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ABSTRACTS

Batteries & Energy Storage

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

Gang Ji; Partha Gomadam; Zhi Fang; Prabhakar Tamirisa

Abstract: To achieve a robust design of a multi-cell rechargeable battery subsystem for medical applications, device requirements such as device runtime, peak power, charge time, operation temperature, cycle life, and calendar life, are decomposed and flowed down to the battery level. Concurrently, there are performance characteristics of the rechargeable cell, such as cell voltage, impedance, capacity, and capacity fade characteristics. Most of the device requirements and cell performance characteristics have distributions to represent the variabilities due to the various operation scenarios, component-component variability, and manufacturing tolerance. To determine the robustness of a multi-cell rechargeable battery design, we measure the robustness of design by comparing the predicted battery pack performance to the requirements. The scope of this paper is limited to the electrical performance of medical device batteries. An electrical equivalent circuit model for the multi-cell rechargeable battery sub-system is created based on the cell characteristics, charge and discharge control logic defined in the battery management system (BMS), and the expected device workloads. To predict the end-of-service performance of the rechargeable battery, a cell aging model based on the capacity fade and growth of cell internal resistance is developed under the worst-case nominal condition. Distributions of performance indicators are generated with Monte Carlo simulations and the robustness of multi-cell rechargeable battery design is quantified by calculating the value of process capability index Cpk. Keywords-medical devices, rechargeable battery, battery management system, Monte Carlo simulation, robust design

ABSTRACTS

Batteries & Energy Storage – Continued

How electric safety standards are adapting to address the evolving usage of lithium ion batteries in the market

Laurie B. Florence

Standards addressing lithium ion batteries began in the 1980's and 90's with general battery safety standards such as UL 1642 and UL 2054, when batteries were being introduced into portable applications such as electronics. These standards were developed as generic battery safety standards evaluating the safety of cells and battery packs using a common set of tests such as external short circuit and abnormal charge tests. These standards were also primarily performance based safety standards that evaluated the batteries through testing with little in the way of construction criteria. With the increased use of lithium ion batteries in the early 2000's came an increase in incidents in the field leading to development of new safety criteria such as the operating region concept and internal short circuit tests to address internal short circuit concerns in lithium ion batteries. Now lithium ion batteries are in everything from cell phones to electric vehicles, and electrical safety standards have had to adapt to address the unique safety challenges of these expanding applications. As the size and complexity of the battery system and type of applications expand, it is clear that a systems approach to electrical safety is necessary to understand how the battery is used in the end product and to ensure cells operate within their specified operating region. In addition, the use of hazardous voltage, high energy battery systems such as for electric vehicles and energy storage, has required those standards to address electrical shock hazards, arc flash hazards during maintenance and off gassing that could lead to possible fire and explosions to be included as part of the safety evaluation. Although informally, safety analysis has always been part of the battery safety evaluation, a more formalized approach such as FMEAs has been included in the standards for larger format batteries to ensure that all hazards are identified and appropriately mitigated. Also, a functional safety investigation of safety controls is an integral part of the battery safety standard criteria for these large format battery standards. This presentation will go through the progression of North American battery safety standards addressing lithium ion batteries and how they have developed over the years to meet these growing challenges.

ABSTRACTS

Batteries & Energy Storage – Continued

Evolving the safety approach to address the expanded applications of lithium ion batteries

