Endoscope Reprocessing Procedure

1. Guiding Principles

Where endoscopes are used and reprocessed, the health service must comply with current relevant legislation, national & international standards, guidelines and manufacturer's reprocessing instructions.

The purpose of endoscope reprocessing is to provide a reusable endoscope that is safe for patient use. This is achieved using current, evidence-based, best-practice in endoscope reprocessing.

Incorrect use, transport and reprocessing of endoscopes may create a potential risk for patients and staff from infectious agents through cross-contamination.

This procedure applies to staff who use or reprocess endoscopes.

2. Definitions

RMD	Reusable Medical Device (instrument, scope, probe)
IFU	Information for use (reprocessing instructions)
NATA	National Association of Testing Authorities

3. Procedure

3.1 RMD Reprocessing Education

Identifying the minimum training and education required for staff involved in the reprocessing of endoscopes aims to ensure the provision of endoscopes safe for patient use, while satisfying relevant legislation, standards and guidelines.

WACHS is committed to providing a competent and properly trained workforce for reprocessing endoscopes for the provision of safe patient care.

Inadequate training may lead to increased infection control risk to patients and potential workplace injury to staff

Minimum RMD Reprocessing Training Content

- Modes of transmission of infection
- Infection prevention control principles (including standard and transmission-based precautions)
- Hand hygiene (including the importance of removing nail polish, artificial nails and jewellery)

- Workplace health and safety, such as PPE, chemical handling, spill management, biohazard/blood exposure
- Reprocessing tasks
- Instrument tracking
- Documentation and record keeping

Education Record Keeping

The Endoscope Reprocessing Manager/facility should:

- Monitor and ensure compliance with staff endoscope reprocessing competency-based training
- Conduct annual assessment of staff skills to ensure they are competent to safely undertake reprocessing activities
- Maintain records of endoscope reprocessing staff training

3.2 Endoscope Quality Management

Endoscope records keeping will comply with the WA State Records Act, with records kept a minimum 7 years.

The following outlines the requirements for the routine monitoring, validation, maintenance and calibration of endoscope reprocessing equipment, and required corrective actions to be taken when issues are identified.

Endoscope reprocessing machinery (high level disinfectors, drying cabinets etc) must be validated at the following times:

- **Installation Qualification (IQ)** performed at installation, or when equipment is relocated, and provides objective evidence that the equipment processes conform to relevant standards and manufacturer's requirements
- **Operational Qualification (OQ)** performed at installation, or when equipment is relocated, service changed, existing equipment is modified, change to loading configurations is changed, a new RMDs is introduced, or after repair. Provides objective evidence that the equipment processes conform to relevant standards and manufacturer's requirements. An OQ is not considered a PQ.
- **Performance Qualification (PQ)** performed annually at a minimum, as well as after IQ, OQ, repair, change in process, new RMDs, change in load configurations.

Validation Report

The validation report summarises the data collected during the IQ and OQ for equipment, and PQ for specific processes. The Endoscope Reprocessing Area Manager shall review and approve the report. It is the Endoscope Reprocessing Area Manager's responsibility to identify the need for re-qualifications when it is required more often than the minimum specified by the Standards ie when there is a change in process

PQ is to be performed on all equipment each year at a minimum. There is tobe a current PQ validation document in the department for all equipment.

Maintenance and training manuals are to be provided by the company.

Monitoring

Routine monitoring and cleaning of the endoscope reprocessor shall comply with the requirements set out in Table 8.2 of AS/NZS 4187:2014, and company instructions.

Flexible endoscope reprocessor preventative maintenance, testing and recalibration is tooccur as per Table 10.3 in AS/NZS 4187:2014, and 10.1 for peracetic acid sterilising, as well as company instructions

Endoscope storage cabinet preventative maintenance, testing and recalibration occur as per Table 10.2 in AS/NZS 4187:2014, and company instructions.

The quality of the water used to reprocess endoscopes will comply with Table 7.2 in AS/NZS 4187:2014. Water will be tested monthly by a NATA accredited tester, with NATA calibrated equipment, whether they are provided by a contract or the hospital. A current calibration certificate shall be available.

For manual disinfection, process indicators may be used to verify the minimum effective concentration of the chemical disinfectant.

Recordkeeping

The following records must be kept in the department, irrespective of whether the information is found in the patient's file:

Frequency	Criteria
Each list	• Order of patients on the list
Each endoscope reprocessed	• Date of procedure • Patient details • Scope details ie serial number • Name of person performing the manual cleaning phase and connected scope to reprocessor, or immersed in disinfectant • Name of person who removed the scope from the disinfectant or machine and released it for use • For manual disinfection, temp or disinfectant and immersion time in disinfectant
Daily or as per manufacturer's instructions	• Monitoring the minimum effective concentration (MEC) of reusable disinfectant • Name of the person who tested the reusable disinfectant

Frequency	Criteria
Other	• Batch number of disinfectant • Water filtration pressure check • Ultrasonic testing • Date reusable disinfectant decanted into the tank • Date reusable disinfectant changed or filled up (to maintain volume)

Audits

The department will be audited against the AS/NZS4187:2014 standards quarterly, with results tabled to the Infection Control Committee. The results must be documented and an action plan developed to track corrective action and the result of that action. The action shall be reviewed to assess effectiveness.

