Program

Sun, May 13, 2018

3:00pm

Registration
3:00pm - 6:00pm, May 13
Bayshore Foyer

Mon, May 14, 2018

7:00am

Speaker Breakfast
7:00am - 8:00am, May 14
San Carlos

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

Registration
7:00am - 5:00pm, May 14
Bayshore Foyer

7:30am

Continental Breakfast, Networking & Exhibits
7:30am - 8:00am, May 14
Bayshore Ballroom

8:00am

Opening Plenary, Exhibits and Networking, Keynote: Dr. Nancy Leveson
8:00am - 9:20am, May 14
Bayshore Ballroom

About Dr. Nancy Leveson

Dr. Nancy Leveson is Professor of Aeronautics and Astronautics at MIT. She has been working in the field of system safety for 37 years and supervises research in system engineering, hazard analysis, accident analysis, human-automation interaction, management of safety-critical projects, and safety culture. Her latest book, Engineering a Safer World, was published in 2012.

Abstract"Building Safety (and Security) into Your Products"

To be cost-effective, safety must be built into products from the beginning. In this talk I will describe a new, more powerful approach to safety based on systems theory that can be used in the early product concept analysis. The analysis method, called STPA (System-Theoretic Process Analysis) is being used successfully on hundreds of products in most industries around the world.

STPA works for hardware, software, human-automation interaction, and management/operations aspects of safety. It also applies to cyber-security.

Speaker:

Nancy Leveson
MIT

9:20am

Transition/ Networking
9:20am - 9:30am, May 14

9:30am

Compliance 101: The basic requirements for any product
9:30am - 10:30am, May 14
San Jose Ballroom

Compliance 101 Track

John will take you through a product from the plug to the circuit boards inside explaining the common requirements and testing for any product. You'll learn what flame ratings are required for different polymeric parts, how to find and choose the correct UL Recognized Components, fixes for non-compliant creepage and clearances, tips for how to pass strain relief testing and get an understanding of all the common tests - input, temperature, Dielectric Withstand, mechanical abuse and abnormal operation testing.

Speaker:

John Allen
President, Product Safety Consulting

Army Artillery Munition Warhead Explosive Fill Risk Analysis

9:30am - 10:30am, May 14

Santa Clara

Innovation & Emerging Technologies Track

Military grade energetics are, by design, required to operate under extreme conditions. As such, warheads in a munition must demonstrate a high level of structural integrity in order to ensure safe and reliable operation by the Warfighter. In this example which involved an artillery munition, a systematic analytics-driven approach was executed which synthesized physical test data results with probabilistic analysis, non-destructive evaluation, modeling and simulation, and comprehensive risk analysis tools in order to determine the probability of a catastrophic event. Once the severity, probability of detection, occurrence, were synthesized, a model was built to determine the risk of a catastrophic event during firing which then accounts for defect growth occurring as a result of rough-handling. This comprehensive analysis provided a defensible, credible, and interactive snapshot of risk while allowing for a transparent assessment of contribution to risk of the various inputs through sensitivity analyses. This paper will illustrate intersection of product safety, reliability, systems-safety policy, and analytics, and highlight the impact of a holistic multidisciplinary approach. The benefits of this rigorous assessment included quantifying risk to the user, supporting effective decision-making, improving resultant safety and reliability of the munition, and supporting triage and prioritization of future Non-Destructive Evaluation (NDE) screening efforts by identifying at-risk subpopulations.

Speaker:

K

Kevin Singer
US Army ARDEC

D

Douglas Ray
US Army ARDEC

IEC 60601-1-2, 4th Ed. What do I need to do before submitting to the test lab?

9:30am - 10:30am, May 14

San Juan

Medical Track

While the collateral standard IEC 60601-1-2, 4th Ed does change some of the test values, other changes in the standard place an additional responsibility on the manufacturer. This additional responsibility can lead to delays when submitting to the test lab. We need to understand the additional responsibilities, discuss the impact and determine the best steps forward to prevent delays in testing. Addressing these new items up front, can ensure the testing is conducted correctly the first time. To address these additional responsibilities of the manufacturer, we need to discuss the following topics: the role of Risk Management from the standpoint of IEC 60601-1-2, instruction for use and development of the test plan. We will discuss each of the items to allow the manufacturer to better prepare for the

testing.

Speaker:

James Benscoter
UL LLC

Paul D. Evers
Senior Staff Engineer, UL

TCO Certified for Manufacturers
9:30am - 10:30am, May 14
Monterey/Carmel Room

Environmental and Energy Regulation

TCO Certified is an international third party sustainability certification for IT products. By choosing TCO Certified computers, displays and other devices, businesses and organizations around the world are able to help meet environmental and social challenges associated with electronics.

Speaker:

Sören Enholm
CEO, TCO Development

10:30am

Transition/ Networking
10:30am - 10:40am, May 14

10:40am

Global Market Access Overview
10:40am - 11:40am, May 14
San Jose Ballroom

Compliance 101

Navigating the regulatory landscape of global markets is a complex and challenging task.

During this seminar you will learn about the Global Market Access process to help you prepare and effectively navigate global markets. This includes an overview of regulations and processes, understanding legal vs. market driven requirements, test report recognition vs. testing in-country and maintenance of certifications. In addition, we will review the top 10 challenges manufacturer's face when processing international approvals. Join us for this high level overview with a goal to help define market place variants and avoid challenges in your global market access strategy.

Speaker:

N

Nicole Tatum
UL LLC

The Internet of Things- Impacts on Regulatory Issues
10:40am - 11:40am, May 14
Santa Clara

Innovation & Emerging Technologies

The proliferation of connected devices raises some regulatory issues around the world that must be addressed in the near future. Besides the usual concerns of spectral efficiency and interference, issues such as device and data security become crucial societal questions. This means that there will be increase regulatory emphasis on these matters.

Speaker:

Tom Tidwell
Director Nemko Direct for Telecom, Nemko USA

EPEAT Registration for Updated IEEE Standards & Green Electronics Council
10:40am - 11:40am, May 14
Monterey/Carmel Room

Environmental and Energy Regulation

EPEAT Registration for Updated IEEE Standards

Speaker:

Lindsay Fernandez-Salvador
EPEAT Operations Senior Manager, Green Electronics Council

3 Ways to Simplify Medical Device Testing- IEC/ UL 60601-1
10:40am - 11:40am, May 14
San Juan

Medical

Speaker:

Bishan Patel
Application Engineer, Ikonix USA

Anthony Arroyo
Application Engineer, Ikonix USA

11:40am

Lunch, Exhibits and Networking
11:40am - 1:10pm, May 14
Bayshore Ballroom

1:10pm

Managing Product Safety Knowledge
1:10pm - 2:10pm, May 14
San Jose Ballroom

Compliance 101

Product safety is a delightful profession that many of us, frankly, fell into. The broad range of knowledge that enables good product safety engineering can be daunting to practitioners and managers alike. This talk provides, via a case study, a method for identifying and capturing your company's product safety knowledge needs so you can provide robust product safety support and develop yourself professionally.

