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Decision making guideline for the cleaning, disinfection and sterilisation of non-lumen flexible nasendoscopes

1. Purpose

This document outlines best practice decision making guidelines to support Hospital and Health Services (HHSs) in determining the most appropriate cleaning, disinfection and sterilisation technique for their facilities for non-lumen flexible nasendoscopes to promote clinical safety and efficiency.

2. Scope

This Guideline provides information for all Queensland public health system employees (permanent, temporary and casual) and all organisations and individuals acting as its agents (including Visiting Medical Officers and other partners, contractors, consultants and volunteers).

The scope of this Guideline is limited to non-lumen flexible nasendoscopes which are classed as a semi-critical device under AS/NZS 4187: 2014: A medical device that comes into contact with mucous membranes or non-intact skin.

2.1. Out of Scope

This guideline addresses the reprocessing of non-lumen flexible nasendoscopes only. It does not include the following aspects of management:

- Procurement
- Design and installation
- Validation and verification
- Testing methods

3. Related documents

- Standards Australia. AS/NZS 4187:2014. Reprocessing of reusable medical devices in health service organizations.
- Australian Commission on Safety and Quality in Healthcare. Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).https://www.nhmrc.gov.au/guidelines-publications/cd33
- National Safety and Quality Health Service (NSQHS) Standards. http://qheps.health.qld.gov.au/psu/safetyandquality/standards/default.htm
- Endoscopy Manufacturer's instructions manuals, with reference to Instructions for Use
- Queensland Health Risk Management Policy. https://www.health.qld.gov.au/__data/assets/pdf_file/0038/395894/qh-pol-070.pdf
- Queensland Health. Endoscope Reprocessing. http://www.chrispqld.com/endoscopy/default.htm
- Patient Safety and Quality Improvement Service. Patient Safety Communique No. 09/2017. http://qheps.health.qld.gov.au/psu/alerts/docs/ps-comm-092017.pdf
- Department of Health, United Kingdom. 2013. Health Technical Memorandum 01-06: Decontamination of flexible endoscopes. https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes

4. Guideline for Decision Making

4.1. Context

As an independent statutory body, each HHS is responsible for determining the most appropriate clinical practices for their individual circumstances, whilst maintaining compliance with relevant legislative and mandatory standards and best-practice guidelines. Due to varying facility profiles across Queensland, it is acknowledged that different methods for the cleaning, disinfection and sterilisation of certain devices may be necessary. However, HHSs have an obligation to ensure that their decision to adopt a specific technique is made through a deliberate and holistic risk management approach where consideration of individual circumstances is given to ensure clinical safety, efficiency and compliance with AS/NZS4187:2014.

Furthermore, HHSs have an obligation to ensure sustainability of services acknowledging a limited public health budget. Decision making must factor in all elements of risk including the ability to meet demand, availability, cost, staff training and compliance with AS/NZS417:2014. Consideration of high standards of sterilisation and infection control versus cost-benefit and sustainability across different alternatives should be assessed.

An overview of the range of current techniques used in Queensland is located in Appendix A.

4.2. Principles

HHSs should consider the following principles when determining which reprocessing technique is most appropriate for their facility profile(s):

4.2.1. The approach should align to the risk management principles of AS/NZS ISO 31000:2009.

4.2.2. All essential quality requirements outlined in AS/NZS 4187: 2014 must be met.

4.2.3. Specifications for cleaning, disinfecting, packaging and sterilising processes must be developed in accordance with the manufacturer's reprocessing instructions (instructions for use) for the nasendoscope.

4.2.4. Manual cleaning of a reusable medical device (RMD) must only be used:

i. where an RMD manufacturer's validated cleaning instructions require manual cleaning of the RMD; and

ii. as a pre-treatment prior to reprocessing of an RMD in a washer-disinfector.

4.2.5. The use of an automated cleaning process in a washer-disinfector is the preferred means of cleaning as an automated process is more reproducible than a manual cleaning process.

4.2.6. Clinical safety and efficacy must be maintained to ensure optimal patient outcomes.

4.2.7. Efficiency, productivity and cost should be considered to ensure services can maintain demand within financial restraints.

4.2.8. Location and infrastructure requirements should be reviewed to meet necessary standards.

4.2.9. Resourcing and staffing requirements to meet necessary standards should be factored in, including education and training requirements. This may require competency assessments.

