United States National Committee of the IEC

News and Notes






In This Issue

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FOCUS ON: STANDARDS FOR MEDICAL DEVICES

The United States is the world leader in the production of medical technologies, and the largest consumer. It's a robust and dynamic industry, with new and innovative products and systems continually coming to market. U.S. participation in international standardization for these technologies is a key priority to assure a strong future for the industry and safety for people around the world.

Standardizing to Ensure the Safety of Electrical Medical Equipment

By Bernie Liebler, Director, Technology & Regulatory Affairs, Advanced Medical Technology Association (AdvaMed)

A little over two decades ago, I began working on medical device safety standards, as my new job duties included being the Technical Advisor (TA) for the USNC Executive Committee's Technical Advisory Group (TAG) to UEC Technical Committee (TC) 62, *Electrical equipment in medical practice*, and SC 62A, *Common aspects of electrical equipment used in medical practice*. This was a task for which I felt neither well prepared nor extremely confident. Over the years, however, my confidence and I hope my competence increased, while the task grew even more rapidly.

The Electromedical "Bible"

Electrical medical equipment refers to any piece of equipment that runs on electric power, battery or mains (plug-in or permanently connected). Thus it covers items that range from electronic thermometers and home sphygmomanometers (blood pressure cuffs) to MRI machines and CT scanners. With so much territory to cover, the original members of TC 62 adopted a multilevel structure for their standards. They established Subcommittee (SC) 62A to develop a basic, general standard to address the safety concerns common to all of the equipment. Over the years, some of the participants began to refer to this document, IEC 601-1 (now 60601-1, *Medical equipment|medical electrical equipment - Part 1: General requirements for basic safety and essential performance*) as "the bible," which, if you were developing electromedical equipment, was accurate.

They also added three other SCs: SC 62B, *Diagnostic imaging equipment;* SC 62C, *Equipment for radiotherapy, nuclear medicine, and radiation dosimetry;* and SC 62D, *Electromedical equipment*. SCs B and C address standards for equipment in the diagnostic imaging and high-energy therapeutic areas. SC 62D addresses the specific requirements for other particular equipment not covered explicitly in the basic, general standard. The TC handles the coordination of the work of the SCs and creates the occasional document that doesn't fit comfortably in an SC.

Over the years the collection of standards in the 60601 series has grown to over 80 standards, including 8 active collateral standards (e.g., electromagnetic compatibility, usability, and environmentally conscious design). Products must also comply with the

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applicable collaterals to claim compliance with 60601-1. The committee has also developed several additional documents that explicate the TC's safety philosophy, and collects the symbols used in the 60601 collection as well as other similar products. And TC 62 has developed productive relationships with a number of other TCs that produce entries in the 60601 series of standards, either jointly or independently, or develop standards that are related and important to the TC's mission.

A Changing Landscape

In addition to the rapid increase in the number of standards under the TC 62 wing, the complexity of the relationships among the standards and the complexity of the technologies have also grown. This has created the need for TC 62 to move into areas that it had historically not addressed. For example, the committee now addresses robotics, usability, and home health care.

Beginning in the mid-1990s, TC 62 began to realize that the traditional approach to standards for safety of electromedical equipment was beginning to fray. Historically, we had approached safety like most other manufacturers of electrical equipment. Our standards included various design requirements and tests to verify that the manufacturer had included/accomplished them. For example, the standard specified minimum separation distances between current carrying wires and minimum creepage distances across insulation. In addition, IEC 60601-1 adopted a "single-fault" philosophy. In other words, under conditions of a single fault in the protective systems of the equipment, it had to continue to operate safely.

All of this was complicated because the standard applied to medical equipment used in the "patient environment," about a 5-foot circle surrounding the patient. And there is tremendous variety in the condition of patients. Finally, some of this equipment keeps certain patients alive. Thus, many requirements had to be "graded" depending on their use, including where and how they are used in relation to the patient. Electrical leads that could touch the heart must be treated differently than leads that only touch the outer skin layer.

In the 1970s and 1980s, U.S. industry viewed IEC and the International Organization for Standardization (ISO) as "European" standards organizations. And the medical device industry, in particular, viewed standards as a potential barrier to innovation, the industry's lifeblood. This lead to a lack of interest by many U.S. medical device manufacturers in participating in IEC standards work during the development of the first and second editions of IEC 601-1. But this situation has changed much over the last two decades.

In the late 1980s, this view was overtaken by the political reality that the European Common Market was evolving into the European Union. In the very late 1980s, the then European Community (EC) passed its medical devices directives, established its essential requirements (for the safety of medical devices), and mandated that its new medical devices approval regime based on these documents would become effective along with many others at EC 92. In other words, in 1992 the EC's "new approach" to a medical devices regulatory regime would be fully functional. The new approach demanded a strong role for consensus standards to support the medical device approval process.

Of course, the medical device industry became instantly focused on the working of the IEC system and what ultimately became successful U.S. efforts to persuade the EC to use ISO and IEC standards whenever practical.

Electrical Medical Device Standardization Keeps Pace with a Rapidly Expanding Industry

Over the past 50 years, medical offices have become increasingly populated with highly complex equipment used to diagnose and treat medical conditions. Some of this equipment appears only in the doctor's office, some in the operating room, some in the emergency room, and some in patients' homes. The complexity of the task of ensuring that this equipment maintains the safety of the patient and the operator (even as some of it maintains the patient's very life) has grown as the equipment's complexity has grown.

IEC TC 62 and its four SCs address the safety of medical equipment ranging from home-use thermometers to MRI machines and radiation therapy particle accelerators. Some of this equipment supports or maintains life functions – e.g., ventilators, some pacemakers, and implanted defibrillators. Some monitor or measure vital signs like blood pressure, respiration, and oxygen saturation. And some serve a clear diagnostic purpose – e.g., ultrasound, X-ray, and CT scanners.

In recent years, software control of medical equipment has become almost universal. To address the ubiquity of software in medical equipment, TC 62 began working with other TCs and SCs on software development and implementation standards. TC 62 has also adopted a view of the global medical equipment universe and works with ISO TCs on areas such as usability, risk management, and environmental aspects.

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Eventually, these decisions were formalized in the Dresden and Vienna Agreements. Now, ISO and IEC are preferred to CEN and CENELEC as venues for the development of new standards to implement the EU regulatory system. Now, the U.S. plays an extremely active role in international standards for medical electrical equipment, holding two SC secretariats, the chair of the TC, and numerous convenerships among the Working Groups.

Innovation and Adaptation

While the system has evolved, the technology has evolved even faster. Systems that were controlled electromechanically are now controlled electronically with microprocessors and feedback loop circuits, and often with wireless interfaces. For example, some foot switches that were hard wired to the equipment they control are now connected via Bluetooth links. Our own technology has forced us to move our standards into new areas that we had not previously addressed.

