ISPCE 2015 FINAL PROGRAM

as of May 5

EMC Track Chair: Mark Montrose	Compliance 101 Track Chair: Dan Roman	Medical Track Chair: Richard Gardner	Global Regulations & Compliance Management Track Chair: Luiz Claudio Araujo	Innovation & Emerging Technologies Track Chair: Murlin Marks	Energy Storage & Batteries Track Chair: Jan Swart	Safety Science & HBSE Track Chair: Tom Lanzisero	Miscellaneous Standards Track Chair: Ted Eckert	Meals, breaks	General events open to all

Monday	**Grand Ballroom**	**Armstrong**	**Aldrin & Crossfield**	**Lindbergh**	**Garros**
7:00 AM 7:10 AM 7:20 AM 7:30 AM 7:40 AM 7:50 AM	Continental Breakfast and Networking	Speaker Breakfast			
8:00 AM 8:10 AM 8:20 AM 8:30 AM 8:40 AM 8:50 AM	Opening Plenary, Keynote: Stephen Kirk (UL), Exhibits and Networking				
9:00 AM 9:10 AM 9:20 AM	Break & Exhibits				
9:30 AM 9:40 AM 9:50 AM 10:00 AM 10:10 AM 10:20 AM	Open	The basic requirements of a product going from the plug through the enclosure and components - John Allen	The Premortem - Ted Eckert	Medical Device IEC 60601-1 Preliminary Evaluations - Brian Biersach	EMC Fundamentals - Grounding, Shielding, Filtering Design and Layout - Elya Joffe

10:30 AM	Transition/Networking				
10:40 AM	Open	Dielectric Strength Testing Transient Overvoltage Withstand Testing - Richard Nute	Compliance Challenges for Smart Grid and Emerging Smart Systems and Devices - Rudi Schubert	Amendment 1 of IEC 60601-1, 3rd Ed. - What are the changes? - James Benscoter	EMC Fundamentals - Grounding, Shielding, Filtering Design and Layout (Continued) - Elya Joffe
10:50 AM					
11:00 AM					
11:10 AM					
11:20 AM					
11:30 AM					
11:40 AM	Lunch, Exhibits and Networking				
11:50 AM					
12:00 PM					
12:10 PM					
12:20 PM					
12:30 PM					
12:40 PM					
12:50 PM					
1:00 PM					
1:10 PM	Open	Touch Current and Electric Shock Tutorial - Peter Perkins	Electronic Cigarettes, the past, present, and future - Richard Pruen	Medical Safety testing requirements for 60601 safety testing - Jorel Townsend	EMC Fundamentals - Grounding, Shielding, Filtering Design and Layout (Continued) - Elya Joffe
1:20 PM					
1:30 PM					
1:40 PM					
1:50 PM					
2:00 PM					
2:10 PM	Transition/Networking				
2:20 PM	Open	Introduction to IEC 60335 - Household and similar electrical appliances - Safety - Dan Roman	Requirements, Challenges and Opportunities of Microsensors for Wearable Devices - Kai-Hsiang Yen	IEC 60601-1-2 4th Edition EMC - Nicholas Abbondante	Printed Circuit Board Design for EMC Compliance- Mark Montrose
2:30 PM					
2:40 PM					
2:50 PM					
3:00 PM					
3:10 PM					

3:20 PM	Afternoon Break, Exhibits and Networking				
3:30 PM					
3:40 PM					
3:50 PM	Open	Electrical Safety Testing in a Production Environment - Dwayne Davis	62368-1 Discussion Panel - Tom Burke	ISO 14971 Risk Management standard and EU MDD - Steli Loznen	Printed Circuit Board Design for EMC Compliance (Continued) - Mark Montrose
4:00 PM					
4:10 PM					
4:20 PM					
4:30 PM					
4:40 PM					
4:50 PM	Transition/Networking				
5:00 PM	Open	Navigating The Product Certification Maze - Valerie Madarasz	62368-1 Discussion Panel - Continued if necessary	Human Factors Engineering in Medical Devices - Cindy Miller	Printed Circuit Board Design for EMC Compliance (Continued) - Mark Montrose
5:10 PM					
5:20 PM					
5:30 PM					
5:40 PM					
5:50 PM					
6:00 PM	Exhibitor Reception				
6:10 PM					
6:20 PM					
6:30 PM					
6:40 PM					
6:50 PM					
7:00 PM					
7:10 PM					
7:20 PM					

Tuesday	Grand Ballroom	Armstrong	Aldrin & Crossfield	Lindbergh	Garros
7:00 AM	Continental Breakfast and Networking	Speaker Breakfast			
7:10 AM					
7:20 AM					
7:30 AM					
7:40 AM					
7:50 AM					
8:00 AM	Open	Failure Mode & Effects Analysis (FMEA) Methods and Accelerated Testing Concepts - Daren Slee	Update on Regulatory Labeling - Gary Schrempp; Daniece Carpenter	Levels of Conceptual Interoperability Model for Healthcare - Michael Robkin; Sandy Weininger; Benjamin Preciado	New European EMCD, LVD and RED – What´s new? - Michael Loerzer
8:10 AM					
8:20 AM					
8:30 AM					
8:40 AM					
8:50 AM					
9:00 AM	Transition/Networking				
9:10 AM	Open	Seawater Immersion Abuse Testing of Electric and Hybrid Vehicles - Erik Spek	Photobiological Safety of LED Lamps and Lamp Systems: IEC/EN 62471 - David Ellis	Applying STPA-based Hazard Analysis to support Hazard-based Safety Engineering for Systems Built Using Medical Application Platforms - Anura Fernando	Product Compliance under European Law - System, sanctions, current issues - Susanne Wende
9:20 AM					
9:30 AM					
9:40 AM					
9:50 AM					
10:00 AM					
10:10 AM	Awards Ceremony, Coffee Break and Networking				
10:20 AM					
10:30 AM					
10:40 AM					

10:50 AM 11:00 AM 11:10 AM 11:20 AM 11:30 AM 11:40 AM 11:50 AM	Open	Lesson Learned from Battery Failures - Alvin Wu	Laser Illuminated Projectors: Science, Safety and Regulations - Casey Stack	Safety of Medical Robots - Steve Deibele	Consumer Product Safety Compliance - The Current State of CPSC Safety Programs - Charles Joern
12:00 PM 12:10 PM 12:20 PM 12:30 PM 12:40 PM 12:50 PM 1:00 PM	Lunch, Exhibits and Networking				
1:10 PM 1:20 PM 1:30 PM 1:40 PM 1:50 PM	Open	Risk Assessment as a Design Tool for Safety Compliance - Stefan Mozar	Computational Analysis of Electrical Shock Hazard and Safety Evaluation using Human Body Models - Hai Jiang	Risk Evaluation -- Safe Enough for Society - Steve Deibele	Regulatory Changes in Environmental Compliance - Geoffrey Bock
2:00 PM 2:10 PM	Transition/Networking				
2:20 PM 2:30 PM 2:40 PM 2:50 PM 3:00 PM 3:10 PM	Open	A New Structure for the EU LVD Directive - Mark Maynard	HBSE and Insulation Coordination - Richard Nute	A cybersecurity risk assessment methodology for medical devices - Srinivasan Jagannathan; Adam Sorini	The General Motors Ignition Switch Recall - Gary Tornquist
3:20 PM 3:30 PM 3:40 PM 3:50 PM	Afternoon Social/Exhibits				

4:00 PM 4:10 PM 4:20 PM 4:30 PM 4:40 PM 4:50 PM	Open	China New CCC Regulations for 2015 - Thomas Ha	HBSE AND INTERLOCK SCHEMES The interlock model and its parameters - Richard Nute	Towards a Logic-Based Extension of a Relational Software Tool for Coherent Technical Documentation of Medical Devices - Tobias Lueddemann; Jonas [illegible] Roppenecker; Franziska Klein, Tim Lueth	ProductDNA: Traceability for Compliance & Market Access - Rakesh Vazirani
5:00 PM 5:10 PM 5:20 PM 5:30 PM 5:40 PM 5:50 PM 6:00 PM	General Session - Chapter and Technical Committee Updates				

