Applying AS/NZS 5369:2023 to practice in the primary care setting

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Disclosure

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I have no conflicts of interest or financial disclosure with the material in this presentation

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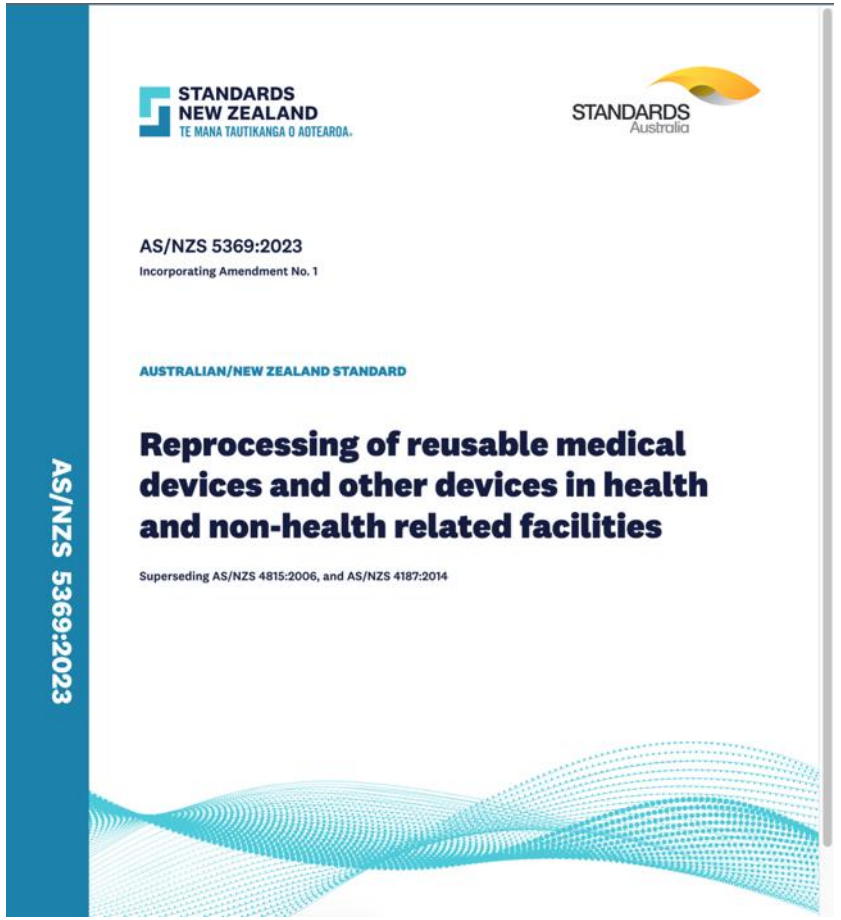

