Issue	International best practice	AS/NZS 2500, AS/NZS 3551	Rationale & references
AS/NZS 2500 incorrectly references AS/NZS 3551 as the safety standard for medical devices	Type testing standards such as the IEC 60601 family of standards are the correct reference for medical device safety and they are typically used to demonstrate compliance of the medical device design with safety and performance essential principles defined in the medical device regulations.	**AS/NZS 2500** includes a so-called "safety triangle" which incorrectly represents AS/NZS 3551 as the safety standard for medical devices - Fig. 4.1. in Section 4.1 of AS/NZS 2500.	MTAA has provided the correct text explaining the 4 factors ensuring patient safety: Safety of patients and other users is ensured when all four safety elements listed below are implemented: (a) Safe electrical environment as per AS/NZS 3003. (b) Safe medical equipment designed and manufactured to relevant standards such as the IEC 60601 series and ISO 13485 (c) Safe medical equipment management e.g. AS/NZS 3551 including, if suitable, the testing procedures in IEC 62353. (d) Safe use of medical electrical equipment e.g. AS/NZS 2500. References: AS/NZS 2500 Guide to the safe use of electricity in patient care
Hospitals often perform servicing /refurbishing of medical equipment and make changes that are not done on behalf of the original manufacturer and which do not constitute 'custom-made devices' as per the regulations. This may lead to patient injury if the medical equipment no longer meets its safety and performance specs.	EU **Medical Devices Regulation 2017/745** and **In-Vitro Diagnostic Medical Devices Regulation 2017/746** require health institutions engaging in manufacturing or modifying medical devices for their internal use to apply for a 'health institution exemption' and meet following conditions: - demonstrate compliance with applicable general safety and performance requirements listed in Annex I of the regulations; - establish an appropriate quality management system (ISO 13485 represents international best practice); - review experience gained from clinical use of the devices and take all necessary corrective actions. - justify that the target group's specific needs cannot be met by an equivalent device on the market; - make information available to the regulatory authorities upon request; - make a declaration containing relevant details about the device publicly available.	**AS/NZS 3551 Section 9 Modification of medical equipment** consists largely of motherhood statements which basically allow healthcare facilities to modify medical equipment other than custom-made devices, without any of the restrictions listed in the EU MDR and IVDR regulations for 'health institution exemption'. This section also states that "*modifications shall only be carried out under the supervision and management of competent person(s*)", without specifying what "competent" looks like or referring to the relevant standards for service provider/ qualification of persons. This section also states that "*The service entity shall, on completion of any modification, test the modified medical equipment, at least to the applicable test requirements of this standard* [i.e., AS/NZS 3551]"; AS/NZS 3551 covers only in-field electrical tests and may not be sufficient to ensure that equipment basic safety and essential performance is maintained. Medical devices must comply at all times with all applicable Essential Principles of safety and performance listed in Schedule 1 of the **Medical Devices Regulations (2002)**. This section also states that "*If the safety function or operability of the medical equipment has been changed, a legible and indelible label shall be permanently secured in a place clearly visible to the user* ". This is a major red flag; labelling alone is not sufficient. The organisation making changes to/ refurbishing the medical equipment must ensure that the medical equipment is safe and effective to use on patients.	Any organisation making changes to/ undertaking refurbishment of medical equipment takes on responsibility of a medical device manufacturer and is liable under the Therapeutic Goods Act. References: **TGA guidance** 'Substantial changes affecting a TGA conformity assessment certificate and Transfers of certificates', 29 June 2017 **UK NHS European Office Briefing** 'Changes in rules for manufacturing or modifying and use of medical devices including in vitro diagnostic medical devices' - January 2018 Issue 24 **ISO/IEC 17020** Conformity assessment - Requirements for the operation of various types of bodies performing inspection **ISO/IEC 17024** Conformity assessment - General requirements for bodies operating certification of persons
