TC62/SEC1015/INF
October 2009

EUROPEAN COMMITTEE FOR ELECTROTECHNICAL STANDARDIZATION (CENELEC)

TECHNICAL COMMITTEE No. 62: ELECTRICALEQUIPMENT IN MEDICAL PRACTICE

SOFTWARE AND MEDICAL DEVICES WORKING GROUP (SAMD).

The SAMD was considered at the meeting of CLC/TC 62 held on 19th June 2009. TC 62 considered that the MDEG was probably not addressing the subject of medical software at the right level. TC 62 supported the exploration of a joint working group with CEN/TC 251 and possibly CEN/CLC TC3 dealing with medical software and software devices. Following up on a meeting between delegates of SAMD and of CEN/TC 251 on June 18, 2009, it was agreed to explore establishing a common approach by involved European standards organizations, possibly a joint working group.

Following this the TC 62 chair and the CENELEC Group on SAMD (Software and Medical Devices) have explored together with representatives of CEN/TC 251 on Health Informatics the possibility of forming a Joint Working Group on Medical Software.

These discussions have been quite fruitful. There is great interest from both sides to cooperate. While the precise form of the joint activity is still to be decided, the first meeting of the joint group is already scheduled for 8th December 2009 at the CEN/CENELEC meeting centre in Brussels. Information about the planned terms of reference for the joint working group is attached as an appendix.

As the interest for this joint activity may be expected to be quite large, the chairs of both CEN/TC 251 and CLC/TC 62 have indicated the wish to restrict participation to a relatively limited group of participants (about 20 people in total) whilst maintaining full transparency. The CLC/TC 62 delegation in this joint activity will be the SAMD group, at present less than 10 participants. This means that there is room for a few additional CLC/TC 62 representatives. National committee are requested to inform the Secretary of CLC/TC 62 Mr. Nick Bradfield e-mail: Nick.bradfield@bsi-global.com of any members who are interested in participating by:

Tuesday 17th November 2009.

The chairs of the TC and SAMD will then decide within three days who will complete the CLC/TC 62 delegation in the joint effort on medical software relating to the Medical Devices Directive.

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TITLE: **Proposal by CEN/TC 251, Health informatics, and CENELEC/TC 62, Electrical equipment in medical practice, to form a Joint Working Group to address standards relating to software as Medical Devices**

SOURCE: **CEN/TC 251 secretariat**

ACTION REQUIRED: **For your approval**
Please send your vote and comments before November 17th to Ms Mary van den Berg: mary.vandenberg@nen.nl

Proposal by CEN/TC 251, Health informatics, and CENELEC/TC 62, Electrical equipment in medical practice, to form a Joint Working Group to address standards relating to Software as Medical Devices.

Background

Three Medical Devices Directives, each in line with the New Approach, regulate medical devices in the EU at present. Broadly speaking, each directive lays out the following:

- Legal 'whereas' clauses;
- Definition of a medical device or accessory and classification rules;
- Articles of Law, surrounding the placing on the market of the device by the manufacturer;
- Acknowledges the use of standards as a means of demonstrating compliance with essential requirements;
- Essential (Safety) Requirements that each product must fulfil before CE-mark;
- Compliance assessment Routes, defining future regulatory processes.

These are the core fundamental elements of each directive. They ensure that each medical device, placed on the market, can be recognised by the user, through its CE-mark, as having undergone a suitable process of assessment by appropriate authorities and is safe and effective for use with any given patient and user.

Many items of software will fall naturally and logically into the definition of Medical Devices Directive 93/42/EEC (MDD) as amended by 2007/47/EC and will be regulated under this directive. The responsibility for providing the compliance evidence rests with the manufacturer who places the product on the market under its own name. While a substantial number of standards harmonized to the MDD exist, or are under development, certain guidance for those manufacturers is still needed.

A different scenario emerges when the clinical application of software is considered, such as the situation whereby a clinical engineering group or IT group, within a hospital, or healthcare provision unit, come together and connect or compile a 'System' for a clinical purpose, e.g. radiotherapy. Such a 'System' can comprise a combination of embedded software in a device with an operating system, perhaps elements of a network system, software of unknown provenance, bespoke software, communication devices and various middleware links, all of which combine to deliver a therapy or diagnosis tool that meets the immediate demands of provision of healthcare today.

The problem is that such 'Systems', which are often bespoke and unique, do not meet the definition of 93/42/EEC as amended by 2007/47/EC and are not 'placed on the market by a manufacturer'. However, they are assembled, 'put into use' with the intended purpose of provision of therapy and diagnosis by the system owner in the hospital. The combination used, its maintenance, verification and the management of risk associated with the often-evolving combination, can all impact patient safety and clinical outcome.

It is important to note that regulatory and interpretative guidance relating to the amended MDD will likely appear. Any standards development will therefore need to take into account this solidification of definitions and borderlines relating to software and software systems.

Purpose

The purpose of this paper is to propose the establishment of a Joint Working Group to address standards relating to software that are medical devices, called medical software in the MDD or relate to medical devices, in the context of medical device regulation.

Scope

The scope of the proposed Joint Working Group shall be to:

1. Monitor actively the regulatory position related to software in the healthcare domain, explicitly including
   - medical software (i.e. software in medical devices, related to medical devices, that is a medical device in its own right), and
   - where the regulatory status is not clear (borderline) and
   - other safety related software used in healthcare

   with intent to achieve maximum consistency in approach of European and international standardization.
2. Monitor the work in other groups such as MDEG, ABHS and NB-MED and provide advice, proposals and suggestions, whether or not solicited.
3. Enable consistent application of 93/42/EEC as amended by 2007/47/EC to software by providing adequate harmonized standards, specifications, and/or technical reports.
4. Provide guidance on managing IT networks on which the Software runs in the Health Care environment and on the need for regulation in that area.

