Proposal Form –
Standards Development Projects

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Please click here for guidance on the proposal submission process.

Proposal title	Revision of AS/NZS 3551:2012 Management programs for medical equipment
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If you are submitting on behalf of an organisation that is different than your current employer, please fill out the information below.	
Nominating organisation	N/A
Primary contact name	-
Primary contact position	-
Primary contact email	-
Primary contact phone	-

Section 1: Scope

1A: Provide details of the proposed documents				
#	**Title** *(e.g. Masonry cement)*	**Project type** *(e.g. revision, amendment[1] or new[2])*	**Designation** *(e.g. AS 1316:2003)*[3]	**Product type** *(e.g. AS, AS Int, SA TS, etc...)* [4]
1	Management programs for medical equipment	Revision	AS/NZS 3551:2012	AS/NZS

1 An amendment is usually only possible for small changes to recently created documents. See Section 4 of Standardisation Guide SG-003: Standards and Other Publications for more details.

[2] If you are proposing to create a new document, please provide a suggested Title.

[3] Use the SAI Global website to obtain the full designation and name of existing documents.

[4] Standards Australia mainly develops Australian Standards (AS) but it also develops the following Product types: Australian Interim Standard (AS Int), Australian Technical Specification (SA TS), Australian Technical Report (SA TR), Handbook (SA HB), Miscellaneous Publication (SA MP), Supplement (Normative), Supplement (Informative), Australian Standard Certified Reference Material (ASCRM). For guidance, see Standardisation Guide SG-003: Standards and Other Publications.

1B: Write a clear and concise statement of the nature of the issue to be addressed by your proposal.
Describe who is affected e.g. businesses, community organisations or individuals affected by the problem. What are the consequences of no action?

The AS/NZS 3551:2012 (incorporating Amendment No. 1) needs to be revised to improve clarity, specificity and correctness of statements; to improve overall structure of the document; to align with existing relevant medical devices regulations and regulatory guidelines; to update references to other standards; and to ensure compliance with the current Standards Australia principles for drafting of standards and guides.

1C: Write a clear and concise proposed scope that will outline how to address the identified issue(s).
Unless this is a proposal for a new document, this should not be a scope of the document, but a scope of the work which you propose to undertake.
Include what is going to be changed from the status quo and summarise the specific intent of the change.
If you wish to include proposed revisions as tracked changes in the standard, or an outline of a new standard, please summarise the scope and note the attachment here, and include the document as an appendix to this form.

The proposed scope for the revision of AS/NZS 3551 document is as follows:

----------END OF PROPOSAL----------

1D: Are you proposing an adoption of an International Standard (i.e. ISO or IEC)? No **If so answer the following:**[5]	
Is it a Modified or Identical Adoption? Note: if Identical use the Proposal Form – Identical Adoption	-
What is the designation? **e.g. ISO 10303.212-2004**	-

[5] Use the SAI Global website to obtain the full designation and name of existing documents.

1E: Is the existing document referenced in Australian State, Territory or Commonwealth legislation or regulatory framework? **For joint documents, also consider New Zealand legislation.**[6]	
*Yes (*List all legislation or regulation that refer to the existing document.[7]*)* ***Note**: For National Construction Code (NCC) and WaterMark proposals, the Australian Building Codes Board (ABCB) needs to be consulted prior to submission.*	Yes (NZ Electricity safety regulations)
No (Go to 1F)	

[6] To search for standards in Australasian legislation, use our search function here.

[7] Use the full formal designation for the relevant legislation, e.g. Explosives Regulation 2013 (NSW). If more than four items of legislation are affected, provide a list as an attachment to this proposal form.

Note: All relevant regulatory authorities must be consulted in the stakeholder consultation.

1F: Is there an ISO/IEC document that also covers the issues in question?	
Yes (Go to 1G)	Yes
No (Go to 1G)	-

1G: Will the proposed document include any conformity assessment requirements?[8]	
Yes	-
No	No

[8] See Standardisation Guide SG-006: Rules for the structure and drafting of Australian Standards. Note that conformity assessment requirements are rarely permitted in a standard. If you selected "yes," please discuss with the relevant National Sector Manager prior to submission.

