ISO/TC 210
Quality management and corresponding general aspects for medical devices

STRATEGIC BUSINESS PLAN 2018
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EXECUTIVE SUMMARY

Quality management is the major focus of ISO/TC 210. The medical device sector is very diverse, with products intended for use by highly skilled professionals, by lay people, as well as by patients. A common element is that all involved expect the products to do what they are intended to do. In addition, authorities must ensure public health to be adequately served by safe and effective quality products. Therefore, quality management for medical devices encompasses a broad domain of activities: product design, including risk management and usability aspects; manufacturing and distribution; installation; documentation and training; and post-market surveillance activities.

In many countries, healthcare is largely publicly funded, which brings a natural stress on available resources for healthcare in combination with optimal access for all citizens. Authorities have a national responsibility, which includes establishing requirements that medical devices or their manufacturers must fulfill in order for the devices to be allowed on the market in their jurisdiction. Conformity assessment bodies, which are often independent organizations, help to establish whether medical devices are compliant with the applicable regulatory requirements. Risk management for medical devices is a lifecycle approach; data collected are fed back into the Quality Management system.

Standards and other documents produced by ISO/TC 210 provide all stakeholders with a means to help perform the above activities. In addition, the deliverables of ISO/TC 210 support other Technical Committees within ISO and IEC for standards that are more product-oriented. ISO/TC 210 thus contributes to the efforts for global regulatory convergence, aiming at better medical devices for better healthcare at acceptable cost. It is the ambition of ISO/TC 210 to have liaison partners representing the broad landscape of stakeholders, including users, patients, healthcare professionals, authorities, industry, and conformity assessment bodies.

Scope

Standardization of requirements and guidance in the field of quality management and corresponding general aspects for products with a medical purpose including connectors.

Excluded:

- generic quality management standards dealt with by ISO/TC 176, and
- quality management standards for pharmaceutical products and healthcare services.
1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry).

ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

The ISO portfolio of deliverables also includes handbooks and practical guides. Following the publication of the third edition of ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes, experts of ISO/TC 210’s WG1 developed the practical guide accompanying that globally used standard. With no formal process for ISO handbooks or practical guides in place, ISO/TC 210 held a Committee Internal Ballot for the practical guide as if for a TR. Comments and other feedback were obtained from the TC membership. This practical guide was published in September 2017 and, in a way, is intended to replace ISO/TR 14969, the guidance developed for ISO 13485:2003. In the meantime, ISO/TR 14969 has been withdrawn.

2 BUSINESS ENVIRONMENT OF ISO/TC 210

2.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to
the scope of ISO/TC 210, and they may significantly influence how the relevant standards
development processes are conducted and the content of the resulting standards:

Products covered by the term “medical device” encompass a broad range: from bandages to MRI-scanners, from tongue depressors to linear accelerators for radiotherapy, and from pregnancy test kits to blood collection tubes, and software-only products. Medical devices are regulated products in many countries and, typically, the applicable legislation defines the type of products covered by that legislation. The definition of a medical device is not identical in many countries so that, what is considered a medical device in one jurisdiction can be subject to a different regulation in another jurisdiction. Some products require highly skilled professional users; other products are intended for use in the home environment. Certain products are intended for use together with medical devices and may be called “accessory to a medical device”, for example tools to aid installation of medical devices, or fixate implantable medical devices.

Today, software-only products can qualify as a medical device if they comply with the definition of a medical device; such products are referred to as software as a medical device (SaMD). With the continuing growth in the use of smartphones and tablets, such SaMD products become more prevalent. This creates a new “borderline” between medical devices and “health information” products, including health and wellness apps. It is noted that regulatory authorities increasingly struggle with this borderline.

Many active medical devices are driven by software, or their use is supported by software. Think of toothbrushes with a connection to a smartphone, or external defibrillators where the recognition of proper electrode placement is determined by a software algorithm.

The medical device sector is made up of a small number of large multi-national medical device manufacturers with a great many small and medium-sized manufacturers. Entrepreneurial, start-up firms continue to drive innovations in many parts of the medical device sector.

The medical device business environment is influenced by several governmental and private sector initiatives, varying from country to country. Such variations are due to, for example, historical financing schemes, and budget constraints on public health authorities. Increasingly, national regulatory requirements for quality management systems apply to the manufacturer of medical devices, to the manufacturer’s supply chain, and to the device distribution chain.

