

IEEE ISPCE 2022 PROGRAM AT A GLANCE

Keynotes

Ethics in Engineering, Making the Right Choices



Jim Bender, P.E. – Senior Staff Engineer Intertek (Plano, TX) North Texas IEEE Product Safety Engineering Society Co-Founder and Chair

This audience interactive engagement provides a lively and stimulating real-life overview highlighting regulatory compliance challenges often associated with time critical high technology product releases.

The 100% fact-based reenactment pulls in audience participation focusing on engineering and management obligations and “gut checks” often encountered with potential ethical vs. legal conflicts associated with new product development, manufacturing and market introduction.

The presentation and ensuing discussions will cover specific legal vs. ethical influencing cornerstones, identification and leverage of the “newspaper test”, the importance of protecting a company’s reputation and the influencing roles and obligations for product regulatory/safety professionals based on a real-life example.

What makes this presentation unique are the “what would you do/what-if” scenarios associated with regulatory compliance challenges impacting critical product release expectations.

UVC and Copper in Disinfection –The Good, the Bad and the Ugly



Steve Reinecke – Proximity Systems

In our daily lives, we encounter multiple surfaces that have been previously touched by someone else. High-touch surfaces are found everywhere. We have self-checkout at the grocery store. We have options to order our meals on a touch-screen before getting in line. There is the pin pad on the point-of-sale device at 1000’s of retail outlets. We hold the handrail on a bus and train. When traveling, we are encouraged to “check in” at a kiosk prior to engaging a live person. All these surfaces have recently been touched by someone else and are not routinely cleaned, and if they have been, there is a high likelihood that the instructions on the liquid cleaning products they are using were not followed.

The pandemic has brought to light many new technologies and engineering innovations. We will discuss how copper and UV disinfection technologies are increasingly providing options for the disinfection of surfaces and indoor environments. This presentation will educate participants on what UVC is and how it works to disinfect surfaces, air, and water. We will compare liquid disinfection products and see how they work. We will discuss how copper is a naturally antimicrobial element that is recognized by the EPA. We will discuss what to look for when purchasing a UVC disinfection device. Topics will revolve around understanding claims of efficacy, safety, and regulatory restrictions. We will discuss questions a purchaser should be prepared to ask a manufacturer of the UVC product before purchase and help purchasers understand, “If something seems too good to be true, it is probably is too good to be true”. Lastly, we will give examples of false and misleading product claims and have an open discussion with all participants in the session.

Batteries & Energy Storage Systems

Codes and Standards for Stationary Energy Storage Installations – NFPA 855, UL 9540, and UL 9540A

Michael R Becker (CSA Group)

Energy storage system manufacturers today must meet a number of regulations before they can successfully deploy and fully commission their systems. One of the primary codes that impact them is the NFPA 855 Standard for Installation of Stationary Energy Storage Systems. NFPA 855 references many product and installation codes that make it complex.

This presentation highlights the clauses of NFPA 855 and the primary standards for Energy Storage Systems – UL 9540 (Energy Storage Systems and Equipment) and UL 9540A (Test Method for Evaluating Thermal Runaway Fire Propagation in Battery Energy Storage Systems) that have an impact and can present challenges for energy storage system manufacturers. Armed with this knowledge, energy storage system manufacturers will be able to address applicable testing and certification requirements early in the process, streamlining deployments and commissioning.

Demystifying Batteries From Cell to End Product

Rich Byczek (Energy Assurance)

IEC 62133-2 has become the global norm for small format Lithium Ion Cells and batteries, but the application of this standard can still lead to confusion when validating compliance of Battery Powered Devices. This presentation clarifies the scope of IEC 62133-2 and it's globally harmonized counterparts, the status of legacy IEC and UL standards, and the relationship to Transportation Testing Regulations. Various certification schemes are addressed, as well as selecting proper alternate or additional battery compliance test requirements. Cell, Component Battery, Integrated battery and Standalone Battery Pack scenarios are explored to better understand the relationships between component and end product requirements.

Lithium Battery Field Failures – Should you engage expert assistance?

John Copeland (INTERTEK TESTING SERVICES NA, INC.)

As the demand for lithium batteries continues to increase, an influx of lower-tier providers has entered the market to meet that demand. Sadly, this has led to a greater chance of thermal runaway events occurring in the field resulting in negative impacts to brand image, legal actions, property damage, and sometimes personal injury. Should this happen to your company, do you have the expertise to go it alone or should you bring in independent experts in the field? This presentation will cover important aspects to be considered when making that decision and the associated risks, expectations when working with a third-party provider, and an overview of the battery failure analysis process. We will also briefly touch on proactive steps that can be taken to better manage risk exposure before there is a field incident.

