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News & views from the IEC

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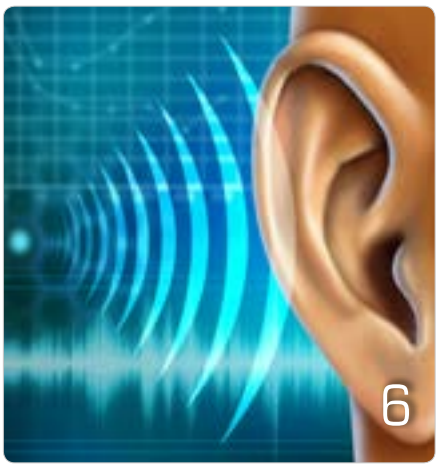
New IEC Vice-President

Dr Yinbiao Shu



4 *A Joint Working Group prepares International Standards for electrical equipment and systems using robotic technology in the medical environment* **6** *Hearing aids help those suffering from this disability live a nearly "normal" life. TC 29 prepares International Standards to ensure they meet the needs of users and practitioners* **10** *The global medical electrical equipment market is expanding rapidly as an aging population needs more care and as millions more people gain access to medical services in the developing world* **14** *Noise represents a health risk for wide sections of the population in many countries, in particular in the industrialized world* **15** *Cooperation between IEC and ITU has produced a new standard that allows multimedia content to be legally used across different platforms* **21** e-tech *profiles Dr Shu Yinbiao, Convenor of the IEC MSB (Market Strategy Board), and recently appointed as third Vice-President of the IEC.*

Focus of the month Medical electrical equipment

This issue of *e-tech* focuses on standardization work and conformity assessment for certain types of medical electrical equipment and systems. From robotic technology to major advances in the performance of hearing aids, several IEC TCs are at work to provide International Standards while IECEE ensures that all equipment operates in the safest possible way.

Medical equipment

Keeping healthy and safe

Claire Marchand,
Managing Editor e-tech.

This month, *e-tech* focuses on standardization work and conformity assessment for certain types of medical electrical equipment and systems.

The trust issue

Medical staff needs to trust the reliability of the instruments and equipment used in medical practices to make a diagnosis or in the operating room to perform surgery.

Widely adopted standards

IEC TC 62 and its SCs prepare International Standards for Electrical equipment in medical practice. Their work entails coordination with many other TCs, such as TC 29: Electroacoustics, which develops International Standards that have contributed to major advances in the performance of hearing aids over the years.

TC 29 also prepares International Standards for equipment used to measure sound levels. These are used in many sectors, including the civil aviation industry to curb noise levels.

Medical robotics developing fast

Medical robotics now represents a fast-developing and significant domain which is having a major impact in the medical environment. It greatly improves the treatment of many illnesses and contributes to a speedy recovery for patients. Experts from IEC SC 62A work in an IEC/ISO Joint Working Group to develop International Standards for medical electrical equipment and systems using robotic technology.

Importance of conformity assessment

While IECEE ensures that electrical and electronic devices and equipment are reliable and meet expectations in terms of performance, safety, durability and other criteria, IECQ certification provides manufacturers of medical electrical equipment with the assurance that the electronic components they use are of the highest quality.

▲ *Medical equipment relies more and more on electronics to provide the most accurate diagnoses and measurement*

◀ *MRI (magnetic resonance imaging) scan and screens*

Dr Robot needs standards too!

With more robots used in medical care, International Standards are vital for safety

Gurvinder S. Virk, Convenor
IEC SC 62A/JWG 9

Robotic systems have been around in industry for more than 50 years. Their introduction to the medical and healthcare environment around the world is much more recent and carries the obvious need to ensure safe usage for patients and medical staff alike. A 2011 created IEC/ISO Joint Working Group prepares International Standards for Medical electrical equipment and systems using robotic technology.

Necessary cooperation

New applications for robots are emerging in the medical sector. Many medical device regulatory regimes, such as the European Commission's Medical Device Directive, classify these robots as medical equipment or medical devices.

The SCs (Subcommittees) and WGs (Working Groups) of IEC TC 62: Electrical equipment in medical practice, have been responsible for carrying out the bulk of the medical equipment standardization work required to produce the IEC 60601 family of standards. These cover the safety requirements for ME (medical electrical) equipment and MES (medical electrical systems) in current use.

The introduction of robots to manufacturing in the early 1960s carried with it the need, satisfied by ISO (International Organization for Standardization), for development of a number of standards. They included standards for robotic vocabulary and characteristics, safety requirements, performance assessment and interfaces. The standards allow for industrial robot regulation as well as for the safe operation of robots as machines that are housed in real or virtual cages to separate them from humans and so prevent harm occurring.

Recently, personal care robots have been introduced. In providing a range of services to people, many of their designated tasks involve close robot-human interaction. This has led to their classification and regulation as machinery and relevant standards are being prepared by ISO TC (Technical Committee) 184/SC (Subcommittee) 2: Robots and robotic devices.

No need to reinvent the wheel

Discussions centring on medical robot standardization issues took place between ISO TC 184/SC 2 and IEC SC 62A: Common aspects of electrical equipment used in medical practice, and demonstrated that both had a valuable role to play in the work. Combining the existing industrial and service robot expertise of ISO TC 184/SC 2 with the medical electrical equipment expertise of IEC TC 62 enabled the key issues to be investigated. This also allowed the medical robot standards needed to fit into the IEC 60601 family to be produced without having to start from scratch and "reinvent the wheel".

It was decided that the first step should be to develop a horizontal medical robot standard, making the link between robots and medical electrical equipment; once this had been done, the work could be followed with a variety of vertical standards for different types of medical robots. In April 2011, IEC TC SC 62A and ISO TC 184/SC 2 set up JWG (Joint Working Group) 9: Medical electrical equipment and systems using robotic technology.

JWG 9's remit is to "develop general requirements and guidance related to the safety of medical electrical equipment and systems that utilize robotic technology. The work encompasses medical applications (including aids for the disabled) covering invasive and non-invasive procedures such as surgery,

Surgeons operating using a da Vinci Si Surgical System (Photo: ©2011 Intuitive Surgical, Inc.)

rehabilitation therapy, imaging and other robots for medical diagnosis and treatment". The group started with 33 experts from 11 countries, it has now 57 experts from 16 countries.

Substantial work so far

JWG 9 brings together experts in the fields of machine safety and medical device safety. The group has been investigating the fundamental difference between ME equipment as defined in IEC 60601-1, Medical electrical equipment, and the emerging medical robots so as to find a common basis for the standardization work on medical robots.

According to its definition, ME equipment is intended for use in the diagnosis, treatment, or monitoring of a patient, or to compensate for or alleviate the effects of disease, injury or disability. As medical robots have the same intended functions, the differences between the two categories need identifying so as to ascertain specifications for the new standardization work. JWG 9 has investigated the issues and has concluded that the key difference is the "degree of autonomy". The expression is found in the ISO 8373 robot vocabulary standard which defines the term "robot" as an "actuated mechanism programmable in two or more axes with a degree of autonomy, moving within its environment, to perform intended tasks". The ISO standard further defines autonomy as the "ability to perform intended tasks based on current state and sensing, without human intervention". Although JWG 9 has recognized that these definitions might need some refinement for medical applications, it is clear that use of the term "medical robot" automatically includes the possibility of autonomous capabilities for ME equipment. This point is not fully addressed within the IEC 60601 family of documents.

The road ahead

ME equipment manufacturers have begun adopting autonomous functionalities into MES, as do the IEC 60601 standards. Some of the results are enhanced outcomes for medical procedures (such as shorter treatment), improved economic value and improved consistency and reliability of MES.

Autonomy in ME equipment and MES however, also introduces additional hazards that need to be addressed more comprehensively than is currently the case with the IEC 60601 documents. This is why a horizontal type standard is being developed, with the title "Medical electrical equipment and medical electrical systems employing a degree of autonomy" rather than restricting attention to "medical robots" alone, although specific standardization work for different types of medical robots is also felt to be needed.

Medical robots have been defined as "robots or robotic devices intended to be used as ME equipment or as MES". So as to explore the various issues involved in medical robot standardization, three types have been investigated by JWG 9: radiotherapy, surgery and rehabilitation robots.

Since it began meeting in 2011 JWG 9 has developed a working definition for the degree of autonomy as a "numerical metric based on the properties and capabilities of the ME equipment indicating the level of the autonomy". This provides a framework for handling autonomy of ME equipment via 4 sub-tasks:

- Monitoring: assessing all information, sensing and other data relevant to assessing status of ME equipment, patient or operator
- Generating: formulating options or task strategies for achieving predefined goals
- Selection: deciding on a particular option or strategy; and
- Execution: carrying out the chosen option through control actions at an interface

It is possible to organize these 4 steps in different ways and example methods have been developed, based on descriptive and numerically weighted approaches and characterizing the varying degree of autonomy, to assist manufacturers with the risk management process.

Emerging functionality calls for new TR

JWG 9 looked at existing ME equipment and MES that have robotic characteristics and examined the suitability of the existing standards in addressing hazards that might be associated with the systems' use. It was concluded that IEC 60601-1, *Medical electrical equipment,* ISO 14971, *Application of risk management to medical devices*, IEC 62366, *Medical devices - Application of usability engineering to medical*

Locomat robotic rehabilitation system (Photo: Hocoma, Switzerland)

Robotic exoskeleton (Photo: Ekso Bionics™)

devices, and IEC 62304, *Medical device software - Software life cycle processes,* provide appropriate general requirements and guidance on how to address these hazards.

However, emerging functionality associated with increased autonomy in ME equipment may result in situations in which basic safety and essential performance during use can no longer be assured by the operator. Current ME equipment standards do not fully address this mode of operation and a new TR (Technical Report) is needed to provide guidance for manufacturers and others in this field. Incorporation of higher levels of autonomy in ME equipment and MES is still new and rapidly evolving and it is felt that the Technical Report does not currently lend itself to general standardization. In addition, the need for particular standards for the 3 types of medical robots identified (radiotherapy, surgery and rehabilitation robots) has been assessed with reference to ISO 13482, a new safety standard for personal care robots that is due to be published soon.

In view of these overall issues, JWG 9 has recently presented its report to the SC 62A plenary meeting (held in Shanghai from 8-19 April 2013) for the standardization work needed at horizontal and vertical levels. The proposals are as follows:

- Technical Report on ME equipment and MES employing a degree of autonomy, with the intention of developing it to a Technical Specification and/or a horizontal Standard under SC62A in due course, and
- specific standards on different categories of medical robots, e.g. Radiotherapy robots under SC 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, and Surgery robots and rehabilitation robots under SC 62D: Electromedical equipment

Full workload in coming years

In spite of their high purchase prices, medical robotic systems are cost-effective as they cut some hazards (such as surgical complications, postoperative infections or bleeding) and the overall length of hospitalization. The fact that they are now being introduced in many developing countries is further proof that they are seen as making economic sense.

Transparency Market Research has estimated the global medical robotic systems market at USD 5,48 billion in 2011, with surgical robots forming the largest segment at USD 3,77 billion. It expects the market to grow at a CAGR (compound annual growth rate) of 12,6% from 2012 to 2018 to reach USD 13,64 billion in 2018, with the market for surgical robots worth USD 8,47 billion.