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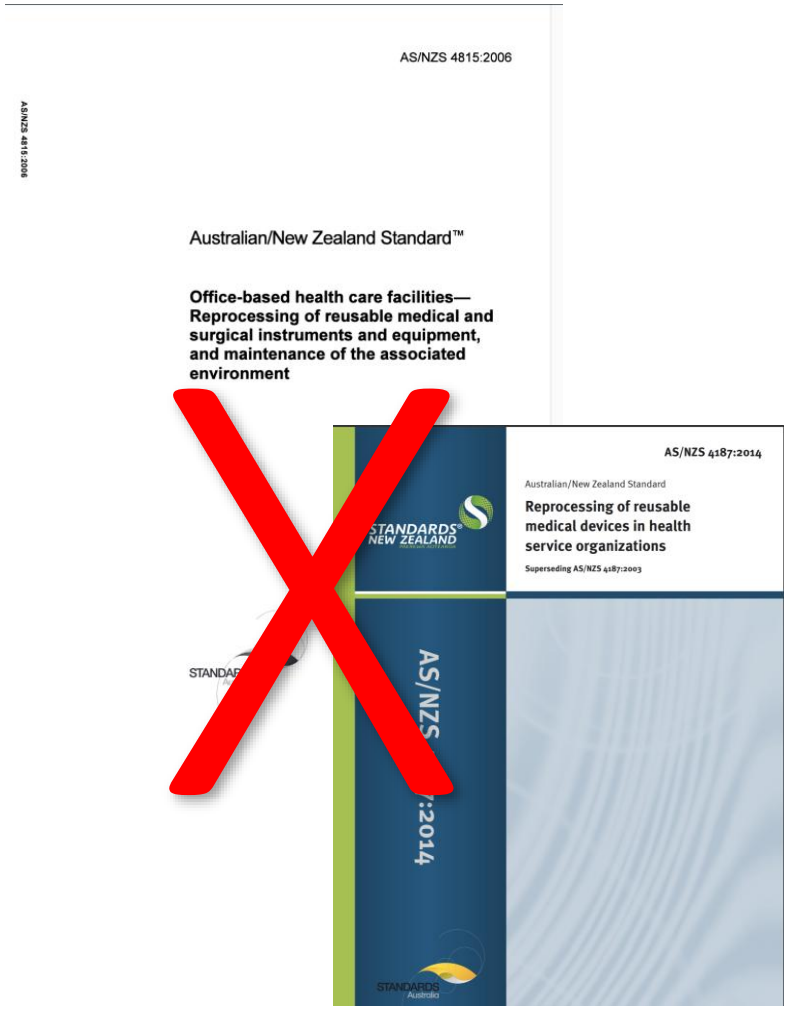

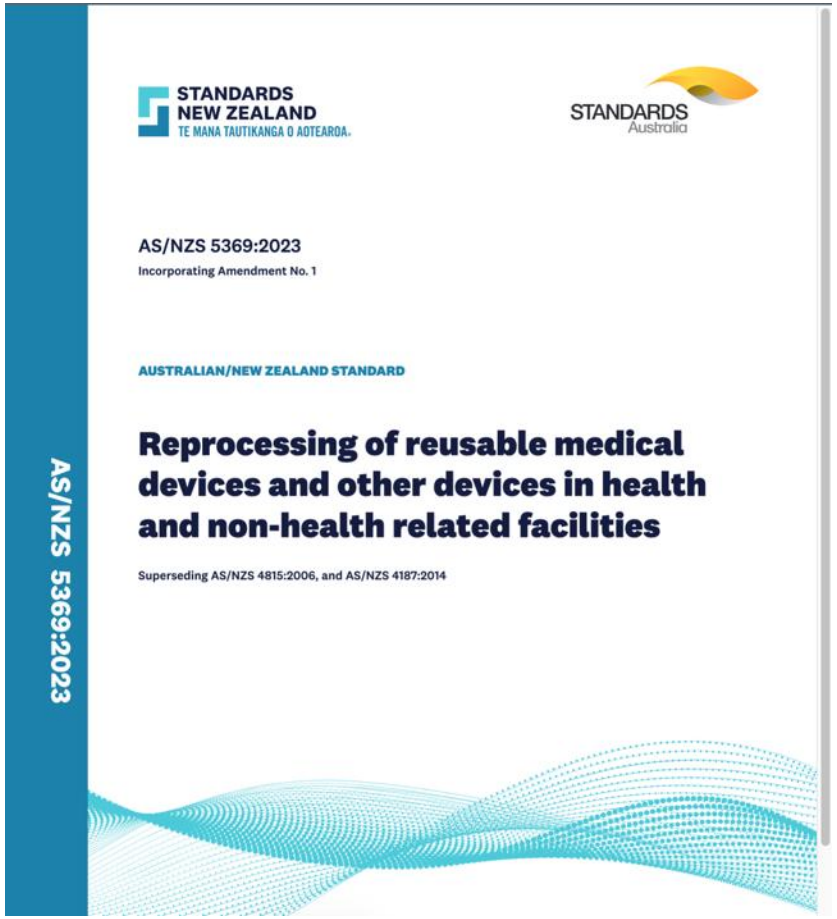

- ~130 pages
- 10 main sections
- Guidance appendices
- Bibliography
- ISO terminology used

AS/NZS 5369:2023 – its purpose

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The standard provides minimum requirements for cleaning, disinfection and sterilisation of reusable medical devices (RMDs)

Reprocessed RMDs shall be safe to use and not pose a risk of transmission of pathogens

Effective reprocessing RMDs plays an important part in preventing infections associated with healthcare

The standard applies to all health care organisations that process RMDs – includes primary care, GP practices, medical centres etc.

