Validation of Cleaning, Disinfecting, Packaging and Sterilising Processes Procedure

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1. Guiding Principles

This procedure:

- provides guidance for WACHS staff who reprocess reusable medical devices (RMDs) and are responsible for planning and participating in the validation of cleaning, disinfecting, packaging and sterilising processes as per Standards Australia AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations.
- gives health care facilities an understanding of how important annual validation of processes is to continued patient safety, business continuity and the protection of the investment made in equipment and instruments.

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.

Cleaning, disinfection, packaging and sterilisation processes are a series of important but separate processes required to ensure a safe and effective RMD is produced. To provide assurance that these processes are consistently delivering satisfactory outcomes they must be validated as per the manufacturer's instructions for use (IFU) and as outlined in AS/NZS 4187:2014. Whilst the physical requirements and outcomes for each of these processes will differ, validation verifies that all defined physical and chemical parameters within the specified tolerances occurs in all processes.

2. Procedure

2.1 Validation

Validation verifies the continued conformance of the equipment with data established during the original study performed when acquiring the equipment and periodically thereafter as per the manufacturer's instructions for use (IFU) and as outlined in AS/NZS 4187:2014. i.e. Installation qualification (IQ), Operational qualification (OQ), and Performance qualification (PQ) [which incorporates physical performance qualification (PPQ) and microbiological performance qualification (MPQ)]. Reports generated at IQ must be maintained for reference. The details supplied by the equipment manufacturer of services required, (i.e. water, steam, electricity) including the quality, maximum demand and the allowable deviations required are to be adhered to.

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

Validation requires pre-planning including:

- developing a plan incorporating a selection of reusable medical devices (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 minimise 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.

Note: Revalidation is to be performed when major changes or repairs are made to the equipment, changes are made in critical consumables used, or changes are made to utilities such as power and water.

Additional revalidation requirements:
As per AS/NZS 4187:2014, section A 10.5 - Assessment of change, processes must be revalidated if changes are made to the equipment, product, packaging materials or packaging process, which could potentially compromise the original validation and affect the sterility, safety or efficacy of sterile medical devices; however, a documented rationale must be developed to support this conclusion.

The following is a list of changes which could affect the status of a validated process:

- sterile barrier system (SBS) material changes.
- new equipment.
- transfer of processes and equipment from one facility or location to another.
- sterilisation-process changes.
- review of end user complaints or non-conforming product, negative trends in quality or process control indicators.
- change in SBS contents that are outside the worst case originally evaluated.
- change of transport route or means e.g. from within the building only to transport between buildings which may involve significantly changed challenges to the package.

The need for revalidation must be evaluated and documented. If the change does not require that all aspects of the original validation be repeated, this revalidation does not have to be as extensive as the initial validation, however a documented rationale must be developed to support the change.

2.2 Validation plan

A validation plan 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 reusable medical devices (RMDs) as well as two reference loads that represent a variety of RMDs in use.
- the cycles to be 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 needed to verify the RMDs acceptance prior to processing such as:
  - 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
- installation qualification (IQ), operational qualification (OQ), performance qualification (PQ) [incorporating physical performance qualification and microbiological performance qualification (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.
- IFU's for new RMDs, new SBS or new critical consumables to be introduced for use.
- water quality test results over the past year and any risk mitigating measures or plans implemented to rectify identified non-compliance.
- IFU for processing, handling, storage and disposal to ensure conformity.

2.3 Cleaning

Reusable medical devices (RMDs) for cleaning may be contaminated with blood, body fluid, chemicals, dirt and/or dust. Depending on the level of soiling, complexity of the RMD and the materials incorporated in the manufacture of the RMD, varying method/s of cleaning may be required. Manufacturer instructions for use (IFUs) must always be adhered to.

Cleaning is the most important step in the processing of RMDs. Application of appropriate processes are required to prevent damage to the RMDs and protect patients from harm.

