Summary of Proposed Changes

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Document Modification History

Version	Status	Release date	Summary of changes
2.0	Current	20 Feb 2026	Document published
1.0	Archived	24 Oct 2025	Document published

1. Introduction

This summary of the proposed changes aims to inform stakeholders of the proposed changes under consideration, in preparation for the upcoming public and government consultation period for this project. It provides:

- an overview of the project's scope, including the purpose of the affected qualification/s
- a summary of the proposed changes to the qualifications and units of competency
- consultation plan, and next steps.

The aim is to ensure stakeholders have a clear understanding of the proposed revisions, the reasons behind them, and how they can meaningfully contribute to shaping the future of these training products during the consultation.

2. Project Overview

This project is part of HumanAbility's suite of training product development initiatives aimed at ensuring qualifications, skill sets and units remain current, industry-relevant and responsive to emerging workforce needs.

A Technical Committee, drawing on expertise across industry, regulatory and provider domains, have guided the development of the draft training products.

A consultation log will be maintained and published to ensure transparency and traceability of stakeholder feedback and project responses.

Once feedback is considered and revisions incorporated, where compliant with the Training Package Organising Framework, the final drafts will be submitted for endorsement and, if approved, implemented and published on the National Training Register.

3. Project Scope

The primary objective of this project is to review 2 sterilisation services qualifications and 8 sterilisation services units of competency within the *HLT Health Training Package*, with an aim of restructuring and redesigning these components to address current and future skill needs, regulatory requirements, the latest technology and sustainable career pathways to support existing and future growth in the industry.

Qualifications

The purpose of these 2 qualifications is to support a specific occupation. The *HLT37015 Certificate III in Sterilisation Services* also supports pathways and applied learning.

- *HLT37015 Certificate III in Sterilisation Services*
- *HLT47015 Certificate IV in Sterilisation Services*

Units of Competency

- *HLTSTE001 Clean and disinfect reusable medical devices*
- *HLTSTE002 Inspect and pack reusable medical devices*
- *HLTSTE003 Sterilise loads*
- *HLTSTE004 Manage sterile stock*
- *HLTSTE005 Care for reusable medical devices*
- *HLTSTE006 Chemically disinfect reusable medical devices*
- *HLTSTE007 Monitor and maintain cleaning and sterilisation equipment*
- *HLTSTE008 Monitor quality of cleaning, sterilisation and packaging processes*

4. Summary of Proposed Changes

4.1 Qualification

Table 1: Proposed changes to *HLT37015M Certificate III in Sterilisation Services*

Section	Draft 2. Public and Government Consultation
Description	Revised application to update terminology. Use of “reusable medical devices” in all instances.
Foundation Skills Outcomes	New field. Indicates the foundation skill outcomes a competent learner is expected to have upon completion of the qualification.
Packaging Rules	Total number of units – 16 units (previously 14 units) Number of core units – 12 core units (previously 10 units) Number of elective units – 4 units (no changes)

Table 2: Proposed changes to *HLT47015M Certificate IV in Sterilisation Services*

Section	Draft 2. Public and Government Consultation
Description	Revised application terminology. Use of “reusable medical devices” in all instances.
Foundation Skills Outcomes	New field. Indicates the foundation skill outcomes a competent learner is expected to have upon completion of the qualification.
Entry Requirements	Entry to qualification is open to individuals who hold: HLT37015 Certificate III in Sterilisation Services OR HLT31112 Certificate III in Sterilisation Services OR

	HLT31107 Certificate III in Sterilisation Services AND 12 months full time experience or part time equivalent in a reprocessing environment
Packaging Rules	Total number of units – 11 units (previously 16 units) Number of core units – 7 units (previously 11 units) Number of elective units - no changes

4.2 Units of Competency

Table 3: Proposed changes to *HLTSTE001M Clean and disinfect reusable medical devices*

Section	Draft 2. Public and Government Consultation
Title	Clean reusable devices to reflect unit outcomes
Application	Reworded to include current terminology
Elements and performance criteria	Elements and performance criteria reworded to include current terminology. Performance criteria reordered to meet workflow requirements References to disinfection removed
Foundation Skills	Added
Performance Evidence	Reworded for clarity
Knowledge Evidence	Reworded for clarity and to incorporate current terminology Additional information included to support performance criteria
Assessment Conditions	Reworded for clarity Assessor requirements updated to include RTO requirements

Table 4: Proposed changes to *HLTSTE002M Inspect and pack reusable medical devices*

Section	Draft 2. Public and Government Consultation
Title	Inspect, assemble and package reusable medical devices to reflect unit outcomes
Application	Reworded to include current terminology and reflect unit outcomes
Elements and performance criteria	Elements and performance criteria reworded to include current terminology Performance Criteria 2.2, 2.7, 3.2 removed as no longer relevant to unit Performance Criteria renumbered to accommodate removal of PC2.2, PC2.7 and PC2.8 Performance Criteria 3.8, 4.7, 4.8, 4.9 added
Foundation skills	Added
Performance Evidence	Reworded for clarity

Knowledge Evidence	Reworded to include current terminology
Foundation Skills	Added
Assessment Conditions	Reordered to meet work role Assessor requirements updated to include RTO requirements

Table 5: Proposed changes to *HLTSTE003M Sterilise loads*

Section	Draft 2. Public and Government Consultation
Title	Reworded to Sterilise reusable medical devices, to include current terminology
Application	Reworded to include current terminology
Elements and Performance Criteria	Reworded to reflect work role and include current terminology Performance criteria reworded to include current equipment used in work role
Performance Evidence	Reworded for clarity
Knowledge Evidence	Reworded to update terminology and clarification
Foundation Skills	Added
Assessment Conditions	Reworded to include current terminology Assessor requirements updated to include RTO requirements

Table 6: Proposed changes to *HLTSTE004M Manage sterile stock*

Section	Draft 2. Public and Government Consultation
Title	Handle, transport and store reusable medical devices to clarify unit outcomes and include current terminology
Application	Reworded to include current terminology and reflect change to unit title
Elements and performance criteria	PCs reworded to include current terminology PCs reordered to reflect workflow
Foundation Skills	Added
Performance Evidence	Updated wording Reworded for clarity
Knowledge Evidence	Updated terminology
Assessment Conditions	Reworded to current terminology Reordered to reflect workflow Assessor requirements updated to include RTO requirements

Table 7: Proposed changes to *HLTSTE005M Care for reusable medical devices*

Section	Draft 2. Public and Government Consultation
Title	Care and maintain reusable medical devices reworded to relect unit outcomes
Application	Reworded to reflect unit title
Elements and Performance Criteria	Reworded to include current terminology Reordered to support workflow Added PCs to support unit outcome
Foundation Skills	Added
Performance evidence	Reworded for clarification Reusable medical device list updated
Knowledge Evidence	Reworded to support performance criteria
Assessment Conditions	Reworded to include updated terminology Assessor requirements updated to include RTO requirements

Table 8: Proposed changes to *HLTSTE006M Chemically disinfect reusable medical devices*

Section	Draft 2. Public and Government Consultation
Title	Disinfect reusable medical devices updated to reflect unit outcome
Application	Reworded to reflect unit outcome and update terminology
Elements and Performance Criteria	All references to cleaning, inspection and packing removed
Foundation Skills	Added
Performance Evidence	Reworded to include disinfection process and clarity
Knowledge Evidence	Reworded to include current terminology, current disinfection methods Reworded to support performance criteria by removing references to cleaning and packing
Assessment Conditions	Reworded to meet unit outcomes and current terminology Assessor requirements updated to include RTO requirements

