Keynote Speaker

Functional Safety – an overview according to IEC 61508 (the original Functional Safety Standard)...and a few 'important' techniques to analyze Semiconductor Components according to ISO 26262.

Bharat Rajaram, PMI - Senior Member of Technical Staff, TI Functional Safety Evangelist, TUV-SUD Certified Functional Safety Professional

We will begin with developing an understanding of what is Functional Safety (by contrasting it with 'Product Safety', 'Quality', 'Reliability', 'Availability', and a field that is gaining immense popularity these days…, 'Cybersecurity'). Subsequently, we will address why we need Functional Safety followed by a hierarchy of standards (type-A: basic, type-B: group, and type-C: product) and the evolution of IEC 61508 till the present day. Then we will understand the progression of 'faults' creating 'errors' which could eventually lead to 'failures' and the concept of HFT (hardware fault tolerance) and the role it plays in Functionally Safe Systems.

Finally, we will briefly overview what it takes to comply with Functional Safety standards and wrap up with a couple of critical recommendations from the ISO 26262 standard for analysis of a Semiconductor SEooC (Safety-Element-out-of-Context) during development i.e., DFA (Dependent Failure Analysis) and Co-existence Analysis to guarantee FFI (Freedom From Interference).

Batteries & Energy Storage Systems

Lithium Battery Swelling – What's the Big Deal?
Emily J. Klein (Element Materials Technology)

Understanding the causes and severity of swelling is critical to determine if there is an underlying safety issue, quality-related matter, or is due to external factors. This presentation will discuss the various aspects of lithium-ion battery swelling, methods for prevention, and techniques to determine potential root causes.

Thermal Runaway Energy Release as a Function of the State of Charge
Artyom Kossolapov (Exponent); May Yen (Exponent); Francesco Colella (Exponent)

Designing safe products powered by lithium batteries requires an understanding of how the battery pack will behave while undergoing thermal runaway. In this work, Fractional Thermal Runaway Calorimetry (FTRC) is used to estimate the energy release from cells at different states of charge when undergoing a thermal runaway.

UN 38.3 Updates 2023
Rich Byczek (Intertek)

This talk provides updates and clears common misconceptions related to Lithium-ion Battery Transportation Testing. Focus on understanding the differences between product safety and transportation regulations, recent changes in requirements and reporting, and incorporation of Sodium Ion Battery requirements.

PSES Tutorial, Compliance 101, Part 1
Ken Kapur (Thermo Fisher Scientific)

- » The intent of this presentation is to provide a basic knowledge of Product Safety and Regulatory Compliance for products sold worldwide.
- » The presentation covers the requirements for those involved in new and existing products and those who need to address global safety requirements.
- » This training will provide the fundamental guidance for product safety which can support geographic sales for import and export around the world.

Compliance 101 Tutorial - Part 2
John Allen (Product Safety Consulting, Inc.)

This presentation is a continuation of presentation #1 (covering Product Safety and Regulatory Compliance for products sold worldwide), looking into the requirements in more detail.

- » We will review requirements in product safety standards and the impact to new designs.
- » Understanding the level of product safety testing in accordance with safety standards will also be covered.
- » We will discuss product safety risks (Electrical, Mechanical, Lasers, Radiation, etc.) and methods to mitigate risk and ensure compliance.
- » 'Design For Compliance' techniques will be discussed as they pertain to complying with global product safety standards (UL, CSA, IEC).
- » Maintaining compliance through product modifications will be included.
- » Challenges and best practices will be shared that will help product designers get a new product to market quickly and efficiently.

PSES Tutorial: Part 3: Global Market Access
Grant Schmidbauer (Nemko North America, Inc.)

Part 3: Once your product complies with (all) the regulatory requirements for the different countries you plan to market the product, you must then obtain the necessary country approvals. This presentation will provide an overview of global market access requirements, and then give more specific requirements for North America, European Union, and some of the other Asian and South American countries.

