

VIRTUAL **ISPCE** 2021

IEEE International Symposium on
Product Compliance Engineering

Virtual Symposium | September 20-24, 2021



ISPCE 2021 SYMPOSIUM PROGRAM

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WELCOME MESSAGE

Hello, I am Banshi Patel, Vice President of Conferences for the Product Safety Engineering Society (PSES). I am also the General Chair for our Flagship conference, ISPCE 2021 – virtual. I would like to welcome you all to our new platform for virtual attendees for ISPCE 2021. We held our first ever virtual event 'SPCE 2020' in November of 2020. We are forging ahead and learning and planning future events as the conditions allow.

And just to share, we have our ISPCE flagship event of PSES (usually in May), and then SPCE (regional Event) in November. We will keep you posted about future events. We are tentatively planning ISPCE 2022 as FACE-2-FACE event in San Diego California in May 2022. We also have other regional events like ISPCE Asia, San Diego Safety Summit (SSSD), etc. and more details are to come for 2022.

We are in a new normal. COVID-19 has created a 'new normal' that has turned our lives upside down. Here is the new reality, COVID-19 is still with us and will be for the foreseeable future. Again in 2021 we had to postpone our FACE-2-FACE conference (ISPCE-2021) and cancel our SPCE-2021 (regional conference). To have one combined event for 2021 we moved the symposium to September (for 2021 only). This is our first time for the virtual conference for main event ISPCE 2021. We will have our regional two-day event (ISPCE-ASIA 2021) in Taiwan on November 30 and December 1, 2021.

Many of you have attended past ISPCEs and SPCEs. We are continuing to build on the highly regarded technical programs of the past years. If this is your first PSES Event ISPCE 2021, welcome, and I hope this is the start of a new tradition for you. You will hear more about the Product Safety Engineering Society (PSES) from our Current President Stefan Mozar.

Our technical program co-chairs: Grant Schmidbauer and Leszek Langiewicz have prepared another excellent technical program for you. We have almost 70 technical sessions. They include keynote speech, presentations, papers, tutorials, panel discussions and unique presentations. You will surely find just what you need to address your current and future issues. And you'll have the opportunity to learn something about technologies that will come in handy in the future. We want this to be a rich experience for you and a benefit to your company. Welcome... Enjoy the conference!

Banshi Patel

PSES VP of Conferences 2020-2022

General Chair of ISPCE (Virtual) 2021





ISPCE 2021 SYMPOSIUM COMMITTEE

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Compliance 101 /201

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Daren Slee

Global Hazardous Locations

Paul Kelly

Jerilyn Merrill

Global Market Access

Maja Bland

Legal Track

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Medical

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Tom P. Lanzisero

OnRule is a world-leading cloud-based software platform to manage the *product regulatory compliance*. OnRule enables enterprises to ***rapidly launch new products in the global marketplace*** by accelerating the product certification process, streamlining collaboration, and delivering up-to-date global regulatory intelligence.

OnRule organizes the compliance records by products, markets, record types, and record disciplines. It creates SmartCerts™ enabling a ***quick search and secured sharing***; the view-only privileges allow the internal and external stakeholders to have visibility on the compliance status and records.

The notifications of upcoming expirations alert the compliance team, ***prevent stop ship and ship hold***; and enable ***proactive budgeting and allocation of resources***. The ***Standards Update Notifications*** inform the enterprises of upcoming changes in the standards and identify the impacted products and records portfolio.

KEYNOTE SPEAKER

Monday, September 20th

Time: 8:00 AM PDT



Jim Bender

North Texas IEEE Product Safety Engineering Society


Incorporating best practices to leverage extended benefits of an effective development and manufacturing certification compliance program.

Abstract

An effective certification development and manufacturing process yields far more benefits than just satisfying NRTL obligations. Developing and implementing a comprehensive product safety certification compliance process taking into account key factors can avoid both needless and costly production delays while influencing a safer product.

This keynote presentation will provide a high-level overview of benefits, importance and examples of three key areas:

1. Specifying design criteria of safety critical components and subassemblies;
2. Recognizing how critical a comprehensive component level procurement specification is to assure an uninterrupted supply chain;
3. Designing components beyond minimum end-product safety certification requirements.



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Assent is the leading supply chain data management solution for the world's top durable goods manufacturers. Shaped by regulatory experts and more than a decade of customer success, our full-service platform provides actionable visibility into multi-tiered supply chains, right down to the part level. This allows you to easily navigate regulatory changes and increase the sustainability of your sourcing and production. We work in three main areas including Product Compliance for regulations like REACH and RoHS; Corporate Social Responsibility for topics such as Conflict Minerals and Human Slavery; and Vendor Management for things like Trade Classification & Origin and Vendor Risk.



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Nemko is your complete source for compliance testing, certification and worldwide market access. Nemko provides one local point of contact for all major market certifications using our Nemko Direct network. Nemko offers EMC, Wireless, Electrical Safety, Field Evaluation/Special Inspection and Environmental testing and certification services, to meet the most complex compliance needs. To ensure success within design-to-deployment phase, Nemko also offers "pre-compliance" reliability testing with our team of experienced engineers.

Our global network of certified laboratories can provide US and Canadian NRTL Safety certification, as well as CB certification for wide variety of wide scope of products and standards. Nemko stands out as a certification body (TCB) that provides certifications for the US, Canada, Taiwan, Hong Kong and Japan. As a leader in global market access, Nemko offers international telecom and type approval certifications for more than 150 countries. With 24 locations worldwide, experienced international staff, and personalized service, Nemko is strategically positioned to provide on time testing, inspection and certification support. Choose Scandinavian trust and visit our website at nemko.com more information.



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ORBIS Compliance is a strategic partner to manufacturers around the world looking for in-depth regulatory knowledge, and dependable and reliable execution of their product compliance strategy for Latin America and Asia.

ORBIS is industry-recognized for being able to “Solve the problems that others can’t.” ORBIS’ engineering and legal experts have in-depth, technical and regulatory knowledge in the telecom, safety, energy efficiency, battery, medical and environmental fields. The hallmark of our culture is accurate execution and accelerated in- country testing and product certifications in the Latin American, Caribbean and Asian regions.

Our time-to-market strategy is fast, and attributed to our direct relationships with regulatory agencies. ORBIS’ mission is driven by our clients’ need to succeed with their regulatory needs.



UL

As the global safety science leader, UL provides the expertise, insights and services necessary to solve critical business challenges. We help our customers achieve their safety, security and sustainability goals, meet quality and performance expectations, manage risk and achieve regulatory compliance.

In the course of our work we meet extraordinary people whose companies are having an extraordinary impact on the world and creating the future. UL’s rigorous scientific processes, experience and solutions empower our customers to innovate fearlessly and drive positive change.

We never stop working for a safer world and our offerings continue to evolve with advancements in science and technology. We provide testing, inspection and certification (TIC), training, advisory and risk management services, decision-making tools and intelligence to help our customers, based in more than 100 countries, meet important business objectives.



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Nemko is a leading supplier of international certificates for electrical and electronic equipment. We have test expertise in medical equipment, household products, lighting products, radio and telecom, IT, maritime, oil and gas. Nemko was among the first in the world to provide market access services and have helped some of the world's largest companies to get their products out across the globe. We have our own businesses in 12 countries in Europe, North America and Asia. The global network is supplemented by several strategic alliances and partnership.

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The company is owned by the foundation NEMKO, which is a private, independent foundation for that purpose to work for sustainability, the environment and safety production, sale and use of electricity equipment.

