The Product Safety Engineering Newsletter

Vol. 9, No. SE September 2013

What's Inside...

Symposium Presentations and Papers

Don't forget to check out our exhibitors

Welcome

On behalf of the Central Texas Chapter of the IEEE Product Safety Engineering Society, I would like to welcome you to the 10th Annual IEEE Symposium on Product Compliance Engineering. For the second time, the Symposium will be held in Austin Texas.

This Symposium marks our 10th anniversary event. From its humble beginnings in San Jose in 2004 the event has grown into the signature and defining event for our Compliance industry. Every year has seen growth in the number, diversity and depth of the presentations, with more exhibitors and significant networking opportunities.

Living up to its reputation as the Live Music Capital of the World, our Symposium will be surrounded this year by the world famous 2013 Austin City Limits Music Festival on October 4-6 and on October 11-13. The University of Texas Longhorns football team will be playing up in Dallas on October 12 in the Red River Rivalry against the Sooners of Oklahoma, an event that takes place in the middle of the State Fair of Texas. The Circuit of the Americas racetrack opened here in Austin last year, and will host its second F1 Grand Prix event in November. Texas in the fall presents an incredible array of entertainment choices with relief from the heat of our long summers.

Our symposium is being held in The Domain. Situated in a beautiful park-like setting, The Domain features more than 100 upscale and mainstream retail stores and restaurants. The Domain area also includes hotels, office space and residential units. Our meeting venue, the Westin Austin at the Domain, is located in the heart of the Domain offering easy walking access to the entire area.

Welcome to Texas Y'all!

Gary Schrempp
2013 IEEE PSES Symposium Chair

Live Music, Live Standards

The 10th Annual IEEE Symposium on Product Compliance Engineering
Austin Texas on October 7, 8, and 9, 2013.

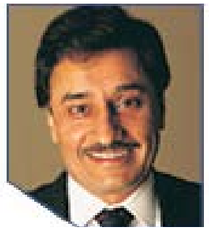
Presentations given by industry experts covering diverse topics such as General Compliance, Leadership, ITE Compliance, Forensics, Medical Devices, and Risk Assessment.

The Keynote Speaker will be Joe Bhatia, President and CEO of ANSI
(American National Standards Institute).

The Symposium will be held at the Westin Austin Hotel at the Domain, a premier Central Texas destination for entertainment, high end shopping, and incredible restaurants.

Austin-Bergstrom International Airport

Keynote



Keynote Speaker: Joe Bhatia, President and CEO of ANSI (American National Standards Institute)

S. Joe Bhatia began his tenure as president and chief executive officer of the American National Standards Institute (ANSI) on January 1, 2006.

Prior to joining ANSI, Mr. Bhatia held the position of executive vice president and chief operating officer of the international group at Underwriters Laboratories Inc. (UL). During his 35-year tenure with the organization Mr. Bhatia assumed positions of progressive leadership in global business operations. His areas of responsibility included engineering, governmental and congressional liaisons, external affairs, follow-up (certification) services and direction of UL_s $300+ million international operations.

In 2009, Mr. Bhatia was elected to serve as vice president for the Pan American Standards Commission (COPANT) for a two-year term. He also serves as vice chairman of the Industry Trade Advisory Committee on Standards and Technical Trade Barriers (ITAC 16), a joint program of the U.S. Department of Commerce and U.S. Trade Representative. A member of the International Organization for Standardization (ISO) Council and its Standing Committee on Strategies, Mr. Bhatia also holds a seat on the Oakton Community College Education Foundation Board and recently retired as a member of the National Fire Protection Association Board of Directors. In addition to his numerous professional affiliations, Mr. Bhatia is a frequent lecturer in the U.S. and around the world on topics such as international trade, technical developments, commercial market access, and health, safety and environmental concerns.

Mr. Bhatia holds a Bachelor of Science in electrical engineering and a Master of Science in business management. He and his wife, Punita, have two sons.

Registration Info

10th Annual IEEE Symposium on Product Compliance Engineering
Austin, Texas October 7, 8, and 9, 2013

	Advance (thru August 9)			Regular (after August 9)		
	Full Conference	One Day	Exhibits Only	Full Conference	One Day	Exhibits Only
Non-Member	$650.00	$450.00	$50.00	$700.00	$475.00	$50.00
Member	$550.00	$375.00	$50.00	$600.00	$400.00	$50.00
Life Member	$150.00	——	$50.00	$200.00	——	$50.00
Student	$150.00	——	$50.00	$200.00	——	$50.00

Register Online

Symposium Website - www.psessymposium.org
Registration - www.psessymposium.org/general/registration

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Affiliate memberships provide reduced conference registration fees and access to IEEE publications. An Affiliate Membership can be converted to a full membership at any time. The exact value of the Affiliate Membership varies depending on what region you live in. See the IEEE Region Map to check your region.

Affiliate Membership Value (USD)	Full Rate	Half year
Regions 1-6 (USA)	$64.50	$32.25
Region 7, incl. GST (Canada)	$67.73	$33.87
Region 7, incl. HST (Canada)	$72.89	$36.45
Regions 8-10	$64.50	$32.25

The Westin Austin at the Domain

Two Queen Room

Main Lobby

The Domain & Hotel Info

The upcoming IEEE Product Safety Syposium will be held at the Westin Austin at the Domain.

