



Australian Government

**Assessment Requirements for
FBPPHM3018 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 5.0.

Performance Evidence

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

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

- accessed Standard Operating Procedure (SOP) information to confirm sterilisation requirements
- confirmed supply of product or materials for the sterilisation process
- prepared items by stacking autoclave dolly with product for terminal sterilisation or wrapping, taping, or sealing in an autoclave bag product for aseptic processing
- marked bags with temperature-sensitive tape or chemical indicators
- positioned any moveable load probe and loaded items in correct orientation according to SOP and validated load pattern requirements
- conducted pre-start checks required for safe operation of the autoclave, including:
 - carried out required area or line clearances
 - inspected equipment condition to identify signs of wear
 - confirmed all safety equipment in place and operational
 - confirmed sterilising equipment clean or sanitised
 - confirmed all pre-start cycles have been run, including a leak test
- confirmed sterilising equipment correctly set up for processing requirements
- selected correct sterilisation cycle as per the SOP
- reviewed cycle print out to confirm the cycle was completed satisfactorily with no alarms or faults
- taken corrective action in response to a non-conformance
- opened autoclave and removed items from autoclave 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 SOP.

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:

- requirements for autoclaving for microbial reduction/sterility
- stages of the sterilisation process, including:
 - relationship between time, temperature and pressure as they affect kill rate
 - variables that impact effectiveness of sterilisation
- nature of items to be sterilised using an autoclave, different cycle types used and related handling and preparation requirements, including:
 - porous loads
 - non-porous loads
 - position of probes
- nature of wrapping materials suitable for use, including:
 - methods used to wrap or bag items
 - methods used to monitor whether time and temperature parameters are met, including heat-sensitive tape or markers
 - significance of validated loading patterns in achieving effective sterilisation
- basic operating principles of equipment, requirements and parameters of autoclave, including:
 - main equipment components including filters, vacuum pumps, condensers and the autoclave chamber
 - utilities requirements for a GMP autoclave including compressed air, electricity, processed water steam supply and cooling water
 - 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 check requirements, including:
 - carrying out required area or line clearances
 - inspecting equipment condition to identify signs of wear
 - confirming all safety equipment in place and operational
 - confirming equipment is clean or sanitised
 - confirming 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 the skills in this unit of competency must take place under the following conditions:

- physical conditions:
 - a workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - autoclave and handling equipment
 - loading bags or 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
 - product and intermediate product specifications, control points and processing parameters
 - workplace documentation relating to sterilisation process and procedures that comply with GMP
 - 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 Volumes, including Implementation Guides, are available at VETNet - <https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>