This exceptional expansion of the medical robotic market suggests a heavy workload for IEC SC 62A/JWG 9 experts for years to come.

Silence is not always golden

IEC International Standards help hearing-impaired people live a more comfortable life

Morand Fachot

Hearing loss reportedly affects the lives of hundreds of millions in the world. Hearing aids help those suffering from this disability live a nearly "normal" life, but still far too few people benefit from these aids. IEC TC 29: Acoustics, has prepared more than a dozen International Standards to ensure hearing aids and related equipment, such as audiometers, meet the needs of users and practitioners.

Not a minor disability

According to the WHO (World Health Organization) over 360 million people in the world have disabling hearing loss, which it defines as loss greater than 40dB (decibels) in the better hearing ear in adults and greater than 30dB in the better hearing ear in children.

There are four categories of hearing loss, with severities ranging from mild to profound. It can affect one ear or both

ears, and leads to difficulty in hearing conversational speech or loud sounds.

The categories include "hard of hearing" people who suffer from mild, moderate or severe hearing loss, and "deaf" people who have profound hearing loss, implying very little or no hearing. Over 90% of those affected are adults and 9% are children. Elderly people have a higher incidence of hearing loss. The human impact of hearing impairment is severe; it affects social and emotional interaction and academic achievement as well as employment and career prospects.

Staggering economic cost

Hearing impairment also has severe adverse economic and societal consequences. A 2006 report estimated that some 16% of EU citizens suffered from hearing loss. It set the total cost for (the whole of) Europe to over 210 billion euros per year at the time. Surveys in the US and other developed economies produced similar conclusions: societies incur costs in the hundreds of thousands of dollars over the lifetime of each individual suffering profound to severe hearing loss, and households with one or more individuals affected by hearing loss have a lower than average income.

Help is at hand

The WHO estimates that half of all cases of hearing loss can be prevented by primary intervention mechanisms such as immunization against certain diseases and reducing exposure to loud occupational and recreational noise. Early diagnosis of hearing problems through screening of individuals at risk and appropriate management can help prevent more serious problems occurring. In spite of its economic cost to society and individuals hearing loss itself is relatively inexpensive to treat. Wearing two modern digital hearing aids makes all the difference in terms of economics for society and quality of life for individuals, yet they are worn by only about one in six of those in developed economies who would benefit from their use.

Improved hearing thanks to IEC International Standards

The public's overall perception of hearing aids is that of rather conspicuous yet often ineffectual devices that sit behind or within someone's ear. However, modern hearing aids are now often unobtrusive and very effective, thanks in no small measure to work by experts from WG (Working Group) 13: Hearing aids, of IEC TC (Technical Committee) 29: Electroacoustics. WG 13 experts have so far prepared 13 International Standards in the IEC 60118 series. These cover measurements of electroacoustical and performance characteristics for various types of hearing aids, as well as methods of measurement, and other specifications. TC 29 has also prepared IEC 60601-2-66, *Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems,* in the Medical electrical equipment series of International Standards, and IEC 62809, a Technical Report that provides an overview of the requirements and tests for the latter.

Other TC 29 WGs prepare standards for equipment intended for hearing impairment issues. They include, among others, WG 10: Audiometric equipment, which prepares International Standards for machines used for evaluating hearing loss, and WG 22: Audio-frequency induction-loop systems and equipment for assisted hearing, that allows wearers of specially equipped hearing aids to get a wireless signal transmitted directly to their ear. In the UK, for instance, these systems are installed in the back seats of all London taxis, in 18 000 post offices, in most churches and cathedrals, and in many museums and public building.

More flexible, efficient and less obtrusive

Hearing aids include an internal microphone, amplifier and receiver as well as various control buttons and a battery.

DSP (digital signal processing) has vastly improved the sound quality and sound processing ability of hearing aids, allowing them to be tailored to each individual's acoustic and environmental needs. This flexibility allows audiologists to "tune" and "retune" hearing aids to the user's preferred sound quality and most needed sound processing characteristics.

Hearing aids are available in several main styles to meet most or all categories of hearing impairment.

Patients have the choice between the following categories, depending on a number of factors and the degree of severity of their impairment:

- BTE (behind-the-ear) models, which are available for all degrees of hearing loss

There are actually hundreds of individual parts inside a hearing aid, such as this Siemens Motions S BTE device (Siemens-Press Image)

Maico digital diagnostic audiometer (Photo: Maico Diagnostic GmbH)

Relative positioning of CIC (completely-in-the-canal) and IIC (invisible-in-canal) hearing aids

- RIC (receiver-in-canal) can be worn comfortably behind the ear but are smaller than standard BTE models; they are available for mild to severe hearing loss
- ITE (in-the-ear) models are made specifically to fit the shape of a wearer's ear canal for maximum benefit and the best possible comfort. They are suitable for mild to severe hearing loss, are less conspicuous and very effective
- CIC (completely-in-the-canal) hearing aids are defined by the location of their faceplate, 1-2 mm inside the aperture of the ear canal. They are very unobtrusive
- IIC (invisible-in-canal) is the most recent category of hearing aids to be made available. It fits to the second bend of the ear canal and offers users a truly invisible solution

In addition to their aesthetic advantages CIC and IIC aids offer many acoustic benefits. They retain some aspects of the ears' natural filtering of sounds, as compared to the microphone placement of BTE-style hearing aids, and are much closer to the eardrum.

Bright prospects for growth

Considering that only a minority of hearing impaired people uses hearing aids, even in developed countries, prospects for the hearing aids market are bright.

If the human, societal and economic costs of hearing impairment are huge, so are the potential benefits for the global hearing aid devices industry. Valued at USD 7,2 billion in 2011, the market is forecast to reach USD 11,3 billion by 2018, growing at a 7% CAGR (compound annual growth rate), according to a recent GBI Research report.

This growth, driven by the development of more efficient and reliable devices, will benefit millions of people. It is being made possible through the efforts of IEC TC 29 experts.

Securing Internet transactions

Standardization of lightweight cryptography: ISO/IEC 29192

Janice Blondeau

As more and more PCs, mobile phones and PDAs (personal digital assistants) go online increased security is necessary for the compact devices which provide their Internet connections. These compact devices, such as RFID (Radio Frequency IDentification)[1] and sensors with wireless communication functions, have limited information processing resources. They require low power-consumption, low-cost technology to encrypt data and to authenticate actions.

Need for low-power, low-cost secure encryption

The IEC and ISO (International Organization for Standardization) have developed and adopted a four-part standard ISO/IEC 29192 on lightweight cryptography which helps to overcome these issues.

What is lightweight cryptography?

Cryptography today combines mathematics, computer science, and electrical engineering. Lightweight cryptography is tailored for specific applications that limit implementation area, programme code size, or power consumption. However, lightweight doesn't mean weaker cryptography.

During the development of ISO/IEC 29192 by JTC (Joint Technical Committee) 1/SC (Sub-committee) 27: IT security techniques many different proposals were tabled

Cryptography combines mathematics, computer science and electrical engineering

[1] Radio frequency identification tag with wireless communication capability

for the precise definition of lightweight cryptography, and as to which mechanisms should be deemed suitable for standardization. All mechanisms standardized in ISO/IEC 29192 provide a minimum security level of at least 80 bits which is adequate to provide at least a few years of security, if the design of the underlying security system is sound.

Structure of the standard

ISO/IEC 29192 *Information technology - Security techniques - Lightweight cryptography* consists of four parts. Part 1 provides definitions of lightweight cryptography, describes the concept, and also defines a model by which hardware oriented mechanisms can be compared. Part 2 is dedicated to block ciphers, Part 3 to stream ciphers, and Part 4 to mechanisms using asymmetric techniques. Recently work has started on developing Part 5 which is dedicated to hash functions, but is not yet available to the public.

Lightweight block ciphers

A block cypher encrypts text by cryptographic key and algorithm applied to a block of data at once as a group rather than to one bit at a time. Block ciphers are the workhorses of cryptography, mainly due to their relative efficiency and ability to be used for a wide range of different applications. They require fewer resources (memory, silicon) to provide similar security services, keeping the implementation overhead, and therefore the cost, low. ISO/IEC 29192-2 offers two choices of lightweight block ciphers: Present and CLEFIA.

Lightweight stream ciphers

A stream cypher encrypts text with a cryptographic key and algorithm bit-by-bit using a pseudo random bit string (or key stream), associated with a secret key. Stream ciphers can offer high encryption speeds, especially when implemented correctly in hardware. ISO/IEC 29192-3 offers two choices of lightweight stream ciphers: Trivium and Enocoro.

Lightweight mechanisms using asymmetric techniques

Lightweight asymmetric techniques, including authentication and key agreement protocols are standardized in Part 4. Although protocols can be constructed with lightweight mechanisms and dedicated protocols from other ISO/IEC standards, the mechanisms described in Part 4 offer attractive options when using asymmetric techniques as described. Asymmetric cryptography does not always offer appropriate lightweight versions. ISO/IEC 29192-4 offers three mechanisms: cryptoGPS, ALIKE and IBS.

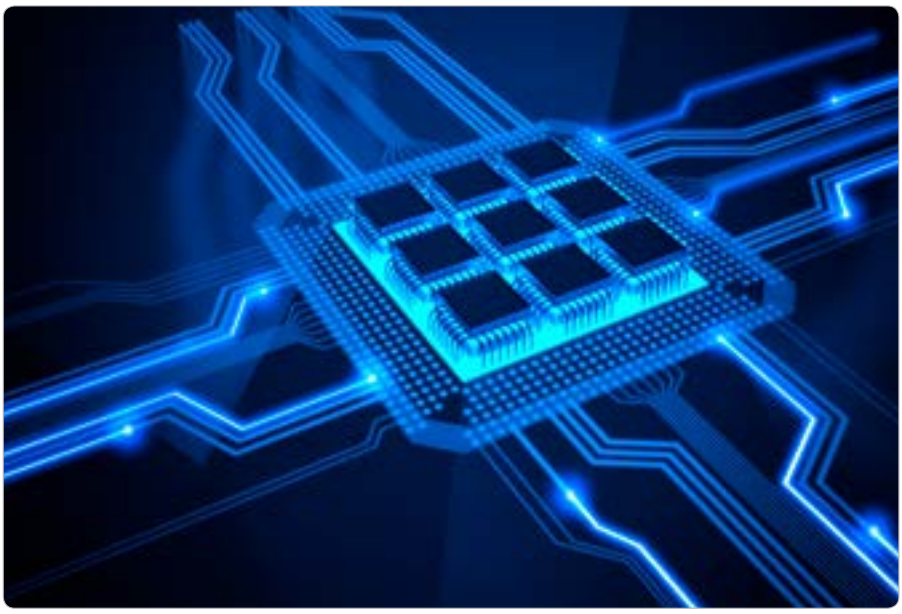
Lightweight hash functions

A hash function maps strings of bits to fixed-length strings of bits, satisfying the following two properties: (1) it is computationally infeasible to find for a given output, an input which maps to this output; and (2) it is computationally infeasible to find for a given input, a second input which maps to the same output. ISO/IEC 29192-5 is now under development.

