

Reprocessing of Reusable Medical Devices Policy Directive

Version No.: 2.0
Approval date: 20 November 2019

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Reprocessing of Reusable Medical Devices Policy Directive

1. Policy Statement

This Policy Directive applies to the reprocessing of all reusable medical devices that require disinfection or sterilisation prior to reuse. This includes any reusable medical device classified using the Spaulding Classification System as a critical medical device or a semi-critical medical device as specified in section 3.1.4: Reprocessing of reusable medical devices as per the *Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)*.

The purpose of this policy directive is to:

- ensure appropriate governance systems are in place within all areas of SA Health where reusable medical devices are reprocessed
- ensure all staff involved in the use and reprocessing of reusable medical devices consistently adhere to the recommendations in the relevant local health network, state, national and international standards and guidelines
- ensure appropriate and regular internal and external audit occurs within all areas of SA Health where reusable medical devices are reprocessed.

Advice on reprocessing of reusable medical devices which have been used on patients at low or high risk of Creutzfeldt-Jakob disease or variant Creutzfeldt-Jakob disease is beyond the scope of this Policy Directive. See the national Infection Control Guidelines specific to Creutzfeldt-Jakob disease at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/icg-guidelines-index.htm>

Reprocessing of non-critical medical devices and other non-critical items is not covered by this Policy Directive but is covered in the Cleaning Standard for Healthcare Facilities Policy Directive.

This Policy Directive is to be read and administered in conjunction with the relevant guidelines, regulations and current Australian and International Standards on sterilisation and reusable medical device reprocessing.

2. Roles and Responsibilities

All SA Health employees or persons who provide health services on behalf of SA Health must adhere to this policy.

2.1 Chief Executive SA Health is responsible for:

- ensuring that executive management for health service organisations within SA Health support the requirements of AS/NZS 4187:2014.

2.2 Executive Director, Health Regulation & Protection through the Director, Communicable Disease Control Branch will:

- maintain and periodically review the effectiveness of the SA Health Reprocessing of Reusable Medical Devices Policy Directive and associated resources.

2.3 Local Health Network Chief Executive Officers will:

- ensure health services within their LHN have appropriate governance systems in place that facilitate reprocessing of reusable medical devices in accordance with the relevant state, national and international standards and guidelines

- ensure sufficient resources are in place to enable effective systems for safe reprocessing of reusable medical devices in accordance with the relevant state, national and international standards and guidelines
- ensure that the day-to-day responsibility for establishing and monitoring the implementation of this policy is delegated to the relevant senior managers.

2.4 Local Health Network Heads of Service and other Senior Managers will:

- develop, implement and monitor local processes to ensure the safe reprocessing of reusable medical devices in accordance with state, national and international standards and guidelines
- ensure requisite infrastructure is available to enable the safe reprocessing of reusable medical devices in accordance with state, national and international standards and guidelines
- ensure staff responsible for management/supervision and those involved in reprocessing of reusable medical devices are appropriately trained
- ensure there is an appropriate staffing structure and workforce planning in order to retain sufficient numbers of appropriately skilled personnel
- facilitate the attendance of reprocessing managers at relevant SA Health meetings in relation to reprocessing governance
- maintain a schedule of regular internal and external audits of the reprocessing of reusable medical devices, at intervals deemed by the LHN as appropriate to manage and control risk
- ensure audit findings are addressed and reported appropriately.

2.5 All SA Health employees involved in reprocessing of reusable medical devices will:

- take all reasonable steps to ensure they reprocess reusable medical devices in accordance with the principles and aims of this policy and its associated guidelines and standards.
- refer to the SA Health reprocessing web page to access relevant policy and procedure documents and audit tools.

2.6 All SA Health employees will:

- take all reasonable steps to ensure they only use reusable medical devices which have intact packaging (where applicable) and have been labelled as having been appropriately reprocessed
- adhere to the principles and aims of this policy and ensure they operate in accordance with its associated guidelines and procedures.