Protection Scheme: Selection and Implementation
Brunno P Covolan (Intertek Testing Services)

Critical to design, is the inclusion of safeguards providing protection from hazardous conditions. The implemented safeguards directly influence the certification process, adding or removing burden to manufacturers. This paper reviews different safety and environmental protective methods, highlighting benefits and commonly encountered certification challenges, providing a reference for effective safeguard selection.

Remedies for "Don't Do" Compliance Certification Traps
James Bender (Intertek)

This publication provides simple remedy considerations for commonly encountered "don't do'" traps when preparing an electrical product for third party safety certification submittal. Featured are the more subtle, but critical preventive lessons-learned considerations often causing time delay, cost and/or other barriers to a seamless certification experience.

On Product Warnings: ANSI Z535.4 and ISO 3864-2 Best Practices, Compliance Issues, and Latest Trends
Erin Earley (Clarion Safety Systems); Angela Lambert (Clarion Safety Systems)

"Failure to warn" and "inadequate warnings" top today's product liability allegations. This presentation will provide an overview of the ANSI Z535.4 and ISO 3864-2 standards and how they form the foundation for effective labels and instructions. The discussion will include label format options, standards updates, and emerging trends.

Achieving Product Safety through Positive Human Interaction: Humans, Humor, and Getting Things Done
Mike Sherman (Sherman PSC LLC)

Persuasive communication skills make our product safety and compliance (PSC) jobs easier. Concise, pithy, and humorous sayings break the ice to help us focus on and solve product safety problems. This presentation provides time tested sayings, insights and philosophies to help you become a more effective product safety professional.

Independent Studies—Creating a Personal Curriculum for a Successful PSC Career
Mike Sherman (Sherman PSC LLC)

Our PSES Tutorials explain how to do product safety/compliance; this presentation explores what to know—from basic scientific and engineering concepts to higher level skills—to succeed. Because your knowledge needs are dictated by your specific products, this presentation takes a checklist approach, so you can build your personal curriculum.

Origins and Basics of Electrical Fire and Shock Protection
Mike Sherman (Sherman PSC LLC)

The basic needs for fire and shock protection for electrical equipment emerged during a tumultuous period in the late 1880s and early 1890s. This presentation looks at that history, summarizes current best protection practices, and adds some hard earned lessons from 30 years of electrical product safety work experience.

Risk Assessment Basics
Patricia Knudsen (Teradata Corporation)

Learn the basics of Risk Assessment:

- » Why it's required
- » Standards and guidance documents
- » Who gives input
- » What situations are covered
- » Aspect to be considered
- » How to proceed
- » Risk Analysis Matrix
- » What if standards don't work for my product?

An Overview of Regulatory Compliance
Grace Lin (HYTORC)

This presentation is an overview of regulatory compliance, from manufacturers' point of view, for electrical and electronic equipment.

Product Safety Compliance-Growth Enabler for Manufacturers
Chaitanya Katekar (Intertek)*

Nearly 51,000 deaths and 28,500,000 medically treated injuries were recorded by US Consumer Product Safety Commission in 2019 and 2020, respectively. Governmental regulatory bodies, third party safety certification laboratories and other jurisdictional authorities help maintain safe product use. This paper provides overview of key regulatory considerations to achieve safer products."

Basic Product Safety for Electronic Products
Julio N Posse (Posse Academy)

This presentation reviews some of the necessary steps required to market safe products. It reviews the hazards associated with these products and how to mitigate them. It discusses the several tools that we can use to accomplish the objective and how to effectively use them.

Navigating a Product Safety Standard- A Primer for Success
James Bender (Intertek); Maryam Mahnoodi (Intertek)

Identifying and correctly applying electrical product safety standards' test requirements are key contributors to help mitigate risks and successful certifications. This paper features a familiar consumer product, allowing a beginner designer to effectively interpretate and apply product safety testing requirements to minimize risks of fire, electrical shock and casualty hazards.