Table 9: Proposed changes to *HLTSTE007M Monitor and maintain cleaning and sterilisation equipment*

Section	Draft 2. Public and Government Consultation
Title	Reworded to Monitor and maintain reprocessing equipment

Application	Reworded to reflect unit outcomes
Elements and Performance Criteria	Reworded to reflect unit outcomes and include current terminology Additional PCs created to support unit outcomes
Foundation Skills	Added
Performance Evidence	Reworded to reflect change in unit outcomes and for clarification
Knowledge Evidence	Reworded to reflect change in unit outcomes and for clarification Additional KE's to support PC's
Assessment Conditions	Reworded to meet unit outcomes and inclusion of current terminology Assessor requirements updated to include RTO requirements

Table 10: Proposed changes to *HLTSTE008M Monitor the quality of cleaning, sterilisation and packaging processes*

Section	Draft 2. Public and Government Consultation
Title	Monitor the quality of reprocessing for reusable medical devices
Application	Reworded to reflect terminology included in unit
Elements and Performance Criteria	Reworded to reflect unit outcomes Reworded to support the work role of the candidate Updated terminology Element 5 reworded and combined with Element 4 and renamed to "Monitor reprocessing and maintenance records". Element 6 renumbered to Element 5
Foundation Skills	Added
Performance Evidence	Reworded for clarity Reordered to reflect workflow
Knowledge Evidence	Reworded to include current terminology
Assessment Conditions	Reworded to include current terminology Assessor requirements updated to include RTO requirements

5. Next Steps

Public and Government Consultation is expected to take place from 20 February 2026 – 13 March 2026.

During the consultation period, the project team will facilitate ways for stakeholders to engage and provide feedback, including the following:

- Consultation survey enabling stakeholders to provide feedback via HumanAbility's website
- Opportunity to provide written feedback via email directly to the project team.

We invite stakeholders including employers, service providers, regulatory bodies, First Nations communities, training organisations, students and communities, to engage in the format that best suits them.

Throughout the consultation, a consultation log of feedback has been maintained and will be made public, along with rationales for any decisions or revisions. After consultation closes, the project team, with input from the Technical Committee, will review all feedback and update the drafts accordingly. Divergent views will be addressed, and if necessary, further validation will occur. Final drafts will then be submitted to the Assurance Body and the Skills Ministers for consideration, endorsement, and implementation.

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HumanAbility is a Jobs and Skills Council funded by the Australian Government Department of Employment and Workplace Relations.

<table>
<tr><td>Qualification code</td><td>HLT37026</td></tr>
<tr><td>Qualification title</td><td>Certificate III in Sterilisation Services</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><td>Release</td><td>Comment</td></tr>
<tr><td>Release 1.</td><td>Total number of units increased from 14 to 16. Core units increased from 10 to 12</td></tr>
</table>
</td></tr>
<tr><td>Qualification description</td><td>This qualification reflects the job role of sterilisation technicians who receive, clean, package and reprocess reusable medical devices and other devices in a sterilising service or reprocessing area. They take responsibility for their own work under general supervision. They combine communication and technical skills and use discretion to adapt and transfer their skills to different situations.
No licensing, legislative, or certification requirements apply to this qualification at the time of publication.</td></tr>
<tr><td>Packaging rules</td><td>Candidates must complete the following:
Total number of units = 16
12 core units
4 elective units, consisting of:
4 units from the electives listed below, or from any endorsed Training Package or Accredited Course
Electives units must ensure the integrity of the qualification’s Australian Qualification Framework (AQF) alignment and contribute to a valid, industry-supported vocational outcome.
Core units</td></tr>
</table>

	BSBMED301 Interpret and apply medical terminology appropriately CHCCOM005 Communicate and work in health or community services CHCDIV001 Work with diverse people HLTINF006 Apply basic principles and practices of infection prevention and control HLTSTE001M Clean and disinfect reusable medical devices HLTSTE002M Inspect and pack reusable medical devices HLTSTE003X Sterilise loads HLTSTE004M Manage sterile stock HLTSTE005M Care for reusable medical devices HLTSTE006M Chemically disinfect reusable medical devices HLTWHS001 Participate in workplace health and safety HLTWHS005 Conduct manual tasks safely **Elective units** BSBINS302 Organise workplace information BSBOPS301 Maintain business resources BSBPEF202 Plan and apply time management BSBPEF301 Organise personal work priorities BSBTEC201 Use business software applications BSBTWK201 Work effectively with others FSKOCM006 Use oral communication skills to participate in workplace teams HLTAID011 Provide First Aid HLTHSS011 Maintain stock inventory TLIE0002 Process work documentation

	Digital literacy outcomes may be included in the Companion Volume Implementation Guide as appropriate.
Entry requirements *Optional field*	*N/A*
Qualification mapping information	*Supersedes and is equivalent to HLT37015 Certificate III in Sterilisation Services.*
Links	*Link to Companion Volume Implementation Guide.*

<table>
<tr><td>Qualification code</td><td>HLT47026</td></tr>
<tr><td>Qualification title</td><td>Certificate IV in Sterilisation Services</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><th>Release</th><th>Comment</th></tr>
<tr><td>Release 1.</td><td>Total number of units reduced from 15 to 11. Core units reduced from 11 to 7. Added new entry requirements.</td></tr>
</table>
</td></tr>
<tr><td>Qualification description
Mandatory field</td><td>This qualification reflects the role of a team leader or senior technician working in a sterilisation or reprocessing area. Individuals take responsibility for their own work and supervise others. They are responsible for the maintenance of quality requirements and monitoring of technical sterilisation functions.
No licensing, legislative or certification requirements apply to this qualification at the time of publication.</td></tr>
<tr><td>Packaging rules</td><td>Candidates must complete the following:
Total number of units = 11
7 core units
4 elective units, consisting of:
at least 2 units from the electives listed below
other 2 units from the electives listed below or from any endorsed Training Package or Accredited Course
Elective units must ensure the integrity of the Australian Qualification Framework (AQF) alignment and contribute to a valid, industry-supported vocational outcome.
Core units</td></tr>
</table>

	BSBLDR411 Demonstrate leadership in the workplace BSBSTR402 Implement continuous improvementHLTINF007 Implement and monitor infection prevention and control standards, policies and procedures HLTSTE007M Monitor and maintain reprocessing equipment HLTSTE008M Monitor quality of reprocessing for reusable medical devicesHLTWHS003 Maintain work health and safetyHLTWHS006 Manage personal stressors in the work environment ***Elective units*** BSBAUD411 Participate in quality audits BSBAUD412 Work within compliance frameworks BSBHRM413 Support the learning and development of teams and individualsBSBLDR413 Lead effective workplace relationships BSBPEF402 Develop personal work prioritiesBSBSTR401 Promote innovation in team environments BSBTWK301 Use inclusive work practices FSKOCM011 Use oral communication skills to facilitate complex workplace team interactions HLTINF004 Manage the prevention and control of infection HLTWHS004 Manage work health and safety TAEDEL414 Mentor in the workplace
Foundation skills outcomes	*Digital literacy outcomes may be included in the Companion Volume Implementation Guide as appropriate.*
Entry requirements	*Entry to this qualification is open to individuals who hold:* *HLT37026 Certificate III in Sterilisation Services or any equivalent successor*

	Or *HLT37015 Certificate III in Sterilisation Services* *Or* *HLT31112 Certificate III in Sterilisation Services* *Or* *HLT31107 Certificate III in Sterilisation Services* *and* *12 months full-time experience or part-time equivalent in a reprocessing environment.*
Qualification mapping information	*Supersedes and is not equivalent to HLT47015 Certificate IV in Sterilisation Services*
Links	*Link to Companion Volume Implementation Guide.*