4.2.10. The technique to address high risk patient groups and individuals must be appropriate.

4.2.11. The technique for afterhours use must be appropriate.

4.2.12. As non-Lumen flexible nasendoscopes are a reusable medical device (RMD) used for the examination of nasopharynx, larynx and hypopharynx, the reprocessing of these endoscopes requires high standards of cleanliness and disinfection as per other flexible endoscopes.

4.3. Manufacturer's Instructions

All essential quality requirements outlined in AS/NZS 4187: 2014 apply. Manufacturer's instructions must be followed. Any cleaning method used must meet AS/NZs 4187 and the manufacturer's instructions.

4.4. Cleaning, Disinfection and Sterilisation of Non-Lumen Flexible Nasendoscopes

4.4.1. Spaulding's classification

The below table (4.3.1) provides general criteria for use in reprocessing and storage of reusable medical devices based on Spaulding's classification. Spaulding's classification is a recognised and rational approach to disinfection and sterilisation which identifies equipment under three categories based on the level of risk associated with their intended use.

Level of risk	Process	Storage
Critical A medical device that comes into contact with the vascular system or sterile tissue and that shall be sterile at the time of use	Clean as soon as possible after using Sterilise by moist heat after cleaning If RMD is heat or moisture sensitive, sterilise using an alternative process, e.g. automated low temperature chemical sterilising process, liquid chemical sterilising process, or ethylene oxide sterilising process	Sterility shall be maintained Packaged RMDs shall be stored to prevent environmental contamination in a designated storage area to protect RMD RMDs processed through a liquid chemical sterilising process shall be used immediately
Semi-critical A medical device that comes into contact with mucous membranes or non-intact skin	Clean as soon as possible after using Sterilise by moist heat after cleaning If the RMD will not tolerate moist heat sterilisation use a low temperature sterilisation process or thermal disinfection or disinfection using a high level instrument grade chemical disinfectant	Store to prevent environmental contamination in a designated storage area to protect RMD
Non-critical A medical device that only comes into contact with intact skin and not mucous membranes	Clean as necessary with detergent solution If further treatment is necessary, disinfect with compatible low level or intermediate level instrument grade disinfectant after cleaning	RMDs shall be stored in a clean dry place to minimize environmental contamination

Source: *AS/NZS4187:2014 Reprocessing of reusable medical devices in health service organizations*

i. Non-lumen flexible nasendoscopes are considered semi-critical reusable medical devices.

ii. Because of their structural complexity and fragility, nasendoscopes may be heat labile. Manufacturers will provide product specific recommendations.

iii. Heat labile scopes require high level chemical disinfection in accordance with AS/NZS4187:2014.

iv. Single use sheaths are not a substitute for reprocessing of scopes.

4.4.2. Cleaning

i. Cleaning describes a process of removal of contamination from an item to the extent necessary for further processing or for intended use. Cleaning can be completed either mechanically or manually.

ii. Manual cleaning of a reusable medical device (RMD) shall only be used—

a) where an RMD manufacturer's validated cleaning instructions require manual cleaning of the RMD; and

b) as a pre-treatment prior to reprocessing of an RMD in a washer-disinfector.

iii. The use of an automated cleaning process in a washer-disinfector is the preferred means of cleaning as an automated process is more reproducible than a manual cleaning process.

iv. Effective and timely cleaning is essential to meeting the sterility assurance level (SAL) for nasendoscope reprocessing.

v. Presence of organic material such as blood, faeces and respiratory secretions after cleaning can result in the failure of sterilisation or disinfection. This may be because either the organic material protects the microorganisms from exposure to the sterilant/ disinfectant or because the disinfectant may be inactivated by contact with organic material.

vi. Rigorous cleaning of nasendoscopes is required to remove such material before disinfection or sterilisation. This should occur immediately after use to prevent the drying of secretions.

vii. The type of detergent, sterilant and/or disinfectant used to reprocess a particular nasendoscope is to be provided and validated by the manufacturer.

viii. Manufacturer's instructions are to be obtained from the vendor prior to scope purchase. Prior to purchasing scopes the HHS is to ensure that it is able to reprocess the scopes as per AS/NZS 4187: 2014 and the manufacturer's recommendations.

ix. To be most effective, cleaning of a contaminated flexible nasendoscope is to take place as soon as possible after use.