Speaker:

Mike Sherman
Product Safety and Compliance Engineer, Graco

The Route of Third- Party Testing in Secure Industrial Internet of Things (IIoT) Compliance- Hazardous Locations, Functional Safety& Cybersecurity

1:10pm - 2:10pm, May 14

Santa Clara

Innovation & Emerging Technologies

The Industrial Internet of Things (IIoT) is well on its way to becoming perhaps the most significant of all the 'industrial revolutions' to date and the most complex. With some projections claiming a 300% increase in IoT-ready devices in just the next 4 years (some 22.5 billion by 2021), and other forecasts suggesting that IIoT investment will make up as much as 40% of some organizations' capex budgets, the Internet of Things in the Industrial space is already well and truly here. The major benefits of IIoT are well known - efficiency & reliability gains, coupled with the ability to record big data for remote analysis. Yet, the challenges and opportunities that IIoT brings in the quest for protecting lives requires an equal focus, particularly when you consider how IIoT will be incorporated into a Hazardous Location (explosive atmosphere). Here, there are a number of elements to consider, including continued hazardous location safety compliance, functional safety assurance and cybersecurity protocols. The convergence of information technology (IT) operational technology (OT) networks, has tremendously increased the risk of cyberattacks that may affect safety, reliability and availability. Modern control systems are no longer isolated but are part of a larger connected infrastructure that can offer significant cost savings but also cybersecurity concerns. Security risks associated with integrating, modifying or maintaining a controller in process can impact overall safety and security. This changes the risk profile that should be considered when designing and/or integrating components in the systems. Often, little consideration is made to their security requirements due to cost constraints. Vendors, system integrators and asset owners face challenges in keeping their systems secure including technical expertise and privacy concerns. The integrators, asset owners and facility managers need cybersecurity assurance when selecting potential hardware and software-based solutions. These solution should be specifically designed and formally evaluated to identify and prevent cybersecurity threats in industrial environments. During this presentation we will uncover: 1. Challenges & risks in IIoT - covering Hazardous Locations, Functional Safety and Cybersecurity 2. Steps to limit the likelihood of such incidents and their impact 3. Keys to third-party evaluation and testing 4. Steps to successful attestation and certification of connected devices

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Speaker:

Matt Jakuc
Global Business Manager - Cybersecurity, CSA Group

IEC 60601-1-2 4th Edition EMC and RMF

1:10pm - 2:10pm, May 14

San Juan

Environmental and Energy Regulation

Repeat of the presentation on IEC 60601-1-2 4th edition with a focus on RMF requirements for EMC This topic is a repeat but is very timely with the upcoming transition at the end of

2018

Speaker:

Nicholas Abbondante
EMC Chief Engineer, Intertek

EU RoHS directive: challenges deriving from exemption rules and IEC 63000 (EN 50581) Eva S. Hink; Marcos Medalla

1:10pm - 2:10pm, May 14

Monterey/Carmel Room

Environmental and Energy Regulation

CE Marking as the proof of RoHS compliance requires manufacturers of Electrical and Electronic Equipment (EEE) to ensure and document the compliance of every single part or material used in the product before being placed on the EU market. Ongoing communication and exchange of information with the entire supply chain, recurring risk-assessments, and reliability are essential in order to set your mind at rest after signing the EU-declaration of conformity. As the list of exemptions is constantly reviewed and several changes are expected in the next years, manufacturers have to be prepared to react to changes and to define their compliance status in a timely manner. Apart from that, the IEC 63000 standard requires detailed information in case exemptions apply to the product. Information about applied exemptions is still not visible enough in the supply chain. Although there is a slight trend towards full material declaration, there are still too many gaps when it comes to significant and compliance-relevant data. The presentation outlines the challenges that manufacturers face when working on technical documentation for compliance with EU RoHS and IEC 63000. Furthermore, it provides a summary and recommendations on how to retrieve required information, focus on exemptions and to support suppliers in enhancing the quality of their compliance data.

Speaker:

E

Eva S. Hink
iPoint

M

Marcos Medalla
iPoint

2:10pm

Transition/ Networking
2:10pm - 2:20pm, May 14

2:20pm

The US Consumer Product Safety Commission says: Stop Using Organohalogens
2:20pm - 3:20pm, May 14
Monterey/Carmel Room

Environmental & Energy Regulation Track

In September 2017, the US Consumer Product Safety Commission issued guidance advising manufacturers to stop using organohalogen flame retardants in plastic electronics enclosures to achieve fire safety requirements. This presentation will explore * the rationale behind this guidance (which they intend to turn into a regulatory requirement), * examples of organohalogens used in enclosures today as well as their environmental and human health-related toxicity, * a case study demonstrating how flame retardants were avoided entirely in a television enclosure, * the impact of decisions like this on the practice of product safety * why the normal approach to product safety has put the electronics industry in this position by a lack of oversight of chemical toxicity safety * What manufacturers, and the industry at large, can do to improve the environmental and human health safety performance of its products

Speaker:

Michael Kirschner
President/Manager, Design Chain Associates, LLC

The New FCC Supplier's Declaration of Conformity Approval Process
2:20pm - 3:20pm, May 14
San Jose Ballroom

Compliance 101

A presentation going over the updated FCC approval process.

Speaker:

Nicholas Abbondante
EMC Chief Engineer, Intertek

An Evaluation of the Safety Standards of E/E/PES Systems with regards to Information Consistency and Enhancements Proposals

2:20pm - 3:20pm, May 14
Santa Clara

Innovation & Emerging Technologies

This paper makes an evaluation of the safety standards of electrical/electronic/programmable electronic safety-related systems (E/E/PES) with regards to consistency of the information provided in these standards and their applicability. It provides open discussion and proposals for essential moot questions utilizing experiences gained in various safety-critical projects in long years, especially in the railway industry. IEC 61508 and CENELEC EN 50126, 50128 and 50129 are used as safety standards in this study.

Speaker:

E

Ersin Hasan Dogruguven
ASELSAN

İlker Üstoğlu
Yildiz Technical University

Risk Management Challenges in Medical Application Platforms
2:20pm - 3:20pm, May 14
San Juan

Medical

BEST PAPER AWARD NOMINEE

Medical devices and systems are increasingly being built using interoperability and platform approaches. Work in the standards community is laying the foundations for safety, security, and risk management approaches for "systems of systems" of medical devices built using "medical application platforms" (MAP). A MAP is a safety- and security- critical real-time computing platform for (a) integrating heterogeneous devices, medical IT systems, and information displays via a communication infrastructure and (b) hosting application programs ("apps") that provide medical utility via the ability to both acquire information from and update/control integrated devices, IT systems, and displays. Risk management, including performing component-level and system-level hazard analyses, is very challenging in this context because activities are spread across different organizations and across different component roles including infrastructure components, conventional medical devices, and software-based application logic. In this paper, we give an overview of risk management challenges associated with building interoperable medical systems using medical application platforms. The presented is framed in terms of ISO 14971 -- the primary medical device risk management standard. In particular, we take each part of the ISO 14971 risk management process and describe how we believe the risk management process should be extended to address interoperable medical systems. This work is funded in part by the National Science Foundation's FDA Scholar-in-Residence program and a Phase II SBIR from the US Army Medical Research and Materiel Command (USAMRMC).

Speaker:

John Hatcliff
Professor, Kansas State University

Eugene Y. Vasserman
Associate Professor, Kansas State University

Todd Carpenter
Chief Engineer - Systems and Architecture, Adventium Labs

Rand Whillock
Senior Principal Research Scientist, Adventium Labs

3:20pm

Afternoon Break, Exhibits and Networking
3:20pm - 3:50pm, May 14
Bayshore Ballroom

3:50pm

Global RoHS
3:50pm - 4:50pm, May 14
San Jose Ballroom

Compliance 101 Track and

Environmental & Energy Regulation Track

Speaker:

Kenneth Stanvick
Intertek

African Wireless Compliance
3:50pm - 4:50pm, May 14
Santa Clara

EMC and Wireless Track

Africa is the world's largest continent, with 51 countries, and includes many of the worlds fastest-developing economies. While most are still in the early stages of developing comprehensive electrical and electronic product requirements, all have frequency spectrum regulatory agencies, with required compliance criteria for wireless and telecom communications devices. This presentation is designed to help understand these requirements, along with information on the best practices for entering these markets.

