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FOCUS ON: STANDARDS OF VALUE TO GOVERNMENT

The *National Technology Transfer and Advancement Act of 1995* (NTTAA) states that “Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards.” Increasingly, agencies are relying on and referencing international standards in such key areas as healthcare technology, energy, and the Smart Grid.

The Value of Standards to One Regulatory Agency

By Carol L. Herman, Retired Director, Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Standards Program

Consensus standards are the workhorse of the medical device review process. While the data is not there to definitively support a reduced review time, it is possible that if the reviewers of premarket submissions did not have voluntary consensus standards to rely on, the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH) would need more reviewers and longer review times to effectively meet their regulatory requirements.

The Keys to the Process

The *Food and Drug Administration Modernization Act* (FDAMA) envisioned that voluntary consensus standards, if used effectively, could help reviewers of medical device premarket submissions to either shorten review times or re-target the review so that more time could be spent on those elements requiring more in-depth review. The latter could be accomplished because reviewers could rely on the appropriate use of standards they have recognized and have confidence in. That confidence comes from

participating in the development and revision of the most relevant medical device standards, as well as a robust recognition process that allows for deviations if there are parts of the standard that do not meet the regulatory needs of the CDRH. This is one of the most valuable tools a regulatory agency can have.

Having said that, the appropriate use of standards is key to the success of the program, and industry plays a significant role in that success. If the wrong standard or the wrong criteria within a standard are used, this can slow down the process and



Federal agencies are directed to participate in the activities of voluntary standards organizations and to adopt and reference voluntary standards in furtherance of U.S. domestic and foreign goals (OMB Circular No. A 119).

ultimately require more review time. Also, there is no provision in the law that allows for the “promise” that the data demonstrating safety and effectiveness will be generated and support the appropriate use of the standard. Consequently, industry is very important, and working closely with the agency *(continued)*

The Value of Standards to One Regulatory Agency (continued)

and following the appropriate standards and guidance can play a significant role in an expeditious product review.

The Near Future

CDRH has and continues to make significant improvements in processes, and the agency has strategically opened offices around the world. However, FDA does not, nor will it, have the resources needed to adequately keep up with the pressure of globalization.

Manufacturers also face pressure to lower costs and improve product while trying to keep pace with emerging technologies and a fast paced global economy. Nanotechnology, robotics, interoperability, systems of systems – just to name a few – will continue to present new and exciting challenges. Global trends will have major implications for CDRH and the medical device industry in the next decade. Strong global safety standards will continue to be needed, as will faster progress towards these standards in order to meet the growing demand.

The Way Forward

My main recommendations for the future of medical device standards are twofold. First, when I was the director of the medical device standards program, I pushed for and was beginning to see movement toward more virtual interactions in developing standards.

This not only reduces travel expenses, but can also allow for more frequent meetings.

We have seen the decline of regulators participating in the standards development process, which is not helpful. There are many committees developing standards of great importance where FDA is the only regulator at the table, and many that even FDA cannot attend. With the limited resources of both government and industry, it has become vitally important that we begin to think differently about how standards get developed.

While nothing can replace the face-to-face interactions of scientists and policy makers, getting standards completed more quickly is a major concern for the entire community. We no longer have the luxury of taking five or more years to develop a standard. Good standards – with performance criteria wherever possible – are needed, and they are needed in a timely way. This is a challenge of utmost importance to the standards developers and participants for the coming decade.

Secondly, speaking of performance criteria, we need more of it. In the early days of medical device standards development there was more. But industry has marched on and products have become more complicated and sophisticated, making it more difficult to provide the coveted criteria and/or limits.

There has also been concern that too much

specificity in standards can contribute to a stifling of innovation and to trade issues. But the pendulum may have swung too far. FDA needs and wants good performance criteria and limits in standards whenever possible. This not only helps the reviewer, but also can help ensure the consistency in the review process that is so desired by industry.

I believe if these improvements can be made in medical device standards, the value of the standards will be greatly improved and continued support from FDA will be secure. But the benefits of these improvements far exceeds just having FDA support. The benefits of strong global standards include stronger global participation, better and safer products, and improvements to public health around the world. FDA as an agency, and CDRH in particular, believe in the value of standards in supporting the regulatory mission and mandate.

During my tenure with CDRH, standards grew well beyond medical devices. Our program became the template for how the entire agency views, tracks, documents, and participates in standardization. While each FDA center has its own regulations, the medical device program became the “gold standard” for how centers can use standards in meeting regulatory requirements. With the new *Food Safety Modernization Act* (FSMA), the Center for Food Safety and Nutrition (CFSAN) is looking closely at how they can leverage national and global standards to accomplish their goals.