Regulatory oversight typically includes a post-market phase: the responsibility of a medical device manufacturer does not stop with the supply or installation of the device. Often, among the legal requirements is to have risk management as an integral element in product development, as well as design considerations for optimal usability (“human factor engineering”) to minimize unintended misuse of the product. Appropriate labelling –documentation, marking and symbols- are important aspects in risk mitigation.

At times, regulatory oversight is coupled with governmental approaches to apply limits on the cost of providing healthcare to persons within national programmes. There is a comparable financial pressure being exerted by private sector insurance and Health Maintenance Organization (HMO)-like programmes.

As a result of the above considerations, there are ongoing efforts to coordinate the work of ISO/TC210 and the development of national and regional regulatory requirements. For example, ISO/TC 210 seeks to collaborate with organizations such as the International Medical Device Regulators Forum (IMDRF) and the Asian Harmonization Working Party (AHWP). These organizations share goals and objectives that are related to those of ISO/TC 210.

### 2.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of ISO/TC 210:
As stated in Section 2.1 above, there is not a single, common definition of “medical device" across the various countries in the world. As a consequence, it is not easy to provide a precise figure for the global medical devices market. A further complication when trying to estimate global market volume is that the market supply chain often has layers between the manufacturer and the end user: so what price-point to take?

In 2016, the International Trade Administration desk of the US Dept. of Commerce, largely aiming at USA exports, published a report estimating market size. In the summary of the ITA report (click here), it is suggested that the global market in 2015 is approx. USD 300 billion.

MedTech Europe developed “The complete Facts and Figures” (click here) in which they provide a good level of detail of medical devices market data in Europe. The overall figure for the EU market (in 2015) is about USD 125 billion. Based on a historical estimate of the market size ratio between the EU and the rest of the world, the estimated global market size for medical devices in 2015 is around USD 400 billion (ex-manufacturer values). The discrepancy with the USD 300 billion ITA estimate might be due to different interpretations of the term “medical device" across the globe.

In a 2017 brochure by DITTA (click here), this international trade organisation estimates the global market for diagnostic imaging, radiation therapy, healthcare IT, electromedical equipment, and radiopharmaceuticals to be approx. USD 110 billion. It suggests that this segment of the medical devices sector is a good 25% of the overall global medical devices market.

In a late 2016 publication, Forbes (click here) estimates global medical device sales values (2015) of USD 371 billion, which is in line with the other data given here. In an attempt to predict the future, Forbes expects that the global medical device market will exceed USD 500 billion in 2021.

A bolder prediction was made by Today’s Medical Developments in June 2015 (click here) suggesting the global medical device sales to far exceed the USD 500 billion already in 2020, “driven by aging population, increasing healthcare expenditure and technology advancement.”

For comparison purposes, the 2015 global market for pharmaceutical products amounts to USD 1072 billion (data taken from: click here) and the 2016 global sales of new cars amounts to some USD 1700 billion (information based on: click here). While the amounts given are substantial, with some USD 60 p.a. per capita spent on medical devices, the investment in medical technology is orders of magnitude below the overall cost of healthcare.

With its many interested parties identified as customer or stakeholder, the medical devices sector is an interesting sector for standards development. Because of the direct impact of medical devices on safety and quality of life, especially for people in need of care, there is great interest in products that are safe to use and do what they promise to do. High quality international standards can help ensure that medical devices are demonstrated to be safe and effective across the globe.

In many countries, government is a major customer/stakeholder as a primary payer for healthcare, as well as a regulator of medical devices. Third party payers (e.g., health insurance companies) and employers who pay for their employees’ health insurance are also major stakeholders.

There are many cases of governmental adoption of standards produced by ISO/TC 210 into legislation, regulations or procurement requirements.

Many of the standards produced by ISO/TC 210 are cited as normative references in International Standards of other ISO and IEC committees such as ISO/TC 76, 121, 150, 172, 194, 198, 212 and IEC/TC 62. Most of the standards produced by ISO/TC 210 have been adopted as national standards by member countries.