Speaker:

Mark Maynard
American Certification Body, Inc.

Medical Devices and Usability Engineering Process
3:50pm - 4:50pm, May 14
San Juan

Compliance 101 Track

Standards that are referenced in IEC 60601-1 Edition 3 Amendment 1 (IEC 60601-1:2012) What you need to know about Usability Engineering Process Human Factors and Usability Integrating Risk Management and Usability Challenges/Pitfalss for Medical Device Manufacturers

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Speaker:

Arathi Sundaresan
TUV Rheinland of North America, Inc.

As Easy as One Two Three
3:50pm - 4:50pm, May 14
Monterey/Carmel Room

Safety Science & HBSE Track

IEC 62368-1 defines three energy levels for each type of hazard. This presentation covers the basic energy levels with a brief overview of the limits within the standard. The presentation covers the three types of users and what protection is required between these users and each energy level. The presentation also gives information on what is considered an injury under the standard for each type of hazard. The hazard types covered include electrical, power, thermal, radiation and physical hazards.

Speaker:

Ted Eckert
Regulatory Compliance Engineer, Microsoft

4:50pm

Transition/ Networking
4:50pm - 5:00pm, May 14

5:00pm

Global Market Access: A Proactive Approach to Compliance
5:00pm - 6:00pm, May 14
San Jose Ballroom

Compliance 101

Discussion topics include: 1. Determine the need for Global Market Access 2. Knowing your regulatory authorities 3. Planning for testing to minimize the need for re-testing 4. Documentation considerations 5. Regulatory Model number 6. Factory Inspections 7. Local Representatives 8. Leveraging existing test reports 9. Helpful tools

Speaker:

Theresa Glenna
Global Market Access, Senior Project Manager, TUV SUD America

Cybersecurity: Is your product really "safe" if you haven't fully considered it?
5:00pm - 6:00pm, May 14
San Juan

Medical

Hardly a day goes by that we don't hear about a new vulnerability. Testing and certification has long been considered the safety baseline for all electronic devices, but most of these standards do not explicitly address cybersecurity. In this presentation we will look at the current state of options, as well as how these may tie to existing standards. We will delve into published cybersecurity standards, as well as draft guidance from the FDA. This presentation will have some medical device specific information, but will include valuable information for all types electronic products.

Speaker:

Naysahn Saeed
CSA Group

Experiments of DC Human Body Resistance I: Equipment, Setup and Contact Materials
5:00pm - 6:00pm, May 14
Monterey/Carmel Room

BEST PAPER AWARD NOMINEE

Safety Science & HBSE Track

Direct Current (DC) applications have become more prevalent in recent years, primarily due to the increased usage of renewable energy and energy storage systems. A review of the existing safety standards and other literature shows that there is limited experimental data on DC human body resistance. In particular, no information was found by the authors describing the repeatability of DC body impedance and the effect of contact material and other variables. The experimental work described here investigated DC human body resistance and the effects of electrode contact material, wet or dry conditions of the skin, and the repeatability of body impedance for a given set of test conditions. Three male adult volunteers participated in this study; each volunteer completed twenty sets of experiments, with each set including four different combinations of test conditions. The results show that the electrode material has an influence on the measured body impedance when the voltage was less than 15 V, supporting the supposition that the observed nonohmic behavior is attributable to Schottky effects. The variability of the tests (measured by the use of the coefficient of variance) is higher at lower voltage and drops as the voltage increases. Wet conditions were found to provide more consistent test results than dry conditions. Due to the improved measurement consistency and its lowered impedance relative to dry conditions, data under wet conditions are preferred for further analysis.

Speaker:

Hai Jiang
Senior Research Engineer, UL

Paul Brazis
UL LLC

Radio Equipment Directive (RED) Updates for Wireless and Similar Products
5:00pm - 5:50pm, May 14
Santa Clara

EMC and Wireless Track

Radio Equipment Directive (RED)Updates for Wireless and Similar Products Jack Black and Bill Stumpf D.L.S. Electronic Systems, Inc. Wheeling, IL The EU enacted formal legislation that

withdrew the Radio and Telecommunications Terminal Equipment (RTTE) Directive 1995/5/EC and replaced it with the Radio Equipment Directive, 2014/53/EU, or RED. This new directive, went into law effective June 13, 2017, after a one year transition. This new directive incorporates several changes related to the scope, standards, and inclusion of safety and performance requirements, The EU will no longer accept a Declaration of Conformity that referenced the RTTE Directive, and all products placed on the market or into use on the EU market must show the RED as the applicable referenced Directive for CE Marking and entrance into the EU marketplace. Amateur radio products, and radio kits, airborne electronics, marine electronics covered under the Marine Equipment Directive 96/98/EC, airborne type products found in Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council (2), and custom built experimental equipment are not included in this directive, and referenced in Annex 1. The RED identifies wireless products that fall under the definition of equipment that intentionally emits or receives radio waves for the purpose of radio communication or radio determination, which makes use of the radio spectrum. This includes any transceiver, transmitter, receiver or product which contains a radio communication or radio determination function. Terminal equipment that does not incorporate any wireless feature, transmitter, or receiver, which was under the scope of the old RTTE directive, is not under the RED, and falls under the EMC directive, along with the Low Voltage Directives. An electrical/electronic product which contains a radio function becomes a radio product in its entirety and therefore must comply with the RED. Consequently, if a manufacturer incorporates radio equipment into a non-radio product, then the product must be evaluated to determine if the incorporated radio equipment is compliant with the RED as installed in the finished product while the finished product is in operation. The rational for this is that the radio may affect the radiated, conducted or immunity characteristics of the host product, and conversely the host product may influence the functionality, radiated, conducted or immunity characteristics of the radio product. Additionally the RED now incorporates formal requirements for conditions found in the Low Voltage & Electromagnetic Compatibility Directives. It also identifies the need to test products for safety that were at one time outside the scope of the Low voltage directive, such as battery operated devices, but not require safety compliance as the low voltage exemptions have been removed, and most electric devices with the wireless capabilities enabled will need to meet these safety provisions. Manufacturers are required to establish a risk assessment to determine operational and performance characteristics that are to monitored and confirmed, and to show risk elevations. Many of the wireless standards that were used to show compliance under the RTTE directive and either no longer applicable, or have also been withdrawn in association with the new RED. The traditional way to show compliance is to test a product to Harmonized Standards, which offers a presumption of conformity with the Essential Requirements of the Directive for the product. The list of applicable standards are published in the EU official journal, and are easily located http://ec.europa.eu/growth/sectors/electrical-engineering/red-directive_en The standards are published by ETSI and CENELEC, and can be located http://www.etsi.org/technologies-clusters/technologies/regulation-legislation/red. Many of these standard incorporate operational and performance characteristics as part of the testing process. After having incorporated a radio product, a manufacturer may elect to reuse the results of a previous EMC Directive or Low Voltage Directive assessment already carried out on their product. If so, the published guide ETSI EG 203 367 provides direction on the reuse of previous assessments based upon Harmonized Standards relevant to radio equipment under either the EMC Directive or the LVD for example. Additionally, the safety portions of the RED include those for RF exposure, those areas will need to be addressed as well. This analysis should include compliance of the combined product including evaluation of the conformity assessment already carried out on the radio product to determine if any additional testing is

