

SRACA VIC AS/NZS 4187 – CSSD & BEYOND

The impact of AS/NZS 4187:2014 on dental services

Amanda Brown
Infection Control Education

DISCLAIMER & DISCLOSURE

- Views and opinions solely mine
- Product identification
- Conflict

© Infection Control Education

SCOPE

- AS/NZS 4187 + Amdts
- Dental practice
- Associated Standards
 - AS/NZS4185:2006
- Pathways to compliance
- RMDs – dental handpieces

© Infection Control Education

ECRI [USA] – 2020 TOP 10 HAZARDS

by healthcare leaders. The hazards selected are based on a rigorous review of ECRI's incident investigations, medical device testing, and public and private incident reporting databases.

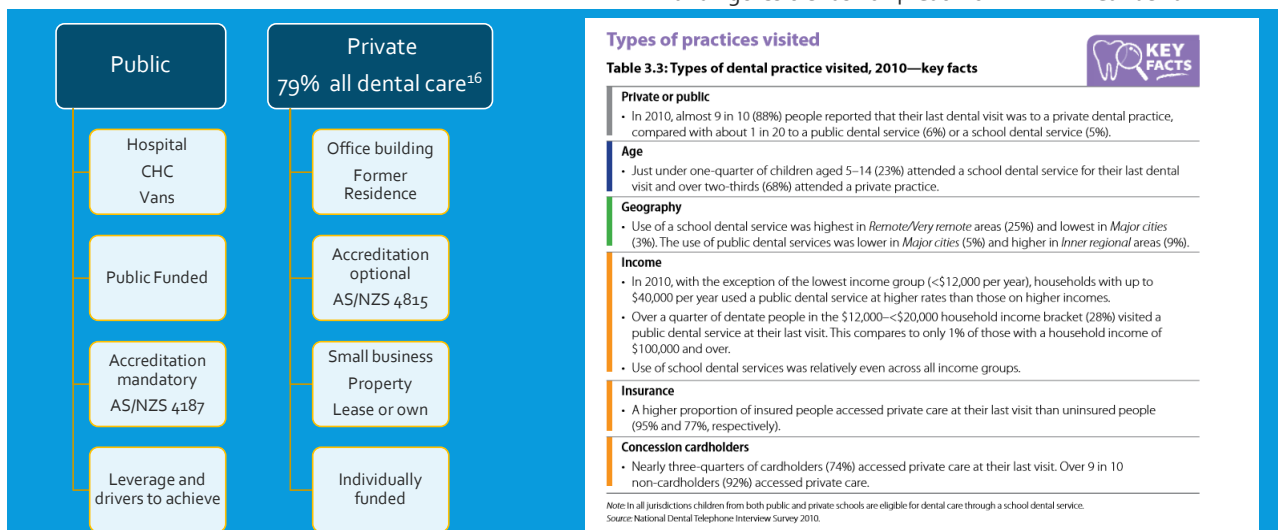
The full list of 2020 hazards includes:

1. **Surgical stapler misuse**—malfunctions and misuse can lead to patient harm.
2. **Point-of-care ultrasound**—speed of adoption has outpaced policies and practices that could prevent misuse or misdiagnosis.
3. **Sterile processing errors in medical/dental offices**—failure to consistently and effectively sterilize contaminated items can lead to patient infections.
4. **Central venous catheter (CVC) risk in at-home hemodialysis**—risks associated with CVCs can be particularly dangerous in the home setting, where family members may be ill-equipped to manage the risks.
5. **Unproven surgical robotic procedures**—surgical robots are being used for an expanding range of procedures, sometimes before the risks have been fully assessed.
6. **Alarm, alert, and notification overload**—high number of notifications can overwhelm clinicians, creating the potential for a significant event to go unaddressed.
7. **Connected home healthcare security risks**—interruption in transfer of patient monitoring data from cybersecurity issues can lead to misdiagnosis or delayed care.
8. **Missing implant data and MRIs**—being unaware of a patient's implant information can put patients in danger and delay MRI scans.
9. **Medication timing errors in EHRs**—critical medications can be delayed if the order generated from the EHR does not match the dose administration time intended by the prescriber.
10. **Loose nuts and bolts in devices**—failure to maintain nuts and bolts on medical equipment can lead to catastrophic accidents, harming patients, clinicians or bystanders.

