

PROGRAM-AT-A-GLANCE



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KEYNOTE SPEAKER

Thinking Outside the Sphere: Human Space Exploration in a Risky Environment

Professor Bonnie J. Dunbar, PhD NAE RSEcorr- Director, Aerospace Human Systems Laboratory (AHSL), Texas A&M University, College Station, TX



Dr. Dunbar, who began her career as an engineer building the space shuttle, flew on five missions, served as a NASA Executive leader, and now teaches about human space vehicle design and operations, discusses past achievements and the future in human space exploration, underscored by the safety lessons learned which helped to reshape institutional thinking.

Dr. Bonnie J. Dunbar is a retired NASA astronaut, engineer, and educator, and currently the John and Bea Slattery Chair in Aerospace Engineering at Texas A&M. She leads the Aerospace Human Systems Laboratory, focusing on human space systems, partial-gravity research, and the development of a human-rated short-arm centrifuge for future Moon and Mars missions.

A member of the National Academy of Engineering, Dr. Dunbar joined Texas A&M through the Chancellor's Research Initiative after serving as an M.D. Anderson Professor at the University of Houston, where she led major STEM programs and directed aerospace and space architecture graduate studies.

During her 27-year NASA career, she flew five Space Shuttle missions—logging more than 50 days in space—and later served in senior leadership roles, including deputy director for Flight Crew Operations and deputy associate administrator for Life and Microgravity Sciences.

Following NASA, Dr. Dunbar served as president and CEO of The Museum of Flight and remains active in aerospace consulting and STEM advocacy. She holds multiple degrees, ten honorary doctorates, and is a Fellow of the American Institute of Aeronautics and Astronautics (AIAA), the Royal Society of Aeronautics, and the American Ceramic Society.

Day 2: Regulatory Jeopardy

Join us for the ISPCE 2026 Regulatory Jeopardy session on Wednesday, May 13, 2026 at 8:00 AM sharp in the ballroom! Watch as three teams race and compete in a hilariously funny and technically challenging showdown. The winning team will donate two widescreen TVs to St. Jude Research Hospital, complete with their get-well signatures on the back and a group photo to be displayed at the hospital in Memphis, TN. Don't miss this exciting event where knowledge meets generosity!

Meet the Team Captains



Clues and Responses Submissions

This year, we are requesting all speakers and authors, including those on the waitlist, to contribute to the 'Clues & Responses' board for the Regulatory Jeopardy game as a Plenary session.

- Your 'Clue' with the 'Response' could be one of your single most controversial topics from your presentation or could be a very well-known fact.
- This year will be more challenging than in the past where we had simple Yes/No, True/False responses from the Clues submitted. BUT NOW, we will require the contestant's response to be in the form of a question, just like you would hear on the television show.
- Therefore, your 'Clue' should be clear & concise (between 10-15 words max) and the 'Response' between 1-5 words max, if possible.
- We ask you to also provide a detailed rationale/explanation for each of your responses, in the event your response/answer needs additional support if challenged by the audience. If the response is complex, you can have the opportunity to provide a hyperlink to a website or redirect them to your upcoming session to get more details.
- Note that not all submissions cannot be guaranteed to be used as there are only 30 Clues/responses on the Jeopardy game board, so the better the Clue (clear & concise), the better the chances.
- And one final reminder. As part of the challenge, if your Clue is used during the game, you cannot provide any hint to your team during the game. You must recuse yourself for that Clue only, BUT you are able to respond to your clue if you are the selected contestant.

Please send your entries to Carolynn Leonard <carolynn.leonard@industrial-ia.com> by completing the attached form found below by April 11th. If you are submitting more than 1 Clue & Response, then you must submit another separate form for each additional 'Clue & Response'. And remember, please be sure to keep the topics current and/or provide some change from the previous year if you are a repeat submitter

Thank you to our Regulatory Jeopardy Sponsor!



DAY 3: FDNY SESSION

Considerations for promoting the safe utilization of various lithium-ion battery technologies in the advancement of public policy initiatives in today's world.

Chief Matt Quinn, Fire Department of New York (FDNY)
UL Solutions, Bruce E. Johnson, Regulatory Services Manager, Codes

In today's world, it can be a struggle for fire departments to keep pace with rapidly evolving technological innovations and the new risks they bring challenging fire department response. Among other challenges, the fire service is facing a variety of alternative energy sources for the built environment, electric vehicles (EV), and micromobility devices, all utilizing lithium-ion batteries. Not only have these technological innovations changed the way people move around, lithium-ion batteries are used in another increasingly common application: Battery Energy Storage Systems (BESS)

This session will focus on the rapidly growing use of batteries in everything from consumer products to micromobility devices, EVs, and BESS, with a focus on potential hazards for responding firefighters and best practices for preparation, response and post-event actions to safely handle lithium-ion battery involved fires.

The first part of the presentation will introduce the basics of lithium-ion battery technology and demonstrate why they fail and how failure affects fire dynamics and fire suppression; creating new risk and challenges for the first responder.

The second part of the presentation will review current best practices for responding firefighters based on the latest scientific research for suppression and lessons learned for past events.

Finally, the presentation will also provide an update on the current state of the battery-powered technology industry and the regulatory environment with an eye to future developments. There is an important role firefighting personnel can play in the code, standard, and regulatory process to help ensure the risks associated with these new and innovative technologies are properly mitigated.

WORKSHOPS

Workshop #1: The Evolution of Safety & Compliance Engineering: From Product Safeguards to Systemic Resilience

Jong-Moon Chung (Yonsei University), Stefan Mozar

The presentation "The Evolution of Safety & Compliance Engineering: From Product Safeguards to Systemic Resilience" describes the evolution of safety engineering over the past century, its shift from product level safeguards to system level resilience, as well as the key milestones (which include compliance, hazard based, systemic, and organizational aspects). In addition, a profile of how safety is now viewed as an emergent property of socio technical systems and AI based compliance standards are described.

WORKSHOPS

Workshop #2: IEEE/PSES-Purdue University Presents: Product Safety: An Introduction for Effective Engineering Design

Jim Bender, P.E., (Intertek), IEEE PSES Vice-President, Education

This course equips Learners with an introduction of basic knowledge and skills to effectively integrate safety principles into engineering design.

Covers analyzing and integrating safety features into product design, understanding ethical and legal responsibilities, and identifying key principles for design safety considerations.

It emphasizes the importance of a proactive approach to minimizing risks of safety incidents over simply implementing reactive measures.

With a focus on mitigating risks of electrical shock and fire hazards, the course provides foundational principles and learning activities throughout, including a quiz at the end and certificate of completion upon successful finish, anticipated at the end of the workshop. .

Moreover, it offers insights into emerging technologies and underscores the importance of prioritizing product safety in design.

For the ISPCE 2026 featured workshop, It is presented by the Product Safety Engineering Society (PSES) of the Institute of Electrical and Electronics Engineers (IEEE) in collaboration with the Purdue University School of Electrical and Computer Engineering.

WORKSHOPS

Workshop #3: Interactive Risk Assessment Workshop: An Advanced, Real World Approach to Product Safety Using ISO 12100

Regan Arndt (Thermo Fisher Scientific), Mark Pearson (Thermo Fisher Scientific)

This interactive session provides a comprehensive overview of assessing potential risks associated with a representative, multi component product throughout its lifecycle, from development to disposal. The session begins with an educational presentation that establishes the regulatory context and foundational expectations for product safety risk assessment using ISO 12100. Participants will be introduced to a more technically complex mock product scenario that incorporates layered hazards, interfaces, foreseeable misuse, and use case variability, creating a realistic framework for applied learning.

