ISPCE 2018

IEEE SYMPOSIUM ON
PRODUCT COMPLIANCE ENGINEERING

SAN JOSE, CALIFORNIA, USA

MAY 14-16, 2018

Sponsored By:

PSES

IEEE

ABSTRACTS

Batteries & Energy Storage Systems

Effects of Dropping a Battery Powered Device: A Look at the Separator and Electrodes after Drop Testing

Troy Hayes (Exponent Failure Analysis Associates, USA)

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

Safety, performance and robustness of smart phone systems

Flore Chiang (Underwriters Laboratories (UL), Taiwan)

Abstract: Due to exceptional mobility, computing power, capacious storage, intuitive user interface (UI) and open operating systems that support hundreds of millions of apps, smartphones have profoundly changed people's daily lives. Unlike other consumer technologies, smartphone is carried in close proximity to the human body, exposed to extreme climate conditions and vulnerable to a wide variety of consumer behaviors, which posed safety risks to consumers. To address the needs of consumers, smartphone manufacturers and the greater smartphone industry, a new standard is developed serving as a technical specification for safety of the single-cell- battery-operated smartphone systems, charging systems and their accessories and peripherals. In this paper, the author will introduce a modern approach for safety of battery-operated devices that is innovated from HBSE (hazard-based safety engineering). Key aspects covered by this standard will be presented too.

Electronic cigarette - a safer alternative to smoking or health hazard?

Flore Chiang (Underwriters Laboratories (UL), Taiwan)

Abstract: Media reports have noted that e-cig fires and explosions may involve the lithium-ion batteries and/or compatibility with the charger. It is known that lithium batteries in e-cig are used in different ways than those in consumer electronics and also e-cigs are an emerging industry that might not have much experience with lithium batteries. These products have been marketed as a smoking cessation tool, or a healthier alternative to cigarettes since 2003. There has been a correlation between the increase in sales and an increase in the number of related incidents. The three basic elements are the cartridge (nicotine/flavor), atomizer (heat), and battery (power). Complications can include nicotine poisoning, toxin ingestion and fire and explosion hazards which can result in injuries to the user. E-cigs differ from traditional cigarettes in the type of hazards that exist. With traditional cigarettes, hazards are inherent and almost identical from product to product. With e- cigs, the electrical hazards can be mitigated with careful design and testing. The following main risks were considered when developing the initial draft of the Standard: battery explosion, battery replacement, atomizer replacement, and accidental activation. UL 8139 is being approved as both an American National Standard (ANSI) for the United States, as well as a Standards Council of Canada (SCC) standard for Canada.

Certification Challenges for Power Banks

Rich Byczek (Intertek,USA)

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

Compliance 101

Global Market Access Overview

Nicole Tatum (UL LLC, USA)

Abstract: Not Available at the Time of Production

Compliance 101: electlric shock, touch current

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 more than 50 years experience in the electronics field.

Compliance 101: The basic requirements for any Product

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

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

Safety Outside the Box

Dan Roman (Colgate-Palmolive Company, USA)

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

Essential Requirements of the Nigerian Information and Communications Equipment Homologation

James Kunle Olorundare, MNSE (Nigerian Communications Commission (NCC), Nigeria &; Bucks New University, United Kingdom (Great Britain)); Adebimpe Olorundare (National Open University of Nigeria, Nigeria)

Abstract: The papers breaks down all the requirements for homologation in Nigeria.It expatiates on the role of the telecommunications industry regulator, Nigerian Communications Commission, the power of the NCC as drawn from the Nigerian Communications Acts, The Nigerian Type Approval Regulation, The Nigerian Type Approval guidelines and other regulatory powers as it relates to equipment type approval/ homologation. It defines homologation as it is within the jurisdiction of the NCC. The Essential requirements

are broken down to the following: The Standards requirements. The adopted standards as it is contained in the European Norms The local exceptional Rules The Need for Declaration of Conformity, Electromagnetic Compatibility Standards, The effective use of Spectrum as required for Nigerian Homologation. The SAR Requirements etc.

