SALHN Audit Tool

Audit Tool and Action Plan for AS 5369:2023

Reprocessing of reusable medical devices and other devices in health and non-health related facilities

Auditor: .....

Facility .....

Audit date: .....

Version 3.0 (February 2024)

Government of South Australia

SA Health

Table of contents

Version control and change history.

Version	Date from	Date to	Amendments
V3.0	20.2.24	Current	
V2.2	7.5.19	15.12.23	Amendment following release of Amendment 2
v2.1	28.12.18	7.5.19	Formatting and add information asset classification
v2.0	13.11.15	28.12.18	Amendment
V1.0	August 2015	13.11.15	Original (AS/NZS4187:2014)

Purpose

To provide a tool that will assist health and non-health facilities to measure and improve their compliance to AS 5369:2023.

Scope

This tool is designed to be used in SALHN where the processing of re-usable medical and surgical equipment is carried out.

The completed audit will assist in providing evidence for accreditation. It is recommended that a % of compliance is determined upon completion of the audit.

General

When using the audit tool you will no doubt, become aware that only requirements of the standard which are mandatory have been included, as the philosophy is, that if these issues are achieved recommendations would be automatically accomplished.

It is recommended that the person/s intending to conduct the audit should read the standard in its entirety.

Auditors guide

- The terms ‘normative’ and ‘informative’ have been used in AS 5369 to define the application of the Appendix to which they apply.
- A ‘normative’ Appendix is an integral part of a Standard, whereas an ‘informative’ Appendix is only for information and guidance.
- Statements expressed in mandatory terms in notes to tables are deemed to be requirements of AS 5369 Standard.
- There are key words used in Australian and ISO standards which need to be followed:
    - SHALL = MANDATORY
    - SHOULD = STRONGLY RECOMMENDED
    - MAY = SUGGESTS THE EXISTENCE OF A SAFE ALTERNATIVE ACTION

Section 1: Abbreviations

AFER	Automated flexible endoscope reprocessor (aka AER or WD for thermolabile endoscopes)
BI	Biological Indicator
ARTG	Australian Register of Therapeutic Goods
CDC	Centers for Disease Control and Prevention
CI	Chemical Indicator
CJD	Classical Creutzfeldt Jacob Disease
EO	Ethylene Oxide
GESA/GENCA	Gastroenterological Society of Australia/Gastroenterological Nurses College of Australia
HLD	High Level Disinfection
IFU	Instructions for Use
IQ	Installation Qualification
MPQ	Microbiological Performance Qualification
MRC	Minimum Recommended Concentration
OQ	Operational Qualification
PCD	Process Challenge Device
PPE	Personal Protective Equipment
PPQ	Physical Performance Qualification
PQ	Performance Qualification
PSBS	Preformed Sterile Barrier System
RMD	Reusable Medical Device
SAL	Sterility Assurance Level
SBS	Sterile Barrier System
SDS	Safety Data Sheet
TGA	Therapeutic Goods Administration
TGO	Therapeutic Goods Order
WD	Washer-Disinfector

Section 2: Quality management

	Rating	Action / evidence	Review date	By whom	Outcomes
2.1 General					
2.1.3 Calibration and preventative maintenance					
Process for calibration and preventative maintenance for all reprocessing equipment including testing devices utilised					
2.3 Documentation					
2.3.2 Policies and procedures					
Evidence that all policies and procedures for reprocessing activities are documented and dated:					
a) Work Health and Safety including staff health, wellbeing, and immunisation. **Note:** this may be held within the organisation)					
b) Purchasing of RMDs/other devices and reprocessing equipment including IFU and critical consumables.					
c) Qualification of equipment including RMDs/other devices and reprocessing equipment.					
d) Validation & requalification of cleaning, disinfection, and sterilisation processes, including rationale used to assign a particular RMD / other device to a specific product family and processing category.					

Rating Key: SC = Substantially Complies PC = Partially Complies NC = Non-Compliant N/A = Not Applicable

	Rating	Action / evidence	Review date	By whom	Outcomes
e) Routine monitoring and control of cleaning, disinfection, and sterilisation processes.					
f) Initial treatment of used RMDs/other devices prior to return to designated reprocessing area/facilities.					

Rating Key: SC = Substantially Complies PC = Partially Complies NC = Non-Compliant N/A = Not Applicable

Section 2: Quality management

	Rating	Action / evidence	Review date	By whom	Outcomes
g) The collection of used RMDs/ other devices from point of use to the designated holding area.					
h) Handling of specialised RMDs/other devices including instruments on loan or on trial.					
i) Cleaning of RMDs/other devices prior to disinfection and/or sterilisation.					
j) Inspection, assembly, and testing (where applicable) of RMDs/other devices prior to disinfection.					
k) Inspection, assembly, and testing (where applicable) and packaging of RMD/other device prior to sterilisation.					
l) Loading and unloading of equipment used to reprocess RMDs/other devices (examples include washer-disinfector (WD), automated flexible endoscope reprocessor (AFER) and steriliser).					
m) Traceability of reprocessed semi-critical and critical RMDs/other devices					
n) Disinfection of cleaned RMDs/other devices					
o) Sterilisation of cleaned RMDs/other devices					
p) Validation and routine control of cleaning, disinfectant, and sterilisation processes.					

Section 2: Quality management

	Rating	Action / evidence	Review date	By whom	Outcomes
q) Release of RMDs/other devices after processing.					
r) Handling, transport, and storage of reprocessed RMDs/other devices.					
s) Cleaning of reprocessing equipment and the reprocessing facility.					
t) Periodic preventative maintenance of reprocessing equipment, including the calibration of monitoring instrumentation.					
u) Action to be taken in the event of a biological or chemical spill or exposure.					
v) Control and analysis of nonconforming RMD's/other devices.					
w) Recall of RMD's/other devices.					
x) Review of deviation reports or other indicators of quality or procedural problems					
y) Handling of product complaints.					
z) Corrective and preventive action.					
aa) Staff training and assessment of competency.					
bb) Business continuity planning including contingency planning in the case of an emergency.					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.3.3 Records					
a) Purchasing of RMDs/other devices and reprocessing equipment.					
b) Monitoring of reprocessing equipment.					
c) Cleaning process records.					
d) Sterilisation process records.					
e) High Level disinfection process records.					
f) Microbiological surveillance testing (*where applicable*).					
g) Cleaning of reprocessing equipment.					
h) Cleaning of reprocessing facility.					
i) Staff training and competency to undertake reprocessing activities.					
j) Staff rosters and allocations.					
k) Maintenance records of RMDs/other devices (*where applicable*) and reprocessing equipment.					
l) IQ, OQ, and PQ for reprocessing equipment (*where applicable*).					
m) Process deviation reports & where applicable records of corrective action or preventative action.					
n) Recall records (where applicable)					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.3.4 Control of documents and records					
Documents required by the standard shall be: • reviewed at defined intervals according to facility's policy+/- regulatory authorities					
• be approved of by designated personnel.					
• controlled & retrievable for the period of time specified.					
Documents & records shall be maintained in designated storage area for a period of time not less than that defined by regulatory authorities/in their absence facility's policy.					
2.4 Management responsibilities					
2.4.1 General					
Organisational structure supports the requirements of the standard.					
Responsibilities and authorities shall be defined, documented, and communicated within the facility and any external stakeholders.					
Relationships established between competent persons who manage, perform and verify work affecting reprocessing.					
Appropriate resources available for reprocessing non-critical, non-invasive RMDs/other devices no matter where this is undertaken to ensure standards are met.					

	Rating	Action / evidence	Review date	By whom	Outcomes
Systems in place to ensure requirements of standard are met at all times regardless of emergency/suboptimal operating conditions e.g., water restrictions.					
Backup procedures including documented processes of how to activate procedures available.					
2.4.2 Resource requirements					
Evidence that the HSO determines and provides the resources to:					
a) Implement the requirements of the Standard and the applicable requirements of the normative reference documents effectively.					
b) Implement quality assurance program and maintain its effectiveness through review.					
c) Meet customer requirements in a timely manner.					
d) Ensure that staffing levels are sufficient to maintain continuous, safe, and efficient operation of the reprocessing facility.					
e) Establish the buildings, workspaces and associated utilities necessary to achieve conformity with requirements for reprocessing of RMDs/other devices					
f) Procure reprocessing equipment appropriate to purpose.					

	Rating	Action / evidence	Review date	By whom	Outcomes
g) Maintain buildings, workspaces, associated utilities and process equipment.					
h) Provide supporting services.					
i) endorse staff training and ongoing education. *NOTE: relevant authority may specify requirements which apply to above list.*					
2.4.3 Reprocessing facility					
The person who is directly responsible for the RMDs/other devices within the facility shall:					
a) Have relevant qualifications and experience in reprocessing RMDs/other devices.					
b) Have authority to implement the requirements of the standard and the applicable requirements of the normative reference documents associated with this standard wherever reprocessing activities occur throughout the entire facility.					
c) Implement policies and procedures to assure the safety and quality of reprocessed RMD's/other devices.					
d) Be directly involved in the supervision of the day-to-day activities within the reprocessing facility.					
e) Demonstrate there is a formal orientation and training program for staff involved in reprocessing:					

	Rating	Action / evidence	Review date	By whom	Outcomes
I. staff are trained and competent to undertake reprocessing activities					
II. periodic assessment of staff competencies at intervals defined by the facility.					
2.4.4 Equipment					
Assessment of turnaround time to reprocess RMDs/other devices including disinfection/sterilisation to assist in operational planning.					
Demonstrate an understanding of the type and amount of equipment required to reprocess RMDs/other devices in facility					
Note: Capacity planning to include review inventory of RMDs/other devices required to meet service demands.					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.4.5 Contracts					
Where activities are undertaken by an external contractor for the facility there is an agreement in place which identifies the responsibilities of each party including the requirement to comply with the current standard.					
Note: this may include reprocessing, equipment maintenance, testing, staffing, and training.					
2.5 Product realisation					
2.4.1 General					
Product realisation relates to product life cycle from determination of patient/client requirements, design, and development, purchasing, control of production, calibration of monitoring and measuring devices.					
2.4.2 Purchasing					
Evidence that facility has procedures for purchasing, reprocessing equipment, RMD's/other devices, and accessories for these devices The procedures for purchasing of selected product includes:					
a) Criteria for product selection and evaluation that are risk based and address WHS requirements.					
b) Involvement of a competent person from reprocessing facility in the selection process prior to the purchase of an RMD/other device.					