Laurie B. Florence

Standards addressing lithium ion batteries began in the 1980's and 90's with general battery safety standards such as UL 1642 and UL 2054, when batteries were being introduced into portable applications such as electronics. These standards were developed as generic battery safety standards evaluating the safety of cells and battery packs using a common set of tests such as external short circuit and abnormal charge tests. These standards were also primarily performance based safety standards that evaluated the batteries through testing with little in the way of construction criteria. With the increased use of lithium ion batteries in the early 2000's came an increase in incidents in the field leading to development of new safety criteria such as the operating region concept and internal short circuit tests to address internal short circuit concerns in lithium ion batteries. Now lithium ion batteries are in everything from cell phones to electric vehicles, and electrical safety standards have had to adapt to address the unique safety challenges of these expanding applications. As the size and complexity of the battery system and type of applications expand, it is clear that a systems approach to electrical safety is necessary to understand how the battery is used in the end product and to ensure cells operate within their specified operating region. In addition, the use of hazardous voltage, high energy battery systems such as for electric vehicles and energy storage, has required those standards to address electrical shock hazards, arc flash hazards during maintenance and off gassing that could lead to possible fire and explosions to be included as part of the safety evaluation. Although informally, safety analysis has always been part of the battery safety evaluation, a more formalized approach such as FMEAs has been included in the standards for larger format batteries to ensure that all hazards are identified and appropriately mitigated. Also, a functional safety investigation of safety controls is an integral part of the battery safety standard criteria for these large format battery standards. This presentation will go through the progression of North American battery safety standards addressing lithium ion batteries and how they have developed over the years to meet these growing challenges.

ABSTRACTS

Batteries & Energy Storage – Continued

North American and IEC Standards: A Comparison in the Approach to Safety of Energy Storage Systems

Laurie B. Florence

There has been a lot of effort in the standards & codes development area to address safety of energy storage systems, especially those that utilize batteries as their storage mechanism. This work has been underway for several years in the USA with the publication of UL 9540, which is the bi-national safety standard for the USA and Canada and UL 1973, which is also a bi-national safety standard for stationary batteries. In addition to these two standards, UL has recently published UL 1974 for repurposing of used batteries and UL 9540A, a large scale fire test method for battery energy storage systems, to address safety gaps and meet regional fire code regulations. At the same time, in the IEC, there has been work on developing safety standards for energy storage systems including publication of a technical specification, IEC 62933-5-1 for general safety of energy storage systems and the ongoing development of IEC 62933-5-2 safety standard for battery energy storage systems. The IEC rechargeable battery committees have also been developing safety standards to address new battery technologies that are being utilized in stationary applications such as lithium ion, flow batteries and high temperature batteries. This presentation will provide an overview of the USA codes and standards and the IEC standards for energy storage systems and batteries for stationary applications. This presentation provides a comparison between the approach taken in the North American standards and codes for energy storage systems and battery safety with that of the IEC. This information may be useful to those in the energy storage system industry planning on developing energy storage systems for an international market including North America.

ABSTRACTS

Batteries & Energy Storage – Continued

Lithium-ion Cell Failure Mechanisms and Mitigation Strategies

Keith Beers

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.

ABSTRACTS

Compliance 101

Compliance 101: ½ day PSES tutorial: Global Market Access

Grant Schmidbauer

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.

Part 1: Compliance 101 with Ken Kapur

- 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.

Part 2: Compliance 201 with John Allen

- We will review requirements in product safety standards and the impact to new designs.
- We will discuss product safety risks (Electrical, Mechanical, Lasers, Radiation, etc.) and methods to mitigate risk and ensure compliance

Part 3: Global Market Access with Grant Schmidbauer

- 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.

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

ABSTRACTS

Compliance 101 - Continued

Compliance 101

Ken Kapur

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 performance specifications, 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 (i.e., 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. Compliance 101 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.

ABSTRACTS

Compliance 101 - Continued

Live to Love your CB Report!

Lars Mellander

Live to Love your CB Report; a presentation for beginners and veterans. The CB report is one of the most critical and valuable documents for compliance. This presentation will go into detail on exactly what the CB contains, how to read a CB report and how to get the most value for your money. The CB is also key to many international certifications and this presentation will advise on how to create a report that will best allow for success. This is critical information that every safety compliance engineer should know and can change your life!! (well at least make it easier…) Think you know everything about a CB report? Come and find out……

Infrared Thermograph

Ted Eckert

Infrared thermography is becoming cheaper and more accessible. IR temperature measurement allows the measurement of temperatures across an entire exposed surface without direct contact. Traditional temperature measurement requires placing thermocouples or other discrete temperature sensors that are not always placed on the hottest locations. IR thermography can easily find hot spots and allows easy visualization of temperature changes. This presentation will discuss how IR thermography can be best used in safety testing. It will cover what testing it is not optimized for. Finally, it will cover potential challenges in using IR thermography in an accredited lab program.