One of our earliest excursions was into the development of safe medical device software. We understood that you cannot test software in the same way as hardware, but you could control the development process so that the work was at the very least traceable. As a result, in 2001 the Association for the Advancement of Medical Instrumentation (AAMI) published AAMI/ANSI SW 68, *Medical device software - Software life cycle processes*. The Food and Drug Administration (FDA) quickly recognized it, and the U.S. introduced it as a New Work Item Proposal in SC 62A. In partnership with ISO TC 210, *Quality management and corresponding general aspects for medical devices*, SC 62A developed IEC 62304, *Medical device software – Software life cycle processes*, which was published in 2006 and is now moving into its second edition.

While we were contemplating our concerns about the ubiquity of software and the need to address its safety issues, it became apparent that the traditional physical/engineering approaches to safety could no longer adequately address all of the potential risks presented by modern medical equipment. Well-known methods account for the traditional risks that we have seen for years (and which are common to most electrical equipment), but software failures, for example, could introduce numbers of unexpected, ill-understood risks that we needed to address. The apparent conclusion was to incorporate risk management into our paradigm.

In addition, in the mid-90s, the second edition of the basic 60601-1 standard ran out of amendments, and the technology was beginning to outstrip the standard. The committee responded by initiating a project to create a third edition. However, this was not simply going to be an update of the same information in the same style. The committee decided to completely rethink the standard. It would still include the standard hardware approaches to basic safety issues. However, it would also be the vehicle for catching up to our digital society (ubiquitous software/digital control) and the doorway into the future. The project was ambitious enough for the committee to request that the SMB grant it a waiver from the standard timelines. The project eventually took a decade to complete.

The most significant change in the standard was to require that the manufacturer manage and mitigate risks according to ISO 14971, *Medical devices - Application of risk management to medical devices* (developed jointly by IEC SC 62A and ISO TC 210). Although what the new standard did was formalize what developers have always done when writing safety standards, the change caused much initial confusion, but that seems now to have mostly abated.

As more medical equipment connects with the Internet, safety threats from external sources are an increasing issue.

Bernie Liebler, Director, Technology & Regulatory Affairs, AdvaMed

The Ultraconnected Future

Another major excursion from our traditional path has been to realize that the widespread adoption of medical equipment that connects with the Internet requires a new approach to ensuring safety. Threats to patient and operator safety can now result from external sources, such as external software errors, data transmission (wired and wireless) errors (which can include command errors), and physical connection failures.

To secure the lid on this latest version of Pandora's Box, TC 62 teamed with ISO TC 215, *Medical informatics*, to develop a new set of standards, the 80001 series. These standards address the actions required to safely integrate medical equipment with health care IT systems and with wireless communications systems. A unique feature of these standards is the requirement that the manufacturer and the user institution enter into an agreement covering the integration of the medical equipment or system with the health care facility's IT systems.

This new cooperative working relationship is certainly the harbinger of much closer working relations in the future as it brings us more advanced aids for the disabled, medical robotics, equipment designed to allow seniors to "age in place," and many other innovations that we can not imagine now, but will soon be on our horizons. ■

Medical Device Standards and Regulation: What, How, and Why

By John G. Abbott, Ph.D., Director, Global Standards, Philips Healthcare

The medical device industry is different. Yes, yes…everyone says that about their sector. "Lighting is different." "Electrical power is different." "Heavy earth moving equipment is different." But from a regulatory and standards perspective, the medical devices sector is truly different. Why? Because, next to perhaps nuclear power plants, medical devices are some of the most highly regulated products sold on the world market.

Just about every major-market country (and many smaller ones) has some regulatory group or agency tasked to oversee both the pre-market and post-market aspects of medical devices – the U.S. Food and Drug Administration (FDA), the Chinese State Food and Drug Administration (SFDA), India's Ministry of Health and Family Welfare (MoHFW), Korea's Food and Drug Administration (KFDA), to name just a few. And while there is little political incentive among agencies to align their forces using common requirements or joint audits, a positive factor is that many regulators use standards as a key part of their regulatory approval process. However, there remain huge opportunities for improvements of both efficiency and safety through even broader use of international standards and common regulatory processes.

What vs. How

It is important to first establish some basic common language, so two quick definitions:

Regulations: Regulations are essentially the "what." They define the objective such as "safe and effective products." Examples are the EU Directives and the U.S. Code of Federal Regulations (CFRs). Regulations are required.

Standards: Standards are the "how." That is, how one demonstrates that they meet the "what" of the regulations. Standards are (mostly) voluntary.

Is there overlap? Yes, no question. There is no bright shining line between "what" and "how." There are always some local conventions you must accommodate in order to sell to a local market. Plugs and sockets are a good example. You simply cannot plug a U.S.-style blade plug into a Euro-style post socket.

Most medical device regulatory systems identify standards formally as providing "a presumption of compliance." That is, by demonstrating that you comply with a listed standard you are presumed to comply with the regulatory requirements in part or in whole. In this "presumption" model, use of standards is voluntary in that you do not have to meet the requirements of the specific standard to demonstrate compliance to the regulations.

To demonstrate performance, manufacturers are often required to include clinical evaluation in their compliance evidence. This is not always straightforward, as in the case of automatic external defibrillators (AEDs).

But if you do not choose this "presumption" path you must demonstrate that you comply with the regulations through some other, often more onerous and (usually) more expensive means to demonstrate that you (at least) meet similar levels of safety and performance.

Recognized standards provide a "short cut" which makes the approval process easier, faster, more predictable, and less expensive. Of course, if the standard does not apply to your product, or you just feel that an alternative approach is better for your business or product, you can always choose different means for demonstrating that you meet the regulations.

There are, however, instances where the concepts of "presumption" and "voluntary" are short-circuited by regulators that formally codify certain standards into their regulatory process as the only way to demonstrate compliance with the regulations. Regulatory agencies can also write their own "standards" in the form of "guides" or "advisory circulars." The disadvantage of this type of regulatory process is that the latest technical insights may not be in the standard, yet such that newer technologies or capabilities can be unintentionally restricted by forcing the product to conform to an older or otherwise established "performance" or other incompatible technology.

The Whys of Regulation

Why are medical devices regulated? There are many reasons but the top three are:

1. Safety
2. Performance
3. Quality/Reliability

Safety: Is the product safe? Safety is not unique to medical devices but it is a leading concern that includes safety to the user/operator, to the subject/patient and, in some jurisdictions, to the environment. Safety of medical electrical equipment is the subject of the IEC 60601-1 family of standards. When

Medical Device Standards and Regulation: What, How, and Why (continued)

claiming compliance with the relevant 60601 standard, a manufacturer must demonstrate that all possible hazards (noise, EMC, alarms, temperature, electrical shock, radiation, mechanical, etc.) are identified and remediated to an acceptable "safe" level. The 60601 standard provides tests and processes by which the manufacturer can demonstrate an acceptable level of safety for their product.