Factors to keep in mind when deciding on an appropriate mechanism

All mechanisms in ISO/IEC 29192 can provide adequate security if implemented correctly, allowing the engineer to focus on the engineering task at hand. The Standard makes a distinction between mechanisms optimized for hardware and mechanisms optimized for software. The final choice of an encryption mechanism may depend upon the amount of information to be transmitted, the required speed, the particular application and the available hardware.

JTC 1 seeks to reflect market requirements Compact online devices require low-cost, low-energy consumption, high-security cryptography



ISO/IEC 29192 on lightweight cryptography looks at three different cipher mechanisms

TC work supports medical devices market

Better and safer treatment with medical electrical equipment and systems

Morand Fachot

The medical devices industry encompasses a wide range of items and technologies, from the simplest wound dressing to highly sophisticated diagnostic and therapeutic equipment. Globally, the sector is worth more than USD 350 billion.

Expanding sector

Worldwide, demand for medical care keeps growing, for a number of reasons. They include aging populations in most regions and increased access to medical services in developing countries. This increasing demand for care drives the need for more MEE (medical electrical equipment) and MES (medical electrical systems). Technology also plays a role in this expansion as traditional manual or mechanical medical equipment and devices, such as blood pressure meters, are being replaced by electronic equivalents.

Not just in hospitals

When MEE and MES are mentioned, the word "hospital" springs to mind as it represents the environment in which they are most widely deployed for diagnostics, surgical intervention, post-surgery care, irradiation and other therapies.

However, MEE and MES are also found in other treatment centres. They are used in dental, skin, aural and ophthalmic care, and also for rehabilitation and assistive care.

IS (International Standards) for MEE and MES are prepared by a number of IEC TCs (Technical Committees) and SCs (Subcommittees).

TC 62: Electrical equipment in medical practice, is central to this process. Its main publication of the IEC 60601 family is, together with its collateral standards, the essential foundation for Standards for MEE and MES. They reference many IS prepared by more than two dozen other IEC TCs and SCs.

From head…

Dental surgery is a sector that makes extensive use of different MEE and MES ranging from essential dedicated pieces of equipment, such as dental chairs and lights, to specialist diagnostic and treatment devices like dental radiography equipment, ultrasound descalers or laser treatment systems that offer effective alternatives to painful hand descalers and drills.

SC 62B: diagnostic imaging equipment, prepares International Standards for systems that include "digital X-ray imaging devices intended to be used in (…) dental radiography". TC 76: Optical radiation safety and laser equipment, develops International Standards for surgical, cosmetic, therapeutic and diagnostic laser equipment that must meet "particular requirements for basic safety and essential performance".

TC 87: Ultrasonics, prepares International Standards for equipment and systems in the domain of ultrasonics. They include ultrasonic surgical equipment, medical diagnostic ultrasonic equipment and HITU (high intensity therapeutic ultrasound) and focusing transducers.

Ophthalmology relies to a great and growing extent on MEE and MES. Examples are air-puff tonometers for measuring intraocular pressure and slit-lamps for examining external and internal parts of the eye. Other MEE and MES,

A CT (computed tomography) scan uses X-rays and a computer to create detailed images of the inside of a body

including specialist lasers, are used for eye treatment and surgery.

Hundreds of millions of people throughout the world suffer from hearing loss caused by disease or exposure to excessive noise. TC 29: Electroacoustics, prepares International Standards for instrumentation designed to measure sound levels and for medical equipment, such as hearing aids, intended for use by hearing-impaired people.

…to limbs

MEE and MES are also employed extensively in the rehabilitation of patients needing to regain full or partial use of their upper or lower limbs following a traumatic injury. Robot-assisted rehabilitation therapy is being used increasingly for this purpose. IEC SC 62A JWG 9: Medical electrical equipment and systems using robotic technology, "develops general requirements and guidance related to the safety of MEE and MES that utilize robotic technology (i.e. medical robots)".

Robotic technology can also be used to equip mobility aids – such as wheelchairs and walkers – with intelligent navigation and control systems.

…and soul

"Socially-interactive robots" have been introduced to the care environment and proved effective, calming patients suffering from Alzheimer's disease and having a similar effect on children.

Remote presence robots can provide telemedicine solutions, enabling medical specialists to communicate remotely with patients in hospital, care or home environments.

Safety comes first

TCs prepare IS for specialist MEE and MES used in medical practice, such as imaging devices and surgical equipment. Other TCs, including TC 29, 76 and 87, are involved in standardization work for equipment that has direct medical application. Additional non-medical electrical equipment is also used in medical practice.

Some equipment and components (lighting, power supplies, etc.) may not be specifically designed for medical applications but are used in MEE and MES. These devices that rely on International Standards prepared by two dozen or so other IEC TCs must meet general and specific requirements for basic safety and essential performance when installed or operated in a medical environment.

These requirements are set by SC 62A: Common aspects of electrical equipment used in medical practice, in its IEC 60601-1 series of International Standards.

Family of Standards

TC 62 standardization work concerning the 60601 series focuses on the safety and performance of MEE and MES. Within this series, specific issues related to categories (e.g. diagnostic imaging equipment, equipment for radiotherapy, nuclear medicine and radiation dosimetry, electromedical equipment) are addressed by a series of collateral standards.

IEC/ISO JWGs have also issued over 20 joint publications (80601 series) covering specific requirements for the basic safety and essential performance of various devices. As more and more medical electrical equipment and systems are introduced to healthcare, which itself is constantly and rapidly developing, standardization work in the relevant domains is set to expand significantly in the future.

Electronic blood pressure monitors have widely replaced their mercury counterparts (Photo: Omron)

Dental chair

Trust your doctor and his equipment

IEC International Standards ensure medical electrical equipment and systems are safe to use and operate

Morand Fachot

Medical care is a matter of trust, patients trust doctors and medical staff who, in turn trust the equipment they use for examining and treating patients. IEC International Standards are developed specifically to ensure medical electrical equipment and systems are safe to operate, for the well-being of patients and users.

Haemodialysis machine waiting for patients...

Wide domain

International Standards in the health-care environment are critically important and cover a wide spectrum of devices, systems and domains. Healthcare includes medical practice as well as emergency medical services, homecare, and the day-to-day support of persons with disabilities.

Several IEC TCs (Technical Committees) and their SCs (Subcommittees) prepare International Standards for systems and equipment used in the medical environment and ensure they are constantly kept up-to-date and improved when needed.

IEC TC 62: Electrical equipment in medical practice, plays a central role in ensuring that equipment and systems not necessarily initially intended for medical environments are either fit for this purpose or need adjusting for it.

Coordinating role

IEC TC 62 has four SCs (Subcommittees) that deal with specific domains and issue all its publications. TC 62 has delegated to its SCs the task of developing standards.

The preparation of International Standards for the design and production of medical electrical equipment requires the participation of many experts from the medical professions, industry, health-care establishments, the IT (information technology) and software worlds and regulatory bodies.

As electrical equipment and systems in medical practice use a wide range of components, TC 62 International Standards and those of its SCs also refer to and use International Standards from many other IEC TCs and SCs. This means that TC 62 is not only a customer of, but also a supplier to, other IEC and ISO (International Organization for Standardization) TCs. As a result, the safety of medical electrical equipment is an inclusive process that includes work carried out by nearly two dozen other IEC TCs.

Four subcommittees are involved in the preparation of standards for this type of equipment. They deal with common and specific aspects of standardization work for different types of equipment.

Common aspects

SC 62A covers common aspects of electrical equipment used in medical practice. It has two WGs (Working Groups) and 10 MTs (Maintenance Teams).

With the (fairly recent) introduction of ICT (information and communication technologies) applications to the medical domain, the scope of the SC's work has expanded significantly with the integration of medical devices into IT networks. SC 62A has now formed JWG (Joint Working Group) 7 with ISO to work on the first standard addressing both networks and medical devices.

As robots are now present in the medical environment, SC 62A has decided to set up JWG 9: Medical electrical equipment and systems using robotic technology. Its task is to "develop general requirements and guidance related to the safety of medical electrical equipment and systems that utilize robotic technology."

(See article on IEC 62A JWG 9 in this *e-tech*). SC 62A has set up a total of 9 JWGs with ISO.

Specific areas

SC 62B prepares international publications for the safety and performance of all kind of medical diagnostic imaging equipment such as X-ray, CT (computed tomography), MRI (magnetic resonance imaging) equipment, including related associated accessories and systems. TC 62B also works on the development of related terminology, concepts, terms and definitions. It has 6 WGs and 3 JWGs.

SC 62C covers equipment for radiotherapy, nuclear medicine and radiation dosimetry. The potential health risks posed by such equipment in terms of its use of high-energy ionizing radiation (in common with some of the diagnostic imaging equipment covered by SC 62B) were not known initially. The illness that killed Nobel Prize-winner Marie Sklodowska-Curie is widely attributed to her long-time exposure at work to ionizing radiation without having taken proper protective measures. Today, the awareness of the risks posed by ionizing radiation and protection against these are high on the list of medical safety priorities. SC 62C has three WGs to deal with these areas.

SC 62D covers electromedical equipment, equipment used to diagnose and monitor patients, and equipment for treating, or used as an aid in the treatment of, patients. This includes, for instance, haemodialysis, haemodiafiltration and haemofiltration machines, electrocardiographic monitoring equipment or nerve and muscle stimulators.

Supplier to other IEC TCs

Other IEC TCs also refer to and use TC 62 International Standards, notable examples are:

TC 29: Electroacoustics, which standardizes instruments used in the field of electroacoustics and appropriate methods of measurement. It covers audiometric equipment as well as the hearing aids and induction loop systems used by hearing-impaired people.

TC 64: prepares International Standards concerning electrical installations and protection against electric shock. It uses SC 62A Standards.

TC 76: Optical radiation safety and laser equipment, prepares International Standards for equipment and systems incorporating lasers and LEDs (light emitting diodes). These must meet acceptable levels of laser radiation and exposure to optical radiation that are determined by independent organizations such as ICNIRP (International Commission on Non-Ionizing Radiation Protection) and CIE (International Commission on Illumination).

TC 87: Ultrasonics, prepares International Standards related to the characteristics, methods of measurement, safety, and specifications of fields, equipment and systems in the domain of ultrasonics. Excluded from the scope of TC 87 are safety standards for MEE (medical electrical equipment) and systems. Despite its apparent scope, human exposure to ultrasonic fields and the need to determine the performance of medical ultrasonic equipment are at the basis of the work of TC 87. A great deal of its work is therefore oriented towards the ultrasonic aspects of medical equipment.

As TC 62, through its SC 62B, prepares, among other things, International Standards for safety and operation of ultrasound scanners some aspects of its work are of direct relevance to the International Standards prepared by TC 87. Both maintain close liaison in fields of common interest.

Synergies

Electric equipment and systems are present everywhere in the health-care environment. They use a wide range of often very complex technologies that require many different parts, from cables and connectors to power supplies and more complex components or systems. As a result, many different IEC TCs are involved in the preparation of the variety of International Standards required for the overall safe operation of such equipment.

With greater reliance on technology to treat an aging population in many countries, the use of electrical devices and systems in the medical domain is bound to increase. The work of IEC TC 62 and its SCs will follow a similar trend. The fact that over 1 000 such experts from 27 participating and 17 observer countries are represented in TC 62 and its SCs attests to the importance the medical profession and MEE manufacturers attach to the safety of their equipment.