3.3 Cleaning, Disinfection and Sterilisation of RMDs

Environmental Cleaning

Environmental cleaning of and Endoscopy Reprocessing area is to occur as per the department's cleaning schedule. Cleaning of machinery is to be done as per manufacturer's instructions. Environmental cleaning and equipment cleaning must be documented as per the schedule and records kept.

All work surfaces, fixtures and fittings must be made of robust, non-shedding material that is easy to clean.

Separate environmental cleaning equipment must be used for clean and dirty areas.

Reprocessing cleaning equipment

Brushes and accessories may be single use. Reusable brushes and cleaning equipment must be ultrasonically cleaned and steam sterilised after each use.

Cleaning adapters and attachments must be cleaned as per manufacturer's instructions.

Single use

It is a breach of the Therapeutic Goods Act to reprocess single-use devices unless the facility is licenced by the TGA to do so. Hospital CSSDs are not licenced or equipped to reprocess single-use devices.

All single-use devices, such as endoscope buttons, must be disposed of by the clinician, at the point of use. Single-use devices that have been opened and not used, must be discarded.

The only exception is single-use devices supplied to CSSD in an intentional unsterile state, with a validated IFU on how they are to be processed.

Single-use sharps are to be discarded at the point of use by the clinician.

Pre-cleaning at the point of use

The reprocessing of a used endoscope starts at the point of use, with clinical staff removing gross soiling and debris immediately after use. Detergent and clean water is to be used, as per GENCA Guidelines and the endoscope IFU, to reduce the risk of biohazard drying and biofilm forming especially inside scope channels.

The endoscope must be reprocessed within 30min – 1 hr of use. To reprocess the endoscope, company reprocessing instructions must be followed.

Personal Protective Equipment

Personal protective equipment (PPE) are to be used as per the PPE Matrix. Any chemical spills are to be managed following the instructions of a purpose designed spill kit.

Cleaning

Meticulous cleaning is essential for a flexible endoscope to be disinfected. Manual cleaning is to be done as per GENCA Guidelines and the scope manufacturer's reprocessing instructions. Incomplete cleaning of duodenoscopes has been implicated in cross infection between patients (Refer to: OD 0399/12: CRE infection prevention and control).

Scopes must be loaded into a mechanical cleaner (ie Soluscope) in a way that all surfaces are cleaned, including channels. Scope unloading is done in a way to limit cross-contamination.

Disinfection

Flexible endoscopes such as gastroscopes and colonoscopes are considered semi-critical devices as per Spaulding's Classification and as such, can be high level disinfected between patient use.

Automated flexible endoscope reprocessors use chemicals such as peracetic acid, to kill pathogens and render the scope safe for patient use.

Drying

Drying methods must not compromise the cleanliness of an endoscope, and may include:

- Airgun
- Disposable lint-free cloth

Drying Cabinet Storage

Endoscopes must be completely dry to ensure no microbiological growth after reprocessing

Endoscopes stored in a TGA-approved, forced-air drying cabinet can be stored and used for up to 7 days.

If a forced-air drying cabinet is not TGA-approved for 7 day storage, endoscopes may be stored up to 72 hrs. If the endoscope storage is not air-forced or well ventilated, then the scope will need to be reprocessed before use.

Endoscope Type	Storage Time
Gastroscope, colonoscope, radial EUS scopes	72 hrs
Duodenoscopes, bronchoscopes and linear EUS scopes	12 hrs
Emergency endoscopes ie intubating bronchoscopes	72 hrs
Enteroscopes	72 hrs when stored in continuous airflow. 12 hours if handing in storage

3.4 Release Criteria

At each stage of reprocessing the endoscope must be assessed to ensure it satisfies the Release Criteria (Table 9.1, AS/NZS 4187:2014) in order to move onto the next phase of the process.
If an endoscope fails to satisfy the Release Criteria at any stage of the process it must be returned to the Decontamination Area to re-start the processes.
An endoscope will not be released for use on a patient unless it satisfies all release criteria.

3.5 RMD Tracking

Tracking of endoscopes will enable the facility to link the use of an endoscope to a patient in the case of a re-call for non-conformance. In order to facilitate a recall of a non-conforming RMD, reprocessed items must have:

- Name of the RMD
- Date reprocessed
- Cycle information for each scope
- Documented evidence the scope has been through reprocessing
- A process to facilitate the tracking of the item's reprocessing history
- A process to identify the patient that an RMD was used on
- Identification of the person who approved the process/ load
- Name, designation of staff involved in procedure
- Name of the person who approved the process

Auditing of compliance with the above is to be done annually. The result is to be used to facilitate clinical staff education on compliance.