Building on this foundation, the workshop transitions into an interactive, hands-on session where attendees actively identify and analyze potential hazards, vulnerabilities, and uncertainties that could impact product safety, users, and the environment. Participants will evaluate the elements of Risk (Severity, Frequency, Probability, Avoidance, and Likelihood) through a live risk assessment demonstration supported by an enhanced calculation spreadsheet. Emphasis is placed on prioritization, justification, and selection of appropriate mitigation strategies aligned with applicable regulations and standards. For those who attended the prior risk assessment workshop in San Francisco, this session offers a deeper, more challenging application through an expanded and more complex product scenario. For first time attendees, it provides a practical, engaging introduction to real world risk assessment that is both accessible and immediately applicable. This is a session not to miss for professionals working in product safety and risk assessment.

WORKSHOPS

Workshop #4: Engage, Inspire, Deliver: A Hands-On Workshop for Conference Speakers

Regan Arndt (Thermo Fisher Scientific), Lars Mellander (Product Safety Consulting, Inc.)

This fun and highly interactive professional learning workshop is designed to help both new and seasoned symposium and conference speakers elevate their presentation skills with confidence and authenticity. Participants will explore practical, easy-to-apply techniques to strengthen stage presence, refine messaging, and create meaningful audience interaction. Through hands-on activities, real-time practice, and guided feedback, attendees will learn how to move beyond static slide delivery and become engaging, dynamic presenters who captivate and connect.

Whether you are preparing for your first conference talk or looking to refresh and energize your speaking style, this workshop provides tools to enhance storytelling, manage nerves, and foster genuine engagement that keeps audiences involved from start to finish. Walk away empowered, inspired, and ready to deliver impactful presentations that resonate long after the session ends.

ACCEPTED: BATTERIES & ENERGY STORAGE

#20: When the Price is Wrong: The risks of cheap battery power banks

Hernan Sanchez (Exponent)

Formal Paper

The ever-growing number of battery-powered devices has led to an increase in the use of battery power banks, with many consumers carrying at least one at all times. Combined with the ever-decreasing costs of battery manufacturing, cheap (or even free) power banks are reaching the hands of consumers. This paper will provide case studies on the quality of free/inexpensive power banks and will discuss safety risks that may arise from the lower quality control associated with the lower costs.

#7: From Code Intent to Engineering Evidence: Modeling and Simulation of BESS Explosion Mitigation Under NFPA 68/69

May Wang (TUV Rheinland of North America Inc.)

Large Battery Energy Storage Systems (BESS) can present deflagration hazards when flammable off-gases accumulate in confined enclosures. This presentation outlines a compliance workflow that maps NFPA 69 (prevention/isolation) and NFPA 68 (venting) intent into auditable evidence. Using scenario-based modeling and simulation, we (1) define a design basis for gas generation, dispersion, and ignition; (2) evaluate prevention layers such as ventilation, detection, and shutdown/isolation logic; and (3) quantify residual overpressure and vent performance when venting is selected. The deliverable is an engineering evidence package templates—assumptions, sensitivity checks, acceptance criteria, and change-control triggers—to support design review and lifecycle modifications for containerized BESS

#19: UL 9540A updates including Large Scale Fire Testing

Michael Anderson (Hithium Energy Storage)

The presentation will update attendees on the latest enhancements and changes to UL 9540A "Test Method for Evaluating Thermal Runaway Fire Propagation in Battery Energy Storage Systems" based off the Sixth Edition (March 2026).

#65: Lithium-Ion Batteries in IT Products - Annex M Testing in IEC 62368-1

Ted Eckert (Microsoft)

IEC 62368-1 includes numerous requirements and tests for lithium-ion batteries. This presentation will cover the basic requirements for the product's design. It will cover the testing requirements for the batteries listed in Annex M. We will look at what the tests are, how they are applied, and what potential hazards the tests are designed to uncover.

#124: EU Battery Regulation (and the changeover from EU Battery Directive)

Rich Byczek (Intertek)

The EU battery regulation recently replaced the former Battery Directive, and gives many new requirements including technical, battery stewardship, and sustainability. These requirements are being phased in over several years, and include CE marking requirements and Notified Body involvement. This talk gives an overview of the latest EU Battery Regulation timeline as well as guidance on navigating the EU's timeline for compliance and how to involve a Notified Body in your compliance planning.

#122: Arc-flash Hazards in Battery Energy Storage Systems (BESS): Empirical Modeling, Energy Calculations and PPE Alignment

Prathamesh Panchal (SGS North America Inc.)

Formal Paper

Battery energy storage systems (BESS) combine high-energy DC sources with grid-connected AC systems, introducing arc-flash hazards beyond traditional models. This paper analyzes arcing behavior, enclosure effects, and arc duration, applies IEEE Std 1584 models, and links incident energy calculations to PPE selection for safer BESS installation and operation.

WAITLIST: BATTERIES & ENERGY STORAGE

#4: Overview of BESS Codes and Standards Framework

Michael Anderson (Hithium Energy Storage)

As battery energy storage systems (BESS) rapidly scale in size, voltage, and deployment, the codes and standards landscape governing their safety and compliance has grown increasingly complex. This presentation provides a clear, structured overview of the BESS codes and standards framework, explaining how product standards, installation codes, fire and explosion safety requirements, and grid interconnection rules interact across the system lifecycle.

The session highlights key U.S. and international standards, including UL 9540, UL 1973, UL 9540A, NFPA 855, the International Fire Code, NFPA 68/69, UL 1741, IEEE 2800, and relevant IEC/ISO documents. Emphasis is placed on understanding the intent and scope of each standard, common areas of overlap, and frequent points of confusion between product certification, system integration, and site approval.

ACCEPTED: COMPLIANCE 101/201

#1: Product Safety: Leveraging leadership-based influencing styles to achieve effective results

James Bender (Intertek)

Formal Paper

Achieving effective product safety is a shared goal for product designers and manufacturers to facilitate their ethical and moral obligation to provide safe products.

This paper provides an overview of effective leadership influencing result-based tools and techniques needed to avoid compliance inefficiencies often seen from bureaucratic management approaches.

#17: Identifying applicable product safety standards: A foundation for safe product design and an effective certification outcome

Trevor Cole (Intertek)

Formal Paper

First-time product safety compliance helps mitigate potential hazards by influencing effective design and manufacturing practices. This paper provides basics to systemically identify applicable nationally recognized safety standards, focusing on fire and electrical shock hazards to influence first-time end-product certifications, minimized time to market product introduction and needless redesign costs.

#3: IEC 62368-1 Ed4, Key changes, adoption, impacts

Grant Schmidbauer (Nemko North America, Inc.)

This presentation will present the current state of IEC 62368-1 (multiple editions), along with EN IEC 62368-1 (multiple editions), the citation status to EU OJ, the main differences of 4th ed. to prior 3rd ed., and finally the current state of adoption of IEC 62368-1 around the world.

ACCEPTED: COMPLIANCE 101/201 CONT.

#67: Effective Risk Assessment for Mitigating Product Safety Certification Roadblocks

Maryam Mahmoodi (Intertek)

Formal Paper

Risk assessment is critical to successful product safety certification, yet it is often treated as a documentation exercise and misapplied in practice. This paper highlights effective ways to mitigate common pitfalls that lead to certification delays and/or failures and presents strategies to improve hazard identification, risk reduction and certification readiness.