ABSTRACTS

Compliance 101 - Continued

Getting Started with Cybersecurity - How Manufacturers Can Approach Emerging Requirement

Laura Elan

Networking and communication technologies, e.g. IoT enabled devices, pose new risks to consumer privacy and network security, including the exposure of sensitive data, exposure to malware, and unauthorized access to networks and information. The good news is that an extensive body of knowledge for cybersecurity exists today. There are many standards and frameworks for organizational and product security available to product development organizations. However, the challenge for companies looking to leverage this knowledge is that cybersecurity is not a single event in a product development lifecycle. Security is a collection of activities which can be at very different levels of maturity across a single enterprise. Most manufacturers today struggle with understanding their current know-how. For this reason, cybersecurity maturity models are getting attention as a mechanism to assess current-state and then improve organization security process, design, verification and maintenance across an IoT enabled product lifecycle. Our presentation will introduce a Cybersecurity Maturity Model and its benefit for Medical Device development organizations.

Compliance 201 - Common Requirements for any Product

John R Allen

This presentation will take you through a household product from the plug into the product. It will confirm and guide on common issues found, the requirements around each of the components and end product considerations. It will also discuss and guide on common testing regardless of the product being considered.

ABSTRACTS

Compliance 101 - Continued

Electric Shock, Compliance 101

Peter Perkins

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.

Origins and Basics of Electrical Fire and Shock Protection

Mike Sherman

This talk explores the origins of concerns about electrically caused fire and shock, their basic mechanisms, and how to protect against them. It also offers some basic tips for designing products for worldwide sales.

Managing Product Safety Knowledge

Mike Sherman

Product safety is a delightful profession that many of us, frankly, fell into. The broad range of knowledge that enables good product safety engineering can be daunting to practitioners and managers alike. This talk provides, via a case study, a method for identifying and capturing your company's product safety knowledge needs so you can provide robust product safety support and develop yourself professionally. I also share some of my favorite resources.

ABSTRACTS

Compliance 101 - Continued

Looking at the Design of the SCIP Database

James Calder

Set to launch on January 5, 2021, the Substances of Concern in Products (SCIP) Database creates new responsibilities for suppliers of articles containing substances of very high concern (SVHCs). However, until its launch, the configuration of the database will remain in flux as stakeholders provide input and feedback. Join James Calder, Vice President of Compliance and Regulatory Programs at Assent Compliance, as he discusses the current state of the SCIP Database. Topics covered in this presentation will include: - The latest design for the European Chemicals Agency (ECHA) SCIP Database. - An overview of the ECHA SCIP Stakeholders' Day Conference held on November 12, 2019, including presentation screenshots. - Input from the IT stakeholders meeting held on December 5, 2019.

Safety Speaking

Gary Tornquist

This presentation draws attempts to sharpen the communication skills of the audience by describing in a hopefully lively way, the nature of typical conversations between safety professionals and other denizens of manufacturing world he/she is likely to meet. Examples include middle managers, upper management, software engineers, suppliers, consultants, end users and my personal favorite lawyers! Successfully navigating conversations with these disparate groups requires a knowledge of their mindsets, values and communications styles.

Basic Product Safety for Electronic Products

Julio Posse

An overview of risks associated with electronic products and the mitigation of those risks.

ABSTRACTS

EMC and Wireless

Application Forms for Wireless Devices - US FCC and ISED Canada

Grace Lin; Nicholas Abbondante

Filling out application forms for regulatory compliance certification applications for wireless devices is the first step toward the success of the applications. This presentation provides instructions to help applicants properly fill out application forms to speed up the TCB and/or CB approval process.