Section 2: Quality management

	Rating	Action / evidence	Review date	By whom	Outcomes
c) Evaluation to ensure compatibility with the reprocessing systems available in the reprocessing facility.					
d) Requirement for the reprocessing equipment to conform to the equipment to be reprocessed. Note: Relevant authority may have additional requirements for purchasing o reprocessing equipment.					
e) TGA requirements for RMDs and accessories of RMDs, and reprocessing equipment entered on the ARTG					
f) Provision of operational IFU for reprocessing equipment and accessories to medical/ other devices.					
g) Provision of documented & validated reprocessing instructions in accordance with ISO 17664-1 or ISO 17664-2 for RMDs (including trial and Loan RMDs/other devices)					
h) Acceptance criteria when taking delivery of equipment or RMDs. (*See Note2,3& 4*)					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.5.3 Idenditification and traceability of product					
2.5.3.1 General					
Evidence of procedures specifying the identification and traceability of critical and semi critical RMD's/other devices including trial and loan RMDs/other devices during reprocessing and subsequent use on patients undergoing surgical or skin/mucous membrane penetration procedures. At a minimum the tracking system shall enable: • individual cycle from specified steriliser in which sterilisation occurred with documentation of parametric release. • identification of individual cycle in which disinfection occurred,					

	Rating	Action / evidence	Review date	By whom	Outcomes
The traceability system provides identification of patient(s) where a non-conforming product has been used in an event that a recall is necessary.					
Notes • System for traceability of complex semi critical RMDs after thermal disinfection which may be stored for later use. • System provides traceability of implantable RMD that is subject to numerous reprocessing cycles e.g., screws & dental burs					
2.5.3.2 Traceability records					
Traceability system provides the following for each RMD/other device:					
a) High level disinfection process records					
I. Type of RMD/other device					
II. Unique identification number of RMD/other device (e.g., serial number)					
III. Date of cleaning of RMD/other device and ID of person responsible.					
IV. ID of person responsible for connecting the RMD/other device to the reprocessing equipment/system/method.					
V. ID of automated equipment used to process RMD/other devices e.g., number of unit if more than one.					
VI. Disinfection process cycle number and date of disinfection.					
VII. Other records including but not limited to:					

Section 2: Quality management

	Rating	Action / evidence	Review date	By whom	Outcomes
(A) Disinfectant (type/brand, batch number, manufacturers' expiry date, date of decanting/opening and in-use expiry date/date of disposal.					
(B) Test strips brand/type, batch number, manufacturers' expiry date, date of decanting/opening of test strips and in-use expiry date/date for disposal, results of any positive/negative controls performed upon opening, results of test strips used for daily MRC/MRC check for each use/cycle; ID of person conducting positive and negative controls and ID of person conducting MRC check.					
(C) Cycle process record/printout, self-disinfection cycles (where required), water filter pressures and date of chemical and filter changes.					

	Rating	Action / evidence	Review date	By whom	Outcomes
(D) Manual immersion into disinfectant, temperature of disinfectant, time of immersion into disinfectant, time removed form disinfectant, final rinse according to chemical disinfectant and RMD/other devices IFU.					
VIII. Documented evidence of attainment of process parameters e.g., process record/printout.					
IX. ID of the person responsible for release of RMD/other device.					
b) Sterilisation – Sterilising process records [see clause 2.2.3(d)]					
I. Date of sterilisation and sterilising process cycle number.					
II. Identification of the steriliser e.g., steriliser identification number or code.					
III. Identification of the RMD/other device (e.g., device name or name of a set of devices) and the number of these within the load.					
IV. Identification of the person responsible for loading the RMDs/other devices into the steriliser.					
V. Other records including:					

Section 2: Quality management

	Rating	Action / evidence	Review date	By whom	Outcomes
(A) Results of any performance tests required to determine functional performance of the equipment prior to use e.g. leak rate test, Bowie and Dick type test.					
(B) Results of chemical and biological monitoring undertaken for individual cycles or on a periodic basis.					
(C) Sterilising agent (where applicable), batch number & expiry date.					
VI. Documented evidence of attainment of process parameters, e.g., process record/printout where applicable. **Note:** Records can be paper based or electronic. Where electronic records are kept procedures should be in place to verify attainment of process parameters at the conclusion of every cycle. If paper based, they should be prepared and maintained so they remain legible for the specified time period					
VII. Identification of the person responsible for release of the RMD/other device (sterilisation load)					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.5.4 Control of monitoring and measuring equipment					
2.5.4.1 General					
Evidence that monitoring and measuring equipment including that which is used for testing purposes is calibrated at specified intervals, or prior to use, traceable to international & national measurement standards.					
Monitoring and measuring equipment shall be:					
a) Identified with its calibration status.					
b) Adjusted and readjusted as necessary.					
c) Protected from adjustments which would invalidate the measurement result					
d) Protected from damage during handling, maintenance, and storage					
2.5.4.2 Documentation					
A calibration report shall be obtained from the person implementing calibration. The report shall include for calibration tests performed for each piece of monitoring and measuring equipment.					
Records of calibration and any adjustments shall be kept.					
The calibration report shall include the certification number of the calibration device used.					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.5.4.2 Non-conformance					
Where equipment is found not to conform to requirements action shall be taken in relation to faulty equipment and any product affected. Records of this action shall be kept.					
2.6 Measurement, analysis, and improvement					
2.6.1 Audits					
Evidence that regular periodic audits are undertaken to confirm that the requirements of the standard are being met.					
Audit findings are documented and where applicable corrective action shall be undertaken to rectify deficiencies.					
Corrective Action is reviewed to ensure that it has been effective in addressing the deficiency.					
2.6.2 Non-confirming RMD/ other device					
Review of nonconforming RMDs/other devices that do not meet acceptance criteria after completion of cleaning, disinfection/ sterilisation processes, and packaging as applicable.					
An investigation is undertaken where required according to facility risk assessment policy.					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.6.3 Corrective actions					
2.6.3.1 General					
Corrective action taken in relation to a non-confirming after delivery or use shall include:					
a) Identification of the nature of the nonconformity (including user concerns or complaints)					
b) Implementation of an action plan to correct the nonconformity					
c) Documentation of action taken					
d) Evaluation of the corrective action to verify effectiveness in resolving the nonconformity.					
e) Where applicable implementation of additional corrective action to further resolve the nonconformity.					
Note: Corrective action may also include undertaking a recall of non-conforming RMD/other device.					
2.6.3.2 Recall procedure					
Recall procedure shall -					
a) Provide examples of situations where recall of a distributed RMD is warranted					
b) The procedure shall emphasise that recall activities should be performed in a timely manner					
c) Identify the person/s responsible for coordinating recall activities					

Section 2: Quality management

	Rating	Action / evidence	Review date	By whom	Outcomes
d) Identify the persons to be notified in the event or recall within or outside the facility					
e) Identify the person/s responsible for retrieving distributed RMDs, including RMDs that have been distributed off-site					
f) Identify the person/s responsible for reporting on recall activities					
g) Identify critical information to be included in a recall notice. Identify departments & the RMD/other device and quantity to be recalled. State the reason & the action to be taken by the persons receiving the recall notice i.e., return of RMD/ other device or holding/quarantining the device pending further instructions					
h) Include the need to reconcile quantities of recalled RMDs/other device with RMD/ other device distribution records.					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.6.3.3 Recall report					
The recall report shall be completed in accordance with facilities policies. At a minimum it shall include:					
a) Identification of circumstances that initiated the need of recall of RMD/other device					
b) Identification of recalled RMD/ other device and reconciliation of quantities recalled with RMD/other device distribution records					
c) Where applicable identification of patients/clients impacted by recall activity and follow up action taken					
d) Identification of the root causes for recall					
e) Identification of corrective actions taken in relation to recall					
f) Identification of the consequences of the recall e.g., cost and time to reprocess recalled RMD/other device, cost of replacing equipment, impact on surgical procedures and where applicable the need for staff retraining.					
g) Recommendations to prevent a recurrence of the circumstances that led to the recall.					

	Rating	Action / evidence	Review date	By whom	Outcomes
2.6.4 Preventable actions					
Identify potential causes of nonconforming RMD/other devices to prevent their occurrence. Evidence of action should include:					
a) Identification of potential cause/s of non-conforming RMD's/other devices					
b) Implementation of an action plan to prevent potential for non-conforming RMDs/other devices.					
c) Documentation of action taken to address potential non-conforming RMDs/other devices.					
d) Evaluation of preventative action taken to verify its effectiveness in preventing the potential for non-conforming RMDs/other devices.					
e) Implementation of additional preventative action to further prevent the potential for nonconforming RMDs/ other devices (*where applicable*).					