Section 2: Net benefit

2A: What will be the impact of the proposed project in the below categories? Explain this in terms of a positive or negative impact on the following "Net Benefit" criteria.[9]

Public health and safety (max 200 words)

Net benefit:

- Improve usefulness of the document by ensuring that it is well-structured, clear, specific and correct
- Comply with the latest Standards Australia principles of document drafting
- Align with state-of-the-art international best practices for managing medical devices to ensure safety and well-being of patients and users;
- Avoid where possible national-only requirements, unless they are duly justified, e.g. necessary due to ensuring patient and user safety, aligning local clinical practices or technical installation requirements;

Social and community impact (max 200 words)

Australian patients, health workers and the community at large deserve the same level of protection afforded by standards as users in other OECD countries. Any deviations from relevant state-of-the-art international standards that are introduced or perpetuated in national-only standards need to be duly justified. If the standard committee HE-003 believes that international standards do not provide adequate level of protection for patients and users of medical equipment, the committee should work with the IEC/ISO relevant committee to change the international standard appropriately.

For example, Section 9 Modification of Medical Equipment needs to be revised to address current sub-standard practices which have led to adverse events. The current text allows healthcare facilities to perform modifications to medical equipment that deviate from manufacturer's original specifications, which contravenes with both the letter and the spirit of the Australian medical devices regulations. MTAA has specific examples of devices that were modified without the knowledge, let alone approval, of the original manufacturer that have caused patient injury.

Environmental impact (max 200 words)

Improving the structure, clarity and usefulness of AS/NZS 3551, as well as aligning with the latest international standards relevant to medical device management such as IEC 62353, ISO 13485 and ISO 14971, as applicable, will not introduce any adverse environmental impact, as it does not increase the use of hazardous substances or the rate of medical device disposal.

Competition (max 200 words)

AS/NZS 3551 is currently used by State health procurement departments as a condition for tenders and as such it significantly affects local manufacturers and suppliers of medical technologies. MTAA has provided numerous examples to the HE-003 committee where conditions in tenders include medical device "compliance with AS/NZS 3551 standard". This is a non-sensical requirement because AS/NZS 3551 is not a type testing standard. Especially small and medium size enterprises are negatively impacted because they do not have the resources of multinational corporations to argue with the State health procurement departments about issues caused by the poor wording in AS/NZS 3551.

Economic impact (max 200 words)
Standards Australia policy states that: "An essential requirement for success for a manufacturer of products for export is that those products comply with international standards. […] Standards Australia's international standards harmonization activities underpin international agreements for mutual recognition and harmonization of regulatory regimes and free trade agreements and arrangements by contributing to the minimization of technical barriers to trade." In general, national-only requirements for medical devices that are introduced or perpetuated without due justification represent additional red tape with no benefit for patient safety. Especially small and medium size enterprises (SMEs) are disadvantaged because national-only requirements introduce new barriers to entry for medical devices that already comply with relevant state-of-the-art international standards.

[9] Add specific facts and examples if possible. Refer to the Guide to Net Benefit. Not all categories may be affected, in which case, leave these blank.

Section 3: Evidence of support — Stakeholder support

3A: Describe the process taken to gain stakeholder support for your proposal (max 100 words)

3B: Identify the Australian stakeholder organisations that you have consulted with.
Evidence of stakeholder support MUST be provided in a letter (on company letterhead) or email (company email only).

At least two New Zealand-based stakeholders must be included for projects relating to joint AS/NZS standards. Include those that do, and those that do not, support the proposal.