#98: Navigating Authority Having Jurisdiction (AHJ) Compliance: Field Evaluations of Industrial, Non-Listed Equipment

Joseph Depner (ICC-ES)

Formal Paper

Installation of custom industrial machinery often encounters regulatory compliance barriers if Nationally Recognized Testing Laboratory (NRTL) certifications are not achieved, resulting in project startup/commissioning delays.

This paper examines field evaluation insights and alternatives to achieve certifications of non-certified/listed equipment based on National Electrical Code requirements and testing methodologies.

#99: Marketing the value of product safety certification approvals – A few hidden gems

Derek Silva (Intertek)

Formal Paper

Marketing product safety certification approvals sounds like an “easy-peasy” college marketing assignment.

But how can value propositions addressing “issue avoidance” be marketed to help prevent product safety occurrences and avoid negatively eroding a manufacturer’s reputation?

This paper overviews the impact product certification has on strategic marketing and branding

ACCEPTED: COMPLIANCE 101/201 CON

#29: 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.

#33: Don't just request a quote, KNOW how to request a quote!

Lars Mellander (Product Safety Consulting, Inc.)

In the compliance world today, things are only getting more difficult. Relying entirely on a test lab or certification body to know every requirement — or determine what isn't required — is no longer enough.

This presentation provides practical guidance, tools, and strategies to help you effectively approach a compliance project and confidently present it for a formal quotation. Whether you believe you already know this process or think you don't need it, attend, and discover just how essential this knowledge truly is.

#53: The Strategic Role of Product Safety Engineers in Proactive Product Development

Brett Gagnon (BrettGagnon.com)

Product safety and compliance are often viewed as final checkpoints—necessary hurdles to clear before a product can be shipped. In practice, this reactive mindset increases cost, compresses schedules, and elevates risk once a product is already in production. This white paper argues that investing additional time and resources earlier in the product design and New Product Introduction (NPI) process consistently delivers better outcomes than attempting to remediate compliance issues after release.

More importantly, it reframes the role of the product safety or compliance engineer: not merely as an owner of electrical safety, EMC, or environmental compliance, but as a critical feedback loop within the organization—one that connects post-market issues back to upstream gaps in design, validation, and decision-making. When properly positioned, product safety engineers help manufacturers balance innovation with discipline, speed with robustness, and creativity with risk reduction.

WAITLIST: COMPLIANCE 101/201

#64: Regulatory Updates on Laboratory Equipments

Santhanand Shanmugam (iLenSys Technologies Pvt. Ltd.), Manoharan Nallasamy (iLenSys Technologies Pvt. Ltd.)

Regulatory and Standards Evolution for Product Safety Compliance in Analytical and Laboratory Instruments.

#25: PSES Tutorial: Part 1: Compliance 101

Ken Kapur (Thermo Fisher Scientific)

This is the first of three parts, for those new to Product Safety and Compliance. This Part 1 of the Tutorial will cover the requirements for those involved in new and existing products and those who need to address global safety requirements.

#26: PSES Tutorial: Part 2: Compliance 201

John Allen (Product Safety Consulting, Inc.)

This is the second of three parts, for those new to Product Safety and Compliance. This Part 2 of the Tutorial will take you through a couple of different products, showing non-compliances, areas of common concerns, tips and tricks on how to get things into compliance. We also take you through UL's online Certifications Directory and their IQ Databases. Both invaluable tools for any designer submitting product for Certification.

#27: PSES Tutorial: Part 3: Global Market Access

Grant Schmidbauer (Nemko North America, Inc.)

This is the third of three parts, for those new to Product Safety and Compliance. This Part 3 of the Tutorial will provide insight that 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.

ACCEPTED: CYBERSECURITY

#2: The CRA - Cyber Resilience Act, with interplay to RED/Cyber

Grant Schmidbauer (Nemko North America, Inc.)

This presentation will provide an overview of the EU Cyber requirements, including Cyber for CRA - Cyber Resilience Act and the interplay between CRA and Cyber for RED/DA. It will include the most current and critical information on status, dates, standards development activity, and applicability of the requirements.

#42: Development of Cybersecurity Regulations Globally

Tom Tidwell (Nemko North America, Inc.)

Explores the current state of cybersecurity regulations worldwide, including the factors driving regulation development.

ACCEPTED: CYBERSECURITY CONT.

#70: Explore the Evolving Regulatory Landscape for Cybersecurity

Ravi Sharma (UL Solutions)

This informative presentation starts by exploring global cybersecurity market trends, focusing on growth areas, market drivers, challenges and differences between consumer and industrial domains.

Then we explore major cybersecurity standards across industries, including:

- ETSI EN 303 645
- ISA/IEC 62443
- UL 2900-2-3
- ISO/IEC 21434

Lastly, we jump into the cybersecurity regulatory landscape, covering:

- Cyber Resilience Act (CRA)
- Radio Equipment Directive (RED)

#119: September 11, 2026 Deadline: Preparing Your Vulnerability Management Program for the EU CRA

Gregory Boyrazian (KokoBo LLC)

The EU Cyber Resilience Act reshapes global product security expectations. This session highlights why timely vulnerability management is essential and how organizations must prepare for mandatory reporting by September 2026. Attendees will learn practical steps to align processes, reduce compliance risk, and meet CRA's far-reaching security obligations.

ACCEPTED: EMC & WIRELESS COMPLIANCE

#9: From Flash Density to Field Reliability: A Population-Weighted Distance Effect Model for Surge Immunity Specifications

Formal Paper

Zhang Qiming (Exponent), Charles Zhu (Amazon), Kael Lan (Amazon), Joyce Xie (Amazon), Kevin Chen (Amazon), Qi Long (Amazon), Andy Tam (Exponent)

Determining lightning surge immunity for outdoor electronics like satellite terminals is complex, as it translates environmental electromagnetic stress into a reliability metric. This paper introduces a data-driven framework using electromagnetics, meteorology, and demographic data. A two-step probabilistic approach is employed: a physics-based Distance Effect Model modifies the Rusck formula to include short-term effects, converting lightning strike distance into a probability distribution of induced voltages. This is combined with geospatial data from the U.S. National Lightning Detection Network and the U.S. Census to link lightning hazards with user and product locations. Weighting risks by population density emphasizes population-weighted reliability, showing that a 4 kV surge threshold provides 99.5% annual coverage for the weighted user base, aiding engineers in design and safety enhancement.

#44: Japan Radio Law MIC

Millicent Rivera (Industrial Inspection and Analysis)

Discover the latest innovations in Japan Radio Law (JRL) compliance and MIC certification for wireless devices. This session explores streamlined approval processes, technical standards for emerging technologies like UWB and IoT, and practical strategies to accelerate market entry in Japan. Attendees will gain actionable insights into regulatory trends, certification best practices, and how to avoid common pitfalls. Join us to ensure your products meet Japan's stringent requirements and stay ahead in a rapidly evolving wireless landscape.

ACCEPTED: EMC & WIRELESS COMPLIANCE CONT.

#45: From Device to Report: FCC and ISED SAR Testing in Practice

Fouzia Syed (Industrial Inspection and analysis)

Which wireless devices require SAR testing, and what does a lab actually need to perform it? This presentation provides a practical overview of SAR requirements in the United States and Canada, covering applicable devices, test setups, and essential equipment. It is intended for attendees seeking a clear path to FCC and ISED SAR compliance.

#60: Radio Enabled IoT - a connected world

Johee Chang (Business Development)

Covering regulatory and industry approvals for the USA, Canada and Europe.

We examine assessment of the radio module, and the further assessment required by the company installing the module. Radio, EMC, Cyber Security, RF safety, conformity, industry and carrier acceptance.

#75: 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.