Section 3: Reprocessing agent characterisation

	Rating	Action / evidence	Review date	By whom	Outcomes
3.1 General					
3.1.1 Introduction					
Reprocessing agent characterisation defines the cleaning, disinfection, and sterilisation agent necessary to demonstrate the microbial effectiveness and to assess the effects that the exposure on RMDs/ other devices and to identify staff safety requirements.					
3.1.2 Reprocessing agent selection					
Cleaning agents, instrument grade chemical disinfectants, HLD systems and liquid chemical sterilising agents intended for use on RMD's/other devices are included in the TGA Australian Register of Therapeutic Goods (ARTG)					
3.1.3 Reprocessing agent information					
At time of acquisition obtain the following information for each cleaning agent(s), disinfectant and sterilising agent:					
a) Safety Data Sheet (SDS)					
b) Regulatory status					
c) Active ingredient(s) and physical/chemical properties, including stability (shelf life).					
d) Microbial efficacy					
e) Toxicity/residues					

Section 3: Reprocessing agent characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
f) Material effects of the agent on RMD's/other devices, including known device material compatibilities and known device material non-compatibilities.					
g) Container/packaging					
h) Labelling, including shelf life and storage requirements.					
i) Directions for use and where intended for the product reuse.					
3.2 Cleaning agents					
Cleaning agents used remove residual soil and organic matter from a used RMD/other device.					
Cleaning agents used have documented specifications from the manufacturer/supplier.					
Cleaning agent not used for RMD/other device if it not recommended in IFU.					
Validated cleaning process with cleaning agent available.					
Cleaning agent shall be:					
a) Intended for use on medical devices					
b) Agent is included on the ARTG					
c) Compatible with the RMDs/ other device being processed and selected method of cleaning.					
d) Diluted and used in accordance with IFU					

Section 3: Reprocessing agent characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
e) Compatible with the available water quality					
f) Biodegradable.					
g) Non-toxic at the in-use dilution.					
h) Nonabrasive					
i) Low foaming					
j) Free rinsing					
k) In liquid form					
3.3 Disinfectant agents and systems					
3.3.1 Disinfection agents					
Chemical disinfectants used to reprocess RMD's/other devices are labelled as an *Instrument grade disinfectant.*					
Disinfecting agents meet the following criteria:					
a) High level instrument grade disinfectant is a minimum grade disinfectant used for disinfection of a semi-critical RMD/other device.					
b) Intermediate or low level disinfectant is a minimum grade disinfectant used for disinfection of a non-critical RMD/other device.					
Evidence that Hospital grade disinfectant are not to be used to reprocess an RMD/other device.					
3.3.2 Disinfection Systems					
Disinfection system entered on ARTG and validated for use with intended RMD/other device.					

Section 3: Reprocessing agent characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
3.4 Sterilising agents					
Specifications for each sterilising agent obtained at time of acquisition. Specification should include the following:					
a) Identity of sterilizing agent					
b) Active ingredient(s)					
c) Shelf life					
d) Storage conditions and shelf life					
e) Requirements to be met for reuse if permitted.					
3.5 Microbicidal effectiveness					
Evidence that where cleaning agents make claims of microbicidal effectiveness it is available with the agent.					
Disinfectants and sterilising agents used outside of the range specified by the supplier of a disinfecting or sterilising system the facility needs to have documented evidence that a comparison of the process with current practice to ascertain process effectiveness. This shall include reference to the following:					
a) For disinfectants and liquid chemical sterilising agents – TGO 54					
b) For moist heat sterilisation – ISO 17665-(series)					
c) For dry heat sterilisation – ISO 20857					
d) For ethylene oxide gas sterilisation ISO 11135. For flexible chamber EO sterilisation – ISO 14937					

	Rating	Action / evidence	Review date	By whom	Outcomes
e) For low temperature steam formaldehyde – ISO 25424					
f) For sterilising processes where no standard applies refer to ISO 14937.					
g) For washer disinfectors – ISO 15883 (relevant part)					
NOTE: For disinfection process technology reference should be mad3e to regulatory status & peer -reviewed publications.					
3.6 Effects on RMD materials					
Cleaning agents, disinfectants and sterilising agents are compatible with the RMD/ other devices and reprocessing equipment.					
A documented assessment of compatibility and the effects on RMD/other device and equipment materials using information provided by the RMD and equipment manufacturers.					
Documented evidence of discussions with stakeholders available where RMD/other device reprocessing is not consistent with validated instructions including effects of repeated exposure.					
3.7 Personnel and environmental safety					
3.7.1 Safety information					
Evidence that SDS for agents used for cleaning, disinfecting and chemical sterilisation and if applicable for its precursor(s) and by products.					

Section 3: Reprocessing agent characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
SDS available is current, and checks undertaken at least annually or as per facility guidelines.					
Evidence that facility has ensured that SDS contains sufficient information about the safe use, handling and storage of the hazardous chemical is readily accessible to:					
a) a worker at the workplace					
b) an emergency services worker					
3.7.2 Enviromental impact					
Evidence that environmental impact assessment is undertaken to ensure compliance with local and national regulatory requirements has been undertaken.					
Evidence that control measures have been implemented and documented where required					
3.7.3 Health and safety procedures					
Evidence that procedures have been developed for storage, handling, PPE, decanting and disposal of chemicals in accordance with SDS and regulatory requirements.					
Evidence that chemical containers including containers holding decanted chemicals are labelled in accordance with regulatory requirements.					
Spill kit available which is suitable for chemicals and emergency procedures documented and readily accessible.					

Section 3: Reprocessing agent characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
3.7.4 Health and safety training					
Evidence that all personnel involved in handling and use of cleaning, disinfectants and chemical sterilising agents have been trained in the safe handling, use and storage of these substances, the use of PPE and procedures for spills and exposure management.					

Section 4: Process and equipment characterisation

	Rating	Action / evidence	Review date	By whom	Outcomes
4.1 General					
Evidence that reprocessing equipment used shall be intended for use to process medical devices.					
a) Process and equipment specifications from the equipment manufacturer.					
b) Review of manufacturers process and equipment specification and establish that is has the services and infrastructure necessary to safely operate the equipment.					
c) Ensure RMDs/other devices are compatible with the processes delivered by the selected reprocessing equipment.					
4.2 Process characterisation					
Evidence of information from equipment manufacturer includes the following:					
a) A detailed description of the process cycle.					
b) The process parameters, together with their tolerances.					
c) The means by which process variables are monitored & controlled.					

Section 4: Process and equipment characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
d) The measures to ensure that a failure to achieve specified process parameters shall not result in ineffective cleaning, disinfecting or sterilizing process being recorded as effective.					
Note: measures might include independent systems for process control & monitoring or the use of cross-checks between process control & process monitoring systems to identify discrepancies that might indicate a fault					
e) Any treatment of product that is required prior to the process to ensure its effectiveness.					
f) A description of the product families/categories that can be safely and effectively processed.					
g) Any restrictions or limitations relating to size, mass, configuration or loading orientation of RMDs/other devices being processed					
h) Post process cycle treatment (*if applicable*)					

	Rating	Action / evidence	Review date	By whom	Outcomes
4.3 Equipment characterisation					
4.3.1 Equipment specifications					
Evidence from the equipment manufacturer detailing specifications for the equipment used to deliver cleaning, disinfecting and sterilising processes. Information shall include the following:					
a) Description of the equipment and any necessary ancillary items, including materials of construction.					
b) A specification for the cleaning agent(s), disinfectant or sterilising agent (as applicable) and the means by which they are delivered to the equipment.					
c) A description of the instrumentation used for controlling, monitoring, and recording of cleaning, disinfection, and sterilisation processes, including the location of sensors.					
d) The identification of fault(s) recognised by the equipment, including the means provided to ensure that a failure to achieve specified process parameters will not result in an ineffective process being recorded as effective.					
e) Details of safety features					
f) The requirements for installation, including those for control of environmental emissions (where *applicable*)					

Section 4: Process and equipment characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
g) A description of the software used for monitoring or controlling the processes, including the validation demonstrating it meets its design intention					
4.3.2 Controlling and monitoring software					
Evidence that the software used for controlling and monitoring cleaning, disinfecting, packaging, and sterilising processes complies with its design intention. Changes to software can affect operation of reprocessing equipment, where this has been undertaken evidence is available.					
4.3.3 Standards for reprocessing equipment					
Equipment utilised for reprocessing of RMDs complies with the applicable standard					
a) Washer disinfectors – ISO 15883(applicable parts)					
b) Ultrasonic cleaners-AS 2773.					
c) Drying Cabinets – AS 5330					
d) Heat Sealers **Note:** no existing equipment standard. Refer to ISO 11607-2 & ISO/TS 16675 for guidance					
e) Steam Sterilisers –large- EN285, ISO TS 22421					
f) Steam Sterilisers-small-EN 13060, ISO TS 22421					

Section 4: Process and equipment characteristics

	Rating	Action / evidence	Review date	By whom	Outcomes
g) Dry Heat Sterilisers **Note:** No existing Standard; refer to ISO 20857 & ISO TS 22421for guidance					
h) Ethylene oxide sterilisers –EN 1422, ISO TS 22421					
i) Steam /formaldehyde sterilizers- EN 14180, ISO TS 22421					
j) Peracetic Acid Sterilizers **Note:** No existing equipment standards. Refer to ISO 14937 & ISO TS 22421 for guidance					
k) Low Temperature Hydrogen peroxide sterilizers – ISO 22441, ISO TS 22421					
l) Aeration cabinets **Note:** No existing equipment standard. Refer to ISO 25424 for steam/formaldehyde or ISO 11135 for ethylene oxide for guidance					
m) Controlled environment storage cabinet for thermolabile endoscopes - EN 16442					
n) Biological indicator (BI) incubators **Note:** No existing equipment standard; refer to ISO 11138-1 or ISO 11138-7 for guidance.					