Hospitals often perform periodic maintenance of medical equipment. AS/NZS 3551 fails to specify that hospitals must document and justify deviations from manufacturer's instructions for periodic maintenance and servicing and implement a monitoring process with corrective actions.	To ensure safe and optimum performance during the lifetime of the medical device, manufacturers must provide information for the appropriate maintenance and servicing of the medical equipment, and users (hospitals) must take into consideration this information to manage medical equipment under their responsibility. TGA regulations stipulate that: "A medical device must be designed and produced in a way that ensures that if [...] the device is regularly maintained and calibrated in accordance with the manufacturer's instructions, the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected." This represents international best practice, also included in the EU and U.S. medical device regulations.	**AS/NZS 3551 Section 10 Assessment intervals** leaves it entirely to the hospitals to decide the frequency of preventive maintenance and periodic performance checks. The hospital is responsible for maintaining the safety and performance of the medical equipment and thus it must document and justify any deviations from manufacturer's recommendations. The AS/NZS 3551 standard does not mention anything about the need to review experience gained from clinical use of the devices and take all necessary corrective actions within an established quality management system.	Where institutional users (hospitals) deviate from manufacturer's instructions (e.g., service and maintenance manuals), they must document and justify such deviations. Patient safety must always come first, cost savings alone should not be the basis for deciding to deviate from manufacturer's instructions. References: **TGA Medical Device Regulations (2002), Schedule 1 - Essential Principles** 4 Long-term safety 13.3 Information to be provided with medical devices - particular requirements 13.4 Instructions for Use

Procurement tenders have been including "compliance with AS/NZS 3551" as a requirement for suppliers of medical devices, ignoring the fact that the correct standards for medical devices are those that define type testing such as the IEC 60601 family of standards.	The standards applicable to medical devices and medical device manufacturers are specified in major regulator-endorsed lists/ databases: - EN Harmonised Standards published in the Official Journal of the European Commission - U.S. FDA Recognized Consensus Standards database - TGA Medical device standards orders International standards for best practice in asset management and for in-field electrical testing already exist: - ISO 55001 for asset management; - IEC 62353 for in-field electrical testing;	**AS/NZS 2500 and 3551** are misleading when they state or imply that AS/NZS 3551 is the standard for medical device safety. Confusing or misleading wording in AS/NZS 2500 and 3511 needs to be revised to ensure clarity with regards to the following: 1) The standards that specify requirements for the safety and performance of medical devices are type testing standards such as the IEC 60601 family of standards, not standards that specify in-field testing. Best practices for manufacturers' processes are defined in process standards such as ISO 13485, ISO 14971 and IEC 62304. 2) AS/NZS 3551 is a 'hybrid' standard comprised of requirements for asset management by hospitals (hospital quality systems processes) and requirements for testing by hospitals (in-field testing by hospitals). 3) AS/NZS 3551 applies to healthcare organisations only and it should never be included in invitations to tender addressed to suppliers of medical devices.	Any organisation making changes to/ undertaking refurbishment of medical equipment not on behalf of the original manufacturer takes on responsibility of a medical device manufacturer and those activities would fall under the medical device regulations. References: **ISO 13485** Medical devices - Quality management systems - Requirements for regulatory purposes **ISO 14971** Medical devices - application of risk management to medical devices **IEC 62304** Medical device software - Software lifecycle processes **ISO 55001** Asset management - Management systems - Requirements **IEC 62353** Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
AS/NZS 3551 fails to comply with key drafting principles defined by Standards Australia and with drafting principles of IEC/ISO standards	The only mandatory requirements for marketed medical devices is to have regulatory approval/ be registered in the jurisdiction where they are put into service. Standards are voluntary unless compliance is specifically called out by the regulatory authority. As per drafting principles, standards must not include: - legal, statutory or regulatory requirements; however standards can include statements such as "refer to the applicable regulatory requirements", as ISO 13485 does; - contractual requirements (claims, guarantees, warranties); - certification process requirements (registration with XYZ organisation) or hiring certain services;	**AS/NZS 3551 Section 2.2.1 Responsibility, authority and communication** states: "*Responsibility for the medical equipment management program shall be assigned to an individual or committee from the staff responsible for the use and application of the medical equipment, biomedical engineering staff employed within the organization, or a qualified and experienced biomedical engineering consultant engaged by the organization.