ACCEPTED: EMERGING TECHNOLOGIES & INNOVATION

#10: A Standardized Product-Level Framework for Quantifying Glare Risk of Photovoltaic Modules Based on BRDF

Formal Paper

Minghao Yuan (TÜV Rheinland Co. Ltd.), Weichun Li (TÜV Rheinland Co. Ltd.), Xuewei Zhou (TÜV Rheinland Co. Ltd.), Qi Gao (TÜV Rheinland Co. Ltd.), Xizhou Xie (TÜV Rheinland Co. Ltd.), Xuanyu Lv (TÜV Rheinland Co. Ltd.)

This work addresses PV glare from a product-level perspective by proposing a structured comparative framework. The evaluation is based on laboratory measurements of the bidirectional reflectance distribution function (BRDF). The measured results are subsequently transformed into glare-source luminance and daylight glare probability (DGP) under a defined standardized modeling condition. The objective is to provide a repeatable method for quantifying the glare risk of PV modules at the product assessment stage.

#11: Does Product Compliance Slow Down Innovation?

Brunno Covolan (Intertek Testing Services), James Bender (Intertek)

Formal Paper

Innovation is widely regarded as the lifeblood for an organization's competitive advantage. It fuels technological advancements, new markets, and evolving consumer demands. In today's heavily regulated markets, companies must navigate complex product compliance requirements before bringing innovations to market. This raises a critical question: Does product compliance slow down innovation?

#16: Assessing the Safety of AI-Based Products: An Evidence-Based Approach to AI Safety Compliance

Young Lee (UL Solutions), Kenneth Boyce (UL Solutions)

Formal Paper

AI introduces safety risks that challenge traditional product compliance engineering. This paper shows how AI safety frameworks can be translated into verifiable, requirements-driven compliance evidence for AI-based products. Using UL 3115 as an illustrative example, it proposes a structured, standards-based approach for assessing and assuring AI product safety.

ACCEPTED: EMERGING TECHNOLOGIES & INNOVATION CONT.

#18: Compliance-by-Design in Large-Scale Online Marketplaces: Engineering Scalable Product Safety and Regulatory Controls

Sureshkumar Karuppuchamy (EBAY Inc)

Formal Paper

The rapid growth of cross-border e-commerce has made online marketplaces critical infrastructure for consumer product circulation in the European Union. While these platforms expand market access and consumer choice, they also increase risks related to unsafe, non-compliant goods.

In response, the EU has strengthened its regulatory framework through updated product safety legislation, enhanced market surveillance, and platform governance under the Digital Services Act.

This paper presents a platform-centric analysis of the EU product safety regime for large-scale online marketplaces. It examines evolving regulatory expectations for digital intermediaries and maps legal obligations to organizational, governance, and technical controls used by marketplace platforms. Drawing on regulatory texts, Commission guidance, and enforcement materials, the paper proposes a compliance-by-design model that embeds product safety requirements into platform architecture and operational workflows.

#117: The Dangers of Mislabeled Lasers Available to General Public

Boris Spokoyny (Exponent)

Just a decade ago, Class 4 lasers were costly and limited to industrial and academic environments. Today, technological advances and falling costs have expanded public access. This problem is exacerbated by mislabeling of high-powered lasers in public marketplaces, creating ocular hazards exceeding what users are led to believe.

#63: AI and Digital Compliance Engineering for Enhanced Product Safety and Applications to Display Systems

Jong-Moon Chung (Yonsei University), Hyun-Ho Bae (Yonsei University), Hyuck-Jun Kim (Yonsei University)

This presentation discusses the role of international standards and regulations in artificial intelligence (AI) and digital compliance engineering to improve product safety. It also introduces technologies used in the development and production of modern display products, examines how these technologies align with key standards, and demonstrates how they meet the requirements of global regulatory frameworks.

ACCEPTED: EMERGING TECHNOLOGIES & INNOVATION CONT

#89: Regulating AI around the world

Tom Tidwell (Nemko North America, Inc.)

This presentation looks at the need to regulate the development and use of artificial intelligence and explores various approaches taken by governments around the globe

ACCEPTED: ENVIRONMENTAL, SUSTAINABILITY, AND GOVERNANCE

#36: Ecodesign Regulations for Products in Europe

Ted Eckert (Microsoft)

European energy efficiency regulations for products have expanded to cover the energy of a product across its entire lifecycle. Product designers must now consider repairability, durability, and at the end of a product's life, recyclability. Energy testing has become more nuanced not just measuring overall energy consumption, but how much work is done with that energy. This presentation will discuss product types, requirements, and labeling requirements. It will conclude with new developments in the European Union.

#40: Global Regulatory Trends and Updates

Santhanand Shanmugam (iLenSys Technologies Pvt. Ltd.)

Product Environmental Compliance is a global requirement for any product manufacturers for the global market, and it is important to have the awareness of the global policies to sell their products hassle-free globally.

#111: The ESG Lens on Environmental Product Regulations: Practical Pathways for Compliance Teams

Jamie Wallisch (Assent)

Environmental regulations (such as extended producer responsibility, product-level emissions, and circularity mandates) are reshaping expectations for product compliance teams. This session clarifies how ESG-driven regulatory regimes intersect with traditional product safety and compliance engineering, offering a framework compliance professionals can adopt to anticipate and operationalize sustainability requirements. Real world examples will highlight linkage opportunities across climate, waste, human rights, and compliance disciplines — transforming regulatory challenges into strategic advantage.

ACCEPTED: FORENSICS & FAILURE ANALYSIS

#14: Predicting the past? Consequence analysis during fire & explosion investigations

Formal Paper

Alejandro Jimenez (Engineering Systems Inc.), Zeynep Ayla (Engineering Systems Inc)

Effective fire and explosion investigations increasingly rely on consequence analysis, yet these empirical models introduce significant aleatoric and epistemic uncertainty. Applying them post-incident requires careful data selection, model validation, and interpretation of results as bounded ranges rather than single values (e.g., overpressure, blast radius, heat release rate). This presentation outlines a structured methodology for integrating consequence analysis into NFPA 921-based investigations, emphasizing uncertainty management and compliance considerations. A case study will be presented demonstrating how this approach supports accurate incident reconstruction and informed engineering judgments.

#41: MOV Thermal Runaway Features: Fire Cause vs. Effect

Formal Paper

Eric Schultz (Engineering Systems Inc), Louis Bilancia (Engineering Systems Inc), Tal Nagourney (Engineering Systems Inc), Keith Cline (Engineering Systems Inc), Tomas Bajzek (Engineering Systems Inc)

Electrical overstress (EOS) can degrade metal-oxide varistors (MOVs), reducing their effective varistor voltage below specification so that the designed operating voltage produces elevated leakage, continuous conduction, and thermal runaway. We test whether this varistor-voltage reduction is dominated by localized conduction channels rather than a uniform, bulk change. EOS MOVs are evaluated by microscopy to spatially correlate damage with microstructural features.

#74: Multi-Point Failure in Weight-Loss Cocoon – A Case Study

Gregory Shoss (ESi)

Formal Paper

Certification and listing of a product does not ensure that the product will not fail or become unsafe over time. Failure of a listed/labeled consumer wellness heating appliance resulted in a severe thermal injury. Investigation showed that a failed internal heater wiring harness contributed to the continuous, uncontrolled heating of the user's abdomen during a treatment session. The case highlights the investigation process, the limitations of component-level safeguards, and underscores the need for system-level failure analysis and robust compliance engineering.

ACCEPTED: FORENSICS & FAILURE ANALYSIS CONT.

