

WELCOME TO SPCE 2024 PROGRAM AT A GLANCE

Welcome Message

Greetings and a warm welcome to the IEEE 2024 Symposium on Product Compliance Engineering (SPCE), hosted in the beautiful state of Minnesota.

Fall in Minnesota is truly breathtaking with its vibrant leaf colors, rich history, unique architecture, diverse culture, amazing food, and significant contributions to various industries. We hope you take the opportunity to explore some of these wonderful aspects while participating in our regional symposium.

We are excited to launch the 2nd regional IEEE Product Safety conference in the US, supporting the Product Safety Engineering Society's mission to be an active part influencing and educating the important discipline of product safety and related conformity compliance practices.

Product safety and conformity assessment has evolved from focusing primarily on fire, electrical shock, and personal injury, by expanding its overall scope to ensuring that products and systems are cyber secure, functionally safe, environmentally friendly, and globally compliant. Today, compliance professionals come from diverse, international backgrounds, including engineering, information technology, inspection, biology, chemistry, law, and more.

No other industry group or professional association hosts such events like ISPCE and SPCE, sharing and networking all these topics with such a diverse gathering of attendees, learning, growing, and celebrating together!

We are proud to feature two keynote speakers.

On day one, our own Jim Bender, P.E., Senior Staff Engineer (Intertek, Plano TX) will present an inspiring kickoff presentation, "***Talking the Regulatory Compliance Language of Management: Propelling your Regulatory Career***".

And on day two, Leslie Curry, Senior Vice President, Global Regulatory Affairs, Ecolab Inc., will speak on "***How to Unlock Marketing Compliance Gold***".

Following the keynote opening presentations, our Technical Program Committee (TPC) for SPCE 2024 has assembled an exciting, multi-track program packed with educational content to help you stay on top of your game and perform your job with confidence, knowing you have the latest product safety and compliance related business and technical intelligence at hand.

There will also be many opportunities during the conference to network, meet your colleagues from other companies, and interact with vendors who supply goods and services that make our work more efficient. How many times a year do you get to do that while taking advantage of this unique opportunity to reconnect with former acquaintances and meet new people?

On behalf of everyone involved in this year's SPCE event planning and technical program management, we want to say "Thank You" to all our Patrons, Exhibitors, Sponsors, Presenters, Authors, Conference Chairs, Conference Management and many others often never seen behind the scenes whose commitment and ongoing dedication is essential to the success of this event.

Again, welcome to Minnesota if you are a visitor...and we can't wait to connect with you at the show!

Sherri Tischler
SPCE 2024 Co-Chair



A handwritten signature in black ink that reads "Sherri".

James Bender, P.E.
SPCE 2024 Co-Chair



A handwritten signature in black ink that reads "James".

KEYNOTE SPEAKER: DAY 1

Talking the Regulatory Compliance Language of Management: Propelling your Regulatory Career

James Bender, P.E. (Intertek)

Author Bio: Jim Bender joined Intertek (Plano, TX) in 2019 as a Senior Staff Engineer, developing and training of product safety and compliance engineering talent and new certification strategies.

Jim is IEEE's Product Safety Compliance Engineering Society's VP, Education, and an IEEE Senior Life Member. Jim retired from Texas Instruments as Director, Product Safety and Regulatory Compliance following a near 40 year career. Jim is a graduate of Purdue University (BSEE/MSE) and a Texas Licensed Professional Engineer.



“A successful career in product safety compliance requires a broad command of technical subject matter expertise. But there is another “not so obvious” requirement to propel one’s career , being “talking the language of management”.

This keynote speech focuses on promoting effective product safety and regulatory compliance “technical deliverables”, leveraging the power of talking the “language of management” necessary to influence organizations to fully realize the merits of safe products. His presentation reflects on real, hands-on experiences from his near five decades accomplished compliance leadership including personal lessons-learned, “on the job” experiences, career set-backs and progression to propel a career in this exciting discipline.