This is just one example of the growing value of standards in the FDA. I am extremely proud to have been a part of this process and all the accomplishments of CDRH and FDA for more than a decade and look forward to continuing this important work but from a different, exciting, and complimentary position. ■



Carol L. Herman,
Retired Director,
FDA/CDRH
Standards Program



Global trends will have major implications for CDRH and the medical device industry in the next decade, and faster progress toward strong safety standards is continually needed.

IEC TC 57 Standards for the Smart Grid: Keeping Pace with Government and Industry Needs

By Scott Neumann
U.S. Technical Advisor, IEC TC 57

As industry and governments around the world focus more and more on the critical development of the Smart Grid, IEC Technical Committee (TC) 57, *Power Systems – management and associated information exchange*, finds itself at the center of the action developing many of the necessary related standards. IEC TC 57 standards are primarily used for information exchanges between energy control centers, within utility enterprises, within energy markets, within substations, on distribution feeders, and up to the customer interface.

IEC 61850

One of the key “families” of TC 57 standards commonly referenced for Smart Grid projects is the IEC 61850 series. IEC 61850, *Communication networks and systems in substations*, is concerned with power system intelligent electronic device (IED) communication and assorted data models. This series of standards is typically realized within the controllers of field equipment used within substations and on distribution feeders. Extensions have also been defined to support equipment related to wind, hydro, and distributed energy resource. The 61850 standards currently available cover aspects such as requirements, system and project management, communication, conformance testing, and more.

CIM

Within the electric utility industry, the terms “common information model” (“CIM”) refer to a logical information model that has been developed by the industry and standardized by IEC TC 57. The CIM family of standards covers the information exchanges needed to integrate control centers, utility enterprise applications, energy markets, and grid operations.

The core CIM standard is IEC 61970-301, *Energy management system application program interface - Part 301: CIM base*. Central to the CIM is the description of electrical equipment,



related connectivity, and measurements.

IEC 61968-11, *Application integration at electric utilities - System interfaces for distribution management - Part 11: CIM extensions for distribution*, is a companion standard that extends the CIM to be supportive of electrical distribution. IEC 62325-301, *Framework for energy market communications - Part 301: CIM extensions for markets*, is another companion standard. All three of these standards are in large part derived from the CIM as represented using Unified Modeling Language (UML). The CIM UML is maintained by a team of volunteer model managers who work with working group members to address issues identified by industry that enable CIM-based standards to be developed by IEC TC57.

The above standards are the basis for annual interoperability testing, where model files are exported from one application and then imported into another application. A large number of vendors have participated in interoperability tests over the last 10 years, as interest was spurred by the Federal Energy Regulatory Commission (FERC) and more recently by European mandates.

A number of important CIM-related specifications are currently in a draft status:

- IEC 61970-456, for exchange of power system state information
- IEC 62361-100, defining naming and design rules for CIM profiles to XML Schemas
- IEC 61968-100, describing the use of enterprise service buses and web services for integration
- IEC 62325 series for energy market communications

Integration

When performing integration of enterprise applications within a utility, the IEC 61968 series of standards is often of interest. Currently in a draft state is the second edition of IEC 61968-1, *Application integration at electric utilities - System interfaces for distribution management - Part 1: Interface architecture and general requirements*, which describes a high-level, logical architecture for integration along with an Interface Reference Model (IRM).

A current topic of strong interest in the industry is the integration of metering systems. Here, IEC 61968-9, *Application integration at electric utilities - System interfaces for distribution management - Part 9: Interfaces for meter reading and control*, provides guidance; a second edition draft recently finished interoperability testing. IEC 61968-9 also serves as the template to define other parts of IEC 61968 that are intended to standardize information exchange between enterprise systems.

Communication and Data Security

Security for the Smart Grid is obviously an area of significant concern for industry and government alike. The IEC 62351 series of technical specifications describes approaches for data and communication security that can be leveraged by protocols defined by IEC TC 57.

Users Group

The UCA International Users Group (UCAIUG) is focused on assisting users and vendors in the deployment of standards developed by IEC TC 57. Among its many services, the UCAIUG provides periodic snapshots of the CIM UML model that can be freely downloaded by members; hosts regular user group meetings in Europe and North America; and sponsors interoperability tests for IEC TC 57 standards.

Further Information

Visit www.ucaiug.org. ■

Cross-Sector Webinar Highlights Government Efforts on Sustainable Purchasing and Reliance on International Standards

Approximately 200 participants from across the standards and business communities as well as other stakeholders tuned in to a one-hour webinar related to environmentally preferable purchasing hosted by the American National Standards Institute (ANSI).