Wednesday	Grand Ballroom	Armstrong	Aldrin & Crossfield	Lindbergh	Garros
7:00 AM	Continental Breakfast and Networking	Speaker Breakfast			
7:10 AM					
7:20 AM					
7:30 AM					
7:40 AM					
7:50 AM					
8:00 AM	Open	EOL Test: Friend or Foe? Challenges with Testing Lithium Ion Batteries in a Manufacturing Environment - Bradley Willard	A Critical Review on China Toys Safety Standards: GB6675-2014 - Shu Lun Mak; Hing Keung Lau	USB Port and Power Delivery - Fan He	Product Safety Program Planning - From Prescriptive to Hazard-Based Safety - Oscar Overton
8:10 AM					
8:20 AM					
8:30 AM					
8:40 AM					
8:50 AM					
9:00 AM	Transition/Networking				
9:10 AM	Open	Child Safety - Button or Coin Batteries - Paul Robinson	UL 61800-5-1 Drive Safety Standard - Seth Carlton; Matt Mollen	Application of HBSE to the fire risk of clothes dryers - Suzanne Smyth; Delmar Morrison; Brenton Cox	Product Compliance Management – A Tool Box to Comply with Legal Obligations - Michael Loerzer
9:20 AM					
9:30 AM					
9:40 AM					
9:50 AM					
10:00 AM	Coffee Break and Networking				
10:10 AM					
10:20 AM					
10:30 AM					
10:40 AM	Open	New Approaches to Safe Ventilation of Equipment Containing Lead Acid and NiCd Batteries - Don Gies	NFPA 70E Standard for Electrical Safety in the Workplace - 2015 Edition - David Dini	Programmable Logic Controller Software Hazard Analysis Using Fault Tree Analysis - Dae-Won Chung	Team Engagement in the Product Compliance Process – Which Teams Should Be Engaged and Why? - Dennis Bartelt; Peter Merguerian
10:50 AM					
11:00 AM					
11:10 AM					
11:20 AM					
11:30 AM					

11:40 AM 11:50 AM	Lunch and Networking				
12:00 PM 12:10 PM 12:20 PM					
12:30 PM 12:40 PM 12:50 PM	Open	Battery Certification For Large Format Applications - Stephen McVay	Assessing Hazards of Systems vs. Products: Case Study of Roof-Mounted Photovoltaic Panels and Fire Testing to ANSI/UL 1703 - Gregory Allen	Functional Safety: An Introduction to Theories, Standards & Applications - Erik Reynolds	When do wearable electronics become medical devices? - Ted Eckert
1:00 PM 1:10 PM 1:20 PM					
1:30 PM 1:40 PM 1:50 PM	Transition/Networking				
2:00 PM 2:10 PM 2:20 PM	Open	Global Certification Requirements for Grid Connectivity: Renewables, Backup Power, and Energy Storage - Howard Liu	Open	Open	When do wearable electronics become medical devices? - Overflow
2:30 PM 2:40 PM 2:50 PM	Transition/Networking				
3:00 PM 3:10 PM 3:20 PM	Closing Session and Wrap-Up				
3:30 PM 3:40 PM 3:50 PM					

7:00 AM - 8:00 AM

Speaker Breakfast

Room: 1

On the day of your presentation, please join us for a special Speaker Breakfast. Breakfast will be available from 7:00 AM - 8:00 AM.

8:00 AM - 9:00 AM

Exhibitor Breakfast

Room: 1

On each day of your exhibiting, please join us for a special Exhibitor Breakfast. The time for the breakfast is from 8:15 AM - 9:00 AM.

8:00 AM - 9:30 AM

Opening Plenary, Keynote Speaker, Exhibits

Room: Grand Ballroom

9:30 AM - 10:30 AM

The Premortem

Room: Aldrin & Crossfield

The Pre-Mortem: An Alternative Method of Predicting Failure

Ted Eckert (Microsoft Corporation, USA)

Most people are familiar with the idea of a postmortem. When referring to product development, the postmortem is a review performed after a failure has occurred. The intention is to look at the failure in detail to figure out the root cause. However, you need not wait until a failure occurs. One management technique with growing popularity is the pre-mortem. The pre-mortem is performed early in the development process. The product development team mentally transports themselves into the future and presupposes that a failure has occurred. The team then runs a hypothetical postmortem using their imaginations to theorize what the causes could be. This technique can often discover potential risks in a product that might not be found with other techniques by working backwards. This technique may also be used to build out a more comprehensive fault-tree analysis.

The basic requirements of a product going from the plug through the enclosure and components

Room: Armstrong

The basic requirements of a product going from the plug through the enclosure and components

John R Allen (Product Safety Consulting, Inc., USA)

This presentation is intended for beginners to Compliance and will provide a great starting point for getting any product headed in the right direction regarding Compliance.

Printed Circuit Board Design for EMC Compliance

Room: Garros

Introduction to Printed Circuit Board Design for EMC Compliance

Mark Montrose (Montrose Compliance Services, Inc., USA)

This tutorial allows engineers to understand how a printed circuit board, integrated into a system enclosure operates in its electromagnetic environment that includes both emissions and immunity regulatory requirements, not to mention self-compatibility. Printed circuit boards must be designed with a focus on transmission line theory along with a sound understanding of electromagnetic theory. To teach complex electromagnetic theory, a unique presentation of "EMC Made Simple®" is given, which means one can convert complicated calculus to algebra by thinking and working in the time domain instead of the frequency domain. In order for transmission lines to propagate an electromagnetic field from source to load means several operational conditions must be present. These conditions include the need for an optimal low loss RF transmission line path along with its return path, proper voltage referencing, and an enhanced power distribution network while incorporating protective design features to minimize common-mode currents injected into interconnects. Proper layout not only assures functionality, but also compliance with EMC requirements for residential, commercial (ITE, medical, communication systems, etc.) and military applications.

Medical Device IEC 60601-1 Preliminary Evaluations

Room: Lindbergh

Medical Device IEC 60601-1 Preliminary Evaluations

Brian Biersach (MECA, USA)

Preliminary Evaluations are the first step in the full evaluation process. They are a design, construction, and documentation review used to identify and address compliance issues, as well as plan for the applicable testing. While this is typically done by the lab that you're using for your evaluation and testing, you can reduce your project time and avoid noncompliance delays by taking these steps. We will be covering six topics that are used in preliminary evaluations to reduce the chance of noncompliances delaying your projects. These topics are: 1) Applicable Standards 2) Construction Review 3) Electrical Requirements 4) Mechanical Requirements 5) Labeling and User Manual (Accompanying Documents) 6) Test Plan Preliminary evaluations also typically cover the risk management process and device requirements, but that topic will be covered by a separate presentation.

10:40 AM - 11:40 AM

Compliance Challenges for Smart Grid and Emerging Smart Systems and Devices

Room: Aldrin & Crossfield

Compliance Challenges for Smart Grid and Emerging Smart Systems and Devices

Rudi Schubert (IEEE Standards Association, USA)

Testing and certification of Smart Grid systems and devices has been a highly active area of interest over the last five year. Extensive industry and government participation has taken place to accelerate the availability of new test programs, however emergence of these programs has taken considerable time. Complexity, culture and challenges in the demand drivers have influenced the pace of test program development. New "smart" technology topics are now beginning to gain momentum that will present compliance opportunities and challenges. Experiences with the Smart Grid are useful and informative to help navigate these new opportunities and implement new testing services to more rapidly support interoperability and technology deployment needs.

Dielectric Strength Testing Transient Overvoltage Withstand Testing

Room: Armstrong

Dielectric Strength Testing Transient Over-voltage Withstand Testing

Richard Nute (IEEE Product Safety Engineering Society & Richard Nute Product Safety Consultant, USA)

Contrary to what is published elsewhere, electric strength testing is not a margin above the voltage to which the insulation is subjected. Instead, the hi-pot test is to determine that the safeguard insulations will withstand the normally-occurring transient overvoltages. This paper discusses why electric strength greater than normal voltage is necessary, and the process of electric strength testing.

Printed Circuit Board Design for EMC Compliance - Continued

Room: Garros

Amendment 1 of IEC 60601-1, 3rd Ed. - What are the changes?

Room: Lindbergh

Amendment 1 of IEC 60601-1, 3rd Ed. - What are the changes?

James Benscoter (UL LLC, USA)

With the adoption of IEC 60601-1, 3rd Ed including Amendment 1 in the Official Journal for the Medical Device Directive, manufacturers now have an effective date for the standard. In addition, OSHA has adopted the standard ES 60601-1:2005 with A1:2012 as the NRTL standard for electrical medical equipment. As manufacturers start to transition to using Amendment 1, they need to be aware of the changes and the impact to them. While many of the changes would be considered a benefit to the manufacturer, other changes will results in more work. It is important to understand the changes to assist in planning to meet the effective date in the EU. For manufacturers planning to get a CB Scheme Certificate to show compliance with Amendment 1, the IECEE has made additional changes that will need to be considered.

11:40 AM - 1:10 PM

Lunch, Exhibits, & Networking

Room: Grand Ballroom

1:10 PM - 2:10 PM

Electronic Cigarettes, the past, present, and future

Room: Aldrin & Crossfield

Electronic Cigarettes, the past, present, and future

Richard Pruen (BTC Battery Testing, United Kingdom)

Electronic cigarettes, a talk on the past history, current situation, and the future. To cover the devices, a brief history, the technology, regulations, and looking to the future. Information on benifits, harm reduction, and the first viable alternative to smoking. Including how an IEEE standard would be of great benefit, in promoting these devices. Electronic cigarettes have begun to out perform NRT, by a wide margin according to the latest studies. With a success rate of around 50% compared with NRT, having a reported success rate of 10% or less. The latest studies will be presented, so the approximate numbers above may change

Touch Current and Electric Shock Tutorial

Room: Armstrong

Touch Current and Electric Shock Tutorial

Peter Perkins (P. E. Perkins PE, USA)

This requested tutorial covers the basis for electric shock protection in electrical equipment. It is build upon the response of the human body to electric current and the ways in which to deal with this in equipment design and evaluation. The methods are technically based upon IEC standards such as IEC 60479, 'Effects of electric current on the human body...' and IEC 60990 'Methods of measurement of touch current...'. A comprehensive presentation of the understanding and application of the needed protections will be presented in this 2 hour tutorial. This tutorial is aimed at engineers and managers working on equipment design and construction as they have to deal with these issues. The author/presenter has more than 50 years experience in the electronics field.

