Australian Government

HLTSTE012 Sterilise reusable medical devices

Release: 1

HLTSTE012 Sterilise reusable medical devices

Modification History

Release	Comments
1	This unit of competency was first released in HLT Health Release 11.0.

Application

This unit describes the skills and knowledge required to select and operate sterilisation equipment to produce sterile reusable medical devices according to organisational procedures. It involves loading items, monitoring and interpreting sterilisation cycle parameters, and verifying results to release items for distribution.

This unit applies to individuals working under general supervision and within established procedures in a range of health and non-health facilities.

The skills in this unit must be applied in accordance with current Commonwealth and State/Territory legislation, Australian Standards and industry codes of practice.

Licensing/Regulatory Information

No licensing, legislative or certification requirements apply to this unit at the time of publication.

Pre-requisite unit(s)

No pre-requisite units

Competency field(s)

N/A

Unit sector(s)

Sterile Medical Equipment

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
Elements define the essential outcomes	*Performance criteria describe the performance required to demonstrate achievement of the element*
1. Prepare sterilisation equipment	1.1 Operate sterilising equipment according to work health and safety, personal protective equipment requirements, manual

	handling techniques, infection prevention and control principles and manufacturer’s instructions for use 1.2 Clean and check steriliser and steriliser accessory equipment according to manufacturer’s instructions for use 1.3 Complete and record sterilising equipment maintenance and performance test cycles 1.4 Interpret and record physical, biological and chemical test results 1.5 Handle, transport, and store chemical sterilants according to safety data sheets (SDS) 1.6 Select and use approved chemical sterilants according to regulatory requirements, safety data sheets (SDS) and manufacturer’s instructions for use
2. Load steriliser	2.1 Select sterilisation method according to reusable medical devices manufacturer's instructions for use, organisational procedures and product family 2.2 Confirm compliance of packaging, sealing and labelling according to organisational procedures 2.3 Confirm compliance of load content and configuration according to annual performance qualification process 2.4 Record reusable medical devices to maintain traceability according to Standard and organisational procedures 2.5 Load steriliser to ensure sterilant contact according to manufacturer’s instructions for use 2.6 Position biological indicators and process challenge devices within the load according to manufacturer's instructions for use and organisational procedures
3. Operate steriliser	3.1 Verify function of steriliser and physical process recording accessories according to manufacturer's instructions for use 3.2 Select sterilising cycle according to reusable medical devices manufacturer's instructions for use, organisational procedures and product family 3.3 Commence sterilising cycle and monitor equipment according to organisational procedures 3.4 Identify, report and action faults according to organisational procedures
4. Unload and release sterilised loads	4.1 Remove sterilised load on completion of cycle according to organisational procedures

	4.2 Identify and record non-conforming reusable medical devices according to organisational procedures 4.3 Inspect and document results for biological and chemical indicators according to manufacturer's instructions for use and organisational procedures 4.4 Place in designated cooling area 4.5 Record and remove compromised reusable medical devices and dismantle for reprocessing 4.6 Verify and confirm sterilisation process 4.7 Confirm cycle records conform to validated process specifications and traceability requirements according to Standard, manufacturer's instructions for use and organisational procedures 4.8 Release load according to Standard and organisational procedures 4.9 Transfer cooled load and dispatch to sterile store area according to organisational procedures
5. Comply with quality sterilising process requirements	5.1 Monitor and maintain sterilisers and related equipment according to the Standard and organisational procedures 5.2 Respond to routine problems according to Standard, manufacturer's instructions for use and organisational procedures 5.3 Complete documentation requirements for sterilising cycles, batch control and load release control 5.4 Identify, document and report non-conformance in the sterilisation process and rectify according to organisational procedures 5.5 Store documentation according to organisational procedures

Foundation skills

The foundation skills essential to performance of this unit, but not explicit in the performance criteria are listed here, along with a brief context statement.