RNZCGP Foundation Standard

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Whare haumanu | The practice

Applicable Indicators

12.1 - Infection control

12.2 - Healthcare waste management

11.2 - All medical equipment is serviced, calibrated and verified annually (autoclave)

13.2 – Hazardous substances

13.3 – Adverse event reporting

The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa

Foundation

Do you need to change any practices?

This document:

- Outlines the key changes
- Maps the old standard to the new requirements
- Includes suggestions for implementation strategies

Key changes that may have resource implications for primary care

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- Emphasises a risk-based approach
- Annual staff training in IPC and Occ health exposures
- Evidence from 3rd party contractors of quality management
- Business continuity planning
- A competent person involved
- An emphasis on preventing and/or managing failed processes
- Facility requirements including flow, sinks, handwashing, ventilation
- Stricter requirements on water quality at all stages

How do you meet the standard?

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- Conduct a gap analysis – tools available online (ACSQHC)
- Use a risk-based approach to determine changes that are necessary to align with the new requirements
- Update or develop an asset management plan, including timelines for future redevelopment or upgrade to the reprocessing service to meet the requirements
- Consider a staged implementation process, informed by the risk assessment

Size shouldn't matter

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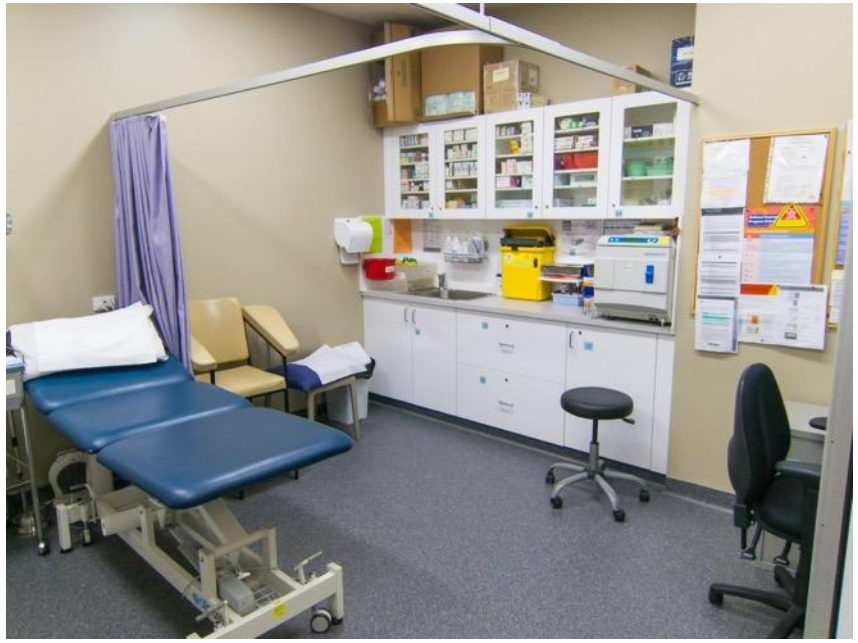
Courtesy AIHMS



Differences:

- Physical facility and equipment
- Ability to segregate processes

Similarities:

- Quality systems
- Staff training and competency
- Conforming to all reprocessing procedures