2.3 Relationship of ISO/TC 210 with European Standards Organisations

At the level of ISO, a close relationship has been established with the European Standards Organisation CEN through the Vienna Agreement (see www.iso.org/va). This Vienna Agreement (VA) aims for efficiency in standards development by avoiding redundant work and parallel voting
for standards of common interest. Europe is the third largest single market globally in terms of population. In addition, Europe is an important factor with its many national committees active in the standards development process.

The European connection for ISO/TC 210 is CEN-CENELEC/TC 3, established in 2007 after combining several European committees –both from CEN and CENELEC- that were active on subdomains of ISO/TC 210. For standards developed under Vienna agreement, parallel voting in Europe takes place through this CEN-CENELEC/TC 3. The relationship with ISO/TC 210 is such that, often, CEN-CENELEC/TC 3 meets in conjunction with plenary meetings of ISO/TC 210.

2.4 Domains in ISO/TC 210

This chapter describes the domains within the medical device sector where ISO/TC 210 has active work items, areas of interest, or documents published.

2.4 a) Quality management

The major focus of ISO/TC 210 is to establish requirements related to quality management systems for the medical devices sector, globally, providing international standards that can be used as the basis for national or regional regulations. In 2016, the 3rd edition of ISO 13485 was published. This standard was developed by WG1 in line with ISO 9001:2015 (which is under ISO/TC 176), yet is a separate document. Convincing argumentation from regulators has led ISO/TC 210 to deviate in content from ISO 9001 and also to not follow the Annex SL format. ISO 13485:2016 is considered fundamental to encouraging and supporting the global harmonization of quality system requirements for medical devices worldwide: it forms the basis for the IMDRF’s medical devices single audit programme (MDSAP). As mentioned above, experts of ISO/TC 210’s WG1 developed ISO 13485:2016 - Medical devices – A practical guide to accompany the standard and provide guidance to users. This practical guide, published in September 2017, is a replacement for ISO/TR 14969, the guidance that was developed for ISO 13485:2003. The WG1 membership continues to maintain active liaison relationships with other WGs in ISO/TC 210, and with other TCs and international stakeholders to ensure alignment and compatibility in quality management system processes that may affect the medical device sector.

2.4 b) Essential Principles and associated standards

The guide to the selection of standards, ISO/TR 16142, was intended to direct users, especially start-up companies, to relevant standards. ISO/TR 16142 was based on a GHTF Guidance document referring to “Essential Principles”. This TR has been revised and published as two standards, still based on Essential Principles: part 1, published in 2016, deals with essential principles applicable to all non-IVD medical devices; and part 2, published in 2017, deals with essential principles applicable to IVD medical devices. WG2 invited other ISO/IEC technical committees responsible for standards for specific medical devices to provide input.

ISO/TC 210’s commitment to the Essential Principles goes a long way back: the Committee adopted already in 2004 resolution #93 (Sydney-3) that reads:

ISO/TC 210 notes that it would be helpful that all medical device standards under development and revision include a synopsis identifying correspondence of its clauses with the essential principles as published by GHTF for presumption of conformity purposes. ISO/TC 210 directs the secretariat to communicate this to GHTF and explore possible mechanisms to achieve this end.

2.4 c) Symbols and nomenclature

Medical device manufacturers seek to reduce efforts of documentation for their products by reducing or rationalising the material accompanying the device. In addition, technical translation can present difficulties in transferring the precise meaning from one language to another. The standard on medical devices symbols (ISO 15223-1) proposes a solution to this problem through
the use of internationally recognised symbols for a number of key items of information with
precisely defined meanings that transcend language, e.g., identification of sterile medical devices.

In 2016, WG3 produced the third edition of ISO 15225. This standard describes the rules and
guidelines for a medical device nomenclature data structure intended to facilitate cooperation of
regulatory bodies and the exchange of data among them. ISO 15225 is the basis for the Global
Medical Device Nomenclature (GMDN), maintained by the GMDN Agency. The need for this
standard has largely been supplanted by the GMDN so ISO/TC 210 has decided to withdraw
ISO 15225. The standard can be reactivated should the need arise in the future.

