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Batteries & Energy Storage Systems

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

David Chao (UL, Taiwan),John Lai (Underwriters Laboratories, Taiwan),Alvin Wu (Underwriters Laboratories Taiwan Co., Ltd., Taiwan),Carl Wang (Underwriters Laboratories Taiwan Co., Ltd, Taiwan)

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

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

John Copeland (Energy Assurance LLC, USA)

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

Lithium-ion Cell Failure Mechanisms and Mitigation Strategies

Keith Beers (Exponent, Inc., USA)

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

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

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

Gang Ji (Medtronic Energy and Component Center & Medtronic PLC, USA),Partha Gomadam (Medtronic Energy and Component Center, USA),Zhi Fang (Medtronic Energy and Component Center, USA),Prabhakar Tamirisa (Medtronic Energy and Component Center, USA)

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

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

Keywords-medical devices, rechargeable battery, battery management system, Monte Carlo simulation, robust design

Compliance 101

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

Jim Bender (Intertek, USA)

An effective certification development and manufacturing process yields far more benefits than just satisfying NRTL obligations.

Developing and implementing a comprehensive product safety certification compliance process taking into account key factors can avoid both needless and costly production delays while influencing a safer product.

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

i) Specifying design criteria of safety critical components and subassemblies;

ii) Recognizing how critical a comprehensive component level procurement specification is to assure an uninterrupted supply chain;

iii) Designing components beyond minimum end-product safety certification requirements.

Electric Shock, Compliance 101

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

This tutorial covers the basis for electric shock protection in electrical equipment. It is build upon the response of the human body to electric current and the ways in which to deal with this in equipment design and evaluation. The methods are technically based upon IEC standards such as IEC 60479, 'Effects of electric current on the human body...' and IEC 60990 'Methods of measurement of touch current...'. A comprehensive presentation of the understanding and application of the needed protections will be presented. This tutorial is aimed at engineers and managers working on equipment design and construction as they have to deal with these issues. The author/presenter has 60 years experience in the electronics field.

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

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

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

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

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

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

PSES Tutorial

Grant Schmidbauer (Nemko USA, Inc., USA),John R Allen (Product Safety Consulting, Inc., USA),Ken Kapur (Thermo Fisher Scientific, USA)

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. While your product must comply with the EMC and SIPI requirements, there are a myriad of other technical requirement 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.

Tutorial content:

Moderator:

- Contact name: Mike Anderson, IEEE/PSES Board of Governors
- Company affiliation: Compliance Manager, Casa Systems, Inc.
- Role: Introduction of PSES tutorial, presentation of speakers and their biographies, manage/moderate logistics throughout tutorial.

Presentation #1: Overview of product safety requirements, ‘Compliance 101’

- Contact name: Ken Kapur, IEEE/PSES Board of Governors
- Company affiliation: Director of Compliance, Thermo Fisher Scientific, Inc.
- Abstract:
- 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.

Presentation #2: Deeper dive into product safety requirements, ‘Compliance 201’

- Contact name: John Allen, IEEE/PSES President
- Company affiliation: President, Product Safety Consulting, Inc.
- Abstract:
- 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.

Presentation #3: Overview of Global Market Access (GMA)

- Contact name: Grant Schmidbauer, IEEE/PSES Board of Governors
- Company affiliation: President, Nemko North America, Inc.
- Abstract:
- 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.

Presentation #4: Panel discussion, Q&A and wrap-up

- Contact name: Mike Anderson, John Allen, Ken Kapur, Grant Schmidbauer
- Abstract:
- Time is made available for interactions with attendees to respond to specific countries/issues that are brought up and/or may have been encountered by the attendees.

Retail Protocols and CPSC quoting tools

Kason Choi (UL, USA)

Can't avoid selling you consumer products Online

In 2021 with the global pandemic you really cant avoid selling a consumer product online. When you start developing or sourcing a product it can be difficult to determine the required product safety requirements. There are tools online to help with this research but you need know know how to find it.

Risk Assessment Basics for EMC, LVD and RED Directives

Patty Knudsen (Teradata Corporation, USA)

EMC & Wireless Compliance

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

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

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

The concern is that an unsafe condition may occur if the electronic standby mode is interfered with, causing a device to start when not intended, or creating a hazardous condition. These acceptance parameters may not have been considered when performing compliance testing under the EMC requirements found in the harmonized standard IEC/EN 55014-2 for immunity.

These tests are required to show compliance to the safety portion of the IEC 60335-1 electrical safety standard, and may not have been considered when testing products for EMC compliance to meet the EMC directive or other electromagnetic testing standard requirements. The LVD directive requires testing, by enabling the standard by mode feature, the safety portion needs to be met.

Brexit and Compliance for the New UKCA Mark

Michael Violette (Washington Laboratories, Ltd, USA)

TBD.

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

Nicholas Abbondante (Intertek, USA)

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

New Conformity Assessment Procedure for Telecommunication Products in Mexico

Will Birchall (CSA Group, Canada),Patricia Medina (CSA Group, Canada)

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

Each importer must obtain their own NOM Certification of Compliance (CoC) and IFT approval

End product manufacturers customers will no longer be allowed to leverage IFT approvals on modular components and now must test and certify the end product

Applicable to products with radio frequency transmitter or transceiver that make use of radio spectrum.

