

## Medical devices

Harmonizing  
quality  
management  
requirements

1. Ensuring worldwide quality for medical devices
2. Quality management and the medical field – A comparison between ISO 9001:2000 and ISO 13485
3. Risk management and medical devices

# 1 Ensuring worldwide quality for medical devices



By Elizabeth A. Bridgman and Hillary Woehrle, Secretariat of ISO/TC 210, *Quality management and corresponding general aspects for medical devices*

*Broadly, ISO/TC 210, Quality management and corresponding general aspects for medical devices, defines its scope as:*

*“Standardization of requirements and guidance in the field of quality management for medical devices.” The field is extensive and rapidly evolving through technological advancements, and the demands run high for medical devices to aim for the utmost in quality for health and safety. But not all national quality systems are the same, and medical devices are highly regulated in virtually all markets. International Standards can help in a number of ways.*

*The authors describe how ISO/TC 210 is undertaking the development of standards with the goal of ensuring quality worldwide for medical devices, and specifically two major thrusts of activity: the global harmonization of quality system requirements and risk management.*

Increasingly, national regulatory oversight of the supply of medical devices includes as a major component an obligation for manufacturers to establish and implement a quality management system. ISO/TC 210’s strategic objectives are to provide a focus for an understanding of the role and application of quality management and the corresponding general aspects of quality principles in standards and guidance required by regulatory authorities and manufacturers. The technical committee seeks to develop standards and guidance for quality management and the corresponding general aspects of quality principles for medical devices that will effectively address the needs of regulatory authorities and manufacturers, as well as to utilize ISO processes to achieve consensus

and compatibility with other ISO/IEC quality management and corresponding general aspects standards. Furthermore, the goals of TC 210 are to protect health and safety, to eliminate trade barriers, and to promote global harmonization.

**“In some regulations, the standards are referenced as requirements.”**

A major effort is being made to harmonize quality system related requirements, globally, using International Standards as the basis for national or trade bloc regulations. Standards concerned with quality systems for medical device manufacturers are intended to be applicable to a



number of countries or regional trading blocs whose regulations reference or call up such requirements. In some regulations, the standards are referenced as requirements. As ISO/TC 176 has revised the ISO 9000 series of standards, the ISO/TC 210 equivalent series must also be revised. ISO 13485, *Quality systems – Medical devices – System requirements for regulatory purposes*, is considered fundamental to encouraging and supporting the global harmonization for medical devices worldwide.

**“Device manufacturers seek to minimize the costs of labelling by reducing or rationalizing labelling variants and achieving international agreement on symbols that can be used in labelling...”**

Risk management is another of the elements of national or regional medical device regulation which has been addressed by TC 210. In this case, the work is carried out in a joint working group with IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*, and the resulting standard ISO 14971, *Medical devices – Application of*

*risk management to medical devices*, carries the logos of both ISO and IEC and has been approved by CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) as well.

Device manufacturers seek to minimize the costs of labelling by reducing or rationalizing labelling variants and achieving international agreement on symbols that can be used in labelling, regardless of the native language of the markets where products are sold. TC 210 has fostered this by producing the symbols standard ISO 15223. And, in cooperation with CEN, ISO/TC 210 has adopted the Global Medical Device Nomenclature (EN ISO 20225) to facilitate exchange of regulatory information.

In addition to the collaboration with IEC (International Electrotechnical Commission), CEN, CENELEC and various ISO committees, ISO/TC 210 has established a Memorandum of Understanding (MoU) with a Global Harmonization Task Force (GHTF), a voluntary group of representatives of medical device regulatory authorities and the regulated industry that was formed some 10 years ago to respond to the growing need for international harmonization in the regulation of medical devices.