4.4.3. Disinfection

i. Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores and can be accomplished by a number of means that include heat and chemicals.

ii. Terminology (as defined by Therapeutic Goods Order No.54 – *Standard for Disinfectants and Sterilants*') which is now widely used to describe disinfectants in terms of their activity includes:

   a. **High-level disinfectants:** a disinfectant that kills all microbial pathogens, except large numbers of bacterial endospores when used as recommended by its manufacturer.

   b. **Intermediate-level disinfectants:** a disinfectant that kills all microbial pathogens except bacterial endospores, when used as recommended by the manufacturer. It is bactericidal, tuberculocidal, fungicidal (against asexual spores but not necessarily dried chlamydospores or sexual spores), and virucidal.

   c. **Low-level disinfectants:** a disinfectant that rapidly kills most vegetative bacteria as well as medium sized lipid containing viruses, when used according to labelling. It cannot be relied upon to destroy, within a practical period, bacterial endospores, mycobacteria, fungi, or all small nonlipid viruses.

iii. Any disinfection process must be carried out in accordance with the current Australian standard AS/NZS 4187: 2014 and manufacturer's instructions.

iv. High-level disinfection is the only acceptable level of disinfection for a semi-critical reusable medical device.

v. All chemicals must be used in accordance with the relevant workplace health and safety legislation. National and State recommendations and guidelines should also be followed.

4.4.4. Sterilisation

i. Sterilisation refers to a physical or chemical process that completely destroys or removes all forms of viable microorganisms from an object, including spores.

ii. Sterilisation can be achieved by means of heat or ionising radiation as well as chemicals.

iii. When describing a sterilisation process, it is not possible to fully assure that the chance of an organism surviving a process is zero. For medical equipment, it is acceptable to achieve a sterility assurance level (SAL) of one in a million chances of a single organism surviving the process.

iv. When chemicals are used to achieve sterilisation of an object they are referred to as chemical sterilants. These same agents used for shorter exposure periods may also be part of the disinfection process.

v. Only chemicals registered with the Therapeutic Goods Administration (TGA) as sterilants under Therapeutic Goods Order (TGO) 54 can be claimed to be sterilants.

4.5. Risk Management

4.5.1. A HHS may elect to undertake a robust and holistic review of services, including a validated risk assessment and treatment planning process. This review must ensure that the risks of a preferred reprocessing technique are managed at a level as low as reasonably practicable when compared to the risks associated with other endorsed reprocessing methods, with high level disinfection as the minimum level of reprocessing required.

4.5.2. A HHS must ensure that there is a formal orientation and training program for staff involved in reprocessing activities, that staff are trained and competent to undertake reprocessing activities and there is ongoing periodic assessment of staff competency at intervals defined by the HHS.

4.5.3. Policies and procedures for reprocessing activities must be documented and dated as per the requirement of AS/NZS4187.

4.5.4. HHSs must liaise with their local Clinical Governance Unit and follow local risk management policies when undertaking a review of reprocessing techniques.

4.5.5. The risks and benefits of the various alternatives should be assessed in consultation with relevant stakeholders, taking into consideration all factors outlined in section 4.7.

4.5.6. Where a risk management approach is taken, considering the above factors, the principles of AS/NZS ISO 31000:2009 (Department of Health, 2015) should be adhered to.

4.5.7. Where a risk management approach is adopted, a detailed and rounded risk assessment should be undertaken and documented to assess and validate the reprocessing technique to be implemented.

4.5.8. Once risks have been analysed, it is necessary to undertake risk treatment planning by considering all viable treatment options and selecting risk treatments based on effectiveness and cost/benefit.

4.6. Governance

4.6.1 The responsibility and accountability for the decision regarding which reprocessing technique is most appropriate for the facility's service is shared between management and clinicians as outlined in table 4.7.1.

4.6.2 Compliance with AS/NZS4187:2014 is mandatory.

4.6.3 Communication with all relevant stakeholders is necessary for ensuring decisions are appropriate and supported.

4.6.4 The risk assessment and decision making approach should be transparent and clearly documented, including details of all considerations as per table 4.7.1.

4.6.5 Once the agreed option has been implemented, it is the responsibility of the HHS to regularly monitor and review the outcomes of the endorsed process.

4.7. Decision Making Approach

4.7.1. It is recommended that the decision regarding which technique to adopt is based on value for money providing it also meets quality and safety, functional, technical and performance requirements of the HHS.

4.7.2. The risks and benefits of the various alternatives for reprocessing should be assessed in consultation with relevant stakeholders and accountable officers, taking into consideration all factors as described below.