#77: USB Type-C Receptacle Melting From Internal Fault Current Caused by Electrochemical Migration

Tal Nagourney (ESi)

Formal Paper

This work details the root cause investigation of overheating USB Type-C connectors. The investigation followed a high number of consumer electronic products returned from the field with thermally damaged Type-C receptacles. Computed tomography (CT) revealed the presence of metallic dendrites growing through voids and joining lines within the injection-molded nylon in the receptacle, which formed short circuits. Energy-dispersive X-ray spectroscopy (EDS) identified the dendrite composition as copper. Dendrite formation was attributed to electrochemical migration (ECM) during charging following contamination with an electrolyte. Ion chromatography indicated the presence of ionic species introduced after manufacture that formed the electrolyte. The failure mode was recreated by deliberately contaminating energized Type-C receptacles with solder flux, which resulted in formation of dendrites that created short circuits and produced similar thermal damage to field-returned samples.

#66: Throwing Down the Gauntlet: Confronting Battery Failures in the Glovebox

Jessica Crosby (Brillouin Consulting), Brian May (ESi), Eric Shultz (ESi)

This presentation outlines the process of battery disassembly for failure analysis using glovebox equipment. The audience will leave with an understanding of the safety risks involved in battery disassembly, techniques for disassembling batteries, glovebox 101, and the types of failures best suited for glovebox work.

ACCEPTED: FUNCTIONAL SAFETY

#106: Application of ISO 26262 to Automotive Semiconductors

Formal Paper

Melissa Mendias (Exponent), Susan Han (Exponent), Rita Garrido Menacho (Exponent)

This paper examines the application of the ISO 26262 functional safety methodology to automotive semiconductors. Components such as microcontrollers and sensors are often developed as a SEooC (Safety Element out of Context) in the absence of a specific vehicle application. The standard provides a framework by which the scope and capabilities of a device are documented to provide assurance that the integrated system will achieve the required safety goals.

#93: AI-based Functional Safety Compliance

Maja Bland (UL Solutions), Nicholas Alexiades (UL Solutions)

This paper will cover how current functional safety standards are applied and new standards are developed to cover safety-critical systems that have AI aspects.

Topics will include:

- UL 3115 - the AI-based system safety standard and how it covers AI-based functional safety
- ISO 8800 and its coverage for the automotive sector
- ISO/IEC 22440 and its coverage for the industrial sector
- The EU AI Act and how harmonized standards may play a role in supporting

ACCEPTED: GLOBAL HAZARDOUS LOCATIONS

#8: Comparison of Non-Incendive Circuits and Ex ic Intrinsic Safety Under Hazardous Area Standards

Yu Shi (Intertek Testing Services), Xiaomeng Di (Intertek Testing Services) Formal Paper

This paper compares non-incendive circuits and Ex ic intrinsic safety under hazardous area standards. Differences in spark analysis, energy limitation, fault consideration, and certification requirements are analyzed to support appropriate protection method selection for equipment used in explosive atmospheres.

#43: Hazardous Location Arc Flash Case Studies: The Hovering Mosquito

Jon Miller (MSA)

The minimum ignition levels of an arc flash within a hazardous location resulting in devastation is astonishing. Arc flash in such hazardous locations can present a significant risk to personnel and property requiring careful consideration of the hazards. A detailed evaluation of various case studies is an effective 'lessons learned' approach for enhancing future risk assessment and implementation of improved mitigation techniques. A risk assessment utilizing knowledge of ignition energy, probability of occurrence, and potential consequence can offer key guidance on establishing mitigation techniques outlined within Codes and Standards. The collective past 'lessons learned' will better prepare us for the preventive actions of the future. This can be done by systematic methods as a preventive action technique providing a means to establish a multi-layered approach for protection of personnel and property against inherent arc flash risks within a hazardous location.

#72: Choosing the Right Ex Product Evaluation or Certification Scheme with Emphasis on North American Markings, Requirements and Standard Alternatives

Jeffrey Lenk (Nemko North America, Inc.)

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. When targeting the North American market, product markings can be a difficult decision, Class/Divisions or Class/Zones are possible for placing your product in this competitive market. How the NRTL Hazardous Locations requirements bring in Ordinary Location evaluations. What are the advantages or disadvantages in using non-harmonized standards. What is the best approach for your needs and products.

ACCEPTED: GLOBAL HAZARDOUS LOCATIONS CONT.

#73: Assemblies and installation of products in Hazardous Locations

Jedd Smith (Nemko North America, Inc.)

In recent years, the approach for certifying assemblies of approved parts has moved towards the application of the 60079-46 standard. This standard brings in requirements for non-electrical equipment and installations per local codes. This presentation will cover the many requirements and the differences between the US, Canadian, ATEX and IECEx schemes.

#88: Operating Equipment in a Flammable Atmosphere

Kristen Lussier (ESi), Michael Hanks (ESi)

Consumer products with electric motors or heating elements are regularly blamed for igniting fires and explosions. However, investigations frequently identify other causes for the incident. A test chamber and procedure were developed for screening products with electrical motors or heating elements to characterize the likelihood of a product igniting flammable vapors. The method is a modified version of MIL-STD-810G Method 511. The test chamber and procedure are suitable for quickly evaluating electrical components and equipment for operation in a flammable atmosphere to determine whether they are plausible ignition sources. The test can be used as part of a fire or explosion investigation, or during a product design process as a safety check.

ACCEPTED: GLOBAL MARKET ACCESS

#12: Is Component Certification Enough? Rethinking IEC 62368-1 Compliance for Rack-Scale Products

John Werner (IBM), Arkadiy Tsfasman (IBM), Wolf Wolbeck (IBM)

As datacenter and enterprise infrastructure moves toward modular architectures, the boundary between certified systems and integrated collections of certified components is increasingly blurred. This interactive session examines a product model in which OEM and in-house components are independently tested/certified to IEC 62368-1, fully assembled/cabled together in a rack, yet intentionally shipped without a top-level system certification, compliance label, or regulatory marking. Each component carries required global approvals, while the assembled rack includes only an identifier label.

The discussion will explore safety, regulatory, and liability, including responsibility in the event of an incident, risks of omitting system-level testing, regional acceptance, and the value of system testing or third-party certification without marking. Participants will also examine customer flexibility, faster deployment, and alternative approaches that balance compliance rigor with time-to-market.

#21: China Regulations Update 2026

Paul Wang (G&M Compliance Inc)

This presentation will introduce the most common certifications for electrical products in China like CCC, SRRC (wireless product), NAL (telecom product), RoHS, Energy label, etc. It includes both brief introduction of each certificate and the most recent updates. You will have a better understanding of how to transfer SDoC to normal CCC, what products can apply for series SRRC, what kind of server products require Energy label, what is the requirement for the new China RoHS standard, and more.

#23: UL Solutions Voluntary EU certification schemes: How they can support European legislation for Low Voltage Directive (LVD) requirements

Maja Bland (UL Solutions), Jesper Olesen (Certification Program Lead, GMA)

Low Voltage Directive (LVD) applies for numerous products sold in the European Union (EU). In the fulfillment of LVD requirements Manufacturers can benefit from CB Scheme, GS-Mark and other ULS voluntary schemes like D-mark and UL-EU. The presentation will shortly address CE marking, Harmonized standards, LVD and voluntary schemes in general. The focus will be topics like: Harmonized standards versus lack of harmonized standards, monitoring of production control, voluntary schemes as sales enhancement and other voluntary scheme benefits.

ACCEPTED: GLOBAL MARKET ACCESS CONT.

#47: India - Telecom Regulation (TEC) & Security Certification (ComSeC)

Paul Wang (G&M Compliance)

India has a strong Compliance requirement, and all the areas are already covered: Safety, Reliability, and RF.