Cleaning includes:

- removal of gross soil (visible blood, tissue and bone) at point of use by scrub nurse
- pre-cleaning as required by IFU at point of use by scrub nurse
- rinsing and flushing following dismantling
- ultrasonic cleaning
- manual cleaning
- mechanical cleaning

The efficacy of cleaning of an RMD is affected by the level of soiling but it is also impacted by:

- unsuitable water quality used for rinsing and washing, increasing bioburden or affecting the efficacy of the cleaning chemicals.
- inadequate concentration, temperature or contact time of the cleaning chemical.
- the amount of friction/pressure applied during the cleaning process.
- damaged or poorly maintained cleaning equipment e.g. blocked spray arms.

2.4 Manual cleaning

An automated process might not be recommended for cleaning of some reusable medical devices (RMDs) e.g. certain fragile or complex RMDs. Where manual cleaning of an RMD is recommended by the manufacturer of the RMD, it is essential that the cleaning procedure clearly describes how the RMD is to be manually cleaned rinsed and dried.

Dedicated manual cleaning equipment and accessories must be available. Cleaning equipment and accessories must be:

- inspected for cleanliness, damage and sustainability for their intended purpose prior to each use
- properly cleaned and thermally disinfected at the conclusion of each cleaning session
- discarded if damaged, worn or contaminated.

Manual cleaning of an RMD shall only be used:

- where an RMD manufacturer's validated cleaning instructions require manual cleaning of the RMD.
- as a pre-treatment prior to reprocessing of an RMD in a washer disinfector.

Note: The use of an automated cleaning process in a washer disinfector (WD) is the preferred means of cleaning as an automated process is more reproducible than a manual cleaning process.

The procedure for manual cleaning of an RMD must include the following directions:

- Flush/rinse the RMD in cool running water to remove gross contamination NB: the working channels of flexible endoscopes must be aspirated and flushed through immediately after use. The external surfaces must be wiped with a lint free single use cloth, using detergent and water, in accordance with the IFU.
- For each cleaning episode, fill a sink with freshly made up warm water and the specified cleaning agent diluted in accordance with the manufacturer's instructions.
- Disassemble or open (where applicable) the RMD for cleaning prior to immersion of the RMD in the cleaning agent.
- Hold the RMD low in the sink to minimise the generation of particle spatter and aerosols during cleaning.
- Properly clean all surfaces of the RMD, including lumens and valves.
- Rinse the cleaned RMD in warm running water.
- Dry the RMD.
- Inspect the reprocessed RMD for completeness and to identify any defects.

Manual cleaning of RMDs must be:

- performed by staff who have received training and are competent to do so
- regularly tested using documented soil and protein residue tests to ensure the efficacy of manual cleaning processes.
- inspected both visually and under magnification to ensure soil and chemical residue have been removed.
- completed with adherence to standard precautions, ensuring appropriate use of PPE to prevent exposure to blood/body fluids during the cleaning process.

Note: PPE is to be worn when handling manually cleaned RMDs, keeping in mind that these items have not been thermally disinfected and may pose an infection transmission risk to staff, surfaces and other RMDs they contact.

2.5 Ultrasonic cleaning

Ultrasonic cleaners may be integrated into a Washer Disinfector (WD), built into a bench, a fixed console or may be mobile. Ultrasonic cleaners may be specifically designed for specialised reusable medical devices (RMDs), for example, micro RMDs, cannulated RMDs or incorporated into systems that include rinsing, cleaning and drying.

Due to the diversity of configurations and functions available it is important that staff receive training in the operation of the ultrasonic cleaner and manufacturer's instructions for use (IFU) must be adhered to as per AS 2773:2019. Section 4. Ultrasonic cleaners operate by passing ultrasonic acoustic waves through a fluid in which bubbles of gas are generated, the bubbles become unstable and implode causing the cleaning effect.

The performance of the ultrasonic cleaner shall be tested daily in accordance with AS 2773 or AS 2773.1, as applicable. An ultrasonic cleaner must be provided for cleaning of an RMD where the RMD IFU for cleaning specify the use of this process, or where pre-treatment of an RMD requires use of an ultrasonic cleaner prior to processing of the RMD in a washer disinfector. An ultrasonic cleaner must be fitted with a lid to prevent the emission of aerosols during use. Lids must be closed whenever the equipment is operated.