Key stakeholder groups	**Organisation Name**	**Contact name**	**Position**	**Letter or email evidence is attached: Y/N**	**Interested in membership of standards committee: Y/N**
Research and academic organisations					
Manufacturer associations					
Testing bodies					
Certification and auditing bodies					
Supplier associations					
User and purchaser associations					
Employer and industry associations					
Professional and technical bodies					
Unions and employee associations					
Consumer and community groups					
Government and regulatory agencies					
Independent experts					
New Zealand stakeholders					
Other					

Section 4: Declaration

Please check that your proposal is complete and all fields have been filled out. Read and complete the declaration, then forward this proposal and any attached documents to Standards Australia at mail@standards.org.au. The named proponent is deemed to have approved the information contained within this proposal and this declaration.

This declaration is a mandatory requirement and proposals will not be considered without it.

I consent to Standards Australia making information relating to Standards development projects public, including information contained within a proposal form I have submitted in part or in full. In the event that Standards Australia publishes proposals on its website, proponent details at page 1 and stakeholder contact details provided at Section 3 will not be included. However, with prior agreement, my contact details may be provided to interested parties wishing to contribute or comment on the proposal or the proposed project.

The information provided in this application is complete, true and accurate to the best of my knowledge. I believe the proposed document will result in Net Benefit[10] to Australia. I have consulted with, and have the support of, national organisations with a relevant interest in this project.

Name of proponent	Val Theisz
Date of declaration	12 December 2018

[10] As defined in the Guide to Net Benefit

Section 5: Instructions and notices

To submit this proposal for Standards Australia consideration:

1. You must complete every section of this form and then submit your initial proposal draft to a National Sector Manager. Use simple, non-technical and concise language and do not use jargon of any kind. For additional information, visit the "Proposing a Project" page on our website.

2. The National Sector Manager will conduct the preliminary review of this form and then guide you as to the next steps.

3. Final submissions, along with evidence of stakeholder support, have to be provided electronically to Standards Australia (mail@standards.org.au) before the closing date of each Prioritisation Round. Please note: you should allow sufficient time to circulate your proposal to stakeholders and collect evidence of support before the Prioritisation Round deadline.

If you have any trouble with the form, you can contact us on (02) 9237 6170, 1800 035 822, or email us at mail@standards.org.au.

For identical adoptions of International Standards please complete the Proposal Form – Identical Adoptions.

Privacy notice: Standards Australia reserves the right to make information relating to Standards development projects public, including information contained within submitted proposal forms in part or in full. In the event that Standards Australia publishes proposals on its website, proponent details at page 1 and stakeholder contact details provided at Section 3 will not be included. However, with prior agreement, your contact details may be provided to interested parties wishing to contribute or comment on the proposal or the proposed project.

Appendix with details of MTAA proposed drafting comments for the revision of AS/NZS 3551:
The proposed drafting comments below were taken from the MTAA Dec 11, 2018 proposal for revising AS/NZS 3551; the marked-up changes reflect the HE-003 committee position to have AS/NZS 3551 as a standard, not a guide.

Title: change to "Management of medical equipment by healthcare organisations" to accurately reflect the intent of the HE-003 committee for this document to be a standard, not a guide, aimed at personnel in healthcare organisations; and to align with relevant references in the AS/NZS 2500 document titled "Guide to the safe use of electricity in patient care" - title currently being revised to: "Guide to the safe use of electrical equipment in patient care" - which is a guide, not a standard, and which references AS/NZS 3551 as an intrinsic part of the so-called "safety triangle".

References: replace "AS/NZS 3200" with "AS/NZS IEC 60601" throughout the document and update all other references to standards according to the latest Standards Australia practice, e.g., remove year of issue.

Preface: revise text to summarise the significant differences between the revised edition and the previous (still current at the time of this proposal) edition.

Foreword: revise text to reflect true intent of the document, i.e., a standard defining minimum requirements, not a guideline.

Clarify/ correct statements, e.g. clarify that "class of medical device" refers to PE-connection and double insulation (rather than regulatory risk classification); replace "routine performance verification" with "routine maintenance" and/or "servicing and repair", as applicable, in line with correct terminology.