The Association for the Advancement of Medical Instrumentation (AAMI) administers the US Secretariat of ISO/TC 210 on behalf of ANSI (see box opposite). □

## Who administers ISO/TC 210?

The Association for the Advancement of Medical Instrumentation (AAMI) administers the US Secretariat of ISO/TC 210 on behalf of ANSI. Founded in 1967, AAMI is a unique alliance of nearly 6 000 members united by a common goal to increase the understanding and beneficial use of medical instrumentation. AAMI is the primary source of consensus and timely information on medical instrumentation and technology; and serves as an education resource for those who manufacture, sell, service, and use medical instruments. Through its technical committees and working groups, AAMI develops and revises national and international standards for the manufacture, use, and maintenance of medical devices. For some 15 years, AAMI and its members have been strong advocates of global harmonization of medical device standards through ISO and IEC. Among AAMI's major standards activities are the ISO/TC 210 and IEC/SC 62A secretariats as well as the secretariats of ISO/TC 198, *Sterilization of healthcare products* and IEC/SC 62D, *Electromedical equipment*. Visit [www.aami.org](http://www.aami.org) for a complete overview of AAMI's role in medical device standards and the other services AAMI offers to the medical technology community worldwide.



*ISO 13485, Quality systems – Medical devices – System requirements for regulatory purposes, is considered fundamental to encouraging and supporting the global harmonization for medical devices worldwide.*

# 2 Quality management and the medical field

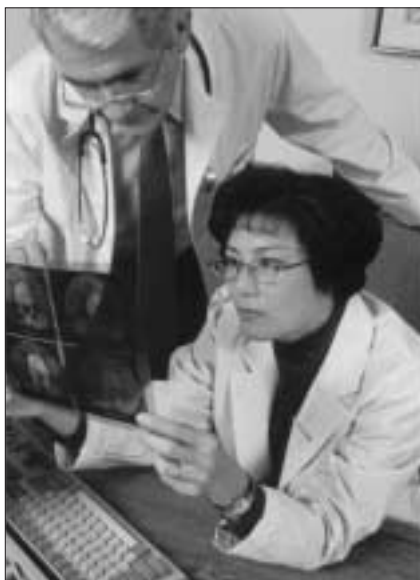


## A comparison between ISO 9001:2000 and ISO 13485

By Ed Kimmelman<sup>1)</sup>

*This article discusses the key contents of ISO/DIS 13485:200X, Quality systems – Medical devices – System requirements for regulatory purposes, the revised quality management system standard for the medical device sector; and relates its contents to that of ISO 9001:2000, the newly revised generic quality management system standard. It outlines medical device sector quality management system issues created by ISO 9001:2000, and recommends courses of action for individual medical device organizations as they review, and possibly, revise their quality management systems to deal with evolving customer and regulatory requirements.*

Organizations in the medical device sector (i.e. product or service providers) are confronted with a variety of relevant quality management system standards that are intended to satisfy organization, customer, and regulatory agency objectives.



These standards are embodied in:

**Regulations** (e.g., the US Quality System Regulation and the Japanese Good Manufacturing Practices Regulation) and

**International Standards** (e.g. ISO 9001 and ISO/DIS 13485), that have been incorporated directly into regulations or have been voluntarily adopted by medical device manufacturing organizations.

### The organizations involved

According to ISO Technical Management Board (TMB) policy, ISO/TC 176, *Quality management and quality assurance*, has the overall responsibility to manage the development of quality management system standards. Consistent with that policy, ISO/TC 176 has overseen the devel-

opment and revision of the ISO 9000 series of standards.

The ISO/TMB has, however, recognized that the medical device sector, due to its heavy regulation worldwide, may require the establishment of standards that are targeted specifically at the sector. As a result, the ISO/TMB approved the creation of ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, to manage the development of medical device sector-specific documents, with the understanding that ISO/TC 176 would still maintain primacy related to quality management system standards in general. One of the key overall objectives of ISO/TC 176 is to avoid the proliferation of sector-specific quality management system standards.

**“The medical device sector, due to its heavy regulation worldwide, may require the establishment of standards that are targeted specifically at the sector.”**

**The Global Harmonization Task Force (GHTF)** is an organization made up of representatives from medical device regulatory agencies in many of the industrialized countries, along with representatives from the medical device industry. The Study Group 3 of the GHTF

1) Consultant, Regulatory affairs/compliance, Quality management systems, Wilmington, USA and Convener, ISO/TC 210/WG 1, Application of quality systems to medical devices.

has succeeded in harmonizing the regulatory quality management system requirements in the major markets around the world and is working to promote their work to other countries.