The ISO 19218 series (Part 1 and Part 2) describe a hierarchal coding structure for describing
medical device adverse events. The coding structure is intended to facilitate the exchange of
information on adverse events between sources (e.g., manufacturers or users such as healthcare
providers) and regulatory authorities. At present, the IMDRF is developing an expanded coding
structure taking account of the structure in ISO 19218. As the IMDRF work evolves, ISO/TC 210
will continue to evaluate the global relevance of the ISO 19218 documents.

2.4 d) Post-market surveillance

As identified before, the responsibility of the manufacturer does not stop with the supply of the
medical device. The newly established WG6 is developing guidance for manufacturers when
setting up an effective post-market surveillance system. While elements of post-market
surveillance are mentioned in the standards for quality management and risk management,
respectively, there is a need for more practical guidance.

2.4 e) Risk management

Risk management is another element of medical device regulation that has been addressed by
ISO/TC 210. ISO 14971, Medical devices - Application of risk management to medical devices, is
the globally recognized standard for risk management in the medical devices sector and is
referred to in over 400 national and international medical device standards.

In 2016, ISO/TC 210 in partnership with IEC/SC 62A initiated a project in JWG1 to revise
ISO 14971. The companion document to this standard, ISO/TR 24971, is also under revision.

JWG1 is furthermore responsible for the maintenance of ISO/IEC Guide 63 - Guide to the
development and inclusion of safety aspects in international standards for medical devices. This
guide is being updated following the revision of ISO/IEC Guide 51 in 2014.

2.4 f) Software

JWG2 of ISO/TC 210, in partnership with IEC/SC 62A, developed the first edition of IEC 62304 on
life-cycle aspects of medical device software. This 2006 standard, a bestseller for IEC/ISO, is
broadly used by manufacturers in the context of regulatory frameworks, both for software as a
medical device and for software in a medical device. An amendment to IEC 62304 was completed
in 2015. A revision of this standard includes a scope change, reflecting that medical device
software is nowadays better framed as health software. This work is undertaken by a joint working

In 2017, JWG2 saw its work on ISO 80002-2 published: “Validation of software for medical device
quality systems”.

2.4 g) Usability

JWG3 of ISO/TC 210 is another partnership with IEC/SC 62A. This JWG3 developed on the basis
of an early version of IEC 60601-1-6, applicable to medical electrical equipment, a generic
standard for the usability -sometimes called “human factors engineering”- of medical devices. This
standard is a process standard to ensure that errors by the intended user and for the intended
purpose of the medical device are minimized. In 2015 and 2016, an update of IEC 62366 was
elaborated and published in two parts: part 1 is the normative standard and part 2 is guidance, published as a technical report.

2.4 h) Connectors

Regulators around the world are concerned at the occurrence of incidents and near incidents associated with inappropriate connection of different medical devices, usually achieved through a "multi-purpose" Luer-type connector. Because of the horizontal nature of the issue, which affects a large number of different types of medical device, ISO/TC 210 was approached to consider leading a standardization effort in this area.

Two groups are active in ISO/TC 210 to develop standards for connectors: WG5 for connectors to reservoir systems in the ISO 18250 series, and JWG4 (ISO lead joint with IEC/SC 62D) for small-bore connectors intended to be connected to medical electrical equipment on the patient end, developing standards in the ISO 80369-series. Both groups are closely aligned and benefit from each other's work. Together, these groups have published an almost full and coherent set of standards and whitepapers. Implementation is under way in clinical settings, in some regions of the world more than in others.

3 BENEFITS EXPECTED FROM THE WORK OF ISO/TC 210

The work of ISO/TC 210 facilitates worldwide trade of medical devices, and imparts knowledge that improves the economics of the medical device industry as a whole. Regulatory authorities and manufacturers have greatly benefited from the use of standards and associated guidance on quality management systems to assure the safety and performance of medical devices. These standards and guidance, originally based on the ISO 9001-concepts for quality management system applied to the medical device industry, has been widely accepted in support of the regulatory process. With the publication of the 3rd edition of ISO 13485 in 2016, it is expected that this important role will only be enhanced in the future, especially now the associated practical guide became available in September 2017. The recent edition of ISO 13485 has also been incorporated in the IMDRF Medical Device Single Audit Programme (MDSAP), which is being put in place in several of the IMDRF jurisdictions.