UN 38.3 Updates and Beyond

Rich Byczek (INTERTEK TESTING SERVICES NA, INC.)

This presentation provides the latest updates and changes to the Lithium Battery transportation testing regime, per UN 38.3 Common misconceptions, Frequently Asked Questions, and Interpretations are given for multiple scenarios. Additionally, this presentation addresses the non-testing updates and interpretations including the UN 38.3 Test Summary Sheet, and updated shipping and labeling regulation changes.

Compliance 101/201

PSES Tutorial:

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 requirements that must also be considered to facilitate the sale of the product.

The plan for this tutorial is to delve into some of the “other 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.

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.

PSES Tutorial: Part 1: Compliance 101

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.

PSES Tutorial: Part 2: Compliance 201

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.

Part 3: Global Market Access

Grant Schmidbauer (Nemko North America, Inc.)

- » 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.

Regulatory Jeopardy (part 1 of 2)

Regan Arndt (Thermo Fisher Scientific)

CE is not a certification! Yes, it's true. You heard it correctly. Now you are thinking to yourself..... "What"?!..... Since when!? Answer: It always has been that way since day one.

Have you ever been in a situation where the certification agency says that they do not accept a CE marked component for your product's NRTL approval? And why do I not need the RoHS mark on my device anymore? Are manufacturers required to have their products certified by an NRTL or is the employer? Is Field labeling by an NRTL the same as NRTL certification?

Register for this fun 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.

This presentation 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.

Regulatory Jeopardy (Part 2 of 2)

Regan Arndt (Thermo Fisher Scientific)

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On Product Warnings: ANSI Z535.4 and ISO 3864-2

Erin Earley (Clarion Safety Systems); Angela Lambert (Clarion Safety Systems)

Everyday, engineers and manufacturers who have responsibility over product safety and compliance face challenges related to ever-changing global codes, standards, and regulations.

The U.S. ANSI Z535 family of consensus standards is commonly used by manufacturers and workplaces – along with its global counterpart, ISO 3864-2 – as a main guideline for following best practices and creating consistency in their safety warnings and instructions.

This presentation will explain the significance of the ANSI Z535 and ISO 3864-2 standards, as well as explore the latest updates and what they mean for today's safety and risk professionals. Of special significance is that ANSI Z535 is being republished this year, in 2022, marking the first time that this family of size standards have changed in over a decade. Additionally, development of a new sub-standard, ANSI Z535.7 is underway, focusing on trends in digitalizing and automation.

This session will be presented by Angela Lambert, who has over a decade of experience in product safety and liability issues. Lambert is the head of standards compliance at Clarion Safety Systems, and serves in leadership roles in ANSI and ISO committees for product safety, workplace safety, and visual safety communication. She is chair of ANSI Z535.1 Safety Colors, a member of ANSI Z535 Committee, the U.S. TAG to ISO/TC 145 and of the U.S. TAG to ISO/TC 283, and is the liaison representative from ISO/TC 145 to ISO/TC 283.

Risk Assessment Basics for EMC, LVD and RED Directives

Patricia Knudsen (Teradata Corporation)

An introduction to risk assessment basics: how to get started, who should give input, and what aspects should be covered.

UL 60335-1 Ed. 6 – Standard for Safety of Household and Similar Electrical Appliances, Part 1: General Requirements

Luiz Claudio Bonilla de Araujo (Whirlpool Corporation)

On October 31, 2016, UL and CSA published this harmonized standard for general household safety requirements and similar appliances. It is the sixth edition of UL 60335-1. It is based on publication IEC 60335-1, Edition 5.1 (Edition 5:2010 including corrigendum 1:2010, corrigendum 2:2011, and amendment 1:2013), issued April 2014.

The objective of this presentation is discuss the technical changes between the 6th and the 5.1 editions, with a focus on those clauses with greater impact on appliances already certified / listed per the previous standard.

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/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.

This is suitable for those newer to the product safety field, those more experienced who are looking for a colorful recap, and those wanting a presentation they can use inside their organizations to spread awareness.

This is also a good foundation for those planning to attend one of Pete Perkins' ISPCE talks on leakage current.

Component Interchangeability for Compliance – Considerations, Challenges and Improvements

Chintan Trivedi (Intertek Testing Services NA, Inc.)

The need for controlling critical safety components and their supporting documentation helps assure an effective safety compliance evaluation. All too often however, design and manufacturing constraints are perceived as barriers. Such barriers, regardless if real or perceived, impact development and manufacturing flexibilities when product life cycles are rapidly evolving along with underlying challenges of the supply chain environment.

