Quality Management and Validation for the Reprocessing of Reusable Medical Devices Procedure

Contents

1. Purpose

This procedure outlines requirements for WA Country Health Service (WACHS) staff who reprocess reusable medical devices (RMDs) and are responsible for quality management and validation processes for cleaning, disinfection, packaging and sterilising, as per AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities.

2. Procedure

The cleaning, disinfection, packaging and sterilisation processes (where applicable) for RMDs/other devices are separate, but equally important, processes that are performed after each patient use to ensure that a reprocessed RMD is safe for continued use in/on another patient. The principles of validation, therefore, apply to each cleaning, disinfection, packaging and sterilisation process and to the equipment used to deliver these processes.

The most difficult to clean, disinfect or sterilise load (batch) is likely to differ for different processes and process cycles of each type of RMD. As such, it is necessary to confirm the processes used in each type of washer-disinfector (WD) and steriliser with the most difficult to clean, disinfect, package or sterilise load for that process.

2.1 Validation

Validation is the systematic process of planning, performing, recording and documenting process outcomes to verify that RMDs consistently achieve the process specifications pre-determined by the manufacturer, as well as comply with the requirements of the relevant industry standards.

A validation protocol should outline the steps to be taken to establish the key elements of the intended cleaning, disinfection, packaging and sterilisation processes (where applicable) for an RMD. The intended outcome of validation is to show that these processes, which were established during process definition, are delivered effectively and in a way that can be replicated, in order to produce a reprocessed RMD that is of the required quality.

As per AS 5369:2023, cleaning, disinfection, packaging and sterilisation processes are to be delivered effectively and reproducibly to the loads of RMDs/other devices being processed in the facility. All processes are to be validated and documented.

Validation consists of the following identified stages:

- Installation qualification (IQ) is undertaken to demonstrate that the reprocessing equipment and any ancillary items have been supplied and installed in accordance with their specification
- Operational qualification (OQ) is carried out either with equipment in an unloaded state or using appropriate test materials to demonstrate the capability of the equipment to deliver the cleaning, disinfection or sterilisation process that has been defined in the equipment specifications
- Performance qualification (PQ) is the stage of validation that uses and exposes the products as specified to the cleaning, disinfection, packaging or sterilisation processes and demonstrates that the equipment consistently operates in accordance with predetermined criteria and the processes yield a product that is clean, disinfected or sterile and meets the specified requirements. There are two components to PQ,

namely physical performance qualification (PPQ) and microbiological performance qualification (MPQ).

Immediately prior to conducting specified IQ, OQ or PQ, the calibration status of all instrumentation, including any test instruments used for monitoring, controlling, indicating or recording are to be confirmed.

The relationship between these stages is outlined in figure 1 below:

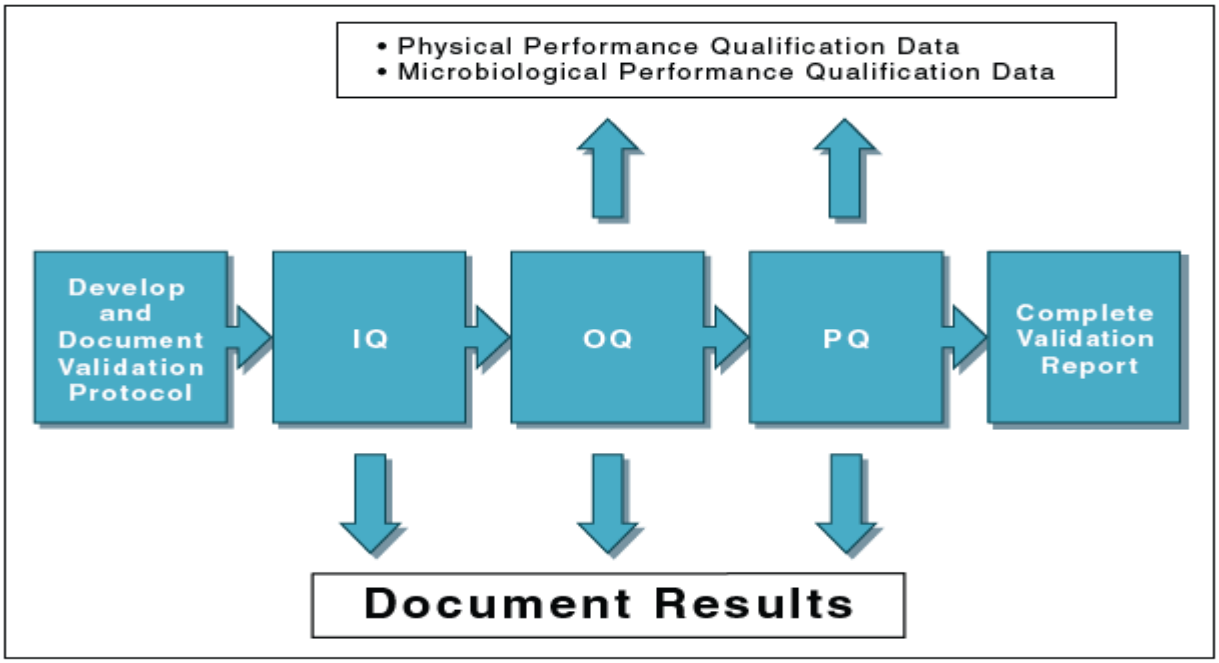

Figure 1 — Validation flowchart for cleaning, disinfection and sterilisation processes. From AS 5369:2023, Figure 7.1 (page 53).