necessary. This transitional assessment can determine if there is a need to repeat the entire conformity assessment already carried out by the manufacturer of the radio equipment or not . It is vey important to make sure that current standard revisions are used when performing this assessment. Involvement of a Notified Body may be needed where non-harmonized standards, nonpublished standards, Harmonized standards are used in part, or standards prior to effective date are used to show compliance with Article 3.2 of the Directive, and a EU-type examination certificate shall be issued that will allow for CE Marking of the product. It is up to the manufacturer to provide the notified body the information needed to determine if the essential requirements are met, and confirm compliance with the EU-type examination certificate. The manufacturer is wholly responsible for the conformity of the product to all applicable EU requirements. This responsibility applies whether the product was designed and manufactured by the manufacturer, or is merely being placed on the market under the manufacturer's name or trademark, and the manufacturer's technical file should include any reports, conclusions, the risk assessment analysis and any technical documents relevant for compliance with the Essential Requirements. These technical documents should include design, manufacture and operation of the radio equipment (reference Annex V of the RED). This technical file must be completed at the time of placing the product on the market, as it may be requested for examination by EU market surveillance authorities, including any transitional or gap analysis. A detailed list is found in Annex V of the RED. The manufacturer must prepare, provide, and have available a Declaration of Conformity (DoC). The DoC must be made available to the authorities of each Member State and must be translated into the language or languages required by the Member State in which the product will be marketed. The manufacturer may wait to translate the DoC into the different languages until requested by the authorities of the particular Member State. If so, a simplified DoC in each language will usually suffice. Additional information can be found in Annex VI of the RED. Standards not listed under the RED may also apply and therefore should be listed on the DoC. For example, a household appliance with a radio function becomes subject to compliance under the RED, but compliance with EN 55014-1 and EN 55014-2 must still be considered as part of the compliance assessment of the appliance product. Similarly, additional EU directives may apply to a product integrating a radio. An example would be a machine subject to the Machinery Directive. In this case, RED standards and Machinery Directive standards, such as 60204-1 apply to the final product, and the Machinery Directive and the associated standard used would also be listed on the DoC. The RTTE Directive is now withdrawn, and the RED directive is applicable. Any product incorporating a radio automatically becomes a radio product subject to the requirements of the RED. Therefore, the DoC should reference the RED and the Harmonized Standards used to assess compliance with the Essential Requirements of the RED. The DOC should not reference the EMC Directive or the LVD, since they no longer apply to combined equipment, but should reference the all the standards that were used to provide the presumption of conformity to the essential requirements .

Speaker:

Jack Black
Business Development Manager, DLS Electronic Systems, Inc

6:00pm

Exhibitor Reception
6:00pm - 7:30pm, May 14
Donner/Siskiyou/Cascade Ballroom

Tue, May 15, 2018

7:00am

Speaker Breakfast
7:00am - 8:00am, May 15
San Carlos

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

Registration
7:00am - 6:00pm, May 15
Bayshore Foyer

7:30am

Continental Breakfast, Networking & Exhibits
7:30am - 8:00am, May 15
Bayshore Ballroom

8:00am

Keynote Speaker: Necia Werner
8:00am - 9:00am, May 15
Bayshore Ballroom

About Dr. Necia Werner

Necia Werner is Associate Teaching Professor of English at Carnegie Mellon University, Vice President of the IEEE Professional Communication Society (PCS), and the PCS Coordinator for IEEE Women in Engineering. Her research interests include developing new methods for blending learning sciences and technology-enhanced learning tools in writing education for STEM students. At Carnegie Mellon, Werner directs the undergraduate writing programs in professional and technical communication, and teaches courses and workshops on proposal writing, oral presentation, technical writing, public communication of research, and engineering communication. Werner holds degrees in English and Psychology from the

University of Wisconsin-Madison, and a PhD in Rhetoric from Carnegie Mellon University.

Speaker:

Necia Werner
Carnegie Mellon University

9:00am

Transition/Networking
9:00am - 9:10am, May 15

9:10am

Global Hazardous Locations 101
9:10am - 10:10am, May 15
San Jose Ballroom

Global Hazardous Locations

Participants will learn about the latest requirements for electrical products intended for use in or relating to hazardous locations (explosive atmospheres). Whether it's Classes, Divisions or Zones, this session can help you design your products for compliance to the proper atmospheric classification, while providing you with greater worldwide market access. Get the answers to your hazardous locations questions from leaders in standards development. Topics include: · What are hazardous locations? · Classifying hazardous locations - Types of explosive atmospheres - Likelihood the atmosphere is present - Ignition-related properties of the atmosphere - Maximum surface temperature · Protection techniques · Standards

Speaker:

John Chambers
Engineering Team Leader , UL, LLC

Russia & the Eurasian Economic Union Compliance
9:10am - 10:10am, May 15
Santa Clara

Global Hazardous Locations Track

An overview of the EMC, Product Safety, and Wireless compliance requirements for the five countries of the Eurasian Economic Union (EEU). The EEU is an economic cooperative

founded in 2010, modeled after the European Union (EU), and currently consists of the five countries of Russia, Armenia, Belarus, Kazakhstan, and Kyrgyzstan.

Speaker:

Mark Maynard
American Certification Body, Inc.

Product Safety Improvements- Legal Ramifications
9:10am - 10:10am, May 15
Monterey/Carmel Room

Speaker:

K

Kenneth Ross
Bowman & Brooke

T

Ted Dorenkamp
Bowman and Brooke

The Development of Proficiency Testing Programme for Electrical and Mechanical Safety Tests
9:10am - 10:10am, May 15
San Jose Ballroom

Global Regulations & Compliance Management Track

The laboratory accreditation is essential for most consumer product testing providers. In the current laboratory accreditation criteria, interlaboratory correlation study or proficiency testing is one of the mandatory requirements. Proficiency testing can help to find out the weakness and potential errors sources of measurement in the testing providers. However, there is a problem of lack of electrical and mechanical proficiency testing programme in Hong Kong and South China region. This paper aimed to explain the development process of a proficiency testing programme that is suitable for electrical and mechanical safety tests. The process tested for homogeneity and stability of specimen will also be discussed in this paper.

Speaker:

Shu-lun Mak
Assistant Professor, The Open University of Hong Kong, Hong Kong

10:10am

Awards Ceremony, Coffee Break, Exhibiting and Networking
10:10am - 10:50am, May 15
Bayshore Ballroom

10:45am

North American Division 2 Certification in 5 Easy Steps
10:45am - 11:45am, May 15
San Jose Ballroom

Global Hazardous Locations

Are you a manufacturer of certified electrical equipment for use in general industrial (ordinary locations) applications? Would you like to expand your market options to include Division 2 hazardous locations (explosive atmosphere) applications? Obtaining Division 2 certification is easier than you may have thought. Learn about the five key design features that can significantly simplify your certification process: 1. External interconnection means 2. Normally non-arcing parts 3. Intended ambient 4. Maximum surface temperatures 5. Environmental considerations

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Speaker:

Paul T. Kelly
UL LLC

Testing of Wireless Devices
10:45am - 11:45am, May 15
Santa Clara

EMC and Wireless Track

This presentation provides an overview of test requirements for common wireless devices such as Bluetooth devices, Wi-Fi devices, etc. With this understanding, applicants can ensure test samples are appropriately prepared for compliance testing, the first and most important step toward regulatory approval.

Speaker:

G

Grace Lin
Intertek

Component Part Manufacturers vs. OEM- What are the Legal and Practical Duties?
10:45am - 11:45am, May 15
Monterey/Carmel Room

Legal Track

Speaker:

T

Ted Dorenkamp
Bowman and Brooke

K

Kenneth Ross
Bowman & Brooke

CCC regulations for Household and similar appliance
10:45am - 11:45am, May 15
San Jose Ballroom

Global Regulations & Compliance Management Track

This presentation will introduce the regulations of CCC certification for household and similar appliance including CCC certification process, series application, factory inspection requirements, use of factory's own test facilities, factory classification rules from ISCCC, certification mode selection, etc.