Unit of Competency code and title

HLTSTE001M Clean reusable medical devices

<table>
<tr><td>Unit code</td><td>HLTSTE001M</td></tr>
<tr><td>Unit title</td><td>Clean reusable medical devices</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><th>Release</th><th>Comments</th></tr>
<tr><td>Release 1.</td><td>Minor changes to the application. Minor changes elements and performance criteria. Minor changes to performance evidence requirements for assessment, Minor changes to knowledge evidence.</td></tr>
</table>
</td></tr>
<tr><td>Application</td><td>This unit describes the skills and knowledge required to sort, inspect and clean soiled reusable medical devices including the effective use of equipment and completion of quality checks and documentation according to organisational procedures.
This unit applies to individuals working under general supervision and within established procedures in a range of health and non-health related facilities that process reusable medical devices.
The skills in this unit must be applied in accordance with current Commonwealth and State/Territory legislation, Australian standards and industry codes of practice.</td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td></tr>
<tr><td>.</td><td>NA</td></tr>
<tr><td>Unit sector</td><td>Sterile Medical Equipment</td></tr>
<tr><td>Elements</td><td>Performance criteria</td></tr>
<tr><td>1. Receive and sort reusable medical devices</td><td>1.1 Prepare and use personal protective equipment (PPE)
1.2 Collect and transport items to cleaning area according to collection procedures and organisational requirements
1.3 Organise workflow using dirty to clean principle
1.4 Sort reusable medical devices and dispose of single use devices and sharps according to organisational procedures</td></tr>
</table>

Unit of Competency code and title

	1.5 Check for completeness of set and for multi-part reusable medical devices 1.6 Identify and separate items requiring segregation or specialised processing 1.7 Identify and respond to priority processing requirements 1.8 Report faulty and damaged items to designated person
2. Prepare contaminated reusable medical devices for cleaning	2.1 Test and prepare equipment and cleaning chemicals for use according to organisational procedures 2.2 Prepare specialised items for specific cleaning procedures according to manufacturer's instructions for use 2.3 Disassemble reusable medical devices and other devices for cleaning processes according to manufacturer's instructions for use 2.4 Determine manual or automated cleaning processes and required equipment according to manufacturer's instructions for use, organisational procedures and product family
3. Pre-cleaning of reusable medical devices	3.1 Perform pre-cleaning using soaking, flushing and brushing techniques for reusable medical devices according to manual handling techniques, manufacturer's instructions for use and organisational procedures 3.2 Operate ultrasonic cleaning equipment in accordance with manufacturer's instructions for use and organisational procedures
4. Complete cleaning of reusable medical devices	4.1 Clean reusable medical devices using manual or automated process including the use of required chemicals according to Standard, manufacturer's instructions for use and organisational policies 4.2 Operate cleaning equipment using safe manual handling techniques 4.3 Minimise the risk of cross contamination during the manual and automated cleaning process

Unit of Competency code and title

	4.4 Verify manual and automated cleaning and drying outcomes against release criteria and reprocess if required
5. Load medical devices for automated cleaning	5.1 Select automated cleaning equipment including loading devices 5.2 Load reusable medical devices into automated cleaning equipment using configurations that optimise cleaning efficacy according to organisational procedures 5.3 Check load content and configuration for compliance with annual performance qualification process and report non-compliance
6. Monitor and maintain quality of cleaning process	6.1 Monitor cleaning processes and respond to routine problems according to Standard and organisational procedures 6.2 Monitor water quality according to organisational procedures 6.3 Complete quality management documentation according to organisational procedures 6.4 Identify and report non-compliance in the cleaning process and action according to organisational procedures. 6.5 Record reusable medical devices using manual or electronic tracking system according to Standard and organisational procedures 6.6 Release load according to Standard and organisational procedures

Unit of Competency code and title

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

Range of conditions

N/A

Assessment requirements	

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 Standard for the sorting, disassembly and cleaning of 3 reusable medical devices on at least 3 separate occasions, 9 devices in total
	• identified and responded to at least 2 processes variations or routine problems listed below:
	  ○ an aborted automated cycle or equipment fault code.
	  ○ a failed cleaning efficacy test
	  ○ *a change in water quality parameters*
	• addressed relevant work health and safety, infection prevention and control and manual task requirements.

Unit of Competency code and title

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:
	• requirements of Standard AS5369 and its role in the cleaning of reusable medical devices
	• interpretation and application of manufacturer's instruction for use across all cleaning stages
	• cleaning requirements, including the use of cleaning brushes and accessories
	• cleaning chemicals included approved instrument grade detergents
	• methods to remove soil, dyes and adhesives
	• cleaning requirements for different types of reusable medical devices including:
	  ○ plain reusable medical devices
	  ○ lumened reusable medical devices
	  ○ specialised and complex reusable medical devices
	• types and features of cleaning and drying equipment, and their monitoring and maintenance requirements
	• steps in the cleaning and disinfection workflow process and the reasons for design of work area
	• routine monitoring and efficacy testing of cleaning processes and equipment
	• water quality monitoring
	• waste minimisation, removal and safe disposal
	  ○ cleaning terminology
	• safe work practices in the cleaning area
	• key aspects of cleaning, including:
	  ○ infection prevention and control
	  ○ personal protective equipment (PPE)

	○ sharps management ○ segregation ○ safe chemical handling ○ safety data sheets ○ importance of maintaining passivation layer lubrication requirement • Spaulding's classification ○ critical ○ semi-critical ○ non-critical • conditions and parameters for cleaning • quality monitoring ○ risk factors ○ control measures.
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* ○ *3 different reusable medical devices requiring cleaning* ○ manufactured soil ○ *PPE* ○ *organisational procedures for operation of cleaning and drying equipment* ○ *traceability and quality assurance documentation* ○ *scenarios including situations requiring problem solving.* *Assessors must satisfy the Standards for Registered Training Organisations (RTO's)/AQF mandatory competency requirements for assessors.*

Unit of Competency code and title

Unit mapping information	*Supersedes and is equivalent to HLTSTE001 Clean and disinfect reusable medical devices.*
Links	*Link to Companion Volume Implementation Guide.*

HLTSTE002M Inspect, assemble and package reusable medical devices

<table>
<tr><td>Unit code</td><td>HLTSTE002M</td><td></td></tr>
<tr><td>Unit title</td><td>Inspect, assemble and package reusable medical devices</td><td></td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><td>Release</td><td>Comment</td></tr>
<tr><td>Release 2.</td><td>Minor changes to application, elements and performance criteria. Minor changes to performance evidence and knowledge evidence.</td></tr>
<tr><td>Release 1.</td><td>Significant changes to application. Significant changes to the elements and performance criteria. Significant changes to performance evidence and knowledge evidence. Minor changes to assessment conditions.</td></tr>
</table>
</td><td></td></tr>
<tr><td>Application</td><td>This unit describes the skills and knowledge required to inspect, assemble and package cleaned reusable medical devices according to manufacturer’s instructions for use.
This unit applies to individuals working under general supervision and within established procedures in a range of health and non-health related 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.</td><td></td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td><td></td></tr>
<tr><td>Competency field</td><td>NA</td><td></td></tr>
</table>