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MONDAY, SEPTEMBER 20, 2021

All time are listed in PDT (UTC -7)

7:45 AM – 8:00 AM	Opening Session		
8:00 AM - 8:50 AM	Keynote Speaker – Jim Bender – Zoom 1		
8:50 AM – 9:00 AM	Transitioning/Networking		
Rooms	Zoom 1	Zoom 2	Zoom 3
9:00 AM - 9:50 AM	PSES Tutorial, Compliance 101 <i>Ken Kapur</i>	Designing Products for Safe Use <i>Michael Wiklund</i>	Appliance and Similar Equipment Testing Standards- EMC Immunity Requirements for Product Safety Compliance under IEC 60335-1 <i>Jack Black</i>
9:50 AM - 10:00 AM	Transitioning/Networking		
10:00 AM - 10:50 AM	PSES Tutorial, Compliance 201 <i>John R Allen</i>	IEC 60601-1-2 ED4.1 What are the changes? <i>Nicholas Abbondante</i>	Modern WIFI Networks <i>Tom Tidwell</i>
10:50 AM - 11:00 AM	Transitioning/Networking		
11:00 AM - 11:30 AM	IEEE PSES corporate sponsorship program		
11:30 AM - 11:50 AM	Exhibitor/Patrons Meet & Greet		
11:50 AM - 12:00 PM	Transitioning/Networking		
12:00 PM - 12:50 PM	PSES Tutorial, Global Market Access <i>Grant Schmidbauer</i>	FDA Pilot - Accreditation Scheme for Conformity Assessment (ASCA) <i>Calvin Luong</i>	The Growth of Open Radio Network <i>Tom Tidwell</i>
12:50 PM - 1:00 PM	Transitioning/Networking		
1:00 PM - 1:50 PM	PSES Tutorial, Panel Discussion <i>Grant Schmidbauer</i> <i>John R Allen</i> <i>Ken Kapur</i>	Conducting Usability Testing to Ensure Medical Device Usability and Use-Safety - A How-to Guide and Demonstration <i>Allison Y. Strohlic</i> <i>Maeve O'Sullivan</i> <i>Tiffany Yang-Train</i>	Brexit and Compliance for the New UKCA Mark <i>Michael Violette</i>
1:50 PM - 2:00 PM	Transitioning/Networking		
2:00 PM - 2:50 PM	Risk Assessment Basics for EMC, LVD and RED Directives <i>Patty Knudsen</i>	The biggest challenge in compliance today, finding good compliance engineers <i>Naysahn Saeed</i>	
2:50 PM - 3:00 PM	Transitioning/Networking		

TUESDAY, SEPTEMBER 21, 2021

All time are listed in PDT (UTC -7)

Rooms	Zoom 1	Zoom 2	Zoom 3
8:00 AM - 8:50 AM	“How to Achieve Global HazLoc Certifications Efficiently and at the Lowest Cost” <i>Behzad Nejad Scott Kiddle</i>	Electric Shock, Compliance 101 <i>Pete Perkins</i>	Changes in European Product Law <i>Dr. Arun Kappor</i>
8:50 AM - 9:00 AM	Transitioning/Networking		
9:00 AM - 9:50 AM	“LED Luminaires - Global Product Safety Compliance” <i>Steven Blais</i>		New legal framework on use of Artificial Intelligence in Europe <i>Dr. Susanne Wende</i>
9:50 AM - 10:00 AM	Transitioning/Networking		
10:00 AM - 10:50 AM	Basics of Lightning Protection for Communication Towers and Buildings <i>Jim Bacher</i>	MEXICO Safety Regulatory Updates NOM-001, NOM-019 and New Testing Requirements <i>Elizabeth Perrier</i>	Panel Discussion “AI and Automation Standards Update US and EU.”
10:50 AM - 11:00 AM	Transitioning/Networking		
11:00 AM - 11:50 AM	Nemko Patron Session		
11:50 AM - 12:00 PM	Transitioning/Networking		
12:00 PM - 12:50 PM	How Pass on the First Trip to the EMC Lab <i>Jim Bacher</i>	BRAZIL New Homologation Model and Regulatory Updates <i>Elizabeth Perrier</i>	Human Factors, Warnings, Instructions in Automation <i>David Cades</i>
11:50 AM - 12:00 PM	Transitioning/Networking		
1:00 PM - 1:50 PM	Leveraging the EU CE Mark for independent 3rd party end-product certifications - Facts and Myths <i>Brunno P Covolan Jim Bender</i>	Global Market Access (GMA+): A Systems Thinking Approach <i>Cedric DSouza</i>	Optional Safety Devices <i>Theodore Dorenkamp</i>

WEDNESDAY, SEPTEMBER 22, 2021

All time are listed in PDT (UTC -7)

Rooms	Zoom 1	Zoom 2	Zoom 3
8:00 AM - 8:50 AM	Protecting against Hazardous Gases & Vapors <i>Jon Miller</i>	UKCA - New Rules for Market Access in Great Britain <i>Gabriella Mazzola</i>	Selection of professionals for product compliance and safety activities <i>Steli Loznen</i>
8:50 AM - 9:00 AM	Transitioning/Networking		
9:00 AM - 9:50 AM	"Challenges in Certifying Skids for Global Hazardous Locations" <i>John Chambers</i>	India BIS and WPC certification <i>Thomas Ha</i>	Patient Safety and Digital Therapy <i>Steli Loznen</i>
9:50 AM - 10:00 AM	Transitioning/Networking		
10:00 AM - 10:50 AM	Assent Patron Session		
10:50 AM - 11:00 PM	Transitioning/Networking		
11:00 AM - 11:50 AM	"Mobile Communication, Computing and Information Technology Equipment for use in Hazardous (Classified) Locations" <i>Ryan Brownlee</i> <i>Dave Burns</i>	Global Market Access for Radio Equipment <i>Hannah Truong</i> <i>Will Birchall</i>	
11:50 AM - 12:00 PM	Transitioning/Networking		
12:00 PM - 12:50 PM		Global RoHS <i>Theresa Glenna</i>	
12:50 PM - 1:00 PM	Transitioning/Networking		
1:00 PM - 1:50 PM	News on Electronic Product Environmental Compliance - Worldwide <i>Aury Hathout</i>	Product Change Regulations and Ongoing Compliance Requirements for Wireless Products - USA, Canada, EU, UK, Japan <i>Vina Kerai</i>	
1:50 PM - 2:00 PM	Transitioning/Networking		

THURSDAY, SEPTEMBER 23, 2021

All time are listed in PDT (UTC -7)

Rooms	Zoom 1	Zoom 2	Zoom 3
8:00 AM - 8:50 AM	Key Changes in the 2020 NEC Affecting Commercial & Industrial Installations <i>Joseph Wages, Jr.</i>	Cybersecurity requirements for IOT devices in Singapore <i>Debora Poon</i>	Electric Shock Hazard Considerations for Fault Managed Power Distribution Technologies <i>Alex Di Sciullo Jones Hai Jiang Randy Ivans</i>
8:50 AM - 9:00 AM	Transitioning/Networking		
9:00 AM - 9:50 AM	"The Importance of Ignition-Protected Components for Hydrocarbon Refrigerants" <i>Krzysztof Rymarski</i>	New Conformity Assessment Procedure for Telecommunication Products in Mexico <i>Patricia Medina</i>	Evaluation of Intelligent and Non-Static Power Sources <i>Peter Perkins Jim Weise</i>
9:50 AM - 10:00 AM	Transitioning/Networking		
10:00 AM - 10:30 AM	IEEE PSES corporate sponsorship program		
10:30 AM - 10:50 AM	Exhibitor/Patrons Meet & Greet		
10:50 AM - 11:00 PM	Transitioning/Networking		
11:00 AM - 11:50 AM	Cell Propagation Trigger Techniques for Thermal Runaway Evaluations <i>Rich Byczek</i>		Book report "The electrical resistance of the human body To technical direct and alternating current" <i>Richard Nute</i>
11:50 AM - 12:00 PM	Transitioning/Networking		
12:00 PM - 12:50 PM	Lithium Battery Thermal Runaway Testing - A view from the End Product <i>John Copeland</i>		Contact Burn Injuries: Experimental Assessments of Short Duration Contact Exposures <i>Francesco Colella Michael Barry James Vickery</i>
12:50 PM - 1:00 PM	Transitioning/Networking		
1:00 PM - 1:50 PM	UL 9540A Cell, Module, Unit test requirements for NFPA 855 compliance <i>Jody Leber</i>		Electrochemical Cell Evidence Collection After Injury, Rupture, or Fire <i>Louis F. Bilancia</i>
1:50 PM - 2:00 PM	Transitioning/Networking		