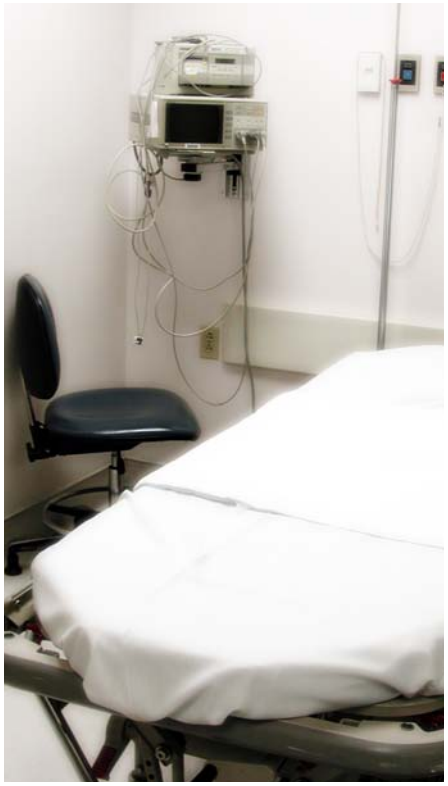
Performance: Does it do what the manufacturer says it does? Can it demonstrably meet the medical claim? Included in this may be a regulated "minimum" level of performance as some jurisdictions may wish to restrict the sale and use of products that fail to deliver a defined level of performance – be it image quality, diagnostic ability, or therapeutic function.

Some technologies have international performance standards, but most do not. Often, these performance standards merely define parameters and preferred test methods. To demonstrate performance, manufacturers are often required to include clinical evaluation in their compliance evidence. This is not always straightforward, as can be seen in the example of automatic external defibrillators (AEDs). In many cases these are used on people who have no heartbeat and no respiration. You apply the product and hope that the heart is restarted and the patient is resuscitated (maybe as much as 15 percent of the time). One might imagine how this would be a problem for human testing and clinical trials.

Quality/Reliability: Most regulatory approvals are based on testing of the first manufactured unit or units. Regulators then expect every subsequent unit to be the same in both safety and performance over the life of the product. To achieve this, manufacturers must demonstrate that they have in place a process whereby they test and certify that every device is effectively identical. Most regulators also require that manufacturers have in place a quality system designed to ensure that good design principles and good manufacturing practices are in use.

These quality systems are typically part of the company's licensing requirements and are often subject to scheduled or surprise audits by the agency's audit/enforcement bureau or agent. International process standards are typically used as the basis for these certifications including such well known standards as ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*, and IEC 62304, *Medical device software – Software lifecycle processes*.

Regulators in many countries demand that the company track a product over its lifetime to ensure it doesn't become unsafe due to the aging process.



Post-Market Surveillance

John G. Abbott, Ph.D., Director, Global Standards, Philips Healthcare

After all the approvals and oversight are complete and the products are out the door, is the manufacturer "finished"? No. Regulators in many countries demand that the company track the product over its lifetime to ensure that it does not become unsafe due to the aging process or as a result of hazards not identified during the product's development and approval process.

In some jurisdictions, this means notifying the regulatory agency of *every* injury or failure resulting from the use of the device including information such as: number of units affected, a description of the underlying fault, and the steps to be taken to resolve the issue. Such steps can include field repairs, updated labeling, software updates or, in extreme cases, removal or "recall" of the product from the field.

This process can also be complex. In the example of the AEDs: if the person is unable to be revived, you may have a reportable event. And while there is "officially" no regulatory obligation to report a death when the device worked as intended, many manufacturers will report *all* deaths if only to protect themselves from future overly aggressive regulatory inspections.

"GHTF" Model

So what does all this mean and what can be done about it? Like all steps in getting a device from concept to market, the regulatory process contributes to the overall cost of the device (and the overall cost of healthcare). Historically, regulatory agencies have developed their systems independently of each other resulting in each agency asking for something different: different forms, different data, different testing, different post-market tracking databases, all for

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essentially the same purpose.

But things are not so bleak. In 1992 regulators from the EU, Canada, Japan, the United States, and Australia created the Global Harmonization Task Force (GHTF) with the goal of standardization of medical device regulation across the world. For 20 years, they worked with other stakeholders including manufacturers and test houses, to develop a "universal" set of regulatory processes. And while the ultimate goal of a single worldwide process with an "accepted once, accepted everywhere" objective is a political impossibility, regulatory agencies are gradually integrating pieces of the GHTF model into their regulatory processes.

Standards Are the Key

Certainly, this analysis only touches on parts of what is, globally, an extremely complex and interactive system. There are commonalities and there are exceptions. And the political aspects of regulation have only been briefly touched on. These can go well beyond the altruistic objective of ensuring the safety of the population and can include the need for local control, a source of funding, and simple domestic job creation, to name a few.

The key underlying commonality in the globe's diverse regulatory processes is the use of standards. And as more and more jurisdictions adopt the GHTF model and integrate international standards into

their regulatory processes, the more we will continue to see improvement; all in the interest of patient safety and cost containment. ■

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IEC TC 62 and Its Subcommittees Undertake Extensive Work

By Hae Choe, Director, Standards, AAMI, USNC TAG TA for IEC SC 62D

The Association for the Advancement of Medical Instrumentation (AAMI) administers the secretariats for two Subcommittees (SCs) under IEC Technical Committee (TC) 62, *Electrical equipment in medical practice*, for the USNC: SC 62A, *Common aspects of electrical equipment used in medical practice;* and SC 62D, *Electromedical equipment*. Serving as the assistant secretary for these SCs has given me insight into the unique features of TC 62 and its SCs.

There are four SCs within TC 62. IEC TC 62 works as the parent committee and oversees the SCs. IEC SC 62A develops collateral standards, which are part 1 standards that provide horizontal structure and serve as an umbrella to the device-specific standards. IEC SC 62D manages a work program which develops the most particular standards with TC 62. These particular standards are part 2 standards and are device specific, which means that they provide the essential safety and performance requirements for specific medical devices. IEC SC 62B works on diagnostic imaging and IEC SC 62C develops standards on radiation, radio therapy, and nuclear medicine. These two SCs are managed by Germany.

The document system of TC 62 is quite extraordinary and unusual within the IEC, I've been told. SC 62A develops and maintains the general standard, IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*. All of the work that is done within TC 62 revolves around this standard in that this is the reference standard upon which all of the other standards are written. Any of the collateral or particular standards are developed with the mindset that the general standard's requirements are to be used, unless there is a specific circumstance which causes the standards to deviate. If this is the case, within the requirements section of the collateral or particular standards the change in the requirements will be specified.

What that means in practice is that when a device is used to test to a particular standard, that particular standard is the main document which should be used. But that particular standard would not have been developed, if not for the existence of the IEC 60601-1.

This fall, the first amendment to IEC 60601-1 is expected to be published. This presents significant challenges for the SCs, since all of the standards that reference IEC 60601-1 will have to either be revised or amended to reference the new amendment. When the current third edition of 60601-1 was published in 2005, the four SCs started revising their collateral and particular standards to reference the new edition. This work is just coming to an end now, almost seven years later; however, that work involved a much more detailed revision to all of the standards.