Led by the U.S. Environmental Protection Agency’s (EPA) Alison Kinn Bennett and Brennan Conaway of the U.S. General Services Administration (GSA), the webinar provided an opportunity for standards developing organizations, product manufacturers, and others to hear firsthand about interagency efforts to develop guidelines for product standards and ecolabels for greening federal procurement.

The session included a robust Q&A session in which participants posed and received answers on questions ranging from the scope of the project to its implementation. All questions submitted during the webinar, including those for which time did not allow a dedicated discussion, will be compiled along with written responses from the speakers and made publicly available at a later date.

“This is clearly a subject of great interest to the standards and business community. And certainly, the topic of standards for green products is an important area of focus for ANSI,” said ANSI’s senior vice president and chief operating officer Fran Schrotter in her opening remarks. “The Institute is committed to working on behalf of our diverse membership, U.S. business and industry, and the overall public good to coordinate the

standardization activities that meet critical national and global priorities.”

Ms. Kinn Bennett and Mr. Conaway provided a high-level overview of the work of the Product Standards and Ecolabels Subgroup, a group co-chaired by GSA and EPA to ensure that the product-related acquisition goals of Executive Order (E.O.) 13514 are met through guidelines for selecting product-related environmental sustainability standards and/or ecolabeling programs. E.O. 13514 seeks to establish an integrated strategy towards sustainability in the federal government and to make reduction of greenhouse gas emissions a priority for federal agencies. Among other measures, the order directs agencies to ensure that 95 percent of new federal contracts require environmentally preferable products and services. According to Ms. Kinn

Bennett and Mr. Conaway, the subgroup is working to create an effective market infrastructure for green products that will assist federal purchasers in more easily identifying products that meet standards. In developing their guidelines for what green standards should be, the Product Standards and Ecolabels Subgroup relied upon documents such as the ANSI Essential Requirements, ISO/IEC Guide 59, *Code of good practice for standardization*, and ISO 14020, *Environmental labels and declarations – general principles*, which reflect the need for openness, balance, consensus, and due process in the standards-setting process.

The subgroup expects to submit a draft final report to the Council for Environmental Quality (CEQ) in February 2012, and to formally release the report for public comment in March 2012.

Further Information

View the webinar presentation [here](#). ■

Guideline Influencers

Standard name	Description	Year
ISO/IEC Guide 65	General requirements for bodies operating product certification systems	1996
ISO 17011 Accreditation	Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies	2004
ISO/IEC 17020	General criteria for the operation of various types of bodies performing inspection.	1998
ISO/IEC 17021	Conformity assessment -- Requirements for bodies providing audit and certification of management systems	2011
ISO 17025	General requirements for the competence of testing and calibration laboratories	2005
ISO/IEC 17050 -1	Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements	2004
ISO/IEC 17050 -2	Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements	2004



Overview of Section 13 Product Standards/Ecolabels Subgroup

The webinar presentation stressed the importance of international standards as a basis for government guidelines for ecolabeling.

Product Standards for Sustainability

In 2009, ANSI hosted a workshop, *Toward Product Standards for Sustainability*, with support from the EPA, to focus on issues related to sustainability and environmental performance standards for products. View the final workshop report [here](#).

USNC NEWS

Committee Update: TC 23 Addresses U.S. Issues

By Dennis Oddsen, Member, IEC TC 23, MT 61916

With adoption of the IEC Technical Committee (TC) 23, *Electrical accessories*, Strategic Business Plan (SBP) by the Standardization Management Board (SMB), TC 23 has committed to addressing the needs of significant markets in accordance with the IEC philosophy: “Projecting one solution that accommodates one market (but not others) as the international standard will not force markets to evolve and coalesce. In such cases, the markets and their related industries will look elsewhere for standards that better accommodate their needs, and IEC will lose its relevance in those markets and industries.” The SBP was approved unanimously by TC 23 in September 2011 at a meeting in Kista, Sweden.

While Subcommittees (SC) 23B, *Plugs, socket-outlets and switches*, and 23H, *Industrial plugs and socket-outlets*, are specifically referenced in the SBP, it is clear that the principle of ensuring that IEC standards do not address one solution for one market while failing to address solutions for other significant markets applies to any SC or TC.

The new TC 23 SBP responds to SMB

decision 136/6, which requested TC 23 to develop a plan to address concerns from the USNC and several other countries regarding standards not reflecting the needs of significant markets. TC 23 set a three-to-five-year objective to publish globally relevant standards, with the express goal that they must meet basic IEC safety standards. This may be achieved using any of the processes covered by the IEC Global Relevance Tool Box.

