



Australian Government

Assessment Requirements for FBPPHM3016 Operate a sterilisation process using an autoclave

Release: 1

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Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

Performance Evidence

An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.

There must be evidence that the individual has operated at least one sterilisation process using an autoclave, including:

- accessed workplace information to confirm sterilisation requirements
- confirmed supply of necessary wrapping, cleaning and material items for the sterilisation process
- prepared items by wrapping and marking with temperature-sensitive tape or material and ensured clothing is folded correctly
- positioned load probe and loaded items in correct orientation according to workplace procedures and load pattern requirements
- conducted pre-start checks required for safe operation of the autoclave, including:
 - carrying out required area or line clearances
 - inspecting equipment condition to identify signs of wear
 - confirming all safety equipment is in place and operational
 - confirming that equipment is clean or sanitised
- confirming that equipment is correctly configured for processing requirements
- started, operated, monitored and adjusted autoclave to achieve required outcomes, including time and temperature parameters
- conducted in-process control checks to confirm the process remains within limits
- collected samples and conducted tests according to workplace procedures
- taken corrective action in response to a non-conformance
- opened autoclave and removed items from autoclave according to workplace procedures
- used process control systems according to workplace procedures
- safely shut down the process according to workplace procedures
- cleaned and maintained work area to meet workplace cleaning standards and environmental requirements
- completed records according to workplace procedures.

Knowledge Evidence

An individual must be able to demonstrate the knowledge required to perform the tasks outlined in the elements and performance criteria of this unit. This includes knowledge of:

- stages of the sterilisation process, including:
 - principles of heat transfer
 - properties of saturated steam
 - the relationship between time, temperature and pressure as they affect the kill rate
 - variables that impact the effectiveness of sterilisation
- the nature of items to be sterilised using an autoclave and related handling and preparation requirements, including:
 - porous loads
 - non-porous loads
 - position of probes
- the nature of wrapping materials suitable for use, including:
 - methods used to wrap items
 - methods used to monitor whether time and temperature parameters are met (including heat-sensitive tape or markers)
 - the significance of loading patterns in achieving effective sterilisation
- basic operating principles of equipment, requirements and parameters of autoclave, including:
 - main equipment components
 - time and temperature parameters required to achieve sterilisation and corrective actions required where operation falls outside specified parameters
 - typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
 - status and purpose of guards
 - equipment operating capacities and applications
 - purpose and location of sensors and related feedback instrumentation
 - corrective actions required where operation is outside of specified parameters
 - calibration schedule and procedures to confirm that instruments are within calibration
- health and safety hazards related to autoclave operation and associated control measures, including working with superheated steam and hot surfaces, manual handling and steam leaks
- pre-start checks requirements, including:
 - carrying out required area or line clearances
 - inspecting equipment condition to identify signs of wear
 - confirming all safety equipment is in place and operational
 - confirming that equipment is clean or sanitised
 - confirming that equipment is correctly configured for processing requirements
- evaluation and in-process monitoring of sterilisation process indicators, including:
 - biological

- chemical
- physical
- methods used to monitor the sterilisation process, including:
 - inspecting
 - measuring
 - testing
- requirements of different shutdowns, including:
 - emergency and routine shutdowns
 - procedures to follow in the event of a power outage
- isolation, lock out and tag out procedures and responsibilities
- operating principles of process control
- Good Manufacturing Practice (GMP) requirements associated with a sterilisation process and related control measures
- environmental issues and controls relevant to the sterilisation process including waste collection and handling procedures
- requirements for completion of workplace documentation.

Assessment Conditions

Assessment of skills must take place under the following conditions:

- physical conditions:
 - a pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - autoclave and handling equipment
 - wrapping materials and tape/heat sensitive markers
 - materials for sterilisation
 - test equipment
 - cleaning materials and equipment associated with sterilisation process
 - record keeping system
- specifications:
 - sterilisation specifications, control points and processing parameters
 - recording requirements and procedures
 - workplace documentation relating to sterilisation process and procedures that comply with GMP requirements
 - load pattern requirements
 - sampling schedules and test procedures
 - cleaning procedures associated with sterilisation process.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>