Amending or revising the amendment for 60601-1 will be a large task, but one that, I hope, will be seamless, so that all standards within the TC 62 can use correct reference for the standards developed within the group. ■

The Alarming State of Medical Device Alarm Systems

By Charles B. Sidebottom, P.E., Director, Corporate Standards, Medtronic Inc.

"One thing I can't stand is the noise, noise, noise, noise!"

— Dr. Seuss's Grinch

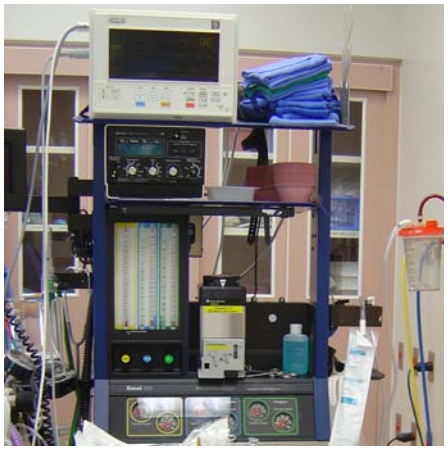
Among the cacophony of sounds, flashing lights, and blinking messages on display panels in today's healthcare facilities, one thing is clear: medical alarm systems are out of control. Clinicians are overwhelmed by an overabundance of data and too little information that is meaningful. This leads to alarm fatigue (also known as alarm overload, alarm burden, alarm indifference, and alarm frustration).

When medical device alarm systems work as intended, they detect either changes in a patient's condition or a problem with the equipment that requires action by the clinical operator. However, in today's health care environment, the truly actionable alarm conditions are too often buried under a blizzard of clinically irrelevant, non-actionable, or self-correcting alarm conditions. The system is just not working the way the health care system needs it to in order to improve patient outcomes.

A Dangerous Dilemma

Alarm fatigue is not just a nuisance; it can contribute to patient harm. In recent years, the U.S. Food and Drug Administration (FDA) has received hundreds of reports of patient deaths that are traceable to alarm-system-related issues. The ECRI Institute now ranks alarm-system-related hazardous situations as number 1 on their Top 10 list of Health Technology Hazards. The Joint Commission and the FDA have announced they are working on developing a systematic strategy to address alarm fatigue.

In support of these efforts, the Association for the Advancement of Medical Instrumentation (AAMI), in partnership with the FDA, the Joint Commission, the American College of Clinical Engineering, and the ECRI Institute, held a multidisciplinary stakeholder Alarm Summit in October 2011. Clinicians,



manufacturers, biomedical professionals, researchers, acoustic experts, regulators, and patient safety advocates came together to share their perspectives on the challenges and opportunities surrounding clinical alarms, and to identify priorities that must be addressed to improve patient care. Among them is strengthening medical electrical equipment standards and contracting language to promote success in all intended use environments.

Responsive Standards

In 2003, IEC Subcommittee (SC) 62A, *Common aspects of electrical equipment used in medical practice*, published the first comprehensive safety standard that addresses medical alarm systems, IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*. The standard deals with a wide array of challenges, including:

- Standardizing a vocabulary to describe alarm states and conditions
- Developing a prioritization of alarm signals based on urgency of action
- Harmonizing alarm signal inactivation states and their indications
- Providing for consistent use of color and rhythm to indicate alarm condition priority
- Permitting intelligent (smart) alarm systems and distributed alarm systems

Originally, some considered the alarm system collateral standard to be optional. Subclause 1.3 of IEC 60601-1:2005 resolved that confusion by declaring that "applicable collateral standards become normative at the date of their publication and shall apply together with this standard." In addition, IEC 60601-1-8 is recognized by the FDA and is a harmonized standard under the European Medical Device Directive.

The IEC SC 62A Alarm Systems Joint Working Group, which is co-convened by John Hedley-Whyte, M.D., with Harvard University and David Osborn, just completed work on an amendment to the second edition of IEC 60601-1-8, which is scheduled for publication later this year. This amendment deals with several key issues including certain testing requirements, a clarification of alarm conditions priorities, and the introduction of a new "alarm acknowledged" state that has been requested by clinicians and manufacturers.

The Alarm Systems Joint Working Group is now laying plans for work on a third edition of the standard to address some of the issues raised at the Alarm Summit. These include:

- Strategies for escalating priorities so true priorities won't be left dangerously unattended over an extended period of time
- Additional requirements for smart alarm systems that use multiple signal inputs from the patient to assess priority
- More comprehensive requirements for distributed alarm systems, as many alarm signals will soon be delivered to wireless devices held by clinical operators, including in the home healthcare environment

Thinking outside the Box

Another issue that emerged at the 2011 Alarm Summit was how few healthcare facilities are tailoring the alarm systems in today's equipment. It may be that the clinical operators don't have too few options, but too many. Anyone who has worked extensively

The Alarming State of Medical Device Alarm Systems (continued)

with Microsoft® Office can understand the problem. One quickly realizes that there are hundreds and hundreds of configuration options available – so many that only the "super user" has the time and the inclination to understand how they work together. So in most cases the system gets used as it comes out of the box.

The same is true with many medical alarm systems. They get used as configured by the manufacturer "out of the box," regardless of whether the equipment is being used in the operating room, intensive care unit, cardiac care unit, or the general patient environment. Given these very different environments of use, is it any wonder that clinical operators are overwhelmed with alarm signals that often turn out to be nuisances?

In 2007, IEC/SC 62A, in partnership with International Organization for Standardization (ISO) Technical Committee (TC) 210, *Quality management and corresponding general aspects for medical devices*, published a comprehensive standard dealing with the usability of medical devices. IEC 62366 *Medical devices - Application of usability engineering to medical devices*, specifies a process for a manufacturer to analyze, specify, design, verify, and validate usability as it relates to the safety of a medical device. Since 2010, compliance with IEC 62366 is required for conformity with IEC 60601-1.

When applying the usability engineering process to the alarm system, the manufacturer needs to focus on the relationship between the operator and the technology – and, above all, the manufacturer needs to keep it simple.

Manufacturers also have to recognize that the clinical operator is often dealing with multiple devices from different manufacturers at the same time. Using common terminology and easily configurable patient-relevant alarm limits and providing common alarm system indications and controls are steps forward. The current standards address many of these issues, but more needs to be done. The next generation of alarm systems standards, already in the planning stage, will address a number of the use issues raised at the Alarm Summit.

A Group Effort

The standards mentioned above are intended for the manufacturers of medical equipment. However, the Alarm Summit clearly pointed out that alarm fatigue can only be adequately dealt with by the combined efforts of all the stakeholders. To address the safe integration of alarm systems as well as other healthcare technology systems, IEC SC 62A, in partnership with ISO TC 215, *Health informatics*, has developed IEC 80001-1, *Application of risk management for IT networks incorporating medical devices - Part 1: Roles, responsibilities and activities*. Several technical reports in the IEC 80001 series that address risk management in a highly networked environment are due for publication in 2012. Also, at the request of the Alarm Systems Joint Working Group, work has begun on a new technical report on alarm system integration that focuses on safety, effectiveness, and data and system security. A draft report is planned for release in 2012.