Also applicable to radio equipped devices that connect to a telecommunications network in the frequency range from 30 MHz to 6 GHz and that are used

Emerging Technologies & Innovations

IoT Cyber security - Hackers are not waiting for regulations

Geir Horthe (Nemko, Norway)

Everybody know that cyber security of IoT products often is weak, yet many seems to "take advantage" of the fact that authorities are moving slow in implementing mandatory requirements.

The fact is however that mandatory requirements do exists and that using cyber security standards will not only improve the security but will also ease trade (imagine the chaos if we did not have any safety standards!)

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

Environmental & Energy Regulations

Greener Electronics getting stronger roots for growth

Rakesh Vazirani (TUV Rheinland, Hong Kong)

Everything that can be electrified, will be.

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

Commercial drivers: Decarbonization, Efficiency

Governmental Drivers: SDGs, NAP

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

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

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

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

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

News on Electronic Product Environmental Compliance - Worldwide

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

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

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

Forensics, Failure & Risk Analysis, Assessment & Management

Analytical Assessments of Thermal Damage in a Perfused Tissue

Francesco Colella (Exponent Inc., USA),May Yen (Exponent Inc., USA)

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

Evaluation of Intelligent and Non-Static Power Sources

Peter Perkins (P. E. Perkins PE, USA),Jim Weise (Adtran, USA)

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

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

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

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

The influence of object thermal mass on temperature thresholds for contact burns

May Yen (Exponent Inc., USA),Francesco Colella (Exponent Inc., USA),Harri Kytomaa (Exponent Inc., USA),Boyd Allin (Facebook Inc., USA),Alex Ockfen (Facebook Inc., USA)

Burn injuries are a recognized hazard in our everyday interactions with consumer products and consumer electronics. They can be painful and life-altering and can cause permanent physical as well as emotional

harm. Our increasing intimacy with consumer electronics including wearables is challenging the current regulatory standard framework. The typical thermal exposure associated with wearables and consumer electronics is characterized by long duration and relatively low temperatures with a contacting object with low thermal mass. As a result, the temperature of the object changes over time and is heavily affected by the transfer of energy to the skin during contact. The current regulatory standards dealing with contact burn injury thresholds assume that the thermal energy contained within the hot object is infinite and that its surface temperature remains approximately constant during contact. This paper presents a comprehensive approach to account for the common scenario where the user contacts a finite thermal mass object. The methodology numerically solves the transient heat transfer equation in living tissues and identifies the burn injury threshold conditions associated with finite thermal mass objects. The model is able to predict burn injury by employing a concept of cumulative equivalent exposure. The predictive capabilities are validated with experimental observations of human burn injuries.

Global Hazardous Locations

Challenges in Certifying Skids for Global Hazardous Locations

John Chambers (UL LLC, USA)

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

Key Changes in the 2020 NEC Affecting Commercial & Industrial Installations

Joseph Wages (IAEI, USA)

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

LED Luminaires - Global Product Safety Compliance

Steve Blais (Emerson Automation Solutions, USA)

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

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

Behzad Nejad (HazCon, USA)

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

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

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

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

Ryan Brownlee (Pepperl+Fuchs, Inc., USA)

Dave Burns (Shell Projects & Technology, USA)

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

Protecting against Hazardous Gases & Vapors

Jon Miller (MSA Safety, USA)

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

The Importance of Ignition-Protected Components for Hydrocarbon Refrigerants

Krzysztof Rymarski (UL LLC, USA)

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

Global Market Access & Regulations, Compliance Management

BRAZIL New Homologation Model and Regulatory Updates

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

In November 2019, Anatel officially announced the restructuring of the

Homologation systems in Brazil. Product Categories, OCD rules, Testing Requirements all to be changed and implemented in April 2020.

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

An interactive session for all attendees.

Global Market Access for Radio Equipment and Equipment used in Hazardous Locations

Hannah Truong (CSA Group, Canada),Will Birchall (CSA Group, Canada)

GMA Radio Approval Introduction

GMA Radio Approvals for 5GHz

Brazil ANATEL Telecommunication Equipment Updates

FCC and ISED Radio Certification

GMA Radio Approval for Medical Equipment

ATEX / IECEx and Global Access of HazLoc Equipment

Global RoHS

Theresa Glenna (TÜV SÜD America, Inc., USA)

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

India BIS & WPC Certification

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

Overview of Current BIS (Safety) and WPC (Wireless) Certification Scheme in India

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

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

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

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

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

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

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

May 2020 the New NOM-001 Regulatory changes will be implemented.

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

A interactive session that will allow interactive learning.

Selection of professionals for product compliance and safety activities

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

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

Selection of professionals for product compliance and safety is the process of choosing the right person for the right position and at the right time.