Spaulding's Classification

Risk	Decontamination process	Storage
Critical (high risk) Item intended to be introduced directly into or have contact with the vascular system or normally sterile areas in the body. Examples may include: Instruments used in minor surgery.	▪ Clean as soon as possible after use ▪ Sterilise by moist heat (if possible)	▪ Sterility to be maintained ▪ Packaged RMDs are to be stored to prevent environmental contamination in a designated storage area
Semi critical (medium risk) A medical device that comes into contact with mucous membranes or non-intact skin. Examples may include instruments for wound care and debridement such as tweezers scissors and probes	▪ Clean as soon as possible after use ▪ Sterilise by moist heat (if possible) ▪ If moist heat sterilisation is not compatible with the RMD, use low temp sterilisation, or high level disinfection (minimum)	▪ Store in a designated storage system such as a drying cabinet, to prevent environmental contamination
Non-critical (low risk) A medical device that comes into contact with intact skin but not mucous membranes. Examples may include a blood pressure cuffs, stethoscopes, reflex hammers, tuning forks, scales etc	▪ Thorough cleaning and low-level disinfection using a compatible, low-level instrument-grade disinfectant or thermal disinfection.	▪ In a clean dry place where environmental contamination is minimised.

Quality & Risk

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Quality

- Quality management – oversees and manages activities and resources to achieve the objectives of reprocessing and prevent nonconformances.
- Quality assurance focuses on doing the right thing every time – how we reprocess RMDs.
- Quality control relates to those checks we do to make sure it is correct – monitoring, audits etc.

Quality

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We are what we repeatedly do. Excellence, then, is not an act but a habit.

[Will Durant/Aristotle]

Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skilful execution.

[John Ruskin]

Risk

The foundation of using a risk-based approach is the identification of threats or hazards that occur throughout the process flow of reprocessing reusable medical devices.

Risk-based approach

- Adopt a risk-based approach – relevant to your setting
  - (see Appendix B AS/NZS 5369)
- Develop a risk assessment process
- Perform a risk analysis to identify hazards and potential non-conformities
- Evaluate the risk and determine an acceptable risk level
- Implement control measures to reduce the risk e.g. workflow design changes

A process flow

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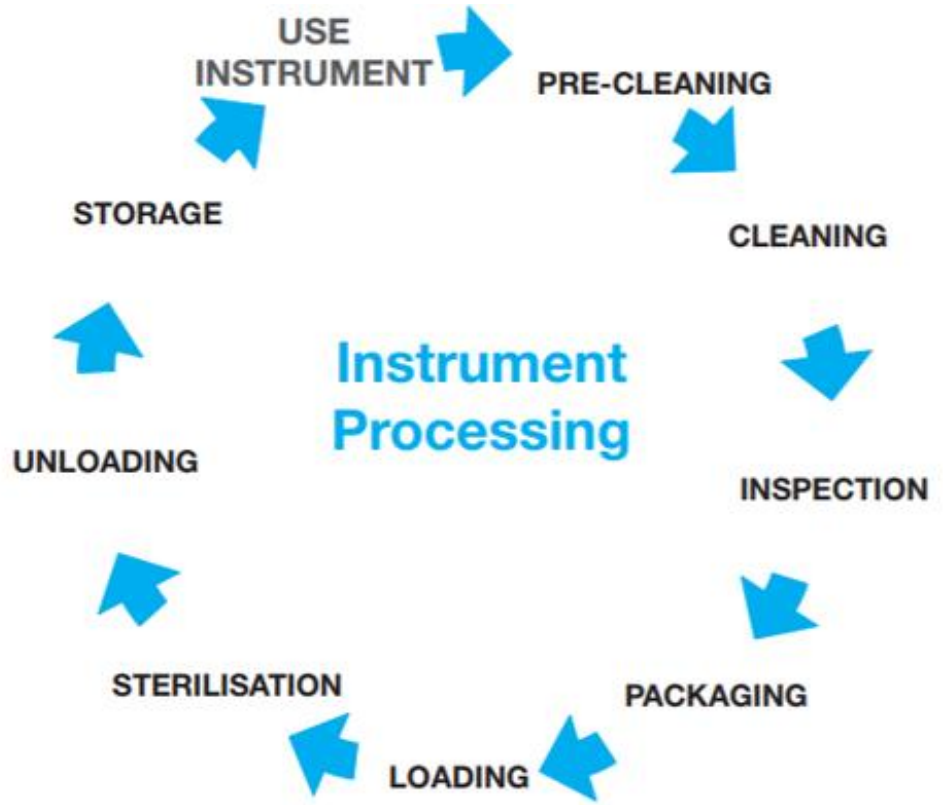
Identify a process flow that best describes the pathway of all your RMDs

