ISO focus
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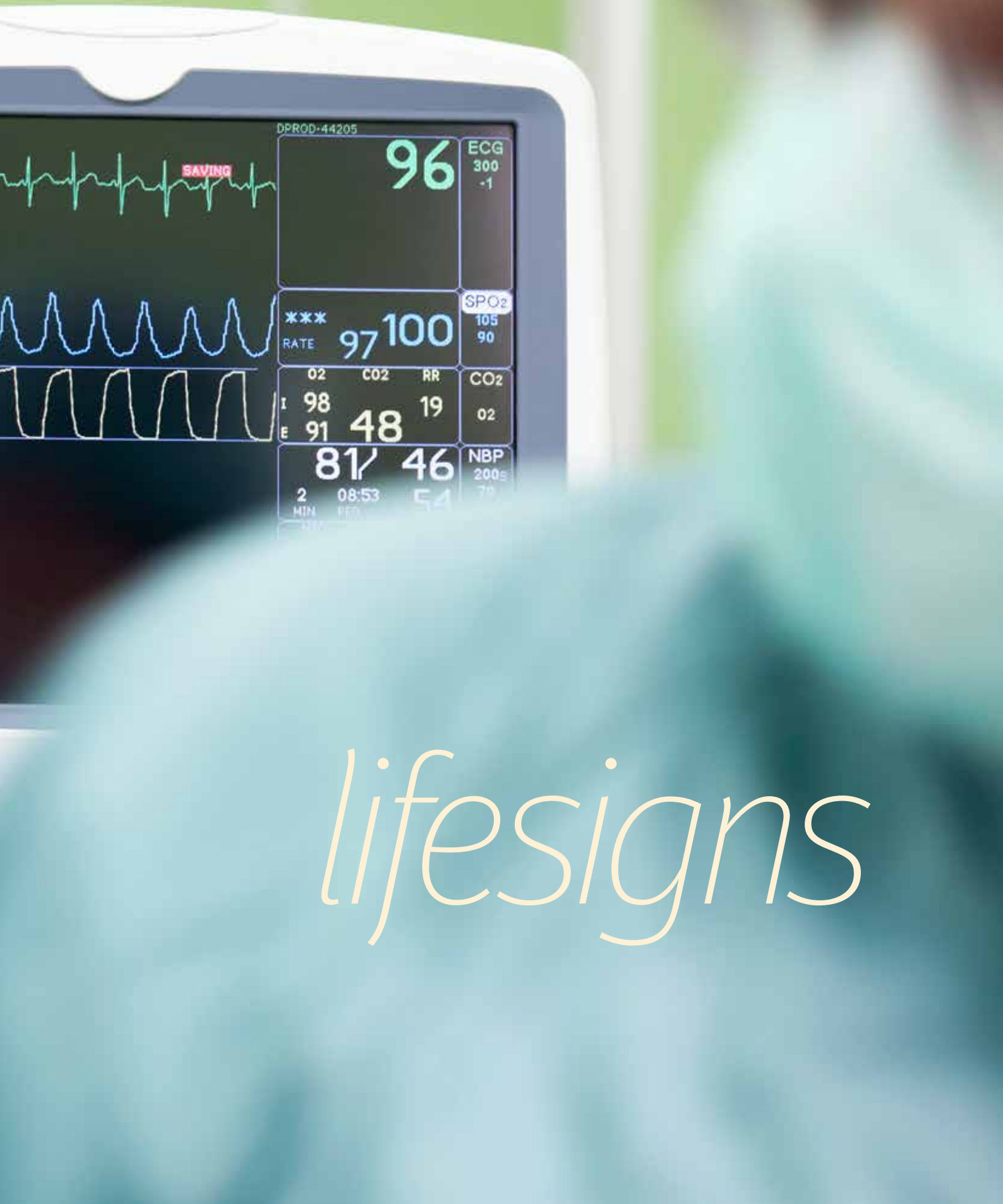

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#115

ISO focus

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***Avelino Brito**, General Manager of AENOR, the Asociación Española de Normalización y Certificación.*

Standards for safer healthcare

Nearly 30 years ago when I started out in standardization, the "core" focus of our work was on industry. Spain was aspiring to catch up with the world's most developed countries while the European Union was in the process of establishing a single market. For these reasons, many of the standards being created at that time were aimed at increasing the capacity of industry.

Not all standards were designed for products. Initiatives from companies and the leading developed countries were instrumental in achieving non-tangible objectives such as quality management, information technology and communication. Over time, it was hoped, these new methods would change the way in which businesses were conducted around the world. And so they did.

Since then, standards have been called upon to tackle new challenges and help solve problems, including in emerging areas of knowledge.

Take, for instance, healthcare. Standards for health are key to enhancing the safety, quality and effectiveness of health products such as medical equipment and devices. They apply to each stage of the production process, from design to materials to production. The contribution of standards to healthcare, however, is not limited to products.

For governments, these standards serve as a fundamental technical basis for healthcare legislation to help ensure that individuals and communities receive the quality of care they deserve. Hence rules, legal frameworks and measures taken in order to assess its compliance have made a significant contribution to the health and lives of people through products and services that are safe, reliable and trustworthy.

For healthcare organizations, standards have been increasingly important for everything indirectly related to the medical practice. This includes the resources needed so that healthcare activities can be developed under the best possible conditions by their main users : healthcare professionals. In fact, quality management has found its niche in supporting multiple healthcare areas. These include the delivery of patient reception services, the security of patient data, complying with environmental issues, maintaining rules, as well as the proper functioning of devices. One example is the AENOR standard UNE 209001, *Guide for the management and maintenance of active non-implantable medical devices*.

These quality management principles have gained momentum, to the extent where they are now being used by health professionals in specific healthcare applications, through standards such as UNE 179007 on quality management systems for assisted human reproduction laboratories. Another valuable national initiative is quality management in liver transplants. The standard was developed in collaboration with the National Transplant Organization – one of Spain's most prominent healthcare institutions and a source of great pride among Spanish citizens for its global leadership.

More recently, risk has also consolidated its position as a critical management concept for improving healthcare. In fact, two standards developed by AENOR in 2013 clearly illustrate the industry's need for managing risk : UNE 179003, which helps companies minimize the potential risks for patients, and UNE 179006, to help implement, document and improve the effectiveness of controls for infections related to medical care in hospitals.

Looking to the future, I would like to think of standardization as the best tool to develop good practices at the global level. Every day, around the world, standards make a vital contribution to servicing healthcare. I believe that we are a strong ally of healthcare professionals and that our collaboration with them – under their leadership and within the scope determined by them – will bring us great satisfaction in years to come. A lot is at stake when factors as essential as life and health are involved. ■

Sparking the conversation on *smart cities*

If you are following our social media accounts, you would have noticed the **#mysmartcity** campaign in the last quarter of 2015. What made this campaign stand out from previous ones is that it took stakeholder participation to the next level.

ISO members played a **key role** in promoting the campaign. For example...

- **AENOR (Spain)**, reached out and successfully engaged local industry and city networks
- **AFNOR (France)** prepared a video featuring Director-General Olivier Peyrat that raised some of the fundamental issues
- **DSM (Malaysia)** organized a national contest encouraging citizens to share pictures of their city

This initiative also saw newcomers to our global social media campaign, like **IRAM, our Argentinian member**, who joined us for the first time.

Objective: to spark off a conversation on:

- How standards can support smart cities
- What solutions are available
- What citizens want in preparation for the World Smart City Forum

The **World Smart City Forum** due to take place in **July 2016**

6 523 243 total audience

Over **930** tweets

Over **420** contributors

Professionals, **associations** and other actors pursuing smart city scenarios also **took part in the action**, together with industries working on smart technologies like Urbiotica or Maptionnaire, among many others.

During one week, **ISO members** and standards organizations like the **IEC** and **ITU**, as well as partners including the **World Council on City Data**, the **Smart Cities Council**, the **European Committee for Standardization (CEN)**, the **European Consumer Voice in Standardisation (ANEC)** and more, talked standards and smart cities on social media.

Cities like Melbourne, Seville, Johannesburg and Minna, and the Peruvian government, to name a few, joined in sending **#mysmartcity tweets**.

Discover the campaign's Website:
www.iso.org/mysmartcity

ISO is updating and expanding its key Identification of Medicinal Products (IDMP) standards to help stem the global toll of death and injury caused by medication errors.

Curbing death and injury with safer medication

by Garry Lambert

Medication errors and adverse drug events can occur in nearly half of all surgical procedures, according to a new study published in the October 2015 issue of *Anesthesiology* [1]. Although focused on 277 operations involving 3 671 medication administrations at the Massachusetts General Hospital, Boston, USA, the disturbing statistic highlights the frequency of drug-related incidents, many caused by mistakes in labelling, incorrect dosage and documentation errors that are occurring on a global scale.

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1) *Anesthesiology* is the journal of the American Society of Anesthesiology: http://anesthesiology.pubs.asahq.org/journal.aspx

Clinicians have access to over 10 000 prescription drugs.

European data and statistics made available by the World Health Organization (WHO), gathered mostly from EU member states, consistently show that medical errors and healthcare-related adverse events occur in 8 % to 12 % of hospitalizations. The UK Department of Health has estimated that about 850 000 adverse events take place each year, representing roughly 10 % of hospital admissions. Health authorities in Denmark, France and Spain have published incidence studies with similar results. Also, some 23 % of EU citizens claim to have been directly affected by a medical error, and 11 % claim to have been prescribed the wrong medication. The probability of patients being harmed while receiving hospital care is even higher in developing countries.

Preventable deaths

Some of the problems are caused by medications that have similar names and look much the same, but have completely different pharmaceutical properties. The situation today is exacerbated by the fact that clinicians have access to an armamentarium of over 10 000 prescription drugs, presenting an increasingly complex and risky challenge to those who prescribe and deliver medications.