The step by step procedure is also explained together with challenges that can constitute a constraints to seamless homologation application processing and the solutions discussed. The RED and R&TTE Requirements are also mentioned including homologation for IoTs as future works.

Global RoHS

Kenneth Stanvick (Intertek, USA)

Abstract: In the world of international regulations, the EU RoHS Directive has undergone changes in requirements, when enacted by various countries across the globe. This has affected electronic product manufacturer's ability to place their products on the global market without addressing the unique requirements imposed by the various implementations. Product manufacturers who are not keeping up with the changes can suffer brand damage, product recall, civil penalties and monetary fines resulting from noncompliance.

This presentation will focus on three specific implementations of RoHS, EU RoHS, China RoHS, and United Arab Emirates RoHS. We will identify common requirements, where the requirements differ and the necessary actions that product manufacturers and their materials manufacturers will need to put in place to ensure compliance.

The New FCC Supplier's Declaration of Conformity Approval Process

Nicholas Abbondante (Intertek, USA)

Abstract: A presentation going over the updated FCC approval process.

Environmental & Energy Regulations

EU RoHS directive: challenges deriving from exemption rules and IEC 63000 (EN 50581)

Eva S. Hink (iPoint-systems GmbH, Germany); Marcos Medalla (iPoint Inc., USA)

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

TCO Certified for Manufacturers

Sören Enholm (TCO Development, Sweden)

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

Forensics, Failure & Risk Analysis, Assessment & Management

Probabilistic Safe-Service Life Assessment of US Army Mortar Weapon System

Douglas Ray (US Army ARDEC, USA)

Abstract: This Physics of Failure (PoF) case-study is a fracture mechanics Modeling & Simulation (M&S) study of a 120mm mortar gun tube (essentially a pressure vessel) reliability from a probabilistic perspective. Best-practices in Uncertainty Quantification (UQ) are utilized to understand the gun barrel PoF fatigue and safety and reliability design margins relative to limit states, pressure variations, operational usage conditions, initial crack sizes, and various locations. Analytical techniques highlighted include Design of Experiments-based M&S emulator incorporating 'live' test data, Monte-Carlo Methods, and Pareto-Frontier Analysis. * Some data has been modified for OPSECreasons*

Metalized Film Capacitors As Fire Pattern

Louis Bilancia (Engineering Systems, Inc., USA)

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

Global Market Access & Regulations, Compliance Management

Certification Schemes for global countries on Electrical safety and Radio approval

Tina Ding (CSA Group, Canada)

Abstract: Certification Schemes for global countries on Electrical safety and Radio approval - Example of typical country approval will be discussed in the presentation, audience also has opportunity to ask any questions they may be interested in! This presentation provides an overview of International Approval on electrical safety and Radio Frequency products. On electrical safety, it summarizes the countries in the world how to define their regulatory frame work under ISO/IEC 17067, based on this frame work, how country set up the technical regulation based on international harmonized standards for product compliance; After this presentation, manufacturers should be able to understand all the terms & definition used in the international approval and be prepared for the new market; Meanwhile, presenter also will introduce the test report acceptance in different countries and explore with manufacturers to find the best option for their products tested and report accepted in other countries with minimum rework. Beside the electrical safety certification scheme, this presentation also summarize the methods of international RF approval to 4 types for more than 160 countries in the world, where indicate what testing are necessary & essential and how manufacturer to select an accredited laboratory for the countries they want to market in the most efficient manner.