4.7.3. The following table highlights the necessary considerations when reviewing a facility's cleaning, disinfection and sterilisation technique for non-lumen flexible nasendoscopes, including the recommended accountable officer (or equivalent) in relation to each factor:

Table 4.7.1

Factors to consider	**Accountable Officer**	**Considerations / Requirements**
Safety and Quality	Chief Executive	□ The technique must demonstrate clinical safety and efficacy to ensure optimal patient outcomes with reference to the clinical services capability framework (CSCF.) □ The technique must comply with the quality requirements as per standard AS/NZS 4187: 2014. □ The technique must comply with occupational health and safety requirements and be safe for staff and patients. □ Endorsement of the technique should be obtained from local Infection control managers / departments.
Sustainability	Chief Executive	□ The reprocessing technique should support the demand for services such that treatment is able to be provided within clinically recommended timeframes for all patients. □ Clinical safety and efficacy should be considered at the individual patient level as well as in the context of the HHS's overall ability to sustainably provide appropriate access to services. □ The total time required for reprocessing should be reasonable such that capacity for services is able to meet demand.
TGA Approval	Chief Executive	□ The medical device and chemicals (including disinfectants and sterilants) should comply with the essential principles for quality, safety and performance as per the Therapeutic Goods Administration (TGA). *It is the manufacturer's responsibility to demonstrate compliance with the essential principles for their medical devices under the TGA including compliance of disinfectants and sterilants.*
Medical Governance	Executive Director Medical Services	□ The risk assessment and decision making process should include clinical representatives involved in the use and reprocessing of nasendoscopes. □ The technique should be endorsed by users of the equipment.

Manufacturer's Instructions	Infection Control Manager / CSSD Manager / other nominated delegate	□ The nasendoscope should be able to be cleaned, disinfected and sterilised in accordance with the device's manufacturer's instructions.
Budget / Financial	Chief Finance Officer	□ A cost-benefit analysis should be undertaken to assess the most appropriate technique for the facility that ensures the best possible outcomes for the patient and the population within the financial constraints.
Size of Fleet	Chief Finance Officer	□ The size of the fleet of nasendoscopes should be sufficient to meet demand including consideration of the total time required for reprocessing correctly to meet activity demands.
Repairs, Maintenance, Replacement	Chief Finance Officer Infection Control Manager / CSSD Manager/ other nominated delegate	□ The impact of the disinfection / sterilisation technique on the lifespan of the nasendoscope should be considered. □ The longevity of nasendoscopes should be reasonable such that costs of repair, maintenance and/or replacement will not restrict or delay access to timely services.
Staffing / Resourcing	Chief Finance Officer Executive Director of Nursing	□ There must be sufficient staff to reliably and safely maintain use of the technique without impacting on patient flow, throughput or sustainability.
Location	Chief Operating Officer	□ The reprocessing area should be resourced with appropriate equipment and staffing to ensure quality standards are maintained. □ The location of reprocessing should support good patient flow and maximise throughput. □ The HHS should consider if centralisation of reprocessing services offers advantages for risk control and quality systems.
Education and Competency	Infection Control Manager / CSSD Manager/ other nominated delegate	□ The technique should enable sufficient staff to be adequately trained in the technique to ensure the service can continue to function safely even during periods of staff leave. □ Training of relevant staff in their role and in the broader context of nasendoscope management, cleaning, disinfection, sterilisation and recontamination prevention should be able to be kept up-to-date. □ Staff review processes must align with AS/NZS 4187: 2014
At Risk Groups	Infection Control Manager / CSSD Manager/ other nominated delegate	□ Assessment of whether the same processes are able to/ will be applied for high risk patients should be undertaken.
Afterhours Use	Infection Control Manager / CSSD Manager/ other nominated delegate	□ Assessment of whether the same processes are able to / will be used after hours should be undertaken.

Documentation, Traceability and Audit	Director Clinical Governance	□ Identification and data capture should be available for use to track and trace all endoscopes, reusable accessories and equipment to ensure appropriate maintenance, reprocessing and traceability to associated patients □ An effective tracking and traceability audit trail should be available to enable identification of the complete life cycle of a unique nasendoscope.
Risk Identification and Management	Director Clinical Governance	□ A risk analysis regarding the reprocessing technique should be undertaken and ensure that mitigating factors and strategies are available to ensure appropriate management processes are in place for adverse patient outcomes. □ Mechanisms for reporting any potential or actual failures in the management and disinfection of nasendoscopes should be clearly defined and available to all staff.