At the Alarm Summit, Frank Block, M.D., co-chair of AAMI's Alarm Standards Committee and a member of the Alarm Systems Joint Working Group, challenged the standards community. Dr. Block asserts that "alarms – and alarm standards – need to be designed as a system, and not just as a 'box.'" He identified several areas where the standards development process and the product could be improved. These include:

Charles B. Sidebottom, P.E., Director, Corporate Standards, Medtronic Inc.; Secretary, IEC SC 62A; Secretary, ISO TC 150, SC 5

- Increased clinician participation and input
- Application of knowledge on the design of medical alarm systems in other, well studied fields, such as manufacturing processes, nuclear power plants, and aviation and air traffic control
- Specificity on acceptable response time for "immediate" response to high-priority alarm signals or "prompt" response to medical-priority alarm signals
- Attention to whether devices should sound alarm signals as well as to their priority and urgency
- More information on how to create or use intelligent, integrated, unified, or distributed alarm systems, which are mentioned in the standards

The Alarm Systems Joint Working Group intends to work on several of these issues in the next edition of IEC 60601-1-8.

In the near term, the AAMI Alarms Committee will focus on the issue of alarm system management with new standards, technical information reports, and guidance documents for industry and users.

In her opening remarks to the Alarm Summit, AAMI president Mary Logan laid out a vision that by 2017 no patient will be harmed by an adverse alarm event. While today's medical alarm system may be out of control, there is much that can be done both in the short and long term to improve safety. To achieve this goal in just five short years will require the concerted and collaborative effort of all the stakeholders. We in the international standards community are committed to doing our part. ■

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ISO/IEC Guide Upgrades Safety Aspects in Medical Device Standards

Source: IEC *e-tech*

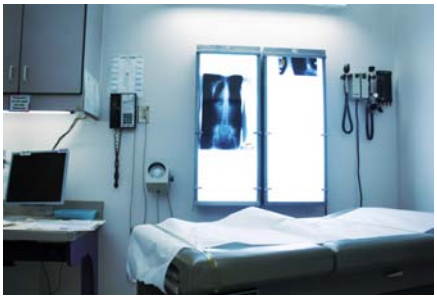
The IEC and the International Organization for Standardization (ISO) have just published a new and improved guide to help standards writers address safety aspects in medical device standards even more thoroughly. ISO/IEC Guide 63, *Guide to the development and inclusion of safety aspects in International Standards for medical devices*, replaces a 1999 edition.

A global approach among manufacturers, users, regulatory authorities, and other stakeholders is needed for the planning and development of medical device safety standards. To create a coherent approach to the treatment of safety in the preparation of standards, close coordination within and among committees responsible for different medical devices is necessary.

ISO/IEC Guide 63 is designed to improve the interface between the standards developing committees and the stakeholders they serve, as well as to make optimal use of resources by only developing medical device safety standards for which there are clear market requirements.

The guide is intended to be used by all ISO and IEC bodies involved in the development of medical device safety standards. It can also be used by non-ISO or IEC standards development organizations at the international, regional, or national levels that are considering or are in the process of developing medical device safety standards and/or comparable documents.

According to Dr. Eamonn Hoxey, chair of ISO Technical Committee (TC) 210, *Quality management and corresponding general aspects for medical devices*, "ISO/IEC Guide 63 will provide a harmonized approach to the concept of safety when developing medical device safety standards. In this way it will help manufacturers and users to collaborate effectively to ensure the safety and performance of medical devices used in health facilities worldwide."



ISO/IEC Guide 63 was prepared jointly by ISO TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC SC 62A, *Common aspects of electrical equipment used in medical practice*, in Joint Working Group (JWG) 1, *Application of risk management to medical devices*. ■

IEC HEADLINES

Moldova Joins the IEC

Source: IEC *e-tech*

The IEC is pleased to announce that the IEC Council has approved the application for IEC Associate Membership from the Republic of Moldova. The IEC Family now comprises 82 members and 81 affiliate countries.

The Republic of Moldova is located between Romania and Ukraine in Eastern Europe. The population is 4.3 million, with 650,000 inhabitants in the capital, Chişinău. Statistics show estimated annual electricity generation of 3,412 billion kilowatt hours (kWh) and consumption of 4,463 billion kWh. The country imports all of its supplies of petroleum, coal, and natural gas. Its main industries are sugar, vegetable oil, food processing, agricultural machinery, foundry equipment, white goods, shoes, and textiles.

Moldova was one of the first countries to join the IEC Affiliate Country Programme for developing countries when it was launched in 2001. In July 2010 it was granted Affiliate Plus status, having adopted more than 90 IEC International Standards as national standards, and having established the Moldovan Electrotechnical Committee (MEC). MEC represents the country's main electrotechnical stakeholders: industry, regulatory authorities, academic institutions, and the national standards body.

The president of MEC, Vitalie Dragancea, is also general director of the National Institute for Standardization and Metrology (INSM), and the secretary of MEC, Tatiana Rusu, is a senior specialist in international relations at INSM.

As an Associate Member, the Republic of Moldova will be able to attend any technical and some management meetings (such as those of Council and the Standardization Management Board) that take place during the annual IEC General Meeting.

Associate Members have access rights and can comment on all IEC technical documents, except Final Draft International Standards (FDISs). They may also request to become Participating (P-) members on a maximum of four Technical Committees (TCs) or Subcommittees with the obligation to vote on the work produced by those committees.

MEC has expressed interest in being a P-Member in TC 13, *Electrical energy measurement, tariff and load control;* TC 34, *Lamps and related equipment;* and TC 88, *Wind turbines*. ■

2011 IEC Young Professional Jonathon Colby: A First-Hand Account of the Program

My name is Jonathan Colby and I am a hydrodynamic engineer with Verdant Power, a marine renewable energy company with main operations in New York City's East River. I was nominated to attend the 2011 IEC Young Professional (YP) program by the U.S. Technical Advisory Group (TAG) to Technical Committee (TC) 114, *Marine Renewable Energy*, and was accepted by the USNC as one of three delegates from the United States.

The 2011 YP program was held in conjunction with the 75th IEC General Meeting in Melbourne, Australia. Overall, the experience was highly rewarding both professionally and personally. As a group of 60 representing nearly 30 countries, we were given a detailed look into the broad range of IEC issues and operations. Perhaps more importantly, we were given a tremendous platform to stand upon and share our experiences with each other and the leadership of the IEC. The ability to interact with individuals from across the globe, with widely varying backgrounds in science, engineering, and IEC experience, was invaluable, as are the friendships I began with my fellow attendees.

I have been active with the IEC since 2008 on TC 114, *Marine energy - Wave, tidal and other water current converters.* I currently serve as a U.S. subject matter expert on Project Team (PT) 62600-200, *Power Performance Assessment of Electricity Producing Tidal Energy Converters*, and as the chair of the U.S. Shadow Committee for this PT. I was able to share my experiences interacting with the IEC in the development of our technical specification with the YP group.