Validation of processing equipment is to be performed by a qualified service provider well versed in the requirements of the standards, and local staff must be present throughout the validation process to ensure routine local practices and outcomes are reflected and documented.

The table below outlines the relevant standards related to Validation processes:

Standard	Reprocessing equipment applicable to processes
AS 2773	For commissioning tests for ultrasonic cleaners
ISO 15883 (the applicable part)	For validation of cleaning and thermal or chemical disinfection processes
ISO 22441	For vaporized hydrogen peroxide sterilization
EN 16442	For drying and storage of endoscopes
AS 5330	For drying cabinets for RMDs
ISO 11607-2	For validation of packaging and heat sealing processes
ISO 17665 (series)	For steam sterilization
ISO 20857	For dry heat sterilization
ISO 11135	For ethylene oxide sterilization
ISO 25424	For steam/formaldehyde sterilization
ISO 14937	For sterilization systems where no other Standard applies
NOTE: Guidance on the application of ISO 11607 2 is provided in ISO TS 16775	

Table 1: Reprocessing equipment applicable to processes

IQ and OQ are to be undertaken for each individual piece of equipment. PQ is to be performed for each process delivered by each piece of equipment.

Validation requires pre-planning including:

- developing a plan incorporating a selection of RMDs from the established product families, that represent the most challenging to process plus two reference loads, representative of daily routine processing
- pre-planning and confirming a time to perform the validation with the manufacturer or external contractor to ensure disruption to normal operation is minimised and mutually convenient
- rostering the appropriately skilled staff to be present to assist with the process
- pre-ordering extra supplies of critical consumables and/or chemicals to allow multiple cycles required to verify process efficacy.

Where variances or less than ideal outcomes result, for example inadequate drying, the process is repeated until the desired outcome is achieved.

Assessment of change (as per AS 5369:2023, 10.5)

Any change to reprocessing equipment or to a process that impacts on the quality of a reprocessed RMD is to be examined. If the effectiveness of the process(es) is altered adversely as a result of the change, then a repeat of part, or all, of IQ, OQ or PQ is to be performed. The outcome of this examination, including the rationale for decisions reached, is to be documented.

Any change in an RMD device, the package or the presentation of the device for reprocessing is to be examined for the impact of this change on the cleaning, disinfection, packaging or sterilisation processes. If the nature of the change requires, aspects of process definition and PQ is to be performed. The outcome of this examination, including the rationale for decisions reached, is to be documented.

2.2 Validation protocol

A validation protocol is to be developed for each process and include identification of the processing equipment and any associated or ancillary equipment used. NB: In the case where process cycles using the same load configuration only differ by the length of the different phases, the cycle being tested could be the shortest cycle proposed for validation and the longer cycles may be validated by extrapolation.

A validation protocol is to be developed for each process of cleaning, disinfection, packaging, and sterilisation and must include:

- the relevant staff responsible e.g. the equipment manufacturer’s designated representative, chemical manufacturer’s representative if required and Sterilisation Services Department (SSD) staff member
- product families selected to represent the most difficult to process RMDs as well as two reference loads that represent loading configurations typical of those used and as specified by the site
- the cycles used for each load and the position of the selected RMDs in the load to challenge the equipment depicted in a diagram or photo
- requirements to verify the RMDs acceptance prior to processing and may include:
  - pre-treatment
  - dismantling

  - removal of all single use components
  - pre-cleaning, brushing and flushing
  - ultrasonic cleaning
  - leak testing
  - soil or protein testing
  - functional testing, electrical testing and lubrication
  - sealing verification
  - visual inspection including magnification
- IQ, OQ, PQ (incorporating PPQ and MPQ reports, and any changes or modifications made to equipment since installation)
- all process audit reports, failures, breaches and recall reports, preventative measures implemented and previous validation reports
- manufacturer's instructions for use (IFU) for new RMDs, new sterile barrier system (SBS) or new critical consumables to be introduced for use
- water quality test results over the past year and any risk mitigation measures or plans implemented to rectify identified non-compliance
- manufacturer's IFU for processing, handling, storage and disposal to ensure conformity.

Requalification

Requalification of all processing equipment must be completed at least annually or whenever a change is made to either an RMD or its packaging, or to the cleaning, disinfection, packaging or sterilisation processes.

As per AS 5369:2023, requalification shall be performed where major changes or repairs to reprocessing equipment have been made which have the potential to affect the efficacy of the processes. The responsibility for determining the necessity and extent of requalification of part or all of IQ, OQ or PQ shall be assigned to a designated competent person. Procedures for requalification shall be specified. Requalification shall be performed in accordance with these procedures. Records of requalification shall be retained.

2.3 Validation report

A validation report is to be prepared in accordance with the validation protocol for each process. The validation report is to include information and data generated during IQ and OQ studies for equipment and during PQ studies for each specified process.

Data obtained and documented during IQ and OQ is to include:
- confirmation that calibration of test equipment has been determined and that calibration of measuring instrumentation fitted to reprocessing equipment has been checked and, where necessary, adjusted
- confirmation that reprocessing equipment has been tested and reproducibly delivers the defined process
- the process parameters (including their tolerances)
- for steam sterilisers, the value set for an air detector or the interpretation of a biological indicator (BI) used alone or in combination with a process challenge device.