KEYNOTE SPEAKER: DAY 2

How to Unlock Marketing Compliance Gold

Leslie Curry (Ecolab Inc.)

Sustained regulatory compliance is a sales enabler. It demonstrates credibility, supply reliability, brand protection, and risk/cost prevention. Done well, compliance can be a competitive advantage.

This keynote focuses on how compliance ‘shows up’ in the sales process, therefore playing a key role in gaining, growing, and retaining customers.

30 years + regulatory affairs across industry sectors, with sales-enabling regulatory experience across sectors, this keynote speaker will provide perspectives on translating compliance to sales enablement.



BATTERIES & ENERGY STORAGE

Oh CELL no! An Examination into the Degradation of Li-Ion Batteries

Brian May (ESi)

Commercially available lithium-ion battery cells were obtained and cycled (repeatedly charged & discharged). Long-term impacts of cycling under different conditions were examined. This presentation highlights the effect cycle rate has upon the degradation of lithium-ion cells. Additionally, an introduction to lithium-ion battery electrochemistry is provided.

COMPLIANCE 101/201

Achieving Product Safety through Positive Human Interaction: Humans, Humor, and Getting Things Done

Mike Sherman (Sherman PSC LLC)

Persuasive communication skills make our product safety and compliance (PSC) jobs easier. Concise, pithy, and humorous sayings break the ice to help us focus on and solve product safety problems.

This presentation provides time tested sayings, insights and philosophies to help you become a more effective product safety professional.

Applicability and Acceptability of Interchangeable Safety Critical Components

Garret Webb (Intertek)

Formal Paper

“Electronic products are manufactured using safety critical components requiring compliance with product safety compliance standards. Realities of supply chain disruptions and component availability impact a manufacturer’s ability to maintain market demand and production levels”.

This paper addresses component interchangeability practices to maintain certification compliance often realized during supply chain shortages.

Button Cell and Coin Battery Product Safety Design Considerations

Maryam Mahmoodi (Intertek); James Bender P.E. (Intertek)

Formal Paper

Primary, non-rechargeable lithium-ion button cells are used in many applications including back-up processor clock circuits to minimize risk of fire/explosion. This paper overviews critically needed “Conditions of Acceptability” including fire enclosure and limiting energy protective measures typically required for recognized coin cells.

COMPLIANCE 101/201 CONT.

Integrating Wireless Technology into Products

Theresa Glenna (TUV SUD)

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

Origins and Basics of Electrical Fire and Shock Protection

Mike Sherman (Sherman PSC LLC)

The basic needs for fire and shock protection for electrical equipment emerged during a tumultuous period in the late 1880s and early 1890s.

This presentation looks at that history, summarizes current best protection practices, and adds some hard-earned lessons from 30 years of electrical product safety work experience.

Successful Certification Management

Brunno P. Covolan P.E. (Intertek)

Formal Paper

The paper will provide practical tools for effectively managing the certification process during the design phase. Often, companies scramble to redesign products at the end of the design cycle to meet regulatory requirements. By implementing a few strategic tools, first-time certification success can be achieved while decreasing peripheral costs.

COMPLIANCE 101/201 WAITLIST

Basics of Alternating Current for Product Safety and Compliance

Mike Sherman (Sherman PSC LLC)

Alternating current (AC) powers our electrical products, and differs from the direct current (DC) commonly inside them.

This presentation explores how AC affects: safety issues such as shock, hi-pot testing, and arc blast; and compliance issues such as voltage ratings, energy efficiency, and EMC.

Includes insights on large, motor-operated equipment.

Independent Studies—Creating a Personal Curriculum for a Successful PSC Career

Mike Sherman (Sherman PSC LLC)

Our PSES Tutorials explain how to do product safety/compliance; this presentation explores what to know—from basic scientific and engineering concepts to higher level skills—to succeed.

Because your knowledge needs are dictated by your specific products, this presentation takes a checklist approach, so you can build your personal curriculum.