The Westin Austin at the Domain
11301 Domain Drive
Austin, TX 78758
512-832-4197

The Westin Austin at the Domain is located in one of the Austin's premiere destinations at the heart of The Domain where you can enjoy upscale shopping, dinning and entertainment. At the Live Music Capital of the World guests can enjoy all Austin has to offer. With close proximity to the Darrell K Royal-Texas Memorial Stadium, 6th street, and the Austin Zoo, guests can experience downtown Austin, the live music scene, great restaurants, sophisticated shopping and much more.

To make your hotel reservations go to: https://www.starwoodmeeting.com/StarGroupsWeb/booking/reservation?id=1302203878&key=3FEF

Room Rate

Single/Double: $149.00 USD

Reservations at this rate can be booked until September 14, 2013.

***If you are encountering any problems booking the conference rate, please contact Kimberly Milne (kmilne@conferencecatalysts.com) at Conference Catalysts, LLC immediately for assistance.**

NOTE: Please book early to get these rates. Austin is a popular travel destination and other large events, such as the ACL Festival will significantly reduce hotel appealability during our symposium week.

From North

Proceed on Loop 1/MoPac Expressway to the Burnet/Duval Exit.
Remain on the access road through the light, and continue until the road curves under Loop 1.
Now heading north, enter the hotel via Domain Boulevard, off the access road.

From Downtown

Follow Interstate 35 North to U.S. Highway 183/Research Boulevard North.
Proceed 5.5 miles to Loop 1/MoPac Expressway North.
Take the Burnet/Duval Exit and immediately enter the hotel via the Domain Boulevard access road.

Approximately 10 minutes

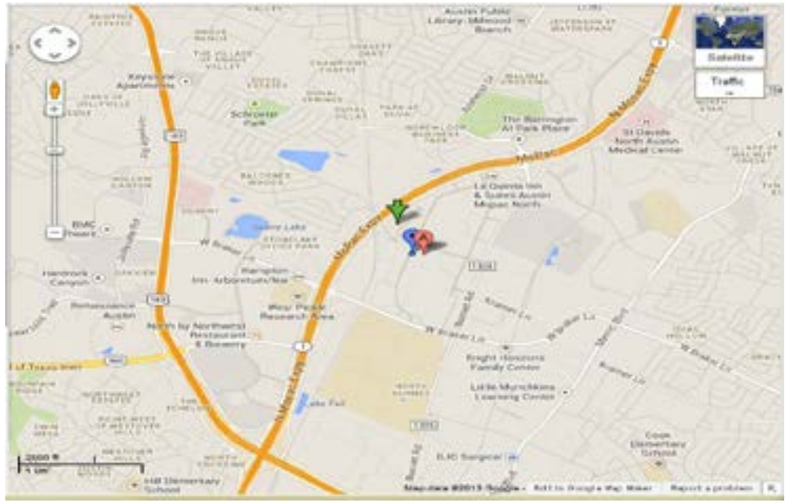
From Austin Bergstrom International Airport (ABIA)

Take Highway 71 West to U.S. Highway 183 North.
Proceed 17 miles on U.S. 183 to Loop 1/MoPac Expressway North.
Take the Burnet/Duval Exit and immediately enter the hotel via the Domain Boulevard access road.

Approximately 25 minutes

From The Arboretum/Great Hills

Take Loop 1/MoPac Expressway North.
Take the Burnet/Duval Exit and immediately enter the hotel via the Domain Boulevard access road.



From West

Follow 360/Capitol of Texas Highway.
Merge onto Mopac/US1 TX-1 Loop North.
Exit Braker Lane.
Turn right onto Braker Lane.
Turn left onto Domain Drive.

From East

Follow US-290 West.
Turn right onto East Parmer Lane/FM 734 West.
Merge onto Mopac/US1: TX-1 Loop South.
Exit Braker Lane
Turn left crossing overpass.
Turn left onto Domain Drive.

Symposium Presentations and Papers

Getting Safety a Seat at the Boardroom Table

By Catherine Jewell

"Synopsis - Getting Safety a Seat in the Executive Boardroom

As Safety issues become more important in product development, a voice for Safety can easily affect the company's bottom line. Safety Executives can make their voices and concerns heard and get a seat at the Boardroom table. It's all a matter of understanding and working with the function, format and structure of executive teams and Boards. This presentation presents three key strategies to get Safety on the Boardroom agenda, plus lots of tips on how to survive and thrive in a Boardroom presentation.

Attendees will learn:
Understanding the culture of the boardroom
3 Strategies for Boardroom attention
How to play to the power influencers
Pre-meeting strategies that work
Choosing one key point to win
Accepting a directional win; implementing details

Format

The program will be a 60-75 minute lecture including short videos clips, questions and answers, and audience participation. In preparation for this event, Jewell will ask to interview 5 Safety Engineers on their Board and Executive Team interactions."

An experience in product comparison for microwave ovens in Argentina

By Silvia L. Diaz Monnier & Andrea Mendez

This work describes the different stages that were necessary in testing microwave ovens for product comparison on the safety laboratory of National Institute of Industrial Technology. The ovens were purchased directly on the market. These stages include technical organization, realization and obtained results. The technical organization included the definition of the type of microwave oven used in comparison, selection of microwave power range, capacity and functionality. After that a selection of test included in comparison was made, taking into account the critical points, the potential interests of users and the capacity of the laboratory. Then the work will explain the criteria used during the realization of tests and the challenges that laboratory should face. Finally, the obtained results will be explained and the exchange of technical information with the responsible of commercialization of each appliance.