To validate an ultrasonic cleaner:

- develop a validation plan, which includes RMDs and cycle/s to be used.
- refer to relevant documents to ensure conformance including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) reports. Process audit reports, reviews and maintenance and repair records are to be available.
- perform the normal daily operation of:
  - filling the cleaner tank with water
  - adding an appropriate low sudsing detergent at the dose recommended by the manufacturer
  - degassing to remove non-condensable gasses to enhance decavitation
  - ensuring the cleaning solution is the correct temperature

  - performing the daily cleaning efficacy tests, for example, pencil or aluminium foil test
  - using a process challenge device (PCD) to routinely ensure efficacy of cleaning lumens
  - performing transducer function performance testing using available commercial devices to ensure effective cavitation occurs
- place assimilated soiled RMDs and cleaning efficacy PCD test into the ultrasonic cleaner using an approved commercial preparation and operate under normal operating conditions.
- ensure control equipment for temperature, degassing, flushing, drying, low water level or failure is operating.
- ensure monitoring and measuring equipment has been calibrated as per IFU and verification is supplied.
- ensure process outcomes are consistently achieved by performing three consecutive loads, consisting of two reference loads and a load that represents the most difficult to clean.

2.6 Mechanical Cleaning

The cleaning of used reusable medical devices (RMDs) is easier to standardise and control when an automated mechanical process is used.

Mechanical cleaning of RMDs is performed by a washer disinfector (WD) or automated endoscope reprocessor (AER) which incorporates cleaning with thermal or chemical disinfection. The RMD processed may be intended for immediate use or intended for further processing such as packing and sterilisation. In either case the process of cleaning and disinfection must be performed adequately to ensure the wellbeing of patients and safety of staff handling the RMDs. The efficacy of the disinfection cycle relies heavily on the cleaning process being performed adequately 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 WD 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 achieving safe and effective RMDs for patient use. Reference documents to ensure conformance including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) reports, process audit reports and reviews and maintenance and repair records are to be available.

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

- the WD’s process of cleaning and thermal disinfection is compatible with the RMDs in use.
- all surfaces of the RMD, both exterior and inner, are cleaned and disinfected adequately.
- the load 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 WDs ability to remove or reduce soiling and contamination during normal operation. The most difficult to process items are usually 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 equal to or 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. Using test soil indicators positioned on every level of the WD and then operating a normal wash cycle only. The disinfection cycle and maybe the drying cycle if needed are not used for this test. ISO 15883.2.5.,6.10, 4.2.1.1
  - ensuring 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.
  - Thermometric testing must occur during a cold start and for three consecutive hot starts to determine consistency as per ISO/TS 15883.5. Recommended temperature controls achieved for flushing no greater than 45°C; for washing as per chemical manufacturer's instructions and for final rinse (disinfection) as per AS/NZS 4187:2014 Table 6.1.
- Dosing of the cleaning chemical is tested to determine that the chemical delivered is at the recommended dose, is the correct dilution and the correct 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 is 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. 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 such as chemical additives need to be considered and accounted for. (Chemical manufacturer's instructions for use (IFU) 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 AERs is required to ensure proper functioning of chemical disinfection dosage, rinsing function and filter efficacy. Routine microbial testing of thermal disinfection processes in a WD is not required as the temperature of the processing solution attained is to be programmed to achieve adequate log kill and verified on the process print out (*ISO 15883.1 and 2).*

2.7 Water Quality

The quality of water used in the cleaning and disinfection process is critical to producing a safe and effective reusable medical device (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/NZS 4187 Amendment 2:2019, Table 7.2 and 7.3.
- **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 washer disinfectors (WDs) and automated endoscope reprocessors (AERs) must mitigate the risk of residual water remaining on the load that contains more than 0.25 EU/ml of Endotoxin for critical RMDs or no greater than 30EU/ml for semi critical RMDs.