A review of the International Electrotechnical Commission (IEC) System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (ECE) component interchangeability guide is presented in this publication. Intent is to explore how to effectively leverage critical safety component parameters and context along with increasing consistency.

Examples of benefits derived from both consistent and structured methodologies as well as inherent limitations are presented in this publication, capturing entire product assembly or limited subassembly levels.

The importance of understanding critical differences between recognized components and listed products

Maria N Martinez (Intertek)

A common question many new safety compliance evaluators investigators encounter early in their career lies within knowing how to effectively understand elements of conformity for safety critical components and products. This begs the question regarding why some safety critical components are recognized while others are listed.

This paper will focus on identifying the differences between a recognized component and a listed product and why such differences play a critical role in end-product safety certifications.

Electric Shock Measurement

Richard Nute (Consultant)

Electric shock is due to current through the body. Body current is due to voltage across the body resistance. However, the body resistance is a function of the applied voltage. At low voltages, the body resistance is high, and the resulting body current is low. At high voltages, the body resistance is low with high body current. This presentation shows that the skin provides the high resistance, but breaks down at a “high” voltage. Measurement of electric shock requires first a voltage measurement. If the voltage is high enough to break down the skin resistance, then body current must be measured.

Cybersecurity

An Introduction to Information Security Management System (ISMS) – ISO 27001 Mark Jackson (Pacific Quality Solutions)

This presentation will provide an overview of ISO 27001, Information Security Management Systems. Areas that will be covered include an overview of the standard, benefits of certification, structure and requirements, and certification process.

Cyber Security for IoT, are you ready for market access to the EU after August 1st, 2024? Lars K Mellander (Nemko)

Cyber security is now not just a very good idea....after August 1st, 2024 it will be a requirement. 2024, may seem like a long way away, but in our world that is very soon. Come find out more and be ready for this change, better now than later!

Cyber Security for Radio Equipment in the EU and Beyond Mark Briggs (UL Verification Services Inc.)

On Jan. 12, 2022, the Official Journal of the European Union published delegated regulation 2022/30/EU, which places cybersecurity, personal data privacy and fraud protection requirements for wireless devices. The rules came into effect Feb. 1, 2022, and become mandatory Aug. 1, 2024.

We will give an overview of the requirements, the current progress in the development of standards, what happens if standards are not harmonised prior to August 1st 2024 and how to best prepare to be in a position declare compliance to these regulations.

We will also look at other cyber security regulations coming into play in the EU and other countries.

Cybersecurity: Definition, Importance and Scope within Product Regulatory Compliance Anoop Tewari (OnRule); Cyril Mecwan (OnRule)

ABSTRACT COMING SOON.

EMC & Wireless Compliance

New FCC RF Exposure Compliance Rules

VINA KERAI (Nemko North America, Inc.)

The FCC has published its latest revisions to the radiofrequency exposure evaluation rules and guidance in the Code of Federal Regulations Title 47 and KDB 447498. Some rules are already in effect with all new rules being mandatory from June 30, 2022. The new rules mark a significant update and change to the criteria and methodology for assessing unintentional and intentionally radiating devices.

As a result of the new rules, certain devices that previously were exempt from specific absorption rate (SAR) evaluation are now subject to SAR evaluation, while other devices which were wholly exempt from RF Exposure exhibit requirements are now within the scope of the FCC's RF exposure requirements. Several other changes are also made to the rules.

This presentation will start to prepare you for the transition to the new RF Exposure requirements. It will provide a basic understanding of the implications of the new rules for your devices and their impact on your work.

Emerging Technologies & Innovations

UL 8400 – Safety Standard Development for VR/AR/MR

Ted Eckert (Microsoft)

UL Standard Technical Panel 8400 is developing a new safety standard for virtual reality, augmented reality, and mixed reality headsets. This presentation covers the standards development process and the potential hazards covered by the draft standard. It will cover the proposed testing and the hazard analysis required by the draft standard.

Emerging Technologies & Innovations

Drone Product Safety Standards and Improvements for Secure Drone Operations and Management

Dongjun Jung (Yonsei University); Sangdo Kim (Yonsei university); Minsoo Joo (Yonsei university); Jong-Moon Chung (Yonsei University)

Due to the development of technology, the drone industry is used in agriculture, medical industry, etc., and is a promising industry not only today but also in the future. However, due to problems such as safety caused by indiscriminate development and use of drones, regulations for safety management and facility requirements are needed. Based on such needs, IEEE is making efforts to standardize drone devices and requirements for safety management for drone safety. In this study, the requirements for drone safety are summarized considering IEEE Std 1936.1 and IEEE Std 1937.1, where an overview of the requirements for drone safety management and payload devices is presented. The establishment of an integrated infrastructure platform to prevent flight collisions, regulations to prevent malicious hacking, and manuals for safety education are presented for improvements to address the safety issues. In addition, improvements in drone category regulations by weight to secure the drone operation safety are proposed in this study.