Section 1 Scope and General

1.1 Scope: Revise the text to a shorter and clearer statement, e.g.: "This document defines minimum requirements for the management of medical equipment by healthcare organisations." Keep 'discussion' text to a minimum while ensuring clarity and accuracy of statements.

1.2 Application: Align as much as possible with section 1.2 Application in AS/NZS 2500.

1.3 Referenced documents: List documents referenced throughout AS/NZS 3551 with necessary corrections; refer also to pint 2 of this proposed scope for the revision of AS/NZS 3551.

1.4 Definitions: Align with applicable definitions from IEC 60601-1, ISO 14971 and ISO 13485 and include acknowledgments where definitions from IEC/ISO standards are used.

Include definitions for serious adverse event, recall actions and safety notification (to regulatory authorities) and acknowledge the source (regulations or regulatory guidelines); alternatively, prompt the reader to refer to "the applicable regulatory requirements" like the ISO 13485 standard does.

Section 2 Medical Equipment Management Program

2.1 General:.

Revise the text on what the management program shall consider to: (a) reflect the risk classification of medical devices as per the regulations; and (b) align with the procurement considerations proposed for the revision of AS/NZS 2500, i.e.:

- evidence that the medical devices/equipment can be legally marketed within the

jurisdiction; or alternatively, that unapproved medical devices/ equipment are/ is used in accordance with applicable regulations for accepted uses of unapproved medical devices such as clinical investigations, special access schemes including humanitarian use and authorised prescribers;

- assessment of suitability for the indications for use and intended use;
- supplier-provided installation, training, commissioning, routine maintenance, servicing and repair support, upgrades, as applicable; and
- economic considerations.

Current items (c) through to (g) appear to be circular requirements/ arguments – consider revising or removing.

Include statements that explain clearly that:

- the purpose of routine maintenance, servicing and repairs is to ensure that the medical equipment operates within the safety and functional specifications defined by the original manufacturer during the lifetime of the medical equipment;
- software upgrades by the original manufacturer shall to be implemented in a timely manner to avoid cybersecurity vulnerability caused by outdated software;
- routine maintenance, servicing and trouble-shooting shall be done as specified in the original manufacturer's servicing manual to ensure the medical equipment operates within specification during its lifetime;

  If no frequency for routine maintenance and servicing is provided (e.g., legacy medical equipment), the routine maintenance and servicing shall be performed at least annually.

  If a different regime is implemented by the responsible organisation, the personnel responsible for the medical equipment management program shall document the justification for the deviation. The justification shall be based on acceptable risk management principles, e.g. following the process defined in ISO 14971 standard, and approved by the authorised person before being implemented.
- any changes to the equipment that deviate from the original manufacturer's specifications, including reprocessing of single-use devices, represent "refurbishing" or "remanufacturing"; entities undertaking refurbishing or remanufacturing activities are regulated as medical device manufacturers and shall comply with applicable regulatory requirements;

2.2 Program support functions: rename this section "**Management responsibility**" to reflect clearly that the ultimate responsibility and accountability lies with management rather than support staff.

Consider aligning with ISO 13485 on specifying requirements for responsible organisations to define, document and communicate within the organisation procedures for: responsibility and authority; internal communication; and resources.

Consider using terminology that aligns with ISO 13485 standard when referring to management systems in healthcare organisations, e.g., for control of documents and control of records covered in section 2.4.1 Control of documentation, 2.5.1 General and 2.5.5 Document control.

2.3 Test equipment: Include "test equipment shall be uniquely identified" and "test equipment calibration status shall be clearly indicated/ affixed on the test equipment", or words to that effect.

2.4 Documentation requirements:

Consider replacing "Operations manual" in section 2.4.2 with "medical equipment database" or "medical equipment information repository" or "medical equipment information library" to avoid confusion with medical equipment operation manual supplied by the manufacturer of the medical equipment. Consider combining with section 2.5 Equipment database.