FRIDAY, SEPTEMBER 24, 2021

All time are listed in PDT (UTC -7)

Rooms	Zoom 1	Zoom 2	Zoom 3
8:00 AM - 9:50 AM	<p>Lithium-ion Cell Failure Mechanisms and Mitigation Strategies</p> <p><i>Keith Beers</i></p>	<p>IoT Cyber security - Hackers are not waiting for regulations</p> <p><i>Geir Horthe</i></p>	<p>Preview: IEC 62368-1, Edition No. 4</p> <p><i>Thomas M Burke</i></p>
8:50 AM - 9:00 AM	Transitioning/Networking		
9:00 AM - 9:50 AM	<p>Analytical Assessments of Thermal Damage in a Perfused Tissue</p> <p><i>Francesco Colella May Yen</i></p>	<p>Wireless Technologies Overview Certifications & China, Russia, Japan case studies</p> <p><i>Maja Bland Di Dai</i></p>	<p>Safety of Service Robots</p> <p><i>Jason R Smith</i></p>
9:50 AM - 10:00 AM	Transitioning/Networking		
10:00 AM - 10:50 AM	UL Patron Session		
10:50 AM - 11:00 AM	Transitioning/Networking		
11:00 AM - 11:50 AM	<p>Influence of an Abnormal Cell on the Impedance Characteristics of Parallel-Connected Lithium-Ion Cells</p> <p><i>David Chao John Lai Alvin Wu Carl Wang</i></p>		<p>Normal, Abnormal & Fault conditions rationalized; providing proper protection in equipment</p> <p><i>Peter Perkins</i></p>
11:50 AM - 12:00 PM	Transitioning/Networking		
12:00 PM - 12:50 PM	<p>Robust Multi-cell Rechargeable Battery Sub-System for Medical Device</p> <p><i>Gang Ji Partha Gomadam Zhi Fang Prabhakar Tamirisa</i></p>		<p>Touch current of DC products; exploring the landscape</p> <p><i>Peter Perkins Joseph McGuire</i></p>
12:50 PM - 1:00 PM	Transitioning/Networking		
1:00 PM - 1:50 PM	<p>UN 38.3 Updates and FAQ</p> <p><i>Rich Byczek</i></p>		<p>Dalziel Revisited application; Analyzing mixed AC/DC waveforms</p> <p><i>Peter Perkins</i></p>
1:50 PM - 2:00 PM	Transitioning/Networking		



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MONDAY, SEPTEMBER 20, 2021

All time are listed in PDT (UTC -7)

Time: 9:00 – 9:50 AM; 10:00 – 10:50 AM; 12:00 – 12:50 PM; 1:00 – 1:50 PM

Compliance 101: PSES Tutorial

Grant Schmidbauer (Nemko USA, Inc., USA)

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

Ken Kapur (Thermo Fisher Scientific, USA)

Abstract: The goal of most companies is not to only design products to be safe, perform according to customer demands, and to meet regulatory requirements, it is to sell those products globally. There are a myriad of technical requirement that must be considered to facilitate the sale of the product.

The plan for this tutorial is to delve into some of the “technical requirements” that products must comply with, including product safety requirements (ie, concepts such as fire, shock, mechanical, temperature, and radiation); and then once your products are compliant, we will discuss the commercialization of the product through obtaining the many country approvals that are needed in order to legally sell the product around the world.

The tutorial is delivered in 4 parts:

1. Compliance 101
2. Compliance 201
3. Global Market Access
4. Panel discussion


This tutorial should be attended by product realization managers, design engineers, test technicians, product regulatory personnel, project managers, marketing personnel, and others interested in learning more about product safety and global market access requirements.

Time: 9:00 – 9:50 AM

Designing Products for Safe Use

Michael Wiklund (Emergo by UL Human Factors Research & Design, USA)

Abstract: Designing for safe use should be the norm within all product development companies. This is true for companies that develop products requiring extensive user interactions and when a use error (i.e., mistake) could lead to serious injury or death. Accordingly, human factors engineering (HFE) should be a normal part of the product development process within a wide range of companies, such as those developing medical products, children’s playthings, industrial equipment, and power tools. Good HFE reliably leads to products that are demonstrably safer, enable users to accomplish tasks, and are satisfying to use as compared to those that were not the focus of HFE. This outcome is good for both manufacturers and consumers, noting that HFE is required in some regulated markets, including perhaps most notably the medical industry. In his presentation, Wiklund's will explain the meaning of "good HFE," claim that the biggest advancement in HFE over the past 25 years is actually its mainstreaming into R&D processes, and share some tips on designing for safe use, drawn from his latest book on the topic.



Time: 9:00 – 9:50 AM

Appliance and Similar Equipment Testing Standards- EMC Immunity Requirements for Product Safety Compliance under IEC 60335-1

Jack Black (DLS Electronic Systems, Inc. & IEEE, USA)

Abstract: "With the increase of appliances equipped with the Internet of Things capabilities, with appliances now in a standby mode, waiting for the wireless operational commands, electronic on/off position, or utilizing an electronic protective control circuit in addition to wireless compliance testing, the need to meet safety standards for wireless and other product safety standards is crucial. When using IEC/EN 60335-1 for compliance testing, additional EMC immunity testing will be needed. These requirements were not applicable unless equipment includes electronic standby mode or safety mode for runaway conditions. Testing parameters may differ from those previously found under the EU EMC Directive, or under the Product Safety requirements found in the Radio Equipment directive, and should be included under the requirements under the Low Voltage Directive.

The concern is that an unsafe condition may occur if the electronic standby mode is interfered with, causing a device to start when not intended, or creating a hazardous condition. These acceptance parameters may not have been considered when performing compliance testing under the EMC requirements found in the harmonized standard IEC/EN 55014-2 for immunity. These tests are required to show compliance to the safety portion of the IEC 60335-1 electrical safety standard, and may not have been considered when testing products for EMC compliance to meet the EMC directive or other electromagnetic testing standard requirements. The LVD directive requires testing, by enabling the standard by mode feature, the safety portion needs to be met."

Time: 10:00 – 10:50 AM

IEC 60601-1-2 ED4.1 What are the changes?

Nicholas Abbondante (Intertek, USA)


Abstract: A presentation on Amendment 1 to the IEC 60601-1-2 ED4.0 medical devices EMC standard.

Time: 10:00 – 10:50 AM

Modern WIFI Networks

Tom Tidwell (Nemko, USA)

Abstract: This presentation will explore the demands of Wireless Local Area Networks and investigate how these demands are being met with new spectrum and technologies such as WIFI6E, Smart Antenna Systems, and mmWave.