"What used to be hospital problems are now concerns in ambulatory and home care settings," said Schabacker. "As healthcare shifts outside the hospital, ECRI remains committed to building awareness about technology hazards to keep patients safe."

DENTISTRY – ORAL HEALTH CARE

AIHW 2014. Oral health and dental care in Australia: key facts and figures trends 2014. Cat. no. DEN 228. Canberra: AIHW.



AS/NZS 4187:2014

- Section 1 Scope and General [90%]
- Section 2 Quality Management [35%]
- Section 3 Reprocessing Agent characterization
- Section 4 Process and Equipment characterization
- Section 5 Product definition [56%]
- Section 6 Process definition
- Section 7 Validation [highlighted]
- Section 8 Routine monitoring and control
- Section 9 Release of RMDs following Reprocessing
- Section 10 Maintaining Process effectiveness

© Infection Control Education

ACSQHC – THE COMMISSION

Advisory

- AS 18/07 Version 2.0

Anticipate

- AS18/07 Version 3

© Infection Control Education

SECTION 1 GENERAL AND SCOPE

Application

Single use

Associated Standards Normative

SECTION 1 NORMATIVE REFERENCES

- AS/NZS 4187 & Amdts
- Ultrasonic cleaners for health care facilities
 - AS 2773:2019
- Washer disinfectors
 - ISO 15883 part 1 & 2
- Sterilisers
 - EN 285 Large Steam
 - ISO 13060 Small Steam
 - ISO 17665 - 1 Sterilisation of health care products – Moist Heat
- Product IFU
 - ISO 17664 Information to be provided by the manufacturer for the processing of resterilisable medical devices

© Infection Control Education

SECTION 2 QUALITY

Numerous & Significant

SYSTEMS, STRUCTURE & SUPPORT

CSSD

- Management
 - Multiple
 - Unit
- HR
- Quality
 - Infection Control
 - OH&S
 - Product evaluation
- IT
- Engineering

- **Policies and Procedures**
- Oversight & Qualifications
- Equipment
- Contracts
- Product realisation
- **Traceability**
- Control and monitoring
- Measurements
- Corrective action recall
- Preventative

Dental Practice

- Public
- Private
 - Dentist
 - Assistant
 - Support staff
 - Receptionist / Practice Manager

