

SFHRAD3

Prepare working environment for manufacture and dispensing of radioactive and non-radioactive medicinal products



Overview

This standard relates to the preparation and on-going monitoring of the environment used for the manufacture of radioactive and non-radioactive medicinal products. It includes maintenance of Principles of Good Manufacturing Practice and associated guidelines for standards of the working environment.

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

SFHRAD3

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Performance criteria

You must be able to:

- P1 check and confirm levels of radiation in the working environment are below acceptable levels in accordance with local rules
- P2 check that work area is sanitised for use
- P3 perform routine physical environmental monitoring by standard testing at prescribed frequency, for example microbial monitoring or airflow testing
- P4 perform standard tests on equipment, for example dose calibrators and isolators, and confirm operation within expected performance parameters
- P5 identify, report and record issues which impact on compliance with regulations or safety of personnel
- P6 take corrective action according to relevant procedures with suitable degree of urgency to resolve factors affecting compliance, safety or security
- P7 ensure availability of documentation for required production
- P8 correctly interpret and apply relevant standard operating procedures

SFHRAD3

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Knowledge and understanding

You need to know and understand:

- K1 principles of Good Manufacturing Practice requirements and associated guidelines for standards of working environment
- K2 the range of relevant standard operating procedures
- K3 radiation protection guidelines and their application including local rules
- K4 methods for both radiation and microbial contamination monitoring
- K5 the type, nature and implications of possible contaminants
- K6 procedures relating to operational capacity and contingency planning
- K7 control measures applicable to prevention and removal of all types of contamination
- K8 the range of standard environmental monitoring tests and their purpose
- K9 expected performance, limitations and calibration of equipment, including dose calibrators and isolators, and range of tests to be undertaken
- K10 the importance of physical environmental monitoring and the required testing frequency
- K11 your own level of responsibility relating to each part of this standard

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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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