XR Product Safety Standards and Improvements for Secure Metaverse Operations and Management

Minsu Choi (Yonsei University); Yuneong Goh (Yonsei University); Jaewook Jung (Yonsei University); Jong-Moon Chung (Yonsei University)

In this study, standard and safety regulations related to metaverse and XR (eXtended Reality), which have been a hot topic in the past few years, are summarized. As the field is still lacking in stabilization and optimization, it is urgent to establish standards, and it is necessary to produce products according to standards and present safety regulations. Among the organizations that establish these standards, activities of IEEE 2888 are considered. Also, this study investigated the current and representative XR devices and examined what characteristics each device has and what possible risks exist. The measures to avoid potential risks and safety regulations to be followed by manufacturers and users are summarized. Finally, the direction of the next generation of XRs and their corresponding standardization and safety discipline measures are discussed.

Taking a UVC disinfection product through regulatory compliance

Steve Reinecke (Proximity Systems)

How do you take an emerging technology through the regulatory process? In this session, Steve Reinecke, Chief Scientist and Regulatory Compliance Officer for Proximity Systems / UV-CLEAN, will share his experience of working with UL to bring the first-ever UVC surface disinfection device through the safety certification, UL 962. Steve will discuss the pitfalls to avoid when dealing with a technology that does not have a clear regulatory standard associated with it. He will also share the challenges of the initial design review and following through with testing. Steve, through his experience, will help you understand how important it is to read and reread all documentation from your NRTL. Steve will also talk about the following standards and how they each posed unique challenges:

UL 991: Standard for Tests for Safety-Related Controls Employing Solid-State Devices

UL 1998: Standard for Software in Programmable Components

IEC/UL 60730-1 Annex H: Standard for Automatic and Electrical Controls for Household and Similar Use

IEC 6247: Photobiological safety of lamps and lamp systems

UL 8802: Investigation for UV Germicidal Equipment and Systems in non-residential locations

UL 8803: Risks of portable germicidal equipment used in homes and other similar areas

ANSI 969 / UL 969 - Standard for labels and markings

Flame Detection Technology Overview & Certification Requirement

Chaitanya Katekar (Intertek)

Statistical data reflects how the industry has been struggling with engulfing fires arising from undesirable events. From 2011 to 2015, an estimated 37,910 fires in industrial and manufacturing properties were collectively reported to United States fire departments per year, which led to approximately \$1.2 billion in property damage and countless (and needless) losses of life. Many years of engineering research have gone into the study of flame characteristics, with the sole intention of early detection of the flame and consequently providing effective alerting means to act, stop, or mitigate flame propagation.

5G Wireless Technology and Developments

Tom Tidwell (Nemko)

An overview of 5th Generation wireless network innovation and how wireless systems such as WIFI and IoT are part of the evolution of wireless mobile networks.

The role of technology in the management of Product Regulatory Compliance

Cyril Mecwan (OnRule)

ABSTRACT COMING SOON.

Ethics

Recognized Components and Ethical Compliance Obligations – Understanding and Fulfilling Conditions of Acceptability

James Bender (Intertek)

Third party safety certifications play a key role in product development and manufacturing. The use of third-party certified components and subassemblies often referred to as “Recognized Components” can greatly simplify end-product certification processes and pending success. This is achieved by minimizing or eliminating duplicated end-product construction and testing efforts of the end-product’s internal components and subassemblies already performed as a part of the Recognized Component’s certification.

This publication provides an overview regarding purpose and importance of “Conditions of Acceptability” (COA) associated with all Recognized Components, along with an interesting focus on ethical implications to meet those obligations.

Product Safety – The Importance and Impact of Ethical Compliance Practices

James Bender (Intertek); Brunno P Covolan (Intertek Testing Services)

Product safety is a key care-about in a product’s cradle-to-grave life cycle, starting from conceptual definition and design, testing, manufacturing and ultimate disposal.

This paper will focus on the importance of product safety compliance practices that cannot be taken for granted when facing production release pressures that challenge not-so-obvious ethical boundaries.

Examples will cover each major part of a product cycle including conceptual definition, design, testing, supporting marketing material (promotional representation that may not align with the product’s certification compliance assessment boundaries including datasheet, whitepapers, manufacturing and disposal.

Laboratory Safety and Ethics

Kacy Stanfill (Intertek)

Abstract — Laboratory Safety is often looked at as a check-list item to only satisfy a regulatory compliance mandate, often failing to consider important ethical obligations to maintain a safety environment.