In addition to the validation protocol and data obtained during IQ, OQ and PQ, the validation report is to include the following, where applicable:

- the equipment specification and any subsequent changes to it, including any details of modification to the instrumentation or controls
- the location and unique identification for the equipment (e.g. serial number together with name and address of the manufacturer, type of equipment and model reference number)
- documentation to demonstrate compliance with the safety specifications
- the pressure vessel report(s)
- a maintenance manual and a planned maintenance schedule for the equipment including operational procedures for all maintenance, checks and tests
- the installation and operating instructions
- copies of any declarations according to the regulations for medical devices or other devices
- details of any faults found and how they have been corrected
- the load configuration for each type of load/product family; and, if applicable, packaged product heat penetration studies for each type of steriliser load/product family
- the parameters used for each cycle and a copy of the specification for each process
- the identity of all personnel together with their professional qualifications (in terms of their competence to do the work) involved in validation
- the program for requalification, periodic testing and routine testing
- review of training manuals for routine operating personnel
- for equipment that is in current use, the results of maintenance and confirmation that data from routine performance tests are satisfactory.

The validation report is to be analysed and approved by a competent person(s). The results of this analysis are to be documented and approved. A copy of the validation report is to be retained.

2.4 Sterilisation validation

Steam sterilisation

Validation of the steam sterilisation process requires implementing a defined and documented procedure necessary to verify routine sterilising of RMDs in use.

RMDs must be assigned to a product family and the results of the sterilisation process achieved on a repeatable consistent basis. Validating the sterilising process involves:

- reviewing IQ, OQ and PQ documents and ensuring processes reflect these pre-determined results and include any ensuing modifications or changes made
- reviewing documented evidence e.g. process record reports, process efficacy audit results and maintenance and repair records. Ensure any issues identified are addressed prior to validation
- ensuring the validation plan is reviewed and updated if necessary; the purchase of extra stock required is coordinated and arrangements made for the process to be conducted at a time and in a manner that least impacts routine operation
- confirming the calibration of monitoring and measuring devices to be used during validation has been performed and certification to verify this is available
- ensuring competent personnel are assigned for the task.

PQ is to demonstrate the attainment of the required sterilising conditions on and throughout an RMD within the specified steriliser load. PQ is to demonstrate attainment of a 10-6 sterility assurance level (SAL) for an RMD that is terminally sterilised. PQ is to be

performed using a load that is representative of loads to be sterilised routinely and which is based on the most challenging load to sterilise. The total mass of the load is to be specified and documented.

PPQ is to determine attainment of the specified critical physical parameter(s) of the sterilisation process within the load, e.g. exposure phase (time at temperature), sterilising agent concentration.

MPQ is to demonstrate the microbiological lethality of the process within the load by the placement of BIs in the load. MPQ studies are to involve the placement of BIs at positions within the load where sterilising conditions are most difficult to achieve.

Key factors associated with a validated, sterilising process that ensures RMDs are sterile include verification that the microbial and physical status of RMDs and critical consumables are suitable and will not affect sterilisation.

These factors include:

- RMDs are clean and dry
- critical consumables are free from dust, holes, and tears
- steam and water quality comply with ISO/TS 17665.2: 2009 (E), A.11.2. and the requirements of AS5369:2023 Table 7.4
- control of the environment where the sterilisation, sorting and packaging of RMDs takes place as required
- control, maintenance, repair and replacement of RMDs and processing equipment.
- compatibility and adequacy of packaging and sealing methods
- competency of staff and their knowledge and adherence to infection prevention and control principles
- the way processed items are transported and stored to maintain sterility.

Validating a sterilising process requires measuring the physical and chemical efficacy of the process. This is done by processing the most difficult to sterilise load of RMDs in use and ensuring the items are presented at the completion of the cycle in the desired state.

Physical tests that confirm the physical parameters of exposure time at temperature and pressure to provide sterility assurance of a load are:

- Steam penetration test – using the most difficult to process RMD from the product family reference list and placing a probe or sensor in the centre of the pack will confirm steam penetration to all parts of the RMD if temperature is maintained for time that represents that sterilisation is achieved.
- Air leakage test – which determines that low leakage during periods of vacuum or because of inadequate air removal does not prevent the presence of saturated steam on the surfaces of RMDs to be sterilised.
- Bowie-Dick – determines that air removal and steam penetration occurs and therefore sterilisation has occurred when a chemical indicator placed in the centre of a test pack has uniform colour change when emulating adequate sterilisation.
- Thermometric test – to determine that the saturated steam temperature is maintained for the desired time at the correlating pressure to achieve sterility requires positioning temperature sensors at varying levels within the packs within the load.
- Pressure test – determines that the maximum change in the chamber pressure does exceed 1000kPA/min(10bar/min) causing damage to the packaging, the equipment and RMDs in the load.

- Load dryness – verifies that the design of the cycle, selection of process parameters and moisture content of steam are sufficient to ensure the load at the end of the cycle has not increased by more than 1%.

Microbiological tests demonstrate the microbial lethality of the load by using BIs positioned alongside thermometric sensors to demonstrate sterility assurance level (SAL 10-6).

If chemical indicators (CIs) and process challenge devices (PCDs) are used routinely then these are to be used during validation and responses recorded.

Refer to the WACHS Validating Steam Sterilisers local work instructions template.

Low temperature sterilisation

Low temperature sterilisation is used for heat sensitive RMDs that cannot withstand the rigors of high heat sterilising processes. Validation of a low temperature sterilising process requires defining the sterilising agent used, determining the microbial effectiveness of the agent and assessing the effects the exposure of the agent has on RMDs, materials and the environment.