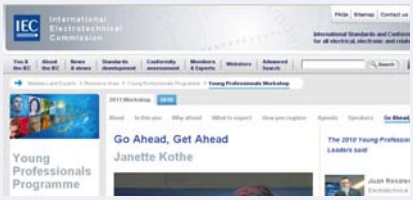
Jonathan Colby

Attending the Standardization Management Board (SMB) and Conformity Assessment Board (CAB) meetings was an excellent way for me to learn how the IEC coordinates standards development activities and functions in various global economic markets. And the opportunity to network over lunch with members of the SMB and CAB allowed me to meet and converse with the convener of a working group on conformity assessment in the marine renewable energy industry.

In addition to attending IEC meetings and YP seminars, we broke into four sub-groups over two days to address questions posed by the IEC and develop responses for the entire YP audience. Working with a small, diverse group of highly motivated and intelligent professionals was a highlight of the program. Our efforts led to informed and organized responses representing a broad range of opinions, and I gained valuable insight into the ways different countries and organizations utilize standards and contribute to the IEC.

At the completion of the three-day workshop, I was elected as one of three leaders for the 2011 group, for which I am honored. As an elected leader, I am working to ensure the continued engagement of 2011 members in the YP program and the IEC at large. To do so, we plan to host web-based seminars highlighting a variety of relevant topics within the IEC, including the role of standardization in emerging industries. I am excited to work closely with my fellow YPs to ensure we all remain active members in the standards development process, both nationally and internationally. ■

HURRY! Nominate 2012 IEC Young Professionals by April 30



The USNC would like to remind all members and stakeholders that submitted nominations for U.S. participants for the 2012 Young Professionals Workshop will be accepted until April 30. The workshop will be held in conjunction with the 76th IEC General Meeting in Oslo, Norway, in October 2012.

Alongside recipients from other nations, the U.S. young professionals will learn more about the IEC and standardization strategies. They will have the opportunity to attend technical meetings, observe meetings of the IEC SMB and CAB, receive guidance from a mentor, visit local industry, and network.

Up to three recipients will be financially supported for their travel and up to three nights of accommodation.

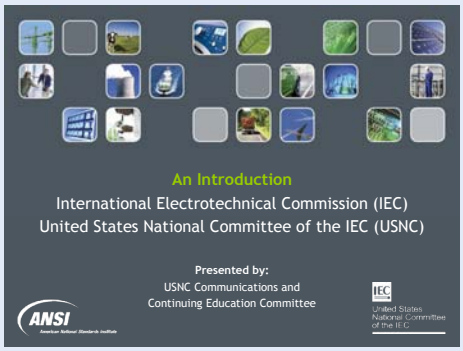
U.S. stakeholders are encouraged to nominate young professionals involved in standardization from industry, government, academia, consumer organizations, or any entity within the U.S. voluntary standards and conformity assessment community that uses, benefits from, or contributes to the IEC's work in electrotechnical standardization and conformance. The program is targeted towards outstanding individuals who are in the early years of their professional career, post university. For more details, visit http://www.iec.ch/members_experts/ypp/.

U.S. nominations must be submitted electronically by April 30, 2012, to Charlie Zegers, general secretary of the USNC, at czegers@ansi.org.

USNC NEWS

Useful New Resources Added to the USNC Website

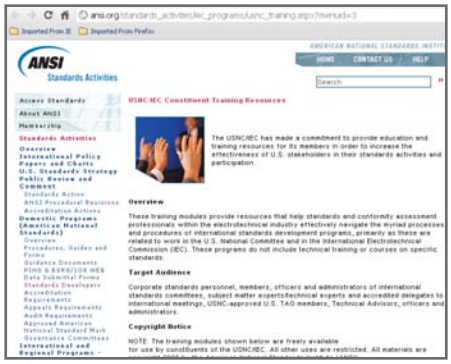
The USNC is pleased to announce a number of new offerings at www.ansi.org/usnc. We invite you to visit the site and take advantage of these great resources.



USNC Generic PowerPoint Presentation

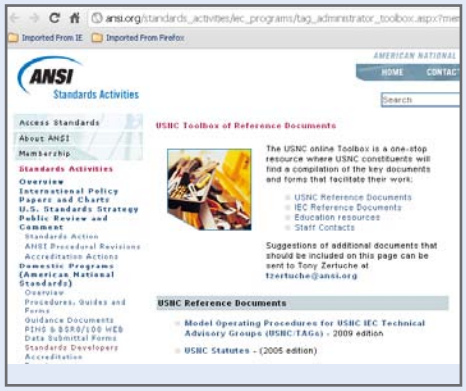
The USNC Communications and Continuing Education Committee has developed a USNC Generic PowerPoint presentation on the fundamentals of the USNC and IEC. It is intended to provide background information on the organizations to general interest groups and government agencies. The presentation is now available for your use. Click here to take a look!

USNC Training Modules Now Available – No Password Necessary!



The USNC/IEC has made a commitment to provide education and training resources for its members in order to increase the effectiveness of U.S. stakeholders in their standards activities and participation.

The six training modules provide a resource to help standards and conformity assessment professionals within the electrotechnical industry effectively navigate the myriad processes and procedures of international standards development programs, primarily as these are related to work in the USNC and the IEC. These programs do not include technical training or courses on specific standards. Click here to take a course!



USNC Toolbox of Reference Documents

The online USNC Toolbox is a one-stop resource where USNC constituents will find a compilation of the key documents and forms that facilitate their work:

- USNC Reference Documents
- IEC Reference Documents
- Education Resources
- Staff Contacts

Click here to check them out!

USNC NEWS

ANSI eStandards Store Purchases Support USNC

Standards developed by IEC can be purchased from a variety of websites, organizations, and third-party resellers. But to see the greatest benefits from dollars spent, USNC members should purchase standards directly from the American National Standards Institute (ANSI), since the revenue from ANSI's eStandards store directly supports the activities and initiatives of the USNC.

The USNC/IEC is a totally integrated committee of ANSI. As such, the Institute provides administrative support to the USNC and its nearly 1,400 managerial, engineering, scientific, and professional participants.

ANSI also provides the fiduciary framework by which the USNC's financial obligations are met, including the payment of annual dues to IEC. And since ANSI is a non-profit organization, the revenue earned from your purchase helps to support the programs and services offered to USNC members, from workshops for U.S. Technical Advisory Group (TAG) Administrators to this latest issue of the *News and Notes* newsletter.

When you purchase IEC standards from ANSI, you are making a commitment to bolster U.S. leadership at the IEC table. And purchasing standards directly from ANSI's eStandards Store offers the additional benefits of cost savings for ANSI members, personal service, and the convenience of one-stop shopping for more than 230,000 standards available for immediate download.

Further information

Contact the ANSI customer support team (212.642.4980; info@ansi.org) or visit the eStandards Store (webstore.ansi.org). ■

ANSI Opens Nominations for 2012 Leadership and Service Awards

The American National Standards Institute (ANSI) has announced the Call for Nominations for its 2012 Leadership and Service Awards.