Speaker:

A

Aiying He
Partner

Paul Wang
Board of Directors, IEEE-Product Safety Engineering Society

11:45am

Lunch, Exhibits and Networking

11:45am - 1:10pm, May 15
Bayshore Ballroom

1:10pm

HazLoc certifications in 90 days (or less)... a piece of cake
1:10pm - 2:10pm, May 15
San Jose Ballroom

Global Hazardous Locations

Frustrated by the amount of time it takes to get your hazardous location certifications? Is management always blaming you for the delay? Do the agencies have you "over a barrel"? No Worries...you're not alone. Lets explore what this certification stuff is all about. This presentation will help demystify the certification and testing process and put the control back in your court.

Speaker:

G

Gary Kozinski
Baker Hughes

Kiss- EMC 2018
1:10pm - 2:10pm, May 15
Santa Clara

EMC and Wireless Track

How to get products to pass on the first trip to the EMC lab with out modification at the lab.

Speaker:

Jim Bacher
Product Compliance Consultant, JB Consulting

Smart and Connected Devices- Smartphones, Connected Devices, Internet of Things and Drones
1:10pm - 2:10pm, May 15
Monterey/Carmel Room

Legal

Speaker:

Ted Dorenkamp
Bowman and Brooke

Susanne Wende
Noerr LLP

South Africa: A closer look at the latest regulatory requirements
1:10pm - 2:10pm, May 15
San Juan

Global Regulations & Compliance Management Track

How to get products to pass on the first trip to the EMC lab with out modification at the lab.

Speaker:

Theresa Glenna
Global Market Access, Senior Project Manager, TUV SUD America

2:10pm

Transition/Networking
2:10pm - 2:20pm, May 15

2:20pm

International Certification for HazLoc Products
2:20pm - 3:20pm, May 15
San Jose Ballroom

Global Hazardous Locations

Demand for HazLoc products is rising all over the world, providing manufacturers in this market with abundant opportunities - but understanding the various national requirements early on in product development is crucial. This presentation focuses on how to obtain international approvals for HazLoc products and outlines requirements for specific countries such as Brazil, Russia, South Korea, China, Taiwan, Japan, and others. While approvals are generally based on the widely accepted IECEx scheme, it's important that manufacturers be aware of national deviations from this scheme and IEC standards in their

target markets - and incorporate those differences during the design stage to save time and money. After this presentation, manufacturers will walk away with a better understanding of global market access and specific country approvals.

Speaker:

P **Polux Sanchez Reyes**
CSA Group

Wireless Compliance for Mexico, Central America and the Caribbean
2:20pm - 3:20pm, May 15
Santa Clara

EMC and Wireless Track

An overview of wireless compliance requirements for Mexico, the ten countries of Central America, and Caribbean nations.

Speaker:

Mark Maynard
American Certification Body, Inc.

Regulatory Update- New Laws and Regulations, Recall Effectiveness and New Directions
2:20pm - 3:20pm, May 15
Monterey/Carmel Room

Legal Track

Speaker:

K **Kenneth Ross**
Bowman & Brooke

S **Susanne Wende**
Noerr LLP

China market access

2:20pm - 3:20pm, May 15
San Juan

Global Regulations & Compliance Management Track

This presentation introduces the regulations and requirements of China market access including customs clearance, CCC certification, SRRC certification for wireless product, NAL license for telecom products, CEL for energy label, RoHS requirement, etc. It will cover general process, documents preparation, technical requirements, tips for fast access of China market, etc.

Speaker:

Paul Wang
Board of Directors, IEEE-Product Safety Engineering Society

3:20pm

Afternoon Social/Exhibits
3:20pm - 3:50pm, May 15

3:45pm

Comparing NEC Division 2 vs IEC Zone 2 Protection Techniques
3:45pm - 4:45pm, May 15
San Jose Ballroom

Global Hazardous Locations

While the risk of ignition and the resulting area classification rules are harmonized between NEC Division 2 hazardous locations and IEC Zone 2 explosive atmospheres, the methods of explosion protection that are permitted in these two areas can be very similar and very different. Understanding these similarities and differences is essential to the effective design of equipment for global installation and use in Division 2 and Zone 2 classified areas. Impacted design features include circuit boards, internal connectors, external plugs and receptacles, switches and relays, and the enclosures in which these features are contained. There are also differences in product quality inspections/audits that will be discussed.

Speaker:

J

John Chambers
Engineering Team Leader , UL, LLC

When Does an Industrial/ Commercial Product Become a Consumer Product and How Can You Prevent it?

3:45pm - 4:45pm, May 15

Monterey/Carmel Room

Legal

Speaker:

K

Kenneth Ross
Bowman & Brooke

S

Susanne Wende
Noerr LLP

Beyond the basics: Save the trauma for when it really counts

3:45pm - 4:45pm, May 15

San Juan

Global Regulations & Compliance Management Track

This presentation is intended to inform of the common pitfalls that hinder the successful Global Market Access launch of your product. We will go into the specific details surrounding the essential considerations that will impact your success. These considerations include: the product type, the markets you intend to sell into, power system considerations, regulatory model numbering scheme, trademark identification, labelling, factory locations, critical components and more; and the importance of having these essential considerations at the 'top of mind' at a very early stage of planning the product launch.

Speaker:

Lars Mellander
Nemko USA

3:50pm

Medical Device EMC Update EN 60601-1-2 4th Edition, Jack Black

3:50pm - 4:50pm, May 15

Santa Clara

Medical Track

EMC and Wireless Track

EN 60601-1-2 4th Edition Medical Device EMC Update Jack Black and Greg Maryniarczyk DLS Electronic Systems, Inc. To show compliance to the EU Medical Device Directive for sales of medical devices in the EU, manufactures must use current revisions of standards, and can no longer show compliance using standards that have been withdrawn. The EMC standard that is most commonly used to show compliance with the Medical Device Directive is EN 60601-1-2: 2007 3rd edition, is being withdrawn effective 12/31/17 and being replaced with EN 60601-1-2: 2015 which is now the 4th edition. This new fourth edition mirrors similar IEC standards that went into effect in 2017. Changes in this standard will greatly effect the test requirements, methodology, and process used to show compliance to the medical device directive. Any medical product placed on the market after the withdrawal date of 12/31/18 using the 3rd edition standard shall be considered non-complaint. Devices already in use or in the marketplace do not have to be removed, only products placed on the market after 12/31/18. There is no grandfather clause for the new standard. The new 4th edition standard identifies different consideration for testing medical devices. This involves the preparation of a risk assessment by the manufacturer, which clearly identifies risks while operating the medical equipment, and this must be included in any formal test plan and processes. The 4th edition standard goes as far as to require that a test plan be provided by the manufacturer. The 4th edition standard also calls out difference intended usage and locations with respect to type of testing needed. This references areas such as home health care, and special environments. Provisions have been made in the 4th edition standard, plus additional references to ancillary standard such as EN 60601-1-11. Most of the requirements for home healthcare devices exceed those for non-homecare devices Many manufacturers are reviewing their products using a transitional or gap analysis, as many of the actual test procedure are the same, but the testining levels and criteria may be different. The tests for emissions are relatively the same as EN 55011 is referenced, and is a currently used standard for radiated and conducted emissions. The operating requirements that are called out in the risk assessment may be more clear or clarified, and additional testing may be required to meet those new operating criteria. The immunity tests have the greatest changes, with practically every immunity test referenced in the old 3rd edition will need to be repeated or replaced with new test data. The test requirements that referenced are as follows, with a very brief explanation as to the extent to the changes: IEC 610000-4-2 ESD Higher Levels IEC 610000-4-3 Radiated Immunity Higher Frequencies/Field Strengths IEC 610000-4-4 Transients Increased Rep Rates IEC 610000-4-5 Surge Additional DC Requirements IEC 610000-4-6 Conducted Immunity 6 Vrms in ISM bands IEC 610000-4-8 Magnetic Field 30 A/m IEC 61000-4-11 Voltage Interruptions Increased Number of Tests These tests are more stringent in most cases, with higher levels of electromagnetic interference involved. Many tests also are specific to a single voltage, and no longer require the minimum and maximum rated voltage requirements found in the 3rd edition. Consideration for higher wireless frequencies are also referenced. Requirements for the declaration of conformity must meet the requirement of the medical device, which went into effect in 2017. Summary The current standards for EMC compliance for medical devices are being withdrawn 12-31-18, and will no longer be considered acceptable for Medical Device Directive Compliance. The 4th edition standards have more emphasis on the manufacturer's knowledge, risk manegement files related for their products, combined with the intended use and location of use. Transitional analysis should be performed to determine what testing needs to be performed to maintain compliance, and the testing must be performed per manufacturers test plan.