Automating Your Cable Testing for Faster Throughput, Better Quality
Glen W. Broderick (Vitrek); Marsha Ryan (WelComm)

This presentation makes real-world testing of cables – and connectors, harnesses, relays and components -- easier and safer for the test engineer. The presenter, Glen Broderick, has advised more than 8,000 companies on testing in the areas of vibration, avionics, RF/military electronics, network test, medical, HV, ATE, battery and electric vehicles.

Ethics

Ethical Venues – Understanding the Newspaper Test
James Bender (Intertek)

Ethics in engineering decision making influence is critical to engineers involved in product development, including product safety. This presentation provides overview of ethical cornerstones including audience interactive discussion leveraging vignettes for lively role playing on "what would you do" ethical challenges, reiterating importance and use of the newspaper test.

Cybersecurity

Cyber Security in Wireless Products
Tom Tidwell (Nemko)

Cyber security regulations have been enacted in most major international markets. Understanding the regulations and the vulnerabilities of wireless systems is important for manufacturers of products with a wireless interface. This presentation will explore the specific requirements and how best to design for and maintain compliance.

Safety Standards in Cybersecurity and Improvements of Multi-access Edge Computing and Management Systems
Jeongyoon Shin (Yonsei University); Jungmin Seo (Yonsei University); Juyeong Hwang (Yonsei University); Byounghoon Son (Yonsei University); Jong-Moon Chung (Yonsei University)*

Since Multi-access Edge Computing (MEC) was developed, technical standards have been established for safety compliance, including cybersecurity. Still, there exists insufficient aspects that need improvement to reliably support commercial systems. Herein, the overall structure and development progress of MEC are summarized, and security issues and possible solutions are proposed.

RED cybersecurity requirements and regulatory landscape
Paul Miller (UL Solutions)

The presentation covers the EU cybersecurity regulatory background and landscape. First, we will provide an overview of the EU cybersecurity regulatory background, which will set the stage for a deeper understanding of the current state of affairs. Next, we will dive into the specifics of the RED Delegated Regulation for Article 3.3 (d)(e)(f) and its importance in ensuring the security and privacy of connected devices, with the future impacts of the Cyber Security Resilience Act. We will also explore the role of ETSI EN 303 645 in providing a common cybersecurity baseline for IoT devices to be a baseline towards compliance.

EMC & Wireless Compliance

Presentation on: Wi-Fi 6E and AFC (Automated Frequency Coordination) The Next Step of Wi-Fi Evolution
Juan M Gonzalez (Nemko USA)

With the development of the new Wi-Fi 6E(802.11ax) and the efforts to ensure worldwide adoption, interoperability, and more secure and reliable technology, Wi-Fi-6E comes with a new element called Automated Frequency Coordination (AFC) System, where the AFC system automatically determines and provides lists of frequencies that are available for use by standard power access points operating in the 5.925-6.425 GHz and 6.525-6.875 GHz bands.

Basics of Lightning Protection for Communication Towers and Buildings
JAMES A BACHER (JBRC Consulting LLC)

This presentation is on how to protect Antenna Towers from lightning strikes. However, the techniques apply to buildings as well.

How Pass on the First Trip to the EMC Lab
JAMES A BACHER (JBRC Consulting LLC)

90% of all products fail on the first trip to the lab (safety and EMC). This presentation goes into how to get your products into the 10% that pass on the first trip to the lab saving time and money.

EMC Margins, Who Needs Them?
JAMES A BACHER (JBRC Consulting LLC)

A presentation on why just meeting the limits is not good enough.

Augmentation of the Extraneous Electromagnetic Radiation from Vehicular Wireless Charging Systems by Coupling to Motor Vehicle Characteristic Modes
James McLean (TDK R&D Corporation)

Wireless power transfer (WPT) systems for electric vehicles (EVs) conforming to the SAE J2954 standard operating in the presence of an EV are shown to excite the characteristic modes of the EV, modifying the extraneous electromagnetic field substantially. This can result in non-negligible power radiated in the HF communications bands.