While many errors do not cause harm, thousands of patients die unnecessarily each year in the EU alone from mistakes in drug selection or dosage. However, figures provided by WHO suggest that 50 % to 70 % of harm caused by medical errors can be prevented through comprehensive systematic approaches to patient safety. "Statistics show that strategies to reduce the rate of adverse events in the EU alone would lead to the prevention of more than 750 000 harm-inflicting medical errors per year, leading to over 3.2 million fewer days of hospitalization, 260 000 fewer incidents of permanent disability, and 95 000 fewer deaths per year."

Beyond the tragic human cost of such errors, the economic benefits of improving patient safety are compelling. A 2014 WHO report[2] cites studies showing that additional hospitalization, litigation costs, infections acquired in hospitals, lost income, disability and medical expenses have set some countries back between USD 6 billion to USD 29 billion per year.

Leading the way

In view of these distressing statistics, it is not surprising that there has been a global demand for internationally harmonized specifications for the identification of medicinal products (IDMP). In response, ISO is leading a major collaborative effort involving medical experts from 32 participating and 27 observing countries, to address this urgent need by developing a set of five international IDMP standards (see infographic on **page 14**).

First published in 2012 and now being updated and expanded to include helpful implementation guides, they facilitate the exchange of medicinal product information between regulators, worldwide data sources and pharmaceutical companies, aid the development, registration and life-cycle management of medicinal products, and provide the basis for the unambiguous identification of those products across regions. The outcome is to improve the robustness of pharmacovigilance – the process of monitoring the use of drugs after they have entered the market – and regulatory activities globally.

Complementing this effort, and in accordance with ISO 11615, technical specification ISO/TS 16791 has been published in the meantime to address issues such as "the right medication for the right patient". It provides guidance on how to implement bar codes to secure the medication process.

2) *Reporting and learning systems for medication errors: the role of pharmacovigilance centres*, published by WHO and developed as part of the "Monitoring Medicines" project (**www.monitoringmedicines.org**) funded by the research Directorate of the European Union under its Seventh Framework Programme.

Adoption of the ISO IDMP standards is gathering pace, with their use being increasingly required by governments around the world. There is general agreement among stakeholders that IDMP will become the required reference information model for all medicinal data submissions worldwide.

The European Medicines Agency (EMA) is in the process of implementing ISO IDMP standards and the European Commission, the European Union (EU) Network Data Board, and the EU ISO IDMP Task Force have endorsed a phased implementation commencing July 2016. Commission Implementing Regulation (EU) No 520/2012 obliges member states, marketing-authorization holders and the EMA to make use of terminologies defined in ISO IDMP standards from that date. Pharmaceutical companies will be required to submit data on medicines to the EMA in accordance with those formats and terminologies.

"The impending EU imperative has been a major driver for completion of the standards in a timely fashion," says Michael Glickman, President, Computer Network Architects, Inc., and Chair of ISO technical committee ISO/TC 215, *Health informatics*. "Also, an initial regional Implementation Guide 'bundled' with the core ISO IDMP standards has allowed us to address the EU's specific requirements while remaining consistent with the core needs."

Although Europe is ahead in regulating and mandating a central product dictionary based on ISO IDMP standards, the US Food and Drug Administration (FDA) is looking at options to update its current standards to be in line with ISO IDMP product definitions. Japanese authorities have also indicated the intention to adopt IDMP standards.

Adoption of the ISO IDMP standards is gathering pace.

Safety is paramount

"New medicines and therapies bring incredible value to the public, but ensuring patient safety is paramount, particularly for global regulators charged with protecting public health. As the EMA moves to require IDMP for registering medical products, this will improve transparency of medical product information and detection of adverse drug reactions throughout the drug development (and product marketing) life cycle. The aim ? To improve patient safety through global data standardization, via ISO IDMP standards," says Bron Kisler, Co-Founder & Vice-President, CDISC (Clinical Data Interchange Standards Consortium).

In the USA, 80 % of active pharmaceutical ingredients and 40 % of finished dosage drugs are imported.

This illustrates the importance of a harmonized approach to global identification with respect to pharmacovigilance, compliance, and information exchange for assessing the quality, purity, potency, safety and efficacy of medicinal products worldwide, comments Vada Perkins of the US FDA, who is also ISO IDMP Project Leader. "The ISO IDMP standards provide a solid foundation for exchanging pharmaceutical information to support regulatory and clinical activities, and enable a much more efficient and effective regulatory review."

He points out that IDMP benefits the regulated industry, independent of compliance to any regulatory mandate. "Master data management and data governance is important to the industry for a variety of reasons (R&D, analytics, M&A activity, etc.), and IDMP directly supports this. So there is a solid value proposition to be made to the pharmaceutical industry, independent of a regulatory mandate."

Globally significant event

Lisa Spellman, Director of Global Standards for the American Health Information Management Association (AHIMA) and Secretary of ISO/TC 215, believes the advent of IDMP is a globally significant event that will change the world. "One might have thought that IDMP already existed, but it did not. Now, thanks to ISO, IDMP will provide a simple structure and methodology to generate global product documentation that can be used worldwide through the entire supply chain."

"IDMP is already changing the world because, as adoption and use of these standards grow, they will help eliminate death and injury caused by medication interactions or allergies, and greatly improve pharmacovigilance and drug monitoring – the process of tracking the outcomes of medication. Even in today's high-tech world, it is not a simple matter to track and document adverse medication events – now at last we have IDMP, and that will make an increasing difference over time."

Christian Hay, Senior Consultant Healthcare, GS1 Global Office, and Convenor of ISO/TC 215 working group WG 6, the ISO IDMP working group specializing in the pharmacy and medicines business, sees IDMP as a major step for enhanced patient safety across the world, and the building block for adverse event reporting and clinical documentation about administered medication. "Stakeholders have joined forces to deliver a global approach for the description of product characteristics. It is a fascinating project – and standardization is just the beginning."

Introduction of the updated "bundle" of ISO IDMP standards will mark a key milestone in progress towards a much safer system of identification of medicinal products. "Completion of the revised ISO IDMP standards and finalization of the corresponding technical specifications and technical report (ISO/TR 14872) are our main priority. We anticipate that this will be completed by the end of 2016/early 2017," confirms Vada Perkins.

Why ISO?

Some interested parties might question why development of the IDMP series of standards was taken through ISO as opposed to regulatory/standardization channels established by the healthcare, medicinal and pharmaceutical products sectors, particularly since IDMP originally evolved from a forum conducted by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

There has been a global demand for the identification of medicinal products.

Initially, the ICH formed an Expert Working Group (M5) to develop ICH requirements for the standardization of medicinal product identifiers and related terminology, Vada Perkins explains. In particular, it identified a need to harmonize product information that would facilitate the electronic exchange of Individual Case Safety Reports (ICSRs) within and across ICH regions using the ICH E2B format in post-marketing pharmacovigilance. This led to a key decision to develop electronic specifications in collaboration with ISO and HL7, a not-for-profit organization that provides standards for the exchange of electronic health information, to enable wider interoperability across regulatory and healthcare communities.

Lisa Spellman adds that IDMP standardization became the responsibility of ISO "because the organization is the largest developer of consensus-based International Standards and has the broadest global reach. The list of IDMP stakeholders is long and includes a breadth of pharmaceutical and policy stakeholders who want these standards to reach the largest possible global audience. And also because the stamp of ISO on a standard carries important weight and trust."

Challenges to IDMP

Nevertheless, the path to developing a robust, practical and effective set of ISO standards has not been without its setbacks. According to Christian Hay, IDMP is an extremely complex domain with a limited number of experts that have the overarching understanding and knowledge required. "However, I see development of the standards as an opportunity to broaden the number of experts," he asserts. "Another challenge is certainly that there is a political pressure to deliver and implement in a short timeline. Nevertheless, in the midst of all this very intense and technical work, our team of experts never forget there are patients – and concern for their care, their safety, their pain must be front of mind."

WG 6 also struggled in meeting regional practices. "The IDMP standards are unique as a series of five different standards with four corresponding technical specifications and one technical report. Regions have their own approaches and processes for medicinal product identification in their areas, which may involve different criteria. Coming to common agreement in core principles/defining elements to uniquely identify a medicinal product without compromising current practices in a region can have its challenges," says Vada Perkins. Fortunately, the standards do provide very concrete requirements for uniquely identifying a medicinal product at a very granular level (through the substances and manufacturing processes) while still allowing the necessary flexibility for medicines regulatory agencies and other stakeholders to operate according to regional requirements.

Dr. Jean-François Forget, Chief Medical Officer for Vidal France, a digital Drug Information System (DIS) provider, says that one of the challenges to IDMP implementation will be to support not only the EMA's pharmacovigilance database (Article 57), but also the computer-generated e-prescription interoperability needs in primary or secondary care. "If we are able to address both, it will create a unique reference repository to describe all the drugs that are on the market in Europe, to be used by actors in public health and by healthcare providers. It will have a positive impact on the global health system, on pharmacovigilance, and on the safety and quality of prescription and delivery, which for sure will contribute to a better world."

What's next?

Once global implementation of ISO IDMP standards is achieved by all international stakeholders, it will be time to revise them for adverse event reporting. That will also be the right time to work intensively on the use of IDMP in the clinical space, says Christian Hay, looking ahead to an IDMP future.

Currently, the standards are only applicable to human medicinal products, but discussions are taking place among the ISO IDMP community to extend the application of the standards to veterinary medicines and foods. "The applicability of the ISO standards to all regulated products within a given jurisdiction would be the ultimate goal; the identification of medicinal products could accommodate other regulated products as there are common elements throughout each regulated domain. A change from IDMP to IDP (identification of products) could be a possibility in the not-so-distant future," Vada Perkins concludes. ■

ISO IDMP standards

ISO is leading a major collaborative effort involving medical experts from 32 participating and 27 observing countries, to address an urgent need by developing a set of five international IDMP standards.

Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange

SUBSTANCES ISO 11238

Regulated information on substances

- Distinguishes "substances", defined by their main general characteristics and their roles in medicinal products (e.g. active, adjuvant, basis of strength, excipient), and "specified substances" listed with specific descriptions (e.g. manufacturing information, purity, grade)

DOSE FORMS, etc. ISO 11239

Regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

- Identifies, for example, injection solution, injection suspension, infusion solution (or a less granular regional term linked to these)

UNITS OF MEASUREMENT ISO 11240

Units of measurement

- Specifies rules for the usage of units of measurement for IDMP
- Defines requirements for traceability to metrological standards
- Establishes reference code systems for units
- Provides structures and rules for mapping between different unit vocabularies and language translations

MPID ISO 11615

Regulated medicinal product information

- Defines, characterizes and uniquely identifies regulated medicinal products for human use during their entire life cycle (development, authorization, post-marketing and renewal or withdrawal from the market)
- Establishes definitions and concepts
- Describes data elements and their structural relationships required for the detailed description and unique identification of medicinal products

The basic pre-defined characteristics of a data carrier identifier can be:

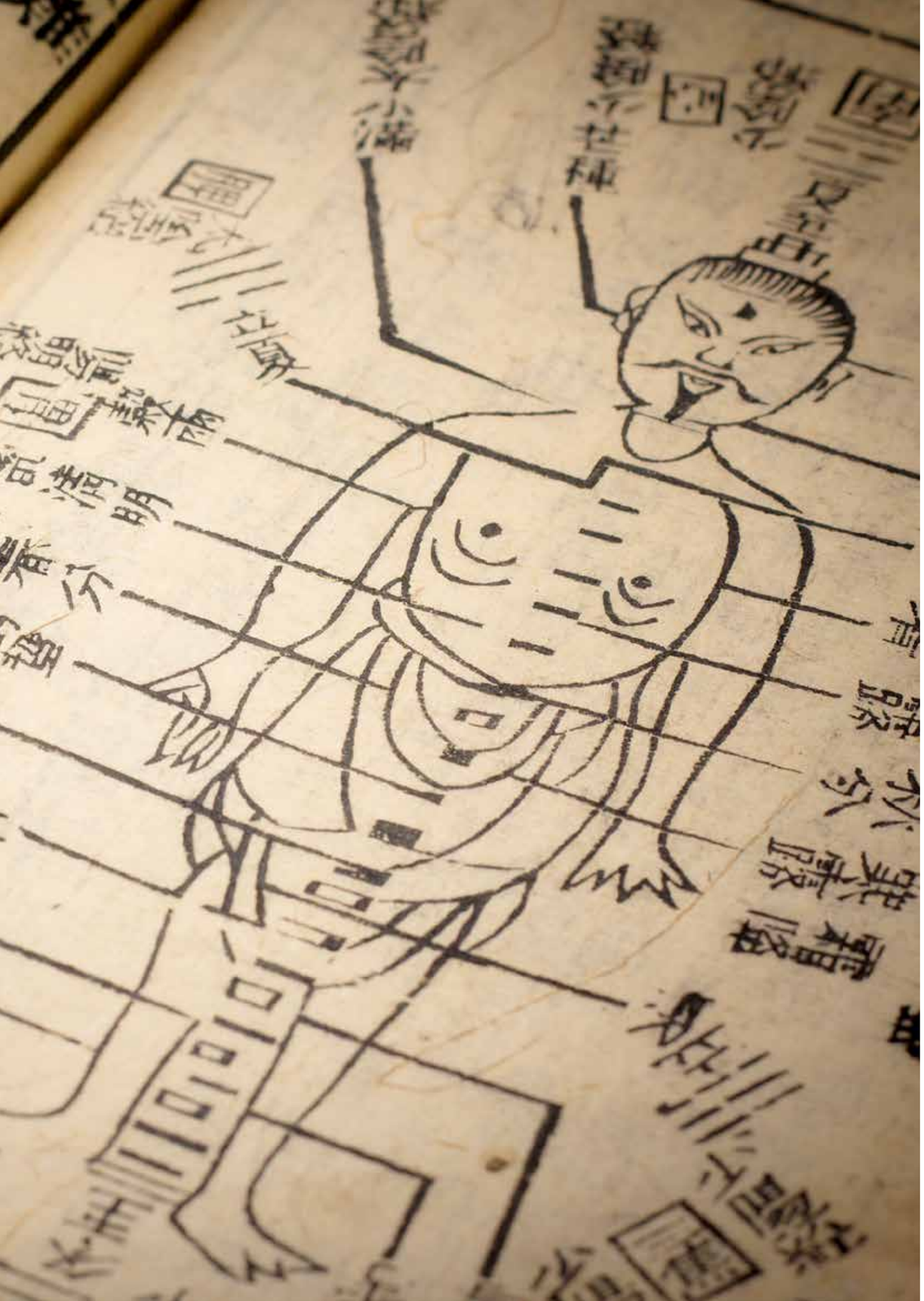
- Product name, product brand and product description
- Formulation (active ingredients)
- Strength
- Dosage (or usage)
- Net quantity (weight, volume, or other dimension impacting trade)
- Packaging configuration

PHPID ISO 11616

Regulated pharmaceutical product information

Pharmaceutical Product Identification (PhPID) based on the following subsets of elements that describe the pharmaceutical product:

- Substance(s) and specified substance(s)
- Strength(s) – Strength units (units of measurement and/or unit of presentation)
- Reference strengths
- Administrable dose form



Putting traditions to the test

by Elizabeth Gasiorowski-Denis

Despite being in existence for so long, Traditional Chinese Medicine (TCM) is still clouded in mystery and myths. Here's one mystery revealed. The 2015 Nobel Prize in Medicine – awarded to a TCM expert for her anti-malarial Artemisinin – has ignited an intense sense of elevated hopes on the future and standards for the sector.

Say the words Traditional Chinese Medicine (TCM) and immediately many people conjure up images of ancient lost texts shrouded in superstition and mystery with doctor nonsense that works largely on the power of suggestion. Right? Not so.

From the claims of healing herbs to pain-reducing acupuncture, TCM takes a holistic approach to health and wellness and focuses as much, if not more, on the prevention of illness as it does on the treatment.

Originated from ancient China, this medical system is based on thousands of years' clinical experience, theory and technology and systematically documented in abundant classical texts, such as *The Yellow Emperor's Internal Classic* (Huang Di Nei Jing) and *Compendium of Materia Medica* (Ben Cao Gang Mu). Today, as many companies are discovering, TCM is also big business, both in China and many Western countries.

According to a 2012 report by market research organization IBISWorld, government support and increasing demand in China have driven TCM to unexpected revenues of USD 25.7 billion in 2012, up 14.8 % from 2011. The industry has grown by 20 % each year on average since 2007, and profitability has continued to rise as well.

And it is not just China and Western countries that are seeing growth. Africa is now China's largest market


Photo: Bengt Nyman

***Tu Youyou**, Nobel laureate in Medicine 2015.*

Tu's winning is an excellent example of TCM's great contribution to the cause of human health.

for the export of medicinal products, both TCM and otherwise, thanks to low cost. In fact, in 2011 this ancient healing art was formally introduced into South Africa's healthcare system (see article on **page 24**). This is pushing TCM from the fringes to the mainstream in terms of demand and acceptance.

Winning big

The landmark success of Chinese national Tu Youyou, the lead discoverer of powerful malaria drug Artemisinin, showcases the industry's growing strengths and rising international standing.

What might seem unusual about her scientific work is that Tu began by looking to the plants used in traditional Chinese medicine. But it is far from the only time a cure has been found in this field and it is unlikely to be the last.

"Tu Youyou and her team developed an effective TM treatment for malaria, but only after following a process recorded in ancient Chinese medicine texts," explains David Graham, Chair of ISO/TC 249, *Traditional Chinese Medicine*.

"It makes you wonder what period of time was required to discover the original treatment process. Such examples will assist the greater integration and acceptance of TCM within the health systems of countries."

But TCM is a slow-moving, contemplative discipline so this will take time. So how should we interpret this arguably seismic shift in international attention on TCM and how should TCM position itself to meet the challenges of the future?

The scrutiny of science

Tu's winning is an excellent example of TCM's great contribution to the cause of human health. While the 2015 Nobel Prize win has ignited an intense sense of elevated hopes for the future, doubts about TCM, and how TCM products are assessed for quality and safety, remain.

"There is a great risk of inferior practitioners or treatments in poorly regulated markets. This can undermine public safety, the reputation of TCM and its trade and commerce," says Graham. He believes that a performance framework, ideally consisting of the registration of practitioners and the regulation of treatments, is the solution. It is not, however, the whole story. "Whatever performance framework is in place," he says, "it must be supported by research and development."

For Dr. Takao Namiki, Professor at the Graduate School of Medicine, Chiba University, Japan, medicine is about efficacy and safety, proven through scientific research. "While TCM is based on observation, it is most important to evaluate traditional medicine from a scientific perspective, looking at its effects on the body and whether the practices are helpful in symptom management."

By consolidating TCM scientific basis and clinical practice, standards will serve as foundations for its future integration into tomorrow's medicine. While some countries have standards, processes and regulations in place for TCM practitioners and products, many others do not. The industry still remains fragmented.

A question of efficacy

This makes the need to maintain quality, safety and efficacy of these traditional practices and products even more important for ISO/TC 249, which is diligently working on various projects to establish International Standards for the TCM industry.