Printed Circuit Board Design for EMC Compliance - Continued

Room: Garros

Medical Safety testing requirements for 60601 safety testing

Room: Lindbergh

Medical Safety testing requirements for 60601 safety testing

Shayne Nofts (Chroma Systems Solutions Inc. & Chroma Systems Soultions Inc., USA); Jorel Townsend (Chroma System Solutions, USA)

2:20 PM - 3:20 PM

Requirements, Challenges and Opportunities of Microsensors for Wearable Devices

Room: Aldrin & Crossfield

Requirements, Challenges and Opportunities of Microsensors for Wearable Devices

Kai-Hsiang Yen (Underwriters Laboratories Taiwan Co., Ltd., Taiwan)

A variety of wearable device prototypes and commercial products have been produced in the course of recent years, which aim at providing real-time feedback information about one's body condition. Especially, the microsensor is the key component of wearable devices and is in direct contact with people or even implanted, its safety, reliability, requirement, sensitivity and biocompatibility to human tissues are crucial. We aimed to review the technologies of microsensors and wireless communication in order to evaluate the application for wearable devices. We conducted a large, comprehensive study in new and innovative microsensing technologies and selected several impressive microsensors such as Accelerometer, Gyroscope, CO2 gas sensor, Blood glucose, Pulse Oximetry, ECG sensor, EEG sensor, EMG sensor to analyze their theory and design for future application. In the same time, the Body Area Network (BAN) communication architectures like Bluetooth Low Energy, UWB, ZigBee, Insteon, Z-Wave, ANT, RFID were compared to figure out the characteristics for instance, frequency band, data rate, multiple access method, coverage area and network topology for the application of wearable devices. Biocompatibility is also an essential consideration when evaluating a material for use in a biomedical application. Biomerics adheres to the highest standards of biocompatibility to ensure its products are safe for use, and has tested its materials according to various regulatory and industry standards adopted for the evaluation of biocompatibility of polymeric materials. From a reliability standpoint, microsensors and actuators are affected by the reliability of the materials and designs of the Micro Electro Mechanical Systems (MEMS) part as well as the fabrication technology used. The signal level may vary from its set zero value when the sensor works and this introduces an error into the measurement equal to the amount of variation. In this study, we provided four critical factors which were biocompatibility, reliability, zero drift and performance to assess the requirements, challenges and opportunities of microsensors for wearable devices application.

Introduction to IEC 60335 - Household and similar electrical appliances

Room: Armstrong

Introduction to IEC 60335 - Household and similar electrical appliances - Safety

Dan Roman (Colgate-Palmolive Company, USA)

We and our families are in contact with household appliances on a daily basis. Their safety is enhanced by complying with standards such as the IEC 60335 series. It is important for product compliance and design engineers to be familiar with the requirements of safety standards for household appliances during the design and production of these products.

EMC Fundamentals - Grounding, Shielding, Filtering Design and Layout

Room: Garros

EMC Fundamentals-Grounding, Shielding, Filtering Design and Layout

Elya Joffe (Elya Joffe - Electromagnetic Solutions, Ltd., Israel)

This presentation has a focus on system level engineering considerations. Printed circuit boards are installed in enclosures that mandate several areas of concern. One of the most important aspects of system design involves grounding and various methodologies to prevent ground loops and other undesired effects related to both signal integrity while minimizing creation of undesired common-mode currents developed both within and between printed circuit boards. Proper grounding of circuits and electrical elements also prevents harm of electric shock. Shielding is a requirement for product designs to guarantee that internally generated, undesired common-mode currents are not propagated to the external environment causing harmful disruption to other electrical systems, or is protected from disruption from external radiated field effects. Shielding is implemented using transmission line theory, same as printed circuit board design requirements. Every electrical device has both input and output circuitry to communicate information to the user. This means penetration of the enclosure must occur generally with cables, interconnects or display panels. Filtering to remove unwanted common-mode currents created by unbalanced circuitry is easily achieved with optimal selection and implementation of discrete components that is presented in this tutorial.

IEC 60601-1-2 4th Edition EMC

Room: Lindbergh

IEC 60601-1-2 4th Edition EMC

Nicholas Abbondante (Intertek, USA)

The fourth edition of IEC 60601-1-2 has been approved, and this means dramatic changes for the medical device industry. This new edition introduces new product categories, new test levels, and eliminates the "life-support" device category.

3:20 PM - 3:50 PM

Afternoon Break, Exhibits and Networking

Room: Grand Ballroom

3:50 PM - 4:50 PM

62368-1 Discussion Panel

Room: Aldrin & Crossfield

62368-1 Discussion Panel

Thomas M Burke, PE (UL LLC, USA)

IEC 62368-1 Ed. No. 1 has been published since 2010. The subsequent Edition No. 2 was published in early 2014, with both EN 62368-1 for Europe and CSA/UL 62368-1 for North America subsequently published in the second half of 2014. As a result, EN 62368-1 is accepted in EU to comply with the EU LVD, and UL 62368-1 is recognized by OSHA as a suitable standard for applicable equipment used in the U.S. workplace. Being such, certifiers and manufactures are beginning to study the Standard and prepare for its implementation, with both EU and the U.S. announcing formal transition dates in year 2019 when the 62368-1 standards will replace both IEC 60065 (AV equipment) and IEC 60950-1 (IT & CT equipment). This is a significant transition since OFF (60950-1) and TRON (60065) combined presently make up over 50% of the activity in the IECEE CB Scheme. The 2015 ISPCE will be a valuable forum for both certifiers and manufacturers to share their experiences, questions, concerns, and related thoughts on the global transition towards the new Standard.

Electrical Safety Testing in a Production Environment

Room: Armstrong

Electrical Safety Testing in a Production Enviroment

Dwayne Davis (Associated Research Inc. & Ikonix Group, Inc, USA)

Power Point Presentation without full paper. This presentation covers operator training, the safe set up of the electrical safety testing workstation, guarding of live parts and safe methods that may be employed in performing the test. How ESD and electrical testing do not mix.

EMC Fundamentals - Grounding, Shielding, Filtering Design and Layout - Continued

Room: Garros

ISO 14971 Risk Management standard and EU MDD

Room: Lindbergh

ISO 14971 Risk Management standard and EU MDD

Steli Loznen (I. T. L Ltd. & Tel Aviv University, Israel)

In November 2010, the European Commission raised a formal objection against the use of several harmonized standards, including EN ISO 14971, followed by an in-depth assessment of the coverage of the Essential Requirements of the Medical Device Directive 93/42/EEC by these standards. As a result of these objections, the Annexes Z to EN ISO 14971 were modified, resulting in EN ISO 14971:2012. The Annexes Z describe the extent of presumption of conformity that can be based on application of the normative requirements of ISO 14971 alone. In October 2014 was published by Notified Body Recommendation Group a Consensus Paper. The paper aims to provide a practical interpretation of these "content deviations" to the Medical Device Directives and give guidance as to how to implement the risk management requirements. The presented work is intended to facilitate common understanding between industry and Notified Bodies of the Risk Management applied to Medical Devices.

5:00 PM - 6:00 PM

62368-1 Discussion Panel - Continued

Room: Aldrin & Crossfield

Navigating The Product Certification Maze

Room: Armstrong

Navigating The Product Certification Maze

Valerie Madarasz (CSA Group, USA)

Product Certification marks are issued by accredited third-party testing & certification agencies and found on a wide variety of products, including electric appliances, HVAC equipment,lighting, consumer electronics and medical equipment. While most jurisdictions require that certification marks appear on products installed in buildings, some confusion remains about what these marks mean, who is qualified to perform the certification and issue the marks, and how testing & certification agencies assist in identifying products that do not meet the applicable standards. This presentation guides the participant through the testing & certification process, and highlights the roles and responsibilities that product manufacturers, standards development organizations, third-party testing & certification agencies and Authorities Having Jurisdiction all share in ensuring that products and equipment when installed will not endanger public safety and health. The course also addresses the importance of combating counterfeit products in the global marketplaces and provides practical tips on identifying such products wich could place consumers at risk of serious injury, illness or death.

