

Ensuring Safety and Efficacy through ISO 14971? Or “ Much Ado about Nothing “?

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Abstract

ISO 14971: Medical Devices — Risk Management — Application of Risk Management to Medical Devices is the definitive world standard for medical devices and is a key element in the regulation of medical devices for assurance of safety and effectiveness. More significantly it is increasingly integrated with, and utilized by, numerous other technical medical device standards. This has helped to ensure the safety and efficacy of medical devices world wide...

The provision of safe and effective devices for patients and health care users is the basis for standards and regulations for medical devices the world over. To this end, work on the standard, ISO 14971: Medical Devices — Risk Management — Application of Risk Management to Medical Devices was initiated about a decade ago. Starting with basic risk management concepts that have been developed over the past 400 years it was adapted to meet the needs of the medical devices sector and it has become the definitive standard for medical devices throughout the world. The standard has been approved as a European Norm, a Japanese Industrial Standard, as well as a national standard in other countries. Currently international medical devices regulatory bodies incorporate requirements that are either included in that standard or are consistent with the standard, thereby, effectively mandating the standard. Thus ISO 14971 has very quickly become the world wide standard for risk management for medical devices and is a key element in the regulation of medical devices for assurance of safety and effectiveness and is essential for all manufacturers of medical devices.

The two issues that drove the initial development of this standard were improper use of risk concepts and technology. First the importation of risk concepts into medical device standards and regulations was inconsistent and inaccurate. Terms such as risk control, risk analysis, risk assessment, hazard analysis were all used interchangeably even in regulations intended to define safety and effectiveness of medical devices. The first task then was to adopt recognized definitions such as used in Guide 51 and to apply them appropriately to the medical devices field.

Secondly, for some forty years particular medical device product standards have implicitly identified hazards associated with a particular device and have, if the risk of harm developing from that hazard was considered significant, incorporated requirements within the standard to prevent that harm from occurring. Requirements for leakage current limitations on medical devices or the requirement for gas specific connectors on breathing circuits are examples. This has been highly successful. However, as the complexity of the interaction of medical devices in the patient environment has increased and as the technological sophistication of medical devices have increased, there has been recognized a need for a more comprehensive risk management approach for medical devices. It is no longer possible to address hazards one technical standard at a time. Recently the Health care Technology Task Force of the World Standards Cooperation further emphasized this point, strongly supporting the risk management approach for medical device standards.

That increased complexity, coupled with wide recognition among standards development committees that there is no absolute certainty of safety, demands that the concept of risk must be addressed in technical standards. Indeed, some aspects of safety can be addressed only through a risk management approach.

ISO 14971 was designed therefore, as a management standard covering all medical devices over the entire life cycle of the device. Management responsibility is identified as the initial—and the key— requirement for successful management of risks. The senior management of the manufacturer is required to:

- establish a risk management process, which includes defined elements, including risk analysis risk evaluation, risk control, and post production monitoring;
- provide adequate resources for the risk management team;
- establish a policy that identifies acceptable risk levels;
- provide appropriate personnel to carry out the process; and
- review the process on a regular basis.

As the medical device risk management which affects all medical devices worldwide, harmonization in the application of ISO 14971 as the standard has developed rapidly through both standards and international regulatory activity. Currently international medical device regulatory bodies incorporate requirements that either are included in 14971 or are consistent with 14971. In international standards, ISO 14971 has been

incorporated or integrated either in whole or in part throughout a wide variety of medical device standards. This is arguably the most efficient and effective method of harmonizing risk management concepts for medical devices and covers the spectrum from medical electrical equipment to heart valves.

My contention is that ISO 14971 in becoming the worldwide standard for risk management for medical devices has helped to ensure the safety and efficacy of medical devices rather than being “much ado about nothing.”

Biography

Professor Dolan's is COTA Fellow at Virginia Polytechnic Institute and State University and Samuel Lunenfeld Professor, University of Toronto, where he is coordinator of the Clinical Engineering Program. For many years, his research had been involved with the defibrillation and artificial heart field as well as with the technology of cardiovascular surgery and intensive care. More recently, Prof. Dolan has begun to consider the problem of technology evaluation and effectiveness.

Dr. Dolan's long standing involvement in international standardization for more that two decades now includes chairing the working group (WG) of the International Standards Organization (ISO), which is addressing risk management issues, including risk assessment, risk estimation, risk control and risk analysis for medical devices and is responsible for ISO 14971 *Medical devices – Risk management for medical devices*.