Skills	Description
Learning skills to:	• use organisational procedures, safety data sheets, manufacturer's instructions and Standards for sterilising reusable medical devices.
Reading skills to:	• interpret organisational procedures, unfamiliar technical safety data sheets, manufacturer's instructions, and Standards to use chemical sterilants.

Numeracy skills to:	• interpret and record physical, biological and chemical test results. • Set and select functions and parameters of sterilising equipment.

Digital literacy outcomes are included in the Foundation Skills Companion Volume.

Range of conditions

N/A

Assessment Requirements for HLTSTE012 Sterilise reusable medical devices

Performance Evidence

The candidate must show evidence of the ability to complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the job role. There must be evidence that the candidate has:

- followed established procedures, work processes and national standards to prepare, operate, load and unload sterilisers and release the sterilised loads on at least 3 separate occasions, including:
    - interpreted and recorded cycle information using at least 1 of the following:
        - manual or electronic tracking system
    - completed all documentation for cycles, tests and load contents, including specialised item
    - addressed relevant work health and safety, infection prevention and control and manual handling requirements
    - identified, reported and implemented corrective actions for routine process problems or equipment faults according to organisational procedures

Knowledge Evidence

The candidate must be able to demonstrate essential knowledge required to effectively complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the work role. This includes knowledge of:

- the requirements of Standard AS5369 for sterilisation
- terminology used in sterilising and methods of sterilisation, including: ISO11139 and methods of sterilisation used in Australia
- routine monitoring for sterilisation processes
- water quality monitoring
- environmental conditions required for efficient functioning of a sterilisation area, including:
    - quarantine protocols
    - conditions and parameters for successful sterilisation
- cleaning protocols and special requirements for sterilisers and load carriers
- features of steam sterilisation, including:
    - cycle stages and physical parameters for successful sterilisation
    - principles of steam generation and steam quality that impact on sterilisation outcomes

    - significant mechanical components of steam sterilisers
    - the biocidal action of steam under pressure and the impact on sterilisation outcomes
    - monitoring equipment and procedures
    - reusable medical device compatibility and limitations
    - safety precautions and procedures
- features of other sterilisation methods, including:
    - low temperature sterilisation
    - ethylene oxide
    - low temperature steam with formaldehyde
    - chemical sterilants
    - dry heat
    - radiation sterilisation
- product family and its purpose for sterilisation
- validation requirements, including:
    - installation qualification
    - operational qualification
    - performance qualification
    - air removal test
    - process challenge device
    - leak rate test
    - physical, chemical and biological monitoring devices
    - calibration
- requirements of quality assurance documentation, including release processes
- traceability requirements for sterilisation
- safe work practices in the sterilisation work area, including:
    - manual handling risks associated with mobilising sterilising trolleys – loading and unloading
    - infection prevention and control
    - personal protective equipment (PPE)
    - problem identification and reporting

Assessment Conditions

Skills must have been demonstrated in the workplace or in a simulated environment that reflects workplace conditions. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
    - AS5369
    - sterilisers and required equipment
    - reusable medical devices
    - personal protective equipment (PPE)
    - manufacturer's instructions for use
    - quality assurance documentation
    - organisational procedures to be followed
- modelling of industry operating conditions, including:
    - requirements for the sterilisation process
    - presence of situations requiring problem-solving

Assessors must satisfy the current Standards for Registered Training Organisations (RTO's)/AQF mandatory competency requirements for assessors.

Mandatory Workplace Requirements

Assessment of performance evidence may be in a workplace setting or an environment that accurately represents a real workplace.

Unit Mapping Information

Previous Code and Title	Equivalence	Comments
HLTSTE003 Sterilise loads	Equivalent	Significant changes to unit application. Minor changes to the elements and performance criteria. Minor change to performance evidence and knowledge evidence.

Links

Companion volumes, including implementation guides, are found on the national training register - https://training.gov.au/training/details/HLT.