The sterilising process must be able to be delivered effectively and consistently and according to a developed validation plan.

The following elements are to be considered as part of physical performance testing for low temperature sterilisers and ancillary devices:

- the sterilant used and means of delivery to the steriliser chamber, i.e. cassette, vapour
- monitoring and measuring equipment and minimum and maximum tolerances
- safety features such as exposure limits for sterilising chemicals and the considerations for safe storage, handling, and disposal
- ventilation requirements for work environment
- specification for software and the control of the process
- use of chemical and biological indicators
- process parameters of exposure time, temperature and sterilising agent concentration.

The steps involved in confirming process effectiveness for low temperature sterilisers are:

- select suitable RMDs from product families that represent the most difficult to process as well as two reference loads that represent routine processing
- calibration of monitoring and measuring equipment ensures the reliability of the process parameters and is to be established prior to validation
- preventative maintenance is to be planned and performed routinely and reviewed reports available
- reports from IQ, OQ and PQ and reports from audit results of routine processing are to be available for comparison
- recommended critical consumables are to be available to ensure that consecutive cycles can be performed
- SBSs used for processing and any ancillary items required such as boosters are to be included
- personnel are to be trained in operating equipment and competent and experienced in performing validation.

Refer to the WACHS Low Temperature Sterilisers local work instructions template.

2.5 Packaging

Packaging is the SBS used to protect RMDs during sterilisation, transporting and storage post sterilisation. The SBS is used to facilitate aseptic presentation at point of use and the methods and must be robust to ensure this is achieved. Packaging includes additional protective packaging if required. NB: Whilst additional protective packaging is not always necessary, a risk assessment is to be performed to determine if conditions of storage are ideal in respective facilities and protective packaging used.

Validation of the SBS typically occurs in conjunction with the validation of the sterilisers and includes the validation of equipment used for sealing i.e. the heat sealer. Refer to AS5369:2023, 7.4.5.2 and WACHS Validation of Preformed Sterile Barrier System – Heat Sealing local work instructions template.

Validation of the heat sealer includes:
- ensuring equipment has been installed and calibrated correctly as per manufacturer's specifications
- ensuring the seal produced by the heat sealer is performed at the appropriate pressure and temperature and the integrity of the seal is tested pre and post sterilisation
- ensuring that sealing will be consistently achieved under local operating conditions.

Validating an SBS requires that the developed plan be followed for three consecutive loads per cycle, specifies the RMDs packaged, the location in the load and the cycle used. It also includes:
- description of the SBS
- description of tamper proof systems to verify integrity of seal for rigid containers
- wrap grade used for sets and method of wrapping used
- method of sealing used for sets and packs
- method of labelling documenting and sterilising
- description of protective packaging (if used)
- handling, distribution and storage criteria for processed items
- staff responsible.

The following packaging processes are to be validated:
- sealing process(es) – e.g. for pouches, reels, and bags
- wrapping process(es) – e.g. for folding and closing of sterilisation wraps
- process(es) for filling and closing reusable containers.

Guidance is provided in ISO/TS 16775:2021, including Annex N, which includes useful checklists to assist in the implementation and documentation of packaging process validation.

Refer to the WACHS Evaluation of Sterile Packaging local work instructions template and WACHS Qualification and Validation of Sterile Barrier System – Reusable Rigid Container local work instructions template.

Heat sealing PQ process confirms that the heat sealing process will consistently produce an acceptable SBS under specified operating conditions. The results of PQ, including compliance with acceptance criteria, are to be documented.

2.6 Mechanical cleaning

Mechanical cleaning of RMDs is performed by a WD or automated flexible endoscope reprocessor (AFER) which incorporates cleaning with thermal or chemical disinfection. The efficacy of the disinfection cycle relies heavily on the cleaning process being performed correctly which requires performing relevant pre-treatments such as soaking, brushing or ultrasonic cleaning, and lumen irrigation to ensure the cleaning process is successful. A validation plan is to be developed in consultation with the relevant WD service technicians/engineers to ensure that the WD operation is representative of the effective processing of RMDs in use and delivers the desired outcomes that comply with the standards whilst providing achieving safe and effective RMDs for patient use. Reference documents to ensure conformance must be available, including (but not limited to) IQ, OQ, and PQ reports, process audit reports and reviews, and maintenance and repair records.

Validation of mechanical cleaning and disinfection processes ensures that the equipment functions correctly and includes confirmation that:

- the WD's cleaning and thermal disinfection processes are compatible with the RMDs
- all surfaces of the RMD are cleaned and disinfected adequately
- the load/s can be correctly aligned in the chamber to achieve adequate processing
- appropriate connections and load carriers are available to permit the adequate flow of process fluids to each device for processing RMDs with lumens or powered devices
- the volume control mechanism is in place to ensure that the dosage of process chemicals is admitted consistently during the process.

Cleaning efficacy tests demonstrate the WD's ability to remove or reduce soiling and contamination during normal operation. The most difficult to process items are often in short supply, expensive and hard to monitor, e.g. fibreoptic endoscopes. Surrogate devices which confirm that soils have been removed from lumens are used for this purpose.

The use of artificial test soils is designed to simulate normal soiling and are equally more difficult to remove.

Test soils used to validate cleaning efficacy are to comply with ISO 15883-5.

