



Australian Government

**HLTSTE016 Monitor quality of
reprocessing for reusable medical devices**

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Modification History

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

Application

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 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
<i>Elements define the essential outcomes</i>	<i>Performance criteria describe the performance required to demonstrate achievement of the element</i>
1. Verify compliance requirements	1.1 Verify registration and compliance status of reusable medical devices against regulatory requirements and manufacturer's instruction for use

	<p>1.2 Identify, document and report non-compliance for reusable medical devices against regulatory requirements, safety data sheets, and manufacturer’s instructions for use</p> <p>1.3 Evaluate process for new, trial and loan reusable medical devices and confirm compatibility with available reprocessing equipment and requirements of Standard</p>
<p>2. Determine quality requirements</p>	<p>2.1 Determine reprocessing quality requirements according to Standards</p> <p>2.2 Evaluate water quality requirements for reusable medical devices according to manufacturer’s instructions for use</p> <p>2.3 Develop monitoring programs for reprocessing reusable medical devices according to Standards and manufacturer’s instructions for use</p> <p>2.4 Complete monitoring programs for reprocessing reusable medical devices</p> <p>2.5 Provide colleagues and stakeholders with monitoring information that complies with Standards and manufacturer’s instructions for use for reprocessing reusable medical devices</p>
<p>3. Verify effectiveness of reprocessing processes</p>	<p>3.1 Audit routine monitoring, preventative maintenance and equipment performance according to Standards and manufacturer’s instructions for use</p> <p>3.2 Analyse technical data according to testing and monitoring systems</p> <p>3.3 Record and report non-conformance according to organisational procedures</p>
<p>4. Monitor reprocessing and maintenance records for reusable medical devices</p>	<p>4.1 Verify maintenance, service, and repair records for general and specialised reusable medical devices according to manufacturer’s instructions for use and organisational procedures</p> <p>4.2 Monitor routine maintenance and records for reusable medical device records for accuracy, completeness and compliance with Standards, manufacturer’s instructions for use and organisational procedures</p> <p>4.3 Evaluate and respond to non-compliant records and reports according to organisational procedures</p> <p>4.4 Manage and update quality monitoring procedures according to Standards and organisational procedures</p>

	<p>4.5 Document findings, corrective actions, and follow-up outcomes in accordance with organisational procedures</p> <p>4.6 Communicate identified issues and required actions in writing to relevant personnel in a timely and effective manner and record follow-up action</p> <p>4.7 Analyse trends in reprocessing, maintenance and water quality records to recommend improvements to processes and procedures</p> <p>4.8 Verify monitoring and record-keeping activities comply with infection prevention and control requirements, work health and safety standards, and manufacturer’s instructions for use</p>
<p>5. Monitor and report on quality and compliance</p>	<p>5.1 Identify areas for improvement to work processes and provide feedback</p> <p>5.2 Monitor overall compliance for traceability, reprocessing and water quality requirements for reusable medical devices according to Standards, manufacturer’s instructions for use and organisational procedures</p> <p>5.3 Consult with stakeholders, incorporate and report feedback according to organisational procedures</p> <p>5.4 Analyse trends and monitoring data to inform continuous quality improvement initiatives and strengthen compliance practices</p>
<p>6. Confirm risk-based approach for reprocessing reusable medical devices</p>	<p>6.1 Plan and develop risk assessment strategy for reprocessing reusable medical devices</p> <p>6.2 Complete risk assessment according to the Standard and organisational procedures</p> <p>6.3 Evaluate risk assessment and determine risk rating according to Standards and organisational procedures</p> <p>6.4 Review and apply risk control strategies according to Standards and organisational procedures</p> <p>6.5 Document and report findings, corrective actions and monitoring requirements according to Standards and organisational procedures</p>

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
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Learning skills to:	<ul style="list-style-type: none">• use organisational procedures, manufacturer's instructions and Standards to monitor the quality of reprocessing reusable equipment.
Reading skills to:	<ul style="list-style-type: none">• interpret technical organisational procedures, manufacturer's instructions, quality management guidelines and Standards to interpret tracking information.
Oral communication skills to:	<ul style="list-style-type: none">• use industry terminology to report compliance and quality assurance requirements.

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

Range of conditions

N/A

Assessment Requirements for HLTSTE016 Monitor quality of reprocessing for 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:

- planned, developed, completed and evaluated risk assessment on at least 2 different stages of 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 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 2 non-compliances identified, including:
 - 1 process improvement 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:

- 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 sterilising and storage according to Standard
- administration and recordkeeping requirements for testing, monitoring and maintenance

- types of non-compliance and corrective actions required
- report writing to identify and document areas of improvement and analyse trends according to organisation requirements
- 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 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
HLTSTE008 Monitor quality of cleaning, sterilisation and packaging processes	Not equivalent	<i>Major changes to elements and performance criteria. Major changes to performance evidence and knowledge evidence.</i>

Links

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

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