The dawn of the information age has led to our heavy reliance on interconnected technology and data networks that power everything from finance and infrastructure to communications and weapon systems. India is investing heavily in defensive cybersecurity measures to protect their critical infrastructure and sensitive information from cyber-attacks. This includes robust firewalls, intrusion detection systems, encryption, and incident response plans.

Every country that has a good ecosystem for certification is working on newer certifications, which are mostly linked to Security testing. It is important to build a very robust certification standard around telecom and security, as these are key certifications that can make a country much more vulnerable to any threats.

#49: Adoption of Wi-Fi 6E & Wi-Fi 7 in Global Markets

Peter Grinager (Approve-IT Inc.)

We'll provide global, regional and key country summaries for WIFI 6E/7 acceptance and certification requirements. Uploaded presentation will be updated to reflect most recent data.

#78: From Labels to Digital Verification: How QR Codes Are Transforming Global Regulatory Frameworks

Elizabeth Perrier (ORBIS Compliance)

QR codes are becoming a key tool in global regulatory compliance, especially in telecommunications and other highly regulated industries. Regulators worldwide are adopting QR-based systems to improve product traceability, authentication, and transparency, often replacing or complementing traditional labels and certification marks. Secure digital verification now provides real-time access to trusted certification and supply-chain data.

ORBIS's presentation will examine this shift toward QR-driven compliance, highlighting regional trends and how governments are using these systems to strengthen oversight and streamline approval processes. The session will also address the growing need for scalable platforms to help manufacturers manage evolving QR code requirements across multiple countries.

ACCEPTED: GLOBAL MARKET ACCESS CONT.

#86: Global Compliance in Motion: Key Regulatory Changes Shaping 2025–2026

Connie Biggs (Global Validity)

GMA updates are evolving quickly, creating both compliance challenges and strategic planning opportunities for manufacturers. Our discussion will include major regulatory developments impacting global product certification, with a focus on changes implemented in late 2025 and those planned for 2026. Topics include key regulatory transitions across the Americas, such as Mexico's move to the CRT framework, implementation of IFT-016 and IFT-017, and 3G sunset timelines in Latin America. The session will also address technology and spectrum shifts, including restrictions on 3G-only devices and other country-specific network limitations. Highlights include certification and labeling updates in Paraguay, Moldova, Nicaragua, Vietnam, and India, as well as regulatory authority changes in regions such as Lebanon and Yemen. The discussion will also incorporate newly announced developments through May, ensuring attendees leave with timely insights to support global compliance strategies.

#91: Labeling From the Perspective of Global Market Access

Tiffany Wong (TUV Rheinland of North America, Inc.)

Labeling—and alternatives to traditional labeling—remain a central focus in global market access, as product labels are a critical component of regulatory approval. This presentation reviews general labeling practices and highlights examples of e-labeling accepted within global market access approvals.

#92: Mexico's New WLAN Regulatory Landscape

Sebastian Medranda Posada (Entirety LLC)

Mexico's DT-IFT-017 standard reshapes how compliance is handled for WLAN devices. This presentation analyzes key technical deviations with international specifications, the current lab capacity and administrative considerations for the transition. We introduce a strategic sample optimization for testing and a preparation checklist for regulatory specialists targeting Mexico approvals.

ACCEPTED: GLOBAL MARKET ACCESS CONT.

#112: GMA Open Panel Discussion

Maja Bland (UL Solutions)

This session will be an open panel discussion, where all in attendance can bring to the table any global market access questions, concerns, issues they have, to be discussed among the experts, as well as contribution by others in attendance.

#79: Ensuring Successful Telecom Equipment Approval in Mexico: NOM-016/NOM-017, MRAs, and Regulatory Updates

Elizabeth Perrier (ORBIS Compliance)

Mexico's updated Telecommunications and Broadcasting regulatory framework is now in effect, introducing new compliance requirements for telecommunications equipment and creating a transition period for manufacturers, testing laboratories, and certification bodies seeking access to the Mexican market.

This presentation will provide an update on the implementation of these changes and guidance on navigating Mexico's homologation and type approval process. It will also address the ongoing Modification of the Mutual Recognition Agreement (MRA) with the United States.

Key focus will be given to the applicability and testing protocols under NOM-016 and NOM-017, including certification pathways, processing timelines, and common challenges. Post-certification obligations and labeling requirements will also be reviewed.

The session aims to help stakeholders achieve efficient approvals and maintain compliance in Mexico's telecommunications market.

#51: Where Not To Apply: Sanctioned Country Updates

Peter Grinager (Approve-IT Inc.)

We'll review all sanctioned countries (level/details of the sanctions, mainly from OFAC) where US based companies are not legally able to sell product. We'll also review changes to existing sanctions. Focus countries will be Venezuela, Belarus/Russia (and how it impacts EAC Marking), Syria, Iran, and Sudan. Uploaded presentation was for EAC updates, we will update.

WAITLIST: GLOBAL MARKET ACCESS

#50: Mexico, Chile & LATAM 2026 Updates

Peter Grinager (Approve-IT Inc.)

We'll provide an update of Mexico's new regulations, mainly transition of IFETEL => CRT, new testing standards, and other relevant NOM updates. We'll also provide an update and step by step review of Chile's new QR Code requirement (starts February 22nd). Finally, we'll add important updates from Brazil. Uploaded presentation is for Mexico only, will update accordingly

#76: Spotlight on Middle East

Theresa Glenna (TUV SUD)

Explore various safety and wireless certification requirements and process for Middle Eastern countries, including Saudi Arabia, UAE, Qatar, Oman, Bahrain, and Kuwait.

ACCEPTED: LEGAL

#15: Balancing legal vs. ethical decision making in product safety/compliance design, development and manufacturing processes - An Open Forum Round Table

James Bender (Intertek)

The challenges of balancing legal vs. ethical decisions in product safety/compliance design, development and manufacturing is often situational and will be featured as a panel-led live audience interactive discussion.

A company's foundational "goodness" can be negatively influenced by near-term profit pressures, customer/stakeholder demands and individual's zest to meet performance-based metrics which often impact but fail to measure doing "what's right," further skewed by not-so obvious regionally-based conflicting product certification compliance regulation adding to the challenges

In this session, audience members identify real or hypothetical situations where key product safety and compliance scenarios having critical legal/ethical outliers potentially creating conflicts and tensions, laying foundation for some interesting expert panel discussion and audience participation.

#22: Unwrapping the PPWR - Navigating the new European Packaging Law

Ulrich Spiegel (Taylor Wessing)

The European Packaging and Packaging Waste Regulation (PPWR) applies from 12 August 2026 and will fundamentally affect export business to the EU. Packaging for all products must meet typical product compliance requirements – from design via documentation to labelling – and is subject to stricter targets for recyclability, reuse, disposal and material reduction. The PPWR applies to all economic operators who make their packaged products available on the European market. As with all product law, the "no compliance, no market" principle applies. The session provides a practical overview of the new legal framework and its implications: What is my company's role under the PPWR? What do I need to understand? And when do I need to do it? Attendees will gain insight into how regulatory packaging requirements translate into design choices, supply chain responsibilities, and pre-market compliance strategies

#31: Navigating the Machinery Regulation w/o Published Guidance: Sifting for Clues

Mike Sherman (Sherman PSC LLC)

The January 2027 Machinery Regulation (MR) deadline looms, but published official guidance remains scarce.

Here are some insights and suggestions to help us survive this change.

ACCEPTED: LEGAL CONT.