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

UKCA - New Rules for Market Access in Great Britain

Gabriella Mazzola (Underwriters Laboratories (UL), Italy)

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

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

Maja Bland (UL LLC, USA),Di Dai (UL International Germany GmbH, Germany),

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

Legal, Regulations, Directives & Consumer Protection

Electric Shock Hazard Considerations for Fault Managed Power Distribution Technologies

Alex Di Sciullo Jones (UL LLC, USA),Hai Jiang (Underwriters Laboratories (UL), USA),Randy Ivans (UL LLC, USA)

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

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

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

Medical Devices

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

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

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

One Emergo team member will serve as the moderator and lead the simulated test session while another role-plays as a test participant and "thinks aloud," sharing their impressions of the product while performing representative device tasks. A third team member, one of Emergo's Research Directors, will present a brief usability testing "primer," describe key aspects of the product evaluation method, and point out key takeaways during the live demo.

Topics covered will include:

>>> FDA and international regulators' expectations for usability testing

>>> How to evaluate if a product-in-development is on the right track

>>> When to put a product-in-development in front of users, and how

>>> How many participants to include in a usability test

The presenters will conclude the presentation by answering attendees' questions on usability testing.

Designing Products for Safe Use

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

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

FDA Pilot - Accreditation Scheme for Conformity Assessment (ASCA)

Calvin Luong (CSA Group, USA)

FDA, has received much public feedback, and is now entering the pilot launch for the Accreditation Scheme for Conformity Assessment (ASCA). The ASCA Pilot launched on September 25, 2020. The purpose is to allow those that participate a more streamlined review process for testing data when delivered as part of an FDA submission package by the medical device manufacturer.

Under the ASCA Pilot, the FDA grants ASCA Recognition to qualified accreditation bodies to accredit testing laboratories to perform premarket testing for medical device manufacturers. ASCA-Recognized accreditation bodies accredit testing laboratories using the specifications of ISO/IEC 17025 and the ASCA program specifications associated with each FDA-recognized consensus standard and test method in their scope of ASCA recognition. Medical device manufacturers may voluntarily use an ASCA-accredited testing laboratory to conduct testing to be included in premarket submissions to the FDA. By doing so, the manufacturer's submission process would be enhanced, reducing the need of FDA to do a full review of the testing process and decreasing the need for requests of additional information regarding testing methodologies, and evidence when coming from an FDA ASCA program sites.

Under the ASCA program key stakeholders (medical device manufacturers and FDA) have a higher level of confidence of the medical device testing which in turn allowing patients receiving a safe and more timely access of medical devices.

Patient Safety and Digital Therapy

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

Focusing on patients' safety represents one of the main principles for management in the sanitary system. Basically, identifying and understanding patients' needs, expectations and protections, represent the essential elements of this principle.

Patient Safety is regarded mainly, as the identification and implementation of means to protect patient against unacceptable risk of harm due to the sanitary processes, taking into consideration the quality of the medical act, the communication doctor-patient, healthcare basic safety, medical equipment, efficiency of data used for the medical processes, etc.

Technological future in healthcare will integrates an artificial intelligence (AI) component at every level, and the impact of application based on new algorithms can lead to the emerge of important opportunities to increase the patient safety. The capability of such devices to process natural language, to learn constantly, to plan based on fixed or variable parameters and to react in context could lead to an impressive decrease in the number of tasks that are currently performed by the healthcare professionals. Given the huge set of possibilities opened by machine learning, the public health can benefit from significant positive changes regarding the Patient Safety. Using AI, each patient could have a much more customized treatment than the one they receive now, and their monitoring and data analysis could be more precise.

Based on the above, the Patient Safety can be established with adequate measures as well as describing and analyzing the situations that could cause harmfully situations for patients.

Safety of Service Robots

Jason R Smith (UL LLC, USA)

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

The biggest challenge in compliance today, finding good compliance engineers

Naysahn Saeed (CSA Group, USA)

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

Safety Science/HBSE

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

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

Contact Burn Injuries: Experimental Assessments of Short Duration Contact Exposures

Francesco Colella (Exponent Inc., USA),Michael Barry (Exponent, Inc., USA),James Vickery (Exponent, Inc., USA)

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

Dalziel Revisited application; Analyzing mixed AC/DC waveforms

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

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

Preview: IEC 62368-1, Edition No. 4

Thomas M Burke, PE (UL LLC, USA)

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

Touch current of DC products; exploring the landscape

Peter Perkins (P. E. Perkins PE, USA),Joseph McGuire (Servetech, USA)

An examination of touch voltage and current for DC powered ITE & AV products with consideration to the requirements established in harmonized international standard IEC 62368-1. The existing requirements in IEC 62368-1 and IEC 60990 do not explicitly prescribe the measurement of touch current for DC powered equipment as a whole. While limits are established for DC, figures and examples are given in reference to AC power and grounding systems along with associated external circuits, which can lead to confusion by the manufacturer or test laboratory.

Consequently, the measurement of touch current may go ignored on DC powered equipment. Furthermore, such devices may be accumulated into a system where the summation of touch current previously assumed safe may exist at hazardous levels. There is an increased necessity to safeguard users against this type of ICT equipment, which may be powered by DC MAINS and can exhibit available power at PS3 levels, voltage exceeding commonly established hazardous levels, and contain either repetitive switching noise or pulsed waveforms which produce touch current.