Toy Products Safety Assessment Model

By Shu Lun Mak

The business organizations are faced with an economic environment in which a fast response to rapid changing customer's requirements and the market environment is necessary. The manufacturers are seeking a solution to reduce the product development cycle. There are many innovative toys products were made in the last decades. Some researches have been done in how to transform the customer's requirement to the features of the toys products. These helped the business organizations to shorten the product development cycle and produce more innovative products. However the safety aspect of these innovative products may be ignored. In the current product safety assessment model, the safety testing and assessment is performed by an accredited third party testing party when the final products are made. It is found that this model may not be effective to minimize the unsafe products in the market. This paper will discuss (i) characteristics of the best sell toys, (ii) examples of children playing behavior, (iii) current toy safety assessment model, (iv) proposed toy safety testing assessment model, and (v) the effectiveness of the proposed toys safety assessment model.

Transients and Surge-Protection Considerations in Electrical Equipment

By Don Gies

"The control and acceptance of transients and surges on power-supply circuits, distribution networks, and electrical utilization equipment can be viewed in terms of the sports analogy of ""offense"" and ""defense"".
On the offense, power utilities and service providers need to control the transients that their power networks deliver to their customers, limiting transients to a maximum acceptable level.
On the defense, electrical utilization equipment needs to tolerate transients up to the maximum levels that may be present at its point of installation, or if it cannot tolerate those maximum levels, protection such as surge protection devices or more robust overcurrent protection must be introduced to the electrical installation.
Overvoltage categories and current interrupting capacities are examples of expected levels of transients on power systems.
From a product safety point of view, this paper explores the maximum levels of transients expected at the points of connection for electrical equipment, and describes customary practice and regulatory rules for tolerating or suppressing power transients for electrical utilization equipment"

Breaking Through the BRICs

By Mark Maynard & Leslie Bai

The emergent markets in Brazil, Russia, India and China, popularly referred to by the acronym BRIC, now are responsible for a growing portion of the profits for most global companies. Companies face strong headwinds produced by the formidable maze of culture, laws, and overlapping regulations, causing confusion surrounding the regulatory requirements. In addition, distance, language, unfamiliar local business norms, and unsophisticated commercial market conditions create further hurdles, making market entry a very difficult and expensive undertaking for the uninformed. For those considering entering the BRIC marketplace with electrical and electronic products, expert market access knowledge is a fundamental requirement. Preparation is paramount to face the distinct and unique obstacles that will be encountered. This paper will reveal all of the pieces in the BRIC game: government agencies, regulatory bodies, required certifications, compliance standards, local representatives, and the key unwritten rules in these developing and growing markets. This information, along with basic project management techniques, can help product developers and manufacturers to access this massive group of desirable customers, navigating clear pathways to marketing and selling their electronic products.

A Comparison between the safety requirements of Medical Devices and ITE

By Paul Lovell

This presentation will show the similarities and differences between the design challenges facing the ITE and medical devices with respect to product safety, concentrating particularly on two series of standards, IEC 60950-x and IEC 60601-x for ITE and medical devices respectively, including general, collateral and particular standards; it will also consider the regulatory environments for both types of products and how the standards relate to this and their use by third parties to permit placement on the market; the differences in approach will also be considered, with the hazard-based and risk-based requirements compared; the unique inter-relationship between the two standards wherein parts of IEC 60950-1 are permitted to be used as a means of compliance in IEC 60601-1, under certain circumstances, will also be commented on.

Communicating Safety to Well Meaning Management

By Gary Tornquist

After handling compliance and safety issues properly, perhaps the next priority for the compliance engineer is communicating with management and partners that in fact he/she has done so. This can be challenging and frustrating on both sides if done poorly. This interactive presentation will review some common pitfalls with different situations and personality types, and give some strategies for increasing the odds of happy outcomes such as continued employment.

What does that mean? A guide to interpretations

By Ted Eckert

IEC 60950-1 is written as a general document intended to cover a wide array of products. The standard would become unwieldy if it were to include specific information for every possible construction of all of the products within the scope. In addition, advances in design and construction techniques will usually outpace updates to the standard. The result is that the safety certification engineer is often left trying to figure out how various clauses apply to a particular product. Knowing and understanding the most common interpretations before designing a product can reduce the risk of problems during the certification process. This paper covers some of the resources available that provide interpretations to the standard and its national and group differences. This paper also discusses techniques for obtaining interpretations where no existing interpretation exists.

Overview of the European Machinery Directive

By Michael Loerzer

The machinery directive (MD) came into force on 2009-12-29. In 1989 the Commission has published the first edition oft he MD. In the meantime the latest version includes some main changes. That was the reason that the Commission has also published guidelines to the application of the MD (2nd edition). The Commission for Occupational Health and Safety and Standardization (KAN) has published a very interesting KAN report no. 40 which shows the main differences between 98/37/EC and the current version 2006/42/EC. Both documents will be presented. Main topics of the presentation are the link between the Low Voltage Directive and the MD, the procedure for partly completed machinery, the current standardization work of CEN/CENELEC, the risk assessment procedure (EN ISO 12100) and the main changes of annex I.