#35: The Authorized Representative (AR) for the EU, what is it all about?

Lars Mellander (Product Safety Consulting Inc.)

This presentation will lay out exactly who needs an AR, what are the EU laws, regulations and directives that are behind this requirement. We will answer the questions; What exactly should be provided to an AR? do I have any options? is it really a must to have? How do I get one? Throughout this presentation you will also further your knowledge on the entire EU/CE Marking process and requirements and discuss the entire concept of "self-declaration"

#94: Digital Products, Digital Risk? Cybersecurity = Product Safety under EU Law

Benedikt Rohrssen (Taylor Wessing)

As connectivity and embedded AI reshape modern products, cybersecurity vulnerabilities increasingly become physical safety hazards. This presentation explains how EU law treats cybersecurity as a core product safety and CE-marking requirement, particularly under the Cyber Resilience Act, and outlines practical strategies to manage lifecycle compliance, enforcement, and liability risks for connected products.

#113: Repair, Refurbishment, Remanufacturing: How the EU's New Legislative Framework Adapts to Circular Economy Imperatives in Product Compliance Engineering

Susanne Wende (Univ. of Applied Science, Munich)

The EU's New Legislative Framework (NLF) was designed in 2008 to ensure free movement of industrial products through technology-neutral essential requirements, module-based conformity assessment, and the CE marking prior to placing on the market. However, the circular economy approach with its focus on repair, refurbishment, remanufacturing, and product-as-a-service models challenges a core concept of the NLF: The singularity of conformity assessment for new or substantially modified products. The European Commission's most recent evaluation of the NLF found that 18.5% of stakeholders considered the NLF's obligations for products undergoing "substantial modification" to be unclear, and most respondents agreed the framework struggles to accommodate products that change during their lifecycle. This presentation examines what "substantial modification" means for repair and remanufacturing in sectors like automotive, electrical equipment, machinery, medical devices and aerospace.

ACCEPTED: LEGAL CONT.

#114: Demystifying European Product Regulation

Rod Freeman (Cooley)

This session will unpick and simplify the complexities of the fast-moving European product regulatory landscape, and provide up to date practical insights into the enforcement trends and changes on the horizon. Areas covered will include:

- The overlapping regimes that cover electrical and electronic equipment
- The regulatory approach to new technologies, including cybersecurity and AI
- Right to Repair and Batteries Regulation - the latest updates
- The future of regulation - simplification or more complexity?
- Looming changes to the UK regime
- Enforcement trends across Europe

The session will also cover the global impacts of European regulatory initiatives, including the important new Resolution on Consumer Product Safety adopted by the United Nations Council on Trade and Development.

#115: Violation of product compliance in the EU – Legal consequences and sanctions for companies and individuals

Arun Kapoor (Noerr)

While companies in the US are encouraged to take preventive product safety measures due to concerns about product liability lawsuits, Europe has a complex system of legal consequences for violations of product law. The possible sanctions range from sales bans and officially enforced recalls, including public warnings, to competition law consequences, fines, and criminal consequences, which – despite all European harmonization – vary from one member state to another. Fines and penalties can also be imposed directly on the responsible persons in the companies concerned. For internal risk management, it is therefore important to understand which sanctions are provided for which violations and who may be specifically affected by these sanctions. The presentation provides an overview of the legal consequences for manufacturers, importers, and distributors.

ACCEPTED: LEGAL CONT.

#116: How to conduct a safety gate risk assessment – best practices for structure, *documentation*, and use *vis-à-vis* authorities and other stakeholders

Arun Kapoor (Noerr)

When products become unsafe in the EU, they often must be withdrawn from the market or recalled from end customers in Europe. In addition, the competent authorities in all affected EU member states must be informed immediately if manufacturers, importers, or distributors have evidence that a product poses a risk. The Safety Gate risk assessment (formerly RAPEX) is a tool that both, authorities, and companies can use to assess whether a product needs to be recalled or whether authorities need to be involved. The risk assessment according to the Safety Gate method is the central basis for decision-making in Europe when dealing with unsafe products. Companies work with this tool just as authorities do within their business.

#120: US product liability update; automation and AI

Theodore Dorenkamp III (Bowman and Brooke)

This session will cover legal trends in product liability specifically on how courts and state laws are dealing with automation and AI in product design, development and safety.

ACCEPTED: MEDICAL

#24: 60601-1 4th Edition - What to Expect

Pamela Gwynn (UL LLC), James Stoia (UL LLC)

In this presentation, we will cover the Design Specifications and Architectural Model of the upcoming 4th Edition of the 60601-1 standard. The following topics will be covered:

- Grouping of general requirements according to source of harm/hazardous situation.
- Incorporation of collateral standards into the base standard.
- Obsoleted technologies that will be removed from the standard.

#96: Applying IEC 60601-1-6 in Practice: Common Usability Gaps and How to Avoid Certification Delays

Tanya Wu (CSA Group)

Usability related findings frequently delay IEC 60601 certifications despite completed testing. Drawing on certification experience, this presentation highlights common usability gaps, offers practical considerations when performing usability engineering, and examines how usability activities can be more effectively integrated with risk management to minimize late-stage issues and certification delays.

#121: Certification of Electrical Medical Devices

William Bisenius (Eurofins/MET Labs)

This presentation will begin with a discussion on when a product is considered a medical device and when a product can be classified as a wellness device. Then we will discuss the elements of medical device compliance and detailing the 60601 General, Particular, & Collateral Standards. Once the requirements that apply to Medical Devices, we will discuss the process to obtain US Certification and FDA Approval using the new FDA-ASCA program. The FDA-ASCA program can significantly reduce the time it takes to get the medical device certified as well as FDA approved. It is important that every electrical medical device developer become knowledgeable in the FDA-ASCA program.

WAITLIST: MEDICAL

#56: Accreditation Scheme for Conformity Assessment (ASCA)

Igor Duspara (Nemko North America, Inc.)

This presentation provides a clear overview of the FDA's Accreditation Scheme for Conformity Assessment (ASCA) program, explaining what the program is, the benefits it offers to medical device manufacturers, the requirements and role of ASCA-accredited laboratories, the step-by-step process followed when conducting ASCA-recognized testing, and the purpose and contents of the ASCA Summary Report that documents testing activities, deviations, and compliance outcomes.

ACCEPTED: SAFETY SCIENCE & HBSE

#48: Critical components of AC Induction Motors – Product Safety Application Considerations

Yang Ye (Intertek)

Formal Paper

Electric AC Induction motors are used in a broad range of electrical/electronic end-use products. Motor performance, reliability, and safety are strongly influenced by the design, integrity and application of critical components. This paper overviews motor types and their critical components affecting motor performance and safety at component and application levels

#59: Bridging Hardware-Based and Functional Safety: A Framework for Integrated System Safety Standards

Aruni Basu (Stellantis)

Formal Paper

IEC 62368-1 provides hazard-based safety requirements for consumer electronics, while ISO 26262 establishes functional safety principles for automotive electrical and electronic systems. As consumer products increasingly incorporate safety-critical autonomous functions, neither standard alone fully addresses the convergence of hardware hazards and functional safety. This paper proposes an integrated system safety framework combining IEC 62368-1 hardware safety engineering with ISO 26262 functional safety principles. The framework introduces four System Safety Integrity Levels, integrates hazard analysis of energy sources and functional failures, and specifies verification methods covering hardware reliability and software systematic failures. Application examples include smart climate systems, autonomous kitchen appliances, and adaptive personal care devices, demonstrating comprehensive lifecycle safety assurance for autonomous consumer electronics.