EMC Fundamentals - Grounding, Shielding, Filtering Design and Layout - Continued

Room: Garros

Human Factors Engineering in Medical Devices

Room: Garros

Human Factors Engineering in Medical Devices

Cindy Miller (GE Healthcare, USA)

Human Factors Engineering is a process to help provide objective evidence that a medical device is safe and effective. In 2007, IEC 62366 was published and then later recognized by the FDA. It is also required for CE Mark. Today, IEC 62366 is under revision. The new standard has new requirements. This presentation will discuss the basics of what is human factors engineering, the requirements of the standard, and the expectations of the FDA. The presentation will also discuss how human factors engineering integrates into Design Controls. Lastly, best practices and examples will be provided to relate the standard into practice. Introduction What is Human Factors Engineering? Where is it used? Standards/Regulations in Healthcare IEC 62366 IEC 62366:2007 vs IEC 62366:2007 Amdt1:2014 vs IEC 62366-1 Draft FDA Draft Guidance How does IEC 62366 integrate with Design Controls Title 21 Part 820? AAMI HE 75 Appling Human Factors Engineering into medical devices Best Practices Examples Summary Q&A

6:00 PM - 7:30 PM

Exhibitor Reception

Room: Grand Ballroom

7:00 AM - 8:00 AM

Speaker Breakfast

Room: 1

On the day of your presentation, please join us for a special Speaker Breakfast. Breakfast will be available from 7:00 AM - 8:00 AM.

8:00 AM - 9:00 AM

Exhibitor Breakfast

Room: 1

On each day of your exhibiting, please join us for a special Exhibitor Breakfast. The time for the breakfast is from 8:15 AM - 9:00 AM.

Update on Regulatory Labeling

Room: Aldrin & Crossfield

Update on Regulatory Labeling

Gary Schrempp and Daniece Carpenter (Dell Inc, USA)

Overview of the topic of regulatory labeling, including discussion of recent changes allowing for e-labeling.

8:00 AM - 8:50 AM

Failure Mode & Effects Analysis (FMEA) Methods and Accelerated Testing Concepts

Room: Armstrong

Failure Mode & Effects Analysis (FMEA) Methods and Accelerated Testing Concepts

Daren Slee (Exponent Engineering and Scientific Consulting, USA)

FMEA Methods and Accelerated Testing Concepts: Failure Mode & Effects Analysis (FMEA) is a method often used at different stages product development to understand risk from various failure modes. This relative risk of failure modes is used to determine if mitigating action is necessary. FMEA assigns quantitative values to qualitative assessments with a collaborative approach. Accelerated Testing is testing to speed up failure or to prove robustness of products. Highly Accelerated Life Testing (HALT) is a method to test products to improve robustness of products. Accelerated testing is sometimes expected to predict product life. Various aspects of different FMEA approaches and inputs will be discussed along with Accelerated Testing concepts.

8:00 AM - 9:00 AM

Levels of Conceptual Interoperability Model for Healthcare

Room: Garros

Levels of Conceptual Interoperability Model for Healthcare

Michael Robkin (Anakena Solutions Inc. & MDPNP. org, USA); Sandy Weininger (U.S. Food and Drug Administration & Center for Devices and Radiological Health, USA);Benjamin Preciado (Anakena Solutions Inc., USA); Julian Goldman (Massachusetts General Hospital, USA)

The Medical Device and Healthcare Information Technology (HIT) industries have not achieved safe PNP cross-manufacturer (heterogeneous) interoperability although it has been achieved decades ago in other safety critical industries. We believe that the Levels of Conceptual Interoperability Model (LCIM) [1] offers an essential account of the disparity and thereby offers insight for how to achieve safe PNP cross-manufacturer interoperability in HIT. The LCIM is a conceptual framework for interoperability first developed for military simulation and modeling. We have expanded its scope and detail while applying it to medical devices. Our results show that safe interoperability minimally requires system components that are aligned about a conceptual model (i.e. manufacturers are operating at level 6). Furthermore, such devices can be assured to be safely interoperable cross-manufacturer only if different manufacturers share the conceptual model embodied by the communicating devices. We identify some root causes preventing this realization.

New European EMCD, LVD and RED - What´s new?

Room: Garros

New European EMCD, LVD and RED – What´s new?

Michael Loerzer (Globalnorm GmbH, Germany)
With respect to the New Legislative Framework the Commission has published nine updated EU Directives. Such Directives are the new Low Voltage Directive 2014/35/EU (LVD) and the EMC Directive 2014/30/EU (EMCD). Both Directives include the new requirement to perform a risk analysis and assessment. An applicable reference for this issue is the IEC guide 116 "Guidelines for safety related risk assessment and risk reduction for low voltage equipment". In General the content of the updated Directives are in line with the Decision 768/2008/EC and include the clear obligations of the economic operators (manufacturer, authorized representative, importer and distributor). They shall apply the new Union harmonization legislation from the 20th of April 2016 on. On the other hand the Commission will revise existing Union harmonization legislation in detail within the SLIM process (simpler legislation of the internal market). That means, regulations will be changed in detail. An example is the new Radio Equipment Directive (RED) 2014/53/EU which is a revision of the formerly R&TTE Directive 1999/5/EC. The new RED contains new and changed requirements to place radio equipment on the EU market. The presentation includes an overview of the new updated Directives and the common changes to place products on the EU market. In the second part the specific changes of the RED will be presented. Finally an outlook of forthcoming Union harmonization legislation will be given (e. g. the new market surveillance regulation).

9:10 AM - 10:10 AM

Photobiological Safety of LED Lamps and Lamp Systems: IEC/EN 62471

Room: Aldrin & Crossfield

Photobiological Safety of LED Lamps and Lamp Systems: IEC/EN 62471

David Ellis (Intertek, USA)
As white light LEDs become widely used in many lighting products, assessment of the unique "blue light" hazard is critical. IEC/EN 62471, Photobiological Safety of Lamps and Lamp Systems, applies to the photobiological safety of lamps and lamp systems, including LEDs and luminaires, and defines exposure limits, measurement techniques, and the classification scheme for the evaluation and control of photobiological hazards. There are various biological hazards considered with IEC/EN 62471. Biological effects and potential hazards of exposure to skin, the front surfaces of the eye (cornea, conjunctiva, and lens), and the retina are evaluated through six specific hazards. The presentation will outline these hazards, the two distinct measurements of irradiance and radiance, and how sources of optical radiation are classified into risk groups based on their potential photobiological hazard. Evaluating photobiological safety of lamps and lamp systems is a legal requirement in Europe, and IEC/EN 62471 was fully applied to all LED lighting products in 2009, but other countries have been slow to follow the European mandatory testing lead. Awareness efforts outside of Europe are providing a greater understanding of LED radiation hazards, risk classification, permissible exposure time, and labeling requirements with regard to photobiological compliance. During this presentation David Ellis from Intertek will discuss best practices and industry trends in global testing and compliance with regard to photobiological safety.

Seawater Immersion Abuse Testing of Electric and Hybrid Vehicles

Room: Armstrong

Seawater Immersion Abuse Testing of Electric and Hybrid Vehicles

Erik J Spek (TUV SUD Canada Inc., Canada)
When automotive engineers design a hybrid or electric vehicle, they use tools such as Design Verification Plan and Report (DVP&Rs) to consider most conceivable abuse circumstances for hybrid and electric vehicles (xEVs) such as electrical, thermal and mechanical abuse and up to pack level. However, man and nature sometimes present circumstances that have not been tested for or are considered to be of too low a frequency to verify. One of these cases is the immersion of complete xEVs in seawater in circumstances similar to those encountered during Hurricane Sandy in Port Newark, New Jersey in 2012. The consequence of seawater immersion in that case was spontaneous fire in a small number of hybrid electric vehicles. This event and others were drivers for the National Highway Traffic Safety Administration to conduct a program of investigation for possible future development of standards or regulations should they be deemed necessary. This paper describes the methods developed by TÜV SÜD to safely conduct seawater immersion tests on a variety of xEVs. The immersion tests were performed in 2014 on twelve different xEVs and measurements of temperatures, voltages, emitted gases and battery electrical isolation were recorded. The key findings from these tests were an understanding of how hazardous seawater immersion can be for xEVs and what electrical components and systems are susceptible to seawater immersion with subsequent risks of fire, electrical shock and cell venting.

Product Compliance under European Law - System, sanctions, current issues

Room: Garros

Presentation (without Full Paper) Product Compliance under European Law - System, sanctions, current issues

Susanne Wende (Noerr LLP, Germany)
Placing products onto the European market is regulated by a variety of European and national provisions. It is

sometimes difficult to categorize the different regulations and to get a clear picture on their scope. Quite often, European and national regulations overlap and slightly differ from each other which makes the application rather difficult. The presentation will address some of these difficulties. It intends to give some guidance on how to find out the relevant requirements for a specific product and how to deal with them. In its first part, the presentation will give an overview on the system of European product compliance law: The regulatory framework may be divided in product safety related provisions and other product compliance provisions. There are some legal differences making such distinction logical. These differences will be pointed out (e.g. regarding notification obligations, consequences of non-compliance). The presentation will also show common aspects in the application of all product compliance provisions. The second part will focus on specific categories of (non-safety related) product compliance provisions: Environmental Product Law, Energy Efficiency Law and Chemical Product Law. These seem to be specifically important and of interest to the potential audience. The scope and system of each category including possible consequences of non-compliance will be explained. Examples will be presented to show challenges of interpretation and application of the provisions as well as possible approaches to solve them. The examples will at the same time take up current topics. Main issues discussed from the European perspective are for example Industry 4.0, wearables, smart grids and remote control of electronic devices via mobile and the relevant product compliance legal framework. New combinations of provisions are to be applied and new questions of application raised.