Section 5: Product definition

	Rating	Action / evidence	Review date	By whom	Outcomes
5.1 General					
5.1.1 General					
Evidence that RMDs/other devices to be cleaned and disinfected/sterilised are defined					
Microbial quality of the RMDs/other devices prior to disinfection or sterilisation and any associated materials used to package and present RMDs/other devices for sterilisation are specified. This may be inferred by instructions for processing equipment have been followed.					
5.1.2 Classification for reprocessing					
Evidence that RMDs are categorised as:					
a) Critical					
b) Semi-critical					
c) Non-critical					

Section 5: Product definition

	Rating	Action / evidence	Review date	By whom	Outcomes
After cleaning, using a validated cleaning process:					
I. Critical RMDs/other devices are: terminally sterilised by a validated moist heat sterilising process between uses on individual patients/clients unless the RMD/other devices are heat /moisture labile and not able to withstand the process. OR Where non-compatible with moist heat sterilisation validated low temperature sterilisation is undertaken between uses.					
II. (ii) Semi-critical RMDs /other devices are:					
(A) sterilised by either a validated moist heat or low temperature sterilising process between uses on individual patients/clients unless the RMD/other device is not compatible with these processes					

	Rating	Action / evidence	Review date	By whom	Outcomes
(B) Where RMD/other device that is not compatible with sterilisation it is subject to a validated thermal disinfection process between uses on individual patients/clients unless the RMD is not compatible with this process and					
(C) If RMD/other device is unable to withstand a thermal disinfecting process then validated high level disinfection process to be undertaken between uses on individual patients/clients (refer to Clause 6.3.5)					
III. Non-critical RMDs are subject to a validated disinfection process (where applicable) as per frequency defined by facility.					
Storage of RMDs/other devices following reprocessing (Table 5.1):					
• Critical RMD/other device where packaged are stored in a designated storage area.					
• Critical RMD/other device which has been sterilised through liquid chemical sterilisation the RMD /other device is used immediately					

	Rating	Action / evidence	Review date	By whom	Outcomes
• Semi critical RMD/other device stored in designated storage location e.g., controlled environment drying cabinet.					
• Non-critical RMD/other device stored in clean dry place.					
5.1.3 Policies and procedures					
Evidence that policies and procedures for reprocessing RMDs/other devices not limited to the following:					
a) A new RMD/other device that is being introduced, on loan or being returned from maintenance or repair shall be processed at a minimum by a validated cleaning and further processing method in accordance with devices IFU.					
b) RMDs/other devices that require off-site repair or maintenance shall be processed at a minimum by a validated cleaning and high-level disinfection process in accordance with devices IFU. If this is not possible due to the nature of the damage, then the manufacturer shall be consulted to ensure the RMD is prepared and packaged for transportation in a manner suitable for safe transportation.					

Section 5: Product definition

	Rating	Action / evidence	Review date	By whom	Outcomes
c) Prior to release off site a loan or trial RMD/other device shall be processed at a minimum by a validated cleaning and high-level disinfection process in accordance with the IFU. Note: Some organisations require loan and trial RMDs to be cleaned and sterilised prior to their release off site.					
d) RMDs/other devices that have been opened for a procedure but not used shall be considered contaminated and reprocessed as per IFU.					
e) RMDs that come in contact with sterile body cavities or used on the critical aseptic field during invasive field shall be considered as critical medical devices. Reprocessing of these shall be in accordance with IFU and reprocessed at highest level possible. Single-use sheaths, sleeves/protective barriers shall not be used as a substitute for cleaning, disinfection, or sterilisation.					
f) Single-use medical or other device that is past their expiry date or opened but unused shall only be reprocessed if this is permitted by the devices reprocessing instructions. Where reprocessing is permitted it shall be undertaken as per validated instructions provided with the device.					

	Rating	Action / evidence	Review date	By whom	Outcomes
Evidence that medical devices labelled as single use shall not be reprocessed or reused.					
5.2 Product families					
Classification of RMD/other device into product family assists with the development of processing conditions. The following shall be considered and documented: Note: reference should be made to the manufacturers IFU.					
a) Description of the RMD/other device& intended use					
b) Description of materials used to make the RMD/other device					
c) The design of the RMD/other device including design characteristics that can affect selection of a cleaning, disinfecting or sterilising process.					
d) The physical characteristics of the RMD/other device, including its mass, surface area and thermal conductivity.					
e) Packaging of the RMD/other device, including the SBS for the sterilized devices.					

	Rating	Action / evidence	Review date	By whom	Outcomes
5.3 Limiting values					
Evidence of the limiting values for each process variable for the cleaning, disinfecting and sterilizing processes to which an RMD/other device is subjected shall be specified to prevent adverse effects on performance of the RMD/other device and its packaging.					
Evidence of corrective action taken where the limiting values are exceeded. Note: examples of process variables include temperature, pressure, humidity, chemical concentration, immersion compatibility, exposure time and rates of change of pressure and or temperature.					
5.4 Pre-disinfection and pre-sterilisation cleanliness of RMDs/ other devices					
Evidence that the cleanliness of the devices and packaging (*where applicable*) presented for disinfection or sterilisation is controlled and shall not compromise the effectiveness of the process.					
5.5 Packaging systems					
5.5.1 General					
Evidence that the SBS for RMDs/other device that are to be terminally sterilised are specified and conform with ISO 11607-1 and ISO 11607-2.					

	Rating	Action / evidence	Review date	By whom	Outcomes
5.5.2 Compatibility					
Evidence that the SBS is compatible with the sterilising process. The SBS shall allow the removal of air from the packaging and device, ingress and egress of sterilising agent and removal of water vapour (*where applicable*).					
5.5.3 Protective packaging					
Evidence that protective packaging if used shall protect the SBS and its contents until point of use.					
Evidence that the protective packaging if applied prior to sterilisation is compatible with the sterilising process.					

	Rating	Action / evidence	Review date	By whom	Outcomes
5.6 Reprocessing environment					
5.6.1 General					
Evidence that the facility has provided a physical environment and equipment required to reprocess all RMDs/other devices at the required quality. This includes requirements of environmental control in areas that can impact the bioburden of an RMD i.e., control of temperature, humidity, traffic flow and reprocessing, ventilation, and air flow.					
Where RMD/other device is reprocessed at point of use a dedicated areas is available which is separate to patient/client treatment room/area. Where activities occur in the same location evidence of the following available: • risk assessment • activities not undertaken simultaneously. • Requirements for environmental control, effective segregation of clean and dirty activities, unidirectional workflow and fixtures and fittings are suitable					
5.6.2 Facility design					
Evidence that the reprocessing facility is designed, constructed, maintained, and controlled to provide effective segregation of clean and dirty activities.					

	Rating	Action / evidence	Review date	By whom	Outcomes
Design of the facility shall minimise the risk from cross contamination of a cleaned, disinfected, and sterilized RMD.					
Evidence of a process map or flow diagram which addresses risks of contamination including airflows managed; unidirectional workflows from dirty to clean where pass through capability is not available to achieve segregation of clean and dirty activities.					
5.6.3 Facility finishes					
Where windows are present, they are not opened.					
Areas which are inaccessible for cleaning are minimal e.g., windows, ledges, and other areas.					
Finishes on walls, ceilings and other surfaces shall be flush, smooth, non-shedding, water resistant and able to withstand frequent cleaning.					
Junctions between the walls and floors shall be coved and flush.					
Floors are covered in a sealed, non-slip material that is washable.					
5.6.4 Fixtures and finishing					
Evidence that the following are constructed of robust, non-shedding materials, easy to clean and maintained in a good condition:					
a) Work surfaces					
b) Fittings, fixtures window treatment, shelving and furniture					

	Rating	Action / evidence	Review date	By whom	Outcomes
c) Shelving designed and installed to enable safe handling practices and have smooth surfaces that do not damage product, packaging, or other materials.					
d) Fittings are flush with wall surface and ceilings (where possible)					
5.6.5 RMD / other devices cleaning sinks					
Evidence that there are:					
a) Sink workstations provide sufficient bench space to facilitate unidirectional flow & to minimise risk of cross contamination					
b) Dedicated sinks for pre-treatment, manual cleaning & rinsing of RMD/other device					
c) Sinks of sufficient depth & size to allow RMD/other device to be completely immersed					
d) Cleaning sinks are not used for any other purpose e.g., hand hygiene					
e) Sinks are ergonomically designed where possible					
f) Facilities to enable water flushing on dirty side and air flushing oof lumened device					
5.6.6 Water					
Water of the required quality is specified for use in the reprocessing facility; refer to Section 7.					

Section 5: Product definition

	Rating	Action / evidence	Review date	By whom	Outcomes
5.6.7 Workstations					
Evidence that there is:					
a) Sufficient electrical supply, computer terminal points available					
b) Ergonomically designed to allow safe and effective reprocessing activities					
c) Suitable equipped for preparation and packaging of RMDs/other devices					
d) Adequate size to accommodate activities					
e) Adequate space between workstations for the safe movement of equipment and staff					
f) Ergonomic risk assessment to identify needs					
g) Height adjustable and ergonomically safe to promote operator safety					
5.6.8 Lighting					
Evidence that there is:					
a) adequate lighting is provided to enable thorough visual examination of an RMD/other device					
b) task lighting and magnification provided					
c) ceiling lights flush fitted					
5.6.9 Storage					
Evidence that there is:					
a) Bulk items are stored external to the cleaning and packing area					

Section 5: Product definition

	Rating	Action / evidence	Review date	By whom	Outcomes
b) Safe storage facilities for chemicals in accordance with Work Health and Safety requirements					
c) Dedicated area within the steriliser unloading zone for cooling of sterilised RMDs/other devices					
d) Dedicated area for the storage of reprocessed RMDs/other devices that have been released for use					

Section 5: Product definition

	Rating	Action / evidence	Review date	By whom	Outcomes
5.6.10 Facility cleaning					
Evidence that there is:					
a) Reprocessing area is cleaned regularly in accordance with a documented procedure and schedule.					
b) Reprocessing area is always maintained in a hygienic condition					
c) Separate, dedicated cleaning equipment is provided for both the dirty and clean work areas.					
5.6.11 Entry to facility					
Evidence that entry to the reprocessing facility is restricted to authorised personnel					
5.6.12 Hand hygiene					
Evidence that there are:					
a) Sufficient hand hygiene facilities available and accessible in each of the work areas					
b) Hand hygiene basins not located in clean work areas due to risks associated with aerosol contamination.					
c) Hand hygiene basins located in ante room/corridor accessible from clean area.					
d) Alcohol based hand rubs (ABHR) and liquid soaps approved for use in the facility are used					
e) Training on use of ABHR and hand hygiene is undertaken					

	Rating	Action / evidence	Review date	By whom	Outcomes
f) Hand creams are not used when performing reprocessing activities.					
g) Residue from hand hygiene products shall not be transferred to RMDs or packaging					
5.6.13 Personal Protective equipment (PPE)					
Appropriate PPE accessible in each work area					
5.6.14 Waste disposal					
Evidence that disposal of waste meets the requirements of relevant authority.					
5.6.15 Ventiliation					
Evidence that ventilation of reprocessing and storage areas shall be: a) Dirty room as per AS1668.2 b) Inspection, assembly, and packaging area as per AS1668.2 c) Storage area for reprocessed RMDs is temperature and relative humidity controlled. d) Sterile Storerooms adjoining theatres and set up room as per AS1668.2. Where other areas are used then evidence of risk assessment undertaken. e) Inspection, assembly, packaging rooms and sterile storerooms continuously operating.					