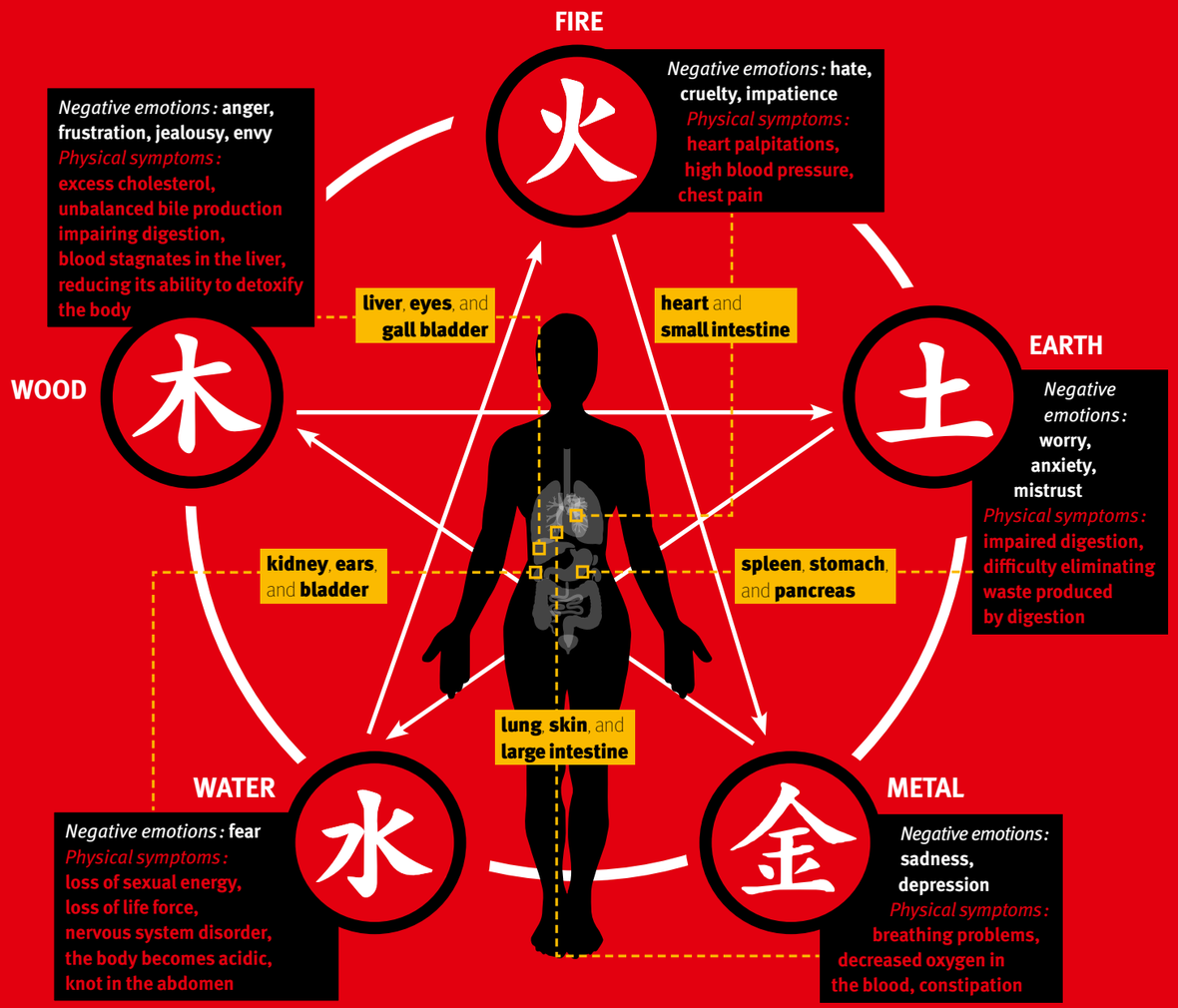
The main scope of the committee's work is to develop standards on TCM raw materials and products, quality and safety of medical equipment, information and terminology and TCM-related services. So far, its efforts have led to the publication of five International Standards in the last two years:

- ISO 17217-1:2014, *Traditional Chinese Medicine – Ginseng seeds and seedlings – Part 1: Panax ginseng C.A. Meyer*
- ISO 17218:2014, *Sterile acupuncture needles for single use*
- ISO 18664:2015, *Traditional Chinese Medicine – Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*
- ISO 18665:2015, *Traditional Chinese Medicine – Herbal decoction apparatus*
- ISO 18666:2015, *Traditional Chinese Medicine – General requirements of moxibustion devices*

Traditional Chinese Medicine

THE FIVE ELEMENTS

Traditional Chinese Medicine takes a holistic approach to health and wellness and focuses as much, if not more, on the prevention of illness as it does on the treatment.



Preparing herbal remedies in a Hong Kong dispensary.

The committee is set to make great progress in the coming years.

With 30 projects under development and 12 new work item proposals, the committee is set to make great progress in the coming years.

Today, ISO/TC 249 has 20 countries participating in its work with another 16 as observers, including three liaison organizations: the World Health Organization (WHO), the World Federation of Acupuncture-Moxibustion Societies (WFAS) and the World Federation of Chinese Medicine Societies (WFCMS).

The committee has made great efforts in increasing cooperation with other international organizations, explains Yuandong Shen, Chair of Shanghai TCM Doctors Associate, and Secretary of ISO/TC 249. "We believe that our collaboration with relevant organizations will help us realize complementary advantages, share resources, and cooperate for mutual benefits in TCM medicines."

Recently, the WHO issued its *WHO Traditional Medicine Strategy 2014-2023*. The document aims to support member states in developing proactive policies and implementing action plans that will strengthen the role traditional medicine plays in keeping populations healthy.

It builds on work the WHO has undertaken over the past decade to investigate and strategize on the future of traditional medicines around the world.

Meeting market needs

With the global growth of TCM, governments, industry experts and companies around the world are focusing their endeavours on how to use TCM more scientifically, safely and effectively.

The market need for TCM standards is unprecedented, explains David Graham. "International Standards are increasingly important in the environment of trade agreements between countries or regions. These will help harmonize requirements, thus removing barriers to trade, define acceptable performance and provide a resource for countries and others to use."

International Standards have the capacity to enhance TCM trade and industry growth, explains Dr. Sun-mi Choi, Professor at the Korea Institute of Oriental Medicine and Convenor of one of the many working groups of ISO/TC 249. "The safety and quality of raw materials, manufactured products and medical devices used in TCM need to be ensured," she says. "Developing a standards framework will not only benefit patients, but expand the industry's success even further."

According to Shen, the pharmaceutical industry is a special sector where the absence of a global regulated practice for TCM has become the obstruction for cross-border trade and quality safety control in the field.

"The International Standards being developed will help provide a technical basis for government regulations, market supervision, industrial management and the delivery of quality and efficient public services. Together, they will lay a solid foundation for better, quality services and protect human health."

So how, then, do standards help? To put it simply, TCM standards impact TCM clinical practice, products and equipment in the various links from technical development, raw material procurement, processing and production to sales and after-sale services as well as internal management of the industry.

The bottom line

The bottom line is that there is no magic cure or one solution that fixes everything. It takes a good balance to create the foundations for good health. TCM is a map to holistic healing, no matter what predicament a patient finds themself in at any given time. More importantly, Chinese medicine may have much to offer in terms of things we can do to prevent illness and disease, optimize our health, and enhance our well-being.

Ask yourself this. Do you think Chinese medicine would have survived for more than 3 000 years and spread to every corner of the globe if it wasn't a powerful, complete system of healing?

Whatever one's views or skepticism, standards to support public health, safety and trade are needed more than ever. The road to a TCM standards framework may not be quick (or painless), but it's more or less the path that all agree should be taken. The end result will not look anything like a 16th-century Chinese medicine cabinet, but the benefits will be far more palatable to regulators, scientists, doctors, the TCM industry and, of course, patients worldwide. ■

Do you think Chinese medicine would have survived for more than 3 000 years and spread to every corner of the globe if it wasn't a powerful, complete system of healing?

Marrying Traditional Chinese Medicine and modern medicine faces numerous challenges. Here, the South African Bureau of Standards (SABS), ISO member for the country, explains why it's a journey worth taking.

Serving South Africa **the Chinese way**

MEMBER EXCELLENCE

Africa has a tradition of using herbal medicine. For millennia, its people have healed the sick with herbal or animal-derived remedies, handed down through generations. Today, traditional (or ancestral) African medicine is still much more prevalent than its conventional Western counterpart. In fact, an estimated 70 % of the population in Africa uses traditional medicine for its primary healthcare, according to the World Health Organization (WHO). It's no surprise, therefore, that Traditional Chinese Medicine (TCM) is rapidly gaining appeal.

Deeply rooted

South Africa is one of the countries on the African continent where the TCM market is comparatively well developed, with TCM clinics operating for more than 30 years. It is also one of the few countries that has made significant progress integrating traditional and complementary medicine, including into the legislative framework.

In 2000, the South African government went through the legislative process of recognizing the legality of TCM, including acupuncture. Since then, TCM doctors have been regulated by the Allied Health Practitioners Council – reporting to the Department of Health – while TCM medicines are regulated under the Complementary Medicines Regulations of the South African Health Products Regulatory Authority (SAHPRA) Act.

Due for a revival

With increasingly growing government support, TCM is a booming industry in South Africa. Today, TCM products are becoming increasingly available and accessible over the counter nationwide. And with an influx of these products – some of questionable quality – International Standards are more important than ever. This is where ISO technical committee ISO/TC 249, *Traditional Chinese Medicine*, comes in.

The South African Bureau of Standards (SABS), ISO member for the country, actively participates in the work of ISO/TC 249. It takes part in several of its working groups, including one dealing with TCM products at the raw material stage and another dealing with the manufacturing stage.

SABS continues to participate actively in ISO/TC 249.

Amanda Gcabashe, *SABS' specialist in traditional medicine.*

Photo : SABS

In 2013, SABS hosted the ISO/TC 249 plenary in South Africa with some 180 TCM experts from all over the world. It was an important event in many ways. On the one hand, it represented an opportunity for South African traditional healers to interact with TCM professionals from different horizons and observe discussions at the International Standards level. On the other, the outputs and expert opinions rendered at the plenary sparked renewed interest in the SABs mirror committee on TCM and, of course, in the creation of a technical committee for African Traditional Medicine.

Market demands

Making traditional medicine truly mainstream – incorporating its knowledge into modern healthcare and ensuring it meets modern safety and efficacy standards – is no easy task and is far from complete. Developing ISO International Standards for TCM is therefore key, and of upmost importance, to:

- Ensure the quality and safety of TCM products and/or services
- Improve patient safety and satisfy their expectations and requirements
- Facilitate the use of TCM in a more scientific, safer and efficient manner
- Comply with relevant legislation
- Boost TCM enterprises and the country's economic growth

Whether considered a complimentary treatment or a primary one, TCM is on the rise in South Africa and SABS is optimistic about its future prospects. ISO standards will be an important step in building the profession's reputation and prestige across South Africa and on the African continent. To this end, SABS continues to participate actively in ISO/TC 249, uses the TCM standards in development, and promotes the heritage passed down from Chinese ancestors so as to bring more healing possibilities to Africa and the world over. ■

DIABETES
how to diagnose

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin to regulate its blood sugar.