Applying STPA-based Hazard Analysis to support Hazard-based Safety Engineering for Systems Built Using Medical Application Platforms

Room: Lindbergh

Applying STPA-based Hazard Analysis to support Hazard-based Safety Engineering for Systems Built Using Medical Application Platforms

Sam Procter and John Hatcliff (Kansas State University, USA); Anura Fernando (Underwriters Laboratories, USA); Kim Fowler (Kansas State University, USA); Sandy Weininger(U.S. Food and Drug Administration & Center for Devices and Radiological Health, USA)

Modern medical devices increasingly incorporate connectivity mechanisms that offer the potential to integrate devices via network / middleware technology into larger systems of cooperating components. Initial integration efforts in the industry have focused on streaming device data into electronic health records and integrating information from multiple devices into customizable displays. However, there are numerous clinical motivations for moving beyond these basic integration efforts to develop frameworks that orchestrate the actions of cooperating devices to realize scenarios with "closed loop" control, automate clinical workflows, and even automatically construct and conduct patient treatments. A Medical Application Platform (MAP) is an emerging vision that would provide device and health information system interoperability, safety critical network middleware, and an execution environment for clinical applications ("apps") that encode the envisioned medical system integration tasks described above. Work on MAPs utilizes the Integrated Clinical Environment (ICE) ASTM F2761 standard to ground the presentation of interoperability architectures. Realizing that the MAP vision could bring about a paradigm shift that can dramatically increase effectiveness and reduce costs of health care delivery, our work has focused on detailing the approach and coordinating with domain and regulatory experts. However, numerous challenges exist that are preventing this vision of deeply integrated and highly beneficial cyber-physical medical systems from being realized. One significant challenge involves developing appropriate hazard analysis techniques and risk management approaches that support third-party safety certification as well as regulatory submissions. Our research team – which includes representatives from academia (Kansas State University), testing and certification organizations (Underwriters Laboratory), and government regulatory agencies (US FDA) – is exploring the use of Systems Theoretic Process Analysis (STPA) as the basis for a novel risk management paradigm for Medical Application Platforms. This work is being carried out in the context of our participation in the development of the UL / AAMI 2800 family of standards for medical device interoperability safety. Risk management in this context requires reasoning about safety properties of systems that include both component and component interactions between hardware and software as well as humans and computers. These systems present challenges that traditional hazard analysis approaches such as Fault Tree Analysis (FTA) and Failure Modes and Effects Analysis (FMEA) have trouble addressing. However, STPA shows significant promise due to its general principles that can apply to hardware, software, computerized, and human process elements. We are designing a risk management framework for MAP-based systems that includes STPA as a central feature. In this context, risk management activities are spread across components from different vendors that are developed separately and then integrated. STPA's systems-focused methodology has proven crucial to uncovering risks caused both at within individual components as well at the (harder to analyze) component interaction layer. In this presentation, we provide background on the concept of Medical Application Platform and the unique challenges of carrying out hazard analyses and risk management in this context. We give an overview of the goals of STPA hazard analysis and the method by which it is applied. We illustrate the use of STPA-based hazard analysis for an MAP-based integrated clinical system that provides automated patient monitoring and a safety-interlock for Patient-Controlled Analgesia (PCA) infusion. We present our research findings regarding the effectiveness of STPA for this application and provide a road map for how STPA might be integrated into a broader standards-aligned risk management framework for MAP-based interoperable systems.

10:50 AM - 11:50 AM

Laser Illuminated Projectors: Science, Safety and Regulations

Room: Aldrin & Crossfield

Laser Illuminated Projectors: Science, Safety and Regulations

Casey Stack (IEC TC-76 ANSI Z136 & Laser Compliance, USA)

The general public was first introduced to the concept of the 'LASER' in the 1964 James Bond cinematic movie thriller, 'Goldfinger'. Today, laser technology has progressed such that cinemas globally will begin screening movies in 2015 with 'Laser Illuminated Projectors' (LIPs). In addition to cinema usage, many manufacturers are releasing enterprise and home theater projectors based on 'direct laser' and 'laser phosphor hybrid' illumination. Video projection is the first of many illumination applications to realize the vast technical, environmental and economic benefits of laser replacement of conventional lamps. However, although most LIPs present no increase in ocular hazard as compared to their lamp based predecessors, 40 year-old vestigial laser regulations are impeding the timely introduction of these highly efficient and beneficial LIPs, in many regions. Changes have been implemented to some international laser products standards such as the IEC 60825-1 based on safety studies, and are awaiting final publication. But challenges still exist. Additionally, until the U.S. FDA CDRH publishes a new Laser Notice or updates the current 'Laser Notice No. 50', some U.S. market LIPs remain in limbo. LIPs are the first industry of hundreds of future applications to move to laser light sources, even pushing aside LEDs. Prepare for your customer's future compliance, come and learn how to make laser sources as safe as conventional lamps, and how projectors are breaking the new regulatory path for many future industries. Optical laser safety and regulatory background, changes to laser regulations, and a regulatory change roadmap will be presented in detail.

Lesson Learned from Battery Failures

Room: Armstrong

Lesson Learned from Battery Failures

Alvin Wu (Underwriters Laboratories Taiwan Co., Ltd., Taiwan)

Lithium ion battery is the most dominant technology for all portable and off-grid applications due to its excellent performance. However, the safety risk in suing a lithium-ion battery is sometimes a very challenging issue. In this report, UL will introduce the forensic analysis methodologies to explore and analyze the battery safety issues via studying 3 contributing factors, including design, quality and use scenarios. Some case studies will be also demonstrated to show the practical strategies how the root causes behind each battery failure could be identified.

Consumer Product Safety Compliance - The Current State of CPSC Safety Programs

Room: Garros

Consumer Product Safety Compliance - The Current State of CPSC Safety Programs

Charles Joern, Jr. (Joern Law Firm, USA)

This program describes the development and current state of U.S. Consumer Product Safety Commission (CPSC) safety compliance programs. The presentation includes the essential elements that the CPSC expects to find in compliance programs involving consumer products, as well as the CPSC's enforcement philosophy concerning the implementation of such compliance programs. The presentation also reviews the implications and effects of establishing such CPSC product safety programs. The primary conclusion of the presentation is that a well designed and implemented safety compliance program will benefit consumer product companies from a CPSC regulatory perspective and from other perspectives.

Safety of Medical Robots

Room: Lindbergh

Safety of Medical Robots

Frank O'Brien (O'Brien Compliance Management, USA);Steven Deibele (O'Brien Compliance MAnagement, USA)

Surgical robots for soft tissue and hard bone surgery are becoming more prevalent. Talk will discuss existing requirements, and possible short falls. We'll look at a risk driven approach by identifying typical hazards and typical risk control measures. There's proposal for new IEC 60601 particulars for rehabilitation and surgical robots. There's a technical reference for degree of autonomy. We'll look at robot safety requirements from the industrial robot sector, and see how these can dovetail with medical requirements. Over last 10 years, author has been involved in medical robotic safety evaluations for all major manufacturers, e.g. Intuitive Surgical, Mako/Stryker, and many others. He participates on AAMI and IEC TC62D working group responsible for medical robotic safety. Duration is approx 1 h including room for Q&A.

1:10 PM - 2:10 PM

Computational Analysis of Electrical Shock Hazard and Safety Evaluation using Human Body Models

Room: Aldrin & Crossfield

Computational Analysis of Electrical Shock Hazard and Safety Evaluation using Human Body Models

Hai Jiang (Underwriters Laboratories (UL), USA); Paul Larsen(ANSYS Inc., USA); Marc Horner (ANSYS Inc, USA)

Electrical shock and burn are very dangerous electrical hazards for both workplace safety and for the general public. To effectively prevent the hazard while still meeting the current or voltage requirements for proper product function, it is important for the industry and standard writers to understand the different physiological effects of the electrical shock, the current path and the level of touch current during a hazardous scenario. Underwriters Laboratories (UL) has a long history conducting research in this area and working with the International Electrotechnical Commission (IEC) TC64 MT4 Working Group to advance the standards in this area. However, due to moral and legal reasons, it is impossible to conduct experiments directly on human beings, especially at the power line frequency (50 or 60 Hz) which is understood as the most dangerous for electrical shock comparing to higher frequency. Therefore, predictive electromagnetic computer models that utilize digital human body models (or human phantoms) may be used in place of experiments on human bodies. In this presentation, first, the simplified electrical circuit model currently used in UL 101 and IEC 60479 standards is reviewed. Second, a more complicated circuit model based on Santis experiments is discussed. This circuit model can be used for a wide frequency range from 0 Hz to 110 MHz based on Santis results. The PCB board is designed here and fabricated to validate the model. In this work, the simulation results of this circuit are compared with measured results for the PCB board, and excellent agreement is achieved. Next, the numerical human body model is reviewed. There is a long history of the use of numerical human body models for evaluating the radiation hazard and Specific Absorption Rate (SAR) value at radio frequencies, but this is not the case for electrical shock and burn hazard for the lower frequency range (below 1 MHz), and especially power line frequencies (50 or 60 Hz). We will review the previous research in this area, which is limited, and then discuss the research that is currently being conducted in the predictive modeling group at UL in collaboration with ANSYS, Inc. Some preliminary results will be demonstrated.