ISO and IEC have published many technical standards for a large number of medical devices. The requirements in those standards, addressing safety and performance aspects for different types of medical devices, are greatly enhanced by identifying common quality principles in general standards. Such common standards are produced by ISO/TC 210, whose documents represent a consensus on requirements that foster product innovation by industry while promoting systematic approaches to assure safety and performance.

Other substantial benefits to patients coming from documents by ISO/TC 210 are those related to small-bore connectors. The rationale for this work is the ambition to dramatically reduce the incident rate compared to the use of conventional connectors in the supply of gas, liquids or even food. In the coming years, a massive uptake of new connectors in healthcare is expected. That will likely **not** reduce the direct cost for healthcare delivery organisations but will reduce incident rates related to misconnection to a fraction of the present situation, and thus save cost and patient suffering, including deaths.
Major benefits from the work of ISO/TC 210 lie in its assistance to the international harmonization of requirements for quality management systems cited by regulation. Such harmonization can result in quicker and less expensive introduction of beneficial medical device technology to healthcare providers throughout the world, including in developing economies.

4 REPRESENTATION AND PARTICIPATION IN ISO/TC 210

4.1 Membership

Countries/ISO member bodies that are P and O members of ISO/TC 210

4.2 Analysis of the participation

4.2.1 Country membership

Per October 2017, ISO/TC 210 had 40 P-members and 17 O-members. As the chart shows, most of the larger countries are involved in ISO/TC 210; however, membership from the African continent is low. Also in South-East Asia, improvement in membership is possible.

4.2.2 Committees in liaison with ISO/TC 210

The table below provides an overview of Committees in liaison with ISO/TC 210. Some of these liaisons relate to the fact that ISO/TC 210 is developing mostly horizontal standards and related documents. Through such liaison, Committees developing standards that reference standards or other output from ISO/TC 210 can stay better abreast of ongoing projects. ISO/TC 210 intends to approach the Committees in liaison to verify if the liaison is still functioning.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC/TC 56</td>
<td>Dependability</td>
</tr>
<tr>
<td>IEC/TC 62</td>
<td>Electrical equipment in medical practice</td>
</tr>
<tr>
<td>IEC/SC 62A</td>
<td>Common aspects of electrical equipment used in medical practice</td>
</tr>
<tr>
<td>IEC/SC 62D</td>
<td>Electromedical equipment</td>
</tr>
<tr>
<td>ISO/CASCO</td>
<td>Committee on conformity assessment</td>
</tr>
<tr>
<td>ISO/IEC JTC 1/SC 7</td>
<td>Software and systems engineering</td>
</tr>
<tr>
<td>ISO/TC 76</td>
<td>Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use</td>
</tr>
<tr>
<td>ISO/TC 84</td>
<td>Devices for administration of medicinal products and catheters</td>
</tr>
<tr>
<td>ISO/TC 106</td>
<td>Dentistry</td>
</tr>
<tr>
<td>ISO/TC 121</td>
<td>Anaesthetic and respiratory equipment</td>
</tr>
<tr>
<td>ISO/TC 150</td>
<td>Implants for surgery</td>
</tr>
<tr>
<td>ISO/TC 157</td>
<td>Non-systemic contraceptives and STI barrier prophylactics</td>
</tr>
<tr>
<td>ISO/TC 168</td>
<td>Prosthetics and orthotics</td>
</tr>
<tr>
<td>ISO/TC 170</td>
<td>Surgical instruments</td>
</tr>
<tr>
<td>ISO/TC 172/SC 5</td>
<td>Microscopes and endoscopes</td>
</tr>
<tr>
<td>ISO/TC 172/SC 7</td>
<td>Ophthalmic optics and instruments</td>
</tr>
<tr>
<td>ISO/TC 173</td>
<td>Assistive products for persons with disability</td>
</tr>
<tr>
<td>ISO/TC 173/SC 2</td>
<td>Classification and terminology</td>
</tr>
<tr>
<td>ISO/TC 176</td>
<td>Quality management and quality assurance</td>
</tr>
<tr>
<td>ISO/TC 176/SC 2</td>
<td>Quality systems</td>
</tr>
</tbody>
</table>

Reference
4.2.3 Societal organizations in liaison with ISO/TC 210

The table below provides an overview of societal organizations in liaison with ISO/TC 210. All these organizations are liaisons of Category A, with the exception of GEDSA, which is a Category D type liaison. ISO/TC 210 considers it important that societal organisations of stakeholders actively contribute to the work of the TC. Societal organisations of stakeholders – preferably international in character- in the medical device sector with an interest to establish a liaison with ISO/TC 210 can contact the TC secretary.