WORLD HEALTH DAY

DIABETES FIGURES

in 2008

About 347 million
people worldwide had diabetes.

in 2012

Diabetes was responsible for
1.5 million
deaths, with over **80 %** occurring in low- and middle-income countries.

in 2014

9 % of adults of 18 years and older suffered from diabetes.

in 2030

The WHO predicts that diabetes will be the **7th** leading cause of death.

TWO MAJOR FORMS OF DIABETES

Type 1 diabetes

characterized by a lack of insulin production

A large proportion of diabetes cases are preventable, especially Type 2.

Type 2 diabetes

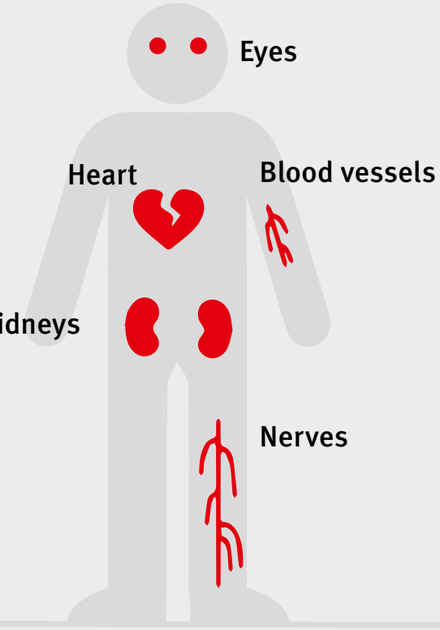
results from the body's ineffective use of insulin

Type 2 diabetes is the most common form of diabetes.

Source: WHO

POTENTIAL COMPLICATIONS

Raised blood sugar is a common corollary of uncontrolled diabetes, which over time leads to serious damage to many of the body's systems, including:



LIFESTYLE CHANGES

"Scale up prevention, strengthen care, and enhance surveillance" – such is the motto for preventing and reducing diabetes and its consequences.

- Maintaining a **normal body weight**
- Having regular **blood tests**
- Taking regular **physical activity**
- Adopting a **healthy diet**

ISO'S CONTRIBUTION

Among the 26 International Standards published by ISO/TC 212 on clinical laboratory testing, **one focuses directly on diabetes: ISO 15197:2013**, ***In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus***

UN SDG 3

Efforts to prevent and treat diabetes are important to achieve the **United Nations Sustainable Development Goal 3** target of reducing premature mortality from non-communicable diseases (NCDs) by one-third by 2030.

The patient comes first

With medical devices ranging from simple needles to life-saving high-tech implants, ensuring the highest possible level of safety is one of the industry's greatest priorities. Here, as the Chair of the ISO technical committee for quality management and related general aspects for medical devices, Dr. Eamonn Hoxey shares his thoughts about the industry, its exponential growth, and why uniform and consistent standards are important.

Many medical devices are invasive by nature – they probe in and around the human body. While some explore the anatomy, cut away disease and repair damage, others remain inside the body, such as a prosthetic hip, an artery stent, a new valve or a pacemaker.

Combining the highest-of-standard design and performance characteristics for medical devices with the complicated business model of healthcare itself – and the field's stiff regulatory requirements – makes for one of the most complex and demanding industry sectors known for any manufactured products.

To manage this complexity, says Dr. Eamonn Hoxey, Johnson & Johnson's Vice President for Medical Devices Strategic Quality and Compliance Programmes, ISO standards are essential. They bring quality medical devices to market and sustain them throughout their life cycle.

***Dr. Eamonn Hoxey**, Chair of ISO technical committee ISO/TC 210,* Quality management and corresponding general aspects for medical devices.

As Chair of ISO technical committee ISO/TC 210 for quality management and related general aspects for medical devices, he also argues that ISO standards can support the regulatory requirements that oversee their safety and performance. Following are the latest trends in medical devices standardization, which Dr. Hoxey believes is embracing the dynamic change that is taking place in the industry.

***ISOfocus*: How do you determine when a medical device is safe for patient care?**

Dr. Eamonn Hoxey: A systematic approach to risk management is applied throughout the life cycle of a medical device. Initially, in design and development, risks to safety and performance are identified and measures devised to eliminate or mitigate them. The design then undergoes stringent verification and validation to demonstrate the effectiveness of the risk controls that have been introduced, and confirm that any remaining risk is acceptable when weighed against the clinical benefits. Throughout the use phase, the medical device is further monitored to determine any unidentified risks and the effectiveness of the risk controls in place, so that action can be taken if there are any unexpected events.
ISO/TC 210 has developed standards to support the regulatory requirements that oversee safety and performance of medical devices. The design and development of these devices is part of the manufacturer's quality management system (QMS) and

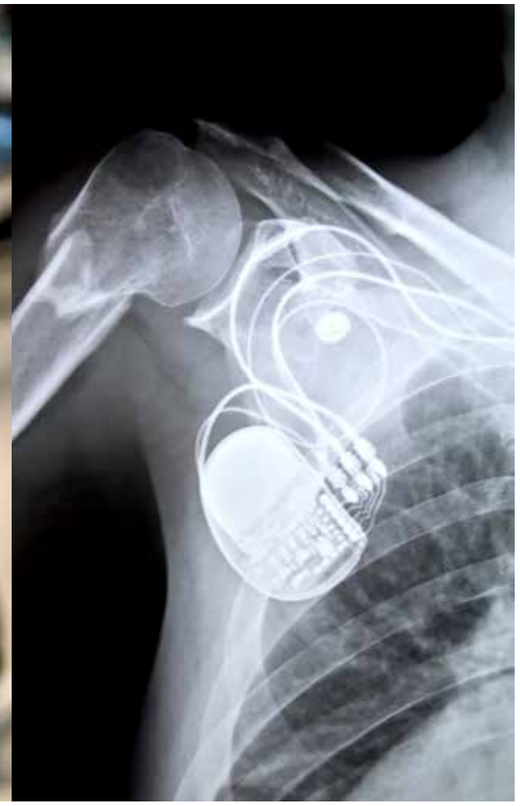
Medical devices are a critical element in the safe delivery of healthcare.

ISO 13485 provides requirements for the design and development process, including the incorporation of risk management. In addition, the standard covers the analysis of feedback from experience in the use phase and the conduct of post-market surveillance. As an effective complement, ISO 14971 describes a systematic approach to risk management that can be applied throughout the medical device's life cycle.

To what extent do ISO standards impact the safety, quality and reliability of our health services?

"Health services" is a broad term that encompasses all aspects of the delivery of healthcare to patients in a wide variety of settings – from hospital wards to laboratories, from hospital outpatients to general-practice surgeries, from home healthcare to first aid. One particular area in which ISO standards play a significant role is the life cycle of healthcare technology, from design and development through the supply chain to the point of use.

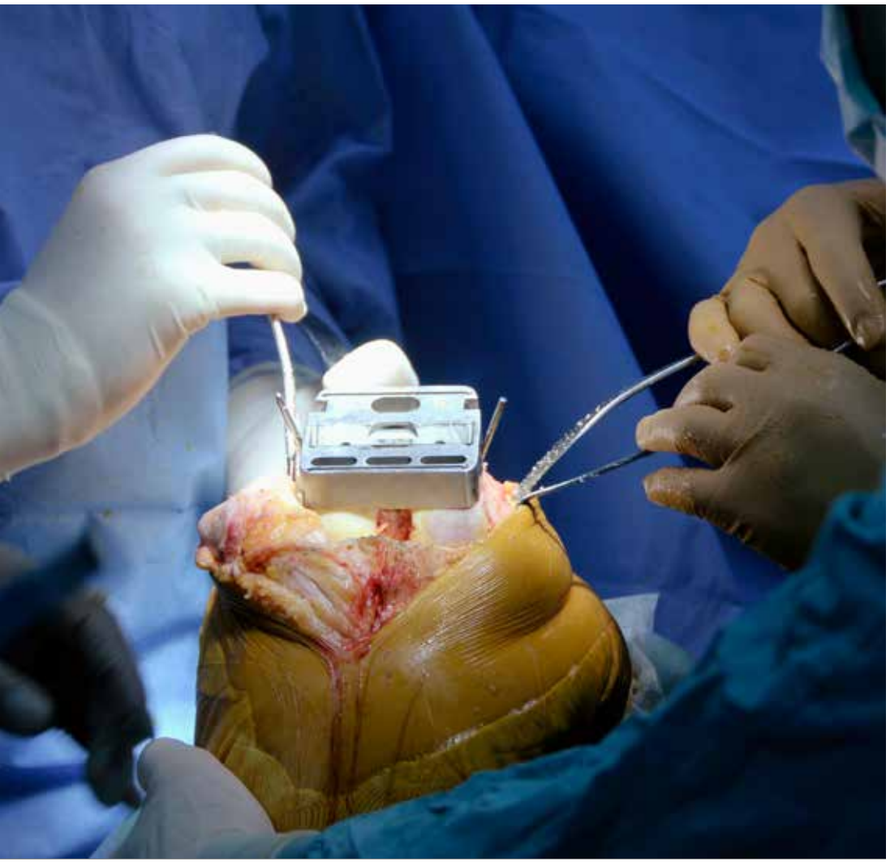
Healthcare technology is used throughout the delivery of health services in a variety of settings. Its scope is enormous and includes sophisticated diagnostic imaging and laboratory equipment, devices used in surgical procedures, aids to daily living and equipment sold over the counter in a variety of retail settings. Healthcare technology is vital to the efficient and effective operation of healthcare delivery and contributes to changing the lives of patients and caregivers on a daily basis.
There is a wide range of ISO standards used in the life cycle of healthcare technology. ISO technical committee ISO/TC 210 is involved in a number of general areas that span the full range of products. Examples are standards for a QMS used for regulatory purposes, risk management processes used in the life cycle of medical devices, symbols used to convey information on labels and avoid the need for translation of critical information into multiple languages, and small-bore connectors used in combining devices to provide therapy to patients.