CYBERSECURITY

Compliance Validation in the Service Mesh Architecture

Rami Alboqmi (University of Tulsa); Rose Gamble (University of Tulsa)

Formal Paper

The rise in popularity of microservice architecture (MSA) requires the integration of compliance requirements into potential self-adaptive solutions at runtime. Non-compliant MSA applications could result in penalties or missed business opportunities. A service mesh in cloud-native computing manages service-to-service communications in deployed MSA applications. Each service in an MSA application must meet one or more compliance requirements. However, the current implementation of the service mesh self-adaptive solutions cannot apply adaptations based on imposed compliance requirements at runtime. This study introduces an initial ability called compliance validation to allow the service mesh to manage self-adaptation, particularly dynamic access control (AC) policies, while considering imposed compliance requirements at runtime. We conduct experiments on an e-commerce MSA application called TeaStore using Kubernetes, the orchestration solution, and Istio as the service mesh platform.

Emerging Cyber-Attacks on Smart Devices and Smart Contract Blockchains for Future Compliance Engineering Considerations

Jong-Moon Chung (Yonsei University)

There has been a significant increase in cyber-attacks on consumer products and services that created various security problems, which results in a need for preparation of future compliance engineering processes. In this presentation, product and service safety issues related to cyber-attacks on smart devices and smart contracts are described.

Navigating Cybersecurity for the EU

Lars K Mellander (Nemko)

This presentation will provide a general overview of the EU Cyber requirements and the Cyber Security Act. To include the most current and critical information on status, dates and applicability of the standard/act. Both the EU RED Cyber considerations and the Cyber Security Act will be discussed and the differences between the two requirements. Discussion on "what do to?!", best practice suggestions and why there is no need to panic (yet...)

EMERGING TECHNOLOGIES & INNOVATION

Artificial Intelligence: A New Regulatory Framework for Safe Innovation and Protection of Rights

Elizabeth Perrier (ORBIS Compliance); Tom Franich (Orbis Compliance)

Artificial Intelligence (AI) offers tremendous potential for economic, environmental, and social advancements. However, it also presents significant risks that could impact public interests and fundamental rights. This presentation will explore the newly proposed regulatory framework designed to address these challenges, ensuring AI innovations are both safe and respectful of individual rights. We will delve into how the regulation sets forth comprehensive rules for managing high-risk AI systems.

Compliance Management, Compliance and Technical Documentation Management

Rekha Tiwari; Santhanand Shanmugam (iLenSys Technologies Pvt. Ltd.) Formal Paper

This paper focuses on Records Management, Data Security, and Audit, highlighting the benefits of a Compliance Management System (CMS) for regulatory adherence and operational efficiency. It explores AI and blockchain's roles in improving CMS and documentation management, advocating a proactive, tech-integrated approach to compliance for enhanced resilience and strategic advantage with business benefits.

Keywords: compliance management, technical documentation, regulatory compliance, compliance management systems, AI in compliance, blockchain in documentation, operational efficiency

Hydrogen Horizons: Illuminating the Path to a Sustainable and Safe Energy Future

Chaitanya Katekar (Intertek) Formal Paper

This paper presents an overview of hydrogen as a pivotal contributor to the global shift toward a low-carbon, sustainable energy future. It underscores the critical considerations on implementing robust safety protocols for secure hydrogen technology deployment across diverse applications, as well as potential risks with inherent explosive nature of Hydrogen.

EMERGING TECHNOLOGIES & INNOVATION CONT.

Methods for Leakage Current Test and Mitigation for Recreational Vessels

David Sullivan-Nightengale (Intertek)

Formal Paper

Leakage current from large recreational vessels and house boats is one of the leading causes of electrical shock drowning. This can occur in a marina, home dock, or underway. This paper describes new and modified verification methods to identify, assess, and mitigate leakage current in these vessels.