Presented in conjunction with World Standards Week, the awards recognize individuals who have made significant contributions to voluntary consensus standardization and conformity assessment programs and have consistently demonstrated a commitment to their industry, their nation, and the enhancement of the global standardization system. To be held October 9-12, 2012, in Washington, DC, World Standards Week is an annual event where members of the standards and conformity assessment community come together in the spirit of cooperation and collaboration.

Last year, 6 USNC members and leaders were among the winners of ANSI Leadership and Service Awards:

- **John G. Abbott, Ph.D.,** Philips Healthcare – Meritorious Service Award
- **Jean M. Baronas,** Sony Electronics (consultant) – Meritorious Service Award
- **Sonya M. Bird,** Underwriters Laboratories Inc. – Meritorious Service Award
- **Ralph M. Showers,** Ph.D., University of Pennsylvania (retired) – Elihu Thomson Electrotechnology Medal
- **Robert A. Williams,** Underwriters Laboratories Inc. – Howard Coonley Medal
- **James E. Matthews, III,** Corning Incorporated – Astin-Polk International Standards Medal

"The annual awards program is a long-standing and valuable ANSI tradition," said S. Joe Bhatia, ANSI president and CEO. "We welcome this opportunity each year to recognize the tremendous contributions that individuals with diverse backgrounds and perspectives make to standards and conformity assessment issues that affect both the economy and our well-being."

Representatives of industry, government, academia, consumer organizations, and the U.S. voluntary consensus standards and conformity assessment community, with the exception of current officers of the Institute's Board of Directors, are considered eligible for an award. Recipients will be chosen from the list of nominees by an awards committee comprised of the officers of the ANSI Board of Directors.

ANSI will honor the 2012 award recipients on Wednesday evening, October 10, at a banquet and ceremony to be held at the Newseum in Washington, DC.

Nominations are due by Friday, June 29, 2012 (5 p.m. Eastern). Letters of support from members of the standardization community attesting to the nominee's outstanding achievements that demonstrate their appropriateness for the award are strongly encouraged.

Further information

For more information and to access nomination forms, visit www.ansi.org/awards. ■

LATEST LITERATURE FROM THE IEC

Stay up on all the recent brochures, news releases, and other publications from the IEC by clicking on the links below.

Piracy in Electrical and Electronic Products
http://www.iec.ch/about/brochures/pdf/conformity_assessment/IEC_Counterfeiting_brochure_LR.pdf

The Force Multiplier for ICT innovation – ISO/IEC JTC 1 Standards
http://www.iec.ch/about/brochures/pdf/technology/ict_innovation.pdf

IEC Young Professionals Programme 2012 Workshop
http://www.iec.ch/members_experts/ypp/workshop/pdf/2012_workshop_flyer.pdf

***e-tech Magazine* – News & Views**
http://www.iec.ch/etech/2012/etech_0312/etech_03_2012.htm

ON THE GRID

NIST Releases Updated Smart Grid Framework for the Nation

With the view toward modernizing the nation's electric power system, the National Institute of Standards and Technology (NIST) recently released an updated roadmap for the Smart Grid. The *NIST Framework and Roadmap for Smart Grid Interoperability Standards, Release 2.0*, lays out a vision for transforming the nation's electric power system into an interoperable Smart Grid to deliver electricity efficiently, reliably, and securely. The document incorporates feedback received during a public comment period, and reflects input from a wide range of stakeholder groups.

"Release 2.0 represents a significant update to the NIST Release 1.0 Framework," said George Arnold, the National Coordinator for Smart Grid Interoperability at NIST. "In addition to the comments received through the public review, we vetted the draft framework in advance with the Smart Grid Interoperability Panel (SGIP) and other groups. The document reflects the consensus-based process the SGIP uses to coordinate development of Smart Grid standards."

The SGIP was created by NIST in November 2009 to provide an open forum for members to collaborate on standards development. Through the SGIP, NIST collaborates with the private sector in coordinating Smart Grid standards. Its more than 1,900 volunteer members from 740 organizations serve as technical experts who work together to create usable standards for the Smart Grid. Hundreds of such standards – covering matters ranging from wireless communication to home energy meters to electric cars – are needed to ensure the many elements of the Smart Grid will work together seamlessly.

According to NIST, hundreds of standards, ranging from those for wireless communication to home energy meters to electric cars, are needed to ensure that the many elements of the Smart Grid will work together seamlessly. Version 2.0 of the framework builds upon NIST's initial January 2010 report with an expanded list of standards, new cybersecurity guidance, and product-testing proposals to support an interoperable Smart Grid.

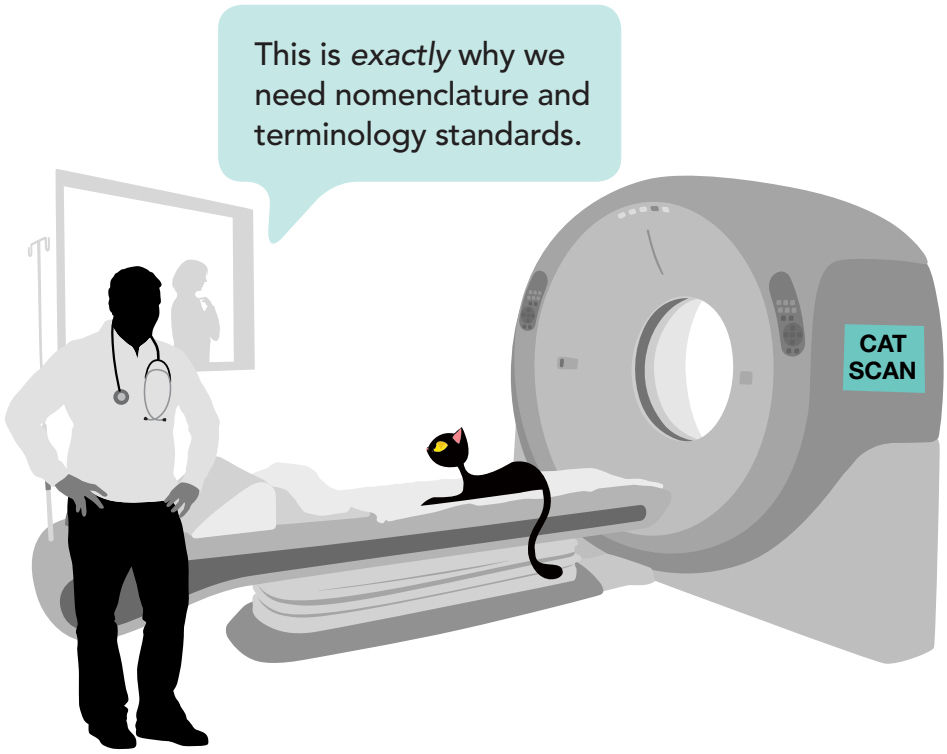
In total, Release 2.0 adds 22 standards, specifications, and guidelines to the initial 75 that NIST recommended in the January 2010 roadmap. Further additions to the 1.0 version include:

- a new chapter on the roles of the Smart Grid Interoperability Panel (SGIP);
- an expanded view of the architecture of the Smart Grid;
- a number of developments related to ensuring cybersecurity for the Smart Grid, including a risk management framework to provide guidance on security practices;
- a new framework for testing the conformity of devices and systems to be connected to the Smart Grid – the Interoperability Process Reference Manual;
- information on the coordination of U.S. Smart Grid standards efforts with similar efforts in other parts of the world; and
- an overview of future areas of work, including electromagnetic disturbance and interference, and improvements to SGIP processes.