2.8 Packaging

Packaging is the sterile barrier system (SBS) used to protect reusable medical devices (RMDs) during sterilisation transporting and storage post sterilisation. An SBS is used to facilitate aseptic presentation at point of use and methods used to secure SBS must achieve this. Packaging includes additional protective packaging if required.

Note: 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 if not.

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 AS/NZS 4187, 7.4.4.2.

Validating an SBS requires that the developed plan is followed for three consecutive loads per cycle, specifies the RMDs packaged and 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 sterilizing
- description of protective packaging if used
- handling, distribution and storage criteria for processed items
- staff responsible

Additional guidance is provided in ISO/TS 16775:2014, including Annex D, which includes useful checklists to assist in the implementation and documentation of packaging process validation.

The following packaging processes shall 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.

Heat sealing process performance qualification (PQ) shall demonstrate that the heat-sealing process will consistently produce acceptable sterile barrier systems under specified operating conditions. The results of PQ, including compliance with acceptance criteria, shall be documented.

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.

2.9 Sterilisation

Steam sterilisation

Validation of the steam sterilisation process requires implementing a defined and documented procedure necessary to verify routine sterilising of in use reusable medical devices (RMDs). RMDs must be assigned to a product family and the results of the sterilisation process achieved on a repeatable consistent basis.

The elements of validating the sterilising process involves:
- reviewing installation qualification (IQ), operational qualification (OQ) and performance qualification (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 arranged 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 shall demonstrate the attainment of the required sterilizing conditions on and throughout an RMD within the specified steriliser load. PQ shall demonstrate attainment of a 10-6 sterility assurance level (SAL) for an RMD that is terminally sterilised. PQ shall 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 shall be specified and documented.

There are two components to PQ, namely physical performance qualification (PPQ) and microbiological performance qualification (MPQ):

- PPQ shall verify attainment of the specified critical physical parameter/s of the sterilising process within the load, e.g. exposure time at temperature, sterilising agent concentration.
- MPQ shall demonstrate the microbiological lethality of the process within the load by the placement of biological indicators in the load. MPQ studies shall involve placement of biological indicators at positions within the load where sterilising conditions are most difficult to achieve.

Key factors associated with a properly 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 AS/NZS 4187 amendment 2:2109 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 manner in which 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 which confirms the physical parameters of exposure time at temperature and pressure that gives sterility assurance of the 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 as a result of inadequate air removal does not prevent the presence of saturated steam on the surfaces of RMDs to be sterilised.
- Bowie and 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 different 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 biological indicators positioned alongside thermometric sensors to demonstrate sterility assurance level, (SAL 10-6).

If chemical indicators and performance challenge devices are used routinely then these are to be used during validation and responses recorded. Indicators chosen are to comply with ISO 11138:7 2019 and 11140:1 2014.

Low temperature sterilisation

Low temperature sterilisation is used for heat sensitive reusable medical devices (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.

Physical performance – includes any ancillary devices and the following:
- the sterilant used and the means it is delivered 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.

Microbial effectiveness
- Microbial effectiveness requires identifying that the agent used for sterilisation is in date and intended for use.
- Reference microorganisms that have known high resistance to sterilising agents in the form of recommended chemical and biological indicators are used to verify lethality.
- Identifying process variables that affect lethality of the microbial effectiveness such as inadequate cleaning, moisture and residues of cleaning and disinfection.
- Ensure the delivery of the correct dose, temperature and contact time of the sterilising agent is attained.

- The effects the agent's residues may have on staff and patients is to be known and safety data information is to be available in case of a spill.

Process effectiveness

- 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 installation qualification (IQ), operational qualification (OQ) and performance qualification (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.
- Sterile barrier system (SBS) 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.

3. Definitions

Biological indicator (BI)	A test system containing viable microorganisms providing a defined resistance to a specified sterilisation process.
Calibration	A set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values released by standards.
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 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 characterized by similar attributed such as mass, material, construction, shapes, lumens, sterile barrier systems (SBS) or packaging system and which present a similar challenge to the cleaning, disinfecting and/or sterilising processes.
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.