5. Appendix

- **Appendix A**: Overview of Current Techniques in Queensland

6. References

- Centre for Healthcare Related Infection Surveillance and Prevention 2017, 'Endoscope Reprocessing', retrieved 21 August 2017, http://www.chrispqld.com/endoscopy/default.htm
- Standards Australia/ Standards New Zealand. AS/NZS 4187:2014. Reprocessing of reusable medical devices in health service organizations, 4th edn, SAI Global Limited, Sydney, NSW / Wellington, NZ
- Department of Health 2015, 'Risk Management Policy', retrieved 21 August 2017, https://www.health.qld.gov.au/__data/assets/pdf_file/0038/395894/qh-pol-070.pdf
- Office of Legislative Drafting and Publishing 2009, 'Therapeutic Goods Order No.54 – Standard for Disinfectants and Sterilants', retrieved 04 October 2017, https://www.legislation.gov.au/Details/F2009C00327

7. Document approval details

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8. Version control

Version	Date	Prepared by	Comments / reason for update
1.0	27/10/2017	Ear, Nose and Throat (ENT) Surgery Sterilisation Review working party	Final version approved for publication

Appendix A: Overview of Current Techniques Used in Queensland

In May 2017, HHS nominated contacts (ENT Medical Directors and ENT Outpatient Clinical nurse or equivalent) were asked to complete a survey on their hospitals current approach to reprocessing flexible nasendoscopes (non-lumen) used in Outpatient Departments.

A summary of the responses is outlined below:

- All sites surveyed indicated they maintain a permanent record of maintenance and reprocessing and have a system to track endoscopes and patients that includes recording the endoscope number in the patient record.
- All sites but one (who provided no response) indicated using the same technique for high risk patients / groups.

Peer Group	Remoteness	Main brand of Scope	Number of scopes available	Average use per scope / week	Processing Location	Disposable endosheath used	Disinfection and/or sterilisation technique	HLD or Device used	Average reprocessing time per scope	Cleaning & storage Guidelines available	Key factors in decision re: current technique
Principal Referral	Major cities	Olympus	32	5 - 10	CSSD	No	Low temperature sterilisation	Hydrogen peroxide 50%	180 min	No	
Principal Referral	Major cities	Olympus	30	>20	OPD	No	Manual disinfection	Tristel	< 15 min	Yes	Reduced breakages compared to CSSD
Principal Referral	Major cities	Olympus	25	30	OPD	No	Manual disinfection	Tristel	< 15 min	Yes	Continuity, reduced breakages and repairs, reduced turnaround time, increased scope availability, patient safety maintained
Principal Referral	Outer Regional	Storz	4	5 - 10	CSSD	Yes	Low temperature sterilisation		15 - 30 min	Yes	
A	Major cities	Storz	28	5 - 10	OPD	No	Manual disinfection	Tristel followed by ATP verification	< 15 min	Yes	
A	Major cities	Storz	24	11 - 20	OPD	No	Manual Disinfection	Tristel	< 15 min	Yes	Reduced breakages and turnaround time compared to CSSD

A	Major cities	Olympus	9	11 - 20	OPD	No	Manual Disinfection	Tristel	< 15 min	Yes	
A	Major cities	Olympus	4	5 - 10	OPD	No	Manual disinfection	Tristel	15 - 30 min	Yes	
A	Inner Regional	Storz	51	< 5	OPD & CSSD	No	Automated endoscope reprocessors followed by low temperature sterilisation	Sterrad		Yes	Technique implemented to comply with standards for the cleaning/sterilisation of reusable medical devices
A	Inner Regional	Storz	25	5 - 10	CSSD	No	Automated Endoscope Reprocessors	Medivator	15 - 30 min	Yes	As per standard AS/NZS 4187:2014
A	Inner Regional	Olympus	9	5 - 10	OPD	No	Manual disinfection	Sonidet Detergent / Cidex Disinfectant	15 - 30 min	Yes	
A	Outer Regional	Storz	16	5 - 10	CSSD	No	Automated endoscope reprocessors followed by low temperature sterilisation	Sterrad	120 min	Yes	Infection Control Guidelines
B	Major cities	Olympus & Storz	2	< 5	CSSD		Manual disinfection and Low Temperature sterilisation	Sterrad	15 - 30 min	Yes	Manufacturer's Instructions
C	Outer Regional	Explorant	1	< 5	Endoscope cleaning room	No	Automated Endoscope Reprocessors	Medivator Advantage Plus	35 - 40 min	Yes	Research of automatic flexible endoscope reprocessors (AFERS)
Children's	Major cities	Storz	2	< 5	Designated "treatment" room	No	Manual disinfection	Tristel	< 15 min	Yes	As an outreach service in remote areas without sterilisation facilities, a high level disinfection method is required due to transport