3.6 Microtesting

Flexible endoscopes shall undergo microtesting for the purposed of microbiological surveillance, to monitor the effectiveness of the cleaning and disinfecting processes. If the scope is reprocessed, it must be left for 12 hours before microtesting.

Flexible endoscopes on loan or returned from repair will be microtested within 72hrs of receipt by the facility.

The sample shall be collected by staff trained in the correct microtesting technique, as per the GENCA Guidelines and company IFU.

The results are to be reported to the Infection Control Committee quarterly. This is to include any action taken with regards to the reporting of a positive results

Endoscope	Testing Frequency	Method of Testing
Gastrointestinal endoscopes (ie Gastroscope, Colonoscope)	Every 3 months	As per GENCA Guidelines
Bronchoscope	Every 4 weeks	As per GENCA Guidelines
Endoscopic ultrasound device	Every 4 weeks	As per GENCA Guidelines
Sterilise and wrapped endoscopes	Every 3 months	As per GENCA Guidelines
Loan or repaired endoscopes	Within 72hrs of receipt, then as per above	As per GENCA Guidelines Testing is to occur within 72hrs of receipt and quarantines until a negative result is confirmed. The loan scope is to then be entered onto the routine microtesting schedule for the time it remains in the department
Automated flexible endoscope reprocessors (AFERs)	Every 4 weeks	As per machine IFU
Water used rinsing endoscopes	Every 4 weeks, or 3 months if filtered to 0.2u	As per AS/NZS 4187:2014 Table 7.2 Must be monitored every 4 weeks if a filter bank is not in use or every 3 months where rinse water is filtered to 0.2u.

Microtesting positive result

Positive results from microtesting endoscopes are interpreted using the 201GENCA Infection Control in Endoscopy Guidelines recommendations.

Process for investigating a positive microbiological result from endoscope microtesting		
Sample	**Investigation**	**Action**
One or two microorganisms repeatedly found on the same endoscope	Possible internal endoscope fault or scope damage	• Contact manufacturer • Send for repair
One microorganism repeatedly isolated from 2 or more endoscopes	Consider poor collection technique if: *Coag negative staph, Staph aureus, micrococci, diptheroids or Bacillus species*	• Review sample collection technique • Repeat collection • Cease use of reprocessing machine until source of contamination is found
Two or more organisms repeatedly found on 2 or more scopes	Consider a problem with the cleaning or disinfection process	• Review all cleaning and disinfection procedures, compliance and endoscope reprocessor function

When a positive result is returned from microtesting, further screening may take place, in consultation with a Clinical Microbiologist if:

- There is suspected clinical cross contamination from the endoscope use
- Positive surveillance results are reported
- There is an alteration to the plumbing leading to the endoscope reprocessor
- New procedures are implemented in CSSD
- New models of equipment are introduced ie a new type of scope, a new reprocessor

The 2011 GENCA Infection Control in Endoscopy Guidelines provides instruction on managing the response to a positive microtesting result.

3.7 Endoscope transport

Endoscopes are to be transported in their designated endoscope tray. A cover is to be used during transport to indicate if the endoscope has been used, or is clean. The tray is to be transported flat on a trolley.

When transporting outside the hospital, a dedicated transport case must be used. The endoscope is to be reprocessed prior to transport, to ensure it is safe for others to handle. Documentation of reprocessing is to be included with the scope as evidence. If the scope is damaged and reprocessing may cause further damage, refer to manufacturer's instructions for how to proceed.

Incorrect transport of and endoscope may result in the item being inadvertently contaminated prior to use, presenting an infection control risk. Alternately, an incorrectly transported soiled item presents an OSH hazard.

4. Roles and responsibilities

All Staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be, and contribute to the provision of safe patient care.

5. Compliance

Inclusion of a compliance statement congruent to the applicable Act is compulsory.

This procedure is required by AS/NZS 4187:2014 Reprocessing Standards. Failure to comply with this procedure may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Employment Policy Framework issued pursuant to section 26 of the *Health Services Act 2016* (HSA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

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

6. Records Management

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

Records Management Policy
Health Record Management Policy

7. Evaluation

Evaluation of this procedure is to be carried out by the CSSD or Theatre Manager. The following means or tools are to be used:

- Audit results as evidence of meeting the requirements of the standards

8. Standards

National Safety and Quality Health Service Standards (Second edition 2017) -
NSQHS Standard 3 – Preventing and controlling hospital acquired infections
Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)
ACORN Australian Perioperative Nursing Standards (2015)
AS/NZS 4187:2014 Reusable medical device reprocessing standards

9. Legislation

Therapeutic Goods Act (1989)

10. References

NSQHS Standard 3 – Preventing and controlling hospital acquired infections
AS/NZS 4187:2014 Reusable medical device reprocessing standards
2011 GENCA Infection Control in Endoscopy

11. Related WA Health System Policies

OD 0404/12: Reprocessing diagnostic ultrasound devices

OD 0369/12: Reprocessing infant feeding devices

OD 0456/12: CJD risk assessment and management

OD 0399/12: CRE infection prevention and control

12. Policy Framework

Public Health

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

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