Medical devices play an ever-increasing role in transforming healthcare delivery, but there is a dramatic "risk to life" angle in lack of interoperability or misconnection. Could you please elaborate?

Medical devices are a critical element in the safe delivery of healthcare and command a high degree of safety and performance. As the clinical environment becomes more complex and the technology more sophisticated, particularly with the interaction of multiple medical devices used on a single patient, the need to consider the total system rather than the individual components also increases.

The growing application of a systems approach and consideration of issues, such as human factors and usability, in the design and development of medical devices are accordingly becoming more important. ISO/TC 210, in conjunction with IEC/TC 62 on electrical equipment used in medical practice, has developed a number of standards that apply systematic approaches to quality management, risk management and usability, and has in preparation a series of standards on small-bore connectors intended to reduce the risk of misconnection of devices at the patient interface.



ISO standards play a significant role.

How important is a QMS to medical devices? Why was it necessary to update ISO 13485? What will be the additional benefits of the revised version?

A QMS is a critical element for medical devices, required by the regulations in most jurisdictions to integrate the control of a product's life cycle. Hence, it was necessary to update ISO 13485 to reflect the latest developments in technology as well as the expectations of manufacturers and regulators.

The main benefit of the revision will be greater transparency of the requirements and alignment between the regulators, auditing bodies and manufacturers of medical devices. Areas that have been strengthened include the interaction between the QMS and regulatory requirements, the applicability of the standard throughout the medical device's life cycle, for example across distributors and importers, and the wider incorporation of risk management principles throughout the QMS.

Why is Johnson & Johnson participating in ISO standards work and what kind of benefits does the company stand to gain?

Johnson & Johnson welcomes the chance to participate in standards development. It provides an opportunity to address common challenges for manufacturers, regulators and users and help develop solutions that benefit all parties, ultimately for the good of the patient. In addition, there is great scope for professional development for our staff as they acquire both technical knowledge and interpersonal skills. ■

NEW CASCO CHAIR

Frank Makamo, Executive of the Certification Division at the South African Bureau of Standards (SABS), ISO member for the country, is the new Chair of ISO's Committee on conformity assessment as of 1 January 2016.

Mr. Makamo joined SABS in 1998 and held a number of positions before being appointed the Executive responsible for the Certification division in 2011. He has extensive experience of standards development and conformity assessment policy in South Africa and internationally.

The ISO Committee on conformity assessment (ISO/CASCO) is one of the largest committees in ISO, with 90 member countries participating and another 40 as observers. Its mission is to develop harmonized and internationally accepted policy on conformity assessment, liaise with industry sectors and intergovernmental agencies with regard to conformity assessment activities, and promote the use of the CASCO toolbox internationally to facilitate global trade.

Frank Makamo succeeds Lane Hallenbeck, Vice President for accreditation services at the American National Standards Institute (ANSI), ISO member for the USA, for an initial two-year term.

STANDARDS AT THE WEF IN DAVOS

***Kevin McKinley**, Acting ISO Secretary-General, and **Roberto Azevêdo**, Director-General of the World Trade Organization, at the WEF.*

Acting ISO Secretary-General Kevin McKinley joined the brightest minds from government, business and society at the World Economic Forum (WEF) Annual Meeting in Davos, Switzerland, last January. Held under the theme "Mastering the Fourth Industrial Revolution", the WEF tackled big issues about some of the most important global challenges of our time.

Previous industrial revolutions saw work change from manual to mechanical to automated production. Today, innovative cyber-physical systems like robots, 3D printing and driverless cars are disrupting industry faster than ever before. We live in an interconnected world, where breakthrough technologies, demographic shifts and political transformations have far-reaching societal and economic implications.

Emerging technologies are double-edged swords. They make our lives easier, safer and healthier, but they carry new risks. New technologies also raise questions about the city of the future, as global urban infrastructure is predicted to double in the next 35 years.

It is therefore essential to world peace and prosperity that global leaders address the ethical issues surrounding technology. As repositories of the world's best practice, ISO standards will play a key role in this fourth revolution, opening up opportunities, but also setting expectations, boundaries and limits – to support the decisions made in the collaborative spirit of Davos.

CONFORMITY ASSESSMENT WORKSHOP

Some 130 industry representatives, government regulators, economic leaders and other stakeholders attended a conformity assessment workshop in December 2015 organized by the World Standards Cooperation (WSC) – a high-level partnership of IEC, ISO and ITU – and hosted by the United Nations Economic Commission for Europe (UNECE).

The workshop included four panels and several tools demonstrations to further understanding and provide practical insights into such issues as product safety, personnel competence and environmental impacts. The importance and benefits of using the ISO/CASCO Toolbox was highlighted as the bridge between defining requirements in standards and determining fulfilment of those requirements through conformity assessment.

Workshop participants confirmed interest in building on the success of the workshop with similar events in the future.

Presentations and other reference documents are available here:
www.wsccaworkshop.com

ISO TO HOLD GLOBAL SERVICES WORKSHOP

Discover the potential for services standardization in ISO! As international trade in services become an even greater driver of economic growth, both in developed and developing countries, market demand for standards to ensure the quality of service delivery is steadily increasing. How can ISO step up to meet this demand?

Join us for this interactive workshop on 13 and 14 June 2016 to explore how ISO International Standards can best help design, assess and measure service excellence, benefitting both business and consumers.

Further details on the event will be shared as they become available. For more information, please contact Belinda Cleeland at cleeland@iso.org.

NEW BURST OF MINING ACTIVITY

ISO/TC 82, *Mining*, which had lain dormant for several years, was re-activated at the end of 2012 and has met several times since then. During the course of these meetings, the committee welcomed new members, bringing its total membership to 20 participating countries and 21 observers, and conducted a revision of its structure, its scope and its work programme.

ISO/TC 82 mainly develops specifications relating to specialized mining machinery and equipment used in opencast mines, as well as all types of underground mining machinery and equipment. To date, the committee has already published 36 International Standards and is working on three major projects on machine safety, structures for mine shafts and the classification of mining accidents. Two additional projects, which are still at the preliminary stage, focus on drilling rigs and a template for the public reporting of exploration results, mineral resources and mineral reserves.

Make **water management** *your business*

by Marcio Viegas

Water is the source of life, and business. Yet despite its seeming abundance, water crises have been identified as one of the highest global risks of our time. On the occasion of the United Nations World Water Day, we look at why measuring our water footprint is taking on a new appeal.

Only 1% of the world's water is freshwater.

Water is not just vital to sustain life; it's also a crucial resource for businesses. From food and clothing to cars and mobile phones, it is an essential input throughout the supply chain. And with plenty of free-running water, rain, and even floods, it is hard for us to imagine it ever running out.

Yet only 1% of the world's water is freshwater, available for consumption. To make matters worse, the precious liquid is unevenly distributed across the Earth, with some regions blessed with bountiful rainfall while others are plagued with prolonged droughts. Add to that an exploding global population, polluted waterways and the devastating effects of climate change and it's no wonder the World Economic Forum identifies water crises as one of the three risks with the highest potential global impact – far above the spread of infectious diseases and interstate conflict.

Supplied at the flick of a tap, water is also generally cheap and is often taken for granted until there is a severe shortage episode – as seen recently in California and São Paulo – bringing agriculture and industry to a standstill and costing billions of dollars to the economy. Managing our "blue gold" efficiently is therefore paramount to developing flourishing societies and businesses.

Celebrated annually on 22 March, World Water Day highlights a specific aspect of freshwater. Under this year's theme "Water and jobs", it focuses on the two-way relationship between water and decent work opportunities in the quest for sustainable development.

How big is your footprint?

Water is an invaluable commodity in terms of trade and economics. For example, it takes 15 000 l of water to produce 1 kg of beef. Water consumption in the supply chain represents as much as 90% of the total water footprint of industrial users. What then happens when the taps run dry?

In the World Economic Forum's Global Risks Report 2016, chief executives and world leaders said they regarded water crises among the top five global risks to business. And with good reason – water scarcity or pollution incidents can halt production, disrupt the supply chain, lead to conflict with other water users, and harm corporate reputations. In the light of looming water scarcity and the growing demand for resources, businesses and government are taking note of the need to better manage their water.

Current patterns of production and consumption undoubtedly have an impact on the environment, climate change and water resources.

Understanding this impact – or "footprint" – is a vital step towards finding strategies to reduce it. This can be achieved by measuring its use, and the impact of this use, throughout the life cycles of products, processes and organizations.
The solution comes in the form of water footprint assessment (WFA), a technique to better understand an organization's water-related impacts so that they can be better managed. In fact, its popularity is such among the business world that WFA methodologies have mushroomed in the last decade.
To reign in the confusion, in 2009 ISO launched a global effort to develop a harmonized framework for the quantification and reporting of water footprints. The result was ISO 14046:2014, designed to help organizations assess and report the potential impacts of water use and pollution of products and processes, based on a life-cycle assessment.

A business decision

Developed by experts from all over the world, the standard has already seen good uptake across many sectors in over a hundred countries, starting with the more water-intensive industries such as food and beverages, power and utilities, construction, and chemicals. But interest is also rising in the automotive and oil & gas industries, where the need to properly manage water shortage risks is gaining ground.
The main driver behind the movement is risk management and the realization that organizations cannot afford to be grounded for lack of water or because of the burden they impose on the environment. Interestingly, agriculture, which is responsible for around 70 % of the global water consumption and is the first to be impacted when it runs dry, has yet to get firmly on board, although it may soon come round to the idea that it can produce more with the same amount of water.

Drinking from the same fount

So what is the appeal of ISO 14046? For a start, it is the first truly "international" standard for water footprinting based on life-cycle assessment. This is important because it provides organizations with the means to measure their water footprint in a uniform and accurate manner across the globe.
ISO 14046 comes with 50 definitions which lay down basic concepts of water footprinting that are accepted worldwide. The standard also puts forward 13 principles, notably the importance of considering a water footprint assessment from a "life-cycle perspective", i.e. taking into consideration all stages of the life cycle of a product or an organization.
Secondly, the standard's content is flexible enough to be applied to products, processes and organizations. Moreover, it is at the pinnacle of hydrological knowledge and includes geographical and temporal dimensions that help determine the quantum of water used and the changes in water quality.