• Electrical Safety international certification schemes: ISO/IEC 17067 Certification Scheme been adopted in the global markets with typical type of below (will summarize countries in the schemes): Scheme 5 Scheme 1, 1b Scheme 2 Others schemes outlined in ISO/IEC 17067

Safety Test report acceptance with typical types of below: CB report/Certificate under CB scheme IEC ILAC test report under ILAC 17025 Test report per national standards where test lab needs national standard accreditation and acceptance by local regulator

• Radio and Telecom Global approval in three major types: Route 1. SDoC procedure Route 2: Countries accepting EN or FCC reports for issuing national approval Route 3: National standards established however allow foreign labs to be accredited or MRA lab test report Route 4: National standards established and only national accredited lab for local testing

---

Navigating Global Compliance in Asia

Nicole Tatum (UL LLC, USA)

Abstract: Not Available at the Time of Production

CCC Regulations for Household and Similar Appliance

Aiying He (Partner, P.R. China); Paul Wang (G&;M Compliance &; G&;M Compliance, P.R. China)

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

China market access

Paul Wang (G&;M Compliance &; G&;M Compliance, P.R. China)

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

The US Consumer Product Safety Commission says: Stop Using Organohalogens

Michael Kirschner (Design Chain Associates, LLC, USA)

Abstract: In September 2017, the US Consumer Product Safety Commission issued guidance advising manufacturers to stop using organohalogen flame retardants in plastic electronics enclosures to achieve fire safety requirements. This presentation will explore

* the rationale behind this guidance (which they intend to turn into a regulatory requirement),
* examples of organohalogens used in enclosures today as well as their environmental and human health-related toxicity, * a case study demonstrating how flame retardants were avoided entirely in a television enclosure, * the impact of decisions like this on the practice of product safety * why the normal approach to product safety has put the electronics industry in this position by a lack of oversight of chemical toxicity safety * What manufacturers, and the industry at large, can do to improve the environmental and human health safety performance of its products.

Wireless Compliance in ASEAN Region: Singapore, Indonesia, Malaysia

Theresa Glenna (TUV SUD America Inc., USA)

Abstract: The Wireless Compliance requirements in the countries of Singapore, Indonesia, and Malaysia are not well known.

This presentation will cover the wireless requirements for each of these countries in detail. Information about scope of approval, allowed frequency bands, documentation, testing and report requirements, labeling, and local representation is included.

South Africa: A closer look at the latest regulatory requirements

Theresa Glenna (TUV SUD America Inc., USA)

Abstract: This presentation will give a brief history of changes in regulatory requirements in South Africa. It will then go into detail describing the current requirements for Safety, EMC, and Radio/Telecom products. Testing and report requirements, documentation, labeling, and local representation considerations will be included, as well as some tips for obtaining the approvals in a timely manner.

The Internet of Things - Impacts on regulatory issues

Tom Tidwell (Nemko USA, Canada)

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

Innovative approach to proactive maintenance of regulatory compliance approvals

Roger Martin (Compliance Dynamics, LLC, USA)

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

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

Lars Mellander (Testing-Compliance &; Nemko USA, USA)

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

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

Lars Mellander (Testing-Compliance &; Nemko USA, USA)

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

Labeling and Marking Requirements for Telecom and Electrical Products in Latin America

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

Abstract: Product Labeling is an important part of the Compliance process that directly affects the flow of imported goods into a country. If not done correctly, it can cause shipment delays, increase costs and impact revenue.

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

Hazard Based Safety Engineering & Safety Science

IEC 62368-1: As Easy as One Two Three

Ted Eckert (Microsoft Corporation, USA)

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

IEC 62368-1: Safety of AV/ICT Equipment - Instructional Safeguards In-depth

Thomas Burke (UL LLC, USA)

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

Integration of Industry 4.0 and Assessment Model for Product Safety

Chi Ho Li (The Open University of Hong Kong, Hong Kong)

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

Introduction to Electrically-caused Fire

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

Abstract: Electrically-caused fire and fire parameters are defined.

An Automatic RFID Detection based Railway Identification System

Hongxu Zhu, Kim Fung Tsang, Chung Kit Wu and Hao Ran Chi (City University of Hong Kong, Hong Kong)

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

Self-Defense Against Transient Voltages and Currents in Product Safety Evaluations

Don Gies (New Jersey Institute of Technology, USA)

Abstract: This paper examines transient voltage and current that electrical products are expected to withstand when undergoing product safety certification. These include expected power system, switching, or atmospheric transients and voltage-withstand voltages.