Time: 12:00 - 12:50 PM

FDA Pilot - Accreditation Scheme for Conformity Assessment (ASCA)

Calvin Luong (CSA Group, USA)

Abstract: FDA, has received much public feedback, and is now entering the pilot launch for the Accreditation Scheme for Conformity Assessment (ASCA). The ASCA Pilot launched on September 25, 2020. The purpose is to allow those that participate a more streamlined review process for testing data when delivered as part of an FDA submission package by the medical device manufacturer. Under the ASCA Pilot, the FDA grants ASCA Recognition to qualified accreditation bodies to accredit testing laboratories to perform premarket testing for medical device manufacturers. ASCA-Recognized accreditation bodies accredit testing laboratories using the specifications of ISO/IEC 17025 and the ASCA program specifications associated with each FDA-recognized consensus standard and test method in their scope of ASCA recognition. Medical device manufacturers may voluntarily use an ASCA-accredited testing laboratory to conduct testing to be included in premarket submissions to the FDA. By doing so, the manufacturer's submission process would be enhanced, reducing the need of FDA to do a full review of the testing process and decreasing the need for requests of additional information regarding testing methodologies, and evidence when coming from an FDA ASCA program sites. Under the ASCA program key stakeholders (medical device manufacturers and FDA) have a higher level of confidence of the medical device testing which in turn allowing patients receiving a safe and more timely access of medical devices.

Time: 12:00 - 12:50 PM

The Growth of Open Radio Networks

Tom Tidwell (Nemko, USA)

Abstract: The explosion of wirelessly networked devices has placed a demand on network providers to build more flexible and adaptable network infrastructure. This presentation will explore the move toward open radio access networks (ORAN) and dynamic spectrum sharing and the impact on the wireless industry

Time: 1:00 – 1:50 PM

Conducting Usability Testing to Ensure Medical Device Usability and Use-Safety - A How-to Guide and Demonstration


Allison Y. Strochlic (Emergo by UL HFR&D Team, USA)

Maeve O'Sullivan (Emergo by UL HFR&D Team, USA)

Tiffany Yang-Train (Emergo by UL HFR&D Team, USA)

Abstract: "In this engaging session, members of Emergo by UL's Human Factors Research & Design team will conduct a live demonstration of a medical device usability test. You will see a simulated formative usability test designed to identify a device's strengths and opportunities for improvement from a safety, effectiveness, and user-satisfaction standpoint. The team will be testing a device that includes hardware, software, and labeling user interface components - tentatively, a glucose meter with a smartphone-based application that enables users to review specific readings and glucose level trends.

One Emergo team member will serve as the moderator and lead the simulated test session while another role-plays as a test participant and ""thinks aloud,"" sharing their impressions of the product while performing representative device tasks. A third team member, one of Emergo's Research



Directors, will present a brief usability testing ""primer,"" describe key aspects of the product evaluation method, and point out key takeaways during the live demo.

Time: 1:00 – 1:50 PM

Brexit and Compliance for the New UKCA Mark

Michael Violette (Washington Laboratories, Ltd, USA)

Abstract: TBD.

Time: 2:00 – 2:50 PM

The biggest challenge in compliance today, finding good compliance engineers

Naysahn Saeed (CSA Group, USA)

Abstract: Over the past decade and a half, compliance for medical devices has evolved into an entirely different world, with the growing importance of software in medical devices, and the applicability of both risk management standards and usability (human factors) standards, the scope of work facing our modern-day safety/compliance engineer is something quite different to what it was even a decade ago. Where the evaluation of a process and related documentation may have been a small portion of the work in the past, today the tables are turning, requiring new skills and a new approach to product compliance and safety. This presentation will address some of the many challenges facing those involved in the certification process, the new skills required of safety/compliance engineers, and how this affects the way safety agencies and manufacturer's work together and go about certifying products.

Time: 2:00 – 2:50 PM

New Conformity Assessment Procedure for Telecommunication Products in Mexico

Will Birchall (CSA Group, USA)

Abstract: Starting February 25th 2021 a new technical standard IFT-012-2019 for SAR entered in effect Each importer must obtain their own NOM Certification of Compliance (CoC) and IFT approval End product manufacturers customers will no longer be allowed to leverage IFT approvals on modular components and now must test and certify the end product Applicable to products with radio frequency transmitter or transceiver that make use of radio spectrum. Also applicable to radio equipped devices that connect to a telecommunications network in the frequency range from 30 MHz to 6 GHz and that are used

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TUESDAY, SEPTEMBER 21, 2021

Time: 8:00 - 8:50 AM

“How to Achieve Global HazLoc Certifications Efficiently and at the Lowest Cost”

Behzad Nejad (HazCon, Canada)

Scott Kiddle (ABB Inc, USA)

Abstract: "Certification by an impartial third-party or certification agency is an attestation that minimum relevant safety and performance standards have been met. The certification process for electrical products being designed and manufactured for use in hazardous locations is especially stringent because of the associated risk of explosion."

In this presentation, we will review the requirements related to HazLoc products for the following certifications: IECEx, ATEX, CA/US, and UKCA. Then, we will briefly explain the appropriate Ex markings, applicable Standards and protection techniques. This information is essential for manufacturers as they consider in which countries/regions they want to sell their HazLoc products; what certifications are required there; and what HazLoc markings are needed for the final installation location.

Manufacturers of HazLoc products need to be aware of these requirements (and the necessity of compliance) before designing and planning to manufacture such equipment. This presentation will then focus on ways to reduce the time and expense involved in obtaining certification - how to achieve certification efficiently and at the lowest cost. Manufacturers wanting their electrical products to be approved for use in a hazardous location will benefit from the information contained in this presentation."

Time: 8:00 - 8:50 AM

Electric Shock, Compliance 101


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

Abstract: 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 60 years experience in the electronics field.

Time: 8:10 – 8:50 AM

Changes in European Product Law *Dr. Arun Kapoor (Partner, Noerr)*

Abstract: The session will provide an overview on the new legal basis for market surveillance for non-food products in Europe, the new regulations for market surveillance in e-commerce and the extension of the powers of the market surveillance authorities. The session will further give an inside view from the legal practice on the system of notification obligations for non-food products in Europe, notification obligations for b2c and b2b products, best practice and sanction risks. The session will also point to the main changes for economic operators caused by the new EU Machinery Regulation.



Time: 9:00 - 9:50 AM

“LED Luminaires- Global Product Safety Compliance”

Steven Blais (Emerson/Appleton Group)

Abstract: LED Luminaires are rapidly becoming the premier light source in industrial establishments. As such, product safety compliance has become more intensive due to rapid advancements in LED light source technology. This paper presentation will address the product compliance activities and requirements that are enforced by the accredited third-party certification agencies based on consensus product safety standards for both Hazardous Locations and Ordinary Locations usage. Additionally, this paper presentation will address important guidance to the safety stakeholder community on how to verify compliance of an LED Luminaire based on the industrial application and the regional conformity assessment systems that are enforced. This paper presentation is by a manufacturer that has products certified to the several global industrial applications and with the several accredited third-part certification agencies globally.

Time: 9:00 - 9:50 AM

Retail Protocols and CPSC quoting tools

Kason Choi (UL, USA)

Abstract: "Can't avoid selling you consumer products Online in 2021 with the global pandemic you really can't avoid selling a consumer product online. When you start developing or sourcing a product it can be difficult to determine the required product safety requirements. There are tools online to help with this research but you need know how to find it."

Time: 9:00 - 9:50 AM

New legal framework on use of Artificial Intelligence in Europe

Dr. Susanne Wende (Technical University Berlin)


Abstract: This session will provide an overview on the current legal framework on use of AI in electronic devices and provide some guidance on how to minimize legal risks when placing those products on the market in Europe. The session also covers current drafts of legal acts on the use of AI and civil liability in this context.