TRIANGULAR MICROSTRIP PATCH ANTENNA DESIGN FOR 5G USER SIDE

Dr.Tadele A. Abose (Addis Ababa University)

Formal Paper

Researchers are developing advanced technology for next-generation wireless networks, focusing on 5G to meet increasing user demands. A critical aspect is designing a 5G antenna with wide bandwidth for optimal performance. This research project uses HFSS software to build a triangular microstrip patch antenna operating at 28GHz, achieving superior performance metrics, addressing previous shortcomings.

EMC & WIRELESS COMPLIANCE

ELECTROMAGNETIC COMPATIBILITY AND RADIO COMPLIANCE FOR MEDICAL DEVICES

David Schaefer (Element Materials Technology)

This presentation covers EMC and radio compliance for medical devices. It starts with a high-level review of basic EMC requirements in IEC 60601-1-2, and then details compliance requirements when integrating a radio into the medical device. This includes regulatory testing for the FCC and EU including ANSI C63.27.

Making Technology "Smart" with RF

Steve Liu (RF Safety Laboratory, LLC)

Adding off-the-shelf Bluetooth or WIFI RF modules in an innovative way can have a huge positive impact on end-user experience and setting apart a product line from others.

This is true for medical devices that require constant monitoring whether from an external device worn on the body, or something simplifying cables in the Operating Room. Or designers today are looking to wireless charging and powering circuits from a distance, to solve end-user problems.

As a designer, it's hard to know where to start if their idea will execute in the regulatory perspective. And often, the last thing you want to think about! This presentation will cover some common implementations and give real world examples to help understand the key things to "things to think about" with a focus on US and Canadian wireless regulations.

Mastering EMC: The Importance of Pre-Compliance Testing

David Connor (Striper Solutions LLC)

Early detection of EMC issues can significantly reduce product development costs and time-to-market. This paper explores the application of practical EMC pre-compliance strategies to ensure regulatory compliance for a wide range of products. By combining technical expertise with regulatory knowledge, engineers can develop effective compliance strategies and mitigate risks.

EMC & WIRELESS COMPLIANCE CONT.

RF Exposure for Unintentional Radiators

Tom Tidwell (Nemko)

This presentation will explore the FCC requirement to consider emissions from Unintentional Radiators as potential RF exposure sources.

EMC & WIRELESS COMPLIANCE WAITLIST

Radio Signal Management in Medical Environments

Tom Tidwell (Nemko)

This presentation will examine the elements of analyzing risk and evaluating equipment to determine its suitability to operate in medical and clinical environments.

The Next Step of WIFI Evolution

Tom Tidwell (Nemko)

This presentation will show the evolution of WIFI technologies, with a focus on WIFI6E and WIFI 7. We will explore the regulations as well as the technologies.

ENVIRONMENTAL, SUSTAINABILITY, GOVERNANCE

US PFAS and EPA TSCA reporting requirement Santhanand Shanmugam (iLenSys Technologies Pvt. Ltd.)

per- and polyfluoroalkyl substances – known as PFAS.

They all contain carbon-fluorine bonds, which are one of the strongest chemical bonds in organic chemistry. They are also called forever chemicals, they are everywhere.

The Environmental Protection Agency (EPA) has finalized reporting and recordkeeping requirements for Per- and Polyfluoroalkyl Substances (PFAS) under the Toxic Substances Control Act (TSCA) section 8 (a) (7).

ETHICAL CORNERSTONES OF EFFECTIVE COMPLIANCE

Ethical Cornerstones of Effective Compliance and Certification for Automotive Sector

Alexis O Reyna (Harman)

Establishing an ethical framework in compliance is essential to have control over the management of all the certifications that apply to a Head Unit in the automotive sector. Therefore, defining management levels allows for a coherent and effective management system in regulatory compliance maintaining the ethical guide.

FORENSICS & FAILURE ANALYSIS

From Design to Failure: Engineering and Human Factors Insights

Emanuele Grossi (Exponent); Daniel Palac (Exponent)

Investigating consumer product failures often requires a combination of engineering and human factors considerations to determine overall risk of injury, understand user behavior, and assess and investigate regulatory issues and compliance. Using real-world examples, this presentation provides engineering and human factors insights into consumer product failure analysis focused on product safety.