Resolve ambiguities and consolidate text as appropriate - for example, section 2.4.2 (a) requires that the operations manual includes "details of any medical equipment"; section 2.5 also requires that the equipment database includes "2.5.2 Medical equipment details".

Include clear requirements on documenting serious adverse events and their reporting to regulatory agencies, and any recall actions in section 2.4.4.

2.5 Equipment database: Clarify the relationship with "operations manual" in section 2.4.2.

Replace "unique identifying number" in section 2.5.2 (a) with "Unique Device Identification (UDI)" and include a reference to IMDRF Guidance UDI WG/N7.

Replace "corrective maintenance" with "servicing and repair" in section 2.5.3 (b).

Include "medical equipment that has been repaired and subsequently approved for use by the healthcare organisation shall be identified to distinguish it from equipment supplied and maintained by the original manufacturer or supplier, for example by means of a QC sticker with the date of repair" or words to that effect.

2.6 Major program functions: Delete this section and consolidate any information or references that need retaining with section 2.1 General.

Section 3 Regulatory Compliance

Delete this section altogether because it is both outdated and incomplete. Also, the Standards Australia rules for document drafting prohibit reproducing, selectively or otherwise, regulatory requirements. An acceptable reference to regulatory requirements is, for example: "applicable regulatory requirements [shall be] met", as an example of using such wording see ISO 13485:2016, sec. 7.2.2 c).

Reference to applicable regulatory compliance is being proposed to be included in section 2.1 General: "evidence that the medical devices/equipment can be legally marketed within the jurisdiction; or alternatively, that unapproved medical devices/ equipment are/ is used in accordance with applicable regulations for accepted uses of unapproved medical devices such as clinical investigations, special access schemes including humanitarian use and authorised prescribers".

Include a list of applicable regulations in the Bibliography.

Section 4 Procurement: rename this section to "**Medical equipment selection process and criteria**" to reflect more accurately the intent and scope of this process.

4.1 Scope: Rename this section to "**General**" to be consistent with Section 2 and to follow the general structure of a Standards Australia document (no need for each individual section to have its own scope sub-section).

Clarify the intent of this section to avoid misinterpretation, for example: "This section describes the process and criteria for selecting the medical equipment that best meets the needs of the patients and the needs of the healthcare organisation."

4.2 Procurement procedures: Rename this section to "**Evaluation criteria and process**"

4.2.1 General: move the text directly under section 4.2. Specify the evaluation criteria and identify the functions responsible to decide on each of the criteria, e.g., in the form of a

table (table is indicative only, HE-003 committee to decide which function is responsible for assessing the medical device/ equipment against which evaluation criteria):

Evaluation criteria	**Responsible function**
Medical device/ equipment indications for use and intended use	Healthcare professionals – doctors, nurses, allied health professionals, as applicable
Regulatory compliance	Compliance officer
Technical specifications, including ease of cleaning, disinfection and sterilisation if applicable (typically available in the IFUs)	Biomedical engineering
Compatibility with existing healthcare facility infrastructure and other equipment likely to be used together with the purchased device/ equipment	Biomedical engineering
Supplier-provided services, e.g., installation, training, commissioning, routine maintenance, servicing and repair support, upgrades, as applicable	Biomedical engineering Procurement officer
Economic considerations	Procurement officer

Each evaluation criterion should be assigned a score in accordance with the healthcare organisation priorities. The device/ equipment with the highest score should be selected. Keep records of the selection p[rocess.

Delete section 4.2.2 Regulatory compliance, as already covered in the proposed changes to section 2.1 General.

Delete heading **4.2.3 Medical equipment devices on loan, lease or hire**, consolidate content with that of existing section **8 Medical equipment not owned by the organization,** rename title to "**Medical equipment on consignment**" and move text as a sub-section of **Section 2 Medical Equipment Management Program**, because medical equipment on loan, on trial or hired undergoes the same visual inspection and testing as the medical equipment owned by the healthcare organisation.