***Marcio Viegas**, Managing Director of SUST4IN.*
marcio.viegas@SUST4IN.com

Based on life-cycle assessment, ISO 14046 specifically helps assess the magnitude of potential environmental impacts related to water, identifying opportunities to cut down those impacts, promote water management optimization at all levels, and provide reliable and scientifically consistent information for reporting water footprint data that can be monitored over time.

No trivial exercise

A water footprint assessment according to ISO 14046 is the result of a comprehensive analysis including four phases:

1. **Goal and scope definition:** identifying the life-cycle assessment's purpose and determining the boundaries
2. **Inventory analysis:** quantifying the energy, raw material inputs and environmental releases associated with each stage of production
3. **Impact analysis:** assessing the impacts on human health and the environment associated with the energy and raw material inputs, and environmental releases quantified by the inventory
4. **Interpretation of results:** evaluating opportunities to reduce energy and material inputs, or environmental impacts at each stage of the product life-cycle

ISO 14046 is the first truly "international" standard for water footprinting.

The assessment culminates in a water footprint profile that considers various environmental impacts – from scarcity to eutrophication (i.e. the addition to water bodies of external nutrients) to acidification and more – making it possible to identify the weak points in the life cycle of the system studied. These then become the focal point for improving the system from an environmental point of view.
Water footprinting, however, is no trivial exercise. A good way to start is by assessing the water scarcity footprint of an organization. Water is a local resource bound to seasonal variations, so the impact of its use on, for instance, water scarcity can only be evaluated by comparing the water consumption against the locally available water resources. To mitigate this, one solution is to normalize the values obtained – using the concept of litres or cubic metres of water equivalent – with each local scarcity level and, if relevant, at different seasons.

A reference for the future

ISO 14046, it seems, is poised for success, not least because it supports the United Nations Sustainable Development Goals (SDGs). Adopted in 2015 as part of the 2030 Agenda for Sustainable Development, the SDGs cover a wide range of drivers across the three pillars of sustainable development, including a dedicated goal on water and sanitation (SDG 6) that sets out to "ensure availability and sustainable management of water and sanitation for all".
With water at the very core of sustainable development, SDG 6 not only has strong linkages to all the other SDGs (food, health, cities and sustainable consumption and production), it has the ability to underpin them.
As more and more organizations jump on the bandwagon, ISO 14046 is well on course to becoming the international reference for water footprint assessment and reporting. This can lead to a more robust risk management and, potentially, increased production and better products, as the water "bottlenecks" and impacts are better understood. ■

Photo: International SOS

International SOS *breaks virtual ground*

With people living in rural areas where visiting a clinic is difficult, and travellers increasingly globetrotting to far-off places, International SOS delivers remote medical support and travel security assistance to millions around the world. Here, the company's management tells how strict processes are needed to ensure quality in the provision of telehealth services, and how ISO/TS 13131 has helped it reach a new high.

The telehealth concept is at the cutting edge of technology.

It's midnight and you're burning with fever. You power up your computer and visit one of the many Websites that feature online access to physicians 24/7. Within minutes, you're engaging in a video consultation with a board-certified physician who evaluates you, provides clinical instruction, and even prescribes medication in some cases. Soon afterwards, you're back in bed resting with a prescription waiting to be filled.

Welcome to the world of telehealth (also called telemedicine), where the use of electronic information and telecommunications technologies supports long-distance clinical care. It is a world in which access to healthcare is paramount and simple. Distance is no longer a barrier to services because technology is there to fill the gap.

Dr. Ryan Copeland, Regional Medical Director at International SOS, which provides remote medical assistance to millions of clients around the world, says ISO/TS 13131 guidelines for the delivery of telehealth services enable the company to ensure consistent, quality remote medical assistance while safeguarding a client's private data. And the sky's the limit in this new medical niche.

Working in some of the most inhospitable places on earth, International SOS offers medical care where it is not available or where cultural and language barriers exist. Its telehealth services platform provides medical information, advice, and referrals 24/7 365 days a year to clients travelling or working abroad. In a recent interview with *ISOfocus*, Dr. Copeland discusses virtual healthcare delivery and how ISO/TS 13131 for telehealth services provides the "gold standard" for the company's platform.

***ISOfocus*: How does telehealth improve the patient experience?**

Dr. Ryan Copeland: The telehealth concept is at the cutting edge of technology, typically including video-conferencing, the Internet, store-and-forward devices, streaming media, and terrestrial and wireless communications. This is a revolution in the realm of medical provision, which expands patients' options and their access to appropriate care. It also provides peace of mind – particularly for people who are travelling or are far from quality healthcare.

In its simplest form, telehealth is delivering healthcare from a distance. The capability allows patients to access medical support that they may not otherwise have – either due to location, medical specialty, or even language limitations.

Telehealth is a form of medical provision that extends the reach of care, reduces the need for travel and mobility, supports choice in health service delivery, preventive care, individual self-care, and may also increase the overall efficiency of treatment. For people travelling or living in a new country, the benefits of a trusted telehealth service provider are significant. The patient gets consistent, quality care, no matter where they are in the world.

Photo : International SOS

A patient visits a doctor at the International SOS Almaty Clinic, a medical centre for travellers and expatriates in Kazakhstan.

We have been a leader in telehealth services for 30 years.

What are the biggest benefits of telehealth technology?

With national healthcare services buckling under the pressures of growing demand and affordability, telehealth has sparked interest as a solution to reduce the cost of care and increase overall system capacity. The benefits it affords across the healthcare ecosystem are immense.

Patients: Easier access to medical guidance on a 24/7 basis from home, the office, while travelling, and even abroad.

Insurers: Telehealth is a much more cost-effective method of treatment versus an in-person visit to an urgent care clinic. Even if a patient requires subsequent in-person care, telehealth can be used to triage and validate the need, or provide initial guidance quickly and improve the longer-term outcome (and total cost of care).

Hospitals: Ability to reduce non-acute patients showing up in the emergency room (e.g. a patient presenting to emergency with a seasonal flu).

Employers: By creating a private space or capability for telehealth consults at the workplace, it reduces hours of lost time due to travel and waiting per employee and promotes a positive message to staff, helping them access care more easily.

Why did International SOS decide to implement ISO/TS 13131?

Our business is providing medical advice and travel security assistance to millions of people around the world. Therefore, it is vital that we employ strict processes to ensure consistent quality in the delivery of these services.

International SOS invests heavily in quality programmes. We have been a leader in telehealth services for 30 years. By being the first company in the world to be certified to ISO/TS 13131, we were able to showcase the processes and practices we employ in the provision of our telehealth care.

Telemedicine has become popular amongst organizations as employers look to reduce costs and improve productivity whilst delivering an enhanced quality of care. As a result, the number of companies trying to enter the telehealth space has increased dramatically. The guidelines for the delivery of telehealth services are there to ensure providers administer consistent, quality remote medical assistance and have policies in place to safeguard their clients' private data.

What are the challenges with implementing a telemedicine platform? How can ISO/TS 13131 overcome these barriers?

Technology, security, global reach and expertise are some of the issues healthcare providers face when building a telehealth platform. Investing in appropriate technological solutions, like remote diagnostic devices, training, and the supporting infrastructure can be significant. And, once the technology is in place, there must be very stringent data security and processes to safeguard patient privacy.

Global reach and capability are also a major challenge for many healthcare providers as regulations on delivering medical advice across borders vary by country. Regional expertise is also required – simple things like knowing the local name for a particular pharmaceutical, to the more complex development of a network of vetted, quality medical providers if in-person treatment is recommended.

About International SOS

With over 11 000 employees operating in more than 90 countries worldwide, International SOS (**www.internationalsos.com**) helps organizations manage the health and safety risks facing their travellers and global workforce. Founded in 1985, the company's "people first" approach remains true today. This commitment extends to its risk mitigation services and focus on an organization's Duty of Care, helping clients achieve service excellence and a competitive advantage. Clients include 83% of the Fortune Global 100s leading multinational corporations, insurers and financial institutions as well as governmental and non-governmental organizations.

Dr. Ryan Copeland in the International SOS London Assistance Centre.

Photo : International SOS

To be certified to ISO/TS 13131, companies need to demonstrate consistent implementation of the following:

- Management of telehealth quality processes
- Management of financial resources to support telehealth services
- Processes relating to people such as workforce planning, healthcare planning, and responsibilities
- Provision of infrastructure and facilities resources for telehealth services
- Management of information and technology resources used in telehealth services

What, in your opinion, are the most important benefits of ISO/TS 13131?

One of the key benefits of ISO/TS 13131 has been the provision of quality telehealth services, thus ensuring seamless cooperation globally, interoperability of systems and a reliably high standard of delivery, no matter where in the world our assistance is required.
This allows for increased diagnostic certainty, maximizing the opportunity to confirm a correct diagnosis and initiate appropriate treatment early on. A further important outcome is the improved ability to promote continuity of care and expedite clinical care pathways by early telehealth intervention, which is especially relevant for patients in more remote locations or locations with reduced healthcare provision.

How would you describe the implementation process (challenges, time, staff, etc.)?

In response to International SOS's request, BSI, ISO member for the UK, developed a certification specification scheme for ISO/TS 13131. The scheme, which was completed in August 2015, specifies conformance to ISO 9001 as a prerequisite for undergoing an ISO/TS 13131 audit, and the International SOS quality management system is certified to ISO 9001 globally.
Ahead of the company's audit and to ensure conformity to ISO/TS 13131, the team undertook a gap analysis between the ISO certification specification and International SOS's standards. Where the team felt that ISO/TS 13131 provided more specific criteria than the company's existing standards, they earmarked these for improvements at International SOS's next annual standards review.
In terms of preparing for the audit, all applicable staff completed two-hour workshops in small groups. The two-day audit then took place in September 2015. Happily, the auditors found no non-conformances and no recommendations were made; and the certificate was issued in October 2015.