Section 6: Process definitions

	Rating	Action / evidence	Review date	By whom	Outcomes
6.1 General					
6.1.1 Introduction					
Evidence that detailed specification of cleaning, disinfection, packaging and sterilisation processes defined for RMD/other device.					
Processes each RMD/other device or product family defined:					
a) cleaning					
b) disinfecting					
c) packaging					
d) sterilising.					
Evidence that safety, quality, and performance is demonstrated by ensuring that: • Devices not cleaned are not disinfected or sterilised. • RMD/other device is not stored in disinfectant before or after any form of processing. • Recontamination risk of unwrapped RMDs/other devices is managed					
Chemical and biological indicators used during validation and monitoring are specified and conform to the relevant ISO/EN standards.					
All steps specified in reprocessing procedures are followed to produce an RMD/other device to the required quality.					

	Rating	Action / evidence	Review date	By whom	Outcomes
IFU reviewed and utilised when developing process specifications for the following:					
a) cleaning					
b) disinfecting					
c) packaging					
d) sterilising.					
Where deviation of operational instructions (ISO 17664 series) occurs then validation of the alternative process(es) shall be undertaken in consultation with the manufacturer and documented.					

	Rating	Action / evidence	Review date	By whom	Outcomes
6.1.2 Immediate use steriliation					
Protocols have been developed which define and validate Immediate Use Sterilisation.					
RMD/other device sterilised without a SBS are used immediately.					
Immediate ‘Use Sterilisation’ is not used routinely as a convenience to meet end user needs or as a cost saving mechanism.					
Transfer method of sterilised RMD/other device minimises exposure to air and environmental contaminants and clearly documented.					
RMD/other device sterilised by the Immediate Use Sterilisation method are not stored for future use.					
RMD/other device sterilised by the Immediate Use Sterilisation method are not held to use in another procedure.					
6.2 Cleaning process definition					
6.2.1 General					
Used RMD/other device are cleaned after each patient/client use.					
Cleaning processes are compatible with the device and are in accordance with the validated cleaning instructions provided by the manufacturer.					

	Rating	Action / evidence	Review date	By whom	Outcomes
Evidence available that indicated that where cleaning requirements are unable to be met then alternative / single use RMD/other device considered and purchased.					
6.2.2 Transportation and pre-treatment					
6.2.2.1 Transportation					
Procedures for the transportation of used RMDs/other devices which demonstrate methods used protect the RMD/other device, personnel and the environment from contamination and harm.					
6.2.2.2 Pre-treatment					
Procedures or the pre-treatment of used RMD/other device at the point of use.					
Pre-treatment includes the following:					
a) Remove gross soil					
b) Do not cause damage to the RMD					
c) Do not compromise the subsequent cleaning, disinfecting and sterilising processes					
d) Minimise the risk of drying contaminants					
There is a specified time between the use of device and the subsequent reprocessing.					
Specified actions to be taken if the above time is exceeded.					

Section 6: Process definition

	Rating	Action / evidence	Review date	By whom	Outcomes
6.2.3 Cleaning					
Cleaning procedures for:					
a) Disassembly of a RMD prior to pre-treatment or cleaning. Methods are in alignment with the IFU and do not damage the device.					
b) Segregation of an RMD/other device to allocated cleaning pathways: Where facility has WD: 1) Manual cleaning only 2) Manual cleaning with ultrasonic pre-treatment prior to WD 3) Cleaning in WD without pre-treatment e.g., Genesis container In facilities without WD: 1) Manual cleaning only 2) Manual cleaning and ultrasonic cleaning					
c) Manual cleaning of RMDs is only used for the following:					
i. As per manufacturer's instructions for use.					
ii. As a pre-treatment prior to reprocessing in a washer disinfector.					
d) Manual cleaning in non-health facilities only where devices validated cleaning instructions require or permit manual cleaning of device.					

Section 6: Process definition

	Rating	Action / evidence	Review date	By whom	Outcomes
e) Visible soil removed using an ultrasonic cleaner before reprocessing. Where ultrasonic does not provide complete cleaning process, device is to be removed and subjected to further manual or mechanical cleaning process.					
f) Device loaded into cleaning equipment enable all aspects of device are exposed including internal lumens to the cleaning process, Device is loaded in a manner which protect damage occurring and when unloading the risk of cross contamination is minimised.					
g) Drying methods do not compromise the cleanliness of an RMD.					
Drying cabinets are preferred however where not available low-linting cloths / compressed instrument grade compressed air can be used. Where compressed air is used WH&S management is to be included in procedure.					
h) Cleaning equipment and accessories is undertaken in accordance with manufacturer's instructions and recorded. .					

Section 6: Process definition

	Rating	Action / evidence	Review date	By whom	Outcomes
Brushes and other accessories used in pre-treatment or manual cleaning are to be cleaned and thermally disinfected/ sterilised at a minimum daily.					

	Rating	Action / evidence	Review date	By whom	Outcomes
6.3 Disinfecting process definition					
6.3.1 General					
The purpose is to define specification for the process to kill microorganisms on a clean RMD/other device to achieve low, intermediate, or high-level disinfection. Disinfection where recommended by IFU is to be followed.					
6.3.2 Categorising RMDs/ other devices for disinfection					
RMD/other device that requires exposure to a disinfecting process shall be categorised as either semi-critical or non-critical according to the Spaulding classification.					
6.3.3 Non-critical RMDs/ other devices					
Non-critical devices are re-processed using thermal disinfection or an instrument grade disinfection agent in accordance with procedure.					
The IFU shall be followed for exposure time, temperature, pH, and water quality for dilution of disinfectant or post rinsing to ensure the specified level of disinfection is achieved.					
6.3.4 Non-heatable semi-critical RMD/ other device					
A semi-critical RMD/other device that cannot withstand moist heat shall be subject to low temperature sterilisation; thermal disinfection or high level disinfection process in accordance with a documented procedure (refer to Clause 5.1.3)					

	Rating	Action / evidence	Review date	By whom	Outcomes
Washer-disinfectors achieve thermal disinfection and are required to be compliant with relevant part of ISO 15883. (See Table 6.1)					
6.3.5 Heat labile semi-critical RMD/ other device					
Evidence that heat labile semi-critical RMDs/ other devices undergo high level disinfection					
When performed in a washer disinfector this is compliant with ISO 15883.					
In case of equipment malfunction or breakdown a contingency plan is available.					
Where manual immersion is undertaken documented procedures for handling, storage, and use of the disinfectant					
The chemical disinfectant IFU is followed in relation to exposure time, temperature, pH and water quality post disinfection rinsing to ensure that the specified level of disinfection is achieved and documented when used.					
After removal from the disinfectant RMD/ other device is rinsed in a sufficient volume of water of suitable.					
RMD/ other device where intended for use in sterile cavities, in known immune-compromised patients or for invasive procedures are rinsed with sterile water or water filtered through a 0.22µm sterilising grade filter following high level disinfection					

Section 6: Process definition

	Rating	Action / evidence	Review date	By whom	Outcomes
Some types of RMD/ other device due to design are unable to be fully immersed during cleaning and disinfection processes. Procedures are in place to minimise the risk of cross contamination during the reprocessing of these devices.					
6.4 Packaging process definition					
6.4.1 General					
SBS and protective packaging does not impede effective sterilisation and maintains sterility of a RMD until the point of use.					
Evidence that packaged RMD/ other devices which are sterilised by steam the sterilising cycle includes a drying phase.					
Evidence that single use SBS is exposed to a single sterilising process.					

	Rating	Action / evidence	Review date	By whom	Outcomes
6.4.2 Packaging procedures					
Evidence that procedures have been developed and implemented for the following activities:					
a) Inspection, assembly and testing of RMD/other device is undertaken prior to packaging in accordance with RMD/other device IFU for testing maintenance, lubrication, and calibration.					
b) The packaging manufacturer's instructions for use are followed. This includes: • Selection, use and type of SBS/ PSBS • Method of wrapping (where applicable) • Method of sealing/closure • Use of tray liners, tip protectors and labelling					
i. Packaging materials and sterile barrier systems are in accordance with ISO 11607-1 and the corresponding part of the EN 868 series. If reusable fabrics are used, then they comply with AS 3789.8					
ii. Tray liners, tip protectors and other materials that are used for the assembly and presentation of a packaged RMD/ other devices are intended for that purpose					

	Rating	Action / evidence	Review date	By whom	Outcomes
iii. The selected method of packaging permits aseptic presentation of the RMD/other device.					
iv. Methods of sealing and closure ensure the integrity and maintenance of sterility of the packaged RMD/ other device until the point of use. For heat sealed PSBS, the sealing process parameters and their tolerances are specified and documented. Sealing methods that comprise integrity of the SBS are not used.					
v. The method of sealing is tamper evident.					
vi. A packaged RMD/ other device is labelled prior to sterilisation. Labelling identifies the contents and provides information for batch control. The method and materials used for labelling do not compromise the sterilisation process and the label remains securely attached until the point of use.					
6.5 Sterilising process definition					
6.5.1 General					
Terminally sterilised RMD/other device achieve a SAL of 10^{-6}.					