Basics of Lightning Protection for Communication Towers and Buildings

James A Bacher

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

How Pass on the First Trip to the EMC Lab

James A Bacher

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

Radio Equipment Directive Fundamentals

Tom Tidwell

An overview of the EU Radio Equipment Directive including updates on harmonized standards and frequency allocations.

ABSTRACTS

EMC and Wireless – Continued

FCC Radio Module Testing in Host Devices - FCC Radio Module Testing Guidance for Final Integrators

Nicholas Abbondante

When an FCC certified radio module is used in a way that is not covered by an existing FCC Grant of Authorization, additional testing and FCC filings can apply to the radio. This presentation is about testing of radio modules in host products, when the radio module is used within the existing grant restrictions, and the existing FCC certification applies.

ABSTRACTS

Emerging Technologies

Comparison of Manufacturing Screening Methods for Laser Safety Compliance

Edward T Fei; Erwin K Lau

In recent years, laser products are becoming more prevalent, and one area of growth has been the use of lasers in depth sensing and infrared illumination. For these applications, the lasers are integrated into systems such that the illumination is over a wide area. Such laser systems must maintain its classification rating across the entire field of illumination. So in order to ensure that the final devices comply with laser safety requirements, manufacturers must devise screening mechanisms to evaluate the devices. In this paper, we describe a number of screening mechanisms and safety strategies, and we compare the advantages and disadvantages of each.

Enhancing the safety for immersive technology equipment (VR/AR/MR)

Flore Chiang

It is anticipated that the market acceptance of VR/AR/MR technology equipment will be accelerated by the nearing 5G and Wi-Fi 6 and yet there is no specific safety standard in the market. The majority of the VR/AR/MR technology equipment comes in the form of head-mounted displays and therefore is battery-powered and is in close vicinity of the human body that necessitates onerous battery safety requirements. Based on the research, 25% to 40% of consumers said they experienced motion sickness with VR HMD, and yet this industry's projected growth to $48.5 billion in sales by 2025, according to GVR. High latency is the main cause of latency-induced motion sickness that needs to be addressed as well. Moreover, other safety aspects such as irritated or inflamed skin (bio-compatibility), neck strain, should be considered for greater consumer acceptance. This standard, UL 8400, as well as many other standards, is intended to address safety concerns arising from emerging VR/AR/MR technology and enhance consumer safety as it prevails. It is also anticipated that VR/AR/MR equipment will become commonplace in workplace environments furthering the need for a system safety standard for these products, e.g., prolonged use at work.

ABSTRACTS

Emerging Technologies – Continued

Customized 3D Printing Sensor Development for Predictive Maintenance in Structural Health Monitoring

Seung Ki Moon

For structural health monitoring, the identification of potential failures is able to understand and predict the impact of component and system risks. Additive manufacturing (AM) or 3D printing has been penetrating deeper and wider into various industries, due to its free-form, cost effectiveness, free-tooling capabilities, and mature processes. Electronics is also a huge and very promising application field for multi-material AM technologies. This paper introduces a method to develop customized sensors for structural health monitoring by integrating 3D printing technologies and the existing sensing technologies. In the proposed method, failure mode effect and analysis (FMEA) and System Dynamics (SD) are used to determine critical components and potential failures. Finite effective analysis (FEA) is applied to identify and understand component failure mechanisms. FEA can provide the useful engineering information of structural health conditions, such as stress, strain and heat transfer process. And, then we use the results from the FEMA, SD, and FEA to determine the types and positions of the customized sensors for the structural health monitoring. And, a multidisciplinary design optimization approach is proposed to determine optimal process parameter values of the printed line morphology for a 3D printed sensor in AJP process. In the proposed approach, a genetic algorithm (GA) is applied to optimize the values of the process parameters under the conflicting relationship between line width, line thickness and line roughness in the AJP process. To demonstrate the usefulness of the proposed design method, Aerosol Jet technology is applied to fabricate the proposed sensors for the health monitoring.

Wireless Power Transfer Fundamentals

Tom Tidwell

A discussion of Wireless Power Transmission technology and the current status and development of regulatory standards worldwide.