#100: Protective Earthing requirements in IEC based 62368-1 IT/AV safety standards

Kathy Ma (Intertek)

Formal Paper

Protective earthing is a means to provide supplemental protection against potential electric shock hazards found in Class I equipment for metal parts end-products. This article provides interpretations and guidance for protective earthing requirements covered in IEC 62368-1: 2023, Ed.4 (Audio/video, information and communication technology equipment – Part 1: Safety requirements)

ACCEPTED: SAFETY SCIENCE & HBSE CONT.

#85: From Fault to Safety: Interpreting Short Circuit Current Rating (SCCR) in Busway/Fitting Systems per UL 857 (Busways) and IEC 61439-6 (Busbar Trunking Systems (Busways))

Yogi Joshi (Intertek Inc.)

Formal Paper

Short-Circuit Current Rating (SCCR) is critical for busway safety, defining withstand fault currents while minimizing risk-influenced hazards. This paper overviews SCCR implementation, over-current protection device interactions, and component versus assembly ratings featuring UL 857/IEC 61439-6 (Busway/Fittings) comparisons and differences to promote safe, busway application standards-alignment.

#52: Photovoltaic (PV) Module Product Safety/Certification Qualification: Standards Revision Impact

Bo Li (Intertek)

Formal Paper

The updated UL 61730, Photovoltaic (PV) Module Safety Qualification, 3rd Edition aligns with IEC 61730 2023 revision, mandating stricter PV module product safety construction and testing certification requirements.

This paper overviews revisions covering operating ambient temperature and expanded component qualifications, reflecting anticipated "real-world" end-product application uses.

#57: Navigating Standards and Challenges for Coolant Distribution Units (CDUs)

Igor Duspara (Nemko North America, Inc.)

This presentation will explore the challenges and regulatory requirements associated with coolant distribution units (CDUs), focusing on how to determine whether ITAV equipment standards such as IEC 62368-1 or household/heat-pump-related standards like IEC 60335-1 and IEC 60335-2-40 apply. It will provide a clear comparison of these standards, highlight the unique testing difficulties CDUs present, and examine common failure modes encountered during evaluation, enabling attendees to better navigate compliance pathways and design more robust, standards-aligned CDU systems.

ACCEPTED: SAFETY SCIENCE & HBSE CONT.

#58: Engineering Compliance for IEC 62368-1, Annex Y: Construction, Testing, and NEMA/UL 50E Integration

Igor Duspara (Nemko North America, Inc.)

This presentation provides an overview of IEC 62368-1 Annex Y, explaining when the Annex applies, the associated testing requirements, and the constructional requirements necessary to ensure compliance with prescribed safeguards. It will also outline U.S. and Canadian national deviations, including the integration of NEMA/UL 50E enclosure ratings used in North America, and how these deviations influence enclosure design, environmental protection needs, and overall compliance strategies for products entering both U.S. and Canadian markets.

#90: Detecting the Signs: Enhancing Monitoring Strategies for Utility-Scale Battery Energy Storage Systems (BESS)

Timothy Chevalier (Brillouin, Inc.)

Large-scale battery infrastructure requires effective monitoring to reduce operational risks and ensure reliability. This study explores enhanced strategies, including historical data analysis and real-time analytics with AI-driven anomaly detection, for detecting system degradation and reducing the risk of catastrophic failure in utility-scale battery energy storage systems.

#97: Risk Assessment of Consumer Products: Practical Approaches and Challenges

Emanuele Grossi (Exponent)

This presentation explores practical approaches and common challenges in the risk assessment of consumer products. Drawing on real-world examples from product recalls and failure analysis investigations, it provides actionable insights for navigating challenges encountered throughout the risk assessment process.

#105: Engineering Safety and Interchangeability at Higher DC voltages in AI Data-Center Power Conversion Systems

Kiran Kutty (Heron Power Electronics Company)

As data centers transition to 800 Vdc power to support AI-scale workloads, safety and interoperability challenges emerge that mirror earlier shifts in renewable energy systems. Lessons from solar and energy storage—where high-voltage DC is routine—highlight the need for coordinated, system-level design and cross-vendor alignment to ensure safe, scalable deployment.

GLOBAL MARKET ACCESS PANEL

Practical Strategies for Global Compliance

This interactive panel will explore today's evolving global market access landscape, offering practical guidance on regulatory compliance, market entry, and successful product launches. Panelists will provide an overview of key market access requirements while engaging directly with the audience through open Q&A.

Topics include managing restricted substances and regulatory exemptions, staying ahead of global compliance changes, and navigating regional requirements with a focus on LATAM markets. The discussion will also cover emerging trends such as the role of AI in regulatory strategy, best practices for maintaining compliance documentation, and proven approaches to launching products efficiently and compliantly.

Drawing perspectives from regulatory leadership, consulting, and manufacturing, the panel will share actionable insights on partnering with testing and certification bodies, anticipating market changes, and ensuring products reach their intended markets fully compliant.

Maja Bland, Global Market Access Specialist, will lead the panel and guide the discussion with practical, strategic insights.

Our Panelists:

Mark Pearson, Director, Regulatory Compliance, Thermo Fisher Scientific



I am a senior, multi-disciplinary engineer with 30+ years of industry experience and recognized expertise in product safety compliance. I have worked with EU and US certification agencies across multiple product categories, including laboratory and medical devices, to IEC 61010 and IEC 60601 standards.

I serve as Chair of IEC Technical Committee TC66 (IEC 61010) and liaison to seven additional international technical committees. My regulatory experience spans the full product lifecycle, including risk management, field actions, product registration, and negotiation with competent authorities and certification bodies such as the EPA, European Commission, and multiple NRTLs.

I am the author and lead developer of IEC 61010-2-011, an international standard for refrigerated laboratory equipment. In my current role, I oversee global product governance across 340+ sites, 22 divisions, and 110,000+ employees within a \$44B organization, covering product safety certification as well as chemical and environmental compliance.

GLOBAL MARKET ACCESS PANEL CONT.

Monrad Monsen, Hardware Compliance Strategist, Oracle



Hardware Compliance Strategist identifying the electromagnetic compatibility (EMC), safety and RoHS requirements for import and sales in all countries and regions around the world for information technology products (servers, storage, switches, etc.). Member of the US delegation to international CISPR/I EMC standards for multimedia & information technology products. Chairman for IEEE EMC Society's Technical Committee 2 (EMC Measurements).

Maja Bland, Global Market Access Product Specialist, UL Solutions



With 11+ years of experience in the testing and certification industry with focus as Project Manager for GMA UL, TUV SUD, BV (7 layers).

In her role at UL Solutions, she focuses on market access strategy for the lab equipment, medical devices, and information technology (IT) products to meet the local certification requirements for world-wide market launch. She provides technical support to UL Solutions customers who seek to get their products ready and launched globally. Involved with IEEE PSES as GMA Track Chair since 2020, and current IEEE PSES VP of Conferences, and Liaison to IEEE Women in Engineering.

Elizabeth Perrier, CEO, Orbis Compliance



Elizabeth Perrier with more than a 15 years of experience in product regulatory compliance, Elizabeth is passionate about making a meaningful difference in the industry by simplifying regulatory challenges and enabling companies to bring innovative products to global markets.

Elizabeth holds a Master's degree in Telecommunications Management and is a Project Management Professional (PMP) from San José State University, California.

She is an active leader in the global compliance community, collaborating with industry associations, regulatory bodies, and international working groups to advance best practices in product compliance. Elizabeth is a frequent contributor to industry publications and a sought-after speaker at local and international events covering telecommunications, AI, environmental compliance, product safety, and global regulatory policy.