Section 6: Process definition

	Rating	Action / evidence	Review date	By whom	Outcomes
An RMD/ other device has a manufacturers supplied sterilising process definition.					
RMD/ other device manufacturers have provided instructions for sterilisation.					
The facility has confirmed it has the capability to sterilise RMD/other device to the IFU.					
The manufacturer of the steriliser has provided IFUs to ensure correct operation and cycles are used.					
Where IFU for RMD/other device specifies use of extended sterilization cycle it is utilised. Evidence of adherence to requirement is required.					
Extended sterilization cycles are not utilised unless permitted by RMD/ other device IFU due to risk of change in functionality or lifespan may occur.					
PQ if undertaken to determine if SAL can be met for RMD/other devices, packs, and RMD sets is documented (see Clause A.6.5.1)					
Process definition and validation is undertaken where processes are a) outside of steriliser's supplied cycles or b) recommended as suitable process for the RMD/other device are followed.					

Section 6: Process definition

	Rating	Action / evidence	Review date	By whom	Outcomes
6.5.2 Sterilisation procedures					
Procedures have been developed and implemented for the following:					
a) The selection of sterilisation processes to be applied to the RMD/ other device.					
b) Loading the steriliser including any restrictions or limitations & loading orientation of devices.					
c) Methods for routine monitoring and control of the sterilisation process.					
d) Unloading the steriliser including environmental control of area where cooling occurs					
e) Load release criteria (Clause 9.1,9.2& 9.3).					
6.5.3 Moist heat sterilisation					
Sterilising holding time and temperature are within the sterilisation temperature band. (Table6.2)					
Minimum steam dryness value of 0.95 to equivalent to 95% dry saturated steam, (EN285)					

Section 6: Process definition

	Rating	Action / evidence	Review date	By whom	Outcomes
6.5.4 Ethylene oxide sterisation					
Process definition complies with the following:					
a) ISO 11135					
b) ISO 14937.					
A sterilising agent of ethylene oxide and a diluent gas has a specified mixture.					
There is a gas leak detector if gas supply is not self-contained within the sterilisation chamber.					
ETO residual levels controlled and conform with ISO 10993-7.					
6.5.5 Dry heat					
Process definitions comply with ISO 20857.					
6.5.6 Low temperature sterilisation system					
Evidence that:					
a) The sterilising process system is validated for efficacy. (ISO 14937 or ISO 25424 for LTSF and ISO 2241 for Low temperature vaporised Hydrogen Peroxide)					
b) Comprehensive IFU available.					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
7 Validation					
7.1 Stages of Validation					
Evidence that: cleaning, disinfection, packaging, and sterilisation processes are validated and documented					
Installation Qualification (IQ) of reprocessing equipment and ancillary items have been supplied and installed in accordance with specification.					
Operational Qualification (OQ) undertaken in unloaded or using test materials to demonstrate equipment delivers process within equipment specifications.					
Performance Qualification (PQ) uses and exposes products and demonstrates equipment consistently operates in accordance with predetermined criteria & processes yield product that is clean, disinfected/sterile and meets specified requirements.					
Equipment used for validation is calibrated immediately prior to IQ, OQ, PQ. Tests and checks to be performed are specified, documented and the results recorded					
Where sterilising equipment is unable to be validated on-site the service provider uses OQ and PQ which complies with offsite validations in accordance with AS 5369.					

	Rating	Action / evidence	Review date	By whom	Outcomes
RMD/other devices used for validation and configurations of typical loads used are specified by and representative of the facility.					
Upon return of the steriliser if sent off-site the facility the performance of the steriliser shall be checked.					
The facility shall check and review:					
a) Service provider test report					
b) Conduct of steriliser performance (e.g., vacuum test, leak test and Bowie and Dick -type test)					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
c) Process cycles using equivalent reference loads incorporating biological and where applicable, chemical indicators distributed throughout the load prior to using the steriliser for processing RMD's for patient/client use					
References shall be made to applicable AS/National/ISO standards for requirements of IQ, OQ and PQ (see Table 7.1).					
Evidence that IQ and PQ are undertaken for each piece of equipment and PQ for each process delivered by the piece of equipment e.g., each cycle type used in WD or steam steriliser					
Validation protocol for each process including identification of processing equipment and any associated or ancillary equipment used.					
Validation of cleaning, disinfection, packaging, and sterilisation processes is documented as a report.					

	Rating	Action / evidence	Review date	By whom	Outcomes
7.2 Installation qualification (IQ)					
7.2.1 General					
Services and environment are assessed prior to acquisition of equipment and documented.					
Documentation for reprocessing equipment and ancillary items have been supplied and installed in accordance with specification.					
7.2.2 Equipment installation qualification					
Evidence that prior to installation of new or relocated reprocessing equipment that:					
a) The location where the equipment is to be installed has been specified					
b) Environmental conditions in the specified location are in accordance with design specifications.					
c) The required services (water, steam, air) are in accordance with the design specifications					
d) Detailed equipment specifications, calibrations documentation and operational instructions for the equipment have been provided (see Section 4).					
Note: A certification body e.g., NATA may be used to certify of calibration of the equipment.					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
***7.2.3* Services qualification**					
7.2.3.1 Water quality					
Supplied water to the reprocessing facility meets the requirements outlined in AS 5369 and is documented.					
Results of tests conducted on water are recorded and include:					
Minimum quality of water for precleaning and rinse shall be: a) Water hardness no greater than 150mg/L b) Chloride no greater than 120mg/L					
Final Rinse water shall meet specifications of table 7.2 and 7.3 and recorded.					
7.2.3.2 Steam Quality					
7.2.3.2.1 Steam quality tests					
Steam quality tests shall be performed upon installation, relocation or change of steam supply and documented.					
Steam quality and acceptance criteria shall include: a) dryness value $\geq$ 0.95% b) non-condensable gases $\leq$ 3.5% V/V c) superheat not to exceed 25 degrees C Where criteria are not met then a record of results, corrective action and retesting is available.					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
7.2.3.2.2 Steam generation for sterilisers					
Where dedicated steam generator is used the feedwater shall be tested during IQ and OQ to demonstrate conformity and results are documented.					
Annual testing of feedwater is undertaken, and results documented.					

	Rating	Action / evidence	Review date	By whom	Outcomes
Steam Sterilisers with a non-dedicated steam generator the steam condensate shall be tested at IQ or OQ and documented					
Steam Condensate purity tested annually					
Where results of feedwater or steam condensate testing deviate from acceptance criteria in Table 7.4 or Table 7.4 of EN 285 corrective action shall be undertaken and feedwater and/ steam purity retested and recorded.					
7.3 Operational qualification (OQ)					
OQ is performed after installation of any equipment in accordance with the applicable national or international standards and IFU:					
a) Immediately after installation or relocation of any reprocessing equipment					
b) When a service is changed					
c) When existing equipment is modified to deliver a new process					
d) When introducing new devices or loading configurations to ensure performance requirements established during original or subsequent OQ continue to be met					
e) After repair, prior to equipment being put back into service.					

	Rating	Action / evidence	Review date	By whom	Outcomes
7.4 Performance qualification (PQ)					
7.4.1 General					
PQ is performed by a competent person and in accordance with the applicable national or international standards.					
PQ is performed:					
a) Immediately after IQ and OQ for newly installed or relocated equipment					
b) When repairs are made, or a service is changed that might adversely impact the quality of the RMD/ other device (refer Clause 10.5)					
c) When existing equipment is modified to deliver a new process					
d) When introducing a new or modified RMD/ other devices, packaging, or a loading configuration unless equivalence to a previously qualified reference load, device/product family, packaging or loading pattern has been demonstrated					
Evidence that PQ is undertaken using RMD/ other devices that are representative of the range of devices identified as the most difficult to process that are in the facility. Note: Where new RMD/other device is introduced, and it is not equivalent to an existing product family a risk assessment is to be undertaken to determine if PQ is					