Time: 11:00 - 11:50 AM

Basics of Lightning Protection for Communication Towers and Buildings

Jim Bacher (JBRC Consulting LLC, USA)

Abstract: Basics of Lightning Protection. Covers what it takes to prevent damage to electronic devices in a building including those buildings with towers.



Time: 11:00 - 11:50 AM

MEXICO Safety Regulatory Updates NOM-001, NOM-019 and New Testing Requirements

Elizabeth Perrier (Product Regulatory Compliance- Latin America & Orbis Compliance LLC, USA)

Abstract: "May 2020 the New NOM-001 Regulatory changes will be implemented. NOM-019 will be published in 2019. ORBIS will provide a full explanation of the New NOM-019, the changes in testing requirements for the several product categories and the window on the impact of NOM-019 publication which will truly change the way products are certified in Mexico.

A interactive session that will allow interactive learning."

Time: 11:00 - 11:50 AM

Panel Discussion "AI and Automation Standards Update US and EU."

Abstract: This session will focus on the ever-evolving US and EU standards with respect to AI and automation. As AI and automation are two rapidly growing technology areas, it is critical to understand the similarly changing regulatory landscape, as well as what might be on the horizon.

Time: 12:00 - 12:50 PM

How Pass on the First Trip to the EMC Lab."

Jim Bacher (JBRC Consulting LLC, USA)

Abstract: This presentation goes into how I successfully had product pass on the first trip to the lab with no modification and 10 or more dB of margin.


Time: 12:00 - 12:50 PM

BRAZIL New Homologation Model and Regulatory Update

Elizabeth Perrier (Product Regulatory Compliance- Latin America & Orbis Compliance LLC, USA)

Abstract: "In November 2019, Anatel officially announced the restructuring of the Homologation systems in Brazil. Product Categories, OCD rules, Testing Requirements all to be changed and implemented in April 2020.

During this presentation, ORBIS will go through the new Homologation system implemented and provide the before and now examples to clearly explain how the new systems works.



Time: 12:00 - 12:50 PM

Human Factors, Warnings, Instructions in Automation

David Cades (Human Factors, Exponent)

Abstract: This session explains the science of warnings, instructions and safety information communication in the context of automation. We will discuss, from a Human Factors perspective, aspects of traditional warnings and instruction communication that will also apply to automated systems as well as discuss some of the nuances to consider when dealing with products and systems that limit access to or remove the human.

Time: 1:00 - 1:50 PM

Leveraging the EU CE Mark for independent 3rd party end-product certifications - Facts and Myths

Brunno P Covolan (Intertek Testing Services, NA, USA)

Jim Bender (Intertek, USA)

Abstract: "Many companies erroneously conflate the familiar European CE Mark to be equivalent to a North American safety certification recognized component approval. Although a CE Marked component or subassembly cannot solely be used to support a North American recognized component certification, it can offer value to both product developers and independent certification laboratories to optimize component selection.

A common but often unknown situation occurs when a product developer desires end product Listing certification based on critical component/subassembly level CE Mark for North American compliance. Even if the CE Mark is provided against a harmonized standard, more often than not this may not be acceptable to 3rd party safety certification laboratories in absence of additional evaluation considerations.

This paper will provide an overview of the importance and benefits of supplementing any CE Mark product safety compliance claim and supporting certification considerations."

Time: 1:00 - 1:50 PM

Global Market Access (GMA+): A Systems Thinking Approach


Cedric DSouza (12 Laboratory Drive & UL LLC, USA)

Abstract: "Today's GMA approaches focus on mandatory markings for products and components, and the risks to market entry when such products and components are non-compliant. However, application of systems thinking can bring several new dimensions into the traditional approach for GMA.

Systems thinking at front end of product-system development cycles and life cycle approach shows that GMA requirements are not a single point in the cycle. But extend beyond market entry, and well into the product-system lifecycle phases. Basically, front end market requirements can be integrated into each step of the design, build, operate and disposal/reuse phases.

Further the presentation shows that there are other sources of critical requirements, than government mandated regulations, that are needed to satisfy product-system lifecycle.

The presentation also dwells on the pacing problem when innovation outpaces regulations and standards, and how the systems decomposition shows a path to successful product-system launches



into new markets."

Time: 1:00 - 1:50 PM

Optional Safety Devices

Theodore Dorenkamp (Partner, Bowman and Brooke, LLP)

Abstract: This session addresses legal risks of offering safety features or enhancements as optional equipment, as well as post-sale product improvement considerations, and how to identify ways to reduce risk. In this session we will look at a few of the key legal cases, rules and duties that guide this analysis.

WEDNESDAY, SEPTEMBER 22, 2021

Time: 8:00 - 8:50 AM

“Protecting against Hazardous Gases & Vapors”

Jon Miller (MSA Innovation LLC)

Abstract: The risk of loss of life and property in a workplace environment can be reduced by proper application of gas detection equipment in a multi-layer protection scheme. Design, installation and use guidelines that are necessary for proper methods of protection can be overlooked which may add risk to industrial processes and facilities. Differing gas type exposures combined with various hazard risks necessitate careful selection of gas detection equipment as a method of protection. Exposure to toxic or combustible gas or a lack of oxygen can be minimized within a localized area and within the facility-wide infrastructure by utilizing the proper gas detection equipment. A risk assessment with consideration to consequence, frequency of potential exposure, and probability of occurrence of the potential hazards can aide in the selection of proper gas detection equipment. The type, quantity, location, positioning as well as many other aspects associated with the gas detection equipment are an essential part of the risk assessment. A systematic method applied in functional safety practice as a preventive action technique can provide a means to establish a multi-layered approach for protection of personnel and property against hazardous gases and vapors.

Time: 8:00 - 8:50 AM

UKCA - New Rules for Market Access in Great Britain

Gabriella Mazzola (Underwriters Laboratories (UL), Italy)

Abstract: On Jan. 31, 2020, the U.K. officially left the EU with a transition period that maintained the status quo until 31 December 2020. After leaving EU, U.K. implemented a new conformity assessment system and a new national conformity marking the UKCA. We will see an overview of all the regulations that are now applicable in UK and will replace definitively the CE marking starting from Jan. 1st, 2022.


Time: 8:00 - 8:50 AM

Selection of professionals for product compliance and safety activities

Steli Loznen (Cert-Global Ltd. & Tel Aviv University, Israel)

Abstract: "In the Product Compliance and Safety Engineering area exist a high demand for skilled professionals, but the market does not have sufficient supply of qualified candidates to fill the gap. Many companies do not have the engineering personnel available who have the knowledge fundamental to perform the required Product Compliance and Safety objectives due to their lack of education and experience needed to perform these. Unfortunately, Product Compliance and Safety is not a top priority among schools of engineering-and the academic sector is not preparing engineering students to support or replace those engineers who are currently involved in Product Compliance and Safety projects.

Selection of professionals for product compliance and safety is the process of choosing the right person



for the right position and at the right time.

This presentation represents a brief introductory tutorial that explains different methods of hiring and how to make effective and efficient utilization of Recruitment and Selection. In addition, it also explains the best recruitment practices for specific requirements."

Time: 9:00 - 9:50 AM

“Challenges in Certifying Skids for Global Hazardous Locations”

John Chambers (UL LLC)

Abstract: Building skids for global hazardous locations? Need to comply with NEC, CEC, ATEX and IECEx Division and Zone certification, installation and inspection requirements? This presentation will explain the applicable requirements under both the Division and Zone systems. Specific focus will include differentiating between Ex equipment and equipment assemblies, identifying any internal sources of release, performing ignition hazard assessments, applying non-electrical requirements, understanding close versus detailed inspections, and compiling the necessary installation documentation.