Risk Assessment as a Design Tool for Safety Compliance

Room: Armstrong

Risk Assessment as a Design Tool for Safety Compliance

Stefan Mozar (UNSW, Sydney & Dynexsys Pty Ltd, Australia)

Risk Assessment can be a powerful tool for design evaluation. This paper shows how risk assessments, based on Monte Carlo Analysis can effectively be used to identify potential hazards in design, and verify the proposed solutions. The evaluation of a power supply will be used to illustrate this method.

Regulatory Changes in Environmental Compliance

Room: Garros

Regulatory Changes in Environmental Compliance

Geoffrey Bock (TUV Rheinland of North America, Inc., USA)

Significant changes are happening to European environmental regulations. While there has been a great deal of discussion and debate over the past few years, in June 2011 the European Union issued Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment. The new directive recasts Directive 2002/95/EC, and has come to be known in the industry as the RoHS Recast, or RoHS2. We now have to be aware of the new changes coming up for RoHS3. REACH has also thrown a mix of great confusion into the regulatory arena with the demand that "Articles" must not exceed 0.1% by weight of over 161 Substances of Very High Concern (SVHC). The number of SVHCs increases every 6 months, creating a supplier and OEM nightmare. While many of these changes seem confusing, compliance will be mandatory for any company that hopes to sell into the European Union. This presentation seeks to cut through the complications and lay a foundation that is easy to understand.

Risk Evaluation -- Safe Enough for Society

Room: Garros

Risk Evaluation -- Safe Enough for Society

Steven Deibele (O'Brien Compliance MAnagement, USA)

Medical device manufacturers are required to conduct risk management in accordance with ISO 14971, and IEC 60601 series. The standards could leave the impression that risk acceptability is an arbitrary threshold that the manufacturer can determine, but this is not the intent of these standards. After a quick review of the overall risk management process, we'll focus on risk evaluation. We'll look at FDA and EU guidance that speak to the need that risk be reduced as low as possible, consistent with generally acknowledged state of the art and international standards, which take into account economic and technological constraints. Risk acceptability is set by society's values, as is therefore same for all manufacturers. Risk acceptability will change with time, as society's values/perceptions can change, as well as economic and technological constraints. We'll review examples. It's estimated to be 2 hours long. Could be broken into 2x 1 h sections: risk estimation (1 h), and risk evaluation (1 h).

2:20 PM - 3:20 PM

HBSE and Insulation Coordination

Room: Aldrin & Crossfield

HBSE and Insulation Coordination

Richard Nute (IEEE Product Safety Engineering Society & Richard Nute Product Safety Consultant, USA)

Transient overvoltages are normal. Insulation must withstand not only the functional voltage, but also the transient overvoltages. A scheme called "insulation coordination" has been instituted by the International Electrical Commission to promulgate and standardize on coordinating the transient overvoltage suppression with insulation electric strength. This paper addresses the insulation requirements of the scheme.

A New Structure for the EU LVD Directive

Room: Armstrong

A New Structure for the EU LVD Directive

Mark W. Maynard (SIEMIC, Inc. & Telecommunication Certification Body Council, USA)

Changes in the European Union legislative process over the past decade have resulted in common sets of definitions, requirements, roles and responsibilities that are finding their way into EU Directive updates. These changes have shaped the new EU Low Voltage Directive (LVD) 2014/35/EU, helping to ensure products within the scope of this directive are compliant prior to being placed into EU market countries, and remain in compliance throughout their life cycle. This new directive will fully repeal and replace the previous Low Voltage Directive 2006/95/EC on April 20, 2016, at which time all products entering the EU will be required to meet the new 2014/35/EU criteria.

The General Motors Ignition Switch Recall

Room: Garros

The General Motors Ignition Switch Recall

Gary Tornquist (Microsoft Corp., USA)

This paper summaries the events leading up to one of the most significant safety recalls of recent memory, General Motors recalling millions of vehicles for defective ignition switches starting in Feb. or 2014. There are multiple reasons why the recall was necessary and why it took GM a decade to identify and start to remedy. They include: 1) lack of resources for the safety program, 2) information silos within GM, 3) the gradual raising of the safety bar in the automotive industry, 4) a complex problem that crossed system, timing and user interface boundaries, 5)the engineer responsible for the ignition switch design did not follow GM's procedures for qualifying the design and tracking changes, and 6) a safety culture that lacked transparency, visibility and individual responsibility. These issues give other manufacturers and safety professionals much to think about.

A cybersecurity risk assessment methodology for medical devices

Room: Lindbergh

A cybersecurity risk assessment methodology for medical devices

Srinivasan Jagannathan (Exponent, Inc., USA); Adam Sorini(Exponent, USA)

The U.S. Food and Drug Administration (FDA) has expressed an ongoing emphasis on cybersecurity considerations for medical devices. The FDA recently issued guidelines regarding cybersecurity management in premarket submissions. In this paper we present a brief overview of security frameworks, and develop a cybersecurity risk assessment methodology for medical devices. Our approach is essentially the application of a Preliminary Hazards Analysis study, customized to cybersecurity considerations. We illustrate this methodology using a typical, but hypothetical, medical device.

3:20 PM - 4:00 PM

Afternoon Break and Exhibits

Room: Grand Ballroom

4:00 PM - 5:00 PM

HBSE AND INTERLOCK SCHEMES The interlock model and its parameters

Room: Aldrin & Crossfield

HBSE AND INTERLOCK SCHEMES The interlock model and its parameters

Richard Nute (IEEE Product Safety Engineering Society & Richard Nute Product Safety Consultant, USA)

Interlocks are complex safety devices. Models have not been used in specifying requirements for interlocks. This paper uses models to show that an interlock scheme has two actuators and either three or two modes to control the interlocked space. Finally, this paper analyzes the insulation between the hazardous electrical energy source and the interlocked space.

China New CCC Regulations for 2015

Room: Armstrong

China New CCC Regulations for 2015

Thomas Ha (G&M Compliance, Inc., USA)

It has been 10 years since the China Compulsory Certification (CCC) scheme has been implemented. CCC certification scheme started in 2004. CNCA recently reviewed and evaluated the entire CCC certification process. After the review was completed, an updated CCC policy was established for CCC certification. This presentation provides a thorough discussion on the new changes that may impact manufacturers globally.

ProductDNA: Traceability for Compliance & Market Access

Room: Garros

ProductDNA: Traceability for Compliance & Market Access

Rakesh Vazirani (TUV Rheinland, Hong Kong)

a. Problem Statement As our world gears up co-exist more sustainably with our environment, our industries are facing several environmental directives governing global trade. Adherence to these requirements is a must for businesses operating globally in order to avoid the risk of noncompliance and an exclusion from their markets of choice. b. Objectives Exercising due diligence to support safety requirements and ensuring design for environmental compliance requires that organizations capture detailed information to link the supply network with smart safety and sustainability metrics. c. Procedures A digital database Platform is essential that gives manufacturers and their supply chain visibility of their products' compliance status against constantly changing environmental requirements, thus supporting their endeavor of proactive design for compliance. A quality management system must drill all the way down to the chemical-substances in a Bill Of Materials (BOM) - to reveal the compliance risk buried in parts and formulas. Enhanced digital traceability of Product components and compliance analysis against environmental regulations means, hazardous substances can be easily eliminated and costly recalls can be avoided. The underlying data set must be extendable that captures Supplementary Traceability information such as ProductMiles, Energy Usage, Water Usage, Packaging Material Information.

Towards a Logic-Based Extension of a Relational Software Tool for Coherent Technical Documentation of Medical Devices

Room: Lindbergh

Towards a Logic-Based Extension of a Relational Software Tool for Coherent Technical Documentation of Medical Devices

Tobias Lueddemann and Jonas Schiebl (Technical University of Munich, Germany); Daniel Roppenecker (Technische Universität München, Germany); Franziska Klein (Technical University of Munich, Germany); Tim C Lueth (Technische Universität München, Germany)

This work presents a novel software tool for generation of coherent technical documentation. It is based on a relational database system serving as knowledge base incorporating information from the medical device directive and various harmonized standards such as ISO 14971. In order to achieve increased consistency among sections of documentation for medical devices a concept for formal description of technical documentation and an additional logic-based system is presented.