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHWP</td>
<td>Asian Harmonization Working Party</td>
</tr>
<tr>
<td>DITTA</td>
<td>Global Diagnostic Imaging, Healthcare IT &amp; Radiation Therapy Trade Association</td>
</tr>
<tr>
<td>EUROM</td>
<td>European Federation of Precision Mechanical and Optical Industries</td>
</tr>
<tr>
<td>GEDSA</td>
<td>The Global Enteral Device Supplier Association</td>
</tr>
<tr>
<td>MedTech Europe</td>
<td>Alliance of European medical technology industry associations</td>
</tr>
<tr>
<td>WFSA</td>
<td>World Federation of Societies of Anaesthesiologists</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
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</table>

5 OBJECTIVES OF ISO/TC 210 AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of ISO/TC 210

5.1.1 Overall objectives

ISO/IEC Guide 2:2004 reminds us that -by definition- a standard is “a document, ... aimed at the promotion of optimum community benefits.” Therefore, the strategic objectives of ISO/TC 210 are:

1. To help promote and protect the health and safety of patients and users of medical devices by contributing with its deliverables to the safety and effectiveness of medical devices, to the elimination of trade barriers for medical devices, and to the convergence globally of medical device regulation;
2. To develop standards and related documents in the context of quality management and corresponding general aspects of quality principles for medical devices, optimized and intended for use by regulatory authorities and other stakeholders, especially manufacturers;
3. To develop standards and related documents in the context of quality management and corresponding general aspects of quality principles for medical devices that can be referenced by Technical Committees developing standards of more technical or product-specific nature.
5.1.2 Detailed objectives by domain

5.1.2 a) Quality management

With the publication in 2017 of “A practical guide”, the companion to ISO 13485:2016, WG1 has now entered a phase of observing the implementation of ISO 13485:2016. Feedback from users of both the standard and the practical guide is welcomed. This feedback may lead to amendment of these documents in the future.

WG1 will consider the future of ISO 13485. Among the inputs is MDSAP, of which IMDRF developed the concept. MDSAP, the single audit programme for medical device manufacturers, addresses the quality management system requirements of multiple jurisdictions, is gradually developing momentum. For more information, visit www.imdrf.org.

Developments within the ISO programme for management systems standards (High-Level Structure (HLS); cf. ISO/IEC Directives, part 1, Annex SL) will have impact. ISO 13485 is intentionally not adhering to the structure and terminology of the HLS because of conflicts with existing regulatory schemes. WG1 will investigate whether the HLS is acceptable as a format for a future edition of ISO 13485.

5.1.2 b) Essential Principles and associated standards

WG2 has been doing important work in redeveloping the former ISO/TR 16142 into two standards, one for IVD medical devices and one for non-IVD-medical devices. For this purpose, the former GHTF Guidance document on Essential Principles had to be updated by the WG2 members. At IMDRF, renewed interest has arisen for these Essential Principles, which could form a sort of generic set of regulatory requirements for safe and effective medical devices. In 2018, it is expected that IMDRF will publish an updated set of Essential Principles reflecting the “state of art” in regulatory requirements. This set can then be taken to redevelop the two parts in the ISO 16142-series of standards.

A further work item for WG2 is the elaboration of ISO 20417: “Medical Devices -- Requirements for general information to be provided by the manufacturer”. This work item aims to provide a generic set of requirements for product labelling, which should greatly enhance coherence of labelling requirements across many product standards. This project has a clear connection with the ISO 16142 standards and their possible revision based on an updated set of Essential Principles: labelling requirements are among those principles. Publication of ISO 20417 is foreseen for 2019. Collaboration with CEN-CLC TC3 will be sought, as this TC will likely start revision of EN 1041, the European standard with the same purpose for the European medical device legislation.

5.1.2 c) Symbols and nomenclature

ISO/TC 210’s WG3 will further evaluate the symbols recently proposed for addition to ISO 15223-1; consolidation is foreseen for 2018.

