Role of Standards in the Assessment of Medical Devices

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Summary

Important national and supranational regulatory systems for medical devices utilize product and process oriented standards. For these legal codes standards are a possibility to cope with the high demands on technical and scientific expertise in the regulation of medical devices. Standards are also easier to update and can follow the high rate of innovation more efficiently than governmental regulations.

Two approaches of utilizing standards – harmonised standards in the legal system of the EU and recognized standards in the systems of Australia, Canada and the US – are explained and commented. This use of standards has proved itself as being beneficial for all parties involved. However, this use of standards can still be improved. Global standards should be directly engaged in the processes leading to improved and extended use of standards in the regulation of medical devices.

Introduction

I have borrowed the title of my presentation from a document that Study Group 1 of the Global Harmonisation Task Force has published. The parties working together in the GHTF – regulators from industrialised countries and representatives of major medical devices companies and conformity assessment bodies – have a vivid interest in standardisation.

But let me first turn to regulations.

The regulation of medical devices is a difficult business.

On the one hand many medical devices are high risk products that often are used in situations where the lives of individuals and even populations are at stake. Their regulation has to take safety and efficiency aspects carefully into account, and they have to be comprehensive and precise.

On the other hand medical devices cover an extremely wide spectrum of technologies ranging from heavy duty engineering to nanotechnology, and utilising materials from biological preparations to high-tech alloys. To regulate products with such a diverse technical basis requires a considerable breadth of expertise, and it is difficult for a single agency to provide that breadth. At the same time the rate of innovation in medical devices technologies is high. Any detailed prescriptive regulation may quickly be outdated by new developments and can easily become an obstacle to the provision of state of the art products to the public.

EU New and Global Approach Directives

Governmental administrations have increasingly realised this dilemma and sought solutions to it. One consistent solution is the New and Global Approach of the European Union. In this approach the legislation abstains from detailed specifications for the devices in question. Instead, essential requirements for the safety and efficiency of these devices are described in a very broad and general way. In parallel, requirements for a documented quality management including a risk management and post market surveillance system ascertain that those essential requirements are consistently fulfilled. The

essential requirements demand a very high level of safety and efficiency. How this level of safety and efficiency can be attained, however, is left open by the legal text.

The very general character of the essential requirements, and of the requirements for quality management systems, makes them independent from technical and scientific progress and enables regulators to formulate them without much detailed expertise. In addition, general essential requirements and general requirements for quality management systems allow many different ways of complying with them. A New and Global Approach Directive thus does not inhibit technical progress or innovative approaches to solve a known problem. Manufacturers are able to realize new developments and new combinations of known technologies in their products and processes.

At the same time they must demonstrate conclusively that their products satisfy the essential requirements and their processes those of an acceptable quality management system. That puts an enormous burden on the documentation manufacturers must keep, and can easily lead to unproductive and bureaucratic demands. It also creates an unacceptable degree of legal uncertainty: what is good enough to fulfill the regulatory demands, where is the borderline between safety and efficiency necessities and economical feasibilities? To guarantee legal certainty and to limit the burocratic burden New and Global Approach Directives devise the system of “harmonized standards”.

Harmonized Standards

Harmonized standards are European Norms (EN) that are elaborated by the European standardization bodies (CEN, CENELEC, ETSI) under a mandate from the European Commission. The Commission specifies certain essential requirements within a given directive that have to be set out in greater detail. It subsequently mandates and partially finances the development of standards that specify these details. Once CEN, CENELEC or ETSI have carried out a Commission mandate and developed the respective standard this standard will be reviewed. If it is found acceptable, a reference to it will be published in the Official Journal of the European Communities and the standard thus “harmonized”. New and Global Approach Directives also devise mechanisms by which the harmonization can be revoked and the revision of such a standard be initiated.

Manufacturers can use the harmonized standards to reduce their investment into design and documentation costs: It will suffice to follow and demonstrate compliance with the respective harmonized standard instead of looking for new solutions to comply with a certain essential requirement and to give a detailed account of how the requirement has been met. Compliance with a harmonized standard has to be accepted by conformity assessment bodies and regulatory authorities as proof that the essential requirement the standard relates to are satisfied. Conformity assessment bodies will check if that standard actually is adhered to, and regulatory authorities likewise will look for compliance with standards when they examine the technical documentation of a product. In the absence of harmonized standards the manufacturer may use other technical standards, but in this case the scrutiny of conformity assessment bodies and regulatory authorities certainly will be greater.

The use of standards, on the other hand, is voluntary. A manufacturer actually can avoid a standard, even an existing harmonized standard, and realize his very own design. In this case, however, the technical documentation will have to demonstrate in great detail that the product satisfies the essential requirements.