3. Policy Requirements

The following principles apply:

- appropriate reprocessing of reusable medical devices is necessary to minimise, for patients and staff, the risk of infection and risk of adverse reactions from residual cleaning, disinfecting or sterilising agents
- all reusable medical devices must be reprocessed by cleaning, disinfection and/or sterilisation
- the minimum level of reprocessing of a reusable medical device depends on the manufacturer's 'information of use' (UFI) cleaning and sterilisation instructions and the category of use according to the Spaulding classification
- employees involved in reprocessing of reusable medical devices must be appropriately trained to enable compliance with relevant state, national and international standards and guidelines
- appropriate governance systems must be in place.

The following sections describe the minimum standards that apply to all SA Health facilities:

3.1 Governance

All organisations and services in SA Health will ensure:

- Appropriate governance systems are in place, for both central and satellite sites, which facilitate reprocessing of reusable medical devices in accordance with the relevant local health network, state, national and international standards and guidelines.
- Employees with managerial responsibility and accountability for day to day practice in the reprocessing department within the LHN must have relevant qualifications and experience in reprocessing medical devices.

3.2 Reprocessing

All organisations and services in SA Health will ensure:

- All reusable medical devices are reprocessed according to their intended use and the manufacturer's advice and the current Australian Standards. The minimum level of reprocessing for reusable critical medical devices is cleaning followed by sterilisation. The minimum level of reprocessing for reusable semi-critical medical devices is cleaning followed by high level disinfection, although sterilisation is strongly recommended.
- Single use medical devices are not reprocessed.
- Only TGA registered reusable medical devices, cleaning agents, disinfectants or sterilants are to be used. These must be used according to the manufacturer's instructions.
- Note: non-TGA registered items are permissible where these are part of a registered trial or research project that has undergone appropriate risk management and ethics approval processes.
- The reprocessing facility manager is involved in the selection process for purchasing of reusable medical devices to ensure the manufacturer's reprocessing instructions are provided, able to be followed by the organisation or service, and do not contravene current Australian Standards.
- Requisite facilities, infrastructure and workforce are available to enable the safe reprocessing of reusable medical devices in accordance with state, national and international standards and guidelines.
- Policies and procedures regarding reprocessing are documented including the rationale for assigning each reusable medical device type to a particular processing family.
- All reprocessing steps, including cleaning, disinfection, packaging and sterilisation, are validated, controlled and monitored.
- Sterile stock is stored in an environment that complies with AS/NZS4187:2014 and is protected from damage and soiling by monitoring the temperature, humidity and cleanliness of the sterile store environment.
- Systems are in place for verification of the completion of all reprocessing steps prior to release of items for re-use.
- Policies and procedures are available regarding the handling of the following reusable medical devices received by a health care facility:
 - on loan
 - on trial
 - new to the facility
 - returned from repair.

If items are processed offsite, the referring facility must ensure that the sterilisation service provided uses validated cleaning and sterilising processes. In the instance that items are routinely cleaned on one site and sterilised at another, a contract must be drawn up to clearly identify each party's responsibilities for the process.

- Environmental cleaning according to the SA Health Cleaning Standard for Healthcare Facilities and regular maintenance of equipment used in reprocessing processes is undertaken.
- Health service organisations monitor the work provided by any outsourced equipment service providers to ensure their repair and service meets requirements and is based on current national or international measurement standards.
- Processes are in place regarding management of non-conforming reprocessed items, supply complaints and quality or procedural problems.
- Reprocessing staff adhere to specified work practices related to reprocessing of reusable medical devices and their competency is maintained and assessed on a regular basis.
- Recall procedures, including notification requirements, are documented. These should include situations whereby a recall is warranted, both internally or externally-initiated. Internal (within sterilising service departments) recall occurs when a failed process is identified during or after processing but before items are released for use. External (hospital wide) recall can either be due to damaged or sterilisation failure of pre-packaged sterile single use consumables or when items have been released for use by the sterilisation department and found to have been inadequately sterilised.