Time: 9:00 - 9:50 AM

India BIS and WPC certification

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


Abstract: BIS Certification; WPC Certification

Time: 9:00 - 9:50 AM

Patient Safety and Digital Therapy

Steli Loznen (Cert-Global Ltd. & Tel Aviv University, Israel)

Abstract: Focusing on patients' safety represents one of the main principles for management in the sanitary system. Basically, identifying and understanding patients' needs, expectations and protections, represent the essential elements of this principle. Patient Safety is regarded mainly, as the identification and implementation of means to protect patient against unacceptable risk of harm due to the sanitary processes, taking into consideration the quality of the medical act, the communication doctor-patient, healthcare basic safety, medical equipment, efficiency of data used for the medical processes, etc. Technological future in healthcare will integrate an artificial intelligence (AI) component at every level, and the impact of application based on new algorithms can lead to the emerge of important opportunities to increase the patient safety. The capability of such devices to process natural language, to learn constantly, to plan based on fixed or variable parameters and to react in context could lead to an impressive decrease in the number of tasks that are currently performed by the healthcare professionals. Given the huge set of possibilities opened by machine learning, the public health can benefit from significant positive changes regarding the Patient Safety. Using AI, each patient could have a much more customized treatment than the one they receive now, and their monitoring and data analysis could be more precise. Based on the above, the Patient Safety can be established with adequate measures as well as describing and analyzing the situations that could cause harmful situations for patients.



Time: 11:00 - 11:50 AM

“Mobile Communication, Computing and Information Technology Equipment for use in Hazardous (Classified) Locations”

Ryan Brownlee (Pepperl+Fuchs Inc., USA)

Dave Burns (Shell Projects & Technology, USA)

Abstract: The Digitalization efforts taking place in the industrial work place are creating a significant need for thousands to tens-of-thousands of Mobile Communication, Computing and Information Technology Equipment (e.g. tablets, smartphones, heads-up displays and their accessories). To support the digitalization of many if not all operations in plants and manufacturing facilities across the globe, these types of equipment can already be found in use within many industrial processes. This becomes more challenging but more critical in industries like the oil & gas/petrochemical, pharmaceutical, water/waste water, pulp/paper, and general chemical industries due to the fact that many of these have locations within the plant or facility that are identified as hazardous (classified) locations. The hazardous (classified) location identification is due to the presence of flammable liquids, gases or vapors, or the presence of a combustible dust. Any equipment, fixed or mobile, that is used in a hazardous location needs to be properly certified and controlled to assure the needed safety. The increasing demand for digitalization specifically in those industries with hazardous locations require more than just a mobile device identified as industrial or rugged. However, the demand seems to be outpacing knowledge and the standards present in the marketplace. This has resulted in devices deployed into hazardous locations that are not appropriate for use in these locations. Some of this is likely from ignorance; identifying the devices as a non-threat likely due to the fact that we carry them every day generally without any issue, resulting in non-certified devices being used. A second and potentially more serious issue however, is the increasing evidence of "certified" devices placed into the market where the needed information to properly evaluate and manage the device safety is missing or at a minimum drawn into question due to missing relationships between the OEM and the company placing the device into the market. This presentation will examine these issues and provide some possible solutions.

Time: 11:00 - 11:50 AM

Global Market Access for Radio Equipment

Hannah Truong

Will Birchall (CSA Group, Canada)

Abstract: "GMA Radio Approval Introduction
GMA Radio Approvals for 5GHz
Brazil ANATEL Telecommunication Equipment Updates
FCC and ISED Radio Certification
GMA Radio Approval for Medical Equipment"



Consumer drivers: Urbanization, Industrialization, and Higher levels of disposable income.

Commercial drivers: Decarbonization, Efficiency

Governmental Drivers: SDGs, NAP

A) The Challenge > tackling the fastest-growing waste stream in the world > eWaste

B) Policies: Greener Electronics has a NEW best friend > EU Green Deal, and Circular Economy Action Plan

C) Implementation Framework: Integrated approach, including Green Public Procurement, Sustainable Products Initiative

D) Standards & ECO-labels: link for consistent and standardized product evaluation

E) BIG Money: to price financial risk/opportunity thanks to ESG needs addressed by SASB standard, and alliances such as Circular Electronics partnership (cep2030)"

Time: 12:00 - 12:50 PM

Global RoHS

Theresa Glenna (TUV SUD America Inc., USA)

Abstract: Learn about RoHS from a Global Market Access perspective. Several countries have recently implemented RoHS regulations; some of those being Russia (EAEU), UAE, Ukraine, and Taiwan. We will review the requirements, controlled products lists, and important dates.

Time: 1:00 - 1:50 PM

News on Electronic Product Environmental Compliance – Worldwide

Aury Hathout, Canada (211 - 1750 St-Louis & Enviropass, Canada)

Abstract: Product environmental compliance is constantly evolving. Additional requirements have recently affected the Electronics industry, mainly in Europe and the USA: EU RoHS, REACH SVHC and SCIP, US TSCA-BPT.

What is at stake? How to tackle these obligations in a practical way? This what I suggest addressing!"

Time: 1:00 - 1:50 PM

Product Change Regulations and Ongoing Compliance Requirements for Wireless Products - USA, Canada, EU, UK, Japan

Vina Kerai (Nemko, San Diego, CA)

Abstract: "A question I often hear from people making changes to a product whether by hardware component or changing the usage configuration...What am I required to comply with or test, before I can sell my product? The answer to this will vary depending on where the product is being sold, and of course the extent of the change. Product design changes are inevitable and important to the product supply cycle and to meet the ever-growing needs of the marketplace. Though, the rules relating to product changes can often be challenging for manufacturers to navigate and understand due to the differences in the regulatory requirements amongst the various countries where products are sold, the ever-changing rules, and the minimal information presented in the rules and regulations themselves. Considerable knowledge and understanding of the regulations are needed to understand potential test



and certification implications that can be required for certain product modifications.

This presentation covers key product change rules, including newer concepts, and considerations about requirements that apply from a testing and certification perspective for wireless products being sold in the USA, Canada, EU, UK, and Japan. Key areas of assessment such as EMC, RF, RF Exposure, and Electrical Safety which constitute essential requirements will be discussed. Additionally, fundamental guidance will be presented for ongoing compliance rules for products that continue to be placed on the market in these countries and what needs to be done when state-of-the-art standards are released."



THURSDAY, SEPTEMBER 23, 2021

Time: 8:00 - 8:50 AM

Key Changes in the 2020 NEC Affecting Commercial & Industrial Installations

Joseph Wages, Jr. (International Association of Electrical Inspectors)

Abstract: With the 2020 Edition of the National Electrical Code (NEC), NFPA 70, now published, this presentation will focus on key changes that impact the design, production, installation and inspection of electrical equipment for commercial and industrial installations. Topics include reconditioning of equipment; terminal connection torque; branch circuits, feeders, and service load calculations; conductors for general wiring; special occupancies; and hazardous locations.

Time: 8:00 - 8:50 AM

Cybersecurity requirements for IOT devices in Singapore

Debora Poon (Underwriters Laboratories, Singapore)

Abstract: TBD.

Time: 8:00 - 8:50 AM

Electric Shock Hazard Considerations for Fault Managed Power Distribution Technologies

Alex Di Sciuillo Jones (UL LLC, USA)

Hai Jiang (Underwriters Laboratories (UL), USA)

Randy Ivans (UL LLC, USA)

Abstract: "A new technology, Fault Managed Power Distribution, is being developed for residential and commercial power distribution that is purported to be advantageous to conventional distribution. The concept behind this is the use of monitoring and control systems to limit the amount of energy available during a fault to mitigate the risks of fire and electric shock.