Objectives

The two main objectives of the proposed Joint Working Group are as follows.

Standards

The primary role will be to co-ordinate input (including expert's participation in standards development) to international standards to ensure European Regulatory Requirements are met; and, if necessary, to supplement such international standards with specific CEN/CENELEC material.

The proposed Joint Working Group will be concerned with providing adequate standards to enable consistent application of 93/42/EEC as amended by 2007/47/EC to standalone

software – whether or not incorporated into a 'System' as described above. In doing so, it will be seeking to achieve consistency with the emerging international requirements as articulated in, e.g., the Global Harmonization Task Force.

Source of expert consensus

A secondary role will be to provide, under the standards umbrella of the Advisory Board for Health Standards (ABHS) (where both TCs are represented) and in the MDEG regulatory forum (where CEN and CENELEC are represented) input to inform policy and decision-making. In doing so, it will build on the established expertise of the standards committees involved with the development of standards in support of the Medical Devices Directives, using the New Approach, and draw on the health informatics expertise available in CEN/TC 251. The work plan aims to have essential guidance available by the implementation date of the amended MDD, i.e., 21 March 2010.

Role

The role of the proposed Joint Working Group shall be:

- To work within the combined scopes of CENELEC/TC 62 and CEN/TC 251;
- To liaise closely with CEN/CLC/TC 3, Quality management and corresponding general aspects for medical devices[1];
- To work, where the content requires, with other CEN, CENELEC and ETSI TCs, as well as with fora and consortia having specialist expertise;
- To clarify, for the purposes of standards production, and having regard to the New Approach, the understanding of "software used in healthcare" – particularly with respect to the scope of 93/42/EEC as amended by 2007/47/EC;

  NOTE: Ideally an initial report should be ready and available before March 2010 when the revised MDD shall enter into force in the EU;
- To ensure that where appropriate that essential requirements of the MDD are included into standards relating to software in the healthcare domain;
- To harmonize with the risk classification included in the MDD the documents relating to risk and safety classifications for software in the healthcare domain;
- To help produce guidance for both manufacturers and healthcare providers on ensuring patient safety for software in the healthcare domain;
- To coordinate, and appropriately cross-reference, the content of CENELEC/TC 62 and CEN/TC 251 documents relating to health informatics and software in the healthcare domain;

[1] CEN/CLC/TC 3 is a joint TC of CEN and CENELEC. CEN/CLC/TC 3 is the European TC which safeguards that the standards developed in ISO/TC 210 and its WGs are in conformity with the specific essential requirements of the relevant European Directive(s). CEN/CLC/TC 3 has liaisons with CLC/TC 62 and CEN/TC 251.

- To engage with, and contribute consistent European requirements to, international standards work – notably in this context Joint IEC/SC 62A-ISO/TC 210 WG (Medical device software) Joint Working Group 2 and IEC/SC 62A-ISO/TC 215 Joint Working Group 7;
- To provide guidance on managing IT networks upon which software depends in a healthcare environment, to support regulation in this area.

Existing relevant standards

The following European, International, and National standards introduce specific requirements for software – but currently lack a consistent approach to safety in support of 93/42/EEC as amended by 2007/47/EC:

- ISO TS 25238:2007, Health informatics - Classification of safety risks from health software (as a TS not MDD harmonized)
- ISO TR 27809:2007, Health informatics- Measures for ensuring patient safety of health software (as a TR not MDD harmonized)
- ISO/IEC 80001-1, Application of risk management for IT-networks incorporating medical devices (work in progress)2
- IEC TR 80002-1 Medical device software – Guidance on the application of ISO 14971 to medical device software (Approved, at IEC waiting for publication, as a TR no candidate for MDD harmonization)
- EN ISO 14971:2007, Medical devices – Application of risk management to medical devices (MDD harmonized)
- EN IEC 62304:2006, Medical device software – Software life cycle processes (MDD harmonized)
- EN IEC 60601-1-4:1996 + A1:1999, Medical electrical equipment – General requirements for safety – Collateral standard: Programmable electrical medical systems (MDD harmonized)3
- EN IEC 60601-1-6, Medical electrical equipment – General requirements for safety – Collateral standard: Usability (MDD harmonized)
- EN IEC 62366:2007, Medical devices – Application of usability engineering to medical devices (MDD harmonized)

[2] The additional TRs that were discussed in Brussels have been circulated as a question for national committees in IEC with a closing date of September 4. They should be on the agenda for ISO/TC 215 in October.

[3] EN IEC 60601-1:2005 Medical electrical equipment – General requirements for basic safety and essential performance. (60601-1-4 was incorporated into the main standard in the 3rd edition. 60601-1-4 may be used with the 2nd edition of 60601-1 until the second edition it is withdrawn (2012?), then -1-4 will be obsolete. 60601-1:2005 has been listed, so at present either may be used to demonstrate conformance to the essential requirements.

- EN IEC 62274, Medical electrical equipment - Safety of radiotherapy record and verify systems (not MDD harmonized)
- IEC 62083, Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems (MDD harmonized)

Other standards, not identified above, may also be found to have relevance.

Timescale and process

Process

The Joint Working Group will initially be set up for a period of two years, and will then be evaluated jointly by the founding TCs. The JWG will be disbanded when adequate guidance and standards are available.
The following scheme for the leadership of this Joint Working group has been proposed:

	Chair and lead-TC	Co-chair
Year 1	CLC/TC 62	CEN/TC 251
Year 2	CEN/TC 251	CLC/TC 62