Further information

Read the full *NIST Framework and Roadmap for Smart Grid Interoperability Standards* at http://www.nist.gov/smartgrid/upload/NIST_Framework_Release_2-0_corr.pdf. ■

LAUGH TRACK



CONFORMITY ASSESSMENT

New IECEE Service for Energy Efficient Appliances

Source: IEC *e-tech*

Standards can serve as the basis for regulations and legislation in the energy efficiency field. The IEC has a whole catalogue of International Standards that deal not only with safety requirements for appliances and equipment, but also provide metrics and testing specifications to achieve optimum energy consumption.

Manufacturers of appliances and equipment for domestic use can rely on IEC International Standards to develop state-of-the-art products that meet the strictest safety and energy-efficiency requirements. Going a step further, they can rely on the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) to have their products tested and certified.

IECEE has been testing and certifying appliances and equipment for many years, focusing on product safety and, when the standards require it, also providing services covering aspects of performance. Now, in response to industry demand, IECEE has introduced a new product category for energy efficiency.

IECEE has identified a number of IEC International Standards for a variety of appliances – from refrigerators, washing machines and tumble dryers to vacuum cleaners, irons, coffee makers, fans, and microwave ovens, to name just a few – that will serve as a basis for testing the products' energy efficiency performance.

This service will provide a Test Report issued by a IECEE Certification Body Testing Laboratory (CBTL) and validated by a Statement of Test Result (STR) that is issued by an IECEE National Certification Body (NCB). It can be used either as a stand-alone or as a combined safety and energy efficiency/performance service where the Test Report and the STR are included in the Certification Body (CB) Test Certificate or the Full Certification Scheme (FCS) Certificate that is issued by the IECEE NCB.

About IECEE Schemes

A CB Test Certificate is a global passport that allows products to be accepted in all IECEE member countries. It is so well known that global acceptance is a reality, even in countries that are not part of the IECEE community. "One test, one international certificate" opens the doors of the global market.

The IECEE CB Scheme provides the assurance that tested and certified products meet the strictest levels of safety, reliability, and performance in compliance with the relevant IEC International Standards. It helps reduce costs and time to market, eliminates duplicate or multiple testing, and offers a high level of confidence for manufacturers, retailers and consumers alike.

The CB-FCS Scheme for Mutual Recognition of Conformity Assessment Certificates for Electrotechnical Equipment and Components is an extension of the IECEE CB Scheme in that it also includes factory audits and inspections. It goes far beyond product testing and includes a complete quality system and surveillance methods for the factory that manufactures a certified product. This is useful for manufacturers who need to provide proof that products manufactured in a given factory offer a consistent level of quality over time. ■

CONFORMITY ASSESSMENT

LEDs for Ex

Source: IEC *e-tech*

Offshore oil platforms, refineries, shipyards, and gas and oil tankers operate 24 hours a day. Night-shift crews need powerful and reliable lighting to be able to work when it is dark. Lighting fixtures, as with any other piece of equipment or device used in hazardous areas, have to be explosion-proof.

A growing trend for lighting fixtures designed for explosive environments is to replace conventional incandescent light bulbs or HDL high-intensity discharge (HDL) or fluorescent lighting with LEDs. Low voltage and low-operating temperatures make LEDs safer to use in combustible atmospheres, excellent colour rendition improves night vision, and instant switch-on provides added safety for dark areas. Because they last much longer than traditional lighting, they also reduce drastically the need for maintenance. And, last but not least, they consume much less energy than all the other types of light fixtures.

Companies such as Dialight and Hubbell, which offer high-specification LED lighting for hazardous areas, have had their products tested and certified by the IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx).

For all companies producing lighting equipment for hazardous areas, having IECEx certification is essential for providing global access to markets and to avoid having to obtain individual approvals for each country. ■

CONFORMITY ASSESSMENT

NIST to Host Public Workshop on Conformity Assessment

On April 11, the National Institute of Standards and Technology (NIST) will host a public workshop entitled *Conformity Assessment – Approaches and Best Practices*. To be held at NIST's headquarters in Gaithersburg, MD, the workshop will provide a forum for discussion on the current approaches to conformity assessment among federal agencies and the private sector, and help inform a planned update to NIST's Guidance on Federal Conformity Assessment Activities (15 C.F.R. Part 287).

The regulations outline federal agencies' responsibility for evaluating the efficiency and effectiveness of their conformity assessment activities and are intended to help federal agencies improve the management and coordination of their own conformity assessment activities in support of their regulatory, procurement, and other mission objectives. NIST is seeking input from members of the public on potential revisions to the regulations. Discussions at the NIST workshop will inform further development of the guidance.

The conference will include presentations from key government officials, regulators, and industry and conformity assessment experts. Time will be allotted for participant input and discussions.

This event is free, but advance registration is required. The registration deadline is 5 p.m. ET April 3, 2012. For further information, or to register visit http://www.nist.gov/director/sco/ca-workshop-2012.cfm. ■

Upcoming 2012 Issues of *News & Notes*

Quarter II Explosive Atmospheres

Quarter III Focus on China/India

Quarter IV System Standardization: Networking That Works

SAVE THE DATES

Mark Your Calendar for Upcoming Meetings & Events

MAY 2012

CAPCC/TMC/Council Meetings
May 1–3; TIA, Washington, DC

COPANT General Assembly
Period between May 7–11;
Fortaleza, Brazil

ICES Conference, May 10, Bali, Indonesia

WSC Academic Day, May 11, Bali, Indonesia

JUNE 2012

PASC Meeting, June 4–8, Yeosu, Republic of Korea

CAB/SMB/CB Meetings, June 11–14, Boston, MA

August 2012

CAPCC/TMC/Council Meetings
August 28–30, FM Approvals, Norwood, MA

September 2012

ISO General Assembly
September 16–22, San Diego, CA

October 2012

76th IEC General Meeting
October 1 – 5, Oslo, Norway

SMB Meeting	October 1
CAB Meeting	October 2
Council Board	October 3
Council Meeting	October 5

ANSI World Standards Week
October 9 – 12, Newseum, Washington, DC

ANSI American National Standards Institute

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The USNC *News and Notes* newsletter is distributed to the constituency of the United States National Committee (USNC) of the International Electrotechnical Commission (IEC). It provides updates on technical activities and other information of interest to members of the electrotechnical community. Some articles are reprinted with permission from the IEC News log.

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