Emerging Technologies & Innovations

Flame Detection Technology Overview & Certification Requirement
Chaitanya Katekar (Intertek)

There were approximately 36,000 commercial fires with $1.2B property damage/loss of life between 2011 and 2015 reported in the US[1].

This publication summarizes flame characteristics and the role of flame detectors including safety certification requirements to effectively detect early fire/flame eruption and alerting methods to act, stop or mitigate fire.

UL 8400 - Safety for VR/AR/MR
Ted Eckert (Microsoft)

This presentation will give an overview of UL 8400, the draft standard for virtual reality, mixed reality, and augmented reality headsets. It will also give a brief overview of the STP and the timeline for the release of UL 8400.

Safety Standards of EO, IR, and LiDAR Sensors for Autonomous Vehicles and UAV Remote Sensing
Juyeong Hwang (Yonsei University); Byounghoon Son (Yonsei University); Jeongyoon Shin (Yonsei University); Jungmin Seo (Yonsei University); Jong-Moon Chung (Yonsei University)*

Real-time accurate sensing and precision control of Autonomous Vehicles (AVs) and Unmanned Aerial Vehicles (UAVs) are essential, in which safety regulations and compliance engineering is very important. This presentation identifies the principles and safety regulations of sensors, which are commonly used for remote sensing on AVs and UAVs.

Evaluation of Optical Radiation Safety using a retinal radiance meter
XI MOU (Hangzhou SanTest Technology)

This paper describes a novel method to measure optical radiation hazards like effective spectral radiance and angular subtense for optical radiation safety testing. Conventional meters cannot be used for optical safety testing as they are not designed based on human eye optics. This new method complies with IEC 62471 standards.

Environmental & Energy Regulations

Sustainability in the manufacture of electronic products
Tom Tidwell (Nemko)

Regulations related to sustainability and the circular economy are being implemented in the EU and in other economic regions. It would be prudent for manufacturers to begin to understand how to comply with these regulations. This presentation will identify key aspects of sustainability from design and throughout the life cycle of electronic products.

North American Energy Efficiency Basics
Amanda Johnson (Festool)

This presentation will focus on energy efficiency requirements in Canada, the USA and Mexico. It will provide audience members with the resources needed to determine if their products are in scope, what kind of testing is required, and what is needed for registration.

Sustainability is the New Standard of Supply Chain Engagement: How Emerging Standards and Regulations Intersect Product Compliance and ESG
Jamie Wallisch (Assent)

In this presentation, Assent will review the new regulations around sustainability, including the heightened needs to comply with ESG and product compliance in the legislation as well as the effective methods of data collection and delivery of valuable information.

Global ROHS
Theresa Glenna (TUV SUD)

Learn about RoHS from a Global Market Access perspective. Several countries have recently implemented RoHS regulations, but the compliance requirements for each are quite different. We will review the requirements, controlled product lists, and important dates.

Forensics, Failure & Risk Analysis, Assessment & Management

Electrical Fire Patterns In Vegetation

Louis Bilancia (Engineering Systems Inc.)

Branching patterns from electrical currents can leave residual physical patterns on skin, sand, oil, and vegetation. Three case-studies examine Lichtenberg figures charred into dry mustard plants, blackberry stalks, and trees at the wildland fire origin. This paper presents examples of how these patterns form and their use in fire investigation.

Forensic Evidence of Arc Tracking as an Ignition Source

Thomas Bajzek (Engineering Systems Inc.)

Arc tracking is a common cause of electrical fire, yet very few publications have studied this phenomenon. A laboratory experiment was designed and performed to produce ignition from arc tracking in a repeatable manner and characterize the forensic evidence associated with ignition from arc tracking.