5:00 PM - 6:00 PM

Chapter and Technical Committee Updates

Room: Grand Ballroom

7:00 AM - 8:00 AM

Speaker Breakfast

Room: 1

On the day of your presentation, please join us for a special Speaker Breakfast. Breakfast will be available from 7:00 AM - 8:00 AM.

8:00 AM - 9:00 AM

A Critical Review on China Toys Safety Standards: GB6675- 2014

Room: Aldrin & Crossfield

A Critical Review on China Toys Safety Standards: GB6675-2014

Shu Lun Mak and Hing Keung Lau (The Open University of Hong Kong, Hong Kong)

China is one of fastest developing countries. Its Gross domestic product (GDP) was US9.24 trillion in 2013. Due to the high population, many worldwide international toys manufacturers came to sell their products in China. The Standardization Administration of the People's Republic of China (SAC) just published the new China National Toy Safety Standard on May 2014. Although the new standard benchmarked against the international toy safety standards and involved expertise in China, some popular products are still not covered by this new edition and the product certification scheme. The manufacturer may sell some unsafe products in China without any limitation.

EOL Test: Friend or Foe? Challenges with Testing Lithium Ion Batteries in a Manufacturing Environment

Room: Armstrong

EOL Test: Friend or Foe? Challenges with Testing Lithium Ion Batteries in a Manufacturing Environment

Bradley Willard (Zebra Technologies, USA)

Testing the electronic safety protection circuit of a Lithium Ion battery pack in a manufacturing environment is more difficult compared to testing in a laboratory environment. The high-speed nature of factory test creates several challenges that must be addressed prior to production start-up. Those challenges include: 1) not damaging the Lithium ion cell(s), 2) not damaging the battery protection circuit, 3) measuring the protection circuit trip points with reasonable accuracy, and 4) achieving a fast test time. This presentation will review various techniques that can be used to address these unique challenges.

Product Safety Program Planning - From Prescriptive to Hazard-Based Safety

Room: Garros

Product Safety Program Planning - From Prescriptive to Hazard-Based Safety

Oscar Overton, Jr. (Lexmark International, Inc., USA)

The goal of a product safety program is to eliminate mishaps. To accomplish this goal we must design to eliminate energy hazards or reduce the probability of uncontrolled energy release to zero. In reality, neither of these ideals can be realized. Therefore, it is incumbent on product safety engineering to identify the energy sources, determine the energy transfer mechanisms, and establish adequate control, thereby minimizing the risk of a mishap. To be most effective, this effort cannot be ad hoc, but it must be accomplished in a planned process. Unfortunately, because of the nature of prescriptive standards, this ad hoc approach is more the rule than the exception. The advent of hazard-based safety standards reveals that a planned product safety program is essential. This paper presents the rudiments of a Product Safety Planning Program. It explains the basics of a risk assessment process and presents a product safety program outline that can be tailored to each product development project.

USB Port and Power Delivery

Room: Lindbergh

USB Port and Power Delivery

Fan He (UL, LLC, USA)

This paper discusses the interoperability between the computer USB port and handheld devices including power banks, cell phones and tablets. According to USB power delivery standard, a USB2.0 port can supply a maximum current of 0.5A at 5V [1] and a USB3.0 port can supply a maximum current of 0.9A at 5V [2], but the test results indicate that some of the handheld devices can draw 2.5A or more current through their USB ports depending on the design. (There are other requirements and standards specifically addressing USB product safety, but this paper focuses on interoperability related to USB power delivery standards.) Some consumers have reported damages to their computers when charging power banks through the computer USB port. And therefore it is beneficial to investigate if overloading is an issue. This paper provides an overview of the computer USB port power management and handheld device power management. This paper also proposes a solution based on the test results and circuit analysis.

9:10 AM - 10:10 AM

UL 61800-5-1 Drive Safety Standard

Room: Aldrin & Crossfield

UL 61800-5-1 Drive Safety Standard

Seth Carlton and Matt Mollen (UL LLC, USA)

The requirements for safety in regards to electric shock and fire for adjustable speed motor drives have historically been different between the US and European countries, which have required the UL 508C standard for safety and the IEC/EN 61800-5-1 standard for safety, respectively. This has caused undue complications for design and compliance engineers that work for companies which manufacture drives for the global market. They must be knowledgeable of two different sets of safety requirements in order to design and test a drive intended to be sold and installed in US and Europe. Starting several years ago, the US took a significant step towards resolving this issue by beginning development of a new UL standard for drives that would harmonize with the IEC/EN standard. The outcome of this work was UL 61800-5-1, published in 2012. UL 61800-5-1 is a standard that is harmonized with the IEC/EN 61800-5-1 standard, adopting many IEC/EN requirements for the US that were different from requirements in the legacy UL 508C standard. The standard does still contain national differences which either modify or add to certain IEC/EN requirements. These national differences are primarily due to US installation requirements. The result is one standard containing all safety requirements for the US and Europe (and other countries requiring compliance to IEC 61800-5-1). The standard offers a much simpler path for engineers to reduce the safety requirements of multiple countries to a single set of requirements for global market access. This is a presentation without Full Paper describing at a high level the advantages of this standard for manufacturers and certification staff, the technical requirements, and UL's transition plan from the old standard to the new.

Child Safety - Button or Coin Batteries

Room: Armstrong

Child Safety - Button or Coin Batteries

Paul W Robinson (IBM Australia, Australia)

This presentation discusses risks to children from ingesting or swallowing lithium button batteries (cells). It covers the hazards, injury modes, treatment, worldwide injury and death statistics, preventative measures, and reviews what international and other standards are attempting to do about it.

Product Compliance Management - A Tool Box to Comply with Legal Obligations

Room: Garros

Product Compliance Management – A Tool Box to Comply with Legal Obligations

Michael Loerzer (Globalnorm GmbH, Germany)

To be able to place products, as for example household appliances, medical devices, toys, machinery or products of the information and communication technology, on respective markets, the manufacturer or the importer of the products has to be aware of the regulatory frameworks as well as the generally accepted rules of technology and has to continually fulfill these throughout the planned product life cycle. Absolute condition for these requirements is information about the locally applicable market approval requirements for the relevant product category. Only a person who has that information in the individual stages of the manufacturing process reduces possible risks which can occur with the provision of non-compliant products on the markets. These include liability risks for the management or arising expenses for the product recall, damage to the image or losses in sales which can arise because of a ban on sales. In so far information and thus resulting knowledge on the one hand and product compliance management on the other hand are closely connected with one another. The presentation shows possible solutions regarding an efficient requirements management system in conjunction with specific processes

and the required regulatory intelligence of a company.

Application of HBSE to the fire risk of clothes dryers

Room: Lindbergh

Application of HBSE to the fire risk of clothes dryers

Suzanne Smyth (4580 Weaver Pkwy & Exponent Failure Analysis Associates, USA); Delmar "Trey" Morrison andBrenton Cox (Exponent, USA)

Hazard Based Safety Engineering is applied to the fire risk of electric clothes dryers. A brief overview of the basics of HBSE and clothes dryer operation will be presented. The thermal transfer model in HBSE is modified to address ignition of materials commonly found in dryers and extended to cover fire spread. Techniques for addressing fire risk in clothes dryers will be discussed.

10:10 AM - 10:40 AM

Coffee Break

Room: Grand Ballroom

10:40 AM - 11:40 AM

NFPA 70E Standard for Electrical Safety in the Workplace - 2015 Edition

Room: Aldrin & Crossfield

NFPA 70E Standard for Electrical Safety in the Workplace - 2015 Edition

David Dini (UL LLC, USA)

NFPA 70E® Standard for Electrical Safety in the Workplace – 2015 Edition On average in the U.S., one person is electrocuted in the workplace every working day, and over 2,000 workers are sent to burn centers each year with electrical-related burn injuries. This burn hazard is most often the result of an accidental arc flash experienced by an employee working on or near energized electrical equipment. NFPA 70E is the premier standard for electrical safety in the workplace in the U.S. It was first established in the 1970s by an NFPA technical committee to assist OSHA in applying provisions of the Occupational Safety and Health Act of 1970. The purpose of this standard is to provide a practical safe working area for employees relative to the hazards arising from the use of electricity. The current edition of NFPA 70E is the 2015 edition, which was issued during the summer of 2014. Product safety specialists are often involved with the inspection and testing of energized electrical equipment, and this activity is addressed by the scope of NFPA 70E. This presentation by the chair of the NFPA 70E technical committee on electrical safety in the workplace covers the basic principles of this important Standard from the standpoint of the product safety specialist. The presentation also covers aspects of the IEEE/NFPA Arc Flash Collaborative Research Project, a multi-year, multi-million dollar project in support of research and testing to better understand the arc flash phenomena as it relates to the IEEE 1584 Guide for Performing Arc-Flash Hazard Calculations.