Speaker:

Jack Black
Business Development Manager, DLS Electronic Systems, Inc

4:45pm

Transition/Networking
4:45pm - 5:00pm, May 15

5:00pm

Title: TBD
5:00pm - 6:00pm, May 15
San Jose Ballroom

Speaker:

Stefan Mozar
CEO Dynexsys

K

Kao
TBA

Basics of Lightning Protection for Communication Towers
5:00pm - 6:00pm, May 15
Santa Clara

EMC and Wireless Track

Basic introduction in how to protect communications equipment from lightning damage.The same techniques for protecting towers, applies to all buildings whether or not they have towers or antennas. That includes homes and business

Speaker:

Jim Bacher
Product Compliance Consultant, JB Consulting

Harmonizing Normative Organizational Structure and Verification and Validation Concepts for Safety Critical Generic Projects
5:00pm - 6:00pm, May 15
San Juan

Global Regulations & Compliance Management Track

Speaker:

E

Ersin Hasan Dogruguven
ASELSAN

İlker Üstoğlu
Yildiz Technical University

6:00pm

Robotics Demonstration
6:00pm - 7:00pm, May 15
Bayshore Ballroom

7:00pm

Chapter Annual Meeting
7:00pm - 8:00pm, May 15
TBD

The CAM is set for Tuesday at 7pm. If you are a chapter leader – or would like to be one – please join us to share chapter ideas and issues. In the areas where we already have chapters, our members enjoy meeting regularly with fellow product safety and regulatory professionals. IEEE has tremendous resources to help chapters. Our society wants to help you access those resources to build a dynamic program for members.

Want to start a new PSES chapter? We can help guide you with that. As a professional society, we would like all our members to have access to regular chapter meetings. Come to the CAM and help us do it!

Technical Activities Meeting
7:00pm - 8:00pm, May 15
TBD

The Technical Activities General Meeting is set for Tuesday at 7pm. If you are interested in supporting PSES technical activities, please come. The more people who participate the

more we can accomplish as professionals and as a society.

If you are interested in becoming involved in any technical issue, let me know, and we can discuss how you might get involved. Take advantage of this great opportunity for your professional growth!

Wed, May 16, 2018

7:00am

Speaker Breakfast
7:00am - 8:00am, May 16
San Carlos

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

Registration
7:00am - 5:00pm, May 16
Bayshore Foyer

7:30am

Continental Breakfast and Networking
7:30am - 8:00am, May 16
Bayshore Ballroom

8:00am

Primer on Electrical Product Safety
8:00am - 9:00am, May 16
San Jose Ballroom

Compliance 101

Speaker:

Mike Sherman
Product Safety and Compliance Engineer, Graco

Introduction to Electrically-caused Fire
8:00am - 9:00am, May 16
Monterey/Carmel Room

Safety Science & HBSE Track

Electrically-caused fire and fire parameters are defined.

Speaker:

R

Richard Nute
Consultant

Effects of Dropping a Battery Powered Device: a Look at the Separator and Electrodes after Drop Testing
8:00am - 9:00am, May 16
Santa Clara

Energy Storage & Batteries Track

Mobile devices almost invariably experience repeated dropping over their lifetime. Depending on the height of the drop, number of drops, orientation, device covers and contact surfaces, this may or may not manifest itself in visual damage to the device itself. Even when no damage is observed on the device itself, however, damage may occur within the lithium ion battery inside the device. In this talk we examine what is happening inside the battery during such events. Exponent has observed separator pullback or bunching between electrodes after repeated device dropping, resulting in direct exposure of the positive and negative electrodes. Examples of damage observed from such drop testing will be shown along with a discussion of the mechanisms of damage accumulation.

Speaker:

Troy Hayes
Principal Engineer, Exponent

Labeling and Marking Requirements for Telecom and Electrical Products in Latin America
8:00am - 9:00am, May 16
San Juan

EMC and Wireless Tracks

Global Regulations & Compliance Management

Product Labeling is an important part of the Compliance process that directly affects the flow of imported goods into a country. If not done correctly, it can cause shipment delays, increase costs and impact revenue. In this Presentation, we will review the different

requirements for countries that require markings for Telecom and Safety products. Countries included in this review are Argentina, Brazil, Chile, Colombia, Peru, Paraguay and Mexico.

Speaker:

Elizabeth Perrier
CEO, ORBIS Compliance

9:00am

Transition/Networking
9:00am - 9:10am, May 16

9:10am

Compliance 101: electronic shock, touch current
9:10am - 10:10am, May 16
San Jose Ballroom

Compliance 101

This 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. 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.

Speaker:

Peter Perkins
P. E. Perkins PE

IEC 62368-1: Safety of AV/ICT Equipment - Instructional Safeguards in-depth
9:10am - 10:10am, May 16
Monterey/Carmel Room

Safety Science & HBSE Track

IEC 62368-1 is the international standard for safety of audio/video, information and communication technology equipment. One new area addressed in the standard that differs from the legacy standards (IEC 60065 & IEC 60950-1) being replace are the requirements for Instructional Safeguards. Although the definition of an instructional safeguard - instruction invoking specified behavior - is simple, the actual format and details of the instructional safeguards are more involved than manufacturers are used to in the past. However, standardizing the format for instructional safeguards has its advantages, especially in the form of consistent messaging. This presentation looks at the background of instructional safeguards in IEC 62368-1, reviews their common structure via how the standard includes defined elements, and walks through a variety of specific examples.

Speaker:

Thomas Burke
Principal Engineer, Consumer & Enterprise Technology Safety, UL

Certification Challenges for Power Banks
9:10am - 10:10am, May 16
Santa Clara

Energy Storage & Batteries Track

Power banks packs present a unique regulatory and safety certification challenge. Primarily mis-understood is how to define these products: as batteries, chargers, power supplies, or ITE equipment. Product safety standards often address one or several of these product types, but lead to confusion for developers, manufacturers and distributors as to both the regulatory requirements placed on these products as well as the appropriate method to demonstrate product safety. This presentation will discuss various scopes of existing and draft standards as well as applicability of various regulations which may include these devices.

Speaker:

Rich Byczek
Global Director Business Development, Transportation Technologies, Intertek

Navigating Global Compliance in Asia
9:10am - 10:10am, May 16
San Juan

EMC and Wireless Track

Global Regulations & Compliance Management Track

Obtaining approvals in Asia can be a daunting task. What is the difference between CCC & SRRC and PSE & MIC? To find out, join us as we provide an overview of the electrical safety, EMC and wireless approval requirements in China, Japan, S. Korea and Taiwan. For each country and regulation, we will discuss the regulation, key stakeholders, consumer technology products regulated, local representative, sample requirements, approval lead time, factory inspection requirements, certification validity and label requirements. Join us to help you prepare in advance for your next product launch in Asia.