Since most, if not all, information evaluated during the pre-purchasing stage is provided through tenders, consolidate the requirements in 4.2.1, 4.2.4 and 4.2.5 and move the text directly under section 4.2. The consolidated list of items should to be included in the invitation to tender is as follows:

- indications for use and intended use, as defined by the manufacturer
- evidence of compliance with the applicable regulatory requirements, e.g., inclusion in the ARTG (Australia) and/or MedSafe (New Zealand), as applicable
- for unapproved devices only: evidence of authorisation to use the unapproved devices in compliance with applicable regulations such as clinical investigations, special access schemes including humanitarian use and authorised prescribers
- instructions for use (IFUs) – for the patient, for the surgeon etc, as applicable
- technical specifications, including information on the essential performance parameters and the lifetime of the medical device/ equipment, as defined by the manufacturer

- warranty
- installation and calibration instructions, routine maintenance instructions, servicing manuals, troubleshooting instructions, as applicable
- cleaning, disinfection and/or sterilisation instructions with maximum number of cycles, as applicable
- required consumables and spare parts during the medical device/ equipment lifetime, as applicable
- post-sale ongoing support provided by the manufacturer/ supplier: installation, training, commissioning, routine maintenance, servicing and repair support, upgrades, as applicable
- one-off purchase and ongoing costs

Section 5 Acceptance: rename this section "**Acceptance checks**"

5.1 Scope: Merge this section with 5.2 General and keep the name "**General**" to be consistent with Section 2 and to follow the general structure of a Standards Australia document (no need for each individual section to have its own Scope sub-section).

Clarify the intent of this section to avoid misinterpretation, for example: "This section specifies requirements for performing acceptance checks for medical equipment under the responsibility of the healthcare organisation. The acceptance checks include visual inspection and in-field testing, performed before starting to use the equipment, during routine periodic maintenance and after each repair."

Revise section 5 and propose a structured approach to acceptance visual inspection and testing, for example in tabular format. The following table is indicative only, the HE-003 committee needs to decide which visual inspections and acceptance tests should be performed at each stage of using the equipment by the health organisation.

Visual inspection	**Initial checks**	**Routine periodic maintenance**	**Checks after repair**
packaging integrity, checks for any damage that may compromise the function or the required cleanliness or sterility status of the medical device/ equipment	✓	-	-
correct type and quantity of items delivered, including documentation accompanying the medical device/ equipment, checked against the purchase order/ contract and delivery records	✓	-	-
medical device/ equipment markings and documentation, checked for legibility and correctness as per AS/NZS IEC 60601-1 Section 7 ME EQUIPMENT identification, marking and documents	✓	-	✓
function marked on all operator controls and indicators	✓	-	✓
correct type and rating of detachable power supplies, power packs, power boards, power	✓	✓	✓

supply cords and extension cords (e.g., PVC ordinary duty H05VV-F 300/500V), replaceable fuses intended to be used with the medical device/ equipment			
marking and colour coding of connectors to other equipment, as applicable, e.g. as per ISO 80369, AS 4484	✓	✓	✓
warning and caution labels on the device/ equipment	✓	✓	✓
ability to connect to other equipment as intended by the manufacturer and as required by the healthcare organisation for the intended clinical application	✓	-	✓
for permanently installed medical equipment only: ability to install the equipment correctly and securely as intended by the manufacturer and in compliance with AS/NZS 3003, taking into consideration environmental requirements such as exhaust extraction for surgical lasers and safe guiding and securing of cables so that they cannot become trapped or entangled in gear mechanisms or be otherwise damaged	✓	✓	
appropriate protective shielding of areas accessible to maintenance operators, e.g. for replacing filters or for accessing liquid containers, to ensure operator protection against electric shock, hazardous radiation or other possible safety hazards	✓	✓	✓
for equipment incorporating a chain- or cable-suspended mass or requiring a wall- or ceiling-mounted mass: correct installation and fitting of the support mechanisms, including duplicated and independently anchored cables and anti-crash mechanisms, if provided	✓	✓	✓
In-field testing	**Initial, prior to equipment use**	**Routine/ periodic maintenance**	**Checks after repair**
tests to check essential performance as defined by the manufacturer	✓	✓	✓
electrical safety in-field tests as defined in [section]	✓	✓	✓
non-electrical safety in-field tests as defined in [section]	✓	✓	✓

5.3 Acceptance check and inspection: Re-number and rename this section to "**5.2 Visual inspection**". This section needs to provide details for each visual inspection check listed in Section **5.1 General**.