Testing the cleaning efficacy of the mechanical washer includes:

- Ensuring cleaning efficacy of the chamber and load carrier occurs by painting all surfaces with an artificial test soil. Position test soil indicators on every level of the WD and then operating a normal wash cycle; the efficacy of cleaning a load requires using the test soil on the chamber and load carrier as well as on the reference RMD load selected. The results are to be reproducible which requires repeating the process for each type of cycle used during normal operation. The pre-designed validation plan is to be followed.
- Testing the thermometric efficacy of the WD ensures the efficiency of pre-rinsing, efficacy of the cleaning chemicals to remove soils, ability of post wash rinsing to remove chemical residues and the disinfecting ability of the final rinse.
- Uniformity of temperature throughout the chamber and the load is important to achieve adequate processing.
- Uniform temperature distribution during normal processing is verified by placing temperature sensors in locations within the chamber and the load, as specified by the manufacturer and in compliance with ISO 15883.1 Part 4.3. during operating a normal cycle.

- Dosing of the cleaning chemical is tested to determine that the chemical delivered is at the recommended dose, and at the correct dilution and temperature to achieve effective processing.
- Loading carts are to contain RMDs in the configuration according to the validation plan.
- Loading carts can pose a safety risk and therefore cart alignment, fitting and locking mechanisms are to be tested to ensure the process can be performed safely.
- The efficacy of cleaning and rinsing relies on fluid being distributed efficiently throughout the chamber. Blocked spray arms will inhibit this occurring and are to be inspected and cleaned regularly.
- Safety mechanisms are to be tested to ensure one control mode cannot override another control mode:
    - In automatic control mode water, steam, compressed air or chemical cannot be admitted to the chamber until the door is closed, locked and sealed.
    - In manual mode the cycle can be advanced but only sequentially. For stages where removal of chemical and water from the chamber are required, the stage cannot be circumvented.
    - During operation there are no leaks of water, steam, aerosols of chemical, air, gas or effluent.
    - Process residues for example chemical additives need to be considered and accounted for. (Chemical manufacturer's IFUs will provide details of how this can be achieved if residues are harmful). Where the load includes a neutraliser, the volume used is to be at the lower limit and as specified in the IFU.
- Verifying correct parameters of cleaning and disinfection processes have been achieved requires identifying these on the process print out.
- Load dryness is important to prevent microbial growth, prevent damage through staining, rusting, pitting or affecting sterilisation. Surface moisture is to be removed from the load. Hot or compressed air used for the drying stage is to be of a quality which will not impair the cleanliness of the load or introduce microbial contamination.

Chemical efficacy testing

Routine monthly microbiological testing of AFERs is required to ensure proper functioning of chemical disinfection dosage, rinsing function and filter efficacy.

2.7 Ultrasonic cleaning

Ultrasonic cleaners may be integrated into a WD, built into a bench, a fixed console or may be mobile. Ultrasonic cleaners may be specifically designed for reprocessing specialised RMD e.g. micro RMDs, cannulated RMDs or incorporated into systems that include rinsing, cleaning and drying. The performance of the ultrasonic cleaner is to be tested daily in accordance with AS 2773:2019.

Refer to the WACHS Ultrasonic Cleaner local work instructions template.

To commission an ultrasonic cleaner, ensure conformance including IQ, and OQ reports to check that the cleaner is functioning properly. The ultrasonic cleaner may be subjected to additional tests, such as fully loading the ultrasonic cleaner with a test load containing visibly soiled surgical instruments, which are loaded as any routine load to demonstrate its ability to remove test soil. A copy of the test certificate is to be supplied with each ultrasonic cleaner, with all maintenance and subsequent testing results to be documented.

2.8 Quality monitoring activities

All quality monitoring activities are to be recorded in the SSD Equipment and Quality Monitoring Schedule and Recording Template.

Water quality

The quality of water used in the cleaning and disinfection process is critical to producing a safe and effective RMD. The key factors are:

- Water hardness – causes lime scale, damage to heating elements, affects the efficiency of detergents and functionality of equipment.
- Water temperature – is a major factor in efficacy at each stage of cleaning and disinfection:
    - If water temperature is too high at the initial stage this causes coagulation of blood and protein fixing of soils to the surface of the RMD and can inactivate cleaning enzymes in some detergents, rendering them ineffective.
    - If water temperatures are too low during the washing phase it prohibits the removal of fats, oils, and grease, and during the final rinse phase can cause failure of the thermal disinfection of the load.
- Presence of heavy metals – halides, phosphates and silicates risks corrosion, pitting and rusting of metal surfaces of RMDs and processing equipment and can cause tarnishing and discolouration.
- The microbial population – the purpose of cleaning is to remove soiling and thus reduce microbial contamination therefore water must not increase the bioburden load of the RMD. For items that do not undergo further processing, the final rinse must not present a potential hazard to patients. Water quality is to comply with AS 5369:2023 Tables 7.2, 7.3 and 7.4.
- Presence of bacterial endotoxins – bacterial endotoxins are compounds that are resistant to high temperatures and disinfectants and when introduced into the body can cause fever like reactions and other adverse effects. Final stages of processing in WDs and AFERs must mitigate the risk of residual water remaining on the load.

Refer to the WACHS Water Quality Requirements for Reprocessing Reusable Medical Devices local work instructions template and Water Quality Testing Requirements for Cleaning and Final Rinsing of RMDs table.

Chemical and biological indicators and process challenge devices

BIs are used for routine monitoring, qualification and load monitoring in the processing of RMDs. BIs used for microbiological performance qualification and routine monitoring and control (as applicable) are to comply with ISO 11138-1:2017 Sterilization of health care products – Biological indicators – Part 1: General requirements.

