08-01-14 From Karen.

Kris needs to edit for mechanical test purposes

In addition to the standards called out in the 510K testing document, these are additional that I have identified that we need to date. I also gave a long list of electrical standards to Brian for review but cannot find them right away… may be buried in the IneedMD reorg task.

IEC 60068-2-6: Vibration testing F (Sinusoidal test)

IEC 60068-2-27 Shock test

IEC 60068-2-32 Fall test

IEC 60068-2-32amd – later amendment to Free fall test

IEC 60529 – Protection Provided by Enclosures

IEC 60601-1 – Medical Electrical Equipment – Requirements for Safety

IEC 60601-2 – 27 Particular requirements for the safety of electrocardiographic monitoring equipment

UL-60601-1 Underwrites Deviations from IEC-60601-1 Part 1: General Requirements for Safety

Electromagnetic Standards

IEC 60050-161:1990, International Electrotechnical Vocabulary – Chapter 161: Electromagnetic compatibility. Amendment 2 was published in 1998.  IEV online: <http://www.electropedia.org/>

AAMI TIR18/Ed.2 Guidance for Electromagnetic Compatibility

ANSI/AAMI/IEC 60601-1-2:2007/ (R) 201 Medical Electrical Equipment—Part 1–2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

ANSI C63:18: Test Method for Estimating Electromagnetic immunity of Medical Devices

DO-160 Airborne electrical equipment, RTCA, 2004

**13-17: CLSI LIS02-A2, Standard Specification For Transferring Information Between Clinical Instruments And Computer Systems; Approved Standard-Second Edition. (Software/Informatics)**

Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf>

139-1988 - IEEE Recommended Practice for the Measurement of Radio Frequency Emission from Industrial, Scientific, and Medical (ISM) Equipment Installed on User's Premises

C95.6-2002 - IEEE Standard for Safety Levels With Respect to Human Exposure to Electromagnetic Fields, 0-3 kHz

<http://standards.ieee.org/findstds/standard/C95.3-2002.html>

Medical device communication

11073-10101-2004 - Health informatics -- Point-of-care medical device communication -- Part 10101: Nomenclature

<http://standards.ieee.org/develop/project/11073-10101.html>

ANSI C63.18:1997, American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitter

1417-1996 - ANSI/AAMI EC13-1992 - Cardiac Monitors, Heart Rate Meters, and Alarms

<http://standards.ieee.org/findstds/standard/1417-1996.html>

11073-10406-2011 - Health informatics--Personal health device communication Part 10406: Device specialization--Basic electrocardiograph (ECG) (1- to 3-lead ECG)

<http://standards.ieee.org/findstds/standard/11073-10406-2011.html>

Labeling

AAMI TIR12:2010**,** Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers. Association for the Advancement of Medical Instrumentation. Arlington, VA.

AAMI TIR30:2011**,** A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for the Advancement of Medical Instrumentation. Arlington, VA.

Device Labeling

 IEEE 802.11 b/g, IEEE 802.15.4 BluetoothTM class II

 IEC 60601-1-2

International Standards

ISO 14971 Second edition 2007-03-01 Medical devices — Application of risk management to medical devices

ISO technical report TR 21730, Health Informatics – Use of mobile wireless communications and computing technology in healthcare facilities – Recommendations for the management of unintentional electromagnetic interference with medical devices (ISO/TR 21730: 2007(E)

Cleaning

Association for the Advancement of Medical Instrumentation, A compendium of processes, materials, test

methods, and acceptance criteria for cleaning reusable medical devices, AAMI TIR30:2003, Arlington,

VA: AAMI, 2003. Technical Information Report.

Packaging standards

ASTM Packaging standards: Do we need this?

<https://global.ihs.com/search_res.cfm?&rid=Z56&mid=5280>

Coastguard

COREG