ABSTRACTS

Energy & Environment

Update on Material and Substance Requirements for EEE

David Linder

There are various environmental compliance regulations which have been or are being implemented throughout the world and these regulations are continually updated and/or revised. This presentation will be on some of the most recent updates on regulations which cover electrical and electronic products, including: - EU RoHS Directive - EU REACH regulation - US Federal and State Updates (including TSCA and Washington State's 'Safer Products' laws.)

ABSTRACTS

Failure Analysis and Forensics

Electrical Fire Patterns in Vegetation

Louis Bilancia

Licthenberg, Fern patterns, Carbon Tracking, and Fire Patterns The formation of branching patterns in association is commonly associated with electrical discharges. Lightning and electrostatic discharges from a Van DeGraff generator are transient luminous branching patterns, however sometimes the energy the passing of an electrical current leaves residual physical patterns. Such patterns can be captured in skin, sand, oil, and vegetation. Unfortunately for the fire investigator patterns etched into wood-frame structures are often destroyed by subsequent combustion. Sometimes, however, the patterns persist and can serve to indicate what actually happened. Char patterns were found etched into dry mustard plant, blackberry cane, and Douglas fir. The first two were from current sourced by an electric fence charger (used for livestock management) and the third by sway in both the tree and a power transmission line. Examples of how such patterns are formed are presented.

ABSTRACTS

Failure Analysis and Forensics – Continued

Electrochemical Cell Evidence Collection

Louis Bilancia; Gary Tornquist

This paper reports on a chemical assay from several recovered post-fire 18650 cells. We then address some of the aspects of identifying and collecting the cell and battery debris for later analysis. A brief survey of commercially available consumer grade electrochemical cells that would commonly be found in a structure after a fire, also in the context of identification and collection of the artifacts as evidence. Consumer-grade power cell chemistries covered include carbon-zinc (CZn), nickel metal-hydride (NiMH), nickel cadmium (NiCd), flooded lead-acid (FLA), vent-regulated lead-acid (VRLA) including gel and absorbent glass-matt (AGM), prismatic lithium polymer LiPo, and lithium ion (Lion). Other chemistries, of course, exist but are not in prevalent consumer use

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Water Infiltration in Common Residential and Commercial Power Cables Introduced by Capillary Action

Patrick F Murphy; Alex Z Kattamis; Matthew Pooley; Alexander Soane

Damage to electrical power cables caused by complete or partial immersion in flood water in residential and commercial settings is a potentially serious safety concern. Electrical cables with unsealed ends are known to be susceptible to moisture infiltration via capillary action, however, there appears to be a lack of published experimental study of this phenomenon in cables commonly found in residential and commercial installations. This article presents the results of an experiment to quantify the extent of moisture infiltration in service entrance power cables. We cut straight 15 cm long cable sections with open ends from a reel of newly-purchased compact strand aluminum 4/0 XHHW cable. One end of each vertically oriented cable section was left submerged in 2.5 cm of an oxidizing liquid solution for several days. We observed evidence of water infiltration into the cable up to 7 cm above the initial liquid level. The ultimate extent of liquid infiltration and the progression of infiltration over time is expected to depend on the specifics of the cable geometry, design, termination style, and materials.

ABSTRACTS

Global Hazardous Locations

Protecting against Hazardous Gases & Vapors

Jon Miller

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.

Mobil Devices for Hazardous Locations

Dave Burns

This presentation addresses issues associated with the particular requirements for construction, testing and marking for mobile devices (e.g. tablets and phones) and their accessories for use in Class I hazardous locations. The digitalization efforts taking place in the industrial work place are creating a significant demand for mobile phones and tablets to be used in all phases of industrial processes, including applications in flammable atmospheres in the oil and gas/petrochemical industries, amongst other industries. This significant demand has resulted in mobile devices deployed in hazardous locations that are not appropriately evaluated, certified, approved, listed, or labeled for use in these hazardous classified areas.