Experiments of DC Human Body Resistance I: Equipment, Setup, and Contact Materials

Hai Jiang and Paul Brazis (Underwriters Laboratories (UL), USA)

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

Medical Devices

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

James Benscoter and Paul D. Evers (UL LLC, USA)

Abstract: While the collateral standard IEC 60601-1-2, 4th Ed does change some of the test values, other changes in the standard place an additional responsibility on the manufacturer. This additional responsibility can lead to delays when submitting to the test lab. We need to understand the additional responsibilities, discuss the impact and determine the best steps forward to prevent delays in testing. Addressing these new items up front, can ensure the testing is conducted correctly the first time.

To address these additional responsibilities of the manufacturer, we need to discuss the following topics: the role of Risk Management from the standpoint of IEC 60601-1-2, instruction for use and development of the test plan. We will discuss each of the items to allow the manufacturer to better prepare for the testing.

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

Nicholas Abbondante (Intertek, USA)

Abstract: Repeat of the presentation on IEC 60601-1-2 4th edition with a focus on RMF requirements for EMC

This topic is a repeat but is very timely with the upcoming transition at the end of 2018

Risk Management Challenges in Medical Application Platforms

John Hatcliff (Kansas State University, USA)

Abstract: Medical devices and systems are increasingly being built using interoperability and platform approaches. Work in the standards community is laying the foundations for safety, security, and risk management approaches for "systems of systems" of medical devices built using "medical application platforms" (MAP). A MAP is a safety- and security-critical real-time computing platform for (a) integrating heterogeneous devices, medical IT systems, and information displays via a communication infrastructure and (b) hosting application programs ("apps") that provide medical utility via the ability to both acquire information from and update/control integrated devices, IT systems, and displays. Risk management, including performing component-level and system-level hazard analyses, is very challenging in this context because activities are spread across different organizations and across different component roles including infrastructure components, conventional medical devices, and software-based application logic.

In this paper, we give an overview of risk management challenges associated with building interoperable medical systems using medical application platforms. The presented is framed in terms of ISO 14971 -- the primary medical device risk management standard. In particular, we take each part of the ISO 14971 risk management process and describe how we believe the risk management process should be extended to address interoperable medical systems.

This work is funded in part by the National Science Foundation's FDA Scholar-in-Residence program and a Phase II SBIR from the US Army Medical Research and Materiel Command (USAMRMC).

Cybersecurity: Is your product really "safe" if you haven't fully considered it?

Naysahn Saeed (CSA Group, USA)

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

This presentation will have some medical device specific information, but will include valuable information for all types electronic products.

EMC & Wireless Compliance

Testing of Wireless Devices

Grace Lin (Intertek, USA)

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

Basics of Lightning Protection for Communication Towers

James A Bacher (JB Consulting, USA)

Abstract: Basic introduction in how to protect communications equipment from lightning damage. The same techniques for protecting towers, applies to all buildings whether they have towers or antennas. That includes homes and business

---

Kiss-EMC 2018

James A Bacher (JB Consulting, USA)

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

African Wireless Compliance

Mark W. Maynard (American Certification Body, Inc. &; Washington Laboratories, Ltd., USA)

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

Russia & the Eurasian Economic Union Compliance

Mark W. Maynard (American Certification Body, Inc. &; Washington Laboratories, Ltd., USA)

Abstract: An overview of the EMC, Product Safety, and Wireless compliance requirements for the five countries of the Eurasian Economic Union (EEU). The EEU is an economic cooperative founded in 2010, modeled after the European Union (EU), and currently consists of the five countries of Russia, Armenia, Belarus, Kazakhstan, and Kyrgyzstan.