The advantage of specifying how to comply with the essential requirements in harmonized standards is obvious:

1. Standards are elaborated by experts in the respective field of technology. These experts should represent the three parties in the market – manufacturers, users and competent authorities – to ascertain that no interest group outvotes the other parties and the biases of an “easy way out” (manufacturers), unrealistic expectations (users) and excessive demands (competent authorities) can be avoided.
2. Essential requirements require that the solutions adopted by the manufacturer to conform to safety and efficiency principles take the generally acknowledged state of the art into account. Given the

rapid progress of medical technology this requirement would demand frequent revisions of the essential requirements if they would include technical details. It takes much effort and time to change a directive to reflect the state of the art. Standards, on the other hand, can fairly easily be updated. This gives the system an unprecedented flexibility.

3. Standards make it possible to apply essential requirements in a uniform way.

Recognized Standards

The European approach is not totally unique or new. Medical devices authorities like the FDA in the US, the MDB in Canada and the TGA in Australia are using the concept of "recognized standards". In the US, as an example, the use of standards follows the principle of the "least Burdensome Approach" laid down in the FDA Modernization Act of 1997. Such standards have to be issued by a (national or international) standards body that satisfies certain conditions in terms of transparency of its development, consensus of its acceptance and compliance with the laws. Specific FDA committees will review them and evaluate if they are appropriate. Subsequently they will be recognized by publishing, in the Federal Register, their reference as well as the devices and regulations they refer to.

An important difference between US and Canadian recognized standards and European harmonized standards is the fact that in these systems a regulatory authority can not mandate or otherwise initiate the development or revision of a standard. We probably can assume that ANSI, NCCLS or other US standards bodies will react quickly if the FDA establishes the need for a certain standard, but a formalized mechanism that guaranties a high level of legal certainty does not exist.

Even more important is the legal weight of harmonized versus recognized standards: at least in the US concept compliance with these standards does not necessarily have to be accepted, by the FDA or by conformity assessment bodies, as proof of compliance with the respective parts of the Code of Federal Regulations. The authorities may still request extended documentations.

The non-European systems, on the other hand, are liberal in accepting any kind of standard as recognized, provided it has been developed in an acceptable manner and it is good enough to satisfy the intended purpose. European harmonized standards, by contrast, have to be "European Norms (EN)". An ISO standard can easily become a recognized standard in the American, Australian or Canadian, but not in the European system.

Future Developments

Regulators, conformity assessment bodies and industry have for a long time realized the value of recognized and harmonized standards versus rigid and narrow regulatory specifications. As a result the Global Harmonization Task Force (GHTF) where the three parties work together has developed an important guidance paper, the title of which I have stolen for this presentation. The purpose of this paper is to guide regulatory bodies to a safe, efficient and economical, in short a reasonable use of standards in their regulation.

However, there are things that neither the GHTF nor regulators, conformity assessment bodies and industry can not cover:

1. the suitability of standards for their scientific, technical or process oriented purpose;
2. the independence of standards from particular manufacturer or user interests;
3. the global validity and acceptance of standards.

These are demands that the standards bodies will have to respond to. Some of them will be fairly easy to deal with:
I don't think, for instance, that the technical quality of standards issued by the major global, regional or national standards bodies really presents a problem. There are occasional shortcomings, IEC 60601-2-38 (Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds) was such a case where the safety against ignition was not sufficiently covered. But

mechanisms exist by which such standards can be submitted to a more or less urgent review and insufficiencies can be corrected with some efficiency.
To avoid the predominance of particular interests is a more critical issue: ISO/IEC/UTI Directives demand equilibrium of the parties involved in the development of standards. This equilibrium is rarely attained: user organizations and regulatory agencies often lack the funds to attend meetings. Technical Committees try their best to reduce the need for meetings by the use of electronic media and telephone conferences, but there is a limit to those possibilities: in a multilingual environment non-verbal communication is essential to create the mutual confidence that is vital for consensus processes. If standards bodies want to achieve a true equilibrium between the parties involved they will have to work on mechanisms that will allow a wider and more equilibrated participation in the standards development process than today is generally the case.
Global validity is a tough demand to respond to. True, ISO/IEC/UTI standards are global by definition, but they do not count in the system of harmonized standards of the New and Global Approach of the European Union. The Vienna (ISO/CEN) and Dresden (IEC/CENELC) Agreements facilitate the transposition of a standard from the global to the European system and vice versa. However, a truly global approach should avoid those auxiliary processes that add time, cost, bureaucracy, and, worst of all, uncertainty, to the development of standards. Global standards bodies should take the initiative to get directly involved in resolving this question.

There is work to be done by the global standards bodies. This work will profit all parties: it will make global compliance with government regulations much cheaper and more easily calculable for manufacturers, it will make the global surveillance of the performance of products much easier and efficient (think only of a country like Switzerland: a population of 7mio residents is a fairly small statistical basis for the surveillance of the safety of a device; if that basis can be extended to a population of more than 700mio – Switzerland plus the Australia plus Canada plus the EU plus the US – the surveillance will be incredibly more effective) and it will make medical devices safer and more efficient for the treatment of patients.

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[i] DeSain C and Sutton CV, *Risk Management Basics,* Cleveland OH, Advanstar Communications, 2000