Basis for the estimation of measurement uncertainty in safety tests

By Silvia L. Diaz Monnier & Andrea Mendez

To demonstrate their technical competence, a testing laboratory for safety of electrical products should use the international standard ISO 17025 on general requirements for the competence of testing and calibration laboratories. This standard among its conditions requires a statement on the estimated uncertainty of measurement to be included in the test report, where applicable, in the following cases: - When relevant to the validity or application of the test results; - When required by the customer, or - When the uncertainty affects compliance to a specification limit. This paper will address the basis for the calculation of uncertainties in the testing of electrical safety standards, including some examples of calculations.

Estimation of Failure rate of a consumer electric products based on components failure rate and product safety assessment

By Yasuo Harada

We have proposed a method of product safety assessment by using hazards based FTA in our previous study. In the proposal, a risk level of a product was calculated by the FTA and introduced into a manufacturer management system which set criteria for a design and shipment stage in manufacturing. In this paper we focus a failure rate of a component which composes a product and is a dominant cause of unsafe incidents of a product. A failure rate resides in accidental failure mode and wear-out failure mode. Assuming that the probability distribution can be identical at a crossing point of accidental mode and wear-out mode, we estimate a failure rate at crossing point and compared its distribution to normal, Weibull, and log-normal distribution by correlated coefficient and decided a distribution by best fitting. Furthermore we apply the probability distribution to the failure rate calculated by IEC/TR62380 and find that the probability of failure rate for a standard environment is 50% and severer environment failure rate becomes 70% of probability. In result the knowledge of probability distribution can help to set a risk level standard as criteria for a management system according to an environment of product usage.

The Quasi-static Near Electric Field of an Inductive Power Transfer System

By James S. McLean & Robert Sutton

"Inductive Power Transfer (IPT) systems are well suited for the transfer of large amounts of power over relatively small distances such as for the recharging of batteries in electric and hybrid vehicles. However, because of vehicular power requirements and the open nature of such a system, the extraneous electromagnetic field could be hazardous. Consumer IPT systems typically transfer 3-20 kW over a distance of 100-200 mm.

Vehicular IPT systems operate between 20 kHz and 200 kHz and thus, the quasi-static near fields are of greatest concern. Much effort has been directed toward the characterization and reduction of the quasi-static near magnetic fields associated with IPT systems. While the magnetic field in the immediate vicinity of the couplers is necessarily quite intense, the electric field is also surprisingly intense.

We examine the electric field of a typical 3.3 kW vehicular IPT system. In the absence of any electrostatic shield, it is shown that the electric field intensity can exceed 1000 V/m. The presence of an electrostatic shield affects the entire electromagnetic field of an IPT system and hence the efficiency. We investigate using numerical simulations and measurements the extent to which the extraneous electric field can be minimized without sacrificing efficiency."

The Specific Application of the Machinery Directive for Laboratory Equipment

By Michael Loerzer

As the scope of the new Machinery Directive 2006/42/EC has been changed, some equipment in series IEC 61010 formerly beeing only under the Low Voltage Directive now falls under the Machinery Directive too. So new requirements of the Machinery Directive have to be introduced in the series IEC 61010 through an additional standard for the concerned equipment. IEC TC 66 has started the work for the particular standard IEC 61010-2-120 „Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-120: Particular safety requirements for machinery". The publiaction is planned for 2015-05. For the meantime the German Hightech Industry Association (Spectaris) has issued a practical guide for IEC 61010-1 equipment which falls in the scope oft he MD 2006/42/EC also. The presentation gives an update of the standardization work and a view in the German guide to perform a risk assessment. The author was member oft he editorial group „machine safety for laborator equipment" which has prepared the guide.

Human Error and Product Safety: Fitting the Intervention to the Error

By Steven Hall

Common hazard analysis and risk assessment tools can be challenging to use in the case of hazards related to human error. Models and taxonomies of human error can be useful in analyzing these hazards and making decisions about safety interventions. Levels-of-performance based models provide a useful guide to different types of errors (e.g., skill, rule, knowledge or judgment-based). Tools for selecting interventions that consider the type of error that leads to a hazardous situation (e.g., Error Modes and Effects Analysis) can assist with a more sophisticated decision-making process, as compared to following simple rules-of-thumb (e.g., design, guard, warn). The distinction between unintentional and intentional "errors" is particularly helpful. Health behavior and workplace self-protective behavior models can be particularly helpful in understanding intentional violations of safety rules. These models provide the basis of Barrier Analysis, a tool for selecting interventions to promote safety and health behaviors.

Post Fire Analysis of Solid State Circuits Using Bond Wires as Indicators

By Mark Goodson, Lee Green, Michael Custer & Michael Shuttlesworth

"Bond wires often serves as the interconnect between solid state die and leadframes. Bond wire are about 1 mil in diameter, and are made from Au, Al, or Cu. As such, they can also serve as fuses.

The authors present a technique whereby bond wires can be imaged with microfocus x-ray. Bond wires that are partially or completely missing can then have the IC area using CT scan. After the CT scan, 3-D reconstruction will demonstrate the nature of the failure. Based on the fuse characteristic of this small wire, we can state with certainty that an overcurrent condition occurred - which is presumably during the fire event.