	Rating	Action / evidence	Review date	By whom	Outcomes
required. Document where this occurs including outcome of assessment.					
Requalification of the process is performed annually (see Clause 10.4)					
7.4.2 Cleaning processes					
In addition to visual inspection an objective means of assessing the performance of the cleaning process for an RMD/other device is validated and documented.					
7.4.3 Washer-disinfectors					
PQ of WDs is in accordance with the relevant part of the ISO 15883 series (see Clause 1.3)					
7.4.4 Controlled-environment storage cabinets for thermolabile endoscopes					
PQ undertaken as per EN16442 and documented					
7.4.5 Packaging processes					
7.4.5.1 General					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
The following packaging processes are validated and documented (ISO11607-2):					
a) Sealing processes PSBS (e.g., pouches, reels, and bags)					
b) Wrapping processes for SBS (e.g., folding and closing of wraps)					
c) Processes for filling and closing of reusable containers (e.g., Genesis containers)					
7.4.5.2 Heat sealing process performance qualifiication (PQ)					
t Heat sealing process has been validated and documented for PSBS utilised in facility.					
7.4.5.3 Wrapping process performance qualificaiton (PQ)					
Wrapping process for SBS used in facility has been validated and documented.					
The results of PQ, including compliance with acceptance criteria, are documented					
7.4.5.4 Reusable container performance qualificaiton (PQ)					
Evidence has been supplied by the manufacturer that the design of the container allows sterilising conditions to be attained within the contents of the container and that sterility of the contents is maintained after sterilisation					
7.4.6 Sterilising processes					
PQ demonstrates the attainment of the required sterilising conditions on and throughout a RMD within the specified sterilised load					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
PQ demonstrates attainment of a 10^{-6} SAL for a RMD that is terminally sterilised					
Evidence that PQ has been undertaken in accordance with relevant standards (see Clause 1.3)					
PQ is 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 specified and documented					
An RMD/other device used for PQ is packaged in an identical manner to that of the RMD when it is processed routinely					
The manner of presenting a RMD to the process, including the orientation of the RMD, is specified, and documented					
PQ includes assessment of both PPQ (physical performance qualification) and MPQ (microbiological performance qualification)					
a) PPQ verifies attainment of the specified critical physical parameters of the sterilising process within the load (exposure time at temperature, sterilising agent concentration)					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
b) MPQ demonstrates the microbiological lethality of the process within the load by the placement of biological indicators in the load. MPQ studies involve the placement of biological indicators at positions within the load where sterilising conditions are the most difficult to achieve					
For moist heat sterilisation PPQ and MPQ are performed concurrently					
Biological indicators used during PQ:					
i. Conform to part(s) of ISO 11138 applicable to the selected method of sterilisation					
ii. Documented or specified as resistant to the chosen sterilising agent and are more resistant to the selected sterilising agent than any bioburden at risk of remaining on the RMD/ other device after cleaning or disinfection					
iii. Are placed at positions within the packaged RMD/ other device where sterilising conditions are the most likely to be difficult to achieve. *Note: this may be within a PCD.PCDs shall conform to ISO 11135*					
iv. Are subject to the BI testing as per IFU.					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
If used during PQ for other methods of sterilisation, PCDs are equivalent or more challenging to the process than the position in a packaged RMD where sterilising conditions are most likely to be difficult to achieve					
Internal chemical indicators, if used, during PQ shall:					
(A) Conform to relevant part(s) of ISO 11140, applicable to the selected method of sterilisation					
(B) Are placed at positions within the packaged RMD/other device where sterilising conditions are the most likely to be difficult to achieve					
(C) Do not adversely affect the RMD/ other device					
(D) Are not used as the sole means to establish the sterilising process					
PQ studies include a series of at least 3 consecutive cycles to demonstrate reproducibility of the process					
Any exposures outside of the defined tolerances are reviewed and corrective actions determined and instituted before initiating a new series of exposures					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
If a failed exposure can be attributed to factors that are not relevant to the effectiveness of the process being validated (power failure, loss of services, failure of external monitoring instrumentation) then this is to be documented as unrelated to performance and does not require the performance of 3 further consecutive successful cycles.					
For PQ of a moist heat sterilising process the penetration time to all parts of an RMD/other device is to be established and added to the holding time (refer to Table 6.2)					
PQ data is generated during the process to demonstrate attainment of the defined physical and chemical conditions and microbiological lethality within specified tolerances throughout the sterilisation load.					
The relationships between the specified conditions occurring at positions in the load that are used to monitor routine sterilising processes and those conditions occurring throughout the remainder of the load are established by the measurement of specified conditions at predetermined positions throughout the load					
Where applicable following exposure to the process the levels of any process residues are demonstrated as being below the specified regulatory limits					

	Rating	Action / evidence	Review date	By whom	Outcomes
It is demonstrated that an RMD/ other device meets its specified requirements for safety, quality and performance following application of the defined process at the upper tolerances of the process parameters					
7.5 Review and approval of validation					
7.5.1 General					
A validation report is prepared in accordance with the validation protocol for each process					
The validation report for each process includes 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 includes:					
a) Confirmation that calibration of the test equipment has been determined and that calibration of measuring instrumentation fitted to reprocessing equipment has been checked and where necessary adjusted					
b) Confirmation that reprocessing equipment has been tested and reproducibly delivers the defined process					
c) The process parameters (including their tolerances)					
d) For steam sterilisers, the value set for an air detector, or the interpretation of a BI used alone or in combination with a PCD					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
7.5.2 Validation report					
In addition to the validation protocol and data obtained during IQ, OQ and PQ the validation report includes the following where applicable:					
a) The equipment specification and any subsequent changes to it, including any details of modification to the instrumentation or controls					
b) The location and unique identification for the equipment (serial number together with the name and address of the manufacturer, type of equipment and model reference number)					
c) Documentation to demonstrate compliance with the safety specifications					
d) The pressure vessel report(s)					
e) A maintenance manual and a planned maintenance schedule for the equipment including operational procedures for all maintenance, checks and tests					
f) The installation and operational instructions					
g) Copies of any declarations according to regulations for medical or other devices					
h) Details of any faults found and how they have been corrected					

Section 7: Validation

	Rating	Action / evidence	Review date	By whom	Outcomes
i) 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					
j) The parameters used for each cycle and a copy of the specification for each process					
k) The identity of all personnel together with professional qualifications (in terms of their competence to do the work) involved in validation					
l) The programme for requalification, periodic testing, and routine testing					
m) Review of training manuals for routine operating personnel					
n) For equipment that is in current use, the results of maintenance and confirmation that data from routine performance tests are satisfactory					
7.5.3 Approval of validation report					
The validation report is reviewed and approved by the competent person(s)					
The results of this review are documented and approved					
A copy of the validation report is retained					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
8.1 General					
Data is recorded for each cleaning, disinfection, packaging, and sterilising process to demonstrate that the process specifications has been met within the defined tolerances (refer to Tables 8.1 and B.2)					
Records of routine monitoring and control are retained for each operating cycle refer to Clause 2.3.3)					
8.2 Routine monitoring and control of cleaning process					
8.2.1 General					
Routine monitoring and control of the cleaning process is performed in accordance with the requirements of Table 8.1					
8.2.2 Manual cleaning					
The outcome of manual cleaning is checked at the completion by visual inspection					
Final rinse water for manual cleaning shall mirror specifications of water used for automated process (see Table 8.1) and/or be suitable for the intended use of the RMD/ other device					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
8.2.3 Washer disinfectors employing thermal disinfection					
The process record is checked at the completion of each WD cycle to determine the cycle variables as indicated by the RMD/ other device on the WD or shown on the batch process record are within the specified limits as validated.					
The following process variables shall be confirmed at each stage of the process:					
a) Correct functioning of cleaning and drying equipment (water pressure, flow, action)					
b) Cleaning agent dosage					
c) Temperature including the time for which the disinfection temperature was maintained was not less than that specified					
d) Exposure time (time at temperature)					
8.2.4 Ultrasonic					
The performance of the ultrasonic cleaner is tested daily (AS 2773) and recorded.					
8.2.5 Cleaning efficacy inspection					
Cleaning efficacy is checked on completion of the cleaning process for RMD/other device by visual inspection utilising magnification as appropriate.					
8.2.6 Drying cabinets					
Drying cabinet temperature is checked daily and recorded.					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
8.3 Routine monitoring and control of manual chemical disinfectant with high-level instrument grade disinfectant					
For each use of the instrument grade HLD the following monitoring activities are documented according to the IFU:					
a) Temperature of HLD					
b) Contact time					
c) Rinse water volume					
The MRC of the instrument grade HLD is monitored prior to each use according to the IFU, or at least daily, and the results documented					
Chemical Indicators are compatible with the HLD used.					
8.4 Routine monitoring and control of washer-disinfectors employing chemical disinfection for thermolabile endoscope					
The process record and process indicators where used are checked at the completion of each cycle to verify that the process was delivered within defined tolerances or in accordance with the specification and recorded.					
Routine monitoring and control of the chemical disinfecting process is performed in accordance with the requirements of Table 8.1					
Process indicators may be used to determine MRC of chemical disinfectant.					
The following process variables shall be confirmed:					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
a) Correct functioning of disinfecting equipment (water pressure, flow, action, disinfecting agent solution volume and temperature)					
b) In-use chemical disinfecting agent concentration during the disinfection phase, if required					
c) Correct contact /time					
d) Any additional parameters of the WD or disinfection agent					
8.5 Microbiological surveillance of flexible endoscopes with channels					
Flexible endoscopes with channels undergo microbiological surveillance					
Note: Testing is not required for terminally sterilized endoscopes					
Endoscopes are tested at least quarterly in accordance with the GENCA guidelines and results recorded.					
Testing of flexible endoscopes with channels that undergo terminal sterilisation may be required by the facility's policy and where this occurs results are recorded.					
Loaned flexible endoscopes with channels or returning from repair undergo microbiological surveillance within 72 hours of receipt and documented.					
8.6 Routine monitoring and control of packaging process					
Packaging procedures are performed in accordance with the specification developed during process definition(section6)					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
Packaged items visually checked for conformity while preparing loads and where non-compliance occurs items are repackaged to address issue.					
Heat sealers used for sealing PSBS or dust covers are operated in accordance with IFU.					
For impulse and rotary heat sealers without a process record, the temperature that the machine has been set for is recorded daily and a visual check made immediately prior to each episode of sealing to ensure that the correct seal temperature has been reached					
For heat sealers where process variables are monitored for each episode of sealing, achievement of correct process variables are confirmed at the completion of each episode of sealing, or in accordance with the IFU.					
Daily, one or more samples of heat sealed PSBS are checked for seal integrity before and after exposure to the sterilisation process. This check includes a visual assessment of seal integrity over the entire length of the seal, results are to be recorded (BS EN 868-5).					