It has been proposed that cabling for these systems does not need to use conduit, armored cable, or other robust physical protection, with monitoring and control providing hazard mitigation. This potentially results in lower installation costs, increased configuration flexibility, and smaller physical cable size. The outcome is simpler electrical installations in settings that were previously inherently difficult.


Covered are aspects of the technology, relation to electrical codes, and electric shock hazards within the scope of the technology. It is, however, understood that other hazards beyond electric shock require analysis."

Time: 9:00 - 9:50 AM

The Importance of Ignition-Protected Components for Hydrocarbon Refrigerants

Krzysztof Rymarski (UL LLC, USA)

Abstract: Selecting an air conditioning or refrigeration system refrigerant is more difficult now due to



the worldwide elimination of chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs) and the restricted use of hydrofluorocarbons (HFCs). Based on new environmental regulations, the heating, cooling and refrigeration industry started to move away from ozone-depleting, greenhouse gas-producing chemicals, creating a need for replacement refrigerants. Attention turned toward alternatives with a low global warming potential (GWP). These alternatives involved hydrocarbon refrigerants, chosen not only for their environmental friendliness but also for their excellent thermodynamic performance. However, care must be taken in the selection of components used in equipment employing hydrocarbon refrigerants such as propane (R290) and isobutane (R600). This presentation will focus on the ignition-protection requirements necessary for the safe use of these new refrigerants.

Time: 9:00 - 9:50 AM

New Conformity Assessment Procedure for Telecommunication Products in Mexico

Will Birchall (CSA Group, Canada)

Patricia Medina (CSA Group, Canada)

Abstract: "Starting February 25th 2021 a new technical standard IFT-012-2019 for SAR entered in effect

Each importer must obtain their own NOM Certification of Compliance (CoC) and IFT approval
End product manufacturers customers will no longer be allowed to leverage IFT approvals on modular components and now must test and certify the end product

Applicable to products with radio frequency transmitter or transceiver that make use of radio spectrum.
Also applicable to radio equipped devices that connect to a telecommunications network in the frequency range from 30 MHz to 6 GHz and that are used"

Time: 9:00 - 9:50 AM

Evaluation of Intelligent and Non-Static Power Sources

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

Jim Weise (Adtran, USA)


Abstract: More complex power sources are coming into use including those that supply power over communication cables, e.g. USB and PoE. The evaluation of these more complex sources has been problematic in use. This paper reviews, as an example, the needed updates in the evaluation of these sources that would be applied to IEC 62338-1, the principle standard for evaluating these sources today.

Time: 11:00 - 11:50 AM

Cell Propagation Trigger Techniques for Thermal Runaway Evaluations

Rich Byczek (Intertek, USA)

Abstract: TBD.



Time: 11:00 - 11:50 AM

Book report "The electrical resistance of the human body To technical direct and alternating current"

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

Abstract: This is a report of the doctoral dissertation by Heinrich Freiberger in 1933. Freiberger researched body impedance and resistance that are still valid and in use today, and are the basis for IEC TR 60479-1 and IEC 60990. His dissertation, in German, is included in the IEC TR 60479 bibliography. His objective was to analyze electric shock incidents by examination of the body resistance. Frieberger measured the body resistances of corpses and living bodies. Tests on corpses were with skin and with skin removed. He was able to show that the body resistance is comprised of skin resistance and internal resistance. The skin resistance is a function of the applied voltage, while the internal resistance is constant.

Time: 12:00 - 12:50 PM

Lithium Battery Thermal Runaway Testing - A view from the End Product

John Copeland (Energy Assurance LLC, USA)

Abstract: Rechargeable lithium-ion batteries power our portable world offering high energy density, but with a risk of thermal runaway. Can your end-product mitigate this risk if the unthinkable happens during shipment, storage, or worse, in use by a consumer? What are some available options to proactively and safely explore this phenomenon?

Time: 12:00 - 12:50 PM


Contact Burn Injuries: Experimental Assessments of Short Duration Contact Exposures

Francesco Colella (Exponent Inc., USA)

Michael Barry (Exponent, Inc., USA)

James Vickery (Exponent, Inc., USA)

Abstract: "The quantification of contact burn injury risk is an important part of many product development cycles and hazard assessments for industrial processes. Two well-known standards relied upon for performing these assessments are primarily based on experiments conducted in the 1940s. Partially due to the manner in which these experiments were conducted, the standards implicitly make the assumption that the objects have a semi-infinite reservoir of energy. In this paper, a series of experiments were conducted by taking thermesthesiometer measurements of different materials, having different thicknesses, at different temperatures. In general, the risk of a burn injury occurring shows little dependence on the thickness of the material. In this way, for short term exposures, a surface temperature measurement of the object is likely sufficient to assess the risk of a burn injury occurring. Measurements did confirm, however, that for longer exposures with thinner materials, the severity of the heat exposure decreases, likely due to the energy dissipating from the limited thermal mass of the object."



Time: 1:00 - 1:50 PM

UL 9540A Cell, Module, Unit test requirements for NFPA 855 compliance

Jody Leber (CSA, USA)

Abstract: TBD.

Time: 1:00 - 1:50 PM

Electrochemical Cell Evidence Collection After Injury, Rupture, or Fire

Louis F. Bilancia (P.E., Engsys)

Abstract: TBD.



FRIDAY, SEPTEMBER 24, 2021

Time: 8:00 - 8:50 AM

Lithium-ion Cell Failure Mechanisms and Mitigation Strategies

Keith Beers (Exponent, Inc., USA)

Abstract: "Despite the ubiquitous use of lithium-ion batteries in mobile electronic devices, the technology is not perfect. When properly designed, manufactured, and handled, they can provide safe and reliable portable energy storage. Unfortunately, both individual lithium-ion cells and assembled battery packs can fail in diverse ways, and the effort required by product designers and manufacturers to produce a high-quality, safe final product is substantial. Understanding the possible mechanisms that could cause a failure allows manufactures to improve their design and reliability testing plans, and ultimately create a better battery-powered device."

In this presentation, we will provide a brief review of the fundamentals of lithium-ion battery technology to discuss the various mechanisms through which cells experience performance and / or safety issues. Where possible, mechanisms will be discussed alongside test data, recreation scenarios, or through the review of case studies. The implications of cell form factor and chemistry will also be discussed. The talk will conclude with a discussion of strategies for mitigating the risk of such failures. The contents of this talk will draw heavily from the collective experience of a leading failure analysis firm that has been involved with numerous investigations into lithium-ion battery failures and recalls, and the talk will be relevant across many different product types from wearables to consumer electronics, automotive applications, and stationary storage."

Time: 8:00 - 8:50 AM

IoT Cyber security - Hackers are not waiting for regulations

Geir Horthe (Nemko, Norway)

Abstract: "Everybody know that cyber security of IoT products often is weak, yet many seems to ""take advantage"" of the fact that authorities are moving slow in implementing mandatory requirements. The fact is however that mandatory requirements do exists and that using cyber security standards will not only improve the security but will also ease trade (imagine the chaos if we did not have any safety standards!)"

I want to touch on the need and advantages of regulations as well as current and emerging requirements both in Europe and outside."



Time: 8:00 - 8:50 AM

Preview: IEC 62368-1, Edition No. 4

Thomas M Burke (UL LLC, USA)

Abstract: Edition No. 3 of IEC 62368-1 was published in 2018 as IEC 62368-1:2018. Since then, IEC TC108, the technical committee responsible for safety of electronic equipment within the field of audio/video, information technology and communication technology, has been hard at work on the next 4th Edition of IEC 62368-1. Having been an IEC Standard for three editions already one might think that there is less work to do as IEC TC108 prepares this next edition. However, because of the fact that IEC 62368-1 replaced both IEC 60065 and IEC 60950-1, two complex standards in themselves, and the fact that the scope of the Standard encompasses such a broad diversity of products, components, technologies and constructions, there remains considerable continuing work to both refine the existing requirements and be prepared to cover the latest technologies and constructions, regardless of the hazard-based, performance-oriented content of IEC 62368-1. This presentation will provide a peak into the anticipated changes to be incorporated into Edition No. 4, as well as touching on its likely publication schedule.