This is reinforced in the Action Plan and addresses the concerns of the USNC as follows: “To enable progress against the time objective, National Committees of TC 23 and its SCs may submit document(s) through the relevant secretariat by requesting the publication of a Draft for Comment (DC), New Proposal (NP), or similar document to initiate the process for modifying existing standards to reflect the needs of significant markets. The document(s) shall be in accordance with IEC Directives. Further, the initiation date (against which the



three-to-five years will be measured) will be the date of the Result of Voting (RVN) in the case of an NP, or the issuing date in the case of other documents when agreed within the TC/SC.”

The TC 23 SBP points out that it may be helpful to identify differences between existing and proposed alternative solutions and to categorize these differences as “permanent” or “temporary.” TC 23 Maintenance Team (MT) 61916 has been given the task of defining these two terms. MT 61916 has also been tasked with analyzing IEC basic safety standards and determining which are relevant to TC 23 standards and what the appropriate parameters would be. And MT 61916 will analyze the Tool Box and determine the most appropriate tools. The SBP makes clear that this work by MT 61916 is not intended to delay the submittal of proposals from the U.S. or other countries.

It is now the responsibility of the U.S. to develop responsible proposals to address the needs of the U.S. and related markets. ■

USNC NEWS

Committee Update: TC 46 – Technical Concerns from the FCC

By Roger Mathews, U.S. Technical Advisor, IEC TC 46

The USNC Technical Advisory Group (TAG) for Technical Committee (TC) 46, *Cables, wires, waveguides, R.F. connectors, R.F., and microwave passive components and accessories*, recently hosted meetings in Myrtle Beach, SC, to cover working documents for coaxial and symmetric cables, radio frequency (RF), microwave, and passive components.

TC 46 has been tasked with updating the standards by changing the specifications to harmonize requests from other countries. With the global market affecting all aspects of communications, even subtle changes in dimensions or material could mean that the connector interface or cables that we rely

on become incompatible with the existing infrastructure. And we need to be careful as we move forward to not redefine what has been the foundation of our technology.

During the TC 46 committee meeting, the Federal Communications Commission (FCC) raised technical concerns regarding a document that has ramifications on how we measure RF power. *Document 46 A 1027 CDV* addresses IEC 61196-1-119, *Coaxial communication cables – Part 1-119: Electrical test methods - R.F. Power Rating*.

The U.S. requested a change of the term “rms power.” The term is a misnomer and is used incorrectly. For RF power: V_{rms} * I_{rms} = average power, NOT rms power.

Established bodies such as ANSI, ETSI, NIST and the ITU all agree that “mean power” is the correct terminology, not “rms power.”

A change like this – even though it’s innocent (and just because some manufacturer put a button for “rms power” on the equipment) – does not mean that standards groups should ignore decades of convention or practice to facilitate change that would be costly to the U.S. position.

We need participation from all in monitoring the activities and attending IEC TC meetings to firmly establish U.S. views. Luckily, the FCC caught this one and forwarded the information to TC 46. We wonder how many others are missed. ■

USNC NEWS

New IEC Committees and Groups Need Your Participation

The IEC has approved the establishment of a new Project Committee (PC), Technical Committee (TC), and two Strategic Groups (SG). The USNC has indicated its intent to become a participating member of these groups and is currently welcoming interested parties that would like to participate.

PC 118, Smart Grid

A new – and first – Project Committee for the IEC.

Initial Scope: Smart Grid

User Interface, Part 1: Standard of exchange interface between demand-side smart equipment and the grid and Smart Grid User Interface, Part 3: Power Demand Response Standard

TC 119, Printed Electronics

Initial Scope: Standardization of terminology, materials, processes, equipments, products, and health/safety/environment which are related to the printing methods for electronics.

SG 5, Ambient Assisted Living

Initial Scope: Management and coordination



of Ambient Assisted Living (AAL) standardization work in IEC TCs, to establish and achieve interoperability and interconnectivity of AAL. AAL stands for methods, concepts, systems, products, and services supporting elderly people and people with disabilities in their daily lives, using technical and social as well as medical

systems and providing accessibility.

SG 6, Electrotechnology for Mobility

Initial Scope: Management and coordination of standardization work for Electrotechnology for Mobility in IEC, to establish and achieve interoperability and interconnectivity.