The LIFEPAK® 15 monitor/defibrillator can also send patient data (Photo: © 2013 Physio-Control, Inc)

Carl Zeiss PRESBYOND® laser surgery system to treat patients with presbyopia (Photo: Carl Zeiss)

Tackling noise effectively

IEC TC 29 develops Standards to measure noise and lower its negative impact

Morand Fachot

Noise is second only to pollution in terms of negative environmental impact, a fact often overlooked as it is not as easy to see. Noise is estimated to cost countries huge sums every year: there is evidence that up to 40% of the population within some industrialized countries is affected. IEC TC (Technical Committee) 29: Electroacoustics, work aims to measure and lower the negative impact of noise.

Negative health and economic impact

Besides provoking hearing problems ranging from mild to total hearing loss, noise has other negative effects on human health.

Research has shown that long-term exposure to excessive noise levels leads to a higher incidence of cardiovascular and other health problems.

Excessive noise may also affect the unborn. Studies in Japan and the US point to a possible correlation between exposure of the unborn to excessive noise in the womb and low birth weight and even birth defects.

Sound level meter

Excessive noise may result from high volumes of road or air traffic or from noise in the work place. Its economic impact is severe, with noise-induced hearing loss representing the leading occupational illness in industrialized nations, according to the WHO (World Health Organization).

Measuring noise is the first step

The measurement of airborne sound can evaluate whether or not a noise source is excessive. As well as protecting the environment we live in, such measurement helps to control the risk of hearing damage being caused, including at work.

TC 29 Standards specify the performance requirements of instruments such as audiometers, which are devices designed to measure hearing for diagnostic purposes or for conserving or restoring hearing. Other TC 29 Standards concern head and ear simulators for the measurement and calibration of hearing aids, as well as other test devices.

A number of TC 29 WGs (Working Groups) and MT (Maintenance Teams) develop new or update existing International Standards for sound measurement instruments.

Permanent monitoring stations are also required, for example to measure noise around airports, and new technology means in some cases these can be interrogated remotely, often in real-time.

On the ground and in the air

A clear example of the importance of TC 29 work in the domain of environmental protection can be found in several ICAO (International Civil Aviation Organization) documents. ICAO is the UN (United Nations) specialized agency that codifies the principles and techniques of international air navigation.

Aircraft noise has a significant environmental impact. This has led to operational limitations and opposition to airport expansions/constructions. Reducing aircraft noise on the ground and in the air is a priority for ICAO and the civil aviation industry.

Volume I of ICAO's Annex 16 to the *Convention on International Civil Aviation - Environmental Protection. - Aircraft Noise,* makes extensive reference not only to IEC 61265, *Instruments for measurement of aircraft noise*, but also to a dozen other TC 29 International Standards that set out the performance requirements of measurement instruments (precision sound level meters, sound calibrators, microphones, filters, etc.).

Likewise, ICAO's Environmental Technical Manual Volume I - *Procedures for the Noise Certification of Aircraft,* makes reference to several TC 29 International Standards.

These references demonstrate the significance of the TC's work as well as its contribution to reducing the environmental impact and to the expansion of a major global economic sector.

Alleviating adverse impact

Excessive noise can lead to a range of hearing loss of variable severity. A natural development of the basic work on audiometers has been the preparation of International Standards for hearing aids.

TC 29 has published 13 International Standards for hearing aids in the IEC 60118 series. These cover measurement of electroacoustic and

performance characteristics, as well as EMC (electromagnetic compatibility), signal processing for various types of hearing aids and induction loop systems that are installed in public places, transportation networks and other places.

TC 29 has also prepared IEC 60601-2-66, *Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems,* in the Medical electrical equipment series of International Standards.

Cooperation

TC 29 work has an impact in many fields and requires cooperation with a number of IEC TCs as well as with other organizations, such as ICAO mentioned above.

TC 29 is a supplier of standards to a variety of other TCs as well as a customer of theirs. This reciprocal arrangement applies to IEC TC 87: Ultrasonics, TC 100: Audio, video and multimedia systems and equipment and TC 108: Safety of electronic equipment within the field of audio/video, information technology and communication technology.

IEC TC 62: Electrical equipment in medical practice, and TC 106: Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure use TC 29 Standards.

TC 29 is also a supplier of Standards to ISO (International Organization for Standardization) and to its TCs that prepare standards for Acoustics, Noise, and Use and calibration of vibration and shock measuring instruments.

Future work

TC 29 identifies a number of areas that will see significant technological advances in coming years.

Recent developments in cheaper, silicon-based microphones and the ability to modify their characteristics to give a measurement grade device means that options should open up in the future to use wireless distributed arrays of these microphones. This should help provide live 'noise maps', which currently are usually generated by software. Future Standards within TC 29 will include these new microphone types. Consideration will also be given to new microphones with digital outputs, and to those with integrated preamplifiers, as well as to new techniques for optical calibration.

Ground crews are submitted to loud noise from jet engines (Photo: With the permission of Rolls-Royce plc, © Rolls-Royce plc 2012)

In the hearing aids domain, work is starting to focus on the rationalization of ear simulators and at looking at developing new devices for neonates and children.

Given the growing demand for the wide range of devices and systems covered by TC 29 International Standards, and technological progress that require new or updated Standards, this TC is set to have a full agenda in coming years and beyond.

Legal sharing of digital media content made easier

IEC and ITU cooperate to develop cross-platform IPTV standard

Janice Blondeau

As consumers become increasingly mobile, digital media solutions need to deliver flexibility across technology platforms and devices, while protecting content producers rights. Combining digital rights management (DRM) technology and interoperability has been a priority of the digital media industry for several years.

New standard enables multimedia interoperability

Cooperation between the IEC, the world's leading standards body in electrotechnology, and ITU (International Telecom Union) has produced a new standard that allows multimedia content to be legally used across different platforms.

The new standard IEC 62698, *Multimedia home server systems - Rights information interoperability for IPTV* provides a standardized framework, such as that for material under copyright, to ensure that multimedia content can be shared legally across different systems.

Recommendation ITU-T H.751 "Metadata for rights information interoperability in IPTV services" is technically aligned with IEC 62698.

Better access to digital content improves the consumer experience (Photo: Comtrend)

First fruits of inter-agency cooperation

The parallel texts are the first product of an inter-agency cooperation initiated in 2008 in São Paulo, Brazil, at a high level meeting between experts from IEC TC (Technical Committee) 100: Audio, video and multimedia systems and equipment and ITU-T Study Group 16: Multimedia coding, systems and applications.

International Standard IEC 62698 was prepared by IEC TC 100/TA (Technical Area) 8: Multimedia home server systems, with parts of the text developed in collaboration with ITU-T Study Group 16.

"Better access to digital content improves the consumer experience", said David Felland, Chairman of IEC TC 100. "In a first for IEC TC 100 and ITU-T Study Group 16, members of these two groups have joined their knowledge and expertise to develop an international solution that directly addresses the issue of interoperability of digital rights information," Felland added.

Common interpretation, terms and specifications

ITU-T H.751 | IEC 62698 provides clear mechanisms for flexible digital distribution, allowing for simple exchanges of content. This enables service providers to implement common interpretation and integration of rights information.

"The standard targets interoperability to ensure that service providers and device manufacturers can easily exchange rights information across their current content management systems.

It provides a high-level specification of the metadata for rights information interoperability, with common semantics and core elements," said Nobuyuki Kinoshita, Project Leader of IEC 62698 and media supervisor in Development Department of Dentsu Inc's Platform Business Division.

In other words, the standard finds the greatest common denominators in rights expressions (syntactic embodiments of rights) to encourage the mutual use of rights information.

Rights information interoperability defined

Defined in this standard are common terms and core elements on rights information interoperability for IPTV systems, including content identity, permission issuer identity and permission receiver identity used to bridge between rights-related metadata.

To date, a lack of rules for flexible, legal digital distribution has meant that consumers can be locked into solutions offered by a single IPTV service provider. For example, consumers can not necessarily access the same multimedia content if they change their IPTV service provider when they move from one home to another.

More about IPTV

IPTV (Internet Protocol television) is the delivery of television services to subscribers via a packet switched network that employs the IP protocol, rather than being delivered through traditional land, satellite or cable television formats.

Metadata refers to data describing aspects of data, or information about information presented in the form of "structured, encoded data that describe characteristics of information-bearing entities to aid in the identification, discovery, assessment and management of the described entities".

IPTV metadata is information on multimedia services and content which provides a descriptive and structural framework for managing IPTV services spanning television, audio, video, text, graphics and data.

Rights information metadata in particular refers to information on the rights granted to end-users of multimedia content, stipulating pre-defined 'utilization functions' including permissions to view/hear, copy, modify, record, excerpt, sample, store or distribute content; restrictions on times or hours content can be played, viewed or heard; and obligations such as payment.

IEC TC 100

This Technical Committee prepares international publications in the field of audio, video and multimedia systems and equipment.

It deals with the performance, methods of measurement for consumer and professional equipment and their application in systems and its interoperability with other systems or equipment.

Internet Protocol TV

Television services delivered to subscribers via a packet switched network that employs the IP protocol.

Trust is the keyword

IECEE leads the way in electromedical equipment safety and performance

Claire Marchand

A few weeks ago, as I underwent eye surgery, I realized that I was much more worried about the outcome than about the operation itself. Why was that? Given the numerous problems caused by poor eyesight since I was a kid, I had difficulties imagining a world that wasn't hazy and out of focus, a world in which I would see sharp outlines and well-defined silhouettes. As for surgery, I had total confidence in the skills of my ophthalmologist. I trust him.

A matter of trust

Trust is the key word here. It is essential in the doctor-patient relationship. I had trust in my doctor and in his diagnosis. I believed him when he told me that surgery was the only option open to me. Had I not trusted him, I would have seen another specialist.

But this goes further than the doctor-patient relationship. My ophthalmologist – and by extension any medical practitioner – has to trust the performance of the optometric apparatus he uses to make a diagnosis. And as a surgeon, he has to trust the reliability of the instruments and equipment used in the operation room, be they surgical lighting, lasers or magnifiers, to name but a few.

A powerful tool

Manufacturers of medical electrical and electronic equipment – from well-established multinational companies to SMEs (small and medium enterprises) that specialize in high-technology niche markets – have a powerful tool at their disposal for ensuring that their products meet the strictest requirements in terms of safety, reliability and performance: IECEE.

IECEE (IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components) ensures that electrical and electronic devices and equipment are reliable and meet expectations in terms of performance, safety, durability and other criteria. This includes not only medical electrical equipment but also risk hazards for patients, those who operate the equipment – such as doctors and nurses – and maintenance personnel. IECEE has put a special emphasis on this sector in recent years.

Compliance with IEC International Standards

In the IECEE CB (Certification Body) Scheme, medical equipment has its own product category, MED, comprising dozens of IEC International Standards against which products are to be tested and certified. It includes the IEC 60601 series of standards on the safety and performance of medical electrical equipment, and in particular IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance,* which is widely accepted throughout the world. It can be said that compliance with IEC 60601-1 has become a *de facto* requirement for the commercialization of electrical medical equipment in many countries.

