



# Engineers Australia

College of Biomedical Engineering

## AS/NZS 3551 Workshop

June 2010



# AS 3551

- First published 1988 – AS 3551 ~ 30 pages
- Revised 1996 – AS/NZS 3551 ~ 55 pages
- 3<sup>rd</sup> Edition 2004 – AS/NZS 3551 – 56 Pages
  - Amendment 1 – September 2005
  - Amendment 2 – pending .....
- Current Draft – June 2010 – 85 Pages

# The standards development process

- SA Committee HE-003 – Medical Electrical Equipment
  - HE-003-01 – General Safety Requirements
    - HE-003-02 – AS/NZS 3551 Revision

# HE-003

- Australasian College of Physical Scientists and Engineers in Medicine
- Australasian Society for Ultrasound in Medicine
- Australian Chamber of Commerce and Industry
- Australian Dental Association
- Australian Institute of Radiography
- Australian Radiation Protection and Nuclear Safety Agency
- Australian Society of Anaesthetists
- Australian and New Zealand College of Anaesthetists
- Auckland Healthcare (New Zealand)
- Canterbury District Health Board
- College of Biomedical Engineering – Engineers Australia
- Commonwealth Department of Health and Ageing
- Department of Defence (Australia)
- Medical Industry Association of Australia Inc
- Ministry of Economic Development (New Zealand)
- Testing Interests (Australia)
- The Royal Australian and New Zealand College of Radiologists
- Wairarapa District Health Board
- Wairarapa District Health Board
- N.S.W Dept of Commerce

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# Current draft

- Work commenced ~ 2006 ..... grand plans !
  - On-hold until mid/late 2009
    - SA business review
      - Many projects stopped or placed on hold .....funding !
      - GFC made it even worse
  - Amendment 2 pending .....
    - Given approval to finalise ..... by end June 2010 !

# Consultation

- Small sub-committee commenced work mid 2009
- Informal consultation QLD and NSW – late 2009
- Formal consultation – EPSM-ABEC 2009
- 3 committee meetings HE-003-01-02
  - Invited 3 external contributors with expertise to offer to participate

# Reference documents

- IEC 60601-1:2005 – Medical electrical equipment – General requirements for safety and essential performance
- AS IEC Part 2 subordinate documents

# Reference Documents

- Medical Devices & Equipment Management: Repair & Maintenance Provision – MDA June 2000
- Managing Medical Devices – MHRA – November 2006
- Medical Devices Policy – V3.0 - – Wandsworth NHS – May 2009
- The Medical devices regulations – Implications on healthcare and other related establishments – Bulletin number 18 – MHRA – January 2006
- Use of medical devices – Improving safety and performance – COCIR and EUROM
- Translation of Austrian Standard – DRAFT OVE/ONORM E 8751- 1 – Recurrent test and test after repair of medical electrical equipment: Part 1 – General requirements – Austrian Standards – August 2002
- ANSI/AAMI EQ56:1999(R)2004 - Recommended practice for a medical equipment management program

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# Reference Documents

- **IEC 60930:1988 – Guidelines for administrative, medical and nursing staff concerned with the safe use of medical electrical equipment**
- **IEC 300-3-9:1995 - Application guide – risk analysis of technological systems**
- **IEC 60300.3.3:2005 –Dependability management – Application guide – life cycle costing**
- **IEC 60300.3.11:2005 –Dependability management – Application guide – Reliability centred maintenance**
- **IEC 60300.3.14:2005 –Dependability management – Application guide – Maintenance & maintenance support**
- **IEC 60300.3.16:2008 –Dependability management – Application guide – Guidelines for specifications of maintenance support services**
- **IEC 62353:2007 – Medical electrical equipment – recurrent test and test after repair of medical electrical equipment**

# Reference documents

- AS/NZS 4360:2004 – Risk management
- AS/NZS HB 436:2004 – Risk management guidelines
- AS/NZS HB 240:2004 – Guidelines for managing risk in outsourcing situations
- AS/NZS HB 158:2006 – Delivering assurance based on AS/NZS 4360:2004
- AS/NZS ISO 31000:2009 – Risk management – Principles and guidelines
- AS ISO 14971:2000 – Medical devices – Application of risk management to medical devices

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# Today

- DR 10023 – Draft for public comment
  - Revision of AS/NZS 3551 – Technical management programs for medical devices
  - Released - 17 June 2010
  - Closing date for comment – 19 August 2010

# CMBE sponsored consultation workshops

- Brisbane - 28 June
- Sydney – 1 July
- Melbourne – 5 July
- Adelaide – 8 July
- Perth – 12 July
- Canberra - ~ end July
- New Zealand – maybe .....
- **Today is your chance !!**

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# How to contribute

- Read the draft
  - Done that already ..... haven't we !!
- Participate today
- Consider the discussion and interaction to come
- Prepare and submit your comments

# Submitting comments .....

- The form –

- [www.standards.com.au/catalogue/misc/Public%20Comment%20Form.doc](http://www.standards.com.au/catalogue/misc/Public%20Comment%20Form.doc)

- If that's too hard to remember, a link is in the draft

Why the form .....