Unit sector	Sterile Medical Equipment	
Elements	**Performance criteria**	
1. Prepare for inspection and packing	1.1 Select and wear appropriate attire and complete personal hygiene requirements according to organisational procedures 1.2 Clean work area prior to processing reusable medical devices according to infection prevention and control guidelines 1.3 Prepare and test auxiliary equipment for use and document results 1.4 Retrieve clean reusable medical devices according to organisational procedures 1.5 Minimise the risk of cross contamination of cleaned reusable medical devices	
2. Inspect reusable medical devices	2.1 Sort and separate reusable medical devices according to, specialties, product families, packaging and reprocessing requirements, according to manufacturer's instructions for use 2.2 Visually inspect all reusable medical device surfaces for cleanliness and dryness 2.3 Determine the need for a magnified viewer and use it based on device complexity 2.4 Identify non-compliant reusable medical devices and return for reprocessing according to organisational procedures 2.5 Inspect reusable medical devices for completeness and functionality according to manufacturer's instructions for use 2.6 Complete insulation testing and document results according to manufacturer's instructions for use and organisational procedures	
3. Prepare and assemble	3.1 Select, inspect and prepare reusable medical device tray	

reusable medical devices	3.2 Open, unlock and reassemble hinged, ratcheted or multi-part reusable medical devices to confirm functionality and completeness 3.3 Disassemble multi-part reusable medical devices to ensure sterilant contacts all surfaces 3.4 Assemble reusable medical devices according to the reusable medical device tray checklist and organisational procedures 3.5 Lubricate reusable medical devices according to manufacturer's instructions for use 3.6 Prepare reusable hollow ware sets with all openings facing the same direction 3.7 Protect delicate and sharp reusable medical devices according to organisational procedures 3.8 Process chemical indicators according to organisational procedures	
4. Package reusable medical devices	4.1 Select sterile barrier systems according to sterilisation method, organisational procedures and manufacturer's instructions for use 4.2 Inspect sterile barrier systems for cleanliness and defects 4.3 Prepare auxiliary equipment including rigid containers in accordance with manufacturer's instructions for use 4.4 Pack and seal sterile barrier systems according to manufacturer's instructions for use and organisational procedures 4.5 Label sterile barrier systems according to organisational traceability and storage procedures 4.6 Prepare and package semi-critical disinfected reusable medical devices for storage and transfer to appropriate location 4.7 Record quality assurance documentation using a tracking system 4.8 Assemble, inspect and package reusable medical devices according to safe manual handling techniques	

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*

Range of conditions

N/A

Assessment requirements

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 for the inspection, assembly, packaging and labelling of 3 reusable medical devices on at least 3 separate occasions, 9 devices in total, ensuring the total evidence includes at least one of each of the following:
  - solid plain reusable medical devices
  - reusable medical devices requiring disassemble
  - reusable medical devices with textured surface
  - delicate reusable medical devices
  - manual and powered reusable medical devices
- operated and monitored equipment required for packaging reusable medical devices on at least 3 separate occasions, ensuring the total evidence includes at least one of each of the following cannulated devices:
  - illuminated magnifier
  - cannulated, lumened reusable medical devices
  - blind ended instruments
  - insulation testing and inspection of integrity of electrosurgical devices

	• completed quality assurance documentation for each of the 3 occasions, including recording and reporting any identified process and maintenance problems or variations • addressed relevant work health and safety, infection prevention and control and manual handling requirements.	

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:
	• packaging in relation to client safety, and implications of negligence
	• the requirements of AS5369 and its role in inspection, assembly and packaging reusable medical devices and other devices
	• the role of regulatory requirements, safety data sheets (SDS) for sterile barrier systems
	• different types of sterile barrier systems including:
	  ○ single use
	  ○ rigid containers
	  ○ preformed sterile barrier systems
	• product families and their relationship to reprocessing requirements
	• use of reusable medical devices in different operative procedures
	• testing and inspection requirements for reusable medical devices:
	  ○ ensure reusable medical device is clean, free from soil and dry prior to packing	

	○ systems for identifying reusable medical devices and other devices ○ importance of inspection of insulation testing ○ report and remove damaged devices according to organisational procedures • features of inspection, assembly, packing and test equipment including: ○ air guns ○ lighted magnification ○ automated lubrication device ○ heat sealer ○ drying cabinets ○ height adjustable workstations ○ insulation testing ○ labelling systems ○ manual and electronic tracking systems ○ patient specific implants ○ instrument checklists ○ reporting processes • packaging materials and wrapping techniques: ○ ensuring packaging material meets integrity standards ○ relationship of sterile barrier systems and wrapping material to sterilisation method used ○ sealing materials ○ single use and reusable sterile barrier systems ○ rigid reusable container systems • classes of chemical indicators • electronic or manual tracking, identification and traceability systems • performance qualification for packaging • features of quality assurance documentation	

	• safe work practices in the inspection and packing work area:
	  ○ manual task risk factors
	  ○ *infection prevention and control*
	  ○ *personal hygiene, including facial hair.*	

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
	  ○ PPE
	  ○ equipment manufacturer's instructions for use
	  ○ sterile barrier systems
	  ○ insulation testing systems
	  ○ heat sealing equipment with different temperatures
	  ○ sterile barriers systems
	  ○ quality assurance documentation
	  ○ electronic or manual tracking system
	  ○ inspection, assembly and packing procedures
	• modelling industry operating conditions, including:
	  ○ presence of situations requiring problem solving.
	
	Assessors must satisfy the Standards for Registered Training Organisations (RTO's)/AQF mandatory competency requirements for assessors	

Unit mapping information	Supersedes and is equivalent to HLTSTE002 Inspect and pack reusable medical devices	
Links	*Link to Companion Volume Implementation Guide.*	

HLTSTE003X Sterilise reusable medical devices

<table>
<tr><td>Unit code</td><td>HLTSTE003X</td></tr>
<tr><td>Unit title</td><td>Sterilise reusable medical devices</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><td>Release</td><td>Comment</td></tr>
<tr><td>Release 1</td><td>Significant changes to application. Minor changes to the elements and performance criteria. Minor change to performance evidence. Minor changes to knowledge evidence.</td></tr>
</table>
</td></tr>
<tr><td>Application</td><td>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.</td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td></tr>
<tr><td>Competency field</td><td>NA</td></tr>
<tr><td>Unit sector</td><td>Sterile Medical Equipment</td></tr>
</table>

Elements Performance criteria	**Performance criteria** Performance criteria describe the performance needed to demonstrate achievement of the element. Required knowledge, skills and application should be considered and clearly articulated.
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, store and use chemical sterilants in accordance with 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 appropriate sterilisation method according to reusable medical devices manufacturer's instructions for use 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 and organisational procedures 3.3 Commence the sterilising cycle and monitor equipment operation to ensure cycle parameters are met 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 4.3 Process, inspect and document results for external biological and chemical indicators, cycle parameters and batch control device according to manufacturer's instructions for use 4.4 Monitor load and place in designated cooling area 4.5 Record and remove compromised reusable medical devices and dismantle for reprocessing 4.6 Verify and record sterilising processes confirming cycle records conform to validated process specifications and

	traceability requirements according to Standard, manufacturer's instructions for use and organisational procedures 4.7 Transfer cooled load and dispatch to sterile store area according to organisational procedures 4.8 Release load according to Standard and organisational procedures
5. Comply with quality management requirements	5.1 Respond to routine problems according to Standard, manufacturer's instructions for use and organisational procedures 5.2 Monitor and maintain sterilisers and related equipment according to the Standard and organisational procedures 5.3 Complete documentation requirements for sterilising cycles, batch control and load release control 5.4 Identify and report steriliser faults and non-compliance and implement corrective actions within scope of own job role 5.5 Report and document all steriliser faults, malfunctions and load non-compliance 5.6 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