Outside the Cell - Battery Failure Analysis

Daren Slee (ESi)

Lithium Ion cells and other cell types are generally implemented in multicell systems known as batteries. Batteries require electrical, thermal, and mechanical management. Electrical management includes charge and discharge control, overcharge and undercharge protection, and overcurrent protection. Thermal management requires protection against charging and discharging under both overtemperature and undertemperature conditions as well as possible modification of electrical conditions based on temperature. Mechanical management includes both the protection of batteries from outside forces and safeguards to contain battery energy. This presentation will focus on the world that cells want to live in and what happens when the cells are allowed to deviate from that world. It will focus on failure analysis methodology and case studies involving battery failure analysis.

GLOBAL HAZARDOUS LOCATIONS

Choosing the Right Ex Product Evaluation and Certification Scheme with Emphasis on converting for Asian Market

Jeffrey Lenk (Nemko)

The IECEx, ATEX and NRTL certification schemes are all options when bringing a product to markets that may be utilized in a Hazardous Location. Harmonized Standards exist that allow the application of common requirements. However, the use of Zones and Class/Divisions are not fully harmonized. What is the best approach for your needs and products. When targeting the Asian market, what is perceived to be harmonized under the IECEx system, may leave products in customs. This session provides an overview of the certification schemes and the distinctions between the different Asian markets, their requirements, and the best practices for achieving successful conversion.

Enhancing Safety in Hazardous Locations: A Guide to Regulatory Compliance for Manufacturers

Mahinder Singh (Intertek)

Formal Paper

Explosions in hazardous locations are a potential concern, despite the presence of stringent compliance product safety standards to help mitigate technical complexities and challenges for manufacturers. This paper provides an overview of hazardous location product safety requirements helping manufacturers navigate successful product designs.

Ignition Compliance Requirement of Intrinsic Safety Electrical Apparatus

Xiaomeng Di (Intertek)

Formal Paper

Spark and thermal ignition overview: How to meet ignition requirements through assessment and/or related safety focusing on 1) Spark ignition includes resistive, capacitive and inductive sources, and, 2) Thermal ignition including consideration on temperature for small components.

GLOBAL MARKET ACCESS

Asia countries acceptance of IEC 62368-1 for IT/AV products

Vanessa Wen (Nemko); Grant Schmidbauer (Nemko)

The latest edition of IEC 62368-1 was published in May 2023 (ie, 4th ed.), and then in April 2024 the European version was published by CENELEC as EN IEC 62368-1:2024. With the soon publication of the binational USA (UL 62368-1:202x) and Canadian (CSA C22.2 No. 62368-1:202x) standard either later this year or early next year, the global acceptance of this standard is starting to take shape. This presentation will share the current known and expected adoption of IEC 62368-1 around the world, focusing mostly on Asia countries.

Beyond Type Approval: A Detailed Review of Regulatory Requirements in Saudi Arabia, Kuwait, and the UAE & the Role of the G-Mark

Peter Grinager (Approve-IT Inc.)

We'll provide a detailed country profile that includes a full summary of wireless/telecom, electrical safety, EMC, RoHS, and pre-shipment/import requirements (SASO, etc). We'll also explain the role of the Gulf Conformity Mark (G-Mark) in the region.

Live to LOVE your CB report

Lars K Mellander (Nemko)

A crowd favorite, refreshed! This VERY specific, interactive and detailed review of best practices and what you must know when requesting or starting a CB report/certification process. This may seem "basic" but after 20 years in the industry, I rarely see a CB report that could not be made better. The CB report is possibly the most valuable asset we have in the compliance industry, and absolutely critical that you are aware of how to get the most value for your money. This presentation will cover critical recent and updated changes (i.e. IEC 62680-1-3 & 1-2) that I've seen manufacturer's face with respect to CB reports, and how you make a CB scheme report work to meet current global requirements.