Testing shows that failed bond wires are present not because of the thermal energy of the fire, but from an overcurrent condition. We demonstrate that this further step in FA can be used regardless of whether or not an engineer can specifically identify an IC in terms of its part number. When the part number is known, circuit analysis can be used to help postulate a hypothesis at to why an IC failed, and if that failure is related to the fire's cause."

Advances in labelling & branding technology for portable devices

By Derek Cumming

"""Advances in labelling & branding technology for portable devices"", by Derek Cumming, Group Technical Director, Worldmark International Ltd.

The paper will discuss recent advances in coating and material science for label and branding applications on portable devices. Specific subjects addressed will include:

• Ultrathin & flame retardant solutions for battery wraps and labels • Advances in durability and cosmetic appearance of print on demand, thermal transfer labelling for regulatory labels • SpextroMark discrete letter brand logos - 100% nickel free and decorative solutions. An alternative • How brand protection and authentication technology can be incorporated into existing label types.

Chemistry is at the very core of the surface coating technology which enables the above products and solutions. The paper will present and discuss key aspects and industry trends and requirements in this field. Several case studies will be used in the presentation to highlight specific applications."

Using Risk Management to successfully identify Essential Performance for your device

By L. Saeed

"Based on experience gained from both work done for a medical device manufacturer, and through the process of evaluating and certifying a range of different medical devices on behalf of an independent test house, this presentation describes a method of using risk management to help an organization determine what the potential essential performance of the their device may be, and then to further examine and reduce the defined potential essential performance to the true essential performance of the device.

With a brief overview of the key concepts of risk management, this presentation should be of use not only to those with extensive risk management knowledge and experience, but also to those with limited or basic understanding of the risk management process as defined by ISO 14971."

Health Monitoring of Lithium-ion Batteries

By Bhanu Sood, Michael Pecht & Michael Osterman

An integrated technique for health monitoring and remaining useful life prediction of lithium-ion batteries is presented in this paper. Real-time measurements are performed using an ultrasonic acoustic transducer and sensor that are attached to the external surfaces of a lithium-ion battery. This battery is part of a larger pack that consists of multiple batteries connected in series, parallel or a combination of the two. Real time data from the ultrasonic sensor is used to non-destructively evaluate the internal condition of vital interfaces such as the interface between the anode current collector and anode active material, and the cathode current collector and cathode material. Inter-electrode gap inside the battery is also measured. Information about the extent of change in state or degradation at these vital interfaces is used for predicting the remaining life of the whole pack. An empirical model is adopted to emulate the battery degradation trend, and real-time measurements from the ultrasonic sensor are utilized to update the degradation model.

Evaluation of Reliability Data on Cochlear Implants

By Bhanu Sood & Michael Pecht

Cochlear implants are electronic devices used for providing useful hearing sensation to patients with severe to profound hearing loss. Once implanted, these devices are intended to last throughout the life of the patient. However, the existing reliability reporting and qualification standards for cochlear implants do not include a method for predicting reliability of the cochlear implant system before it is marketed to clinics. The tests in use today do not accurately replicate the life cycle stresses and thus do not ensure high quality and reliability. As many implant standards were originally developed from the product standards for pacemakers it is only natural that they need to evolve to fit the differing profiles to which cochlear implants are exposed. This paper provides guidelines for evaluating system level reliability of a cochlear implants using component level bench testing results. The methods used in the paper are the fault tree analysis and reliability block diagram, both of which are based on the approaches described in IEEE 1413.1.

Legal Issues Surrounding Medical Devices: From how to get your Medical Device on the Market to how to defend your Medical Device from liability claims

By Randall Christian

This presentation by a seasoned medical device lawyer will provide an overview of the legal issues surrounding medical devices in the United States. First, we will discuss a roadmap for getting your medical device on the market, including determining what is a medical device, device classification, and premarket approval requirements. The presentation will then turn to liability issues surrounding medical devices once they are available on the market. We will discuss the best ways for avoiding liability claims and how to defend your product from claims and lawsuits alleging manufacturing defect, design defect, and marketing defects. We will also discuss recent trends in medical device litigation.

An overview of large format Li-ion cell response to electrical abuse tests

By Erik J. Spek & Mehdi Hosseinfar

Lithium-ion battery is considered a safety hazard when electrically abused. Incidents involving violent reaction of consumer electronic batteries to overcharge are well-publicized. Large format Li-ion cells for vehicle traction use the same building blocks and hence susceptible to abusive conditions. TÜV SÜD a global third party test organization has performed hundreds of electrical abuse tests on Li-ion cells of various attributes. In this presentation, the results of these tests are analyzed and the effect of test parameters and cell characteristics on the cell response is evaluated. The analyzed data are used to improve overcharge test method and to answer key questions regarding how to deal with compromised cells and packs after an accident.

Requirements for Testing Lithium-ion Batteries for Transportation

By Rich Byczek

"Challenges associated with transporting lithium-ion batteries confuse even the largest manufacturers because of the national and international complex regulations. Manufacturers are typically familiar with the testing needed to ensure the safety and performance of products. However, few manufacturers consider the testing required to transport and ship lithium-ion batteries to other countries during the research and development phase, if at all.

Even though the certification testing process covers the majority of the requirements, labeling, packaging, shipping names, number of batteries per box and other details affect how lithium-ion batteries can be transported.