RNZCGP example

Assess the risk for every step in the RMD lifecycle



- Location
- Facilities
- Equipment
- Management
- Policies and procedures

A process map of workflow

Sinks; brushes; location to clean RMDs; water quality; ultrasonic cleaning

Good light, magnification

Correct size of pouches; overfilled pouches

Cooling racks; packs are not stacked

Humidity; temperature; enclosed

Facility and environment. Adequate equipment and instruments. Staff training. Written procedures. Management support.

Meeting the standard – common areas for improvement

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- An increase in required documentation - the standard repeatedly requires procedures and processes to be documented
- Maintaining all records of testing, validation etc.
- Validation reports require sign-off by a competent person
- Having a competent person responsible for and involved in all aspects of RMD reprocessing including purchasing
- Quality of cleaning and final rinse water
- Always following the IFU for the device
- Management support for resources, training, equipment, and business continuity etc.

Documentation

- Local policies and procedures for reprocessing – all stages
- Documents and records that should be maintained include:
  - purchasing records
  - monitoring of reprocessing equipment records
  - cleaning process records
  - cleaning of the reprocessing facility
  - sterilisation and high-level disinfection process records
  - staff training and competency records
  - maintenance records for RMDs and other devices and reprocessing equipment
  - records of Installation Qualification, Operational Qualification and Performance Qualification for reprocessing
  - recall records
  - and more ……..

Equipment inventory

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- A register of all approved RMDs
- Categorisation using Spauldings Classification
- Access to the manufacturer instructions for use (IFU) for each item
- Product family assesment for instruments – determines the sterilisation requirements
- Autoclave cycle required for each RMD
- Enough instruments to avoid immediate-use (flash) sterilisation

Facility design

- Unidirectional flow of work to prevent cross contamination
- No hand-washing basins in clean areas
- Two cleaning sinks
- Sterile storage
- Address serious gaps
  - re-design
  - future funding (asset management)

- Physical separation between soiled, clean and sterile zone
- The risk of cross-infection spread by staff is minimized