ABSTRACTS

Global Hazardous Locations – Continued

Key Changes in the 2020 NEC Affecting Commercial & Industrial Installations

Joseph Wages

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.

Challenges in Certifying Skids for Global Hazardous Locations

John Chambers

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.

ABSTRACTS

Global Hazardous Locations – Continued

LED Luminaires - Global Product Safety Compliance

Nicholas Sansone

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.

The Importance of Ignition-Protected Components for Hydrocarbon Refrigerants

Krzysztof Rymarski

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.

ABSTRACTS

Global Market Access

Regulatory changes in Mexico

Polux Sanchez Reyes

When importing products into MX, it's critical for the business to know exactly what the regulatory requirements are in order to avoid any inconvenience for custom clearance or when marketing the product. This presentation contains the latest information in regards NOM regulation and the recent changes that are affecting the industry. It will provide a guide to know which path forward needs to be followed by customers based on the recent changes in MX that are impacting and will impact the common certification process as well as the test standards to demonstrate compliance. On the other hand, companies can now access the Mexican market by leveraging the Mexican Equivalency Agreement with Canada and the USA by following a particular procedure in order for these certificates to be accepted by customs as equivalent to a NOM Certificate. Products (AV and IT / High-Tech) with a certificate issued by any North American CB in accordance with the applicable equivalent CSA or UL standard are considered equivalent to a NOM certificate and products do not require a proper NOM certificate. For companies that still need to go through the NOM Certification process, there are different routes of certification where they can leverage on existing test reports without the need to send samples to MX for testing.

India Certification Overview- BIS Safety and WPC Wireless

Thomas Ha

Overview of India BIS Safety and WPC Wireless product certification. This presentation covers detailed BIS and WPC certification processes including sample study, best practices and lessons learned with important tips.

ABSTRACTS

Global Market Access – Continued

GMA Basics for Radio and Wireless Approvals with focus on Europe

Julia Gresser

Wireless functions and technologies are becoming more and more prominent and relevant. Networks and related wireless devices are driving our ever more connected world. They are increasing the need for manufacturers to understand the requirements to sell their product abroad and the knowledge how to implement a module with wireless functions to their current product. This session will provide a solid foundation and understanding of the general principles and requirements, as well as the approval process to gain access to the European market.

New regulations of China CCC, SDoC and RoHS

Paul Wang

This presentation introduces the new regulations of China CCC, SDoC and China RoHS. The SDoC regulation added voluntary certification scheme. China RoHS was mandatory for several products since Nov 1 2019.

BRAZIL New Homologation Model and Regulatory Updates

Elizabeth Perrier

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.

ABSTRACTS

Global Market Access – Continued

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

Elizabeth Perrier

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.

ABSTRACTS

Legal, Regulations, Directives & Consumer Protection

The need for adequate sampling in a well-functioning market surveillance system

Ivan Hendrikx; Nikola Tuneski

Current regulatory requirements for products emphasize more on faster access of products to the market while at the same time increasing post-market or markets surveillance actions. Doing this way the cost of market surveillance actions are increasing and therefore market surveillance shall be more carefully planned to keep costs reasonable. In this regard, adequate sampling is essential for the well-functioning of a market surveillance system. As small as possible statistically significant sample size is the main factor that determines the costs of market surveillance actions. This paper studies various possibilities for calculation of the size of the sample with an emphasis on the method based on the binomial distribution. Examples, comparisons, and conclusions are provided.

ABSTRACTS

Legal, Regulations, Directives & Consumer Protection

Product Liability and Regulatory Compliance Risk Mitigation

Elizabeth Reese

This presentation will provide an overview of current trends in product liability litigation, recent product safety regulatory developments, and a general overview of the legal landscape governing product safety, including the Consumer Product Safety Act, Consumer Product Safety Improvement Act, the Toxic Substances Control Act, and voluntary industry standards. The presentation will focus specifically on the increased threat to the retail industry associated with CPSC activities and the public scrutiny accompanying EPA's new TSCA process for the review and regulation of chemicals commonly found in consumer products. It will offer strategies for proactively addressing potential supply chain disruptions caused by product safety issues and new or proposed regulations, and will discuss "best practices" for product safety compliance programs and for resolving product safety issues in ways designed to improve consumer safety and reduce companies' risk.