3.3 Records

All organisations and services in SA Health will ensure:

- Records are kept in accordance with the requirements of AS/NZS 4187:2014 including:
 - process records of cleaning, high level disinfection, and sterilising.
 - records of cleaning, maintenance and monitoring of reprocessing equipment
 - records of staff training and competency assessment.
- Sterilising and reprocessing records are retained in accordance with SA Government General Disposal Schedule no 28 - item 3.8.2. There is a system of traceability of each reusable critical or semi-critical device or instrument set to the individual patient.
- A record of patients who have procedures using reusable instruments is maintained, such as documentation of instruments or instrument sets used for the procedure in the patient's medical record.

3.4 Audit

All organisations and services in SA Health will ensure:

- A system of regular documented internal audit to identify any practice changes and improvements required.
- A system of external audit of reprocessing of reusable medical devices is in place to ensure compliance with current National reprocessing standards.
- Deficiencies identified in either internal or external audit are addressed, as required, with documentation of any corrective action(s), and are reported to the highest level of clinical governance within the LHN.

3.5 Staff training

All organisations and services in SA Health will ensure:

- Staff who have direct responsibility for the reprocessing of reusable medical devices have relevant qualifications and experience in reprocessing and/or sterilising technology, i.e. have completed a nationally recognised sterilisation competency-based course.
- Staff who undertake reprocessing of reusable medical instruments are trained in the necessary procedures.
- A training schedule for ongoing education and competency assessment for staff who undertake reprocessing of reusable medical devices is in place.

4. Implementation & Monitoring

Risk assessment and risk management should be an integral part of reprocessing of reusable medical devices protocols. The Australian Guidelines for the Prevention of Infection in Health Care 2019 has taken this approach. For more detail on the application of risk management techniques, see Section 3.1.4 of these Guidelines.

All risks and hazards must be identified, actioned, documented and reported to the Local Health Network's risk management unit and the appropriate controls applied. The effectiveness of the risk controls should be regularly assessed.

It is important that compliance with all elements of this policy is demonstrated. This will be achieved by scheduled auditing of the processes addressed within this document. The audit results and an action plan to address identified deficiencies must be reported to the relevant governance committees.








There must be regular reporting to local clinical governance committees by each local health network of agreed work activity and work quality indicators relating to reprocessing of reusable medical devices.

All incidents, i.e. failure in the reprocessing process, must be reported via the Safety Learning System (SLS).

Compliance with this policy directive will be assessed by monitoring the hospital accreditation results for standards 3, and through review of incident reports related to reprocessing recorded in the SA Health Safety Learning System.

The effectiveness of this policy will be reviewed in 2022.

5. National Safety and Quality Health Service Standards

							
National Standard 1 Clinical Governance	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare-Associated Infection	National Standard 4 Medication Safety	National Standard 5 Comprehensive Care	National Standard 6 Communicating for Safety	National Standard 7 Blood Management	National Standard 8 Recognising & Responding to Acute Deterioration
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Definitions

In the context of this document:

- **Cleaning** means: the removal of contamination from an item to the extent necessary for further processing or for intended use.
- **Critical medical device** means: a medical instrument or piece of equipment that comes into contact with the vascular system or sterile tissue and that must be sterile at the time of use.
- **Disinfection** means: a reduction in the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.
- **Non-critical medical device** means: a medical instrument or piece of equipment that only comes into contact with intact skin (and not mucous membranes).
- **Reprocessing** means: a process of cleaning, disinfecting or sterilising an item to render it safe for use on a patient according to its intended use.
- **Reusable medical device (RMD)** refers to: a medical instrument or piece of equipment that, after the appropriate reprocessing can be safely used on another patient.
- **Semi-critical medical device** refers to: a medical instrument or piece of equipment that comes into contact with mucous membranes or non-intact skin.
- **Single use medical device** refers to: a medical device which is intended to be used on an individual patient during a single procedure and then discarded.
- **Single patient use** means: the medical device can be used more than once on one patient only. The manufacturer must state if and how the device should be decontaminated between uses and how many times the device can be used prior to disposal.
- **Spaulding Classification System** refers to: a system for assessing the level of reprocessing required based on the degree of risk for infection involved in the use of the items.
- **Sterilisation** means: a validated process to render a product free from viable microorganisms.

