Achieving Goals via the Politics of International Standards

Background

In 1992, the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturer's Association (NEMA) jointly published *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*, colloquially known as the Output Display Standard (ODS). All major manufacturers modified their new products to meet the requirements of the standard and by 1994, over 90% of new diagnostic ultrasound equipment was in compliance with ODS.

The AIUM/NEMA effort was initiated in the U.S. with the intent to address U.S. law and the result was a domestic standard – even though both AIUM and NEMA were international organizations with professionals and companies from several countries.

Problem

Because the AIUM/NEMA standard was considered a U.S. standard by the International Electrotechnical Commission (IEC), the European standards bodies took a different path by establishing Ultrasound Technical Committee (TC87). IEC TC87 was assigned the safety responsibility for medical ultrasound and in 1992, published IEC 1157, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*, later renumbered IEC 61157. And while this standard was never integrated into the fledgling European Union "New Approach" Directive system, its proponents were able to find a German insurance company that was willing to require it for the purposes of reimbursement.

Emboldened by their success with IEC 61157, TC87 embarked on their own set of safety classification standards for diagnostic ultrasound equipment. Proponents of ODS encouraged TC87 to simply adopt ODS since it was already well towards universal implementation. But because ODS was not a European standard, the TC87 leadership rejected the request. Subsequently, the proponents of ODS then made the same proposal to IEC TC62, Electrical equipment in medical practice, where the proposal was accepted. TC62 created Subcommittee 62B (SC62B) and was tasked with drafting and publishing an IEC version of ODS as a particular standard of the 60601 family.

The stage was now set for an epic battle within IEC: two TCs developing incompatible standards on the same topic with the manufacturers caught in the middle.

Approach

In 1994, the U.S. sponsored a meeting of TC87 in San Francisco, CA. Because the project leader of SC62B happened to live in the area he held a project team meeting at the same time. Attendees quickly learned that the TC87 projects were completely different from the already accepted and implemented ODS, and industry objections to the TC87 standards were being patently ignored. On the other hand, the more desirable (to industry) SC62B version of ODS was stumbling along driven by a weak project leader. If both standards were to pass,

manufacturers would have to implement two conflicting safety control methodologies at considerable cost, incomprehensible confusion by the users, and no improvement in the actual safety of the products – essentially a complicated and confusing system that would cost more and provide no additional benefit to the customer or their patients.

It was this meeting in San Francisco that drove industry to get actively involved in the TC87 standards development process. An industry expert from one of the major manufacturers became an active participant and a U.S. delegate to both TC87 and SC62B attending every relevant meeting from then on. This active participation in two very differently run TCs allowed the expert to learn about the IEC process, how to lobby, and what it takes to pass and defeat a standard.

In anticipation of the intent to publish the first Committee Draft for Vote (CDV) of the TC87, the industry expert volunteered, with the backing of his company, to sponsor the TC87 plenary and Working Group (WG) meetings in Seattle, WA in the fall of 1999. By that time, he had managed to establish himself as a reliable participant and was fighting strongly, with other sympathetic industry participants, against the TC87 standards.

By the end of the Seattle meeting, the industry representatives succeeded in changing key wording in the classification standard. But to their surprise, when the CDV was published, the TC Chairman had changed the relevant text back to the unacceptable wording that had been negotiated out. Pleas to correct this went unheeded and the CDV was published with the offending text in place.

Outcome

In 1999, a large, multi-national corporation acquired the manufacturer where the industry expert worked. Upon merging, the new company made contact with their Europe counterparts and quickly discovered that the new, larger company was a major player in IEC activities with many colleagues in key positions within the IEC community.

With a concerted lobbying effort of both European and non-European national committees, the defeat of the CDVs of the TC87 standards was attained by a total of one vote. As a result of this success, a similar lobbying effort was initiated to have the TC62 safety question resolved by the Standardization Management Board (SMB). This effort was also successful in favor of TC62.

The crisis passed, the SC62B standard was published (IEC 60601-2-37, *Medical electrical equipment*), and the TC87 classification standards vanished from the scene.