Wireless Compliance for Mexico, Central America, and the Caribbean

Mark W. Maynard (American Certification Body, Inc. &; Washington Laboratories, Ltd., USA)

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

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

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

Abstract: To show compliance to the EU Medical Device Directive for sales of medical devices in the EU, manufactures must use current revisions of standards, and can no longer show compliance using standards that have been withdrawn. The EMC standard that is most commonly used to show compliance with the Medical Device Directive is EN 60601-1-2: 2007 3rd edition, is being withdrawn effective 12/31/17 and being replaced with EN 60601-1-2: 2015 which is now the 4th edition. This new fourth edition mirrors similar IEC standards that went into effect in 2017. Changes in this standard will greatly effect the test requirements, methodology, and process used to show compliance to the medical device directive. Any medical product placed on the market after the withdrawal date of 12/31/18 using the 3rd edition standard shall be considered non-complaint. Devices already in use or in the marketplace do not have to be removed, only products placed on the market after 12/31/18. There is no grandfather clause for the new standard. The new 4th edition standard identifies different consideration for testing medical devices. This involves the preparation of a risk assessment by the manufacturer, which clearly identifies risks while operating the medical equipment, and this must be included in any formal test plan and processes. The 4th edition standard goes as far as to require that a test plan be provided by the manufacturer.

Radio Equipment Directive (RED) Updates for Wireless and Similar Products

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

Abstract: The EU enacted formal legislation that withdrew the Radio and Telecommunications Terminal Equipment (RTTE) Directive 1995/5/EC and replaced it with the Radio Equipment Directive, 2014/53/EU, or RED. This new directive, went into law effective June 13, 2017, after a one year transition. This new directive incorporates several changes related to the scope, standards, and inclusion of safety and performance requirements, The EU will no longer accept a Declaration of Conformity that referenced the RTTE Directive, and all products placed on the market or into use on the EU market must show the RED as the applicable referenced Directive for CE Marking and entrance into the EU marketplace.

Global Hazardous Locations

International Certification for HazLoc Products

Tina Ding (CSA Group, Canada)

Abstract: Demand for HazLoc products is rising all over the world, providing manufacturers in this market with abundant opportunities - but understanding the various national requirements early on in product development is crucial. This presentation focuses on how to obtain international approvals for HazLoc products and outlines requirements for specific countries such as Brazil, Russia, South Korea, China, Taiwan, Japan, and others. While approvals are generally based on the widely accepted IECEx scheme, it's important that manufacturers be aware of national deviations from this scheme and IEC standards in their target markets - and incorporate those differences during the design stage to save time and money. After this presentation, manufacturers will walk away with a better understanding of global market access and specific country approvals.

Global Hazardous Locations 101

John Chambers (UL LLC, USA)

Abstract: Participants will learn about the latest requirements for electrical products intended for use in or relating to hazardous locations (explosive atmospheres). Whether it's Classes, Divisions or Zones, this session can help you design your products for compliance to the proper atmospheric classification, while providing you with greater worldwide market access. Get the answers to your hazardous locations questions from leaders in standards development. Topics include:

· What are hazardous locations?

· Classifying hazardous locations

- Types of explosive atmospheres

- Likelihood the atmosphere is present

- Ignition-related properties of the atmosphere

- Maximum surface temperature

· Protection techniques

· Standards

North American Division 2 Certification in 5 Easy Steps

Paul T. Kelly (UL LLC, USA)

Abstract: Are you a manufacturer of certified electrical equipment for use in general industrial (ordinary locations) applications? Would you like to expand your market options to include Division 2 hazardous locations (explosive atmosphere) applications? Obtaining Division 2 certification is easier than you may have thought. Learn about the five key design features that can significantly simplify your certification process:

1. External interconnection means

2. Normally non-arcing parts

3. Intended ambient

4. Maximum surface temperatures

5. Environmental considerations

Comparing NEC Division 2 vs IEC Zone 2 Protection Techniques

Paul T. Kelly (UL LLC, USA)

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

The Role of Third-Party Testing in Securing Industrial Internet of Things (IIoT) compliance - Hazardous Locations, Functional Safety & Cybersecurity

Matt Jakuc (CSA Group, USA)

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

---

HazLoc certifications in 90 days (or less)...a piece of cake

Gary Kozinski (Baker Hughes, a GE Company &; GE Oil &; Gas, USA)

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

Legal, Regulations, Directives & Consumer Protection

Understanding and Investigating Burn Injuries

Kenneth Lee (Exponent, USA)

Abstract: Burn injuries are a common occurrence in industrial settings and everyday life, and often involve consumer products. Despite the prevalence of burn injuries, understanding the burn risks that may accompany industrial processes or commonplace consumer products, as well as investigating these types of injuries, can be a difficult task.