GLOBAL MARKET ACCESS CONT.

Wireless Approvals Tips, noted country updates Brazil and Mexico

Maja Bland (UL Solutions)

Global Market Access regulations and homologation requirements are in continuous motion, adjusting to accommodate new innovative and sustainable ways of manufacturing. Join Maja Bland of UL Solutions market access team (maja.bland@ul.com) for information on GMA certifications tips, with select country updates (Brazil and Mexico).

GLOBAL MARKET ACCESS WAITLIST

Pre-compliance for Global Market Access

Theresa Glenna (TUV SUD)

There are a number of aspects a company should be aware of when preparing to launch their product on the global market. Learn tips and tricks of how to prepare for a smooth market access experience. Subjects covered include component and design considerations, labeling, testing, product documentation, and ensuring you have the correct test reports to minimize surprises.

Regulatory Updates For The MENA Region

Lars K Mellander (Nemko)

Over the last few years, there appears to be a much greater need for MENA based certifications. Certifications and type approvals that have been "required" for years, are now becoming a must to obtain or at least consider. This presentation provides the reasons for the recent growth in this requirement, along with updated requirements and best practices to gain market access to the MENA region.

LEGAL

Product Liability and Product Compliance in Europe

Arun Kapoor (Noerr)

Product liability and product compliance are closely linked in Europe. While product liability risks tend to be lower than in the USA, the regulatory requirements are more complex. Products of all kinds may only be sold in Europe if they meet the regulatory requirements for safety, environmental compatibility and other aspects. These requirements are largely standardized throughout Europe with national peculiarities in the individual countries. Arun Kapoor as an European Product Regulation lawyer provides an overview of the systems of product regulation in Europe and explains the system of conformity assessment with the help of harmonized standards and notified bodies. It shows what US companies need to consider when selling products in Europe.

Product regulation in Europe - Current developments you should be aware of

Arun Kapoor (Noerr)

A large number of new product regulations have recently come into force in Europe. Many more are expected in the coming months. Almost all of these new regulations relate to the two megatrends of the Green Deal and digitalization. Arun Kapoor provides an overview of the following new regulations from the perspective of a European product regulatory lawyer, which are of particular importance for the distribution of products in Europe.

Product Safety Ethical Challenges and Obligations – An Audience Participation/Round Table

James Bender P.E. (Intertek); Arun Kapoor (Noerr)

A product under intense production release pressure has serious non-compliance safety findings identified by a NRTL evaluating the product for Listing.

Revisions are required to mitigate the safety findings, but the manufacturer's initial customers don't require independent safety certifications.

What key considerations, candidate actions and ramifications are faced by the manufacturer?

MEDICAL

Effective EMC & Wireless Co-Existence Test Plans for Medical Devices

Thomas J Brumbaugh (TUV SUD)

A strong EMC/Wireless Test Plan can be one of the most helpful tools during a regulatory submission. As a manufacturer, it is your chance to demonstrate to any reviewer that you as a manufacturer has thoroughly considered all risks that can occur and devised a strategy to test for them. It's also your opportunity to define your Intended and Essential Performance clearly.

Unfortunately, many medical device manufacturers do not adequately document this in a cohesive and detailed way... and some manufacturers don't even develop a test plan prior to testing.

In this presentation, we will discuss the benefits of putting in the time EARLY to develop a test plan for EMC and Wireless testing so that you end up saving even more time during the regulatory submission process end-to-end and prevent any need for re-testing.

SAFETY SCIENCE & HBSE

Human Factors and it's Role in Product Safety Design

Nicolaus Faino (ESi)

Human factors can be simply defined as the study of how humans interact with their environment. This presentation will introduce a variety of human factors concepts, such as affordance and conspicuity, and how they relate to product safety design. We will discuss how these concepts are applied in real-world designs and their impact on safety.

IEC & EN 62368-1 - Navigating multiple editions of IT/AV standard - Strategies and Solutions

Grant Schmidbauer (Nemko)

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

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