Range of conditions

Assessment requirements

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 Standard to prepare, operate, load and unload sterilisers and release the sterilised loads on at least 3 separate occasions, including: o interpreted and recorded cycle information using at least one of the following: o manual or electronic tracking system o completed all documentation for cycles, tests and load contents, including specialised item o addressed relevant work health and safety, infection prevention and control and manual handling requirements o identified, reported and implemented corrective actions for routine process problem or equipment fault 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: o quarantine protocols o conditions and parameters for successful sterilisation • cleaning protocols and special requirements for sterilisers and load carriers: • features of steam sterilisation including: o cycle stages and physical parameters for successful sterilisation o principles of steam generation and steam quality that impact on sterilisation outcomes o 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:
	  ○ Identifying manual handling risks associated with mobilising sterilising trolleys – loading and unloading
	  ○ infection prevention and control
	  ○ 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
	  ○ PPE
	  ○ 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 Standards for Registered Training Organisations* (RTO's)/AQF mandatory competency *requirements for assessors*.
Unit mapping information	*Supercedes and is equivalent to HLTSTE003 Sterilise Loads*
Links	*Link to Companion Volume Implementation Guide.*

HLTSTE004M Handle, transport and store reusable medical devices

<table>
<tr><td>Unit code</td><td>HLTSTE004M</td></tr>
<tr><td>Unit title</td><td>Handle, transport and store reusable medical devices</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><td>Release</td><td>Comment</td></tr>
<tr><td>Release 1.</td><td>Significant changes to the application, elements and performance criteria. Significant change to performance evidence and knowledge evidence.</td></tr>
<tr><td>Release 2.</td><td>Minor changes to the application, elements and performance criteria. Minor change to performance evidence and knowledge evidence.</td></tr>
</table>
</td></tr>
<tr><td>Application</td><td>This unit of competency describes the skills and knowledge required to handle, transport and store reusable medical devices according to organisational procedures.
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.</td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td></tr>
<tr><td>Competency field</td><td>NA</td></tr>
<tr><td>Unit sector</td><td>Sterile Medical Equipment</td></tr>
</table>

Elements	Performance criteria Performance criteria describe the performance needed to demonstrate achievement of the element. Required knowledge, skills and application should be considered and clearly articulated.
1. Handling reprocessed reusable medical devices	1.1 Select and wear appropriate attire according to organisational procedures 1.2 Perform hand hygiene according to infection prevention and control guidelines and organisational procedures 1.3 Minimise handling of reprocessed reusable medical devices to maintain integrity 1.4 Inspect reusable medical devices for packaging integrity, labelling and batch control 1.5 Identify appropriate processing indicator 1.6 Document and report non-conforming reusable medical devices according to organisational procedures 1.7 Apply secondary protective packaging to reprocessed items according to prevent contamination during transport
2. Transport reprocessed reusable medical devices	2.1 Handle and transport reusable medical devices according to safe manual handling techniques 2.2 Clean and maintain transport equipment according to Standard and organisational procedures 2.3 Load and handle transport equipment safely 2.4 Verify that dedicated transport equipment is clean, fully enclosed and correctly labelled prior to loading 2.5 Transport reusable medical devices following designated route and timetable according to organisational procedures 2.6 Segregate sterile reusable medical devices from contaminated items to avoid contamination
3. Store clean, disinfected and	3.1 Identify dedicated storage areas for clean, disinfected and sterile reusable medical devices according to organisational procedures

sterile reusable medical devices	3.2 Verify storage area and cleanliness requirements according to Standard, manufacturer's instructions for use and organisational procedures 3.3 Monitor and record temperature of dedicated storage cabinets according to manufacturer's instructions for use and organisational procedures 3.4 Check and monitor HEPA filter and air pressure in sterile storage areas 3.5 Decant sterile consumables in designated area prior to transfer into the sterile storage area 3.6 Monitor access and traffic in the sterile storage area according to organisational policies
4. Maintain stock levels	4.1 Complete stock rotation practices according to organisational procedures 4.2 Identify and re-call non-conforming reusable medical devices according to organisational procedures 4.3 Identify and discard non-conforming single use consumables 4.4 Assess and calculate stock and imprest levels 4.5 Interpret and document stock order requirements according to organisational procedures 4.6 Prepare, fill and distribute orders to relevant destination using traceability systems and documented processes 4.7 Document and report supply discrepancies according to organisational procedures
5. Monitor and maintain quality of storage process	5.1 Follow batch control identification requirements according to organisational procedures 5.2 Identify, document and report non-conforming reusable medical devices according to organisational procedures 5.3 Document and report quality assurance requirements including traceability according to organisational procedures

Foundation skills

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

Skills	Description

Range of conditions

Assessment requirements	
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 standard for sterile stock management on at least 3 different occasions, including on each occasion, handled and stored at least 2 loads of clean and disinfected reusable medical devices and 2 loads of sterile reusable medical devices: o selecting and using personal protective equipment (PPE) and appropriate attire o maintaining environmental conditions o maintaining stock at required levels o handling stock to maintain sterile conditions o responding to non-compliance • completed documentation using at least one of the following: o manual or electronic tracking system • addressed relevant work health and safety, infection prevention and control and manual handling requirements.
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 handling, transport and storage of reusable medical devices
	• storage and stock management principles for reusable medical devices:
	  ○ types of storage requirements
	  ○ handling reusable medical devices
	  ○ maintaining sterility
	  ○ time-related shelf-life event-related shelf life
	  ○ factors that affect the shelf life of sterile stock
	  ○ environmental factors that compromise sterility
	  ○ procedures to restrict access
	  ○ traceability and quality assurance documentation
	  ○ monitor and maintain clean storage environments
	• controlled storage environment
	  ○ temperature and humidity
	• recall procedures
	• features of a transport system required to maintain sterility of packaged items
	  ○ clean transport system
	  ○ fully enclosed transport system
	  ○ clearly labelled transport system
	• designated storage requirements for cleaned, disinfected and sterile reusable medical devices
	• safe work practices in the sterilisation work area:
	  ○ risk factors associated with manual tasks
	  ○ infection prevention and control
	  ○ personal hygiene
	  ○ PPE.

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
	  ○ PPE and appropriate attire
	  ○ a designated sterile stock area
	  ○ cleaned and disinfected reusable medical devices
	  ○ sterile reusable medical devices
	  ○ stock management and ordering system
	  ○ transport equipment
	  ○ quality assurance documentation
	  ○ workplace procedures to be followed
	modelling of industry operating conditions, including presence of situations requiring problem solving.
	Assessors must satisfy the Standards for Registered Training Organisations (RTO's)/AQF mandatory competency requirements for assessors.

Unit mapping information	Supersedes and is equivalent to HLTSTE004 Manage sterile stock
Links	Link to Companion Volume Implementation Guide.

HLTSTE005M Care and maintain reusable medical devices

<table>
<tr><td>Unit code</td><td>HLTSTE005M</td></tr>
<tr><td>Unit title</td><td>Care and maintain reusable medical devices</td></tr>
<tr><td>Modification History</td><td>
<table>
<tr><td>Release</td><td>Comments</td></tr>
<tr><td>Release 2</td><td>Minor changes to application. Significant changes to the elements and performance criteria. Significant changes to performance evidence, and knowledge evidence.</td></tr>
</table>
</td></tr>
<tr><td>Application</td><td>This unit describes the skills and knowledge required to maintain reusable medical devices during reprocessing.