Additional requirements to transport lithium-ion batteries are in place to ensure minimal level of safety has been addressed. Every part of the supply chain has a shared responsibility to ensure that all current requirements are met and any extra testing or checks are completed.

During this presentation, Intertek expert Rich Byczek will discuss the national and international standards required for lithium-ion batteries to be transported in the market. He will also focus on the testing necessary for transporting lithium-ion batteries. The presentation will help manufacturers address this need to create batteries that will meet the requirements needed to bring products to market faster and begin earning revenue sooner."

Solar Panel Grounding and Bonding Methods for Lightning Protection and Galvanic Compatibility

By Dheena Moongilan

Two types of photovoltaic (PV) power system installation are used for residential power; systems without battery backup; and systems with battery backup. The residential PV power system, generator and loads are located in same building. The PV panels are typically roof-top mounted and the DC/AC inverters are either collocated or inside the building. Transformer-less inverter are more prevalent because of their efficiency and cost. But they are not galvanically isolated from PV panels. The PV system is grounded to Grounding-electrode according to NEC690.41-64. The roof-mounted PV panels are susceptible to lightning surges. The electrode to soil must have resistance lower than 100Ω (<10Ω is recommended). Higher resistance returns the lightning current into residential electrical system. There will be always a small potential difference between housing and its ground interconnection. The potential differences between PV system housing and its ground wire and inverter housing and its ground wire are opposite potential therefore same galvanic rules can't be applied to PV panels and battery and inverter housing. This paper discusses galvanic compatibility issues of PV panels and battery and inverter housings. Multiple electrode grounding is suggested for minimizing lightning damages. Effectiveness multipoint electrodes and their installation distances in different soil are discussed.

A Study into the effect of Smartphone Development on Antenna Design

By Atsushi Maeda & Keiichi Ohizumi

Modularization was supposed to accelerate a new smartphone product to market because of black box theory. In order to expose many problems areas especially an invisible conflict between RF engineering and mechanical engineering in the smartphone development stage, we propose a comprehensive study into prospects for the visualization of smartphone design process by Design Structure Matrix. Therefore, we can found antenna design process is certainly changing rapidly. The process seems to move toward a model of a software development approach. It is also found noncompliance in engineering is a special problem, particularly when RF products such as smartphone affect the engineering itself.

Counterfeit Electronics - Tools and Techniques for Detection and Mitigation (Tutorial)

By Bhanu Sood

"In recent years, the prevalence of counterfeit electronic parts has only increased, with reports of parts discovered in medical systems, military electronics, and process control equipment. This increased risk has not only focused the spotlight on counterfeit component detection methods, but the ability of these techniques to uncover suspect parts that are produced using sophisticated counterfeit creation techniques.

This tutorial being proposed for IEEE ISPCE 2013 will guide participants through a brief overview of the requirements of the latest Industry Test Laboratory Standards that standardize practices to detect suspect counterfeit electronic parts, to maximize the use of authentic parts, and to ensure consistency across the supply-chain for test techniques and requirements. The overview will be followed by an in-depth review of the sampling, inspection equipment, testing and reporting requirements. This part emphasizes specific materials characterization tools and techniques that are increasingly being deployed for positive identification of suspect parts. The PDC Instructor is closely involved with the development of the SAE AS6171 - Test Methods Standard; Counterfeit Electronic Parts, and the attendees to the class will gain insight on adopting and utilizing these standards to the advantage of your organization."

10 Things You Should Know About NEBS

By Dave Larusso

"This presentation covers the ten most important things to know when attempting to apply the hundreds of requirements which must be met to get your product into a phone company's Central Office. Zeroing in on these items will help you design, test, and get your product approved for deployment.

Network Equipment-Building System (NEBS) requirements are the most common set of safety, spatial and environmental design guidelines applied to telecommunications equipment in the United States. These requirements are critical to maintaining a robust telecommunications infrastructure. The NEBS equipment design guidelines are described in Telcordia documents GR-63-CORE (Physical Protection) and GR-1089-CORE (EMC and Electrical Safety)."

HBSE and Risk Assessment

By Richard Nute

Existing risk assessment starting points are rather nebulous and abstract. While not expressly stated, existing risk assessment processes start with the situation where no safeguards are in place -- which is an impossible situation. Models for injury and safety taken from Hazard Based Safety Engineering can be a good starting point for risk assessment. This paper presents alternative definitions of hazard, risk, and safety that are less abstract than those presented in ISO Guide 51. The HBSE models provide a means for establishing probability of injury. The HBSE process is a coherent process for performing risk assessment as well as the next step, establishing safety for each hazard.

Linking Risk Assessment and Functional Safety

By Mark Fessler & Douglas S. G. Nix

Significant confusion exists for machine builders who are using risk assessment and functional safety techniques in the design of industrial machinery, arising from the use of multiple functional safety approaches in different jurisdictions. Clear explanation of the approach to mapping risk assessment to functional safety requirements is not provided by the standards. Using a consistent risk scoring approach, correctly mapped to one or more functional safety models, is critical to ensuring repeatable, reliable functional safety assessment. This paper shows that correct selection and use of a single risk scoring tool to drive the reliability requirements for the safety related parts of the control system is critical to achieving effective risk control, while minimizing complexity, construction costs and lifetime maintenance costs. One approach to mapping a risk scoring tool output to the functional safety requirements is explored, based on ISO 13849-1:06 and IEC 62061:05, and using existing risk assessment tools as working examples.

