Symposium on using IEC standardization work to support medical device regulation

Report and recommendations

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1. Abstract

A symposium at the IEC General Meeting in Shanghai explored the scope for closer collaboration between IEC standards developers and regulators responsible for medical devices. The 30 participants included regulators, national standards bodies, standards developers, conformity assessment specialists and industry experts.

Katharine Fraga, Head of IEC Membership, Governance and Strategy, opened the symposium. She underlined the important contribution made by international standards to safety, consumer confidence and global trade. Ms. Fraga described IEC Standards as a valuable tool for public policymakers that contributed to harmonization of policy at the regional and international levels. She added that when IEC standards were the basis of the technical regulation, companies in the regulator's country could be more competitive at the global level too.

The Secretary of IEC Technical Committee 62: Electrical equipment in medical practice, Norbert Bischof, and the Vice Chair of IECEE (the System of Conformity Assessment Schemes for Electrotechnical Equipment and Components), Steve Margis, also took part.

IEC technical committees have been developing international standards for the safety and performance of electrical equipment used in medical practice for more than 50 years. A number of TCs carry out work covering both medical electrical equipment and medical electrical systems. IEC TC 62 develops international standards and other publications for electrical equipment in medical practice. The best known publication of TC 62, the IEC 60601 series, has become a widely accepted benchmark for medical electrical equipment around the world.

IECEE ensures that the standard is properly implemented and that devices meet expectations in terms of compliance with identified IEC standards. IECEE certification is based on the principle of mutual recognition by its members. It plays an essential role in facilitating international trade and allowing access to the marketplace for vendors, retailers and buyers.

Scott Colburn of the USPHS, the part of the US Food and Drug Administration that deals with medical devices, represented the International Medical Device Regulators Forum, a voluntary group of regulators from around the world.

The speakers agreed that international standards benefitted both industry and regulators but that more work was needed to optimize collaboration.

2. Background and objectives

2.1 Background

IEC and IMDRF signed a Memorandum of Understanding in 2018 to exchange strategic information and technical expertise regularly in the area of medical devices. The symposium was a consequence of the agreement.

2.2 2.2. Objectives

The goal of the event was to increase dialogue between standards makers, industry players and regulators to achieve greater understanding about the opportunities to use IEC work to support harmonization of regulatory requirements around the world. In addition, the symposium was designed to help regulators have greater appreciation of how they can be involved in IEC work to ensure standardization work takes their needs into account.

3. Summary of presentations

3.1 Katharine Fraga – Head, IEC Membership, Governance and Strategy

The IEC provides a global knowledge platform where around 20 000 experts represent the electrotechnical needs of their national stakeholders around the world. Experts working in more than 200 technical committees and subcommittees develop the technical specifications, measurement and rating methodologies that allow millions of electrical and electronic devices and systems to work together safely and efficiently everywhere.

International standards make an important contribution to safety, consumer confidence and global trade. IEC Standards are a valuable tool for public policymakers that contribute to the harmonization of policies at the regional and international levels. When IEC standards are the basis of technical regulation, companies in the regulator's country can be more competitive at the global level too.

Standards provide recognized solutions and have a high degree of acceptance. They are cost effective and continuously updated. They reduce the time to market and minimize unnecessary barriers to trade.

IEC and ISO developed the briefing paper Using and referencing IEC and ISO standards to support public policy to help regulators glean the maximum benefits from using international standards. This includes using IEC and ISO standards in legislation or regulation as well as to support public policy decisions or actions. The publication includes several case studies.

Standards provide even more value when they are combined with conformity assessment, which covers testing and certification. The IEC Conformity Assessment Systems are a framework of common rules and methodologies that ensure consistent results from anywhere in the world.

IEC and ISO cannot offer their standards free of charge because the development costs are substantial and ongoing. These include the cost of programme management, document distribution and tools for committee management, voting and collaborative working, as well as supplying information and providing technical, editorial and publishing expertise to their committee experts and national members. Much of these costs are funded through the sale of standards.

There are good reasons for regulators to participate in standardization work, including the ability to influence the development of standards or conformity assessment. Participation also gives access to technical resources, communication and networking with peers in industry.

3.2 Scott Colburn – Captain, USPHS and Chair, International Medical Device Regulators Forum Standards Working Group

The IMDRF is a voluntary group of regulators from around the world. Their mission is to accelerate international medical device regulatory harmonization and convergence. IMDRF members include medical device regulatory authorities in the following countries:

- Australia - Therapeutic Goods Administration
- Brazil - National Health Surveillance Agency (ANVISA)
- Canada - Health Canada
- China - China Food and Drug Administration
- Europe - European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
- Japan - Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour and Welfare
- Russia - Russian Ministry of Health
- Singapore - Health Sciences Authority
- South Korea - Ministry of Food and Drug Safety
- United States - US Food and Drug Administration

The IMDRF is strengthening its relationship with IEC and ISO. It values the ability to influence international standards that are conditions for international trade and have a direct impact on competitiveness and national priorities. It is beneficial to take part in the development of standards that may be adopted by regulators or affect regional and national regulatory policies.

The IMDRF believes in the importance of promoting the development of standards that facilitate and shape innovation in ways that are advantageous to public health, as well as initiating relevant new standards. Engaging with a wide range of stakeholders at both the domestic and international levels makes it possible to build relationships and partnerships of mutual benefit. Regulatory participation in IEC work provides opportunities for technical and policy discussions with industry experts, NGOs and international counterparts.