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.</td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td></tr>
<tr><td>Competency field</td><td>NA</td></tr>
<tr><td>Unit sector</td><td>Sterile Medical Equipment</td></tr>
<tr><td>Elements
Performance criteria</td><td>Performance criteria
Performance criteria describe the performance needed to demonstrate achievement of the element. Required knowledge, skills and application should be considered and clearly articulated.</td></tr>
</table>

1.Introducing new reusable medical devices	1.1 Verify new reusable medical devices are registered according to regulatory requirements and manufacturer's instructions for use 1.2 Reprocess new reusable medical devices prior to initial use according to manufacturer's instructions for use 1.3 Confirm reusable medical devices are compatible with available reprocessing equipment
2. Care and maintenance requirements for general and specialised reusable medical devices	2.1 Identify the composition, manufacturing process, corrosion risk, passivation and surfaces requiring remedial processes of reusable medical devices according to manufacturer's instructions for use and organisational procedures 2.2 Disassemble reusable medical devices to assess for corrosion to prevent patient risk and material degradation according to work health and safety, infection prevention and control and personal protective equipment, manual handling requirements and organisational procedures 2.3 Complete remedial processes according to manufacturer's instructions for use and organisational procedures 2.4 Identify reusable medical devices requiring insulation testing according to manufacturer's instructions for use 2.5 Assess reprocessing capacity of reusable medical devices according to manufacturer's instructions for use 2.6 Lubricate and reassemble reusable medical devices according to manufacturer's instructions for use and organisational procedures
3. Process for repairing and servicing reusable medical devices	3.1 Identify and report faulty reusable medical devices according to manufacturer's instructions for use and organisational procedures 3.2 Process faulty reusable medical devices prior to sending for service or repair according to safe manual handling

	requirements, manufacturer's instructions for use and organisational procedures 3.3 Document traceability requirements for servicing and repair of reusable medical devices requiring repair or service according to organisational procedures 3.4 Complete return from servicing procedures for repaired reusable medical devices according to the Standard, manufacturer's instruction for use and organisational procedures
4. Monitor and maintain quality processes	4.1 Complete required quality documentation for general and specialised reusable medical devices

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

Range of conditions

Optional field

Assessment requirements

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 Standard for the care, maintenance and insulation testing of 9 reusable medical devices from the list

	below, on at least 3 separate occasions including: ○ disassembly and re-assembly of multi-part reusable medical devices • inspection of reprocessed reusable medical devices including: ○ scissors ○ box joints and screw joints ○ a solid plain instrument ○ forceps ○ cannulated devices • prepared a range reusable medical devices, including: ○ solid plain reusable medical devices ○ those requiring disassembly ○ those with textured surfaces ○ delicate items ○ manual and powered items ○ cannulated devices including: ○ cannulated items, lumens ○ blind ended reusable medical devices • identified and responded to routine process and maintenance problems and variations • addressed relevant work health and safety, infection prevention and control and manual handling requirements.

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:
	• duty of care and impact of care of reusable medical devices on operative procedures and patient care outcomes
	• the requirements of Standard AS5369 and its role in the care and maintenance of reusable medical devices
	• care and maintenance requirements for general and specialised reusable medical devices including:
	  ○ validated manufacturer's instructions for use
	• Spaulding classifications
	  ○ critical
	  ○ semi-critical
	  ○ non-critical
	• role of regulatory requirements and safety data sheets for the identification, manufacturing registration and chemical use for reusable medical devices
	• product families including general and specialised reusable medical devices
	• use of reusable medical devices in different operative procedures
	• manual handling and work health and safety requirements

	• infection prevention and control requirements • preparation and inspection requirements for reusable medical devices • personal protective equipment • chemicals and principles of passivation • systems for identifying reusable medical devices • reusable medical devices material, design and composition and their relationship to reprocessing requirements • impact of repeated processing, potential surface changes to reusable medical devices and preventative measures • risks for potential surface changes, rust, discolouration and other factors that affect reusable medical devices • contact corrosion and metal compatibility • risk assessment and corrective actions • leak testing and requirements for the reprocessing of flexible endoscopes • importance of inspection of insulation testing • instrument repair requirements and process • process for purchasing and introducing new reusable medical devices • process for introducing loan reusable medical devices.

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
	  ○ operational cleaning and drying equipment
	  ○ cleaning procedures to be followed by the candidate
	  ○ equipment manufacturer's instructions for use
	• *personal protective equipment*
	• modelling of industry operating conditions, including:
	  ○ requirements for the cleaning process
	  ○ presence of situations requiring problem solving.
	
	Assessors must satisfy the Standards for Registered Training Organisations (RTO's)/AQF mandatory competency requirements for assessors.

Unit mapping information	*Supersedes and is equivalent to HLTSTE005 Care for reusable medical devices*
Links	*Link to Companion Volume Implementation Guide.*

HLTSTE006M Disinfect reusable medical devices

<table>
<tr><td>Unit code</td><td>HLTSTE006M</td></tr>
<tr><td>Unit title</td><td>Disinfect reusable medical devices</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><td>Release</td><td>Comment</td></tr>
<tr><td>Release 1</td><td>Significant changes to the elements and performance criteria. Minor changes to performance evidence and knowledge evidence.</td></tr>
</table>
</td></tr>
<tr><td>Application</td><td>This unit describes the skills and knowledge required to follow procedures to safely undertake the disinfection process, and complete quality checks and documentation for reusable medical devices and other equipment.

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

The skills in this unit must be applied in accordance with current Commonwealth and State/Territory legislation, Australian and industry codes of practice.</td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td></tr>
<tr><td>Competency field</td><td>NA</td></tr>
<tr><td>Unit sector</td><td>Sterile Medical Equipment</td></tr>
<tr><td>Elements</td><td>Performance criteria</td></tr>
</table>

Performance criteria	Performance criteria describe the performance needed to demonstrate achievement of the element. Required knowledge, skills and application should be considered and clearly articulated.
1. Prepare reusable medical devices for disinfection	1.1 Conduct infection prevention and control procedures according to organisational requirements 1.2 Select and use personal protection equipment (PPE) according to organisational requirements 1.3 Test disinfection equipment functionality according to manufacturer's instructions for use, regulatory requirements, and Spaulding's classification 1.4 Disassemble reusable medical devices prior to disinfection according to manufacturer's instructions for use 1.5 Clean reusable medical devices prior to disinfection
2. Load and operate disinfection system	2.1 Identify and monitor disinfection process according to manufacturer's instructions for use 2.2 Select and handle chemicals in accordance with regulatory requirements, manufacturer's instructions for use, safe manual handling techniques and safety data sheets 2.3 Transport and store chemicals in accordance with regulatory requirements, manufacturer's instructions for use, safe manual handling techniques and safety data sheets 2.4 Select disinfection system cycle and complete disinfection process based on product family according to Standard, manufacturer's instructions for use and organisational procedures 2.5 Monitor and report hazards to supervisor during disinfection process
3. Unload and release disinfection process	3.1 Remove load on completion of cycle according to organisational procedures 3.2 Complete cycle documentation according to organisational procedures

	3.3 Verify disinfection process parameters and indicator results to confirm cycle success 3.4 Track reusable medical devices using a tracking system according to the traceability requirements, Standard and organisational procedures 3.5 Validate cycle according to Standard, manufacturer's instructions for use and organisational procedures 3.6 Record cycle according to Standard, manufacturer's instructions for use and organisational procedures 3.7 Release load according to Standard and organisational procedures
4. Monitor and maintain quality of disinfection process	4.1 Monitor and respond to routine problems according to manufacturer's instructions for use, Standard and organisational procedures 4.2 Monitor water quality according to Standards, manufacturer's instructions for use and organisational procedures 4.3 Identify and report non-compliance in the disinfection process and action 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

Range of conditions

Optional field

Specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional

contexts) are included. Range is restricted to essential operating conditions and any other variables essential to the work environment.	
Assessment requirements	
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. For each of the cycles, there must be evidence that the candidate has: • followed established organisational procedures, manufacturer's instructions for use and Standard for the disinfection of 3 different types of reusable medical devices across 3 separate occasions (9 devices in total) • operated and monitored disinfection systems, including selection of 3 different disinfectant types • identified and reported routine process and maintenance problems and variations • documented tests for each of the 9 cycles.