BIs are to be used according to the manufacturer's IFU in low temperature sterilisers at frequencies determined by the facility for validated moist heat sterilisation process.

CIs are used to verify that critical parameters are met in the reprocessing of RMDs. CIs are to comply with ISO 11140-1:2014 Sterilization of health care products – Chemical indicators – Part 1: General requirements and be selected according to the sterilisation method used.

CIs are to be used:

- as part of PQ if internal chemical indicators are to be used routinely on the exterior of each packaged RMD
- according to the manufacturer's IFU for low temperature sterilisation systems using a liquid chemical sterilising agent
- in every load where semi-critical RMDs are sterilised unwrapped
- by placing at the most difficult-to-sterilise location
- included in loan and/or repair RMDs that are left unwrapped to identify processed from unprocessed loads.

Process challenge devices

A PCD is used to assess the effective performance of a sterilisation process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult RMD routinely processed.

PCDs are to be used in every load to confirm that the equipment is working correctly and operating within specifications.

Note that for pre-vacuum sterilisers without an air detector it is recommended that the use of PCDs is considered to verify the absence of residual air that might affect the sterility of the load.

2.9 Tracking and traceability

The reprocessing of RMDs, including loan and trial items, require quality systems to validate the effectiveness of all stages of instrument reprocessing. Appropriate management of quality tracking systems ensure that staff can promptly recall a sterilised product if required, tracking it from when it was dispatched from the SSD to receipt by the user area. This process provides WACHS with the ability to link every stage of reprocessing RMDs to patients for whom they are used.

Tracking systems

All RMDs reprocessed in SSD must be scanned into and recorded in the manual or electronic tracking system enabling users to track the location, reprocessing history and usage of each item. All machines, tray lists and processed instruments must be registered in the tracking system by SSD staff when purchasing to ensure the history and information for each use is documented.

In the absence of an electronic tracking system, sterilised RMDs must be tracked manually via the use of the sterilisation batch load indicator labels utilising a paper-based system that conforms to the requirements of AS 5369:2023. Load indicator labels are to be removed from the relevant pack and included in the patient's health record to ensure instruments maintain traceability to an individual patient in the event of a recall.

The following information is to be recorded in the electronic tracking system:

- location of each RMD at every stage of the procedure/process.
- date of the washing/sterilising cycle.
- washer/steriliser number or code.
- cycle load or number.
- process parameters.

- identity of the person undertaking processing at each stage, including release of load contents
- specific contents of the load
- total number of individual items contained in the load
- readout result of physical, chemical or biological/enzymatic indicators used
- storage location
- dispatch location
- patient the RMD has been used on.

Batch load indicator labels

- All RMDs reprocessed and sterilised in SSD are to be tracked via affixed product identification and traceability stickers (batch load indicator labels) adhered to each reprocessed item or tray.
- The batch load indicator label is to link the sterilising unit and batch information to the RMD and to the patient. The batch label facilitates the identification and location of the RMD in the event of a recall.
- Batch load indicator labels are to be placed on each RMD or tray and must include the:
  - date
  - steriliser number
  - cycle load number.
- The batch load indicator labels are to be removed from the relevant pack and included in the patient's health record to ensure instruments have traceability to an individual patient.
- Any single sterile RMD or tray that does not have a batch load indicator label attached must not be used and is to be returned to SSD and reported to the SSD Manager/ Supervisor.

Manual tracking

Manual tracking of RMDs must occur within WACHS hospitals that do not have an electronic tracking system or in any area in the event of an electronic tracking system failure.

Staff using RMDs must action the following to ensure tracking and future traceability of these items:

- prior to use, ensure the integrity of the RMD pack and ensure external sterilisation process indicators are the correct colour
- retain the RMD load indicator label and affix it to the patient's health record.

Tracking of RMDs requiring repair or replacement

Tracking of RMDs is to be undertaken using the electronic tracking system or manual log system when instruments are sent for maintenance or when new instruments are included in a tray/set (e.g. broken instruments have been replaced). Accurate instrument identification supports the reunification of instruments with their trays following repair or replacement.

2.10 Repair and maintenance

Maintenance contracts for all reprocessing equipment must be secured as part of all purchasing agreements. Management of unscheduled maintenance or repairs must form part of the initial purchasing agreement and be addressed within the agreed timeframes.

Replacement programs must exist for all reprocessing equipment to minimise service failures and maintain up-to-date processing capabilities and efficiencies in production.

Documented records of repairs and maintenance must be kept either on paper files or electronically.

A written report is to be obtained upon completion of all preventive maintenance. A copy of the Certificate of Service and Validation is to be displayed near the equipment.

Periodic preventative maintenance of reprocessing equipment is required, including calibration of monitoring instrumentation. Planned maintenance is to be performed by qualified service providers at intervals recommended by the manufacturer and in compliance with the requirements of AS 5369:2023.

Electrical safety checks of all RMD reprocessing equipment are to be maintained as part of the divisional preventative maintenance program and records of maintenance must be retained in an easily accessible location.

Periodic preventative maintenance of RMDs

Preventative maintenance of RMDs may include, as relevant:
- inspection for alignment, sharpness etc.
- insulation testing
- lubrication of hinges and joins.

Maintenance must be undertaken in compliance with the manufacturer's IFU and documented.

Faults and repairs

Faults and deviations from required parameters must be reported to the SSD Manager/ Supervisor immediately and corrective action/s taken.

Where a fault has the potential to impact on the quality and safety of an RMD or on operator and patient safety, the equipment is to be removed from use immediately pending repair.