Selection of professionals for product compliance and safety activities

Steli Loznen

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.

ABSTRACTS

Legal, Regulations, Directives & Consumer Protection

Additional Topics

Liability prevention for component part suppliers

A PL topic (optional safety devices, autonomous tech, or duty to train users/customers) joint presentation with an expert e.g., Jason Hertzberg.

The new Market Surveillance Regulation (EU) 2019/1020 – Impact on product compliance requirements and market surveillance practice in Europe

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Brexit and its short and long term impact on importing products to the remaining European Economic Area Member States

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New developments in product compliance and product liability with regard to connected and smart devices and AI

Cybersecurity Act (Regulation (EU) 2019/881) and the European Commission approach to set up a regulatory framework for use of AI)

ABSTRACTS

Medical

What to expect with Amendment 2 of IEC 60601-1 and related collaterals?

Pamela Gwynn

Any changes to a standard can create concern within a company on the effects it will have on their products. The concern is even greater for medical device manufacturers that must show compliance to the new standard once the regulatory bodies set a date. In this session, we will discuss the changes that are expected with Amendment 2 to allow you to start thinking about how this will affect your products. We will cover the high level changes occurring to the standard. With any amendment to the base standard, it will have other effects. We will additionally discuss the other effect the amendment will have to the 60601 series of standards.

Magnetic Resonance (MR) Safety Testing for Active and Passive Medical Devices

Norbert Kaula; Ji Chen

Approximately 40 million MRI scans are performed in the US annually and 100 cases of thermal injury are reported to MAUDE database annually. Close to 5% of all subjects scanned by MRI have medical implants and carry a higher risk of injury. To ensure public safety, MRI labeling should be provided to MRI technologist for all implantable devices. In this paper, we will introduce the standards for both, passive and active devices, used for MRI labeling. These standards are involving, consequently, the MRI labeling is a moving target. The technical background and physics of these standards will be discussed so that manufactures can use the essences of these standards to obtain MRI labeling. Early MR evaluation of device versus finished device characterization will be discussed. Techniques on how to combine the standard testing procedures with recent technical advancement will be presented for safe MRI labeling submission.

ABSTRACTS

Hazard Based Safety Engineering & Safety

Graphical Programming Languages for Functional Safety

Nick Berezowski; Markus Haid; Jeet Biswas; Ishak Boyaci

This research recommend the use of a a graphical full variability programming language for safetyrelated system developments, in order to create framework conditions that result in a general ap-proach for graphical languages. From a technical point of view, graphical pro-gramming languages are just another depiction of the implementation that is very similar to the models of textbased languages, but represent the implementation of graphical languages. Thus, they can substitute for well-known semiformal methods, such as UML, provided that appropriate regulations are adhered to. Among other things, emphasis is placed on tendentious technology innovations in order to consider them for future projects. For an initial process development only the basic standard IEC 61508 is needed. To create a qualifiable development in a graph-ical development environment requires specific methods and approaches that can not be dictated solely by the development environment and require a clear definition in terms of functional safety. During the specification of requirements for safety-related systems, all relevant informations, such as requirements for the system, subsystems and components, must be recorded. Semiformal and formal methods can provide a detailed specification of the requirements. Due to their graphical structures, semiformal methods are to be understood as similar to graphic code and thus preferable to formal methods. Forward traceability should be possible, especially at higher safety integrity levels between all phases of the software safety lifecycle. A com-puterized tool could support these relation-ships. To comply with the requirements of the basic standard, a language subset must be defined which excludes the use of unsafe programming language constructs and checks their compli-ance with static analysis tools. A graphical programming language to be used must have a strict typing. Compliance checking can be done through in-program programming tests or, if necessary, additional static testing. Since no already certified tools exist, tried-and-tested tools and translators should be used. These must be regarded as established and not error-prone in the relevant area of a safety-related system to be used. Defensive programming can only be used in necessary places, since it also worsens the understanding of the complete program. The modular approach offers several submethods, all of which must be adhered to in a graphical programming language. Some graphical languages inherently have a modular flow-controlled structure that supports these methods. In general, a monitoring device should work with separation between monitoring and monitored computer in order to demonstrate a general independence for the introduction of a programming language.