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 importance of cleaning prior to disinfection
	• impact of high-level disinfection in patient safety, and the implications of negligence
	• the requirements of AS5369 for disinfection
	• critical parameters for disinfection including:
	  ○ time
	  ○ temperature
	  ○ chemical concentration
	• documentation requirements for traceability in the event of a process failure.

	• levels of disinfection and its application for reprocessing different reusable medical devices
	• disinfection systems, including:
	  ○ manual disinfection
	  ○ automated disinfection
	  ○ thermal disinfection
	  ○ chemical disinfection
	  ○ automatic endoscope reprocessors
	  ○ other disinfection systems
	• reprocessing of endoscopes including the Gastroenterological Nurses College Australia (GENCA) Guidelines and the fundamental knowledge of microbiological surveillance requirements
	• key aspects of high-level disinfectants including:
	  ○ terminology
	  ○ reusable medical devices requiring disinfection
	• Spaulding's classification
	  ○ critical
	  ○ semi critical
	  ○ non-critical
	• load release criteria for disinfected reusable medical devices
	• Regulatory requirements, safety data sheets and manufacturer's instructions for use for chemicals including:
	  ○ cleaning agents and disinfectants
	• routine monitoring and documentation of the disinfection process
	• water quality monitoring process
	• storage requirements for reusable medical devices according to manufacturer's instructions for use and organisational procedures

	• prevention of recontamination of disinfected reusable medical devices and other devices
	• safe work practices including:
	  ○ fume extraction devices
	  ○ spill kit
	  ○ leak testing
	  ○ infection prevention and control principles
	  ○ microbiological surveillance
	  ○ personal protective equipment
	  ○ maintain integrity of disinfected reusable medical devices
	• identify risk factors of manual handling tasks involved including:
	  ○ relevant parameters, specific system controls and monitoring indicators.

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:
	• AS5369
	• PPE
	• disinfection equipment and accessories
	• identify, remove and report non-conformance
	• reusable medical devices requiring disinfection
	• modelling of industry operating conditions, including:
	  ○ requirements for the cleaning process prior to disinfection
	  ○ presence of situations requiring problem solving.
	• Assessors must satisfy the Standards for Registered Training Organisations (RTO's) requirements for assessors.

Unit mapping information	*Supersedes and is not equivalent to HLTSTE006 Chemically disinfect reusable medical devices*

Mandatory field	
Links	*Link to Companion Volume Implementation Guide.*

HLTSTE007M Monitor and maintain reprocessing equipment

<table>
<tr><td>Unit code</td><td>HLTSTE007M</td></tr>
<tr><td>Unit title</td><td>Monitor and maintain reprocessing equipment</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><td>Release</td><td>Comment</td></tr>
<tr><td>Release 1.</td><td>Minor changes to application. Significant changes to elements and performance criteria. Minor changes to knowledge evidence.</td></tr>
<tr><td>Release 2.</td><td>Minor changes to application. Minor changes to elements and performance criteria. Minor changes to knowledge evidence.</td></tr>
</table>
</td></tr>
<tr><td>Application</td><td>This unit of competency describes the skills and knowledge required to plan, implement, and monitor maintenance and operational requirements for reprocessing equipment, ensuring it functions safely, reliably, and in line with manufacturer instructions, organisational procedures, and relevant standards. Individuals in this role are responsible for scheduling and performing maintenance, monitoring equipment performance, addressing faults or non-compliance, and keeping accurate records for traceability.
This unit is designed for individuals who ensure reusable medical devices are processed safely and in compliance with workplace, regulatory, and organisational requirements.

The skills in this unit must be applied in accordance with current Commonwealth and State/Territory legislation, Australian standard and industry codes of practice.</td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td></tr>
</table>

Competency field	N/A
Unit sector	Health Sterile Medical Equipment
Elements	**Performance criteria** Performance criteria describe the performance needed to demonstrate achievement of the element. Required knowledge, skills and application should be considered and clearly articulated.
1. Determine compliance requirements for reprocessing equipment	1.1 Verify registration and operational status of reprocessing equipment according to regulatory requirements, safety data sheets, and manufacturer's instruction for use 1.2 Ensure cleaning, disinfection and sterilising agents used with reprocessing equipment meet manufacturer's specifications and safety requirements 1.3 Verify ongoing compliance of reprocessing equipment with manufacturer's instructions for use and organisational procedures 1.4 Assess and monitor water quality requirements to ensure suitability for reprocessing equipment according to Standard and manufacturer's instructions for use 1.5 Identify, document and report equipment faults, performance issues, or non-compliance in line with regulatory and organisational requirements
2. Plan monitoring and maintenance of reprocessing equipment	2.1 Determine of scope for routine monitoring and preventative maintenance requirements according to Standard and manufacturer's instructions for use in consultation with supervisor 2.2 Develop for routine monitoring and preventative maintenance schedules according to requirements of the Standards and manufacturer's instructions for use

3. Monitor and maintain reprocessing equipment	3.1 Audit routine monitoring, preventative maintenance and equipment performance according to Standard and manufacturer's instructions for use 3.2 Review compliance with routine monitoring and preventive maintenance requirements and report discrepancies in line with Standards and organisational procedures 3.3 Analyse performance qualification data to determine compliance and operational effectiveness of reprocessing equipment 3.4 Develop and implement performance requalification schedules according to requirements of Standard 3.5 Identify equipment non-compliances, trouble shoot faults and determine appropriate corrective action within scope of responsibility 3.6 Escalate issues outside scope of responsibility promptly according to organisational procedures 3.7 Apply business continuity procedures in response to equipment failure or non-compliance
4. Maintain records and reports	4.1 Verify monitoring, preventative maintenance and repair records to ensure they are complete and maintained according to organisational procedures 4.2 Analyse non-compliant records and reports and take appropriate corrective actions according to organisational procedures 4.3 Manage recall processes in consultation with a supervisor according to Standard and organisational procedures.
5. Monitor and report on quality and compliance	5.1 Collate and analyse performance feedback from stakeholders to identify equipment trends, recurring issues or potential systemic noncompliance according to organisational procedures

	5.2 Prepare and submit reports on equipment performance, maintenance and compliance highlighting areas for improvement or corrective action 5.3 Provide recommendations to supervisors or relevant stakeholders for process or equipment improvements based on analysis of monitoring and feedback data

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

Range of conditions

Assessment requirements

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:
	• developed, implemented and evaluated monitoring and maintenance plans for at least 2 different types of reprocessing equipment including:
	  ○ requalification schedule
	  ○ validation of water quality requirements
	• validated at least 2 different types of reprocessing equipment for compliance with registration according to regulatory requirements, safety data sheets and manufacturer's instructions for use
	• evaluated at least 2 different types of cleaning, disinfection or sterilsing agents for compliance