How safe is safe? - An interactive discussion on quantifying safety

By Richard Johnson

"Synopsis - Getting Safety a Seat in the Executive Boardroom

As Safety issues become more important in product development, a voice for Safety can easily affect the company's bottom line. Safety Executives can make their voices and concerns heard and get a seat at the Boardroom table. It's all a matter of understanding and working with the function, format and structure of executive teams and Boards. This presentation presents three key strategies to get Safety on the Boardroom agenda, plus lots of tips on how to survive and thrive in a Boardroom presentation.

Attendees will learn: * Understanding the culture of the boardroom * 3 Strategies for Boardroom attention * How to play to the power influencers * Pre-meeting strategies that work * Choosing one key point to win * Accepting a directional win; implementing details

Format

The program will be a 60-75 minute lecture including short videos clips, questions and answers, and audience participation. In preparation for this event, Jewell will ask to interview 5 Safety Engineers on their Board and Executive Team interactions."

Writer's Workshop

By Douglas S. G. Nix & Peter Perkins

"This tutorial explores the process used for taking an idea and turning it into a formal paper and presentation. The workshop is aimed at working professionals who would like to share their work with others, but are unsure about how to start, and what the requirements are.

The workshop explores: * IEEE Format * Writing the Abstract * Structure and Flow * Citing and referencing IEEE-style, avoiding plagiarism * Peer Review * Converting existing Presentations into Papers * Developing the Presentation * Presentation Techniques"

Merging ISO 13849-1 & IEC 62061: Update on progress

By Douglas S. G. Nix

This presentation updates listeners on the current state of work done by ISO TC199/JWG1 on the merger of ISO 13849-1/-2 and IEC 62061. News is drawn from recent committee meetings.

IEC 60601-1, An Evolving safety philosophy

By Charles Sidebottom

For more than 35 years, IEC 60601-1 has been one of the most widely recognized standards for demonstrating the safety of medical electrical equipment. Over the years, the IEC 60601 series has grown to include almost a hundred standards addressing basic and functional safety. The medical electrical equipment covered by the IEC 60601 family range from hand-held clinical thermometers and pulse oximeters used in clinical, emergency and homecare situations to magnetic resonance imaging (MRI) and radiation therapy systems that occupy suites of rooms in modern healthcare facilities. This session will focus of the evolution of the IEC 60601 safety philosophy beginning with the seminal publication, IEC Technical Report 60513, Fundamental aspects of safety standards for medical electrical equipment, and continuing through the third edition of IEC 60601-1 and its first amendment. The presentation will conclude with a look at what the immediate future may hold as the safety philosophy continues to evolve as industry identifies new ways of dealing with hazardous situations that arise with new technology and new applications for medical electrical equipment.

The 3rd ed of IEC 60601-1 and the interoperability of MEE

By Steli Loznen

As now the interoperability become a practical aspect of MEE use in the healthcare, the paper focus in the links between the Essential Performance, Clinical Function and the Interoperability. Interoperability will increase patient safety, reduce costs and improve efficiencies in the operating room and other clinical settings. Device integration and interoperability could help physicians make sense of disparate patient data and clinical function of MEE. A particular reference to the Essential Performance requested by third edition of IEC 60601-1 standard and his First Amendment is done for a better understanding of the needs of the interoperability. IEC 60601-1 standard is compared with other existent standards developed by ISO, IEEE and other standards developer.

Risk Management per 3rd ed of IEC 60601-1 and the Regulatory Bodies

By Steli Loznen

When IEC 60601-1 3rd ed standard have becomes mandatory, the manufacturers of Medical Electrical Equipment needs to comply with the clause 4.2 of this standard. The specified clause request that a Risk Management process, according with ISO 14971, to be conducted. A similar request is done by the Regulatory Bodies (i.e. Notified Bodies in EU, FDA in USA, etc.) for the certification. Sometime exist a very significant gap in the different interpretation of this requirement by Testing Houses and Regulatory Bodies. The paper analyzes the main aspects of the Risk Management File and the different position on the reviews of this document by Testing Houses and Regulatory Bodies. A proposal to harmonize these points of view is the main objective of the paper. Are presented some hints how a manufacturer of MEE need to issue a RMF to be accepted both by Testing Houses and Regulatory Bodies.

Understanding Radiation Safety of High-Intensity Light-Emitting Diodes

By Erwin K. Lau

Light emitting diodes (LEDs) continue to advance with respect to optical power and the conventional wisdom that they are safe with respect to radiation hazard to eye and skin may no longer hold. The governing standards for LED radiation hazard rating, including IEC 62471, may not account for these new high-power LEDs, especially for specific applications that require typical use closer than the standard 200 mm, such as pulse oximetry and optical tomography. Because LEDs are small sources with divergent radiation cones, the irradiance increases as the observer approaches the LED, and may exceed the levels of safety for both eye and skin. Additionally, the natural aversion response to bright lights may not be present for near-infrared LEDs.

Understanding the Requirements of Standard IEC 60601-1-11

By Michael Brousseau

"Manufacturers producing medical electrical equipment for the home healthcare environment must now meet the mandatory requirements of IEC 60601-1-11. The new provision has requirements stating that a risk management file must now be part of compliance. The standard focuses on the chances of failure in a particular situation and determines the hazard potential of the error. Risk scenarios and assessments must be established by the manufacturer and documented in the risk management file in order to achieve freedom from unacceptable risk.

