SFHRAD13
Assess the quality of radioactive medicinal products

Overview

This standard relates to the assessment of the quality of radioactive and non-radioactive medicinal products, and the starting materials used in their manufacture, whether prepared on site or procured in ready-to-use-form.

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

SFHRAD13
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Performance criteria

You must be able to:

- P1 test quality using specified range of tests for product and using validated analytical technique
- P2 complete relevant records accurately
- P3 confirm test results conform to specification and relevant standards
- P4 identify and report details of non-conforming products according to approved procedures
- P5 in the event of non-compliance, inform users and report via a recognised reporting scheme
- P6 correctly apply relevant standard operating procedures

SFHRAD13

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Knowledge and understanding

You need to know and understand:

K1 principles of Good Manufacturing Practice and their application
K2 analytical techniques and associated equipment for quality control
K3 recording and reporting mechanisms for both conforming and non-conforming products, including recall procedures
K4 the range of quality control tests, their selection and use
K5 radiation protection guidelines and their application
K6 range of relevant standard operating procedures
K7 possible pitfalls and potential artefacts of the analytical technique used

SFHRAD13
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Additional Information

External links

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

Dimension: HWB10 Products to meet health and wellbeing needs

SFHRAD13

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