© Infection Control Education

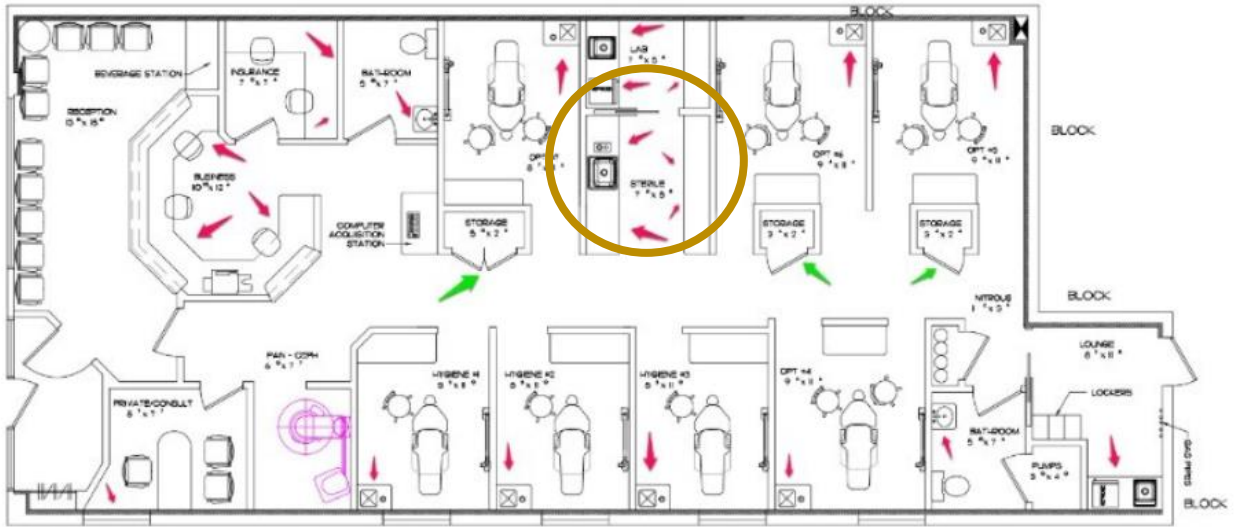
SECTION 5&6 PRODUCT AND PROCESS DEFINITION

Distinct and separate physical segregation of the cleaning areas from the other reprocessing area is integral to meeting the requirements of this Standard [5.6.2]

Manual cleaning shall only be used where the manufacturer's validated IFU **require** manual cleaning [6.2.3]

Pass through technology – Washer disinfectors

EXAMPLE OF TYPICAL LAYOUT - RATIOS



Google Images

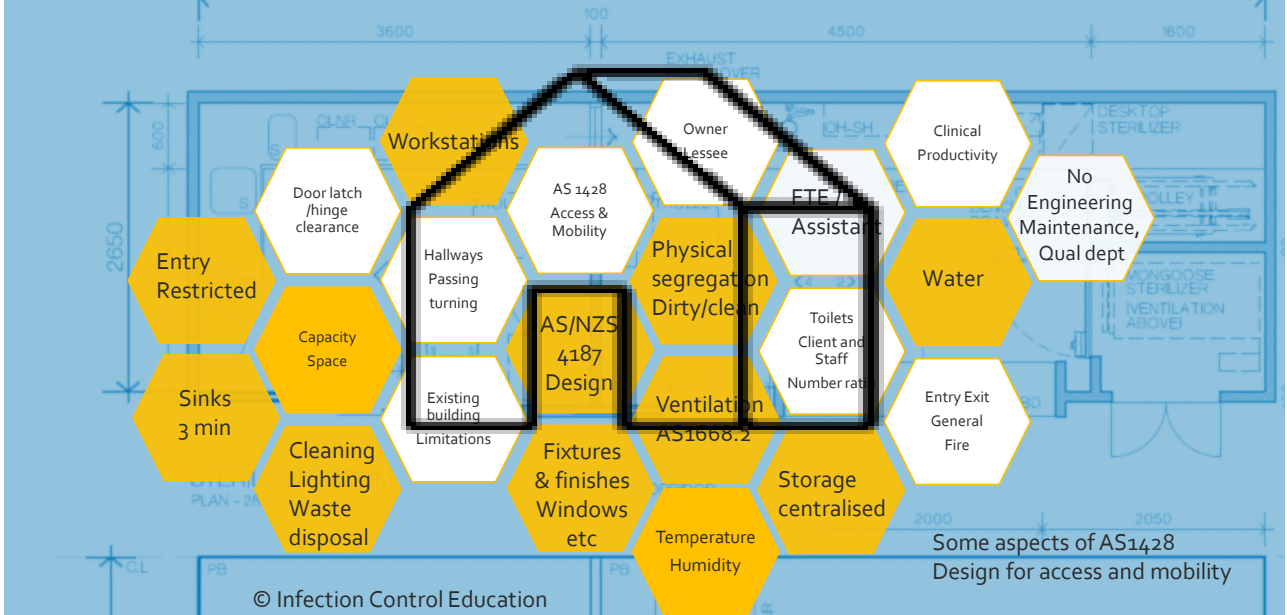
AS/NZS 4187 PRODUCT DEFINITION 5.6 REPROCESSING ENVIRONMENT

Designed, constructed, maintained and controlledto minimise the risk from cross contamination...facilitated by a unidirectional work flow from dirty to clean.