4. Roles and Responsibilities

Health Service Organisations are responsible in ensuring that adequate resources and support is provided to allow the annual validating of all processing equipment.

All **sterilising services staff** are responsible for ensuring the processing of reusable medical devices (RMDs) complies with the requirements of the standards. Producing safe and effective RMDs for patient use requires that processing equipment is adequately maintained and operated and conforms with manufacturers specifications in the form of annual validation.

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

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS/NZS 4187:2014

Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to section 26 of the Health Services Act 2016 and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

6. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System in accordance with the Records Management Policy.

All WACHS clinical records must be managed in accordance with the Health Record Management Policy

7. Evaluation

Continuous monitoring and auditing of all checklists, regular - daily, weekly, monthly and annual reporting.

Ensure that risk assessments are completed, outcomes evaluated, and action taken as required.

Continuous evaluation of audit results and annual validation reports by Department managers, tabled and discussed at IPC and then onto Regional Safety Quality meetings.

Evaluation gained from regular monitoring will contribute to compliance to Standards, good patient outcomes and improved staff satisfaction.

8. Standards

National Safety and Quality Health Service Standards – 3.01, 3.02, 3.04, 3.05, 3.06, 3.07, 3.08,3.09, 3.10, 3.11, 3.12, 3.13 & 3.17.

AS/NZS 4187:2014 and amendment 2:2019, Reprocessing of reusable medical devices in health service organizations.

AS 2773:2019 Ultrasonic cleaners for health service organisations
International Organisation for Standardisation (ISO)
ISO 15883:2006.

- Part 1: Washer-Disinfectors General Requirements, Terms and Definitions and Tests requirements.
- Part 2 Requirements for Washer-Disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils and glassware, etc.
- Part 5 Test soils and methods for demonstrating cleaning efficacy.

ISO 14937: 2015. Sterilisation of health care products — General requirements for Characterization of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices.

ISO 13485: 2016. Quality management for medical devices.

ISO 11607.2: 2019. Packaging for terminally sterilised medical devices
- Part 2: Validation Requirements for Forming, Sealing and Assembly Processes.

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

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.

ISO/TS 17665:2006. Sterilisation of health care products — Moist Heat
- Part 1: Requirements for the development, validation and routine control of a sterilisation process for medical devices.
- Part 2:2009. Sterilisation of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1.

ISO 25424:2018. Sterilisation of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilisation process for medical devices.

ISO 11138-7:2019. Sterilisation of health care products — Biological indicators – Part &: Guidance for the selection, use and interpretation of results.

ISO 11140-1:2014 Sterilisation of health care products — Chemical indicators- Part 1: General requirements.

Note: Standards can be purchased via https://infostore.saiglobal.com/en-au/Standards/ISO-15883-1-2006-612594_SAIG_ISO_ISO_1405208/

9. Legislation

Therapeutic Goods Act 1989 (Cwlth)
Health Services Act 2016 (WA)

10. References

1. Australian College of Perioperative Nurses (ACORN) – Standards for Perioperative Nursing in Australia 16th Edition, May 2020.
2. Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care. Part D: Washer-disinfectors. 2016.
3. Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care. Part C: Steam sterilisation. 2016. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/545864/HTM0101PartD.pdf
4. National Health and Medical Research Council (2019) Australian Guidelines for the Prevention and Control of Infection in Healthcare. Canberra: Commonwealth of Australia.

11. Related Forms

Nil

12. Related Policy Documents

WACHS Chemical and Biological Indicators and Process Challenge Devices Procedure
WACHS Packing, Wrapping and Sealing Reusable Medical Devices Procedure
WACHS Reprocessing Reusable Medical Device Policy
WACHS Reusable Medical Devices on Loan and Instruments on Trial Procedure
WACHS Thermal Disinfection of Reusable Medical Devices Procedure
WACHS Tracking and Traceability of Reusable Medical Devices Procedure

13. Related WA Health System Policies

MP 0134/20 – National Safety and Quality Health Service Standards Accreditation Policy

14. Policy Framework

Clinical Governance, Safety and Quality

This document can be made available in alternative formats on request for a person with a disability

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