On the nomenclature part, after the withdrawal of ISO 15225 (see also 2.4 c)), only the two Technical Specifications in the ISO 19218 series remain. The subject of these documents, coding for adverse events (AE), is being elaborated at the IMDRF with a slightly wider scope than is covered by the ISO documents. Both parts of ISO 19218 are up for review by the end of 2017 but at the 2017 plenary meeting of ISO/TC 210, it was resolved that this should be postponed by one year. It is expected that the IMDRF will publish its documents in 2018, and have a maintenance mechanism established.

If IMDRF decides that its AE coding tables prevail over the ISO 19218 documents, ISO/TC 210 will investigate together with the IMDRF if it can provide added value on this subject.
5.1.2 d) Post-market surveillance

Post Market Surveillance (PMS) is an important process within the manufacturer’s quality management and risk management system. PMS allows the manufacturer to detect problems and incidents, should they occur, and take appropriate action or, even in the absence of issues, to improve the medical device.

Several regulatory frameworks for medical devices nowadays require PMS activities and the revised European legislation on medical devices, published in May 2017, places even more emphasis on PMS. However, there are no documents available that provide comprehensive guidance to manufacturers how to develop and perform PMS-activities. WG 6 is developing ISO/TR 20416 to provide such guidance. For this project, WG6 collaborates with WG1 and JWG1 to prevent unnecessary redundancy. Publication of this TR is expected in 2019.

5.1.2 e) Risk management


The revision will essentially keep the risk management process unchanged yet seeks an update of certain requirements in ISO 14971. This update concerns in particular the consideration of benefits and risks related to security aspects, the risk management report, and the collection and analysis of production and post-production information. Most of the guidance will be transferred to ISO/TR 24971. New guidance on specific topics may be developed, e.g., on cyber-security. Publication of the new editions can be expected mid-2019.

5.1.2 f) Software

As mentioned in 2.4 f), JWG2 has been the engine for the development of several documents on medical device software, among others IEC 62304, and was the leading group in this field. After the 2017 publication of ISO 80002-2, there is at present no active work item for JWG2. In view of JWG2’s competence and reputation, ISO/TC 210 will investigate whether this JWG can continue to contribute to the development of standards in the medical/health software domain. In this investigation, ISO/TC 210 considers that software is a horizontal aspect of medical/health devices, sometimes even a software product is the complete medical/health device, and that ISO/TC 210 is the leading ISO TC on aspects such as quality management, usability, and risk management for medical/health devices.

Should this investigation not result in a new work item or in a joint activity with other TC’s projects, JWG2 might be disbanded.

5.1.2 g) Usability

JWG3 of ISO/TC 210 plans to keep the joint ISO and IEC usability standard series current under IEC lead- as new usability engineering methodologies evolve, e.g. through relevant national usability engineering standards and guidance.

After completion of Amendment 1 to IEC 62366-1, JWG3 will investigate and add to the series, as appropriate, expanding its coverage in the usability engineering domain. Under consideration is the development of TRs in the areas of Instructional Materials, Anthropometrics and Biomechanics, and Cultural Differences in User Interfaces.
5.1.2 h) Small-bore connectors

JWG4 of ISO/TC 210 has nearly completed the first edition of the ISO 80369 series for small-bore connectors, which was developed to reduce the risk of tubing misconnections between different clinical applications (e.g., enteral and intravenous). JWG4 has published, and made available in the public folders of TC 210 and JWG4, an implementation guideline (originally developed by German Coalition for Patient Safety (Aktionsbündnis Patientensicherheit/APS) for ISO 80369 connectors. In addition, the second edition of ISO 80369-1 (general requirements) is expected to be published in early 2018 as well as an Amendment to ISO 80369-3 (enteral applications). JWG4 is considering additional new work item proposals for other applications if/where they are justified. JWG4 anticipates an NP for a neonatal connector for limb-cuff inflation applications.

WG5 of ISO/TC 210 anticipates publication of the first edition of four parts (-1, -3, -7, and -8) in the ISO18250 series of reservoir connectors in 2018. Reservoir connectors were broken out of the 80369 series of small-bore connectors in 2013 due to a different risk profile. WG5 is considering additional new work item proposals for other applications if/where they are justified, especially urinary/renal and irrigation applications.