The basis for the GHTF agreement on quality management system requirements is ISO 13485:1996. While the quality management system regulations in the individual GHTF countries may not follow the format of ISO 13485:1996, the substance of the requirements is consistent with that found in this standard.

**ISO/TC 210 working group 1** is charged with the responsibility to develop international quality management system standards for the medical device sector. It has developed three standards:

- ISO 13485:1996, *Quality systems – Medical devices – Particular requirements for the application of ISO 9001*
- ISO 13488:1996, *Quality systems – Medical devices – Particular requirements for the application of ISO 9002*
- ISO 14969:1999, *Quality systems – Medical devices – Guidance on the application of ISO 13485 and ISO 13488*.

### **ISO 13488 will be withdrawn**

ISO/TC 210 has decided to follow the ISO/TC 176 “applications” approach, and to withdraw ISO 13488, the former equivalent to ISO 9002, *Quality systems – Model for quality assurance in production, installation and servicing*.

The European Community has developed an approach for applying the new version of ISO 9001 to the conformity assessment requirements of the various New Approach directives. They have documented that approach in the foreword of EN/ISO 9001:2000. A similar foreword will be included in EN/ISO 13485:200X.

### **What will happen to ISO 14969?**

ISO 14969 is a standard that provides guidance on the application of ISO 13485. Because ISO/TC 176 has decided to eliminate ISO 9000-2, ISO/TC 210 will repub-

lish ISO 14969 as a stand-alone Technical Report (TR), following the same organizational structure as ISO/DIS 13485. ISO/TR 14969:200X will contain much of the same guidance as in the 1999 version of this document, and it will contain more detailed guidance related to quality planning, design and development, and process validation.

The titles of these standards reflect the fact that they are based directly on the 1994 versions of the ISO 9000 series of standards, both in content and format. For example, essentially all of the requirements of ISO 9001:1994 are carried over to ISO 13485:1996, with the addition of particular requirements that are relevant to all medical devices or to some classes of medical devices. Many of these particular requirements come directly from existing regulations.

**“There is now general agreement that the needs of the medical device sector would be best served by a separate quality management system standard...”**

ISO/TC 210/WG 1 continues to review and update these standards, based on the changing needs of the medical device sector.

### **The revision of the ISO 9000 series of standards**

In 2000, ISO/TC 176 published a revised version of the ISO 9000 series of standards. Key elements of this revision included:

- The adoption of the “process approach” to quality management, with the resultant reformatting of ISO 9001:2000 to reflect the key quality management system processes (i.e. management, resources, product realization, and measurement/improvement). Within these major process

areas are sub-processes dealing with quality management, system management planning, management review, human resources, work environment, design and development, purchasing, production, monitoring and measurement, analysis of data, improvement, and others.

- The elimination of ISO 9002 and ISO 9003, through the use of an applications approach (ISO 9001:2000, clause 1.2) that allows the organization to disregard quality management system requirements for product realization processes they do not perform (e.g. design and development).
- The refocusing of the objectives of ISO 9001:2000 and ISO 9004:2000 is such that ISO 9001:2000 describes a quality management system intended to meet customer requirements, while ISO 9004:2000 provides quality management system recommendations for business excellence.
- Within ISO 9001:2000, the strengthening of requirements related to customer satisfaction and continual improvement, and the reduction of requirements related to procedural documentation.
- The elimination of ISO 8402 by including relevant quality management system definitions in ISO 9000:2000.

### **Proliferation of quality management system standards**

Over the last six years there has been direct interaction between the ISO/TC 176 and ISO/TC 210 committees as each has developed its own standards. There is now general agreement that the needs of the medical device sector would be best served by a separate quality management system standard, based, in great measure, on ISO 9001:2000, with some of the ISO 9001:2000 requirements removed, and a number of requirements added.