Requalification of the equipment is to be performed if major works or repairs are undertaken that have the potential to affect the efficacy of the sterilisation process.

Notification of a faulty RMD

The process for notification of a faulty RMD is as follows:
- Place a plastic clip and/or identification tag on the RMD, documenting details of the fault on an identification tag or form as defined by the site.
- Send to the SSD at the end of the procedure.

- The RMD is to be washed and reprocessed in SSD. If full disinfection cannot be completed effectively, advice should be sought from the manufacturer about how to prepare and package the RMD for transport.
- Complete a Universal Cleaning and Sterilisation Guarantee ("Green Form") with evidence of thermal disinfection or sterilisation.
- Send the RMD for repair to the designated repairer.

Where a critical RMD is not available for an extended period, the SSD Manager/ Supervisor must advise the Shift Coordinator and Perioperative Services Manager so that alternative arrangements can be made to ensure that surgery is not compromised.

2.11 Cleaning processes

Appropriate cleaning and disinfection of all equipment and environmental surfaces must be undertaken as per the department cleaning schedule. Cleaning audits are to be performed regularly and non-conformance must be addressed immediately.

Refer to the WACHS Environmental Cleaning Policy and the WACHS SSD Environmental Cleaning Record for further information as required.

2.12 Auditing

Audits should be undertaken at a minimum as per the site's audit schedule using the relevant audit tools. Following each audit, any identified issues/concerns should be escalated to the responsible person to ensure issues are rectified as soon as practicable.

Refer to the SSD Audit Schedule and Audit Tool Templates.

2.13 Documentation and record keeping

Completed task lists, cleaning audits and reports are to be stored and maintained in HPE Records Manager (TRIM) in a designated folder accessible to relevant key personnel including the Perioperative Services Manager, SSD Manager/Supervisor, the Environmental Cleaning Team Leader/Manager and Infection Prevention and Control Lead.

3. Roles and Responsibilities

Health Service Organisations are responsible for ensuring that adequate resources and support are provided to ensure a safe working environment for all staff.

SSD Manager/Supervisor is to implement the requirements of this document to ensure the processing of RMDs is compliant with AS 5369:2023 and associated normative references and ensure the quality and safety of reprocessed RMDs.

Sterilisation Technicians must comply with the requirements of this document and report non-compliance to the SSD Manager/Supervisor or Perioperative Services Manager.

All staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

4. Monitoring and Evaluation

Regular monitoring will contribute to compliance with relevant Standards, good quality patient outcomes and improved staff satisfaction.

The SSD Manager/Supervisor or Perioperative Services Manager is responsible for ensuring that:

- monitoring of compliance with this document is carried out in line with AS 5369:2023
- risk assessments are completed, outcomes evaluated and actions taken as required
- regular cleaning audits are undertaken as per the SSD's audit schedule and action/s are identified and implemented as required.

All identified issues must be escalated and reported to the local Perioperative Management Committee and Infection Prevention and Control Committee. They are also to be tabled at the Regional Infection Prevention and Control Committee meetings, with any issues escalated to the Regional Safety and Quality Committee.

Evaluation of audit results and annual validation reports by department managers that are tabled and discussed at the Sterilisation Services/Perioperative Services/Surgical Services Committee meetings however named and escalation of concerns to the Infection Prevention and Control Committee meetings and the Regional Safety Quality meetings as relevant.

5. References

Australian College of Perioperative Nurses (ACORN) – Standards for Perioperative Nursing in Australia. 2023.

Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care. Part C: Steam sterilisation. 2016. NHS England » Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care.

Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care. Part D: Washer-disinfectors. 2016. NHS England » Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care.

National Health and Medical Research Council, Australian Commission on Safety and Quality in Healthcare. Australian guidelines for the prevention and control of infection in healthcare. Canberra ACT: NHMRC; 2019 [Accessed: 19 April 2024].

AS 2773:2019. Ultrasonic cleaners for health service organisations. Available from WACHS Library - Standards.

ISO 15883-2:2024. Washer-disinfectors Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. Available from WACHS Library - Standards.

ISO 15883-3:2024. Washer-disinfectors Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers. WACHS Library - Standards.

ISO 15883-6:2011. Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment. Available from WACHS Library - Standards.

ISO 15883-1:2024. Washer-disinfectors — Part 1: General requirements, terms and definitions and tests. Available from WACHS Library - Standards.

ISO 15883-5:2021. Washer-disinfectors Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy. Available from WACHS Library - Standards.

AS 5369:2023. Reprocessing of reusable medical devices and other devices in health and non-health related facilities. Available from WACHS Library - Standards.

AS ISO 13485:2017. Medical devices - Quality management systems - Requirements for regulatory processes. Available from WACHS Library - Standards.

ISO 11138-7:2019. Sterilisation of health care products — Biological indicators – Part 1: General requirements. Available from WACHS Library - Standards.

ISO 11140-1:2014. Sterilisation of health care products — Chemical indicators – Part 1: General requirements. Available from WACHS Library - Standards.

ISO 11607.2: 2019. Packaging for terminally sterilised medical devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes. Available from WACHS Library - Standards.

ISO 14937:2009. Sterilisation of health care products — General requirements for characterisation of a sterilising agent and the development, validation, and routine control of a sterilisation process for medical devices. Available from WACHS Library - Standards.

ISO/TS 16775:2021. Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2. Available from WACHS Library - Standards.