This paper provides an overview of laboratory safety practices presented from a compliance perspective, tying each consideration beyond the “regulatory obligation”. It will focus on why such practices and obligations are important to satisfy ethical cornerstones to preserve employee safety in the laboratory featured through third party safety certification laboratory examples.

Forensics, Failure & Risk Analysis, Assessment & Management

Forensic Analysis of Trucking and Equipment Accidents and Failures

Patrick D Riedlinger (ESI)

Program Abstract:

Heavy vehicles and Farm/Industrial equipment often have unique and spectacular results when accidents occur, from human failures or direct machine failures. Patrick Riedlinger, PE, accident Reconstructionist will show case studies and methods of analysis in heavy vehicle accidents.

Global Hazardous Locations

Designing UL508A & UL698A Industrial Control Panels Intended for Installation in Hazardous Locations

Aaron J Roberts (ABB)

Designing industrial control panels brings a unique set of challenges when designing to meet customer specific requirements. Add in the requirements of UL508A as the general standard for safety and additional requirements when designing for hazardous location and the design requirements can seem staggering. Additional marking and manufacturer requirements listed in the Descriptive Reports can add to the confusion. During this presentation and discussion, we will address the standards utilized, common protection techniques for designing for installation in hazardous locations, and good engineering practices to help simplify the design loop. Component verification, audits, documentation, and personnel competence will be among the topics to be addressed.

Why influence global HazLoc standards?

Frederick S Kiddle (ABB)

Knowledge is power when participating in standards development. This presentation will cover the movement in harmonization of standards, and why it is important to participate in technical committees. Although the principles shared in the presentation can apply in the process of standards development, this presentation focuses specifically on hazardous location (HazLoc) standards development. Understanding and getting involved in the process for the adoption and maintenance of conformity standards provides the opportunity to help influence the development of these standards for business and safety benefit.

Manufacturers, certifiers, users and inspectors/regulators of HazLoc equipment should take notice of the fact that standards have a direct impact on their bottom line! Global harmonization of product standards is a win-win for everyone; however, it sometimes becomes complex when challenged with compromise or adoption for national differences to satisfy local requirements. Intimate knowledge on the state-of-the-art standards assures longevity of the business at hand.

Global conformity assessment of equipment for hazardous (classified) locations

William Fiske (Intertek)

The four pillars of product safety are standards, conformity assessment, installation codes, and code enforcement. If any one of them fails, the entire system fails, resulting in a dangerous condition. In explosive atmospheres, the consequences of a failure in the safety system are much greater than the consequences of failure in normal industrial occupancies.

Due to the grave consequences of accidents in hazardous (classified) locations, there are more rigorous requirements in the equipment standards, different approaches to conformity assessment, and more rigorous installation requirements. This session mainly focuses on the conformity assessment aspect of the system.

As the topic of this session is global conformity assessment, the International Electrotechnical Commission System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System) will be the principal subject of the session. IECEx is the only global conformity assessment system related to hazardous (classified) locations. There are also regional hazardous locations conformity assessment schemes of some significance. A few of these will be described, including their similarities to and differences from IECEx.

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.

Hydrogen Technologies for Refueling Station Facilities

Robert A Deadman (UL LLC); Paul T Kelly (UL LLC)

There are estimates that ten million metric tons of hydrogen are currently produced in the United States every year. Applications for hydrogen include oil refining, ammonia industries, metals refining, liquid fuels (e.g., biofuels, synfuels), heat generation, energy storage, and transportation. This presentation will be about hydrogen technologies for refueling station facilities.

HAZLOC EQUIPMENT MANUFACTURERS AUDIT CHALLENGES, OSHA NRTL Factory Surveillance (29 CFR 1910.7) vs IECEx/ATEX Quality system (ISO/IEC 80079-34)

Onasis Greene (Intel Corp)

OSHA requirements for NRTL factory surveillance of hazardous location equipment is a minimum of four (4) factory surveillance visits per year. This requirement does not consider a reduction in the minimum number of visits based on the robustness of the manufacturer's quality system or incidents history. The NRTL surveillance requirement is not checklist based, compared to ISO/IEC 80079-34, leading to the potential for inconsistent practice across NRTLs. This presentation will touch on the pros and cons of the OSHA NRTL factory surveillance program to answer the question, "Can industry influence OSHA to lean towards an approach based on, or more aligned with, the IECEx and ATEX quality system to promote consistency while maintaining safety?".

Global Market Access & Regulations, Compliance Management

Global Impact of Adding Wireless Technology to Products

Theresa Glenna (TUV SUD)

Adding wireless technology to a product adds a layer of certification requirements which can be challenging to navigate. Learn about different methods of integrating wireless modules and how you can leverage 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.