Eye surgery

Emphasis on risk management

But IECEE has gone further. In 2007 it set up the IECEE MEE (Medical Electrical Equipment) Task Force whose responsibility is to deal with the implementation of risk management requirements in the third edition of IEC 60601-1, published in 2005.

The Task Force consists of about 20 members who represent various interests in the field of medical electrical equipment (industry, government agencies, certification bodies, IEC Technical Committees). The group meets once a year and is responsible for:

Surgical microscope (Photo: Zeiss)

- developing guidelines and working instructions on how to implement the relevant clauses of IEC 60601-1 in helping manufacturers demonstrate compliance with the "risk management process" as defined in ISO (International Organization for Standardization) 14971, *Medical devices - Application of risk management to medical devices*
- establishing a consensus with methods that are acceptable for determining compliance with all the relevant clauses (in relation to ISO 14971) of IEC 60601-1
- developing a checklist aimed at assisting the medical equipment industry, official authorities and stakeholders around the world to test in the appropriate manner
- acting as an Advisory Group on the common understanding of ISO 14971 with respect to IEC 60601-1
- organizing specific training sessions dealing with risk management issues

Mutual recognition

IECEE certification, based on the principle of mutual recognition (reciprocal acceptance) by its members of test results for obtaining certification or approval at national level, is also essential in facilitating international trade and allowing direct access to the marketplace for regulators, vendors, retailers or buyers. It eliminates unnecessary duplicate testing and reduces the costs related to the certification process.

Since 1985, the IECEE has positioned itself as the global testing and certification system for electrotechnical equipment, issuing more than 500 000 certificates that are recognized worldwide.
The system is still developing new programmes to provide manufacturers and consumers alike with the highest possible levels of safety, performance and reliability.

More information on IECEE: www.iecee.org

Mining: A high-risk activity

IECEx ensures protection and safety for Ex equipment and workforce

Claire Marchand

Miners, especially those working in underground mines, live a highly risky existence. The dangers range from cave-ins and explosions to ones they cannot see, such as carbon monoxide and methane gas. Modern mining techniques, machinery and equipment provide better protection than ever before and mining is aeons away from the time when miners brought canaries into the pits to provide early warning of the presence of gas. If the canary struggled – or died – they knew they were at risk.

Since time immemorial men have been digging and searching for metals all over the world. Throughout the 19th century, Europe, with the introduction of industrial-type mining, dominated this sector, but by the end of the century, the European mining industry had declined dramatically. North America took the lead, only to experience the same downfall as Europe, when in the second half of the 20th century, developing countries, often ex-colonies, gained independence and started to exploit their own mineral resources. Africa, Latin America and Asia have emerged as big players in the mining sector in the past 20 or 30 years.

Despite the geographical shift in dominance, mining still takes place on all continents. Although the need for safety measures to prevent accidents and protect workers continues to grow, accidents still occur and kill far too many people. While the nature of the work itself makes it impossible to eliminate all risks, there are many areas where action can be taken to minimize potential hazards.

Modern roof bolters are automated to completely remove the risk of having the operator exposed to falling rock while roof bolting is carried out

Multiple hazards

Gases can poison workers or displace oxygen in the mine, causing asphyxiation. Gas detection equipment has become mandatory in some countries. Miners that do not carry such equipment while underground are obviously deprived of an instant alert system that can save their lives, especially since some of the gases are totally odorless and invisible to the human eye.

Proper ventilation systems inside underground mines provide constant fresh air supplies to work areas and help avoid exposure to the harmful gases, heat and dust that can cause severe injury, illness or even death.

While roof bolters are among the loudest machines, most of the equipment used in mining exposes workers to extremely high levels of noise which can result in severe hearing loss.

Cave-ins and rock falls in the mine tunnels, pits and rooms are common and can trap miners underground. In 2010, 33 workers in a Chilean mine were trapped for 69 days about 700 metres underground and five kilometres from the mine entrance, before being brought back to the surface in a high-profile operation.

Specific Ex equipment

While mining continues to be one of the world's most dangerous occupations, the introduction of modern technology has helped reduce some of the risks associated with it. Automation and the remote operation of some of the machinery are now commonplace in the industry.

From the earmuffs that protect workers from exposure to high noise levels to excavators and roof bolters, all equipment used in mining activities has to be designed, manufactured, tested and certified to specific Ex requirements.

All players in the mining sector have a powerful tool at their disposal to ensure that all pieces of equipment, from the smallest to the largest and the heaviest, will perform in the safest and most reliable way.

And who provides this powerful tool? The IEC.

Built to IEC International Standards...

IEC International Standards prepared by IEC TC (Technical Committee) 31: Equipment for explosive atmospheres, provide designers, manufacturers, installers, maintenance and repair specialists with the specifications and requirements against which Ex equipment has to be built, installed and repaired. Market demand for these standards has increased significantly in recent years and many countries have adopted them.

...tested and certified by IECEx

IECEx, the IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres, has several solutions for manufacturers of equipment used in the mining sector. The System has put in place a number of Schemes that provide assurance that equipment and systems are manufactured and operated according to the highest International Standards of safety.

Safety and protection

A great number of companies rely on IECEx for the testing and certification of their products. Manufacturers have to meet the very strict requirements specified in the IEC 60079 series of International Standards on explosive atmospheres as well as those put in place by national or regional regulations and legislation. Proving their adherence to those requirements can be costly and time-intensive. An IECEx certificate is like a passport for manufacturers of Ex equipment: it provides clear proof of compliance with International Standards and it certifies that the equipment in question carries the requisite level of protection.

Maintenance and repair of Ex equipment

Because Ex equipment has a much higher capital cost than the same equipment used elsewhere, repairing it is often more cost-effective than replacing it. The IECEx Certified Service Facilities Scheme assesses and certifies that organizations and workshops that provide repair and overhaul services to the Ex industry do so according to the strict requirements of IEC International Standard 60079-19, *Explosive atmospheres - Part 19: Equipment repair, overhaul and reclamation.* This ensures that unique Ex safety features are not compromised during the repair or overhaul process. The system includes on-site audits prior to issuing the IECEx Certificate and periodic audit reports.

Machinery and equipment used in mining, such as excavators...

...or even mining trucks have extremely high noise power levels workers have to be protected from

Highly-skilled workforce

To cover all safety aspects in Ex environments and to complement the Certified Equipment Scheme, IECEx has developed the IECEx Certification of Personnel Competence Scheme for assessing and certifying individuals working in potentially hazardous areas.

The IECEx CoPC (Certificate of Personnel Competence) provides independent proof that the certificate holder has the required qualifications and experience for working on electrical equipment located in hazardous areas and can implement IEC International Standards covering explosive atmospheres.

For the CoPC, competence is defined as "the ability to apply knowledge" rather than simply assessing knowledge. In this sense, the assessment of persons includes assessing their ability to perform certain Ex-related tasks.

Hearts are not meant to be broken

IECQ components help to advance artificial hearts

Aliyah Esmail

The heart has been a symbol of human emotion and complexity since before Common Era. The ancient Egyptians believed that the heart ruled the way people thought, their wisdom and who they were. The ancient Greeks thought that it was the heart, and not the brain, that controlled logic and emotion.
It was in the Middle Ages, when Valentine's Day gained popularity, that the concept of romantic love became associated with the broken heart.

Medicine moves less quickly than love

In a recent post, Shutterstock Blog explained that the ancient Greeks understood that blood pumped through the heart because of their experiments on dead bodies. They, however, were not able to understand that the heart could be replaced. But, as stated in Wired.com, it was not until 1967, when South African surgeon Christiaan Barnard and his team of 30, successfully transplanted the first heart into a person. The patient died 18 days after the operation because of complications. In 1969, Barnard transplanted a heart into Dorothy Fisher, who survived for 24 years after the transplant.

IECQ does worldwide approval and certification of electronic components in medical equipment (Photo: CARMAT)

Fewer heart transplants without technology

Today, around 100 000 people worldwide are waiting for heart transplants. There are only about 4 000 heart donors every year. Technological developments have profoundly altered the practice of medicine.

From the simplest to the most complex, medical devices increasingly rely on electronics. From the digital thermometer and blood pressure kit used at home to tele- and micro-surgery, the possibilities are infinite. French company CARMAT recently announced that in the next few months, Belgium, Poland, Saudi Arabia and Slovenia will be testing out the first fully artificial heart. This heart and other fully artificial organs would not be possible if each part did not work exactly as planned.

IECQ makes it safe and reliable

While safety, reliability and performance are important for all electronic devices, equipment and systems, they are crucial in the medical sector because lives are at stake. It is essential that only high quality components are used in the manufacturing of these devices.

IECQ certification allows all manufacturers and suppliers of electronic equipment, as well as medical practices and hospitals, to make sure the devices and equipment they acquire contain safe, reliable and high quality electronic components.

As a worldwide approval and certification system covering the supply of electronic components, assemblies and associated materials and processes, IECQ, the IEC Quality Assessment System for Electronic Components, tests and certifies components using quality assessment specifications based on IEC International Standards.

The wide range of electronic components covered by IECQ is used in all kinds of technologies, from the smallest device to the very complex equipment.

Profiling Dr Shu Yinbiao

3rd Vice-President of IEC

Janice Blondeau

This *e-tech* article profiles Dr Shu Yinbiao, Convenor of the MSB (Market Strategy Board), and third Vice-President of the IEC. He has the responsibility of fostering the IEC's efforts to remain close to the market.

Dr Shu Yinbiao, third Vice-President of the IEC and Convenor of the Market Strategy Board

Solid and diverse background

A senior engineer in power systems and automation, Shu was awarded his PhD from Wuhan University, China. He holds the position of President of SGCC (State Grid Corporation of China), is a member of Energy Experts Consultative Committee of the Chinese State Council, and Acting chairman of CSEE (Chinese Society for Electrical Engineering). Shu is also Chairman of IEC/MSB Chinese Experts Committee and Deputy Director of the Chinese National Energy Industry Wind Standardization Technical Committee. He is also senior member of IEEE.

He has been extensively involved in the technical research and management of power grid planning, engineering, dispatch and operation. Shu has contributed to the development and application of power grid planning technology, UHV power transmission technology, and complex power grid operation and control. He has also focussed on the integration of wind power, solar power and other new energy sources into grid technology and Smart Grid standardization.

Active in IEC work

Since 2008, Shu has already served as the secretary of IEC TC (Technical Committee) 115: High Voltage Direct Current (HVDC) transmission for DC voltages above 100 kV; he has been a member of the SMB (Standardization Management Board) SG (Strategic Group) 2 on UHV (Ultra High Voltage) Technologies; and also a member of MSB.

In February 2012, following the formal end of Enno Liess's MSB convenorship, the IEC President appointed Shu as Convenor of the Market Strategy Board. He has served in this role since then.

At the forefront of market trends

As third Vice-President of the IEC, Shu is charged with the dual responsibilities of leading the MSB membership renewal and its technology-watch effort. The 2011 IEC Masterplan highlighted emerging markets and technologies as one of the Commission's strategic priorities. It is the MSB that identifies the principal technological trends and market needs in the fields that IEC is active in. It sets strategies to maximize input from primary markets and points to priorities for the technical and conformity assessment work of the IEC, improving the Commission's response to the needs of innovative and fast-moving markets.

