



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH2014A Operate a terminal sterilisation process

Revision Number: 1

FDFPH2014A Operate a terminal sterilisation process

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required to set up, operate, adjust and shut down a terminal sterilisation process using an autoclave. This may be used to sterilise items such as product prior to packing, equipment parts and clothing.
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Application of the Unit

Application of the unit	This unit has application in a production environment. It typically targets the production worker responsible for applying basic operating principles to the operation and monitoring of an autoclave.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.
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Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.
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Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare the equipment and process for operation	1.1. Items to be sterilised are confirmed and prepared 1.2. The autoclave is prepared for operation 1.3. Operating parameters are selected as required to meet safety and terminal sterilisation requirements 1.4. Pre-start checks are carried out as required by workplace requirements 1.5. Items are loaded according to load pattern
2. Operate the autoclave to terminally sterilise items	2.1. The autoclave is started and operated according to workplace procedures 2.2. Time and temperature parameters are monitored to confirm requirements are met 2.3. Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements 2.4. Workplace records are maintained according to workplace recording requirements 2.5. Work is conducted in accordance with workplace environmental guidelines
3. Remove items and follow shut down procedures	3.1. Items are removed from the autoclave according to workplace procedures 3.2. The process is shut down according to workplace procedures 3.3. Maintenance requirements are identified and reported according to workplace reporting requirements

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Ability to:

- access workplace information to identify sterilisation requirements
- select, fit and use personal protective clothing and/or equipment
- confirm supply of necessary materials and services
- prepare items by wrapping and marking with temperature-sensitive tape/material and ensure clothing is folded correctly
- load items according to loading pattern
- conduct pre-start checks on the autoclave, such as inspecting equipment condition to confirm that all water has been drained, pulling a vacuum to remove as much air as possible from the autoclave, selecting appropriate settings to meet sterilisation requirements, cancelling isolation or lock outs as required, confirming that equipment is clean and operational, positioning sensors and controls correctly, and ensuring all safety guards/signs are in place and operational
- start, operate and monitor the autoclave to confirm that the required outcomes are achieved, such as monitoring time, temperature and pressure gauges
- identify out-of-specification results and take appropriate corrective action within level of responsibility
- follow procedures to open autoclave and remove items from the autoclave to maintain sterility and personal safety
- respond to and/or report equipment failure within level of responsibility
- locate emergency stop functions on equipment
- follow isolation and lock out/tag out procedures as required to take process off-line in preparation for cleaning and/or maintenance within level of responsibility
- complete workplace records
- maintain work area to meet housekeeping standards
- use process control systems according to enterprise procedures
- collect samples and conduct tests according to enterprise procedures
- conduct routine maintenance according to enterprise procedures
- use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor
- work cooperatively within a culturally diverse workforce

Required knowledge

Knowledge of:

- purpose and basic principles of terminal sterilisation, including principles of heat

REQUIRED SKILLS AND KNOWLEDGE

- transfer, properties of saturated steam, and the relationship between time, temperature and pressure as they affect the kill rate
- the nature of items to be sterilised using an autoclave and related preparation requirements, such as handling/preparation requirements for porous and non-porous loads
- the nature of wrapping materials suitable for use, the methods used to wrap items, methods used to monitor that time/temperature parameters are met - typically heat-sensitive tape or markers and the significance of loading patterns in achieving effective sterilisation
- basic operating principles of equipment, such as main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation, and where relevant, the calibration schedule and procedures to confirm that instruments are within calibration
- services required and action to take if services are not available
- time/temperature parameters required to achieve terminal sterilisation and corrective action required where operation is outside specified operating parameters
- typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
- methods used to monitor the sterilisation process, such as inspecting, measuring and testing as required
- inspection or test points (control points) and the related procedures and recording requirements
- possible causes of variation in outcome and corrective action required
- occupational health and safety (OHS) hazards related to autoclave operation and associated control measures, such as working with superheated steam and around hot surfaces, manual handling and steam leaks
- purpose and limitations of protective clothing and equipment
- emergency and routine shutdown procedures and procedures to follow in the event of a power outage
- isolation, lock out and tag out procedures and responsibilities
- procedures and responsibility for recording and reporting information on autoclave performance
- environmental issues and controls relevant to the process, including waste/rework collection and handling procedures related to the process
- basic operating principles of process control, where relevant, including the relationship between control panels and systems and the physical equipment
- sampling and testing associated with process monitoring and control where relevant
- routine maintenance procedures where relevant
- cleaning and sanitation procedures where relevant

Evidence Guide

EVIDENCE GUIDE

The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.

Overview of assessment

Assessment must be carried out in a manner that recognises the cultural and literacy requirements of the assessee and is appropriate to the work performed. Competence in this unit must be achieved in accordance with food safety standards and regulations.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Evidence of ability to:

- conduct pre-start checks on autoclave and materials to be sterilised
- start, operate, monitor and adjust autoclave to achieve required quality outcomes
- take corrective action in response to typical faults and inconsistencies
- complete workplace records as required
- apply safe work practices and identify OHS hazards and controls
- safely shut down equipment and remove items
- apply food safety procedures to work practices.

Context of and specific resources for assessment

Assessment must occur in a real or simulated workplace where the assessee has access to:

- personal protective clothing and equipment
- work procedures, including advice on safe work practices, GMP, quality and environmental requirements
- information on equipment capacity and operating parameters
- sterilisation schedule/instructions
- specifications, control points and processing parameters
- autoclave equipment and services
- wrapping materials and tape/heat sensitive markers as required
- items to be sterilised
- materials handling equipment as required
- sampling schedules and test procedures and equipment as required

EVIDENCE GUIDE	
	• documentation and recording requirements and procedures • cleaning procedures, materials and equipment as required.
Method of assessment	This unit should be assessed together with core units and other units of competency relevant to the function or work role. Examples could be: • FDFOP2004A Clean and sanitise equipment • FDFOP2011A Conduct routine maintenance • FDFOP2013A Apply sampling procedures • FDFOP2030A Operate a process control interface • MSL973001A Perform basic tests.
Guidance information for assessment	To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

Range Statement

RANGE STATEMENT	
The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.	
Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity
Workplace information	Workplace information may include: • standard operating procedures (SOPs) • specifications • production schedules and instructions • manufacturers' advice • standard forms and reports
Materials	Materials include: • wrapping material • printed paper rolls • temperature-sensitive tape or other indicator
Operation of equipment and processes	Operation of equipment and processes may require: • the use of simple control panels
Services	Services may need to be confirmed. Typical examples include: • power

RANGE STATEMENT

	• steam • water • vacuum and compressed air
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Unit Sector(s)

Unit sector	Pharmaceutical manufacturing
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Competency field

Competency field	
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Co-requisite units

Co-requisite units		