RoHS directive – Quo vadis?

Eva S. Hink-Lemke (iPoint systems GmbH)

In 2011, the RoHS directive 2011/65/EU was published as the recast of the first RoHS directive 2002/95/EC.

The new directive, being a “single-market” directive is ruled under CE marking and established one of the first connections between technical requirements and environmental aspects. It has put more responsibility on industry by establishing new rules and processes for exemptions. It demands a process for regular review of the restricted substances list. This ensures that the requirements of the directive will be adapted to the technical progress from time to time.

In 2022, we are still waiting for many news and decisions for the future direction of RoHS:

- 9 exemptions for commonly used exemptions from Annex III (e.g. lead in alloys) have been reviewed since 2020 as they were about to expire in 2021. The recommendation has been published in early 2022. Now, we are waiting for the decision from the EU commission and the draft of the amending directive.
- In 2018, a review of the list of restricted substances in Annex II was started and finalized in 2021. Several priority substances were assessed with regards to their hazard impacts and use in EEE. The EU Commission has not yet decided if and which substances will be put on Annex II in the future.
- The directive as such is under review. The major question is, if those restrictions shall continue to be regulated under a CE directive or if it shall be incorporated into the REACH regulation, e.g. Annex XVII. What will be the impact on industry? Will there be a change on the conformity procedure? How might a change influence other RoHS-like legislation worldwide?

The presentation will provide the latest up-to-date information on relevant developments on the EU-RoHS directive. Relevant details, news and changes will be highlighted and industry-relevant recommendations will be given, e.g. how to ensure and document compliance as well as how to optimize the communication within the supply chain.

Mexico Regulatory Telecom and Safety Updates

Elizabeth Perrier (ORBIS Compliance, Ilc)

Mexico has been implementing many regulatory changes in their Conformity Assessment framework that are hard to understand and plan for. This session will provide the clear and concise explanation of the changes and how they impact your current approval and guide you how to plan for the future. Safety Regulations will also be included in this seminar as NOM-019 is soon to be published having lasting impacts in the way the products are testing and approved today. We look forward to a dynamic discussion with attendees.

India Certification Overview (BIS – Safety, WPC – Wireless and TEC – Telecom)

Kapil Sapru (G&M Compliance); Thomas K. Ha (G&M Compliance, Inc.)

We would like to present in brief the India certification process, focussing on Safety, Wireless, and Telecom. We would also like to present different products which are mandatory in these certifications. One of the case studies presented in this deck will give a clear idea, of how the certification process works.

Mexico – Market Access and compliance changes 2022

Maja Bland (UL)

Thinking about exporting into Mexico? Are you already selling into the market and wondering how the changes recently communicated for electronics and wireless products have affected your existing compliance records?

In this presentation we will cover the following in our Agenda:

What are the Compliance Requirements (Safety, Wireless, Energy Efficiency)

What is Mexico HS code (harmonized tariff code) – and how this code drives regulatory requirements?

What's new: Regulatory Updates focused on:

IFT revision to PEC June 27th 2022 enforcement.

NOM-019-SE-2021 status of enforcement impact on DGN equivalency agreement process.

Please join us in further unravelling the mysteries of Market Access compliance in Mexico.

Organizing and managing compliance data

Tom Tidwell (Nemko)

It is becoming increasingly difficult to keep current with regulations internationally. We need methods and tools to maintain regulatory data that will allow us to define the requirements for new and existing products.

An Overview of the Latin American Regulatory Landscape

Tom Tidwell (Nemko)

Regulations in Latin American countries are changing and requirements are being added for Cyber Security and Energy Efficiency.

Certification Documentation Management: Critical Must Have's for Success!

Brunno P Covolan (Intertek Testing Services)

Critical to the engineering discipline is the ability to control and manage design and product specific documents. From product inception to end-of-life, documentation is created and released to communicate critical compliance care-about and features. These include performance specifications, market study and feedback assessments, user manuals, and many more. Sadly, and all too often, documentation to support product safety certification is not always captured during its most critical time, dealt with as an often-reactive afterthought prior to the safety compliance evaluation.

The importance of certification document management cannot be overstated. Implementing a proactive approach that captures compliance critical care-about can help to favorably influence product deployment costs and avoid product redesigns to lead to a successful and effective product launch.

India Market Access – Focus on TEC

Grant Schmidbauer (Nemko North America, Inc.)

This presentation will discuss market access into India, with heavy focus on latest TEC/MTCTE regulations.