Functional Safety

Functional Safety for IIoT Products
Layne Lueckemeyer (CSA Group)

The accelerating growth of the Internet of Things (IoT) and Industrial Internet of Things (IIoT) has connected our world with smart devices and technologies. With connected devices in smart home appliances to industrial manufacturing, it's essential to implement safety-related systems controls to minimize risk to people, property, and the environment.

Functional Safety Compliance for the Energy Storage Industry
Layne Lueckemeyer (CSA Group)

As the Energy Storage market grows, manufacturers struggle with regulatory issues facing them every day. These hurdles can be time-consuming and expensive to overcome. Increased reliance on electronics and software for safety monitoring and critical safety controls drives the need to consider Functional Safety in addition to Electrical Safety requirements.

Protective and Functional Safety Control - Interpretative Differences
Chintan Trivedi (Intertek Testing Services NA, Inc.)

Protective and Functional Safety Control - Interpretative Differences

Global Hazardous Locations

HazLoc Markings – Global Alphabet Soup
John Chambers (UL LLC)*; Jerilyn Merrill (UL LLC - Northbrook, IL)

Navigating the complex landscape of global hazardous locations and explosive atmospheres is a challenge, and the variety of global markings used on products can look like alphabet soup. This presentation will help you understand HazLoc and explosive atmospheres markings, and the certifications that they support, including North American, ATEX, IECEx, INMETRO and UKEx certifications.

Safety in your Hazardous (Classified) Areas
Jon D Miller (MSA)

"This presentation will cover the use of safety equipment (i.e. flame/gas/smoke) with an emphasis on the draft UL 1498 standard that addresses the selection of standards for the evaluation of gas detection equipment in alignment with American National Standards Institute (ANSI) published requirements.

Global Market Access for Hazardous Locations
Nancy Lin (CSA Group)

Wondering how you can get your hazardous products access to the global markets? This presentation will provide certification world map for HazLoc for 15 countries/regions. You will learn about certification schemes, processes and general requirements in each country/region.

Identifying and managing risks of combustible dust explosions
William Fiske (Intertek)

Combustible dusts inclusive of fibers, flyings and fine particles, has fueled many explosions and flash fires since the industrial revolution began, many avoidable or less destructive.This presentation covers what combustible dusts are and associated dangers, reducing probability of dust ignition, ways to mitigate explosion damages and seeking additional information.

Changes Effecting Hazardous (Classified) Locations based on the 2023 NEC
Joseph J Wages Jr. (IAEI)

The material for this meeting will focus on Hazardous Location requirements for the 2023 NEC code cycle. This will be based on material from IAEI's Analysis of Changes- 2023 NEC. The presentation will discuss code-wide changes as well as focus on Chapter 5 changes that were reported by IAEI code making panel members.

Preparing and Sustaining Ex certification – Addressing Significant Changes for Intrinsically Safe Devices in New Edition of IEC 60079-11
Frederick S Kiddle (ABB); Behzad Nejad (Hazcon Inc.)

Preparing critical documents for Ex certification needs to be sustainable over the life of a product. Addressing significant changes between editions in IEC Ex standards can become a challenge when conducting a gap analysis. An example presented is the new edition of IEC 60079-11 where there are 31 major technical changes!

Global Market Access & Regulations, Compliance Management

New NOM/Mexico Conformity Assessment Procedure for Telecommunication Products

Jose Luis Hernandez (CSA Group)

How will the new Mexican Conformity Assessment Procedure for Telecommunication Products impact your business? Now in effect, the IFT Procedure increases alignment with 5G and IoT global trends. Learn about:

- » Significant changes to accreditation process
- » Four new certification schemes
- » The product certification process
- » The rules for surveillance, suspension, and cancellation

Market access for radio products in Latin America with a focus on Brazil

Julia Gresser (CSA Group Bayern GmbH)

With a high population in Latin America and the Caribbean, and the continued demand for connected devices, this could be a potential growth market for many manufacturers. In the presentation, you will get an overview of radio approvals in Latin America with focus on Brazil, also including important regulatory updates.