- Finishes
- Fixtures
- Sinks
- **Water**
- Workstations
- Lighting
- **Storage**
- Cleaning
- **Entry**
- Hand hygiene
- Waste
- **Ventilation**

© Infection Control Education

SO MANY ELEMENTS NOT ENOUGH SPACE



SECTION 7 VALIDATION

- Cleaning
- Packaging
- Sterilisers
- Water
- Other parties

DENTAL SERVICES

Do you have the capacity?

- Physical
 - Equipment
 - including loading equipment
- Amenities
 - Water - pressure, storage
 - Related regulation
 - Plant rooms
 - Air handling
- Cost
 - Upfront
 - Ongoing
- Contingencies
- HR / Expertise
 - Establish
 - Operate
 - Monitor & maintain

© Infection Control Education

IF IT'S ACHIEVABLE, IS IT VIABLE?

REALITY

- Meet the requirements of AS/NZS4187 and Amdts
- Facilitate safe and efficient reprocessing
- Meet the clinical needs of clients

Audit, Gap Analysis, Implementation Plan, Funds
or Alternative Business Plan

© Infection Control Education

IN THE MEANTIME

- Validate cleaning
- Validate sealing
- Storage - monitor
- Test water
- Evaluate current inventory and use – documenting loads

AS/NZS 4187 & 4815 8.2.5.5

© Infection Control Education

ALTERNATIVE

Outsourcing reprocessing services

Process considerations

IMPACT ON ALTERNATE SERVICES

- Volume
- Supply and demand
- Complexities

© Infection Control Education

GUIDANCE

- Australian Code on Transport of Dangerous Goods

2.6.3.2.3.9medical devices or equipment potentially contaminated with or containing infectious substances which are being transported for disinfection, cleaning, sterilisation, repair, or equipment evaluation are not subject to the provisions of this Code if packed in packagings designed and constructed in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents. Packagings must be designed to meet the construction requirements listed in 6.1.4 or 6.6.5.

- National Pathology Accreditation Advisory Council: *Requirements for the packaging and transport of pathology specimens and associated materials (Fourth Edition 2013)*

- AS/NZS 4187

- Recent literature

© Infection Control Education

DENTAL – PRE TREATMENT & DISPATCH

- Clean at the point of use – manual risk
- Pre treat manual and ultrasonic 3
- Dry and containerize
- Time to terminal processing 5
- Monitoring cleaning 6

Handpieces

- External clean IFU
- Automated device [internal clean] 4

Process Monitoring

- Delays – criteria and contingency
- Ultrasonic and Handpiece unit

3. Franz et al Reprocessing of dental instruments in washer disinfectors: does a representative soil test exist in dentistry? 2012

4. Offner D et al *Evaluation of the mechanical cleaning efficacy of dental handpieces* AJIC 10 3 [2019] e73-e80

5. Evangelista S et al *Effectiveness of manual versus automated cleaning on Staphylococcus epidermidis biofilm removal from the surface of surgical instruments* AJIC 000 [2019]1-8

6. Alfa M *Medical instrument reprocessing: current issues with cleaning and cleaning monitoring* AJIC 47[2019]

© Infection Control Education

ACCESS TO SITE

- Access to a site [with established compliant systems]
 - Contract
- Consignment documentation
 - Number of cases
 - Contents
 - Time
 - Persons dispatch / receipt
- Communication - deviations and complaints and responsibilities
- Manual handling
- Environmental conditions