Contents will include:

- » Indian Economy
- » Indian TIC Market
- » Updates on BIS/CRS scheme
- » Updates on TEC/MTCTE scheme
- » Upcoming Mandatory scheme – Machinery

The presentation will be further updated just prior to ISPCE in September, to ensure latest information is presented.

China GB/T 9254.1 CCC Standard Update

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

GB / T 9254.1 Standard Overview

The EMC standard (GB/T 9254.1) for China CCC certification has been updated. This standard is applicable to ITE, A/V, broadcast receiving equipment,

entertainment lighting control equipment and their

combinations with rated AC (RMS) or DC voltage not exceeding

600V. This presentation will provide in details the changes and updates.

Beyond the Basics, save the trauma for when it really counts

Lars K Mellander (Nemko)

Critical things you need to know to be ready for a market release. Whether a limited market or global, mistakes are the start can mean serious issues that can be avoided. You think you know all needed? Come and find out, starting off right, means a much better life early.

Mexico, things you need to know and what to expect

Lars K Mellander (Nemko)

A detailed overview on Market Access to Mexico. Items covered are what I see on a daily basis that can be avoided and at the very least you should be aware of. No need to avoid this market, come and find out more.

An update of the very latest for Global Market Access

Lars K Mellander (Nemko)

Come and find out what are the most current changes are in the world of Global Market Access. It is impossible to know everything(!) and even if you do, it will change next week! I will be sharing what I think you need to know the most, not just an overview(!) the details that you need to know and what the best path may be for you to get there.

Homologation tricks and tips

Cyril Mecwan (OnRule); Thomas L Killam (OnRule)

Abstract Coming Soon.

Hazard Based Safety Engineering & Safety Science

Risks of Recent Automatic Doors for Pedestrians

Toru Nakata (National Institute of Advanced Industrial Science and Technology (AIST))

Automatic doors settled in entrances of buildings have been used for a long time, so people regard them as quite safe. Incidents around automatic doors in Japan, however, are increasing with changing their incident modes. Although the safety measures for the doors seem enough effective only for small and light doors, they are applied on larger and heavier doors without review on safety. The standard and conventional strategy is limitation of kinematic energy of moving doors. This strategy cannot be applied when the door itself is very heavy. Furthermore, it becomes a disadvantage to avoid collision with pedestrians because the doors are not allowed to move quickly due to the limitation of kinematic energy. The conventional safety measures are contaminated with risks now. This paper reports the change of risks of automatic doors in Japan, and the author propose a reform idea for the safety measures.

USB Breaking the 100W Barrier

William H Susiene (Intel Corporation)

Provides an overview of latest USB Power Delivery (PD) Extended Power Range (EPR) from a safety perspective, including background on USB's historic challenges with IEC 62368-3, and the collaboration effort between USB IF, IEC TC100, and IEC TC108 to align on future standards requirements that support safety and interoperability. The presentation will also touch on the new protocol safeguards and functional safety concepts to address soft errors in communication.

Datacenter Liquid Cooling Revolution

William H Susiene (Intel Corporation)

Provides an overview of different emerging liquid cooling thermal solutions for Datacenters, including some pros/cons, background on IEC 62368-1 requirements, and the collaboration between TC108 & ASHRAE to support new modular concept for IEC 62368-1, 4th Edition. The presentation will also touch on 2-phase systems and some of the challenges with greener refrigerants (e.g. A2L).

Calibrating HV Systems Safely

Glen W. Broderick (Vitrex)

Calibrating high voltage instruments and systems presents several unique challenges. They can seem rather trivial if you know about them – but can kill you if you don't. Assuming that the audience is already familiar with calibration and traceability, this presentation focuses on the specific issues of working with high voltage, the factors that affect accuracy, and how to make measurements safely.

Topics discussed include types of HV instruments; instrument errors, probe errors, sources and control of these errors; and understanding HV specs.

Finally, it covers the basics of setting up a workstation in ways that can improve the safety of those in the area.

Legal, Regulations, Directives & Consumer Protection

Improving Safety in Europe – Detecting Counterfeit Certificates from FFP2 Masks: A Text-Mining Approach

Franz Wieck (University of Wuppertal); Ninja vom Stein (University of Wuppertal); Manuel Löwer (University of Wuppertal)

The large volume of new products poses major challenges for market surveillance authorities and accredited testing bodies. This lack of verification leads to defective products being sold. For personal protective equipment, e.g., FFP2 masks, this leads to an increased safety risk. To reduce this risk, this paper proposes a solution to identify non-compliant products by analyzing the required certificates, especially the type examination reports. To enable automated evaluation, this paper presents a text-mining approach for verification. It consists of three steps: i) requirements identification of certificates, ii) data extraction and analysis and iii) evaluation of the results using a decision tree classifier. Finally, the algorithm is validated using a case study of several counterfeit FFP2 type examination reports. The result shows that the text-mining approach is capable of distinguishing fakes from real certificates. The ability to analyze certificates in an automated way will completely change the way market surveillance authorities and accredited verification bodies check documents.