5.2 Identified strategies to achieve ISO/TC 210’s defined objectives

ISO/TC 210 will, in its ambition to develop standards and guidance for quality management and the corresponding general aspects of quality principles for medical devices that will effectively address the requirements of regulatory authorities, customers, and manufacturers:

a) Reach out to organizations of regulators in medical devices sector, such as the International Medical Device Regulators Forum (IMDRF), the Asian Harmonisation Working Party (AHWP), and the World Health Organization (WHO);

b) Liaise with other ISO and IEC technical committees to ensure that quality management standards developed reflect the needs of the regulatory authorities and manufacturers;

c) Liaise with societal organisations of stakeholders, preferably at international level.

As regards item a), ISO/TC 210 seeks, through the Vienna Agreement, to develop standards that simultaneously meet the requirements of the European stakeholders.

As regards item b), special mention is for the close cooperation with IEC/SC 62A for the development of standards that address risk management system requirements for regulatory agencies and manufacturers, as well as maintenance support for ISO/IEC Guide 63, as well as for the close cooperation with IEC/SC 62D for the development of a series of standards for small-bore connectors for liquids and gases.

As regards item c), organisations representing medical device users and medical professionals will be actively approached.

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF ISO/TC 210’s WORK PROGRAMME

Major influences are regulatory and financial. Financial impact comes from the background of the experts involved in the drafting. Typically, these experts have the standards work in addition to a “day-to-day job”, and do not receive compensation from the standards development organisations. Regulatory impact comes from the desire to have standards adopted and recognized in regulatory frameworks, sometimes leading to additional comments or even an extra voting round.
Normally in ISO/TC 210, new work items are carefully developed and planned, so that already from the onset a realistic planning is made. Nevertheless, it may happen that unforeseen complications arise in consensus building during the development work.

ISO/TC 210 is committed to help improve the quality of medical devices available to citizens; everything else is --at best-- secondary.

Factors that may impact the completion of the proposed work programme are:

1. Experts from medical device stakeholders, including officials from regulatory authorities, are increasingly overloaded with the daily work in their organizations. Most projects in standards development take between 2 and 4 years to come to full bloom. Organizational dynamics in that timeframe, like mergers, acquisitions, restructuring, or refocusing of activities, may lead to experts disappearing from the drafting team before project completion.

2. In recent years, the European Commission and a national EU Competent Authority challenged several standards, including ISO 14971 and ISO 13485. This had direct implication for these standards, including lengthy deliberations to establish correlation tables between the content of the standard and the applicable legislation. In this process, the close liaison of ISO/TC 210 with CEN/CLC TC 3 proved vital. Unclear is whether there will be a long-term implication, for example in specific European requirements, possibly delaying publication of ISO standards or, perhaps, reduced interest from European experts to participate in standards development.

3. ISO/TC 145 has adopted a general principle that limits the use of alphanumeric characters within a linear frame. This may inhibit the adoption of useful symbols for the medical device sector. ISO/TC 210 will work with ISO/TC 145 to provide information on the special needs for medical device labelling to utilise alphanumeric characters.

4. Standards and related documents developed by ISO/TC 210 aim to improve the quality of medical devices, to reduce the risk of operating them and, in general, to contribute to "community benefits". Not coincidentally, this is also the aim of regulations for medical devices. ISO/TC 210 is proud that many of its standards have been adopted and/or are referenced in a growing number of regulatory frameworks. As these regulations are typically a national competence and standards development in ISO is international, attempts to address the various regulatory requirements is sometimes complicating the consensus process. Care must be taken to avoid serious delay in development times. Because of this potential complication, ISO/TC 210 believes it must continue to liaise with regulators and, where possible, intensify communication with regulatory organizations to improve the quality and usefulness of its standards.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF ISO/TC 210

This section gives an overview of ISO/TC 210’s structure, its scope, information on existing and planned standardization projects, and its publications through links to available websites.
Since July 2017, ISO/TC 210 has its own publicly available website where information is given about the activities within ISO/TC 210: https://committee.iso.org/home/tc210.

**Glossary of terms and abbreviations used in ISO/TC Business Plans**

**General information on the principles of ISO's technical work**