Any entities interested in these positions are invited to contact:

Tony Zertuche

USNC/IEC Deputy General Secretary

Email: tzertuche@ansi.org

Tel: 212.642.4892 ■

USNC NEWS

Save the Date! USNC/IEC Instructor-Led Online Course March 28

The USNC has set the date for its instructor-led training course on Effective Participation in the Development of Globally Relevant IEC Standards. **The course will be held March 28, 2012.**

This course is designed to give tips of the trade and advice to those U.S. delegates who wish to work on and improve their skills as representatives. Participants will learn, in

great detail, what to do before, during, and after a meeting, as well as how to put your best foot forward when representing the United States. Also covered will be correct delegate conduct and behavior and the most effective ways to represent yourself as a delegate for the United States.

Registration details and further information are forthcoming. ■

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). ■



American Jonathan Colby Named IEC Young Professional Leader

The USNC is pleased to announce that American Jonathon Colby was among the three international IEC Young Professionals voted as this year's Young Professional Leaders at the 75th IEC General Meeting (GM) in Melbourne, Australia. The other two people receiving the highest number of votes were Elaine Clayton of Australia and David Tackie of Denmark.

Mr. Colby represented the United States as one of the two U.S. winners of the 2011 IEC Young Professionals Workshop competition, held in conjunction with the 2011 GM. Launched in 2010 at the 74th IEC GM in Seattle, the Young Professionals Program brings together the world's upcoming expert engineers, technicians, and managers, and provides them with the opportunity to shape the future of international standardization and

conformity assessment in electrotechnology.

Mr. Colby is a hydrodynamic engineer with Verdant Power. A highly regarded subject matter expert in marine hydrokinetic energy, his technical leadership is recognized and respected by his fellow members of the U.S. Technical Advisory Group (TAG) to IEC Technical Committee (TC) 114, *Marine energy*. His product developments for marine renewable energy are considered noteworthy milestones in the acceleration of this technology. He served as chair for the U.S. Shadow Committee for PT62600-200, *Power Performance Assessment of Electricity Producing Tidal Energy Converters*.

While in Melbourne, Mr. Colby wasted no time in taking on his leadership role, and paired up with one of the 2010 Young Professionals Leader, Janette Kothe of

Germany, to turn ideas into action. The two put together a joint statement to the annual German-U.S. dinner meeting that highlighted their experiences from the Young Professionals Workshop and laid out specific recommendations for the continuing success of the program. They focused on ways to achieve the following three main goals:

- Teaching young professionals about the structures, procedures, and importance of the IEC
- Helping young professionals get more involved in the IEC community (as experts on national and international level)
- Providing fresh and independent input and opinions to current discussions within the IEC community

Mr. Colby will be working with the USNC to help look at ways to develop the U.S. program, so you can expect to hear a good deal more from him in the near future. The USNC congratulates him and the other leaders on their outstanding achievement. ■



Jonathan Colby

USNC Announces Call for 2012 Young Professionals Nominees



Following IEC General Secretary Ronnie Amit's official launch of the 2012 IEC Young Professionals Program, the USNC invites all members and stakeholders to submit nominations for U.S. participants for the Young Professionals Workshop. 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 selected will learn more about the IEC, standardization strategies, and conformity assessment. In addition to the dedicated workshop, they will have the opportunity to attend technical

meetings, observe a meeting of the IEC Standardization Management Board, benefit from the guidance of 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.

Further details on how to submit nominations are forthcoming.



Janette Kothe of Germany was a 2010 Young Professionals Leader, featured on the IEC website.

IEC HEADLINES

Frans Vreeswijk Named Next IEC General Secretary and CEO

The IEC has announced that Frans Vreeswijk has been approved by the IEC Council as the next General Secretary and CEO of the IEC, beginning October 1, 2012. Mr. Vreeswijk will succeed Ronnie Amit in the position after his 2012 retirement.

Following Mr. Amit's retirement announcement in 2010, a selection committee comprising IEC President Klaus Wucherer, Ph.D., Immediate Past President Jacques

Régis, and Past President Sei-ichi Takayanagi, Ph.D., was established to find a successor who, in particular, would be able to take on the vital tasks defined in the 2011 Masterplan. Following an in-depth evaluation and a particularly challenging selection process due to a very high level of suitability among the candidates, the selection committee recommended that the Council approve the appointment of Mr. Vreeswijk. The recommendation was unanimously supported by the Executive Committee (ExCo) and the Council Board (CB) at their October 2011 meetings, and was then approved by Council.

To ensure a smooth transition, Mr. Vreeswijk will commence his duties as Deputy General Secretary in March 2012, assuming his full role as General Secretary and CEO at the 2012 Oslo General Meeting. Mr. Amit will remain available full-time as Special Adviser to the IEC President through January 2013, and then on a reduced-time basis until completion of the February 2014 management meetings.