Facility design

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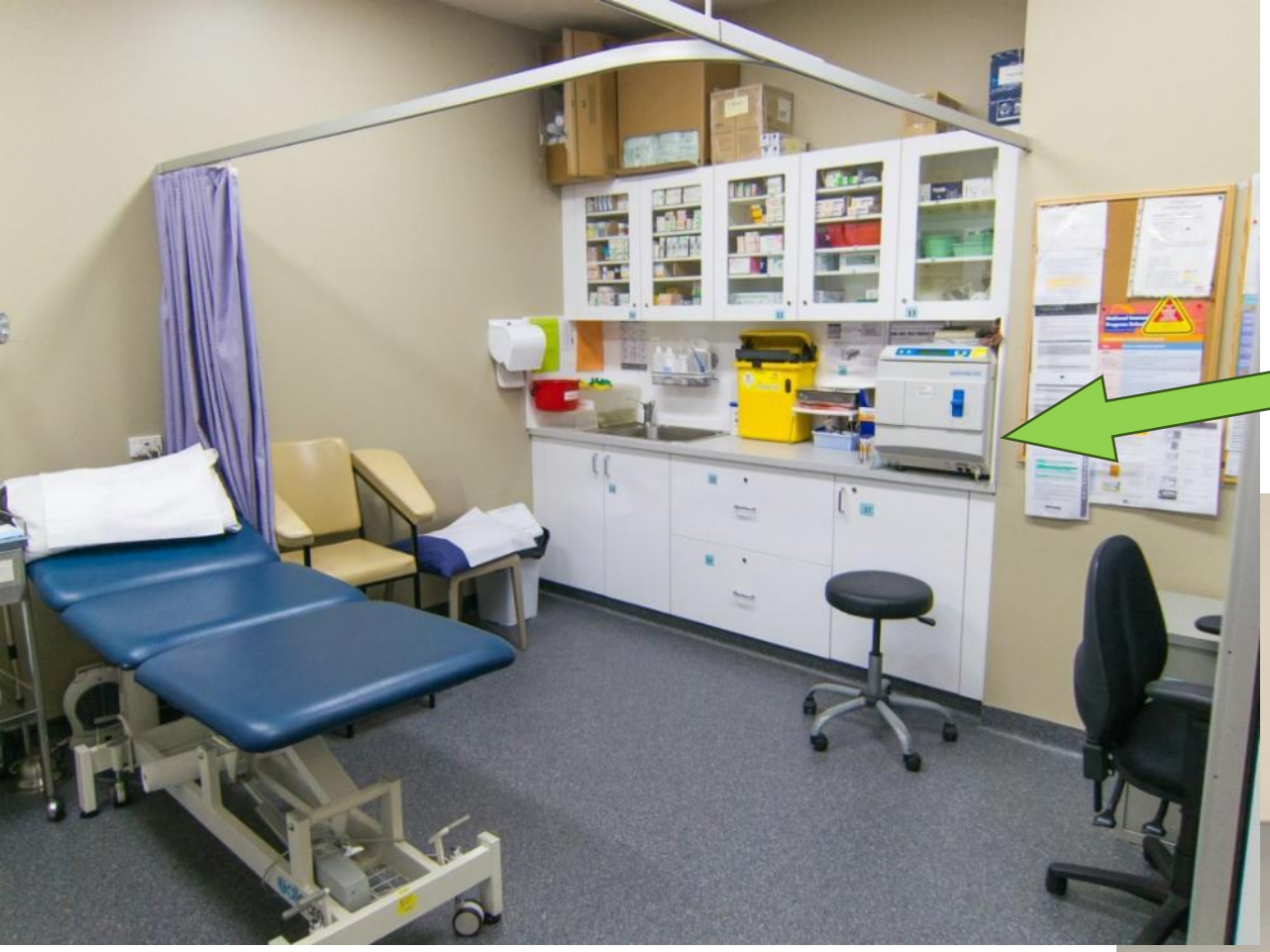

Benchtop steriliser

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Environmental control

- Humidity and temperature
  - Important for sterile storage
  - Cheap small loggers available
- Ventilation: Emphasis on a risk-based approach in determining the design and operation of ventilation systems
  - 12 air changes per hour
  - Air in dirty area should not be able to contaminate clean or sterile RMDs

Training and competency

- At orientation/induction
- Regularly after that
- Infection prevention and control topics
  - Hand hygiene
  - Use of PPE
  - Safe use of sharps
  - Blood and body fluid/substance exposures
  - Waste management
- Competency in undertaking reprocessing procedures

Key take-aways

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- Safe and effective reprocessing of RMDs is essential to prevent HAIs
- Reprocessing must be underpinned by a good quality management systems
- Use a risk assesment approach to determine what you need to improve to comply with the standard
- Ensure there is a nominated competent person who oversees the processes
- Have written documents for all procedures that are up-to-date
- Ensure all persons reprocessing RMDs are trained and competent

Resources

- The Royal New Zealand College of General Practitioners (RNZCGP) Foundation webpages
- The Royal Australian College of General Practitioners Infection prevention and control guidelines for general practices - August 2023
- Australian College for Infection Prevention and Control (ACIPC) video series on AS/NZS 5369 topics (available for non-members) and other resources
- New Zealand Sterile Sciences Association (NZSSA)
- Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Australian Dental Association (ADA) Guidelines for Infection Prevention and Control. 2026. 5th Amended edition (Public version)
- World Federation for Hospital Sterilisation Sciences

- Thank you for listening – I hope you enjoyed my presentation
- If anyone wants to contact me directly my details are: ruth@vectorconsulting.co.nz