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 AS5369 for routine monitoring and preventative maintenance of reprocessing equipment • the accreditation process for health and non-health facilities • features, functions and tracking and monitoring systems of different reprocessing equipment including: o ultrasonic cleaners o reusable medical device washer disinfectors o case cart washer disinfectors o multi-chamber washer disinfectors o automated lubrication devices utilised for dental o leak testers o drying cabinets o automatic endoscope reprocessor o endoscope controlled environment storage/drying cabinet • disinfection systems including: o insulation testers o steam sterilisers o heat sealers o low temperature sterilisers o manual and automated chemical dispensing system • routine monitoring including: o frequency of testing o optional monitoring o mandatory monitoring o manufacturer's instructions for use • preventative maintenance including:

	○ frequency of maintenance ○ mandatory maintenance ○ manufacturer's instructions for use water quality requirements • water quality requirements • validation requirements including: ○ installation qualification ○ operational qualification ○ performance qualification • contingency planning • administration and record keeping requirements including: ○ routine monitoring and testing ○ validation requirements ○ preventative maintenance and repair ○ recall systems ○ reporting requirements of Standard AS5369 • Statistical Interpretation: ○ basic understanding of how to read data logs and sensor outputs during a validation cycle • Recall Triggers: ○ specific criteria that necessitate a device recall.
Assessment conditions	Skills must have been demonstrated in the workplace or simulated environment that reflects workplace conditions. The following conditions must be met for this unit: • use of suitable facilities, equipment and resources, including: ○ AS5369 ○ multiple types of reprocessing equipment ○ test data for analysis for completion ○ manufacturer’s instructions for use ○ technical manuals ○ safety data sheets

	○ historical maintenance repair, repair and water records ○ actual or simulated technical data sets for performance qualification analysis modeling of industry operating conditions, including scenarios involving equipment non-compliance or service interruptions requiring problem-solving and escalation • business continuity plans: ○ tracking and monitoring systems. *Assessors must satisfy the Standards for Registered Training Organisations (RTO's)/AQF mandatory competency requirements for assessors.*
Unit mapping information	*Supersedes and is equivalent to HLTSTE007 Monitor and maintain cleaning and sterilisation equipment*
	Link to Companion Volume Implementation Guide.

HLTSTE008M Monitor quality of reprocessing for reusable medical devices

<table>
<tr><td>Unit code</td><td>HLTSTE008M</td></tr>
<tr><td>Unit title</td><td>Monitor quality of reprocessing for reusable medical devices</td></tr>
<tr><td>Modification history</td><td>
<table>
<tr><td>Release</td><td>Comment</td></tr>
<tr><td>Release 2.</td><td>Major changes to the elements and performance criteria. Major changes to performance evidence and knowledge evidence.</td></tr>
<tr><td>Release 1.</td><td>Major changes to the elements and performance criteria. Major changes to performance evidence and knowledge evidence.</td></tr>
</table>
</td></tr>
<tr><td>Application</td><td>This unit of competency describes the skills and knowledge required to determine quality compliance requirements, and develop and document quality monitoring for reprocessing of reusable medical devices.
The skills in this unit must be applied in accordance with Commonwealth and State/Territory legislation, Australian standards and industry codes of practice.</td></tr>
<tr><td>Pre-requisite unit</td><td>Nil</td></tr>
<tr><td>Competency field</td><td>NA</td></tr>
<tr><td>Unit sector</td><td>Sterile Medical Equipment</td></tr>
<tr><td>Elements</td><td>Performance criteria</td></tr>
</table>

	Performance criteria describe the performance needed to demonstrate achievement of the element. Required knowledge, skills and application should be considered and clearly articulated.
1. Determine compliance requirements	1.1 Validate registration and compliance status of reprocessing equipment against regulatory requirements and manufacturer's instruction for use. 1.2 Identify, document and report non-compliance for reusable medical devices against regulatory requirements, safety data sheets, and manufacturer's instruction for use. 1.3 Evaluate process for new, trial and loan reusable medical devices and confirm compatibility with available reprocessing equipment and requirements of Standard.
2. Determine quality requirements	2.1 Determine reprocessing quality requirements according to Standards. 2.2 Evaluate water quality requirements for reusable medical devices according to manufacturer's instructions for use. 2.3 Develop monitoring programs for reprocessing reusable medical devices according to Standards and manufacturer's instructions for use. 2.4 Complete monitoring programs for reprocessing reusable medical devices. 2.5 Provide colleagues and stakeholders with monitoring information that complies with Standards and requirements of manufacturer's instructions for use for reprocessing reusable medical devices.
3. Verify effectiveness of	3.1 Audit routine monitoring, preventative maintenance and equipment performance according to Standards and manufacturer's instructions for use.

reprocessing processes	3.2 Analyse technical data according to testing and monitoring systems. 3.3 Record and report non-compliance according to organisational procedures.
4. Monitor reprocessing and maintenance records for sterilisation services	4.1 Verify maintenance, service, and repair records for general and specialised reusable medical devices according to organisational procedures. 4.2 Monitor reprocessing equipment and reusable medical device records for accuracy, completeness and compliance with Standards and organisational procedures. 4.3 Evaluate and respond to non-compliant records and reports according to organisational procedures. 4.4 Manage and update quality monitoring procedures according to Standards and organisational procedures. 4.5 Document findings, corrective actions, and follow-up outcomes in accordance with organisational procedures. 4.6 Communicate identified issues and required actions in writing to relevant personnel in a timely and effective manner and record follow-up action. 4.7 Analyse trends in reprocessing, maintenance and water quality records to recommend improvements to processes and procedures. 4.8 Ensure all monitoring and record-keeping activities comply with infection control requirements, occupational health and safety standards, and manufacturer's instructions for use.
5. Monitor and report on quality and compliance	5.1 Identify areas for improvement to work processes and provide feedback. 5.2 Monitor overall compliance for traceability and reprocessing requirements for reusable medical devices according

	to Standards, manufacturer's instructions for use and organisational procedures. 5.3 Consult with stakeholders and incorporate and report feedback according to organisational procedures. 5.4 Analyse trends and monitoring data to inform continuous quality improvement initiatives and strengthen compliance practices.

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

Assessment requirements

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:* • evaluated 2 different monitoring programs for reprocessing of reusable medical devices • analysed technical data and process verification results for at least 2 different types of reprocessing equipment to determine quality compliance • verified the accuracy of traceability and maintenance records for at least 2 different types of reusable medical devices • conducted at least 1 audit of water quality compliance based on Standards and manufacturer's instructions for use • documented and actioned at least 4 non-compliances identified including: ○ 1 process improvements proposal.
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 AS5369 for monitoring • reprocessing of reusable medical devices • manufacturer's instructions for use for reusable medical devices • review of reprocessing equipment for compliance • according to manufacturer's instructions for use • water quality requirements • properties and purpose of different cleaning, disinfection and sterilising agents • regulatory requirements and safety data sheets for reusable medical devices • product families for all stages of reprocessing • traceability requirements • testing systems requirements for cleaning, packaging, disinfection and storage according to Standard • administration and record keeping requirements for testing, monitoring and maintenance • types of non-compliance and corrective actions required • report writing • risk-based approach according to standards • job role requirements including delegation and escalation when required.
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 ○ manufacturer's instructions for use for testing products ○ organisational procedures ○ reprocessing equipment ○ manufacturer's guidelines for testing products ○ documentation for completion ○ equipment manuals and maintenance and ○ repair record *Assessors must satisfy the Standards for Registered Training Organisations (RTO's)/AQF mandatory competency requirements for assessors.*
Unit mapping information	*Supersedes and is equivalent to HLTSTE008 Monitor quality of cleaning, packaging and sterilisation processes*
Links	*Link to Companion Volume Implementation Guide.*