Global Safety and Energy Efficiency Regulatory updates and trends 2023

Maja Bland (UL)

Maja Bland will provide global Regulatory news updates on electrical safety and energy efficiency for different types of products.This presentation will cover NA, LATAM, EU, ASEAN and MEA regions. Regulatory changes will include finalized new regulations with mandatory effective dates in 2023, to which product sold or exported into different countries should comply with in order to access the respective market or regulatory updates addressing complementary requirements for already regulated products.

Mexico NOM-024 Product Labeling updates and importation impacts

Elizabeth Perrier (ORBIS Compliance)

ORBIS Compliance's goal is to empower our industry with knowledge and help our community to navigate these difficult challenges successfully. New updates are coming into place with the upcoming publication of NOM-024 in Mexico and labeling modifications in Argentina that will have an impact on importation.

- » Our presentation will cover:
- » Mexico Commercial Information Regulations.
- » Mexico Labeling Non-Compliance and Penalties.
- » NOM-024-SCFI-2013 Electronic and Electrical Products.
- » NOM-024-SCFI-2013 Dictamen Process & DGN Permits.
- » NOM-024-SCFI-2013 Update.
- » Argentina - Electrical Safety Certification.
- » Argentina - Exemptions Form B and SDU.

ORBIS Compliance looks to provide the solutions for those who face importation or product retention type issues by presenting how to plan ahead to handle these new updates in the most time effective manner

Success of Telecom Mutual Recognition Agreements

Nathalie Rioux (National Institute of Standards and Technology (NIST))

Telecom Mutual Recognition Agreements (MRAs) reduce the time and cost of placing products in some foreign markets by allowing regulatory testing and certification to the requirements of partner economies to be done locally in the USA. This talk will provide an overview of the telecom MRA program and its benefits.

Digital Product & Material Passport
Eva S. Hink-Lemke (iPoint systems GmbH)

Digital product passports are defined as a data set that summarizes the components, materials, and chemical substances in a product and information on reparability, spare-parts and proper disposal instructions. New drafts of upcoming legislation changes, like EU battery-regulation, require a submission of a DPP. This is challenging industry but helps closing gaps of the circular economy.

This presentation will provide up-to-date information and shows how companies can handle the challenge and benefit from the automation and digitalization.

SCIP – 2.5 years of reporting
Eva S. Hink-Lemke (iPoint systems GmbH)

The EU legislation requires any supplier of so called articles in the European Union to submit information about SVHC >0.1% to the SCIP Database.

What are the lessons learned after more than 2 years of SCIP? How can companies manage the challenges and efforts for collecting, evaluating and reporting the data? How can Non-EU manufactures support their customers and EU-importers?

The presentation provides up-to date input and recommendations how to deal with the challenge of SCIP requirements and benefit from the information collected.

Labeling, and overview and discussion on a critical aspect of compliance that only gets more difficult by the day
Geremy Bradshaw (Nemko USA); Tom Tidwell (Nemko)

This presentation will give an overview of best practices and general rules for labeling, including electronic labeling. Guidance on where the requirements can be found, critical items not to miss and considerations for international markings. Active discussion with audience members on the best practices and solutions for a subject that only gets more challenging by the day.

Regulatory requirements in South Africa
Geremy Bradshaw (Nemko USA); Tom Tidwell (Nemko)

Quite possibly, the most challenging market today, is South Africa, where you now must consider the compliance requirements and recognitions seriously. This presentation will cover:
  » Brief Overview of South Africa (NRCS Safety, SABS EMC, and ICASA Type approval)
  » Type Approval Requirements for non-RF and RF devices
  » Overview of PVoC (Pre-Export Verification of Conformity)

Live to Love your CB Report
Geremy Bradshaw (Nemko USA); Tom Tidwell (Nemko)

This presentation will provide the critical details that you need to know, the mistakes that can happen far too often, and what you can do to assure that you get the most value from the money you spend. From the first-year compliance engineer to the seasoned veteran, key insight will be gained from this presentation.

