BMUS

Technical Discussion, Standards, Guidance and Compliance Statements for Ultrasound

There are several activities related to the technical aspects of ultrasound equipment. These can be divided into:

- Technical discussion documents which help define which are the appropriate parameters to measure.
- Specifications for test procedures for measurements related to ultrasound equipment (eg. acoustic output, image characteristics)
- Guidance on testing regimes for equipment; (eg. for the purposes of acceptance testing, evaluating change in performance with time, and in evaluation of 'fit for purpose' testing)
- Compliance statements concerning design, marketing, description and use of the equipment on patients (eg. safety statements)

In principle the IEC is the main overarching international body responsible for definition of measurement standards. In practice, some individual countries, especially the USA, have their own standards organisations (NEMA and the AIUM) which operate independently of the IEC. In terms of legislative control, the main body is the FDA. The FDA produces compliance requirements for ultrasound manufacturers selling in the US market, whether these are US based companies or based elsewhere in the world. Because of the size of the US market, FDA compliance requirements have become adopted throughout the world. National bodies such as the AIUM, IPEM and BMUS, and larger umbrella groups, play a role in defining guidance for end-users such as Hospital Physicists and Sonographers. Ultrasound safety has received special attention and there are a series of safety statements produced at national (BMUS), European (EFSUMB) and world level (WFUMB). There is current activity to harmonise these safety standards in order to ensure a consistency in different countries.

Relevant bodies

Relevant bodies involved in the above activities are:

International Electrotechnical Commission (IEC).
An international body which produces technical discussion documents and standards for all electrically connected equipment including ultrasound equipment. It has produced a large number of high quality standards on acoustic measurement and safety, and a much more limited set of standards on image quality. Currently there is no activity in Doppler ultrasound.
Many documents available. http://www.iec.ch/

EU and national standards committees.
IEC standards are harmonised within the EU by national standards committees.

FDA (Food and Drug Administration).
An American body which is responsible for regulation of a wide range of activities, including the ultrasound industry. It produces a compliance document for the ultrasound industrial sector detailing permitted description of an ultrasound machine, permitted testing methods and limits to acoustic output.
Guidance for Industry and FDA Staff. Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (2008).
http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm115357.htm

National Electrical Manufacturers Association (NEMA).
An American body which produces standards and compliance statements.
Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3 (2009).
Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 2, also known as the acoustic display standard (2009).
http://www.nema.org/prod/med/ultrasound/

World Federation of Ultrasound in Medicine and Biology (WFUMB).
The umbrella group for regional ultrasound societies. It produces safety statements.
WFUMB Policy on Live Scanning at Commercial Exhibitions (2010)
WFUMB Statement on the Safe Use of Doppler Ultrasound during 11-14 week scans (or earlier in pregnancy) (2011)
WFUMB/ISUOG Policy Statement on Non-medical Use of Ultrasound (2011)
WFUMB Recommendations on Non-medical Use of Ultrasound (2010)
WFUMB Clinical Safety Statement for Diagnostic Ultrasound (2011)
Safety of Nonmedical Use of Ultrasound (2010)
Safety of Ultrasound Contrast Agents (2007)
http://www.wfumb.org/about/statements.aspx

European Federation of Ultrasound in Medicine and Biology (EFSUMB).
The umbrella group for national ultrasound societies within Europe. It produces safety statements.
Clinical safety statement for diagnostic ultrasound (2011)
Souvenir scanning statement (2006)
Guidelines for the safe use of diagnostic ultrasound equipment (created by BMUS, adopted by EFSUMB Board of Directors 2011)
Guidelines for the safe use of extracorporeal shockwave Lithotripsy (ESWL) devices (1994)
Guidelines for the safe use of Doppler Ultrasound for clinical application (1995)
http://www.efsumb.org/ecmus/index.asp

American Institute of Ultrasound in Medicine (AIUM).
The learned society for ultrasound in the USA. It has its own Technical Standards Committee which publishes its own discussion documents and standards via NEMA.
Performance Criteria and Measurements for Doppler Ultrasound Devices: Technical Discussion - 2nd Edition 2006)
Routine Quality Assurance for Diagnostic Ultrasound Equipment.
http://www.aium.org/resources/resources.aspx

Institute of Physics and Engineering in Medicine (IPEM).
The professional body for medical physics in the UK. It has produced discussion documents, test procedures and guidance on testing regimes for ultrasound and Doppler ultrasound equipment.
Quality Assurance of Ultrasound Imaging Systems. 2010
http://www.ipem.ac.uk/publications/ipemreports/Pages/QualityAssuranceofUltrasoundImagingSystems.aspx

British Medical Ultrasound Society (BMUS).
The learned society for ultrasound in the UK. It has produced a series of safety statements.