Time: 9:00 - 9:50 AM

Analytical Assessments of Thermal Damage in a Perfused Tissue

Francesco Colella (Exponent Inc., USA)

May Yen (Exponent Inc., USA)

Abstract: Burn hazard from consumer electronics and wearables is growing more common as we maintain increasingly constant contact with these technologies. Trends in consumer electronics show that consumers are spending more time in contact with devices that dissipate heat. This long duration, low temperature contact with objects of relatively low thermal mass has the potential, under more severe exposure conditions, to cause thermal damage to the skin tissue. However, much of the regulatory guidance is more suited to evaluating burns sustained by short duration contact with hot objects that do not dissipate internal heat. In general, the accurate prediction of the time-temperature response of the skin tissue can be a complicated task due to complexities such as device contact area, skin geometry, skin properties, and heat transfer in the skin due to blood perfusion and metabolic heat generation. However, for most of the contact scenarios, the time-temperature response of the skin can be characterized by (1) initial time-dependent phases controlled by the object thermal mass and initial temperature followed by (2) a steady state phase that is controlled by the heat dissipation inside the device and the thermal and physiological properties of the skin. In the context of wearables or consumer electronics devices with low thermal mass, low initial temperatures and long duration exposures, the amount of energy transferred to the skin during the initial time-dependent phases can be neglected, and a preliminary hazard assessment can be conducted relying on simplified heat transfer calculations for a perfused tissue. This paper presents a number of novel closed form heat transfer solutions to simulate the behavior of a perfused tissue in contact with an object that dissipates heat.



Time: 9:00 - 9:50 AM

Wireless Technologies Overview Certifications & China, Russia, Japan case studies

Maja Bland (UL LLC, USA)

Di Dai (UL International Germany GmbH, Germany)

Abstract: Our agenda for this webinar is 5 parts. Firstly, we would like to introduce what is GMA (Global Market Access), then we will show you some of the common technologies' certification requirements. We will then do a high-level overview of Host vs. Module regulations, and how that will affect the compliance requirements. Next, we will introduce the two different approaches to obtain global type approvals, which are with or without in country testing. Then we will also go through the approval requirement in China, Japan, Russia as examples.

Time: 9:00 - 9:50 AM

Safety of Service Robots

Jason R Smith (UL LLC, USA)

Abstract: As the usage of service robots continues to increase by double-digit percentages, awareness of and safety concerns with service robots will correspondingly increase. In this presentation, we will cover what is a service robot including examples, current trends in the use of service robots, safety concerns of service robots based on expanding user group and operating environments, and what standards have been and are being developed to address these concerns.

Time: 11:00 - 11:50 AM

Influence of an Abnormal Cell on the Impedance Characteristics of Parallel-Connected Lithium-Ion Cells

David Chao (UL, Taiwan)

John Lai (Underwriters Laboratories, Taiwan)

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

Carl Wang (Underwriters Laboratories Taiwan Co., Ltd, Taiwan)

Abstract: For lithium-ion batteries with parallel-connected cells, the effect of abnormal cell(s) is a direct cause of capacity loss and even with safety concerns, but not easy to be detected through voltage measurement. In this study, the EIS of batteries with parallel-connected cells was compared upon two different scenarios: the same Depth of Discharge (DoD) and the same Open Circuit Voltage (OCV) basis. Standard 18650 Lithium-ion cells from two different makers were selected as test samples. According to the result of the study, the real part impedance of normal and abnormal samples at low frequency (e.g., the 0.1Hz) region is significantly different, and the imaginary part impedance of normal and abnormal samples shows a big gap in the frequency range from 0.04 to 100Hz. As a key finding, the corresponding frequency at which it shows the biggest gap in the imaginary part impedance is highly dependent on the ambient temperature, but independent on aging, or the number of parallel-connected cells, or the location where the impedance was measured. This EIS-based method can be a supportive tool for self-diagnosis of battery status.



Time: 11:00 - 11:50 AM

Normal, Abnormal & Fault conditions rationalized; providing proper protection in equipment

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

Abstract: IEC standards developed over the last 75 years have not consistently used the terms Normal, Abnormal and Fault conditions in describing under what conditions a product needs to continue to operate safely. This paper rationalizes operating conditions across these modes and provides more consistency in the design and evaluation process. Product safety standards committees updating their documents in light of this work will be on a better footing for reliably safe products in the field.

Time: 12:00 - 12:50 PM

Robust Multi-cell Rechargeable Battery Sub-System for Medical Device

Gang Ji (Medtronic Energy and Component Center & Medtronic PLC, USA)

Partha Gomadam, Zhi Fang and Prabhakar Tamirisa (Medtronic Energy and Component Center, USA)

Abstract: "To achieve a robust design of a multi-cell rechargeable battery subsystem for medical applications, device requirements such as device runtime, peak power, charge time, operation temperature, cycle life, and calendar life, are decomposed and flowed down to the battery level. Concurrently, there are performance characteristics of the rechargeable cell, such as cell voltage, impedance, capacity, and capacity fade characteristics. Most of the device requirements and cell performance characteristics have distributions to represent the variabilities due to the various operation scenarios, component-component variability, and manufacturing tolerance. To determine the robustness of a multi-cell rechargeable battery design, we measure the robustness of design by comparing the predicted battery pack performance to the requirements. The scope of this paper is limited to the electrical performance of medical device batteries.

An electrical equivalent circuit model for the multi-cell rechargeable battery sub-system is created based on the cell characteristics, charge and discharge control logic defined in the battery management system (BMS), and the expected device workloads. To predict the end-of-service performance of the rechargeable battery, a cell aging model based on the capacity fade and growth of cell internal resistance is developed under the worst-case nominal condition. Distributions of performance indicators are generated with Monte Carlo simulations and the robustness of multi-cell rechargeable battery design is quantified by calculating the value of process capability index Cpk.



Time: 12:00 - 12:50 PM

Touch current of DC products; exploring the landscape

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

Joseph McGuire (Legrand, USA)

Abstract: An examination of touch voltage and current for DC powered ITE & AV products with consideration to the requirements established in harmonized international standard IEC 62368-1. Measurement of several pieces of DC powered ITE found that at least some DC powered products do not generate monopolar/DC waveforms. Assumptions based on electrical ratings alone or improper measurement of open circuit voltage could lead to misclassification of energy sources under IEC 62368-

1. Additionally, misclassifying the nature of the touch current due to these non-monopolar/DC waveforms could result in application of the wrong limits established in IEC 62368-1. Additional clarification in IEC 62368-1 and/or IEC 60990 for DC products has the potential to improve consistency for these measurements.

Time: 1:00 - 1:50 PM

UN 38.3 Updates and FAQ

Rich Byczek (Intertek, USA)

Abstract: TBD.

Time: 1:00 - 1:50 PM

Dalziel Revisited application; Analyzing mixed AC/DC waveforms

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

Abstract: "This paper continues the evaluation of touch current generated by switching circuits within the Dalziel space. This work further confirms the inclusion of impulses below half cycle when compared in the normalized Weiss-LaPique space. All this confirms the usefulness of the Frequency Factor compensated peak touch current measurements for ongoing touch current waveforms as generated by equipment."