India Certification Overview (BIS - Safety, WPC - Wireless and TEC - Telecom)
Thomas K. Ha (G&M Compliance, Inc.)

This presentation will provide the critical details that you need to know, the mistakes that can happen far too often, and what you can do to assure that you get the most value from the money you spend. From the first-year compliance engineer to the seasoned veteran, key insight will be gained from this presentation.

Integrating Wireless Technology into Products
Theresa Glenna (TUV SUD)

Adding wireless technology to a product adds layers of certification requirements which can be challenging to navigate. Learn about different methods of integrating wireless modules and leveraging a pre-approved module. Take home some strategies to refine your compliance plan and ways to make informed decisions to save costs and manage your time to market.

Hazard Based Safety Engineering & Safety Science

Practical Implementation of a Touch Current and Touch Voltage Custom Test Fixture on Enterprise Servers and Mainframes
John S Werner (IBM)

An often misunderstood test during product safety compliance testing is prospective touch voltage, touch current, and protective conductor current. This paper details the nuances of these clauses and the implementation of a custom test fixture designed for high power applications on enterprise servers and mainframes.

IEC and EN 62368-1, many editions, what to do for Europe?
Grant Schmidbauer (Nemko North America, Inc.)

With the many different editions of the two standards, what should manufacturers do, also taking into account the coming 4th ed. of IEC 62368-1 (likely to be published within April this year/2023). This session will give an overview of the different IEC and EN (European) versions of 62368-1, and then delve into the European system for CE marking for LVD when considering a harmonized standard (giving presumption of conformity) vs using a standard that is not harmonized to the OJ. The presentation will provide many useful web links and a glossary of terms.

IEC 62368-1:202x, Ed. 4, main differences
Grant Schmidbauer (Nemko North America, Inc.)

This presentation will present an overview of the main differences between the soon to be published IEC 62368-1:202x, Ed. 4 (planned for April 2023), and prior editions. Since ISPCE 2023 is May 1-3, 2023, the presentation will be 'hot off the press', and either compare the actually published standard, or the latest FDIS (final draft international standard) that has already been through the final commenting period.

Electrical Shock Stimulation for Complex Leakage Current Waveforms
Hai Jiang (UL Solutions)*; Paul Brazis (UL Solutions)

Leakage or touch current tests for electrical shock protection is mandated by safety standards in the process of issuing a safety certification for various electrical products. Currently, UL 101 uses Root-Mean-Square (RMS) values as the leakage current limit, but IEC 60990 uses the peak value. Little research has been done to study which parameter is better defining the electrical shock sensation for non-sinusoidal waveforms. In this paper, electrical shock sensation experiments were conducted for a complex waveform. The deviation percentage is calculated and compared for RMS and peak. The results from an initial experimental investigation showed that peak correlated reaction curves with perceived sensation more closely than RMS.

Current Trends in E-bike Safety
Georgina Lean (Huntley-Fenner Advisors, Inc.)

Questions arise regarding why there is a difference in injury statistics for e-bikes and conventional bicycles. This presentation discusses the ways in which a human factors approach can be utilized to perform a risk assessment in order to address product safety improvements, infrastructure improvements, and bike safety law and education.

Reduced-Order Modeling of Pennes' Bioheat Equation for Thermal Dose Analysis

Francesco Colella (Exponent Inc.)*; Harry Watson (Exponent Inc.)