Mr. Vreeswijk is currently president of the Dutch National Committee (NEC) to the IEC, and a board member of the Dutch National Committee (NEN) to the International

Organization for Standardization (ISO). He is vice president of the Philips Intellectual Property and Standards (IP&S) organization, responsible for all healthcare activities within IP&S and member of its Executive Management Team (EMT). He previously oversaw all standardization activities within the organization, where he has worked since 2005.

Earlier in his career he worked for many years in the research and consumer electronics divisions of Philips. He was a development manager and member of the management teams for VCRs, New Business, Digital TV, and FlatTV. He holds an MS degree in electrical engineering from Delft University of Technology.

The USNC congratulates Mr. Vreeswijk on his appointment and looks forward to a productive period under his leadership. ■



Frans Vreeswijk

A Year of Many Changes for the IEC

2011 was a busy and an exciting year for the IEC. We completed the Masterplan, which will guide the IEC's strategy and actions for the coming years. The SMB is continuing to review the standards development process in order to further improve efficiency and is taking measures to increase effective participation of P-members in TC/SCs.

CAB is preparing for the systems approach in conformity assessment and has intensified work in the areas of renewables such as wind and marine energy, as well as for energy efficiency. The MSB is about to publish a White Paper on Energy Storage, which it developed jointly with the Fraunhofer Institute, and the Affiliate Country Programme has celebrated its 10th anniversary.

It was also a year of many changes: new IEC Officers started their work and others are now reaching the end of their second term, leaving their place for a new group of people. Council Board has confirmed the election of Frans Vreeswijk, who will start at the IEC on March 1 and will take over from me in October 2012.

There are unfortunately areas that haven't changed as much as we would have liked. For one, the global economy is still shaky and in an effort to support our membership, the IEC has further reduced its budget while maintaining and increasing its tools and services.

Looking ahead at the coming year, we are confident that the IEC is on the right track to address the challenges facing us. We thank you for your work and commitment and I wish your family and loved-ones, health, peace, and prosperity in the coming New Year.

—Ronnie Amit, IEC General Secretary and CEO

NEW FEATURE! 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.

e-tech Magazine – News & Views

www.iec.ch/etech/2011/pdf/etech_2011-10_LR.pdf

Welcome to the IEC

www.iec.ch/about/brochures/pdf/about_iec/iec_welcome_en_2010_lr.pdf

IEC Masterplan

www.iec.ch/about/brochures/pdf/strategy/masterplan.pdf

2012 IECEX International Conference

www.iec.ch/meetings/events/pdf/iecex_conference_2012.pdf

IEC – IEEE Global Academic Challenge

www.iecieeechallenge.org/

IEC HEADLINES

IEC and IEEE Launch Global Academic Challenge

The IEC and IEEE have announced the IEC-IEEE Challenge – a global competition centered on the theme “How does electrotechnology impact economic, social, and environmental development?”

Applicants are invited to submit and debate research that explores the wide range of sociological, political, economic, and environmental benefits provided by electrotechnology. The competition is open to anyone affiliated with an institution of higher education, including faculty, professors, lecturers, post-graduate students, and teaching and research staff.

“The challenge is a really exciting opportunity for us to reflect on the last 100 years of electrotechnological innovation, which has seen more inventions produced than in the history of mankind,” said IEC CEO and General Secretary Ronnie Amit. “We are appealing to the leading academic thinkers from the spheres of science, engineering, economics, and beyond to demonstrate how electrotechnology has shaped and influenced how we live, work, and conduct business today.”

Submissions will be judged by a panel including Jacques Régis, former CEO of Hydro Quebec in Montréal and IEC immediate past president; Dr. Moshe Kam, department head of electrical and computer engineering, Drexel University, and 2011 IEEE president; and Paul Markillie, innovation editor at *The Economist*.

First (\$20,000), second (\$15,000), and third (\$10,000) place winners will be honored at a ceremony during the IEC General Meeting in October 2012 in Oslo, Norway. The deadline for final registration is midnight, March 1, 2012 (UTC); submissions must be completed by July 1, 2012, via www.IECIEEEChallenge.org.

Further Information

Visit www.IECIEEEChallenge.org.htm. ■

IEC HEADLINES

JTC 1 Plenary in San Diego Moves ICT Standardization Forward

On November 7-12, the American National Standards Institute (ANSI) hosted the 26th plenary meeting of the International Organization for Standardization (ISO) and IEC Joint Technical Committee (JTC) 1, *Information Technology Standards*, in San Diego.

From computers and credit cards to information security to RFID, JTC 1 has advanced the standardization needs of information and communications technologies (ICT) around the world. The 26th plenary meeting drew 140 representatives from 22 ISO/IEC national member bodies and liaison organizations to further standardization activities in the field.