ABSTRACTS

Hazard Based Safety Engineering & Safety – Continued

Harmonization of IEC and EN 62368-series of standards

Grant Schmidbauer

This presentation will discuss the current market situation in Europe related to the latest edition of the standard EN 62368-1. With the introduction of the European Commission HAS (Harmonized standard) consultant, the publication of harmonized EN standards with the hope of eventual citing of the harmonized standard in the Official Journal of the LVD has seen significant delays. This presentation will untangle, as best as possible, the current situation related to the latest edition of EN 62368-1, and include time for Q&A.

Flexible Design for Information Technology Equipment with Higher Overvoltage Category

Shun Zhang

This paper explores the design schemes and the technical feasibility when information technology equipment not to be installed in the general overvoltage category II environments but with a higher transient overvoltage category (overvoltage category III or IV) for safety compliance consideration. Firstly, we introduce a general overview of the overvoltage, and discuss the different types overvoltage, also make a comparison between temporary overvoltage and transient overvoltage. Secondly, several related standards for reducing the overvoltage category of information technology equipment by the additional surge protection device were rolled out to support the proposed design scheme from the theoretical and regulatory compliance standards perspective. Thirdly, the relevant design considerations were discussed, including critical components selection, minimum clearances requirement, and electric strength requirement, through these discussions, the proposal about reducing overvoltage category could be easier understanding and this will be as a good indication in practice on the economical basis. Finally, the conclusion of this paper has been provided.

ABSTRACTS

Hazard Based Safety Engineering & Safety – Continued

Making safe products safer with Device-integrated Fire Protection

Markus Fiebig, MF

Regularly we see consumer product recalls due to fire hazard. In the last years over 15 million appliance units have been recalled for defects that could cause a fire. Statistics show that 30% of all fires are caused by electricity, mostly starting within electrical devices and appliances. The existing fire protection measures are good, but do not yet include active fire protection within devices. New technologies make it possible to install mini fire extinguishers directly in the electronics. In case a fire starts, the mini fire extinguisher can kill the fire and irreversibly cut the power to avoid re-ignition. The method will reduce the risk of fire consequential damages, reduce recall costs and increase safety according the motto "making safe products safer". This technology can be associated with the term device-integrated fire protection. UL named it CIFEAs (Circuit Interrupters with Fire Extinguishing Agent) and wrote the UL 60692, an amendment to the UL 60691 standard. Further, the German certification body of the property insurance association VdS certified the first products and created an extinguishing test method. The methods developed from UL and VdS were used to start the creation of an international standard. The benefit for society, consumers and manufacturers are clear. New technology needs support and someone to share the word.

Can you have too much safety?

Ted Eckert

Can you every have too much safety built into a system? When should safety mechanisms be added? This will be a short presentation on two case studies of when safety mechanisms were added to a system late in the design process without adequate time for review and testing. It will be followed by an open discussion with the audience on issues ranging from testing, conflicting requirements and user circumvention of safety features.

ABSTRACTS

Miscellaneous

Open Source Medical Device Safety: Loop Artificial Pancreas Case Report

Michael Dorin; Heather Mortonson; Sergio Montenegro

A persistent global challenge is the availability of affordable treatments for chronic conditions. The increasing sophistication of open-source hardware and software systems may provide hope. This report explores the Loop Open-Source Artificial Pancreas (APS). We consider the state of the software source code and report a case study for one individual using the system. Information presented here should be helpful for people with diabetes, considering the incorporation of Loop into their treatment regime or for those considering the development of an open-source medical system.