5.4 Test selection and acceptance testing: Re-number and rename this section to "**5.3**

Acceptance tests". This section needs to provide details for each acceptance in-field test, both electrical (currently Appendix B) and non-electrical (currently Section 6) listed in Section **5.1 General**.

5.5 Documentation of results: Remove this section and move/ consolidate the text of this section with Section **2.4 Documentation**. Recommend using the widely accepted documentation and records best practices, for example those defined in ISO 13485 sections 4.2.4 Control of documents and 4.2.5 Control of records.

5.6 Failed medical equipment: Re-number and rename this section to "**6 Medical equipment malfunction and failure**". This needs to be a high-level section and it should cover:

- analysis of 'fail' results, classification of malfunction/ failure in 'minor', 'moderate', 'major' – for an example of non-conformities grading refer to GHTF/SG3/N19:2012 Grading System for Regulatory Purposes and Information Exchange;
- remedial action, including: identification and prevention of unintended use of quarantined equipment, repair, decommissioning and/or replacement, as applicable – for an example of field safety corrective actions refer to IMDRF/NCAR WG/N14FINAL:2017 Field Safety Corrective Action (FSCA);
- update of medical equipment database/ medical equipment database/ medical equipment information repository/ medical equipment information library (select a term and use it consistently throughout the document);
- notification of malfunction/ failure to original manufacturer/ supplier;

Section 6 Performance verification and maintenance: Remove this section and move/ consolidate the text of this section with that in Section **2.4 Documentation**, proposed section "**5.2 Visual inspection**", proposed section "**5.3 Acceptance tests**" and proposed section "**6 Medical equipment malfunction and failure**".

The current section **6.9 Safety-related notifications, alerts and recalls** should be re-numbered and renamed to "**7 Serious adverse events reporting, alerts and recalls**". Revise this entire section to align with correct definitions from regulations and regulatory guidelines.

Section 7 Medical electrical systems: Remove this section and move/ consolidate the text of this section with that of proposed section "**5.2 Visual inspection**" and proposed section "**5.3 Acceptance tests**".

Section 8 Medical equipment not owned by the organization: Rename title to "**Medical equipment on consignment**" and move this as a sub-section of **Section 2 Medical Equipment Management Program**, because medical equipment on loan, on trial or hired undergoes the same visual inspection and testing as the medical equipment owned by the healthcare organisation.

Section 9 Modification of medical equipment: Delete this section; modifications and upgrades should be covered as proposed in **Section 2 Medical Equipment Management Program**.

Section 10 Assessment intervals: Delete this section; routine maintenance and servicing should be covered as proposed in **Section 2 Medical Equipment Management Program**.

Appendix A Application of risk management principles in establishing a medical equipment management program (Informative): Review the content of this annex to remove duplicative content already covered in other sections. Consider improving the document structure, and the clarity and specificity of the text throughout the document.

Appendix B Electrical safety testing (Normative): Rename title to "**Electrical safety in-field tests**"

to avoid confusion with electrical safety type testing and move as a sub-section of proposed section "**5.3 Acceptance tests**".

Align the electrical safety in-field tests with IEC 62353:2014, unless duly justified for reasons of safety, incompatibility with local installation standards and/or technical correctness.

Appendix C Measuring device (Normative): Move as a sub-section of **Section 2 Medical Equipment Management Program**.

----------END OF PROPOSED DRAFTING COMMENTS----------