Quality AS/NZS4187:2014

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Quality definition

- Define: Oxford dictionary
- The standard of something as measured against other things of a similar kind; the degree of excellence of something: *an improvement in product quality*

Referenced and Bibliography documents

- I13485 Medial devices – Quality management systems – Requirements for

  regulatory purposes
- AS/NZS ISO 9000 Quality management systems requirements
- Australian Commission on Safety and Quality in Health Care (2011), *National Safety and Quality Health Service Standards*.

Available at http://www.safetyandquality.gov.au/

Section 2

- elements of a quality management system that are necessary to ensure the safe and effective reprocessing of RMDs. HSOs shall develop their own workplace procedures based on the requirements of this Standard.
- Documentation – generation and control
- 2.2.2.Policy and procedures documented and dated …..

ACHS National Standards

- National Standard 1
  - Implementing a governance system that sets out the policies, procedures and or protocols:
- Collecting and reviewing performance data
- Implementing prevention strategies based on data analysis
- Ensuring compliance with legislative requirements and relevant industry standards
- Undertaking regular clinical audits

Quality

- Structure – Governance – AS/NZS 4187
- Process – policies/procedures/work instructions/staff education
- Outcomes – audits, audit results – data

  compliance, improvements, resolution to non-comformance

Performance Board to display improvement data

2.3.3 Reprocessing manager

The person directly responsible for the reprocessing of RMD within the facility shall— have relevant qualifications and experience in reprocessing of sterilization technology and/or RMD

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 HSO.

National Standard

- 1.4 orientation and training
- Annual mandatory
- Competency based
- 3.18 Ensuring a workforce who decontaminate reusable medical devices undertake competency-based training in these procedures
- 3.18.1 Action is taken to maximise coverage of the relevant workforce trained in a competency-based program to decontaminate reusable medical devices.

Section 2

- Records - HSO policy and applicable regulatory requirements.

Section 2 Management responsibility

- 2.3 Irrespective of where reprocessing of non-critical, non-invasive RMDs occurs, appropriate resources shall be provided to ensure that the principles of this standard can be followed.
- **2.3.2 Resource requirements**
- The HSO shall determine and provide the resources necessary to
- (b) implement the quality management program and to maintain its effectiveness through review;
- 2.3.3 Reprocessing facility
- (c) implement policies and procedures to assure the quality and safety of reprocessed RMDs;

Section 2

- 2.4.3
- Identification and traceability of product
- NS 3.17 Implementing systems to enable the identification of patients on whom the reusable medical devices has been used.
- NS 3.17.1

  A traceability system that identifies patients who have a procedure using sterile reusable medical instruments and devices is in place

Section 2

- 2.4.4 **Control of monitoring and measuring equipment**
- *2.4.4.1 General*
- ensure 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 or national measurement standards.
- applies to monitoring and measuring devices used by external contractors.

Section 2

- *2.4.4.3 Non-conformance*
- equipment not conforming to requirements, action in relation to the faulty equipment and product affected.
- Records of this action kept.
- Regular periodic audits performed to confirm compliance with this Standard
- Findings documented, corrective actions, document and review effectiveness

Section 2

- 2.5.1 Audits
- Regular periodic audits performed to confirm that the requirements of this Standard are being met.
- The audit findings documented and where applicable, corrective action implemented to rectify deficiencies.
- Corrective action reviewed to ensure that it has been effective in addressing the deficiency.

National Standards

- 3.16
- Reprocessing reusable medical equipment, instruments and devices in accordance with relevant National or International standards and manufacturer instructions.

- 3.16.1 Compliance with relevant National and International standards and manufacturer instructions for cleaning, disinfection and sterilisation reusable instruments and devices is regularly monitored.

Integral components of this Standard

- ISO 16775:2004
- Manufacturer's Instructions
- Being reviewed
- Spaulding's classification
- Critical
- Semi-critical
- Non-critical

Section 2

- **2.5.2 Nonconforming RMD**
- Nonconforming RMD those items that do not meet acceptance criteria after completion of cleaning, disinfecting or sterilizing processes, and packaging, as applicable.
- Investigate non-conformance according to HSO risk assessment policy.
- 2.5.3 Corrective action
- 2.5.3.2Recall

Section 3 Reprocessing agent characterization

- 3.1.3 Steam quality

- 3.2 Water quality
- 5.6.6
- Water of the required quality shall be specified for use in the reprocessing facility (see Section 7).
- Note: The quality of water used at all stages in the cleaning process is critical to the successful outcome of the process. Softened, filtered, demineralized, distilled or RO water can be required for various stages of the cleaning process.

Section 7

- *7.2.3 Water quality*
- Water supplied of a suitable quality for its intended purpose.
- There shall be consultation and an agreement with the supplier of local water to notify the HSO of changes likely to affect the quality of potable water.
- If the local water supply is not of recognised suitable quality then tests shall be conducted prior to equipment installation to demonstrate the water supplied to equipment is in accordance with the manufacturer's specification and the results recorded.
- Softened, filtered, demineralized, reverse osmosis or distilled water shall be provided in accordance with the requirements specified by the equipment manufacturer (see Clauses 6.2).

Section 5 Product definition

- specifying the microbiological quality of the RMDs prior to disinfection and/or sterilization and any associated materials used to package and present RMDs for sterilization.
- Achievement of suitable microbiological quality of RMDs prior to disinfection and/or sterilization can be inferred providing the RMD and processing equipment manufacturer's instructions for cleaning and disinfection (if appropriate) have been followed by the HSO and there is evidence of this.

Section 5

- **REPROCESSING ENVIRONMENT**
- **5.6 General**
- The HSO shall provide the physical environment and equipment necessary for safe and effective reprocessing activities to ensure delivery of an RMD, including loan and trial RMDs, of the required quality.
- This shall include requirements for environmental control in areas that can impact the bioburden of an RMD, e.g. control of temperature, humidity, traffic flow, and reprocessing, ventilation and air flow.

National Standards

- 3.15

Implementing systems for clean and hygienic environment for patient and health care worker

- 3.15.1

Policy and procedure

- Appropriate personal protective attire
- 3.15.2

Policy procedure and or protocol

- For environmental cleaning regularly reviewed
- 3.15.3

An established environmental control schedule is in place and environmental control audits are undertaken regularly.

Section 6 Process definition

- 6.1
- produce an RMD to the required quality it is essential that all steps specified in the reprocessing procedures shall be followed.
- risk that if any of these procedures are bypassed an adverse patient outcome might result.
- Specifications for cleaning, disinfecting, packaging and sterilizing process shall be developed with consideration of the manufacturer's reprocessing instructions for each RMD.

National Standard

- 3.1 Developing and implementing goverance system for effective Infection Prevention and Control to minimise the risk to patients of hospital acquired infections
- 3.1.1 A risk management approach is taken when implementing policies, procedures and/or protocols
- Processing of reusable medical devices
- Single use devices

Section 6

- 6.5.2 sterilization procedures
- *Unloading the sterilizer* (d)
- area in which sterilized items are unloaded controlled.
- environmental conditions in this area not adversely affect the quality of the processed RMD.
- RMDs processed by moist heat or dry heal allowed to cool prior to handling.

Section 7 Validation

- 7.2.3.2 Steam Quality
- 7.4 Performance qualification


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