Important technology watch role

As the third pillar of the IEC management structure, the MSB works closely with the SMB and the CAB (Conformity Assessment Board), which all report to the CB (Council Board).

The MSB has achieved a number of important milestones including the publication of White Papers on the energy challenge, electricity energy storage and grid integration of large-scale renewables and storage.

The IEC community wishes Dr Shu every success in this challenging and important role.

Shu has been actively involved in IEC work across MSB, TC, strategic group and national committee levels

Look ahead…New Delhi calling

IEC Young Professionals 2013 workshop registration closes 30 June

Janice Blondeau

National Committees have until the end of June to register participants, selected at national level, for the IEC Young Professionals Programme 2013 workshop. The workshop will be held in New Delhi in October during the IEC General Meeting. Expanding its expert community to involve more and more qualified people is an ongoing IEC priority. The IEC (YP) Young Professionals programme, now in its fourth successful year, provides a springboard for further involvement in electrotechnical standards and conformity assessment work.

The IEC YP programme has welcomed more than 160 participants in its first three years. Melbourne workshop, 2011

Positive response

In a win-win situation, the programme brings benefits to participants, to their employers and to the IEC. The response from participants and their companies from previous workshops has been positive and enthusiastic.

"It's a fantastic initiative from the IEC to promote young professionals in the industry. There are advantages in both learning and exposure provided for the young professional. The experience will bring short and long term benefits in the future."
(Nipun Sibal of Schneider Electric)

Getting involved

Geared towards younger professionals who already use electrotechnical Standards in their work, the IEC Young Professionals programme provides direct networking opportunities and capacity building to enable them to become tomorrow's leaders in the world of standardization and conformity assessment.

Participants have the opportunity to meet key management, from IEC Officers to members of the SMB (Standardization Management Board) or of the CAB (Conformity Assessment Board). They can also participate in a TC (Technical Committee), as well as network with their peers from all corners of the globe.

Young Professionals 2013 workshop

For the New Delhi workshop, each IEC Member country can register two representatives, chosen via a NC (National Committee) selection process. Participants' prior experience of standardization is varied. Some have a good understanding of the processes involved and have worked in TCs. Others may use International Standards in their daily work of testing and conformity assessment, but have been less involved with the actual writing of Standards and the consensus-based approach used in preparing IEC Standards.

"As a small company, participating in standards development has provided a mechanism for contributing to our industry, corresponding with larger companies, and identifying industry trends and technology advancements. Participation in the workshop has provided a backdrop to the entire process."
(Bill Rawlings, head of Mavi Innovations Inc.)

Seeing Standards in a different light

Workshops participants gain a deeper understanding of standardization and expand their technical expert networks. Moreover they have the satisfaction of seeing where they can make a difference to the bigger picture of electrotechnical Standards. Contacts made through the programme serve the individual participants in their professional development and also benefit the companies they work for.

"The workshop is a great way of getting an introduction to IEC work, meet with top management and decision makers in the IEC, as well as networking with colleagues from all over the world."
(Tore Langeland, Det Norske Veritas (DNV)

"With better understanding of the IEC Standards our organization is able to give better solutions to our clients in a shorter period."
(Chetan Ratna's employer, Power Technics Limited)

Workshop registration
Information about the IEC Young Professionals 2013 workshop is available from National Committees and on the IEC website. Registration will remain open until the end of June.

IEC Young Professionals: Go ahead, Get ahead

Michael Grant
IEC 2012 YP from South Africa: now participating in IEC TC 81/WG 8.

IEC Young Professionals 2013 workshop - New Delhi

The IEC Young Professionals 2013 workshop will be held in New Delhi, India, from 21 to 23 October, in parallel with the IEC 2013 General Meeting. Please contact your NC for further information.

Latin America on IEC map

Events target Argentina, Brazil and Chile

Claire Marchand
As part of its strategy to increase awareness of, and enhance participation in standards development work, the IEC made the decision to have regular training sessions for its members, experts and for the community at large. Three broad geographical regions were defined: Asia, the Americas and Europe.

Focus on Latin America
A year ago, the first set of trainings and workshops took place in Asia – China, Singapore, Japan and Korea. In March 2013, the second series of events, organized by TISS (Technical Information and Support Services) and conducted by IEC Community Business Coordinator Jan-Henrik Tiedemann, in collaboration with IEC-LARC (Latin America Regional Centre) Regional Manager Amaury Santos, focused on three Latin American countries: Brazil, Chile and Argentina.

Because these three countries have different needs, demands and expectations in terms of infrastructure and development, the format and content of the workshops were adapted to each specific audience.

The Brazilian and Argentinian NCs (National Committees) have been in place for a long time. Both have a good number of national mirror technical committees and their experts are familiar with IEC standardization work.

The Chilean NC, established in February 2010, is still in its development stage.

Brazil...
The first event was held in São Paulo Brazil and split into two separate workshops catering to different types of participants. The first day was open to anyone with a potential interest in IEC standardization activities. The aim was to raise awareness of the IEC and entice local experts to participate in IEC work. About 50 people attended, representing a good selection of the Brazilian stakeholders.

The second day was for experts already working in the IEC environment. The training focused on good practices, explaining how they can participate in IEC working groups and project teams as experts and at the same time be a Secretary or Convenor in the corresponding national mirror committee; how they can ensure coordination between the different entities they belong to and share knowledge and expertise acquired at the international level with their peers in the national mirror committees.


IEC-LARC Regional Manager Amaury Santos during the Brazilian workshop

IEC Community Business Coordinator Jan Tiedemann in Argentina

Chilean NC President Victor Ballivian (right) was interviewed during the workshop in Chile

Altogether the objective of the workshops was to give support to the Brazilian NC and its mirror committees.

...and Argentina

The third leg of this tour brought Tiedemann and Santos to Buenos Aires, Argentina, for a one-day workshop with about 40 people in attendance. The Argentinian NC, a long-standing member of the IEC, has had national mirror committees for many years. While the NC and experts have been using the IEC Collaboration Tools, they expressed an interest in having them at the national level as well.

As in Brazil, the first day of the workshop was a success. The only drawback was that a second day of the workshop could not be accomplished since many of the Argentinian experts don't have a sufficient level of English. While all slides were in Spanish, English was used for most of the presentations. Both Tiedemann and Santos felt that having more English-speaking experts would help Argentina to increase its participation in IEC committees and working groups.

Chile

Contrary to its long-established Brazilian and Argentinian counterparts, the IEC NC of Chile is still in its infancy – Chile became an IEC member three years ago.

While the first day of the workshop, in Santiago de Chile, took the form of training for people who are considering participation in IEC standardization work, the second day was devoted to a more in-depth approach that included guidance on how to structure the NC management and set up national mirror committees. The targeted audience consisted of potential experts of said committees.

Tiedemann gave presentations on IEC processes, standardization and diligence; Santos focused on standardization in Latin America; and Victor Ballivian, President of the Chilean NC, talked about his work and the progress made since the NC inception in February 2010.

Laying the groundwork

The three years of hard work done by Ballivian have laid the groundwork for this workshop and its outcome. He has had regular meetings with industry, government officials and other potential stakeholders and produced brochures and leaflets to explain the benefits of participating in IEC work at the national and international levels.

Management structure

The NC already has the embryo of a management structure. Together with the NC President and Secretary, a small group of stakeholders has been meeting on a regular basis. The second day of the workshop, Tiedemann outlined a more formal management structure based on the IEC structure and prepared the grounds to bring onboard more stakeholders. The goal is to set up a Board of Directors and several divisions, reporting to the Board, with specific areas of work, e.g. standardization, conformity assessment, legislation and regulations as well as marketing and sales.

Technical work

At the same time, the NC needs to set up mirror technical committees to bring the country up to speed on standardization matters. Chile had already selected two IEC TCs (Technical Committees) that will have Chilean mirror committees:

- TC 13: Electrical energy measurement, tariff- and load control
- TC 64: Electrical installations and protection against electric shock

More mirror committees will be created once the first two are operational.

Presentations and discussions provided guidance on the structure, functioning and specific tasks attributed to the mirror committees. The process for national adoption of IEC International Standards was also addressed during the workshop.

From theory to practice

The workshop brought immediate results. In its wake, the NC management structure was officially established and mirror committee secretaries were nominated. The next step is now for IEC CO (Central Office) to prepare the IT Collaboration Tools for use at the national level.

The workshop helped strengthen the position of the NC in Chile, providing a good basis on which to move forward. With the management structure, mirror committees and electronic collaboration tools in place, Ballivian can show that the NC is developing well and fully supported by IEC CO.

Future workshops in Latin America

The next leg of the Latin American workshops will bring the organizers to Mexico and Colombia in June 2013.

The IEC family grows

South Sudan joins the IEC Affiliate Country Programme

Aliyah Esmail

In April 2013, the Affiliate Country Programme welcomed South Sudan as its newest participant. This brings the total number of countries in the IEC family to 164.

Map of South Sudan (source UNOCHA)

Increasing efficiency of infrastructure

South Sudan gained independence from Sudan in July 2011. Since gaining independence, South Sudan has struggled with developing its infrastructure and advancing industry after decades at war. One of the steps that the Ministry of Electricity and Dams has taken is to join the IEC Affiliate Country Programme as the country will have greater need for electricity than ever before.

The Affiliate Country Programme gives developing countries the opportunity to get involved with the IEC. Countries participating in the Programme have access to 200 free IEC International Standards for national adoption. The Affiliate Secretariat also helps them become more aware of the benefits of using International Standards and of taking an active part in their development.

Aerial picture of Juba, the capital of South Sudan

Serve the national market by developing expertise

Though South Sudan does not yet have an NSB (National Standards Body), it was able to join the Affiliate Country Programme. Any organization that is entitled to identify and recommend International Standards for national adoption in the field of electrotechnology can represent the country within the Programme.

The main objectives of the Programme are to encourage developing countries to use IEC International Standards at the national level and to acquire the expertise needed to contribute to international standardization work. To meet those goals, the IEC helps Affiliates establish the necessary infrastructure, namely the NEC (National Electrotechnical Committee), involving stakeholders from the public and private sector.

The next step for South Sudan will be to bring together its stakeholders to establish a national electrotechnical committee and start benefiting from what IEC can offer to support electrification programmes and ensure electrical safety for the population.

IECEE certification takes stage in Africa

Conformity Assessment moves safety to the forefront

Aliyah Esmail

In many developing countries, electrical and electronic goods sold locally are imported from all over the world. Due to the dumping of substandard products into these countries, having a guarantee that only safe equipment reaches the local market becomes ever more important. It will therefore be in governments' interest to require compliance with IEC International Standards for electrotechnical imports.

Developing countries are beginning to use IEC Conformity Assessment Systems to ensure that imported electrical and electronic goods rely on IEC International Standards in terms of safety and efficiency.

The IECEE (IEC System for Conformity Assessment of Electrotechnical Equipment and Components) administers third party conformity testing and certification that address the safety, quality, efficiency and overall performance of components and goods for the home, office or health facilities.

First IECEE—AFSEC seminar on electrical safety and Conformity Assessment

IECEE and AFSEC (African Electrotechnical Standardization Commission) are planning an international seminar that will take place in Nairobi, Kenya, 26-27 August 2013.