The United States plays a leading role in the work of ISO/IEC JTC 1, with ANSI serving as secretariat and the InterNational Committee for Information Technology Standards (INCITS) administering the U.S. Technical Advisory Group (TAG) to JTC 1. In addition to this leadership role, INCITS provided the funding for the meeting and was praised by the participants for the outstanding facilities and meeting organization.

At the meeting, Karen Higginbottom, director of standards at Hewlett Packard, was appointed for a second three-year term as JTC 1 chair.

“Under Karen’s leadership, the committee has made tremendous progress toward a large number of key objectives,” said ANSI senior vice president and chief operating officer Frances Schrotter in her opening remarks. “There is no doubt that

she has truly taken JTC 1 to a new level.”

Prompted by previous work related to energy efficiency and greening, JTC 1 created Subcommittee (SC) 39, *Sustainability of and by IT*, with the United States offering to provide the chairman and serve as the secretariat. JTC 1 also congratulated SC 38, *Distributed Application Platforms and Services*, for finalizing its study group report on cloud computing.

JTC 1 extended the scope of one of its subcommittees to allow it to respond to technology developments, in particular in the area of augmented reality. It also encouraged its subcommittees to take up new work and its special working group on planning to explore new areas. Other achievements included the continuation of its ad hoc group on Incubator and approval of Incubator Operational Principles for a one-year pilot project, which may result in two Incubator Groups being created (on Digital Preservation and Wireless Power Transfer/Application for ICT). JTC 1 also moved to extend the term of its ad hoc groups on Structure and on Enabling Tools, and directed the work of its special working group on Smart Grid for the coming year.

JTC 1 received reports from representatives of its liaison organizations including ITU-T, IEC TC100, ISO TC215 and Ecma International, as well as PAS Submitters (DMTF, OASIS, OMG, SNIA, TCG, The Open Group, W3C, and the UPnP Forum). It noted with significant interest the excellent collaborative process which has led to more than 20 Publicly Available Specifications

(PAS) approved last year as ISO/IEC standards from these submitters.

The next ISO/IEC JTC 1 plenary is scheduled for November 5-10, 2012 in Jeju, Korea. ■

Attendees at the 2011 ISO/IEC JTC 1 plenary in San Diego



CONFORMITY ASSESSMENT

2012 IECEx International Conference on Equipment and Services in Explosive Atmospheres Announced

The IEC and IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx), together with the Emirates Authority for Standardization & Metrology (ESMA), and in conjunction with the UN Economic Commission for Europe (UNECE), have announced the 2012 IECEx conference “Equipment and Services in Explosive Atmospheres” in Dubai on March 20-21, 2012.

The two-day event is a unique opportunity for industries in the region to get better acquainted with IECEx and find out how they can best benefit from the systems.

The conference will bring together experts from all over the world involved in international standardization, equipment manufacturing, inspection, repair, and overhaul of Ex equipment and systems, and the assessment and certification of personnel

competence. Issues concerning requirements and regulations in the Gulf Cooperation Council (GCC) region will also be covered.

Through their presentations and direct contact with participants, these experts will share their experience and detailed knowledge on all matters pertaining to the Ex field, such as plant design, principles and practical applications of area classification, installation, and repair, in compliance to IEC International Standards. The event will provide a valuable informational and networking opportunity to anyone involved in the Ex sector.

The IEC has long been involved in developing International Standards for equipment used in hazardous areas. Set up in 1946, IEC Technical Committee (TC) 31, *Equipment for explosive atmospheres*, has a complete series of International Standards that cover all specific requirements for

Ex equipment and systems, from general requirements to protection levels for apparatus used by all sectors that operate in hazardous environments, such as oil refineries, offshore oil rigs, gas plants, mines, sugar refineries, flour mills, grain silos, and the paper and textile sectors.

As a way to ensure compliance with its International Standards, the IEC established IECEx. Since its inception in 1996, IECEx 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:

- Equipment – the IECEx Certified Equipment Scheme
- Services – the IECEx Certified Service Facilities Scheme (e.g., repair and overhaul)
- Personnel competence – IECEx Certification of Personnel Competence Scheme (CoPC)