Safe and functional products require extensive testing in simulated environments to ensure usability, understandability and safety. Many aspects need to be considered including the user, user environment, device, training and post market support to make sure the product is ready for market entry. Manufacturers also need to heavily consider human factors that play a large role in home-use devices.

During this presentation Mike Brousseau, safety group manager for Intertek, will provide attendees with an extensive understanding of IEC 60601-1-11. He will discuss information manufacturers need to know to meet the standards before submitting a product to market and will address the challenges associated with the use of medical devices in the home."

Quantification of combustion hazards of Thermal runaway failures in Lithium-Ion

By Vijay Somandepalli

The failure modes of lithium-ion cells have been extensively studied for consumer product applications where the total energy of the battery system is typically below 100 Wh. As lithium-ion cells and systems become larger and more ubiquitous in their use in applications that demand high energy density capacities like vehicles, grid storage, and industrial backup systems, some failure modes that were rare or non-existent in smaller systems are becoming more common. One potentially hazardous failure mode seen in large lithium-ion systems occurs when flammable gases are emitted from a lithium-ion cell, reach the lower explosion limit in a confined space around the battery and are ignited by electrical activity or the cells themselves. If this scenario occurs, the battery containment and the confined space can become overpressurized, potentially resulting in an explosion and severe damage to the battery, the space in which the battery is located, and the surrounding area.

Patient and Operator - different requirements

By Grant Schmidbauer

IEC 60601-1, 3rd ed. was published in 2005, and with it's introduction, there are significantly different requirements for the patient compared for the operator. The standard has introduced Means of Patient Protection (MOPP) for the patient. The standard has introduced Means of Operator Protection (MOOP) for the operator. The basis of the introduction of MOPP and MOOP, is that for many types of Medical equipment, the operator is a healthy (normal) person, and the Medical equipment has an interface much like a computer, therefore why treat the operator as a patient. As a result, the distinction of treating (protecting) the operator and the patient differently. MOOP protection is based on the protection afforded by IEC 60950-1; whereas MOPP is based on the similar protection afforded by IEC 60601-1 2nd ed. This presentation will look into the main differences between MOPP and MOOP.

Common Pitfalls and Best Practices of ISO 14971 and IEC 60601-1

By Joel Smith

"Recent changes to standards and regulatory requirements now require medical device manufacturers to have a documented risk management system in place to demonstrate that their device is safe. The risk management requirements of IEC 60601-1 Third Edition - Medical equipment/medical electrical equipment are often misinterpreted in supplied documentation and risk management information for certification, making it challenging for manufacturers to understand and meet the stated requirements.

During this presentation, Intertek consultant Joel Smith will provide attendees with detailed information about the clauses that are most often misrepresented in IEC 60601-1. Joel will offer helpful suggestions and observations on what third party testing organizations are looking for in order to comply with the requirements. He will discuss the areas of management requirements, risk policy, risk acceptability criteria, risk management planning, documenting implementation, effectiveness of risk controls and many other areas that are highly contentious.

Presentation attendees will gain a further understanding of the ISO 14971 risk management requirements for IEC 60601-1 Third Edition with focus on the areas resulting in the most non-conformances during certification evaluations."

Rebuilt Medical Electrical Equipment

By Michel Brossoit

"Innovation cycles for medical technology are much shorter than the real functional lifecycle of the ME Equipment/System. Keeping up with the latest inventions in medical technology often makes it necessary to replace ME Equipment/System before it reaches the end of its intended functional life. This adds substantial cost to the owner of such ME Equipment/System and would not support the current trends towards sustainable practices.

Early replacement of installed ME Equipment/System by newer generation technology is economically feasible if the high residual value of the existing ME Equipment/System can be captured. Manufacturers have in operation, various processes for rebuilding existing ME Equipment/System to function like that of newer models in order to capture the residual value of the existing ME Equipment/System . These processes vary greatly and often modify the original ME Equipment/System model in such a way that not only violates the original ME Equipment/System certification, but may also affect the safety level of the finished rebuilt ME Equipment/System product.

Manufacturers have recognized the need to address these processes, and have worked with test houses to develop a suitable program to cover rebuilt ME Equipment. Safety and Quality are the most important aspects considered for this program."

Medical robot safety standardisation

By Gurvinder S. Virk, Alan Cohen & Mike Yvamatequi

The paper presents an overview of the on-going activities within the IEC TC62/SC62A & ISO TC184/SC2 Joint Working Group 9 to develop the basic safety and essential performance requirements for medical robots. The capability of "degree of autonomy" inherent in robots is focused upon to allow for the development of additional hazards and how these may be mitigated. As such autonomous features are being introduced in many forms of medical electrical and systems, the need for guidance by medical equipment manufacturers is growing and is not limited to just medical robot companies. In view of this, the long term proposal seeks to develop a collateral standard fitting the 60601 family of standards. A Technical Report entitled Guidance and interpretation for medical electrical equipment and systems employing a degree of autonomy will be the initial document to be produced. The paper will present an update on this standardization work. In addition, vertical standards for particular types of medical robots building on the recent developments to publish the new safety standard ISO 13482 for personal care robots are being proposed; surgery robots and rehabilitation robots are two vertical standards being investigated.

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