Speaker:

Nicole Tatum
UL LLC

10:10am

Coffee Break and Networking
10:10am - 10:30am, May 16
Bayshore Ballroom

10:30am

Safety Outside the Box
10:30am - 11:30am, May 16
San Jose Ballroom

Compliance 101

Paper will discuss additional requirements that designers and safety professionals may want to consider beyond the base standard for their product based on the environment and user exposure. The example used in this paper is the consideration of toy safety requirements for ITE or CE products when children are likely to be present.

Speaker:

Dan Roman
Colgate-Palmolive Company

Understanding and Investigating Burn Injuries
10:30am - 11:30am, May 16
Monterey/Carmel Room

Safety Science & HBSE

Burn injuries are a common occurrence in industrial settings and everyday life, and often involve consumer products. Despite the prevalence of burn injuries, understanding the burn risks that may accompany industrial processes or commonplace consumer products, as well as investigating these types of injuries, can be a difficult task. The basis for our current scientific understanding of burn injuries is formed by a few landmark studies involving the quantification of burn severity under different thermal exposures. These studies also form the basis for consensus standards (such as ASTM and ISO standards) that provide guidance for assessing the risk of burn injuries. These standards are frequently misinterpreted when used in the context of product safety. Understanding the mechanics of burn injuries, the way in which consensus standards apply or don't apply, and the available tools for evaluating burn hazards are all indispensable to any investigation involving burn injuries. By bringing scientific rigor to the analysis of burn injury hazards, an understanding of the cause of injury becomes clearer. Multiple cases studies will examine typical issues that arise in consumer product safety involving burn injuries and the different tools available to address these issues.

Speaker:

Kenneth Lee
Failure Analysis Engineering Consulting, Senior Engineer, Exponent

Safety, performance and robustness of smartphone systems
10:30am - 11:30am, May 16
Santa Clara

Safety Science & HBSE

Burn injuries are a common occurrence in industrial settings and everyday life, and often involve consumer products. Despite the prevalence of burn injuries, understanding the burn risks that may accompany industrial processes or commonplace consumer products, as well as investigating these types of injuries, can be a difficult task. The basis for our current scientific understanding of burn injuries is formed by a few landmark studies involving the quantification of burn severity under different thermal exposures. These studies also form the basis for consensus standards (such as ASTM and ISO standards) that provide guidance for assessing the risk of burn injuries. These standards are frequently misinterpreted when used in the context of product safety. Understanding the mechanics of burn injuries, the way in which consensus standards apply or don't apply, and the available tools for evaluating burn hazards are all indispensable to any investigation involving burn injuries. By bringing scientific rigor to the analysis of burn injury hazards, an understanding of the cause of injury becomes clearer. Multiple cases studies will examine typical issues that arise in consumer product safety involving burn injuries and the different tools available to address these issues.

Speaker:

Flore Chiang
Principal Engineer (PDE), UL

Certification Schemes for global countries on Electrical safety and Radio approval
10:30am - 11:30am, May 16
San Juan

EMC and Wireless track
Global Regulations & Compliance Management Track

Certification Schemes for global countries on Electrical safety and Radio approval - Example of typical country approval will be discussed in the presentation, audience also has opportunity to ask any questions they may be interested in! This presentation provides an overview of International Approval on electrical safety and Radio Frequency products. On electrical safety, it summarizes the countries in the world how to define their regulatory frame work under ISO/IEC 17067, based on this frame work, how country set up the technical regulation based on international harmonized standards for product compliance; After this presentation, manufacturers should be able to understand all the terms & definition used in the international approval and be prepared for the new market; Meanwhile, presenter also will introduce the test report acceptance in different countries and explore with manufacturers to find the best option for their products tested and report accepted in other countries with minimum rework. Beside the electrical safety certification scheme, this presentation also summarize the methods of international RF approval to 4 types for more than 160 countries in the world, where indicate what testing are necessary & essential and how manufacturer to select an accredited laboratory for the countries they want to market in the most efficient manner. • Electrical Safety international certification schemes: ISO/IEC 17067 Certification Scheme been adopted in the global markets with typical type of below (will summarize countries in the schemes): Scheme 5 Scheme 1, 1b Scheme 2 Others schemes outlined in ISO/IEC 17067 Safety Test report acceptance with typical types of below: CB report/Certificate under CB scheme IEC ILAC test report under ILAC 17025 Test report per national standards where test lab needs national standard accreditation and acceptance by local regulator • Radio and Telecom Global approval in three major types: Route 1. SDoC procedure Route 2: Countries accepting EN or FCC reports for issuing national approval Route 3: National standards established however allow foreign labs to be accredited or MRA lab test report Route 4: National standards established and only national accredited lab for local testing

Speaker:

P

Polux Sanchez Reyes
CSA Group

11:30am

Lunch and Networking
11:30am - 12:00pm, May 16
Bayshore Ballroom

12:00pm

IEC 622368-1 Panel Session
12:00pm - 1:30pm, May 16
Siskiyou

Although available as an IEC standard since 2010, many in the AV & ICT industry have only recently realized the full impact IEC 62368-1 will have on their planning for global product safety certifications in the next few years as the Industry quickly approaches the Standard's formal transition dates - from IEC 60065 & IEC 60950-1 to IEC 62368-1 based standards - in Europe, Canada, the U.S, and elsewhere. As the publication of the Third Edition of IEC 62368-1 is imminent (approx. August 2018), and the first, firm transition dates associated with 62368-1 are only about two years away, **2018 ISPCE** will be a fabulous opportunity to have a **forum** for manufacturers, certifiers, IEC TC108 experts, and other interested parties to share their experiences with the implementation of, and transition to 62368-1, and ask questions critical to strategic business decisions in the next six months and beyond.

At this year's **2018 ISPCE** a special 90-minute **62368-1 Open Forum** will be held for**Registrants,** which will allow for airing of questions on the transition, the application of the Standard, and other aspects of the 62368-1, along with the opportunity for both audience members and a specially-selected Panel to share personal, company and technical committee perspectives. The **Open Forum** will start with a brief update on the latest status of IEC 62368-1 and its national adoptions, plus the latest information on transition schedules. Subsequently, questions both pre-submitted and live (as many as time permits) will be handled, with a variety of the perspectives offered.