The two day event will include a general presentation of conformity assessment at the IEC, as well as three specific sessions on electrical safety for refrigerators, luminaires as well as audio and video electronic equipment.

The seminars will talk about the safety of refrigerating appliances, fixed general purpose luminaires, and audio and video electronics

Conformity Assessment Systems help to ensure that safe equipment reaches the local market

International experts will help African delegates understand the mechanisms to check the conformity of specific products against IEC International Standards and how to access online certificates.

The event is organized in collaboration with several African organizations: AU (African Union), AFREC (African Energy Commission of the African Union), and KEBS (Kenya Bureau of Standards) in partnership with two Kenyan laboratories.

Who should attend?

The event is for experts, senior staff and professionals from the standardization and regulation sectors, retailers, buyers, vendors, as well as from laboratories and utilities in African countries that are involved in AFSEC and/or the IEC Family.

A practical approach

The seminar agenda focuses on capacity building for African experts and will include technical presentations and practical exercises.

Participants will learn to apply three IEC International Standards (see list below) that relate to the electrical safety of refrigerators and luminaires as well as electronic equipment. The technical presentations will also address local problems faced by participants.

IEC 60335-1 and **IEC 60335-2-24** on the safety of refrigerating appliances

IEC 60598-1 and **IEC 60598-2-1** on the safety of fixed general purpose luminaires

IEC 60065 on the safety of audio, video and similar electronic apparatus

About the speakers

The seminar will be conducted by three experts, Pierre de Ruvo, Fabio Gargantini, Jean Lanzo and Ling Vicky Zhang who will share their experience and knowledge, answer questions and provide advice, information and background material.

Pierre de Ruvo - Executive Secretary and Chief Operating Officer of IECEE

In 1998, Pierre de Ruvo became Executive Secretary of the IECEE. He has since been re-elected twice as IECEE Executive Secretary, with the current mandate ending in 2014. De Ruvo was appointed Chairman of

the ILAC-IAF-IEC Steering Committee in 2009. Today, after more than 30 years of experience in Conformity Assessment, while managing the IECEE System, among other duties, he provides lectures all over the world to promote the IECEE and its schemes. The System facilitates trade of electrical and electronic products in the global market.

Fabio Gargantini
Fabio Gargantini has been active for more than 30 years in product testing and certification, with a specialization in domestic equipment, at the national and international levels. He is an IECEE Lead and Technical Assessor for ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, and ISO/IEC 17065, *Conformity assessment -- Requirements for bodies certifying products, processes and services* (formerly ISO/IEC Guide 65), as well as several IEC product standards. Since 2004, working for Electrosuisse, an IECEE CB (Certification Body), he has set up laboratories, conducted company evaluations based on internationally recognized standards and assessed worldwide laboratories operating in the IECEE CB Scheme.

Jean Lanzo
Jean Lanzo is an electronic product designer of test platforms. He has been working in standardization for over 15 years. He is an IECEE Lead Assessor and Technical Assessor. At LCIE, he is an Expert in the Technical Division as well as a Certification Officer. He gives training in electrical safety, LVD, MD, LAN communication protocols, and functional safety.

Ling Vicky Zhang
Ling Vicky Zhang is a Certification Manager with DEKRA Testing and Certification. She has 10 years of experience in international standardization of luminaires, LED products and related matters, including experience as an IECEE technical assessor. She has a Bachelor's Degree in Mechanical Engineering & Automation.

Developing countries can sometimes be the dumping ground of substandard products. It is in governments' interest to comply with IEC International Standards

Practical information
For registration and more information on the event and venues, please contact:
admin@afsec-africa.org.

Nominations and extensions

Latest nominations

Laurianne Trimoulla
The SMB (Standardization Management Board) has approved a number of nominations as well as the extension of the terms of office of existing TC (Technical Committee) Chairmen.

Nominations

Three new ACTEL members

The SMB has nominated Grace Wei as IEC TC 100: Audio, video and multimedia systems and equipment/TA 9: Audio, video and multimedia applications for end-user network, member to ACTEL (Advisory Committee on Telecommunications). Toshihiro Inokuchi becomes TC 100/TA 9 alternate member. Takashi Shibuya is now the Japan NC (National Committee) member to ACTEL. The nominations are effective immediately.

ACTEL deals with coordination activities and guidelines related to infrastructures used for communications. ACTEL is a venue for exchanging information and provides advice intended to avoid the development of conflicting standards.

Two new SMB SG 3 members

The SMB has approved the nomination of Dr Keith Torpy as Australian member to SMB SG (Strategic Group) 3: Smart Grid. Dr Jee-sik Park was also nominated as Korean member to SMB SG 3.

SMB SG 3 was established in 2008 for the development of a framework that includes protocols and model standards to achieve interoperability of smart grid devices and systems. It also aims at developing a long term strategic plan where future new standards work is needed.

New SMB SG 5 member

The SMB has approved the nomination of Cristiano Masini as Italian alternate member to SMB SG 5: Ambient Assisted Living (AAL).

SMB SG 5 was established in 2011 to manage and coordinate AAL standardization work in IEC TCs, to establish and achieve interoperability and interconnectivity of AAL systems, and accessible design of their user interface.

IEC TC 88: Wind turbines now in Denmark

The Danish National Committee has been designated by the SMB to be in charge of the IEC TC 88 secretariat, effective immediately. It is taking over the secretariat from The Netherlands.

TC 88 prepares International Standards for wind turbines that convert wind energy into electrical energy. Their purpose is to provide a basis for design, quality assurance and certification.

Extensions

The extensions of the terms of office of the following IEC TC Chairmen have been approved by SMB:

IEC TC 62

Rodolfo Godinez, fifth extension of term of office as Chairman of TC 62: Electrical equipment in medical practice, for the period of 1 May 2013 to 30 April 2016.

IEC TC 78

First extension to the term of office of George Gela, Chairman of TC 78: Live working, for the period 1 May 2013 to 30 April 2016.

SADCSTAN committed to standards

Standards play an important role in the development of Southern Africa

Aliyah Esmail

Standards are critical to all development efforts throughout the world. Part of the development process includes making standards a part of everyday life so that products that do not work, short out or cause fires will be phased out of the market and become increasingly less available. This will improve African industries' access to global trade. When International Standards are not used, especially in the case of developing economies, trade and economic development can be hampered.

Fifteen Southern African states make up SADC

Paul Johnson is the Secretary of the IEC NC of South Africa, and he represented the IEC at the SADCSTAN meetings

Southern African Development Community Cooperation in Standardization

SADC (Southern African Development Community) STAN (Cooperation in Standardization) is a part of SADC SQAM (Normalization, Quality, Accreditation and Metrology). SADC SQAM is the group coordinating the regional activities of SQAM, including SADCSTAN, the standardization branch of SADC, within a framework agreed by the Ministers of Trade and Industry of all SADC member states.

The group aims to promote regional cooperation in the development of harmonized standards and technical regulations, facilitate the exchange of information among members on existing and future standards and technical regulations, and facilitate the adoption of standards by the member states.

Paul Johnson, Executive Secretary of AFSEC (African Electrotechnical Standardization Commission) and Secretary of the IEC NC (National Committee) of South Africa, represented the IEC at the SADCSTAN meeting in Luanda, Angola, at the end of March.

Update on the Affiliate Country Programme

On behalf of the IEC, Johnson presented a message of support to all SADCSTAN members and told them about recent developments in the IEC Affiliate Country Programme. In particular delegates were told that there are now eight National Committees in Africa, including South Africa (currently the only Full Member of the IEC in the region).

Since the last SADCSTAN meeting in April 2012, IEC Affiliate Countries in the SADC region have received copies of 115 IEC International Standards to consider for national adoption.

Webinars used to move Affiliate Countries forward

Webinars were organized with the Democratic Republic of Congo and Zambia to help activate the work of their NECs (national electrotechnical committees).

As the IEC works 100% in an electronic environment, one of webinar's main objectives is to provide virtual trainings to IEC Affiliate Countries. The webinars help to support Affiliate Countries so that they can learn to use International Standards and benefit from what the IEC has to offer. The training is conducted by the IEC Affiliate Secretariat at the IEC Central Office in English or in French and can be requested by any Affiliate Country.

The way ahead

Over the next year, the objectives of SADCSTAN are to enhance participation by Angola, Lesotho and Madagascar;

When International Standards are used trade and economic development can flourish

to request membership to the IEC for Namibia and Zambia; and to have Mauritius and Botswana have upgrade to Affiliate Plus.

In 2009, the IEC decided to offer a new status to developing countries that had reached the boundaries of the Affiliate Country Programme. The Affiliate Plus status provides 400 instead of 200 IEC International Standards for adoption free of charge and will give them priority in the forthcoming IEC Mentoring Programme for Affiliates.

Countries in SADC

SADC's (Southern African Development Community) goal is to further socio-economic cooperation and integration as well as political and security cooperation among 15 southern African states: Angola, Botswana, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe, which, together, comprise a population of over 290 million. (CIA Factbook, 2013)

Constructing sustainable infrastructure

International organizations join forces through DCMAS Network

Aliyah Esmail

Infrastructure is all of the systems that serve as a foundation for a community to develop and grow. This includes roads and railways, energy grids, airports, sewage just to name a few. Infrastructure, physical and regulatory, is interrelated.

In spite of this interdependence, for many countries, taking all parts into consideration at once is beyond their budget. Even in developed countries, there may be issues of cost and/or ownership, such as when two or more countries share or borrow technical infrastructure or services. What is important from a sustainable development and trade perspective is to ensure that societies and industries in developing countries have access to technical infrastructure that reflects their specific needs.

IEC cooperates with other international organizations

The DCMAS (Developing Countries in Metrology, Accreditation and Standardization) Network helps to bring together specialized organizations that operate at an international level and that are active in promoting and implementing MAS activities (metrology, accreditation and standardization) as a tool for sustainable economic and infrastructure development.

The Network was created so that participating international organizations can exchange information on their initiatives, work together, and provide a means of pooling expertise. This collaborative forum facilitates the development of strategic partnerships and the coordination of their initiatives.

IEC presented an update of its Affiliate Country Programme

The DCMAS Network meeting took place on 12 April 2013 in Geneva, Switzerland at the UNECE (United Nations Economic Commission for Europe) headquarters as they head the DCMAS Secretariat until the end of 2013. The IEC was represented by Françoise Rauser, in charge of the IEC Affiliate Country Programme and International Liaisons.

Rauser, who is in charge of the Programme and as such is dealing with developing and emerging economies, is

DCMAS works to ameliorate infrastructure in developing countries

focused on trying to help these countries to build infrastructure. She spoke in general about the Affiliate Country Programme but of greatest interest were the Affiliate Plus addition to the Programme and the IEC CA (Conformity Assessment) Systems.

Benefits of Affiliate Plus

Affiliate Plus allows countries that have adopted at least 50 IEC International Standards as national ones and have established a NEC (National Electrotechnical Committee), to upgrade to Affiliate Plus. The Affiliate Plus status provides Affiliate Countries with 400 (instead of 200) IEC International Standards free of charge and a mentoring approach on a case-by-case basis. To date, the Programme has 39 NECs established and 18 Affiliate Plus.