# Comments .....

- Because every comment will be considered formally by the Standards Development Committee HE-003-02
  - Technical
  - Grammar
  - Punctuation
  - Typo's.....
- ..... and a rationale documented for acceptance, amendment or rejection.

Now ..... To business !!

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# Section 1 - Scope & General

- 3551 – 2004
  - 18 definitions
- 3551 – 2010
  - 54 definitions
    - Types of maintenance
    - Risk
    - Accessory/spare part
    - Intended use/purpose/normal use
    - Networks
  - **Responsible organisation**
  - **Service entity**

## Section 2 – Medical Equipment Management Program

- 3551 – 2004
  - Major functions
  - Other functions
  - Selection and review of service provider
  - Resources
  
  - Three and half pages
- 3551 2010
  - Program support functions
    - **Responsibility, authority and communication**
    - **Resources**
      - General
      - Human
      - Training
      - Environment
      - Infrastructure
    - **Test Equipment**
    - **Documentation**
      - Control
      - Operations
      - Databases
      - Records
        - » **Systems – parent/child**
  - Six pages

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## Section 2 – Medical Equipment Management Program

- Developing, and looking like .....

..... A Quality Management System

## Section 3 – Regulatory Compliance

- 3551 – 2004
  - Para 3.2.2
- 3551 2010
  - New Section
    - Marketing authorisation
    - EMC
    - Equipment for clinical trial
    - Clarification of clinical trial v's user acceptability trial

## Section 4 - Procurement

- 3551 – 2004
- Section 3
  - General
  - Regulatory compliance
  - Pre-purchase evaluation
  - Tenders and quotations
- 3551 – 2010
  - General
  - Regulatory compliance
  - Pre-purchase evaluation
  - **Devices on loan, lease or hire**
  - Tenders and quotations

## Section 5 - Acceptance

- 3551 – 2004

- Section 4

- Acceptance check and inspection
- Test selection
  - Essential safety and performance parameter tests
  - Frequency of testing removed
  - Documentation of results

- 3551 – 2010

- Acceptance check and inspection
- Test selection
  - **Non-electrical safety tests**
  - **Functional and performance verification tests**
  - **Frequency of testing – now Section 8 – Assessment Intervals**
- Documentation of results

# Section 6 – Maintenance, Assessment & Testing Activities

- 3551 – 2004
  - Inspections
  - Electrical Tests
  - Performance testing (1 para)
  - Documentation
  - Rectification
  - Test equipment
- 3551 – 2010
  - Performance verification
  - Functional testing
    - Protective functions
    - Non-electrical parameters
  - Inspections
  - Documentation
  - Safety testing
  - Electrical safety testing
    - Relationship with 3760

# Section 6 – Maintenance, Assessment & Testing Activities

- 3551 - 2004
- 3551 – 2010
  - Review and confirmation of suitability, adequacy, effectiveness and relevance of program
  - Special circumstances
    - Hire or loan equipment
    - Equipment on trial
    - Testing at remote sites
    - Testing –
      - Scheduling
      - Testing after remedial maintenance
    - Modifications
    - Adverse event investigations
    - Incident Reporting

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# Section 7 – Medical Equipment Systems

- 3551 - 2004
- 3551 – 2010
  - Types of systems
    - Non-medical devices
    - MSO's
    - Functional interconnection of equipment
  - Testing configuration
  - Systems interfacing with ICT equipment

## Section 8 – Assessment Intervals

- 3551 – 2004
  - Para 4.4
    - Risk based
    - Default to annually in absence of risk assessment
- 3551 – 2010
  - New Section
    - Risk based
    - Reviewed for adequacy every three years
    - Default to manufacturers recommendations in absence of risk assessment
    - Guidance of risk based approach in Appendix A

## Section 9 – Equipment configuration

- 3551 - 2004
- 3551 – 2010
  - Config issues recognised
  - Config recorded prior to commissioning
  - Updates documented
  - Config documented
  - Config verified at each service

# Appendix A – Application of Risk Management Principles in establishing .....

- Most contentious issue of redrafting
  - Even tho' introduced in 2004 Standard
  - Good words of wisdom from Qld in draft
  - But risk is very personal .....
    - to the individual
    - to the organisation !
    - and to the courts !!!!
  - And always much easier to assess with the benefit of hindsight !!!!!

Medico- legal – two words from two different environments.

In the legal environment clients pay dollars for decisions which can be taken over many years, after closely examining everything that has happened and with the benefit of hindsight, for the client to ultimately win or lose on a vote of 4 to 3.

Whereas in the medical area, patients can pay with their life for decisions that have to be taken in minutes without the advantage of hindsight and where there is no ambiguity as to the outcome.

**There are few people who have been declared dead by a vote of 4 to 3 !!**

Trevor McPherson, May 1995

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**Open Discussion .....**