7. Associated Policy Directives / Policy Guidelines and Resources

7.1 SA Health Policy Directives and Guidelines

- SA Health Healthcare Associated Infection Prevention Policy Directive (2016). www.sahealth.sa.gov.au/infectionprevention
- SA Health Cleaning Standard for Healthcare Facilities Policy Directive (2018). <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/healthcare+associated+infections/prevention+and+management+of+infections+in+healthcare+settings/environmental+hygiene+in+healthcare>
- SA Health Microbiological Testing of Endoscopes Clinical Guideline (2017) <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/healthcare+associated+infections/prevention+and+management+of+infections+in+healthcare+settings/reprocessing+of+medical+devices>

7.2 National and International Directives and Guidelines

- Gastroenterological Society of Australia (GESA) and Gastroenterological Nurses College of Australia (GENCA) 2010. Infection control in endoscopy Third edition. <http://www.gesa.org.au/resources/clinical-guidelines-and-updates/endoscopy-infection-control/>

- Australian Commission on Safety and Quality in Healthcare. National Safety and Quality Health Service Standards. 2nd ed. Sydney: ACSQHC; 2017. <https://www.safetyandquality.gov.au/our-work/assessment-to-the-nsqhs-standards/nsqhs-standards-second-edition/>
- National Health and Medical Research Council, 2019. Australian Guidelines for the Prevention and Control of Infection in Healthcare, Australian Government. <https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019>
- Rutala, WA, Weber, MD et al. 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. Centers for Disease Control and Prevention. Available from: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
- Standards Australia. AS/NZS 4187:2014. *Reprocessing of reusable medical devices in health service organizations*
- Standards Australia. AS/NZS 4187:2014/Amdt 1:2015. *Reprocessing of reusable medical devices in health service organizations*
- Standards Australia. AS/NZS 4815:2006. *Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*
- Therapeutic Goods Act 1989 (Commonwealth) <https://www.legislation.gov.au/Details/C2015C00471>
- Therapeutic Goods Regulations 1990 (Commonwealth) <https://www.legislation.gov.au/Details/F2016C00154>
- Therapeutic Goods (Medical Devices) Regulations 2002 (Commonwealth) <https://www.legislation.gov.au/Details/F2016C00150>

7.3 SA supporting resources

The following supporting resources are located

on <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/healthcare+associated+infections/prevention+and+management+of+infections+in+healthcare+settings/reprocessing+of+medical+devices>

- SA Health Single-use Medical devices fact sheet (2013).
- SA Health Safe Use of Anaesthetic Equipment & Prevention of Cross-infection Fact Sheet (2015).
- Reprocessing of Basic Life Support (BLS) Equipment Fact Sheet (2019)
- Safe Use of *ortho*-phthalaldehyde (OPA) fact sheet (2018)

Other SA supporting resource

- State Records General Disposal Schedule no 28 for Clinical and Client-related Records of Public Health Units in South Australia. <http://www.archives.sa.gov.au/content/general-disposal-schedules#GDS28>

8. Document Ownership & History

Document developed by: Infection Control Service, Communicable Disease Control Branch, Health Regulation and Protection

File / Objective No.: 2017-02258 | A1502051

Next review due: 20/11/2024

Policy history: Is this a new policy (V1)? **N**

Does this policy amend or update an existing policy? **Y**

If so, which version? Version 1.0

Does this policy replace another policy with a different title? **N**

If so, which policy (title)?

ISBN No.: 978-1-76083-219-3

Approval Date	Version	Who approved New/Revised Version	Reason for Change
20/11/19	v2.0	Chief Public Health Officer	Minor edits to comply with NSQHSS 2nd Ed and national guidelines.
01/08/17	v1.0	SA Policy Committee	Original