© Infection Control Education

CSSD

- | | |
|---|--|
| <ul style="list-style-type: none"> • IFU • Verify compatibility • Full reprocess <ul style="list-style-type: none"> • WD • Package • Tracking <ul style="list-style-type: none"> • Dental software • Sterilise • Pack for dispatch | <p>Considerations</p> <ul style="list-style-type: none"> • Dental materials • Compressed air • W/D loading manifold |
|---|--|

© Infection Control Education

TRANSPORT - STERILE

- Segregated - separate containers
- Secure - Protect contents
- Controlled
 - AS4187 it is stated that environmental controls be maintained as follows:
 - Temperature to be maintained within the range of 18°C - 25°C
 - Relative humidity to be maintained within the range of 35% - 70%
- Monitored
- Consignment document
 - As previous
- Containers management
 - separate pre processing and sterile
 - thermal disinfected
 - internal and external ? wiped
- Manual handling at dispatch and receipt
 - Configuration, weight, intervals and space

© Infection Control Education

STORAGE

- Transport container management
- Sterile stock
 - There may be numerous – dental, podiatry
 - Conditions
 - Minimize and monitor
- Supply and demand
 - Map stock inventory and current sterilization patterns

© Infection Control Education

DENTAL HANDPIECES

Washer Disinfectors

HANDPIECES

- Several brands and a huge range
- Age and experience
- ISO 14457:2017
- IFU – vary accordingly
- Many are nominated WD compatible
- Surgical - dismantle
- Restorative - not dismantled routinely
- Complex with internal fouling^{20, 26}
- Clean external and internal
- Lubrication required post washer
- Sterilised – steam, pouch flat or vertical



© Infection Control Education

HANDPIECE DEVICES & WD

Recent literature

- Limitations⁴
- Increased efficacy required⁴
- Simulated soil tests⁴

4. Offner D et al Evaluation of the mechanical cleaning efficacy of dental handpieces AJIC 10 3 [2019] e73-e80

Washer Disinfector ISO 15883-2

- Load manifold / validated cycle
- IFU

ISO 15883 – 2

5 Mechanical and control requirements

5.1.1 Load connectors / powered and lumen devices

- internal surfaces to be flushed
- Load carrier shall be fitted with connectors specific by device manufacturer
- Connectors shall provide means to drive the instrument and ensure contact with process fluids for the specified times

© Infection Control Education

CONCLUSION

- AS/NZS 4187 + Amdt
- Commission Advisory
- Achievable / viable
- Continued access to care
- Alternatives / concessions
- Action in the meantime
- Examine current practice
- Gap analysis
- Implementation plan
- Consider the alternatives
- Collective effort

Thank you

© Infection Control Education

REFERENCES

2. Australian and New Zealand Standards 4187 2014 + Amdt.
3. Franz et al Reprocessing of dental instruments in washer disinfectors: does a representative soil test exist in dentistry? 2012
4. Offner D et al *Evaluation of the mechanical cleaning efficacy of dental handpieces* AJIC 10 3 [2019] e73-e80
5. Evangelista S et al *Effectiveness of manual versus automated cleaning on Staphylococcus epidermidis biofilm removal from the surface of surgical instruments* AJIC 000 [2019]1-8
6. Alfa M *Medical instrument reprocessing: current issues with cleaning and cleaning monitoring* AJHI 47[2019]
16. Dental Workforce 2012. National health workforce series no.7. Cat. no. HWL 53. Canberra: AIHW.
20. Smith G, Smith A, *Microbial contamination of used dental handpieces* AJIC 42(2014) 1019-21
21. Offner D, Brisset L, Musset A-M. *Cleaning of dental handpieces: A method to test its efficiency, and its evaluation with a washer-disinfector lubricator-dryer.* *Dent Open J.* 2016; 3(1): 10- 16 doi: 10.17140/DOJ-3-129
26. Lopes, L. K. O et al *Complex design of surgical instruments as barrier for cleaning effectiveness, favouring biofilm formation.* AJIC 103[2019] e53-e60