New Approaches to Safe Ventilation of Equipment Containing Lead Acid and NiCd Batteries

Room: Armstrong

Presenter: Don GiesIn recent years, there has been a series of violent explosions involving telecommunication equipment containing lead acid batteries installed in environmentally-sealed outdoor enclosures. A common occurrence with these explosions has been that the manufacturer of the equipment declared compliance with IEC 60950-1 and IEC 60950-22, First Edition, and used battery de-gassing tubes as the sole means of ventilating otherwise environmentally-sealed cabinets. New procedures in IEC 62368-1, IEC 60950-22, Second Edition, and Telcordia Standard GR-487-CORE, Issue 4 have been developed to eliminate this risk of explosion. These procedures apply to both lead-acid and NiCd battery technologies, each known for producing explosive gas as a byproduct of electrolysis. This paper provides a review of lead-acid and NiCd battery technology, a review of known incidents of explosions, and describes the new safety requirements intended for assuring adequate ventilation for equipment containing lead-acid or NiCd batteries.

Team Engagement in the Product Compliance Process - Which Teams Should Be Engaged and Why?

Room: Garros

Team Engagement in the Product Compliance Process -Which Teams Should Be Engaged and Why?

Dennis W Bartelt (360 Compliance Partners & Go Global Compliance Inc., USA); Peter Merguerian (President Go Global Compliance Inc, USA)

The paper provides a perspective as viewed from an organizational standpoint and the importance of having the right teams engaged upfront in the product compliance process. The lack of organization participation, partial activity, or incorrect ownership can be a serious risk to the overall product performance and its compliance to regulations, standards or other key business criteria. The presentation notes the different business groups that need to be included in the product compliance process and the main touch points of some, their roles and how they relate to other team's functions. The presentation is an overview of the program Process Link ™, developed by the authors to assist industry in dealing with organizational challenges associated with maintaining robust product compliance programs. It discusses the high level basis and operating themes as well as examples. Process Link ™ is a program that most compliance officers can develop on their own to identify team engagement risks. It is an interview based program where key leaders of the various teams are asked a series of questions, the responses of which are compared, contrasted and scored against other team's responses. Depending on the answers to these questions gaps on team engagement, roles and responsibilities are identified. Not all of the 30 plus teams will be discussed in the presentation due to time constraints but all attendees will receive a listing of the teams and a sample set of Q&A.

Programmable Logic Controller Software Hazard Analysis Using Fault Tree Analysis

Room: Lindbergh

Programmable Logic Controller Software Hazard Analysis Using Fault Tree Analysis

Dae-Won Chung (Honam University, Korea)

we propose a method of programmable logic controller (PLC) software hazard analysis using fault tree analysis to determine software safety requirements for critical safety systems; to detect software logic errors; and to determine multiple failure sequences, involving different parts of the PLC system (hardware, human, and software), which can lead to hazards; and to guide in the selection of critical run-time checks. This method may be also be used to guide validation testing in order to check and find software vulnerabilities. The interfaces of the software parts of the fault tree can be examined to determine appropriate test input data and appropriate simulation states and events.

12:40 PM - 1:40 PM

Assessing Hazards of Systems vs. Products: Case Study of RoofMounted Photovoltaic Panels and Fire Testing to ANSI/UL 1703

Room: Aldrin & Crossfield

Assessing Hazards of Systems vs. Products: Case Study of Roof-Mounted Photovoltaic Panels and Fire Testing to ANSI/UL 1703

Gregory Allen (Intertek, USA)

For more than a decade, manufacturers of flat-plate photovoltaic modules and panels have had products tested and certified to the ANSI/UL 1703 standard. However, following recent lessons learned about performance characteristics, impact on, and interaction with their host roof structures in the event of a fire, the regulations for fire resistance testing within ANSI/UL 1703 have been updated for the sale of PV products in California as of January 1, 2015 and for all states and other countries by January 1, 2016. Changes to the fire rating testing and classification requirements within updated ANSI/UL 1703 (2013 revision) are new standards and testing procedures that no longer base the subsequent fire rating on the PV module but rather on the combined "system rating" as defined by the racking/mounting and PV module type (which is largely determined by the construction materials) as well as the roof covering. This change will require manufacturers to incorporate new and different testing procedures or to potentially re-test previously tested products. During this presentation Intertek will provide a greater understanding of recent changes to the fire resistance portion of Standard ANSI/UL 1703, why these changes were deemed necessary, and best practices for manufacturers to ensure compliance. Intertek will discuss how the requirements have evolved to date, what we expect for the future, and other areas where considering in situ factors may be recommended for safety and hazard assessment.

Battery Certification For Large Format Applications

Room: Armstrong

Battery Certification For Large Format Applications

Stephen McVay (Intertek, USA)

Certification Options for Stationary and Grid-tied Energy Storage Systems As the Electric Vehicle and renewable energy fields have gained traction in global markets, new large format battery and energy storage systems are already under development. These systems provide multiple certification and compliance challenges. Systems may

be modular in nature, built-on-site and to a custom specification, or may incorporate novel energy storage systems, beyond lead acid and lithium-ion batteries. Additionally, grid-interaction requires inverter circuits and compliance with IEEE 1547 for distributed energy. This discussion reviews the core standards and certification processes for mass production as well as demonstration or custom-built systems. Topics include modular system, full certification and field label processes, for both the energy storage portion and grid-tied components of such systems.

When do wearable electronics become medical devices?

Room: Garros

When do wearable electronics become medical devices?

Ted Eckert (Microsoft Corporation, USA)

Wearable fitness trackers have evolved significantly from basic pedometers to wearable devices that can measure heart rate and other biometric parameters. There are a growing number of associated software applications that allow the user to interpret and analyze the data the device collects. The FDA is starting to take a closer look at these devices to determine which if any are considered a medical device in the eyes of the law. This panel discussion will cover which attributes of the hardware, software and marketing material determine whether a wearable fitness device requires FDA approval.

Product Safety Testing Using Induced Corona

Room: Lindbergh

Presenter: Don GiesExperiments described in this paper show corona initiated between a transformer windings using a hi-pot tester set to AC voltage output, detected with both a spectrum analyzer and a small magnetic loop and with an audio microphone. To the power transmission industry, corona is a cause of power loss and is an interference nuisance for control and communication electronics. Also, it is understood that dielectric-voltage withstand testing (electric strength testing, or hi-pot testing) is the industry norm for determining the adequacy of insulation systems in most electrical products. For reliable operation in a smart-grid environment, all power transformers not only should have dielectric withstanding capability, but also should not produce corona. But can corona detection be used as alternate tool for testing insulation strength, such as for high voltage transformers that might be found in smart-grid applications? This paper explains the phenomenon of corona, presents experiments performed for detecting induced corona, and discusses potential benefits for corona detecting in insulating materials.

1:50 PM - 2:50 PM

Global Certification Requirements for Grid Connectivity: Renewables, Backup Power, and Energy Storage

Room: Armstrong

Global Certification Requirements for Grid Connectivity: Renewables, Backup Power, and Energy Storage

Haiwen (Howard) Liu (Intertek, USA)

New and ongoing developments in grid connectivity have led to multiple updates in global and national certifications and standards for these systems. Renewable sources, as well as more traditional generator systems are further being coupled with multiple energy storage systems to create new energy distribution and backup power systems at the residential, commercial and grid level. As these newer systems may either standalone or interact with the greater electrical grid system, it is critical to understand the safety and utility requirements for the local regions. Additionally, custom-built, prototype or demonstration system create additional challenges as they require customized certification planning. This discussion compares and contrasts the various safety and grid connectivity requirements and alternatives to traditional full certification processes.

When do wearable electronics become medical devices? - Continued

Room: Garros

Functional Safety: An Introduction to Theories, Standards & Applications

Room: Lindbergh

Functional Safety: An Introduction to Theories, Standards & Applications

Erik Reynolds (Intertek, USA)

Functional safety is the use of electronic and/or other types of systems to reduce and mitigate risk for a process or activity. Typically accomplished through equipment with sensory, logic, and acting elements, functional safety is applicable to all industries and is increasingly in demand as manufacturers and end users look to further mitigate risk. This requires the reliability of supplied components, as well as knowledge of failure modes of said components. The development, creation, implementation, and operation of a quality functional safety system requires comprehension of regulatory standards, planning and design elements, risks and hazards, management plans, safety integrity levels (or, SILs), failure modes and effects analysis, and more, and also includes designated responsibility for personnel as well as rigorous documentation. In this presentation, industry and academic experts will discuss how risks, hazards, and safety are quantified and evaluated for various industries and their processes in regard to functional safety. They will discuss how those evaluations, as well as regulatory standards, help determine and impose safety management plans for a process or activity, and illustrate how the functional safety process fits into a manufacturing and product's life cycles, as well as how it can assist with the quality of a product and ensure better process performance.