ISO/TS 17665:2024. Sterilisation of health care products — Moist Heat – Requirements for the development, validation, and routine control of a sterilization process for medical devices. Available from WACHS Library - Standards.

ISO 25424:2018/Amd1:2022. Sterilisation of health care products — Low temperature steam and formaldehyde — Requirements for development, validation, and routine control of a sterilisation process for medical devices. Available from WACHS Library - Standards.

6. Definitions

Term	Definition
Biological indicator (BI)	A test system containing viable microorganisms providing a defined resistance to a specified sterilisation process.
Chemical indicator (CI)	A non-biological indicator test system that reveals change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process.
Cleaning	The removal of contamination from an item to the extent necessary for further processing for intended use.
Competent person	A person who has, through a combination or training, education and experience, acquired knowledge and skills enabling that person to correctly perform a specific task.
Health service organisation (HSO)	A separately constituted health service that is responsible for the clinical governance, administration and financial management of a service unit providing health care.
Immediate use sterilisation	A process in which sterilised reusable medical devices (RMDs) are transferred aseptically to the sterile field in the shortest practicable time after removal from the steriliser.
Installation qualification (IQ)	A process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.
Manufacturer's instructions for use (IFU)	Instructions for use (IFU) provided by the manufacturer of the medical device and/or accessories (e.g. sterile barrier systems, reusable medical devices or washer disinfectors).
Medical device	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific purpose/s of: • diagnosis, prevention, monitoring, treatment or alleviation of disease • diagnosis, monitoring, treatment, alleviation of or compensation for an injury • investigation, replacement, modification or support of the anatomy or of a physiological process • supporting or sustaining life • control of conception • disinfection of medical devices • providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Operational qualification (OQ)	A process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

Performance qualification (PQ)	A process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with the operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.
Pre-treatment	The initial treatment of a used reusable medical device (RMD) performed at the point of use prior to reprocessing.
Process Challenge Device (PCD)	An item designed to constitute a defined resistance to a sterilisation process and used to assess performance of the process.
Product	The result of a process.
Product family	Groups or subgroups of product characterised by similar attributed such as mass, material, construction, shapes, lumens, sterile barrier system (SBS) or packaging system and which present a similar challenge to the cleaning, disinfecting and/or sterilising processes.
Regular cleaning	Periodic cleaning tasks that must be undertaken on a recurring frequency, but not daily (e.g. weekly, or monthly).
Reusable medical device (RMD)	A medical device that is designated or intended by its manufacturer as suitable for reprocessing and reuse. It is not a medical device that is designated or intended by its manufacturer for single use only.
Standard precautions	Work practices that constitute the first line approach to infection prevention and control in the health care environment.
Sterile	Free from viable microorganisms.
Sterile barrier system (SBS)	Minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at point of use.
Sterilisation Services Department (SSD)	Also known as Central Sterilising Services Department, Sterile Processing Department, Central Supply Department. An integrated department in a Health Service Organisation that performs cleaning, disinfection, and sterilising actions on RMDs and manages storage of sterile stock and consumables.

7. Document Summary

Coverage	WACHS wide
Audience	All WACHS healthcare workers that use or reprocess RMDs
Records Management	Non Clinical: Corporate Recordkeeping Compliance Policy Clinical: Health Record Management Policy
Related Legislation	• *Therapeutic Goods Act 1989* (Cth) • *Health Services Act 2016* (WA)
Related Mandatory Policies / Frameworks	• MP 0134/20 National Safety and Quality Standards Accreditation Policy • Clinical Governance, Safety and Quality Policy Framework
Related WACHS Policy Documents	• Environmental Cleaning Policy • Packing, Wrapping and Sealing Reusable Medical Devices Procedure • Reprocessing Reusable Medical Device Policy • Reusable Medical Devices on Loan and Instruments on Trial Procedure • Thermal Disinfection of Reusable Medical Devices Procedure
Other Related Documents	• Speciality Specific Policy Documents - Surgical Services - Sterilisation Services • SSD Audit Schedule and Audit Tool Templates • SSD Equipment and Quality Monitoring Schedule and Recording Template • WACHS Low Temperature Sterilisers local work instructions template • WACHS SSD Environmental Cleaning Record • WACHS Validating Steam Sterilisers local work instructions template • WACHS Validation of Preformed Sterile Barrier System – Heat Sealing local work instructions template • WACHS Water Quality Requirements for Reprocessing Reusable Medical Devices local work instructions template • Water Quality Testing Requirements for Cleaning and Final Rinsing of RMDs table
Related Forms	Nil
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 3396
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.03, 3.04, 3.05, 3.06, 3.07, 3.08, 3.09, 3.10, 3.11, 3.12, 3.13, 3.14, 3.15 & 3.17

Aged Care Quality Standards	Nil
Chief Psychiatrist's Standards for Clinical Care	Nil
Other Standards	AS 5369:2023. Reprocessing of reusable medical devices and other devices in health and non-health related facilities

8. Document Control

Version	Published date	Current from	Summary of changes
1.00	1 December 2022	1 December 2022	New procedure
1.01	13 March 2023	1 December 2022	Minor correction
2.00	1 October 2024	1 October 2024	Full review, title change and consolidation of other related procedures
2.01	13 December 2024	1 October 2024	Minor amendment to update references

9. Approval

Policy Owner	Executive Director Nursing and Midwifery
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing - Perioperative
Business Unit	Nursing and Midwifery - Surgical Services
EDRMS #	ED-CO-22-331240

This document can be made available in alternative formats on request.