Current trends in powered wearable technologies show that users are spending more time than ever in contact with their devices. Users now wear devices such as smartwatches and fitness trackers up to 24 hours per day to make use of ubiquitous health, exercise, and sleep-tracking features. Long duration contact with these heat dissipating devices increases the thermal dose delivered to user's the skin tissues. Methods for accurate, real-time prediction of the time-temperature response of the skin based on device heat dissipation and external conditions are needed to characterize and monitor the thermal dose received by the user. In this study, reduced-order models (ROMs) based on proper orthogonal decomposition (POD) are developed for modeling transient heat transfer in partially-perfuse tissue in prolonged contact with a heat-generating wearable device. This methodology is able to provide fast, accurate temperature forecasts for arbitrary time-varying boundary conditions, heat sources,

Computational Modeling of Sharp Edge Injury Hazards

Scott Lovald (Exponent); Maysam Gorji (Exponent); Michelle Chen (Exponent); Nikita Pak (Exponent)

This study uses a finite element model of the human dermis to evaluate the laceration risk of generalized product edges. Based on comparison to experimental data, the results indicate there are consistent stress and strain criteria associated with an increase in laceration risk.

Legal, Regulations, Directives & Consumer Protection

Product Liability and Product Compliance in Europe - top important legal developments in 2023
Arun Kapoor (Noerr)

After more than 40 years, Europe is getting a new significantly tightened product liability regime, which will bring numerous innovations, especially for the tech industry. At the same time, after more than 20 years, a new General Product Safety Regulation is coming, which will revise the safety requirements for consumer products. In addition, the basic legal acts for placing machines on the market are changing. With the European Union's Green Deal, economic operators are also facing tougher requirements for supply chain compliance. A new deforestation regulation stipulates that numerous products may only be placed on the market if economic operators can prove that the raw materials were not produced on land that has been deforested. The presentation shows the main legal innovations that the industry in Europe will have to deal with from 2023.

Product Compliance for Artificial Intelligence and Cyber Resilience – New Responsibilities for all Economic Operators
Susanne Wende (Hochschule München)

After almost 10 years of evaluation, careful thinking and discussion, the legal framework for placing digital products on the European market seems to be moving quickly. With a draft Recast Product Liability Directive, a draft AI Act and a draft AI Liability Directive, there are three legislative proposals tackling the responsibilities for digital product features from several perspectives. This session provides an overview on the legal tools and responsibilities for different economic operators and how to address and implement those in companies' product compliance systems. The risk based approach to market access rules for products with AI components together with the broad definition of the term "Artificial Intelligence System" causes challenges for all economic operators. Additionally, the legislative proposals contain quite strict obligations regarding cyber resilience.

Medical Devices

Use of Medical Equipment in the Home Environment – Things to consider
Pamela Gwynn (UL LLC)

The use of medical equipment in the home environment is increasing. Unfortunately, the use of medical equipment designed for use in a healthcare environment may present challenges. In this discussion, we will discuss and highlight some of the challenges and how the use of the guidance documents and standards address them.

Key leakage current differences between medical devices and household products.
Maria N Martinez (Intertek)

Conceptual overview of electrical shock hazards and leakage current differences between medical devices and household products. Focus on the human body's physiological reactions from tingle to heart defibrillation when subjected to varying current and frequency levels up to 600VAC.

Miscellaneous

Regulatory Jeopardy (part 1 of 2)
Regan Arndt (Thermo Fisher Scientific)

After a successful event last year in San Diego and calls for another session this year, we are putting on another show that's even bigger and better!

Come and join the fun in this exciting and interactive 'Jeopardy' themed presentation that demystifies the many misnomers, myths, and misunderstandings that can cause mistakes, mishaps and mayhem in the complex world of Regulatory Compliance.

Regulatory Jeopardy (part 2 of 2)
Regan Arndt (Thermo Fisher Scientific)

This part 2 session immediately follows the part 1 session where a technical panel will discuss some of the difficult questions & answers that were presented in part 1.

It will also provide insight on how to avoid embarrassing and costly mistakes when dealing with test labs and certification agencies leaving you feeling more confident when confronting any issue that involves Product Safety, EMC, CE marking, NRTL certification, Field evaluations and more.