This separate standard would reflect clearly the differences required by the fact that the medical device sector is regulated. As a result, the revised ISO 13485 will bear

a new title, “ *Quality systems – Medical devices – System requirements for regulatory purposes.*”

## Path forward: recommendations

### Key standards publication milestones

ISO 9001:2000 was published in December of 2000, with the guidance that the 1994 version of the standard would remain viable until December of 2003. Because ISO 13485:1996 refers directly to ISO 9001:1994, ISO/TC 210/WG 1 is under time pressure to publish the approved new version of ISO 13485 by the first quarter of 2003. The Draft International Standard

(DIS) version of ISO 13485:200X was published in February 2002.

Such a publication schedule will allow organizations claiming compliance with ISO 13485 to understand the requirements of the new version in time to inform their employees and make any necessary modifications to their quality management systems before the 1994 version of ISO 9001 will be withdrawn. This timing will also allow third party registrars and notified bodies to adjust their assessment procedures, and to arrange assessment schedules to ensure no lapses in registrations and an orderly transition.

### Determine standards strategy

It will be important that individual organizations use their management review processes to discuss and determine their quality management system standards compliance objectives; should they work for compliance with ISO 9001:2000, ISO 13485:200X, or both?

In the absence of any customer or regulatory requirements to comply with ISO 9001, my recommendation to medical device organizations is to seek registration to ISO 13485:200X only. Such registration will provide objective evidence of compliance with quality management system requirements consistent with meeting customer requirements and those of the major regulatory agencies around the world. The organization may choose to adopt some of the customer satisfaction and continual improvement requirements of ISO 9001 because it feels that this makes good business sense. But if there are no customer or regulatory reasons for registration to this standard, it would seem unwise to subject the organization to the trauma of third party assessment against these requirements.

It is true that some customers and a number of regulatory agencies in smaller countries are not aware of ISO/DIS 13485, and may require or request compliance with ISO 9001:2000. The GHTF is doing its best to publicize the value of ISO 13485 to regulatory agencies around the world, but it might be necessary for individual organizations to educate their customers and the regulatory agencies with which they deal. These organizations should avail themselves of materials that are available from the GHTF<sup>1)</sup> and the Association for the Advancement of Medical Instrumentation (AAMI)<sup>2)</sup>, which administers the ISO Secretariat for ISO/TC 210.

1 Global Harmonization Task Force Web site: [www.GHTF.org](http://www.GHTF.org)

2 Association for the Advancement of Medical Instrumentation (AAMI) website: [www.aami.org](http://www.aami.org)  
Ms. Hillary Woehrle, Secretary ISO/TC 210, [Hwoehrle@aami.org](mailto:Hwoehrle@aami.org)



## Negotiations with registrars and certification bodies

It will be important that the organization negotiates with its current registrar or notified body and with others that may offer programmes that are more consistent with the organization's objectives. The transition from the 1994 to the 2000 versions of ISO 9001 will likely cause increased demand for quality management system assessments and may lengthen each of these assessments. Getting on the registrar's schedule may be difficult if the organization delays.

If the organization seeks registration to ISO 13485:200X alone, it will be necessary to determine if the registrar is or plans to be qualified for ISO 13485:200X for the relevant medical devices. It may be necessary to help the registrar gather information it requires to plan for assessments and, if necessary, educate its assessors.

If the organization seeks registration to both ISO 9001:2000 and ISO 13485:200X, it will also be necessary to negotiate with the registrar about the process of assessing for both standards, and the costs associated with this process. It will be necessary to determine if dual registration will require more than one assessment, or other significant additional costs.



## Internalize the process approach

One of the things the individual organization can do immediately is internalize the process approach by reviewing it with top management, developing training programs for affected personnel, and beginning to modify its high level documentation to reflect this approach. Both ISO 9001:2000 and ISO/DIS 13485:200X have adopted the process approach, so there is little chance that such efforts will be wasted.