False or incorrect markings and test reports of EEE parts

Steli Loznen (IEEE-Product Safety Engineering Society-Vice-President for T)

In this presentation will be reviewed the means that play an especially critical role in the electronics sector, where one fake marking, component or approval could impact a product's operations and the safety of its users.

Product counterfeiting is a well-known problem, one that has been with us for a very long time. Counterfeit products are not just a passing problem, but are part of a major global industry. It is a fact that false and incorrect marking and documentation issues in the electrical, electronic and electromechanical (EEE) products marketed can be dangerous and unsafe due to use of second choice of raw material, poor assembly, lack of third-party testing and certification, etc. EEE counterfeits affect every segment of the market, including consumer goods, networking and communications, medical, automotive, and aerospace and defense.

We try to help companies and consumers to defend themselves in the ever-expanding market of counterfeit goods and focuses on the means used for detecting and avoiding counterfeit EEE parts that have been remarked or recycled, a review of the applicable standards used for detecting these parts and methods for identifying incorrect test reports, certification or approvals.

Product Safety Compliance – current legal developments in Europe

Arun Kapoor (Noerr)

The new EU Market Surveillance Regulation represents a turning point in European product safety law. For the first time, it harmonizes the official enforcement of product law in Europe, expands the powers of the authorities and tightens the conditions for e-commerce. And the next challenges are already on the horizon. Arun Kapoor gives an overview on the current status of the upcoming new Regulations on General Product Safety, Machinery and Toys.

Responding to Injury Reports – Confronting Regulatory and Legal Risk

Ted Dorenkamp (Bowman and Brooke LLP); Arun Kapoor (Noerr)

A company that manufactures and distributes a consumer-facing product for the EC and US markets received reports of several injuries that have occurred while using the product and has also received a couple of claim letters. Presenters examine how a company might respond to these reports and claims to efficiently address and minimize regulatory and legal risk in both the European and U.S. perspective.

Circular Economy and sustainability – upcoming legal challenges for Product Compliance on the European market

Sonja Leibold (Noerr); Arun Kapoor (Noerr)

In the European legal framework, Product Compliance goes beyond product safety already for quite some time now. As a new drive, more and more complex rules on environmental product compliance apply to different product categories. In the context of a comprehensive strategy on significant limitation of climate change, the European Commission now launched a strategy and first drafts of legislation which go even further and oblige the manufacturer throughout the product life circle. Starting with the mandatory use of recycling materials, covering the durability of products and stretching to disposal characteristics and end-of-lifecycle obligations. This new quantity and quality of legal obligations will force manufacturers placing their products onto the European market to adapt their product compliance management. This session will give a systematic outline on the upcoming challenges and first thoughts how to address them from a manufacturer's perspective"

Medical Devices

Regulations and Concerns for Wearable devices- Understanding on the possible safety and performance issues

Pamela Gwynn (UL LLC)

“Wearable” is a buzzword recently pops on all kinds of media. A “wearable” device seems to be more attractive and creates a lifestyle fashion. People are also talking about “Wearable Technologies”, “Wearable Computing”, “Wearable Devices”, yet what exactly do they mean?

There are two emerging markets: Non-clinical and healthcare – Driven by the awareness of personal wellness and the growth of aging population in highly developed countries, Gaming and entertainment – Supported by a special interest group.

These new applications will impact the existing regulatory requirements and attract the attention of government agency and Certification bodies.

In this presentation, we will discuss the following topics

- » Common understanding of the term “Wearable Device”
- » Landscape of Wearable devices market and application
- » Challenges and Concerns on Designing Wearables
- » Regulatory, Industrial and Performance Specifications

Medical Device IEC 60601-1 compliance

Liam Lam (Nemko)

The presentation will present the administration changes, technical changes, and gap analysis from IEC 60601-1:2005 + AMD1:2012 to IEC 60601-1:2005 +AMD1:2012 + AMD2:2020.

Product Safety Standards and Integration of sensors and Therapies

Todd R Konieczny (Intertek Testing Services NA Inc.)

Medical products are changing from the typical bench top models everyone is familiar with in doctors offices and hospitals. The devices are becoming smaller and wearable and used in everyday in the real world. This makes complying with the standards more challenging and complex. This presentation was created to help breakdown some of the barriers with new technologies and the standards that have not caught up yet.