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**Every Hospital in Australia and New Zealand has a legal and compliance obligation to make sure all Clinical Staff can access the Manufacturer’s Instructions for Use for equipment they use every day**

National Safety and Quality Health Service (NSQHS) Standards

ACHS EQuIPNational Guidelines – **Guideline 15 Corporate Systems and Safety**

**National Safety and Quality Health Service Standard 3**

**3.16** Reprocessing reusable medical equipment, instruments and devices in accordance with relevant national or international standards and manufacturers’ instructions.

**National Safety and Quality Health Service Standard 8**

8.4.1 Key task : Outputs of improvement processes may include :

procedures, protocols and guidelines for the use of and access to equipment

**Criterion 15.15.1**

“ ……..An organisation should have documented management strategies for all medical devices used within its facilities including:

• medical devices owned, leased or rented by the organisation etc …….

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details for the organisation’s Board, executives and managers the minimum

requirements of an effective strategy for the management of medical devices …..”

AS/NZS 3551:2012

S E C T I O N 2 M E D I C A L D E V I C E

M A N A G E M E N T P R O G R A M

2.4.3 2.4.3 Supporting documentation

Documents such as standards, user guides, technical manuals and other supporting publications shall be identified, stored, issued and updated in a controlled manner.

AS/NZS 3551:2004

S E C T I O N 2 M E D I C A L D E V I C E

M A N A G E M E N T P R O G R A M

2.3.4.4 Device-specific documents

*Documents such as technical and user manuals shall be identified and their location recorded in the database.*