### Perform a "gap analysis"

Now that the ISO Central Secretariat has published the DIS version of ISO 13485:200X, it is unlikely that significant substantive changes will be made to this standard. At this point, the DIS should be satisfactory to use as the basis for an analysis of the individual organization's current quality management system

*Both ISO 9001:2000 and the future ISO 13485 have adopted the process approach. Measuring an individual organization's current quality management system against the requirements of ISO/DIS 13485 is not likely to show up many gaps, as one of the objectives of ISO/DIS 13485 was to maintain the status quo with regard to requirements, whence more similarities than differences.*



against the revised requirements. Since one of the objectives of ISO 13485:200X is to maintain the status quo with regard to requirements, it is not likely that an analysis of a compliant quality management system will reveal many "gaps". In any case, starting this process in mid-2002, should provide sufficient time for corrective and preventive action before the end of 2003.

If the individual organization seeks compliance with ISO 9001:2000, it should start its gap analysis immediately. Such an analysis may uncover deficiencies related to customer satisfaction and continual improvement processes.

### In closing – Get started right away

The key is for the individual organization to start its quality management systems strategy efforts right away, keeping in mind what it learns from following the development process for ISO/DIS 13485. That should leave enough time for the organization to effect an orderly and timely quality management system transition. □



# 3 Risk management and medical devices



By Alf. M. Dolan,  
Samuel Lunenfeld professor in  
Clinical Engineering,  
University of Toronto, Canada  
and Convener, Joint ISO/TC  
210 – IEC/SC 62A Working  
Group 1, *Application of risk  
management to medical  
devices*

*This article provides a summary of the background and development of the dual ISO-IEC 14971:2000, Medical Devices – Risk management – Application of risk management to medical devices.*

*The standard, which was developed by a joint ISO/TC 210-IEC/SC62 committee, was issued in December 2000 as the world standard on risk management for medical devices. That it was unanimously approved for publication as an international standard by four bodies, ISO, IEC, CEN and CENELEC, speaks highly for the effectiveness of the joint development process. International regulatory bodies around the world are currently at various stages of implementing the standard.*

Uncertainty is ubiquitous. In scientific research uncertainty is recognized through the reporting of scientific results with accompanying standard deviations or coefficients of variation. A corollary is that when we are uncertain about desired results, we must accept the recognition of the opposite, that undesired results can be equally uncertain. Knowledge of the associated science, engineering, and technology allows the prediction of the likelihood of achieving desired results and, on the other hand, allows the estimation of the risk of occurrence of undesired results. This dichotomy presents the fundamental concepts of risk, which are increasingly important in the field of medical devices.



Over the past several decades, the development of highly effective international technical medical device standards, which are specific to a technical area or even specific to a device, have greatly increased the safety of the devices covered by the standards. The need for those technical standards remains. However, in today's health care climate, the increased sophis-

tication of the patient care environment, the hardware and the software incorporated in medical devices imposes increasing demands upon medical devices and the manufacturers and users of those devices. Furthermore there is an increased regulatory scrutiny related to medical devices, and a trend in modern society to demand "safety" in all technological devices. In effect assurance of "safety" is a demand for zero level of risk.

## **No absolute certainty of safety**

Among standards development committees it is widely recognized that there is no absolute certainty of safety. That, in itself, is recognition that the concept of risk must be addressed in those standards and that some aspects of safety can only be addressed through a risk management approach.

**“Among standards development committees, it is widely recognized that there is no absolute certainty of safety...”**

By definition, that is a recognition of risk and that the concept of risk, which embraces the elements of assessment of probability of an occurrence and a prediction of its associated consequence has been considered in a number of medical devices committees.

One of these committees was SC 62A of the International Electrotechnical Commission (IEC). In the development of IEC 60601-1-4 on programmable devices, the concept of risk was explicit throughout

the document. In IEC 513, the concept is implicit. Within ISO, Working Group 11 of TC 194, in ISO/FDIS 10993-17, *Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances*, has described health-based risk assessment techniques to establish allowable residue limits in medical devices. In ISO/IEC Guide 63 1999, which deals with the development of international standards in the field of health care technology, hazard identification and risk analysis are included.