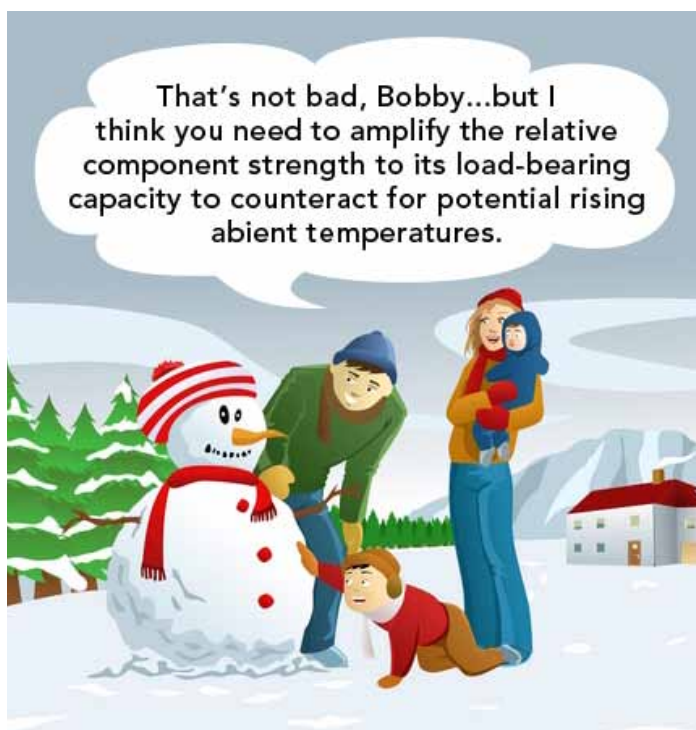
Through more than 50 IECEx-approved Ex certification bodies in 30 countries, IECEx certification has become the world’s single best practice for demonstrating compliance with International Standards. Its credentials include acceptance by end-users – oil and gas producers, mining, transportation, and many more – and also the recent formal endorsement by the United Nations, through UNECE, as the recommended model for regulating the safety of equipment and persons working in areas where the potential for an explosive atmosphere may exist.

Further information

The 2012 IECEx conference will be held at the Dubai Grand Hyatt Hotel, March 20-21, 2012; admission is free but registration is required. To reserve your place, visit the event website at www.iecex.com/dubai/ or send your contact information to info@iecex.com. For more information on IECEx, visit www.iecex.com. ■

LAUGH TRACK

Happy Holidays to Your Family from the USNC/IEC



CONFORMITY ASSESSMENT

SAVE THE DATES

Experts from around the Globe Discuss the Value of International Standards in Conformity Assessment

More than 90 international experts gathered in Montreux, Switzerland, for an October meeting to exchange information and insights on the role of conformity assessment as a vital component of world trade.

According to event host the International Organization for Standardization (ISO), “The use of ISO/IEC standards in conformity assessment procedures allows for harmonization throughout the world, and this, in turn, not only facilitates international trade between countries but also facilitates trade within countries by giving the purchaser of the product or service confidence that it meets the requirements.”

Among the day’s sessions, Randy A. Dougherty and Alister Dalrymple, co-convenors of ISO’s Conformity Assessment Committee (CASCO) working group (WG) 21, led a tutorial on changes to ISO/IEC 17021:2011, *Conformity assessment – Requirements for bodies providing audit and certification of management system*, which was published in February 2011.

Parallel sessions were also held on five of the ISO CASCO WGs. Marcus Schmid,

convenor of WG 31, spoke on the revision of the existing ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*. Laurent Camberou, convenor of WG 33, presented on ISO/IEC Technical Specification (TS) 17022, *Conformity assessment – Requirements and recommendations for the content of a third-party audit report on management systems*. Christian Priller, convenor of WG 29, spoke about ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*, and the future ISO/IEC 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*. Christian Priller on behalf of Ian Cleare, convenor of WG 32, presented the revision of ISO/IEC Guide 67, *Conformity assessment – Fundamentals of product certification*. Cynthia Woodley, convenor of WG 30, updated attendees on revisions to ISO/IEC 17024, *Conformity assessment – General requirements for bodies operating certification of persons*.

ISO Deputy Secretary-General Kevin McKinley paid tribute to Mr. Peyrat for his contributions as ISO CASCO chair; his term will end on December 31, 2011. He will be succeeded by Lane Hallenbeck, vice president for accreditation services at the American National Standards Institute (ANSI). ■

Attendees at the Montreux, Switzerland, meeting on conformity assessment



Upcoming Meetings & Events



JANUARY 2012

CAPCC/TMC/Council Meetings

January 24–26
HP Offices, Palo Alto, CA

FEBRUARY 2012

JDMT/DMT/SMB Meeting

February 13–15, Geneva, Switzerland

MAY 2012

CAPCC/TMC/Council Meetings

May 1–3, TIA, Arlington, VA

COPANT General Assembly

Period between May 7–18
Fortaleza, Brazil

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 (location TBD)

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



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