Importance of conformity assessment

The three IEC CA Systems – IECEE (System for Conformity Testing and Certification of Electrotechnical Equipment and Components), IECEx (System for Certification to Standards Relating to Equipment for use in Explosive Atmospheres) and IECQ (Quality Assessment System for Electronic Components) – certify that components, equipment and systems conform to IEC International Standards.

IECEE represented the IEC in a workshop organized by UNIDO (United Nations Industrial Development Organization) in cooperation with other DCMAS partners in Dhaka, Bangladesh, in February 2012. This event looked to facilitate conformity assessment technical cooperation for joint projects in developing countries. The Asia regional workshop helped to further engage developing countries in their overall standards and conformity assessment performance, while focusing attention on the specific infrastructure gaps that are needed to be overcome if they are to participate in the electrotechnical and telecommunications arena.

IECEx, with the participation of the UNECE, organized a conference on safety in the Ex field in Dubai in March 2012. IECEx also ran a seminar in Côte d'Ivoire in November 2012, in partnership with AFSEC (African Electrotechnical Standardization Commission). The seminar was a unique opportunity for professionals from the gas and electrical industries in Africa to discover the benefits of using IEC Conformity Assessment System for explosive atmospheres, and enabled them to make valuable contacts and network with experts in this field.

Focus on capacity building

With the support of the IEC, AFSEC offered training in standardization for rural electrification. The workshop took place in Johannesburg, South Africa in August 2012 with the participation from representatives of IEC TC (Technical Committee) 82: Solar photovoltaic energy systems

In 2013-2014, the Affiliate Secretariat will be focusing on capacity building on standardization. There will continue to be material posted on the website in order to reach out to everyone in the standardization community.

Development can only be sustainable if it reflects the country's specific needs

DCMAS explained

The DCMAS Network is a group of representatives from specialized international organizations promoting and implementing MAS (metrology, accreditation, and standardization) activities in developing countries. The Network meets once a year to share new developments in programmes for developing countries.

The members are:

- BIPM (International Bureau of Weights and Measures)
- IAF (International Accreditation Forum)
- IEC (International Electrotechnical Commission)
- ILAC (International Laboratory Accreditation Cooperation)
- ISO (International Organization for Standardization)
- ITC (International Trade Centre)
- ITU-T (Telecommunication standardization sector of the International Telecommunication Union)
- OIML (International Organization of Legal Metrology)
- UNIDO (United Nations Industrial Development Organization)
- UNECE ((United Nations Economic Commission for Europe)

DCMAS is open to other appropriate international organizations who wish to support the mutually agreed DCMAS Network objectives.

Ensuring safer design for hearing aids

A recent IEC Standard will ensure millions of hearing impaired will benefit from safer devices

Morand Fachot

Hearing aids are central to the lives of millions of people worldwide. Digital technology has greatly improved their performance over the last 25 years or so. IEC TC (Technical Committee) 29: Electroacoustics, prepares International Standards for hearing aids. Its latest Standard covers safety requirements for these devices.

Digital migration

The technology and circuitry used in hearing aids vary according to the type of the device.

Conventional analogue devices are the least expensive variety. They are designed and adjusted individually by manufacturers. They essentially amplify all sounds (speech and noise) in the same way and are appropriate for many different types of hearing loss. Certain analogue devices can be individually programmed for different listening environments, such as quiet conversation at home, noisy situations like restaurants or large areas like theatres.

Digital devices, first introduced widely in the late 1990s/early 2000s, represent a major breakthrough in hearing aid technology and are increasingly widely adopted. They are more expensive than their analogue equivalents, but are usually self-adjusting, thanks to their use of DSP (digital sound processing), in which sound waves are converted into digital signals. They offer many benefits including improvement in programmability, greater precision in fitting, management of the discomfort that results from high sound volumes and their ability to reduce noise.

TC standardization work on hearing aids

IEC TC 29 work on hearing aids represents one of the group's most significant activities. It has prepared 13 International Standards for these devices in the IEC 60118 series so far. They cover measurement of electroacoustical and performance characteristics, EMC (Electromagnetic compatibility) and many other technical (sound and physical) characteristics.

The basic safety of hearing aids, not specifically addressed as such until recently, became the object of an International Standards in October 2012.

Safety of medical electrical equipment

ME (Medical electrical) equipment and systems must meet specific safety requirements to ensure patients and staff can use and operate them safely and reliably. Safety requirements for these are covered by IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for safety and essential performance.*

TC 29 developed IEC 60601-2-66: *Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems, which supplements* IEC 60601-1 and was published in October 2010.

A hearing instrument is defined as including "all detachable parts that are essential for the performance of its intended use".

This Standard does not apply to cochlear and other implanted hearing instruments or to some other devices, such as induction-loop systems and instruments using infra-red or radio.

CIC (completely in canal) hearing aids (Photo: Starkey)

Analogue BTE (behind the ear) hearing aid

Special hearing aids allow children to live happily

Specific scope

IEC 60601-2-66 is a so-called particular (i.e. specific) Standard.

In the IEC 60601 series, particular Standards may modify, replace or delete requirements contained in the general Standard and collateral Standards as appropriate for the particular piece of ME equipment under consideration. They may add also other basic safety and essential performance obligations which take priority over those covered by the general Standard.

Many subclauses of the general Standard are not applicable to hearing aids – for instance they do not present electrical, fire or heat hazards owing to their low voltage and low energy characteristics.

However, protection against mechanical hazards is given special attention in the particular Standard and devices are submitted to drop tests. The Standard states that hearing instruments "shall have mechanical strength and shall not result in an unacceptable risk due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling".

As a hearing instrument is frequently installed entirely or partially in ear canals "rough surfaces, sharp corners and edges that could result in an unacceptable risk shall be avoided or covered". A hearing instrument that can be worn in the ear canal "shall be safely retrievable by the patient" and it shall be designed in a way that parts do not come loose during use.

The Standard also sets out particular requirements that apply to detachable parts of devices intended for use by infants under 36 months.

As hearing instruments are usually quite small they rarely carry clearly visible graphical symbols, therefore the Standard gives specific guidelines regarding accompanying instructions, and these "must be clear and include warning and safety notices".

Ensuring safer devices

Since they operate at low voltages and are not connected to the mains, hearing instruments present, on the whole, significantly lower risks and hazards than do many other pieces of ME equipment and systems. However, as they are generally installed in ear canals, certain aspects of their design require to be given special attention. IEC 60601-2-66 ensures these are comprehensively addressed, so guaranteeing that these already intrinsically safe devices are made even safer for the millions of users who rely on them.

Financial e-security gets tougher

Better risk management for information security systems

Janice Blondeau

A new IEC and ISO Technical Report enables information security management systems to better manage risks.

A changing environment

As financial organizations use more open networks, e-banking and mobile-banking services, they face new challenges from information security threats. Threats such as phishing, malware and cyber-attacks are becoming more and more frequent and users increasingly need to protect assets and data. To meet these challenges they need a robust information security management system which reduces the risks to financial and customer data.

Sector-specific guidance for banks and financial institutions

A new IEC and ISO (International Organization for Standardization) Technical Report, ISO/IEC/TR 27015, aims to provide additional support to the finance industry to set up an appropriate information security management system for financial services. At the same time it will provide more confidence to customers.

Greater protection of assets and data increases customer confidence

ISO/IEC/TR 27015, Information technology – Security techniques – Information security management guidelines for financial services, defines sector-specific guidance for financial services organizations to support the information security management of their assets and processed information. It is a supplement to the ISO/IEC 27001 family

ISO/IEC/TR 27015, aims to provide additional support to the finance industry to set up an appropriate information security management system

of standards on information security management systems.

Unique information security needs

Nadya Bartol, a member of the team of international experts that developed ISO/IEC/TR 27015, comments: "ISO/IEC 27002 is widely recognized as the baseline standard for information security in all sectors across the globe."

"Organizations providing financial services have a different risk profile than those in other sectors and represent natural attack targets. A high level of trust in the protection of financial and customer data is therefore crucial for them.

Complementary to ISO/IEC 27002 on IT Security techniques

"At a time when the financial sector faces unprecedented focus on legislative and regulatory controls, as well as persistent cyber-attacks, ISO/IEC/TR 27015 complements ISO/IEC 27002 by providing additional information security guidelines specific to financial services organizations, to support them in managing their information security risks."

ISO/IEC/TR 27015, I*nformation technology – Security techniques – Information security management guidelines for financial services,* was developed by ISO/IEC JTC (Joint Technical Committee) 1: Information technology SC (Subcommittee) 27: IT Security techniques.

We can count on Ada

Third edition brings increased security and reliability

Janice Blondeau

Originally developed for the US Department of Defense to consolidate programming languages in military applications, the highly reliable Ada programming language is also used in medical applications, air traffic control, banking and other high-risk industries. Recently Ada has become more flexible and secure with the publication of the third edition of ISO/IEC 8652: Information technology - Programming languages – Ada.

Ada in a medical environment

Widely recognized for its security and reliability, Ada is used in several healthcare applications where software errors can cost lives. In the medical sector Ada programming language is used with biomedical instrumentation, nuclear magnetic resonance imaging and medical analysis programmes.

Protection against malicious use

The latest version of Ada features "contract-based programming" which significantly strengthens programmes against bugs and malicious use. This is found in very few other programming languages.

ISO/IEC 8652: *Information technology - Programming languages - Ada*, was developed by ISO/IEC JTC (Joint Technical Committee) 1: Information technology, SC (Subcommittee) 22: Programming languages, their environments and system software interfaces.

Confidence in Ada's security and dependability

"By publishing Ada as an International Standard, users know that any updates will be accessible to developers around the world, and have confidence in the stability of the updates," says Dr. Joyce Tokar, Convenor of the working group that developed the Standard.

User needs important

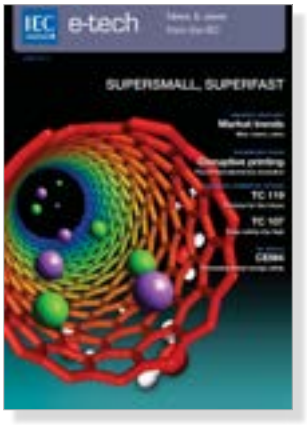
The revision responds to real user needs, for example by improving portability, interfacing to other languages, adding formal support for contract-based programming, and continuing to improve object-oriented and real-time capabilities. The latest version further enhances its capability and expressiveness, as well as the dependability, safety and security of programmes using the language.

Ada is used in several healthcare applications where its security and reliability are key benefits

Ada programming language was named after Augusta Ada King, Countess of Lovelace (1815–1852), who is credited as being the first computer programmer. She was the daughter of poet Lord Byron.

Ada programming language

Developed in the 1970s for the U.S. Department of Defense, Ada was first implemented in the 1980s. Its safety-critical support features means that Ada is now used for military applications, in aviation and air traffic control, and in certain biomedical applications.



Supersmall, superfast

IEC Standardization work makes it possible

Mini, pico, nano, micro are prefixes that are getting ever more common in the electrotechnology world. They are used to describe components, such as MEMS (micro-electromechanical systems), technologies (nanotechnology), installations (pico hydro-stations) or networks (minigrids).

The trend towards the production of smaller systems and products has been made possible by the work of dozens of IEC TCs (Technical Committees) and their SCs (Subcommittees), whose title often indicates that their work focuses on small components

e-tech
News & views from the IEC

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