**“ISO 14971... incorporates the well-established risk management principles developed over the past centuries, builds on the work of other international risk standards, and provides a process for manufacturers of medical devices.”**

ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, was formed in 1994. In recognition of the need for a risk management approach to be applied to medical devices, a working group on risk management was established. The first task assigned to it was to develop a standard describing the principles of the application risk analysis for medical devices. Subsequently that working group became a joint ISO/TC 210-IEC/SC 62A working group. The risk analysis standard ISO 14971-1, *Medical devices – Risk management – Part 1: Application of risk analysis*, was published in 1998.

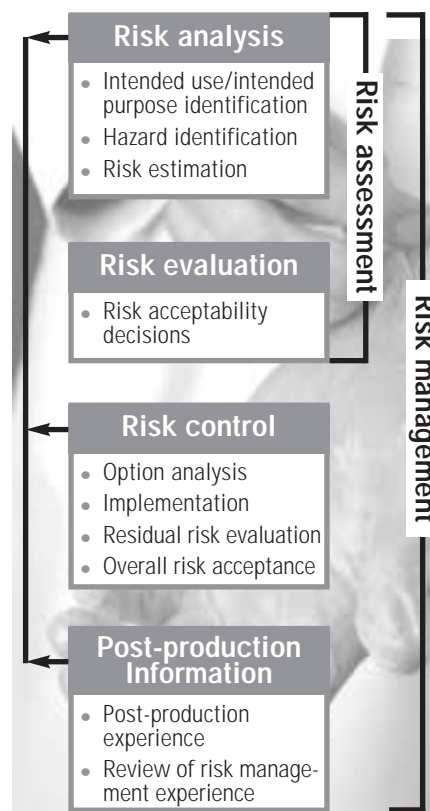
In 1996, work was initiated on a comprehensive risk management standard for medical devices. That document, ISO 14971:2000, *Medical devices – Risk management – Application of risk management to medical devices*, was published in 2000. The standard incorporates the well-established risk manage-

ment principles developed over the past centuries, builds on the work of other international risk standards, and provides a process for manufacturers of medical devices. All the basic principles of risk management apply for medical devices, and the standard specifies that the steps of hazard identification, risk estimation, risk evaluation and risk control must be included in a manufacturer's risk management process.

### Basic concepts

In the standard, clearly there is a parallel with ISO 13485. Management responsibility is identified as the initial and the key requirement for successful management of risks. Management is required to identify the risk management team; to establish a process for establishing acceptable risk levels; to provide appropriate personnel to carry out the process; and to review the process on a regular basis.

The risk management process that is to be defined contains the elements that are summarized in the figure below. In addition there are a number of informative annexes, which are helpful in the implementation of this process.



*Schematic representation of the risk management process (taken from ISO 14971:2000)*

Furthermore there is the requirement that a risk management plan for each device be developed in accordance with the above risk management process. A critical component of the plan includes setting the level of acceptable risk for that device. This is based on the approved corporate process for setting that level. The plan will describe how each element of the risk management process is to be achieved for that device.

Records provide the information on which effective management of risk is based. The specified records are generated at various stages of the analysis, evaluation, and control stages of the process. Records may or may not be incorporated and controlled within the requirements of an existing record system of a quality management system.

The monitoring function referred to in other international risk management standards is incorporated in a requirement for generation of post-market information. This step involves incorporating information generated during in service experience into a feedback process. This information will be useful in the review of the effectiveness of the risk control measures, may serve as a basis for modification of the risk analysis or evaluation, and will serve as a source of information for future risk management plans.

### International harmonization

The risk management standard, ISO 14971, has become the definitive standard for medical devices. Currently, international medical device regulatory bodies incorporate requirements that are either included in that standard or are consistent with the standard. Those requirements are included either as part of the design requirements or part of the overall medical device management process in regulations in various countries. The standard has been approved as a European standard, and will therefore be used in meeting medical device requirements in Europe. Thus ISO 14971 has very quickly become the worldwide standard for risk management for medical devices. □