

## SFHRAD7

### Release manufactured radioactive medicinal products suitable for clinical use



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#### Overview

This standard relates to the release of radioactive medicinal products for clinical use. Manufacture may involve a change in the chemical entity of the starting materials. Release involves compliance with the relevant statutory requirements.

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 check that manufactured products meet defined specifications
- P2 determine necessary corrective action in the event that products do not meet the release specification
- P3 ensure that the equipment and facilities met required standards during manufacture, and take corrective action where appropriate
- P4 ensure that raw materials and finished products have been stored correctly and are within their validated shelf life
- P5 ensure that relevant standard operating procedures have been followed and assess the importance of deviations, taking corrective action where appropriate
- P6 assess the importance of changes to planned production, for example, a change in final volume
- P7 assess and interpret in process and end product quality test results
- P8 approve release of products or reject for clinical use
- P9 complete relevant records accurately

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#### Knowledge and understanding

*You need to know and understand:*

- K1 principles of Good Manufacturing Practice and their application
- K2 radiation protection guidelines and their application, including Local Rules
- K3 approved product specification
- K4 radiolabelling mechanisms and their underlying chemistry
- K5 implications of non-conformity on clinical use
- K6 storage requirements for raw materials and finished products
- K7 the responsibilities associated with final release vs. in process checks
- K8 locally approved procedures for release of radioactive medicinal products,
- K9 recording and reporting mechanisms for non-conforming products
- K10 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

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**Original URN** RAD7

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**Suite** Radiopharmacy

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**Key words** radiopharmaceuticals, radiopharmacy

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