* " Ultimate responsibility and accountability must always reside with the senior management of the organization. The standard must not mandate that a health organization engage biomedical engineering consultants. Consultants on the HE-003 standards committee claim on their company website: "*Our place on the Standards Committee* [i.e., responsible for AS/NZS 3551] *gives us a unique position to understand not only how to implement the standard, but the rationale behind the requirements. We understand your requirements even when you don't. That's our job.* " This is a conflict of interest; these consultants have been opposing all attempts to revise AS/NZS 2500 and 3551 aimed at improving clarity and correcting misleading or false statements. Standard requirements must stand on their own, be clear and specific enough so that their implementation would not rely on individual interpretations.	Standards have often guidelines explaining requirements in more detail and providing examples on how to apply the standard. These should be used rather than take an individual's claim that they know how to apply the standard because they sit on the technical committee. If international standards already exist, Standards Australia policy is to harmonise internationally as much as possible and adopt ISO/IEC standards with or without modifications as AS/NZS standards unless there are good reasons not to. References: **ISO 13485:2016** Medical devices - A practical guide **ISO 24971** Medical devices - Guidance on the application of ISO 14971 **ISO 31000** Risk management guidelines **IEC 31010** Risk management - Risk assessment techniques **ISO 10012** Measurement management systems - Requirements for measurement processes and measuring equipment
AS/NZS 3551 lacks specific requirements regarding standard national requirements for electrical medical equipment which are essential to ensure safe installation and use of mains operated medical electrical equipment.	The international type testing standards represent the best practice for ensuring medical devices/ equipment comply with regulatory requirements for safety and performance. The **IEC 60601-1** standard for general safety of electrical medical equipment specifies clearly and comprehensively the safety requirements for electrical medical equipment. Complete requirements for marking, identification and connection to power supply are specified in **Section 7 ME EQUIPMENT identification, marking**, including requirements for correct connection to supply mains (rated voltage/voltage range and frequency), electrical protection class and other symbols. Complete requirements for connection to mains voltage are specified in **8.11 MAINS PARTS, components and layout**, including a requirement for mains plugs to comply with **IEC TR 60083 for IEC-member countries**. AUS and NZ are both member countries of the IEC, hence AUS and NZ plugs must comply with IEC TR 60083. IEC 60083 is a normative reference quoted by IEC 60601-1 and AS/NZS 60601.1 in section 2.	**AS/NZS 3551 Section 5.3.3 Medical equipment markings and documentation** lists only a small subset of identification and marking requirements, which may lead to an incomplete safety visual check. AS/NZS 3551 fails to mention anything about checking compliance of critical components with component safety standards. Critical components can be replaced during repair and servicing, e.g.: mains plugs, power cord sets, fuses, power switches, switch-mode power supplies. In particular, AS/NZS 3551 fails to mention that mains plugs and sockets must comply with the Australian/ New Zealand national requirements for mains plugs and sockets specified in IEC TR 60083; this specific requirement is however included in IEC 60601-1 and the national adoption of IEC 60601-1. Electrical medical equipment that is certified to IEC 606601-1 incorporates only critical components that are certified to their relevant component safety standards. However, if a hospital purchases electrical medical equipment that is not certified to IEC 60601-1, there is no indication whether critical components comply with the relevant component safety standards or not, and AS/NZS 3551 provides no information/ includes no requirements for dealing with critical components.	AS/NZS 3551 has much weaker safety requirements compared to IEC 60601-1 or the national adoption of IEC 60601-1, and may give management of healthcare organisations a false sense of security. Hospitals and consumer representatives would benefit from clarity about the role and applicability of: - medical device regulations; - type testing standards for demonstrating compliance of medical device design with regulatory requirements of safety and performance; - process standards for demonstrating compliance of quality systems of medical device manufacturers/ organisations taking on manufacturer's role (including hospitals) with regulatory requirements; - process standards for demonstrating compliance with best practice for asset management by hospitals; - in-field testing standards for demonstrating compliance with best practice for recurrent testing and testing after repairs by hospitals. References: **IEC 60601-1** Medical electrical equipment, Part 1: General requirements for basic safety and essential performance **IEC TR 60083** Plugs and socket-outlets for domestic and similar use standardized in member countries of the IEC