Work still needs to be done to ensure that the concerns of regulators are taken on board at the start of the standards development process. Although regulators generally accept the use of standards, this masks differences in degrees of acceptance. The remedy is to communicate with regulators early and often. Early involvement gives regulators the assurance that standards developers are listening, while also helping them to develop relevant and effective regulations. In the end, this makes it more likely that they will make direct use of the standard.

Transparency is a key issue. In order for regulators to be more engaged, they require easier access to information, such as the make-up of the technical committees developing the standards. For instance, it is crucial for regulators dealing with medical devices to know how many clinicians are involved in developing the standards. Improving this kind of knowledge will boost acceptance.

3.3 Steve Margis – Vice Chair, IECEE (IEC System of Conformity Assessment for Electrotechnical Equipment and Components)

IEC conformity assessment services provide a framework that instils trust in the marketplace. IECEE covers 23 categories of electrical equipment and testing services, from batteries, cables and cords, energy efficiency and industrial automation, to office equipment, power tools and electric toys. IECEE conformity assessment schemes offer certification services in accordance with published IEC standards as well as the nationally declared differences for electrical and electronic components, devices and equipment for homes, offices, workshops and health facilities. IEC conformity assessment provides the added value to regulators that, unlike other conformity assessment schemes, it is based on the principle of peer assessment.

Peer assessment ensures competence, consistency and mutual confidence. Conformity assessment bodies around the globe, such as certification bodies and testing laboratories, carry out the work. The fundamental value that the IECEE creates is consistent and comparable conformity assessment results from anywhere in the world. This facilitates trade by eliminating duplication of testing and facilitates market access around the globe in a quicker and more cost-effective manner.

The compliance of medical devices is of critical importance. Other important considerations therefore include cyber security, functional safety and personnel competence. Functional safety is about reducing the level of risk in a device or system. One of the focuses of IECEE is the IEC 61508 series, which provides functional safety standards for the lifecycle of electrical, electronic or programmable electronic systems and products. The IEC is the only organization in the world to provide an international and standardized form of certification which deals with cyber security. The IECEE Industrial Cyber Security Programme focuses on cyber security in accordance with the IEC 62443 series of standards. In addition, the IECEE is developing a conformity assessment market solution to have personnel qualified for their understanding of IEC standards and principles utilized in the IECEE for conformity assessment services.

3.4 Norbert Bischof – Secretary IEC TC 62: Electrical equipment in medical practice, SC 62B and SC 62C

IEC TC 62 was established in 1968. Twenty-nine countries take part in TC 62, while another 20 have observer status. It has four subcommittees and 85 working groups that deal with very distinct domains. It counts 1481 experts from the medical professions (clinicians?), industry, healthcare establishments, IT and software development, as well as regulatory bodies.

International standards that TC 62 and its SCs develop also refer to and use standards from many other IEC TCs and SCs. At the same time, other IEC and ISO TCs use and reference TC 62 standards. The four SCs are:

- SC 62A, covering common aspects of electrical equipment used in medical practice. SC 62A formed a joint working group with ISO to work on the first standard addressing both IT networks and medical devices. IEC 80001-1 enables electric medical devices and IT networks to work better with each other and help to prevent a number of potentially hazardous incidents for patients and equipment operators occurring. It also helps to secure medical data and to its collection, storage and distribution.
- SC 62B prepares international publications on safety and performance for all kinds of medical diagnostic imaging equipment such as X-ray imaging equipment, computed tomography and magnetic resonance imaging, including related associated equipment and accessories.
- SC 62C covers equipment for radiotherapy, nuclear medicine and radiation dosimetry.
- SC 62D covers electromedical equipment and equipment used to diagnose, monitor and treat patients, or used as an aid in their treatment. This includes, for instance, hemodialysis, hemodiafiltration and hemofiltration machines, electrocardiographic monitoring equipment and nerve and muscle stimulators as well as luminaires for surgery and diagnosis, and operating tables.

The best known publication of TC 62, the IEC 60601 series, has become a widely accepted benchmark for medical electrical equipment around the world. IECEE, the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components, ensures that the standard is properly implemented and that devices meet expectations in terms of performance, safety and reliability.

National differences in regulations represent a major cost for manufacturers. Although one international standard for all is not always possible because of specific factors such as climate, the number of differences should be kept to a minimum.

4. Recommendations

4.1 For IEC:

- National Committees should increase outreach to regulators and explain the value proposition of participating in IEC work and how to participate
- Regulators often want to understand what constitutes the international voice: consider making it transparent which stakeholder groups are represented in the work
- Demonstrate the cost savings that IEC can provide for regulators
- Identify and analyze successful case studies of regulator involvement in IEC work to replicate the success in other areas

4.2 For regulators:

- Get involved at the start of the process to optimize the benefit of your participation
- Define needs clearly so that standards can be developed to address those needs

5. Conclusions

The exchanges at the symposium suggest that there is ample scope for improving the effectiveness of collaboration between regulators and standardization experts. Participants identified inefficient communications and limited transparency as key hurdles. The speakers agreed that stakeholders needed to share knowledge about new technologies, as early as possible in order to facilitate more effective collaboration. The regulators taking part in the symposium underlined the benefits of using IEC work to support the harmonization of regulatory requirements but said there should be more opportunities for involvement in standardization activities at an earlier stage, in order to ensure that new standards met their needs. Earlier involvement would also make it easier to incorporate standards into national and regional regulations.