complies with specification
- P5 if required, transfer aliquots of correct volume into suitable containers
- P6 place products securely and safely in correct location for next stage of use
- P7 complete relevant records accurately
- P8 ensure primary container, and secondary container where appropriate, is labelled according to approved procedures
- P9 dispose of waste in accordance with local procedures
- P10 leave work area in clean condition free from contaminants and ready for use
- P11 correctly interpret and apply relevant standard operating procedures
- P12 take relevant corrective action to report risks, discrepancies or deficiencies in quality

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#### Knowledge and understanding

*You need to know and understand:*

- K1 principles of Good Manufacturing Practice principles and their application
- K2 intended use of products
- K3 radiation protection guidelines and their application including local rules
- K4 aseptic techniques and their application
- K5 product specifications
- K6 the range of records required and how to complete and process these
- K7 corrective action to be taken in the event of spillage, breakage damage or contamination and the implications of these events
- K8 need for appropriate diluents, limitations and consequences of over-dilution and need for suitable containers
- K9 basic radiopharmaceutical chemistry
- K10 your own level of responsibility relating to each part of this standard
- K11 the range of equipment and facilities, their purpose and use
- K12 requirements for storage, handling and disposal of radioactive medicinal products
- K13 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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<b>Developed by</b>	Skills for Health
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<b>Version number</b>	1
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<b>Date approved</b>	June 2010
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<b>Validity</b>	Current
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<b>Status</b>	Original
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<b>Originating organisation</b>	Skills for Health
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<b>Original URN</b>	RAD4
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<b>Relevant occupations</b>	Health, Public Services and Care; Medicine and Dentistry; Nursing and Subjects and Vocations Allied; Healthcare and Related Personal Services
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<b>Suite</b>	Radiopharmacy
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<b>Key words</b>	radiopharmaceuticals, radiopharmacy
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