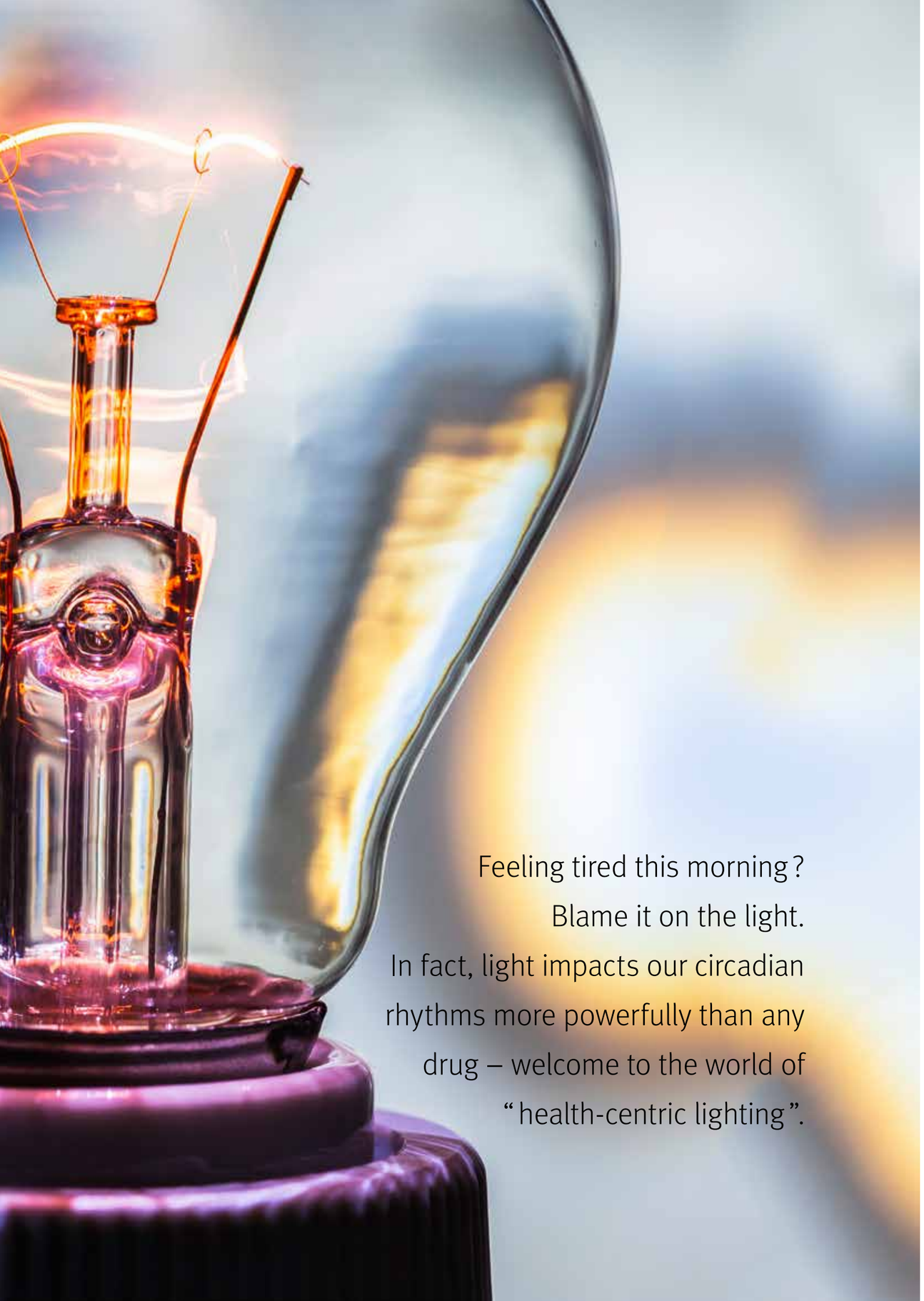
Any predictions for the future of telehealth? And the need for additional ISO standards and documents?

Telehealth will become a standard tool for general practitioners (and hospitals) to manage their existing patients, with whom, incidentally, many doctors already communicate via phone or e-mail when needed. This is set to expand further, resulting in tighter regulations and restrictions.
There are several technological trends driving the increased use of telehealth. These include:

- Rapid adoption of smartphones
- Common use of video for mobile communication
- Increasing Internet access and bandwidth
- Better digital diagnostic tools

With the prospect of lower costs, streamlined exams and greater patient access, telehealth will soon become a standard tool for healthcare providers. We look forward to the future and ISO's contribution to this exciting evolution in the healthcare sector. ■

One of the key benefits of ISO/TS 13131 has been the provision of quality telehealth services.



Things you need to know about **health-centric lighting**

The lights in your home and at the office can make a difference to the way you feel and can even affect your health. In fact, according to a 2015 statement issued by the International Commission on Illumination (CIE), entitled *Recommending proper light at the proper time*, the "non-visual" effects of light are the influence of light on our circadian clock, alertness, sleep patterns and so on.

While the CIE cautions that knowledge in this field is still "premature", it goes on to say that "observations in laboratory and application studies show beneficial effects on human health and performance". There is general agreement that the non-visual effects of light stimulus depend on the spectrum, intensity, duration, timing and temporal pattern of the light exposure.

The variety of physiological responses means researchers are looking at the clinical implications of lighting from a healthcare perspective. In order to get a deeper understanding of what this means in terms of lighting design, we spoke with Prof. Tongsheng Mou, Director of Smart & Health Lighting Research Center, in Zhejiang, China, and founder of Sensing Instruments Co, Ltd, a company dealing with high-quality optical equipment.

***ISOfocus*: Why is lighting important?**

Prof. Tongsheng Mou: Light is a huge aspect of our daily functioning environment, enabling us to see our world in order to interact with it. Light also has an often overlooked impact on our behaviour due to "non-visual" effects. Light exerts these non-visual effects as a regulator of our physiology, hormonal and behavioural systems and serves to drive our 24-hour sleep/wake cycle known as the "circadian rhythm". So what kind of behavioural responses are controlled by light? In short, nearly everything! From levels of cortisol, hunger hormones and body temperature, light really does impact every aspect of our daily physiology and behaviour. Humans are subjected to a substantial amount of artificial lighting, so there is an urgent need to control the luminous environment to promote health and avoid harm.

How bright is the lighting industry?

In the lighting industry, product evolution is advancing, moving from regular LEDs to human-centric lighting (HCL) that can benefit the biological, emotional, health and well-being of people. This is achieved by dimming the smart light source to mimic the levels of sunlight throughout the day.
HCL, a LED-based lighting technology that aims to match light characteristics with human circadian rhythms, is a potential area on which manufacturers are setting their sights and investing in what they hope will be a bright future. IHS Technology, an analytics consultancy with expertise in a number of industries, forecasts the global HCL market is expected to grow from USD 34 million in 2015 to USD 805 million in 2020. Of course, HCL is a very recent concept, as noted in the Lighting Executive Insight Report (2014). There are no industry-wide definitions or standards yet, and it's difficult to predict what the market will look like five years from now.

So how is Sensing involved in lighting breakthroughs?

Here, at Sensing, we focus on high-quality optical equipment used in the lighting quality measurement and photobiological safety assessment. We have pioneered many key breakthroughs in lighting over the past ten years. In fact, we recently developed life-rhythm lighting lamps and lamp systems, specifically engineered to help facilitate a healthy circadian rhythm. This new technology is expected to improve sleep and performance by mimicking a normal day/night cycle.
New products like these lamps and lamp systems, together with recent studies by major universities and health organizations, have increased the public's awareness of the close link between light and health. The technology provides new options to help support good health by using the right light, at the right time, for the right task.

Where do standards fit in?

The effect of light on the body represents a new opportunity to advance the lighting industry, as well as new lighting

THE LIGHT WAVELENGTH SPECTRUM
Using the right light, at the right time, for the right task.

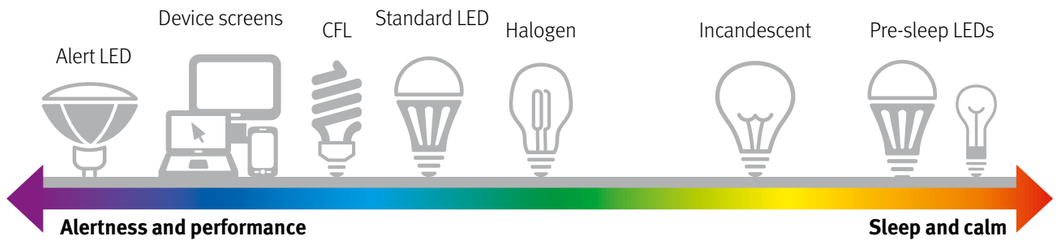


Photo: Sensing

***Prof. Tongsheng Mou**, Director of Smart & Health Lighting Research Center, (right) and **Elizabeth Gasiorowski-Denis**, ISOfocus Editor-in-Chief.*


Photo: Sensing

***Prof. Mou** points to a photometric sphere designed to measure the luminous efficacy and colour performance of lighting sources.*

The global HCL market is expected to grow from USD 34 million in 2015 to USD 805 million in 2020.

standards and guidelines. At Sensing, we believe it is important to participate in the work of ISO technical committee ISO/TC 274, *Light and lighting*, as the future International Standards to come out of these discussions will provide a platform for consistent language with regard to product design, manufacturing and testing for the latest state-of-the-art technologies, not to mention ensure public safety and consumer protection.
As the general lighting landscape continues to evolve, each technology will come with advantages and disadvantages in terms of energy efficiency and light quality, but one thing will remain the same – the importance of standards. The quality, performance, and safety of our lighting environment, not to mention our quality of life will depend on them. So let's work together for an even brighter future.

What does the future hold?

Although scientific researchers still have numerous questions in this field, the first results emerging from the application of these new findings on the non-visual effects of light open a very promising future for improvements. This is true for professional lighting as well as lighting at home.
Before truly human-centric lighting can be developed, however, further investigation needs to be conducted into the relation between lighting and health. One the challenges ahead will be sustaining enough interest (and research funding) to develop that knowledge, so that future lighting systems – and the standards that support them – fulfil the promise of delivering "light for life". ■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