The basis for our current scientific understanding of burn injuries is formed by a few landmark studies involving the quantification of burn severity under different thermal exposures. These studies also form the basis for consensus standards (such as ASTM and ISO standards) that provide guidance for assessing the risk of burn injuries. These standards are frequently misinterpreted when used in the context of product safety.

Understanding the mechanics of burn injuries, the way in which consensus standards apply or don't apply, and the available tools for evaluating burn hazards are all indispensable to any investigation involving burn injuries. By bringing scientific rigor to the analysis of burn injury hazards, an understanding of the cause of injury becomes clearer.

Multiple cases studies will examine typical issues that arise in consumer product safety involving burn injuries and the different tools available to address these issues.

The Development of Proficiency Testing Programme for Electrical and Mechanical Safety Tests

Shu-lun Mak (The Open University of Hong Kong, Hong Kong)

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

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

Ersin Hasan Dogruguven (Yildiz Technical University &; ASELSAN Inc., Turkey); İlker Üstoğlu (Yildiz Technical University, Turkey)

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

Functional Safety

Harmonizing Normative Organizational Structure and Verification & Validation Concepts for Safety Critical Generic Projects

Ersin Hasan Dogruguven (Yildiz Technical University &; ASELSAN Inc., Turkey); İlker Üstoğlu (Yildiz Technical University, Turkey)

Abstract: Generic application/product (GAP) projects have always been challenging, because the system should be designed as much as generic and simply configurable for the final specific applications. If such a generic system is also safety critical, then the complexity of this generic development increases dramatically as the resulted system will have impacts on the human life, property and environment. The safety management plays a major role to keep this though development process under control by avoiding systematic faults. Setting up correct organizational structure as well as applying Verification & Validation (V&V) concepts, which are two fundamental elements of safety management, in an accurate way are therefore crucial. This paper discusses the organizational structure with regards to the current normative status with its drawbacks, proposes an updated organization and a more harmonized V&V concept including relations with safety management and quality assurance by sharing practical experience gained during SIL 4 GAPs.

Miscellaneous

On Product Warnings: The Latest Standards, Best Practices and Trends

Derek Eversdyke (Clarion Safety Systems, USA)

Abstract: For companies that manufacture machinery which has potential hazards associated with its transportation, installation, use, maintenance, decommissioning and/or disposal, creating effective product safety labels is critical. This task must be done right. The stakes are too high for this job to be done incorrectly - people's lives and companies' financial well-being are on the line. Safety labels can do one of twothings:

1. If properly designed, they can dramatically reduce accidents. This not only improves a product's overall safety record but adds to a company's bottom line by reducing product liability litigation and insurance costs.

2. If poorly designed, needed safety communication does not take place and this can lead to accidents that cause injuries. When such accidents happen, companies spend substantial amounts settling or fighting lawsuits because their products lacked "adequate warnings."

With the rise in product liability litigation based on "failure to warn" over the past several decades, product safety labels have become a leading focal point in lawsuits faced by capital equipment manufacturers. This presentation will explore key best practices that are shaping the current "state-of-the-art" for product safety label design focusing on critical product safety label standards, risk assessment, and global warnings that use symbols. This includes how the new occupational safety and health management standard, ISO 45001, drives best practice signage, and the tie-in with up-to-date product safety labels. This insight will help participants formulate an improved safety label strategy that will better protect product users from harm and companies from litigation-related losses.

Army Artillery Munition Warhead Explosive Fill Risk Analysis

Kevin Singer (US Army ARDEC, USA); Douglas M. Ray (US Army ARDEC, USA)

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