As to allow for **Registrants** and Panel Members to best prepare for the **Open Forum,Registrants** for 2018 ISPCE are being offered the opportunity to submit questions in advance of **2018 ISPCE** and the **62368-1 Open Forum.** If you are a **Registrant** and are interested in submitting a question in advance for the **62368-1 Open Forum,** please complete the linked Submission Form and submit via the link below, preferably **by Wednesday, May 9th.**

SUBMIT YOUR QUESTION

Speaker:

R

Rich Pescatore
TBA

Thomas Burke
Principal Engineer, Consumer & Enterprise Technology Safety, UL

Jeff Pasternak
DEG Product Regulatory Business Strategist, Intel Corporation

B

Bob Griffin
IBM

Morten Andersen
Vice President - Certification & Standards, Nemko USA

1:30pm

Transition/Networking
1:30pm - 1:40pm, May 16

1:40pm

Fundamentals of FEMA
1:40pm - 2:40pm, May 16
San Jose Ballroom

Compliance 101 Track

Speaker:

S

Sergio Hernandez
Oculus

Electronic cigarette- a safer alternative to smoking or a health hazard?
1:40pm - 2:40pm, May 16
Santa Clara

Energy Storage & Batteries Track

Speaker:

Flore Chiang
Principal Engineer (PDE), UL

2:40pm

Transition/Networking
2:40pm - 2:50pm, May 16

2:50pm

On Product Warnings: The Latest Standards, Best Practices and Trends
2:50pm - 3:50pm, May 16
San Jose Ballroom

Compliance 101 Track

For companies that manufacture machinery which has potential hazards associated with its transportation, installation, use, maintenance, decommissioning and/or disposal, creating effective product safety labels is critical. This task must be done right. The stakes are too high for this job to be done incorrectly - people's lives and companies' financial well-being are on the line. Safety labels can do one of two things: 1. If properly designed, they can dramatically reduce accidents. This not only improves a product's overall safety record but adds to a company's bottom line by reducing product liability litigation and insurance costs. 2. If poorly designed, needed safety communication does not take place and this can lead to accidents that cause injuries. When such accidents happen, companies spend substantial amounts settling or fighting lawsuits because their products lacked "adequate warnings." With the rise in product liability litigation based on "failure to warn" over the past several decades, product safety labels have become a leading focal point in lawsuits faced by capital equipment manufacturers. This presentation will explore key best practices that are shaping the current "state-of-the-art" for product safety label design focusing on critical product safety label standards, risk assessment, and global warnings that use symbols. This includes how the new occupational safety and health management standard, ISO 45001, drives best practice signage, and the tie-in with up-to-date product safety labels. This insight will help participants formulate an improved safety label strategy that will better protect product users from harm and companies from litigation-related losses.

Speaker:

Derek Eversdyke
Director of Business Development, Clarion Safety Systems

Integration of Industry 4.0 and Assessment Model for Product Safety

2:50pm - 3:50pm, May 16
Monterey/Carmel Room

BEST PAPER AWARD NOMINEE

Safety Science & HBSE

Assessment models are widely applied in new product development process in manufacturing industries to identify potential hazards in the new product development and enhance the core company competence in the consumer product market. The number of product related-accidents has been growing in the past decade. Industry 4.0 is a new concept to increase the product manufacturing efficiency. This paper studies the opportunities of integrating the use of assessment model and Industry 4.0 to improve product safety in new product development process. This paper discusses (i) current assessment models, (ii) current new product development problems, (iii) Industry 4.0 applications, (iv) Integration of assessment model and Industry 4.0, and (vi) two major product-recall cases of consumer products in the US.

Speaker:

Chi Ho Li
The Open University of Hong Kong

Metalized Film Capacitors As Fire Pattern
2:50pm - 3:50pm, May 16
Santa Clara

Forensics Track

NFPA921 defines a fire pattern as a pattern that remains after a fire as a result of a fire. Beyond arc fault mapping very little investigation has been performed or reported on patterns caused by failures in electrical devices or patterns that result in electrical devices that are attacked by fire. The prevalence of polypropylene and polyester metallized capacitors, used as voltage dropping elements in line connected power supplies, increases the significance of recognizing such components after a fire. Fire investigators and engineers would likely find it useful to know whether other electrical or electronic components (other than copper wire) produce and retain fire patterns that indicate whether they were energized when attacked by the fire.

Speaker:

Louis Bilancia
Engineering Systems, Inc.

Risk Assessment of Low Voltage Products LVD Directive 2014/35/EU,Annex III,2

2:50pm - 3:50pm, May 16
San Juan

Global Regulations & Compliance Management Track

A detailed, yet functional overview for risk assessment for ITE equipment. Presentation to include definitions, differences of a risk analyses and risk assessment, the means to show compliance, basic principles of safety integration, tolerable risk and formats/examples of risk assessments. It is the hope that this presentation will give attendees a vital tool that can be used as a solid base and guideline for which a risk assessment can be made.

Speaker:

Lars Mellander
Nemko USA

3:50pm

Transition/Networking
3:50pm - 4:00pm, May 16

4:00pm

Essential Requirements of the Nigerian Information and Communication Equipment Homologation
4:00pm - 5:00pm, May 16
San Jose Ballroom

Compliance 101 Track

Global Market Access Track

The papers breaks down all the requirements for homologation in Nigeria.It expatiates on the role of the telecommunications industry regulator, Nigerian Communications Commission, the power of the NCC as drawn from the Nigerian Communications Acts, The Nigerian Type Approval Regulation, The Nigerian Type Approval guidelines and other regulatory powers as it relates to equipment type approval/homologation. It defines homologation as it is within the jurisdiction of the NCC. The Essential requirements are broken down to the following: The Standards requirements. The adopted standards as it is contained in the European Norms The local exceptional Rules The Need for Declaration of Conformity, Electromagnetic Compatibility Standards, The effective use of Spectrum as required for Nigerian Homologation. The SAR Requirements etc. The step by step procedure is also explained together with challenges that can constitute a constraints to seamless homologation application processing and the solutions discussed. The RED and R&TTE Requirements are also mentioned including homologation for IoTs as future works.

Speaker:

James Kunle Olorundare, SMIEEE
Nigerian Communications Commission (NCC), Nigeria & Bucks New University,

Adebimpe Olorundare
Nigerian Communications Commission (NCC), Nigeria & Bucks New University,

An Automatic RFID Detection based Railway Identification System

4:00pm - 5:00pm, May 16

Monterey/Carmel Room

BEST PAPER AWARD NOMINEE

Safety Science & HBSE Track

Railway safety is a very complicated subject, which is determined by numerous aspects. In Hong Kong, with increasing patronage and traffic density of MTR Railway System, public attention is focused much more on the rail integrity. This paper proposed an automatic RFID detection based railway identification system (RVI) to give the risk assessment to the rail. In the RVI system, RFID detection is applied. In addition, Monte Carlo analysis is applied to select the best position for RFID tags. A trial has considered simulated situation of Hong Kong MTR. The trail involved 8 scenarios, which achieved 89% detection success rate. RVI system helps to enhance the reliability, accuracy and efficiency of remote condition monitoring of rail integrity.

Speaker:

Hongxu Zhu
City University of Hong Kong

Kim Fung Tsang
Associate Professor, City University of Hong Kong

Chung Kit Wu
City University of Hong Kong

Hao Ran Chi
PHD Student, City University of Hong Kong

Probabilistic Safe- Service Life Assessment of US Army Mortar Weapon System
4:00pm - 5:00pm, May 16
Santa Clara

Forensics Track

Speaker:

D

Douglas Ray
US Army ARDEC

Innovative approach to proactive maintenance of regulatory compliance approvals
4:00pm - 5:00pm, May 16
San Juan

Global Regulations & Compliance Management Track

In today's fast moving markets it has become increasingly difficult for companies to efficiently manage change. Adversely affecting their products time to market. Quite often a company's method for addressing NPI including Design Controls, Product Regulatory Compliance, Design History File, and Quality Management end-up taking a singular and separate approach. Managing separate solutions can be inefficient, leading to human and translation errors causing loss of time, costing your project, costing your company. What if the same data (or object) created to support how you manufacture your product, could also be used to track and drive the effectivity of your regulatory compliance approvals... The presentation will speak to, and demonstrate an enterprise business solution that is an innovative and efficient approach to Product Realization through Product Lifecycle Management that simultaneously proactively drives timely maintenance of regulatory compliance approvals.

Speaker:

R

Roger Martin
Founder/President, Compliance Dynamics, LLC

P

Pat Dugan
Compliance Dynamics

5:00pm

Closing Session, Prize Raffle and Wrap-Up

5:00pm - 5:20pm, May 16
Siskiyou