	Rating	Action / evidence	Review date	By whom	Outcomes
Rigid reusable sterilisation containers are subject to a visual inspection prior to each use. The container and the lid are free from any dents or cracks, that the seal/gasket is intact along its entire length and is not compressed or pinched, the closure mechanism (handles) lock firmly into position and that the filter (if applicable) has been replaced or is within the acceptable number of reuse cycles. Where container or lid are non-compliant, they are removed from use and repaired/ replaced.					
8.7 Routine monitoring and control of sterilising process					
8.7.1 General					
Sterilising equipment is checked to ensure that it is functioning as intended each day, prior to being used for the sterilisation of RMDs/ other devices. Results of tests/ checks undertaken are to be documented.					
The process record is checked, and results recorded at the completion of each sterilisation cycle to verify that the process was delivered in accordance with the validated specification. Additional methods of verification may include BI and CI.					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
8.7.2 Low temperature sterilsing systems					
Performance tests are conducted in accordance with the IFU (peracetic acid, hydrogen peroxide, low temperature steam formaldehyde systems and ethylene oxide) and results documented.					
8.7.3 Dry heat					
Performance tests are conducted in accordance with the IFU, and results documented.					
8.7.4 Moist heat					
Document results of daily Bowie Dick type tests undertaken on steam sterilisers that utilise a vacuum for air removal in the pre-sterilisation stage of the process cycle					
Bowie and Dick type tests (large steam sterilisers) conform with ISO 11140-3, ISO 11140-4, or ISO 11140-5 as appropriate					
Air removal and steam penetration tests for small steam sterilisers comply with EN 867-5 or ISO 11140-6					
For steam sterilisers fitted with an air detector perform and document weekly leak rate/vacuum test and air detector function test.					
For sterilisers without an air detector fitted perform and document daily leak rate/vacuum test.					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
8.7.5 Biological indicators					
Biological indicators used for process development (if applicable), MPQ and routine monitoring and control of sterilising processes conform with ISO 11138 series and the relevant part according to the selected method of sterilisation. Reference is made to ISO 14161 when selecting, using, and interpreting the results of biological indicators					
Biological indicators are used as follows:					
a) As part of MPQ					
b) In every load in a validated ETO sterilisation process					
c) According to IFU in dry heat and low temperature sterilisation systems					
d) At frequencies determined by the facility for validated moist heat sterilisation processes					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
8.7.6 Chemical indicators					
Chemical indicators used for process development (if applicable), during PQ and routine monitoring and control of sterilising processes comply with ISO 11140-1 and selected according to the sterilisation method or cycle. Selection, use and interpretation of results shall be in accordance with ISO 15882					
CIs are used as follows:					
a) As part of PQ if internal CI are to be used routinely					
b) On the exterior of each packaged RMD/other device					
c) According to IFU for low temperature sterilisation systems using a liquid chemical sterilising agent					
d) As required by facility's policy for internal indicators					
e) In every load where semi-critical RMDs/other devices are sterilised unwrapped					
8.7.7 Process challenge device (PCD)					
PCDs, if used shall be equivalent or more challenging to the process than the position within a packaged RMD/other device where sterilising conditions are most likely to be difficult to achieve. Selection use and interpretation of results shall be in accordance with ISO 15882.					

Section 8: Routine monitoring and control

	Rating	Action / evidence	Review date	By whom	Outcomes
Where PCDs are used to monitor ETO, the requirements of ISO 11135 are followed					
PCDs used as an air removal and steam penetration test in a small steam steriliser conform ISO 11140-6					

Section 9: Release of RMDs/other devices following reprocessing

	Rating	Action / evidence	Review date	By whom	Outcomes
9.1 General					
The effectiveness of each individual stage of the overall reprocessing procedures (cleaning, disinfection, packaging, sterilisation) are confirmed prior to the device being released to the next stage of reprocessing					
Prior to the release of the device from each stage of the process the cycle record is checked to ensure the process has been delivered in accordance with its specification					
Where used, the results for test soil cleaning indicators, Bis, CIs and PCDs are checked as part of the product release in accordance with the facility's policy.					
Product release from sterilisation processes where BIs are mandatory release is delayed until the results of the BIs testing is known.					
A system should be evident that clearly differentiates between unprocessed and processed RMD/other device within the reprocessing area.					
9.2 RMD/ other device release criteria					
Evidence that there are procedures for the release of RMD/other device at each stage of reprocessing. Procedures are to include required criteria and review of records.(see Table 9.1)					

Section 9: Release of RMDs following reprocessing

	Rating	Action / evidence	Review date	By whom	Outcomes
9.3 RMD/ other device release					
An RMD/ other device is not released unless all acceptance criteria have been met (see Table 9.1)					
Nonconforming RMD/ other device shall be handled or quarantined in accordance with the documented procedure (refer to Clause 2.5)					
9.4 Record of RMD/ other device release					
The system for traceability of released RMDs/ other devices shall conform a minimum with the requirements of Clause 2.5.3.					
9.5 Handling, transport and storage of released reprocessed RMDs/ other devices					
Reprocessed critical/semi-critical RMDs / other devices are handled, transported, and stored in a manner which prevents/minimises the risk of contamination					
Storage areas for sterile RMDs/ other devices including items purchased sterile by the facility shall be maintained to reduce risks of device sterility being compromised.					
Procedure for transporting of sterile RMD/other device including protecting package integrity until the point of use.					
Evidence Monitoring of the environmental conditions including cleaning is undertaken.					
Evidence that systems used for transportation and storage are maintained.					
Evidence that education of staff has been undertaken.					

Section 10: Maintaining process effectiveness

	Rating	Action / evidence	Review date	By whom	Outcomes
10.1 General					
The ongoing effectiveness of cleaning, disinfecting, packaging and sterilising processes are periodically assessed to ensure that each process continues to be delivered within its specification.					
Evidence that facility has agreements in place with suitably trained and/or qualified service providers to undertake preventative maintenance, recalibration, reassessment of process effectiveness and annual requalification for all reprocessing equipment. (For frequencies see Table 10.1,10.2 and 10.3)					
10.2 Calibration					
Instrumentation that is used to control or monitor cleaning, disinfecting, packaging or sterilising (timers, gauges and temperature monitoring devices) are subject to periodic calibration at specified intervals (see Clause 2.5.4)					
10.3 Maintenance of equipment					
10.3.1 General					
Evidence that preventative maintenance of all equipment is planned and undertaken in accordance with documented procedures by the equipment manufacturer					

	Rating	Action / evidence	Review date	By whom	Outcomes
Preventative maintenance undertaken by a competent person e.g., equipment service technician					
Records available indicating every planned maintenance activity and the frequency this is to be undertaken.					
Evidence that all reprocessing equipment undergoes an annual electrical safety check					
Where necessary, air filters are checked and changed as required by the IFU.					
Equipment maintenance records are retained and readily accessible					
10.3.2 Return of use					
Equipment is not used to reprocess an RMD/other device until specified maintenance activities have been satisfactorily completed and documented at a minimum in accordance with Table 10.1					
A maximum period that is permitted for any delay in scheduled maintenance is specified.					
10.3.3 Maintenance records					
The maintenance records identify the equipment and provide a history of routine periodic maintenance as well as unscheduled maintenance and repairs for the equipment					
Records as a minimum include the following information:					

Rating Key: SC = Substantially Complies PC = Partially Complies NC = Non-Compliant N/A = Not Applicable

	Rating	Action / evidence	Review date	By whom	Outcomes
a) The reason for the maintenance or repair					
b) The date of maintenance or repair					
c) The model and serial number of the equipment					
d) The location of the equipment					
e) A description of the maintenance or repair undertaken					
f) Details of the parts replaced					
g) The name of the person or company responsible for performing the maintenance or repair					
h) The name of the person releasing the equipment back into use					
The preventative maintenance schedule, procedures and records are conducted in accordance with the requirements of Section 2.					
10.3.4 Identify faults					
Evidence that faulty equipment is identified, and corrective action is taken to rectify the fault in a timely manner					
Where a fault has the potential to impact on the quality and safety of another device, or on operator safety, then the equipment is removed from use immediately pending repair and documented.					

Rating Key: SC = Substantially Complies PC = Partially Complies NC = Non-Compliant N/A = Not Applicable

	Rating	Action / evidence	Review date	By whom	Outcomes
	Rating	Action / evidence	Review date	By whom	Outcomes
10.3.5 Cleaning of equipment					
Equipment is cleaned in accordance with the facility's established protocol and in conjunction with the IFU					
The methods used and the frequency of cleaning is specified and records are kept (Clause 2.3.2 and 2.3)					
10.4 Requalification					
10.4.1 General					
Requalification is performed and documented at least annually in accordance with Clause 7.4 and whenever a change is made to: a) An RMD/other device b) Packaging c) Process chemicals d) Cleaning, disinfection, packaging, or sterilisation processes e) IFUs		Refer to validation section			

Rating Key: SC = Substantially Complies PC = Partially Complies NC = Non-Compliant N/A = Not Applicable

	Rating	Action / evidence	Review date	By whom	Outcomes
Requalification is performed and documented where major changes or repairs are made to reprocessing equipment that 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 are assigned to a designated competent person					
10.4.2 Procedures for requalificaton					
Procedures for requalification are specified					
Requalification is performed in accordance with these procedures					
Records of requalification are retained					
10.4.3 Review and Acceptance of requalification.					
Evidence that requalification data is reviewed and compared against acceptance criteria to confirm performance of process as originally qualified has been retained.					
Records of review retained with any corrective action(s) taken where acceptance criteria are not met.					
10.5 Assessment of change					
Any change to the reprocessing equipment or to a process that might impact on the quality of a reprocessed RMD is examined and documented.					

Rating Key: SC = Substantially Complies PC = Partially Complies NC = Non-Compliant N/A = Not Applicable

Section 10: Maintaining process effectiveness

	Rating	Action / evidence	Review date	By whom	Outcomes
If the effectiveness of the processes is altered adversely as a result of the change, then repeat of part, or all, of IQ, OQ or PQ is performed (see Section 7) The outcome of this assessment, including the rationale for decisions reached, are documented					
Any change in an RMD/ other device, packaging or the presentation of the device for reprocessing are examined for the impact of this change on the cleaning, disinfecting, packaging or sterilising processes.					
Where necessary, depending on the nature of the change, aspects of process definition and PQ are performed (see Sections 6 and 7)					
The outcome of this assessment, including the rationale for decisions reached, are documented					

Rating Key: SC = Substantially Complies PC = Partially Complies NC = Non-Compliant N/A = Not Applicable