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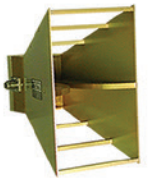

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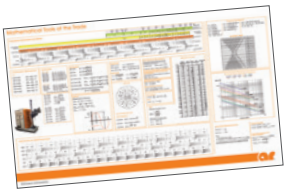

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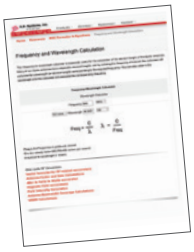

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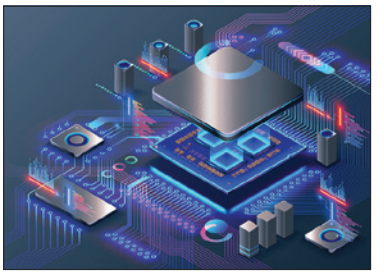
CONTENTS



EU Commission Amends REACH Annexes

The Commission of the European Union (EU) has amended portions of its regulation on the registration, evaluation, authorization, and restriction of chemicals (Regulation (EC) No 1907/2006, also known as REACH) to provide more clarity on the obligations of registrants regarding the submission of required information.

Published in the *Official Journal of the European Union*, Commission Regulation (EU) 2022/477 modifies, adds, or deletes text affecting more than 50 separate points under Annexes VI through X of the REACH regulation. Most of these changes address specific issues related to clarification of the requirements for testing for substances for potential mutagenicity and for reproductive toxicity.

The text changes to the REACH Annexes apply as of October 14, 2022.

FCC Expands List of Communications Equipment That Pose Security Threat

The U.S. Federal Communications Commission (FCC) has added additional products to its list of communications equipment and services that are deemed to pose a risk to U.S. national security or U.S. citizens.

According to a Public Notice, the Commission's Public Safety and Homeland Security Bureau has added the following equipment or services to its "Covered List" under the Secure and Trusted Communications Networks Act of 2019:

- Information security products, solutions, and services supplied, directly or indirectly by AO Kaspersky Lab;
- International telecommunications services provided by China Mobile International USA; and
- Telecommunications services provided by China Telecom (Americas) Corporation.

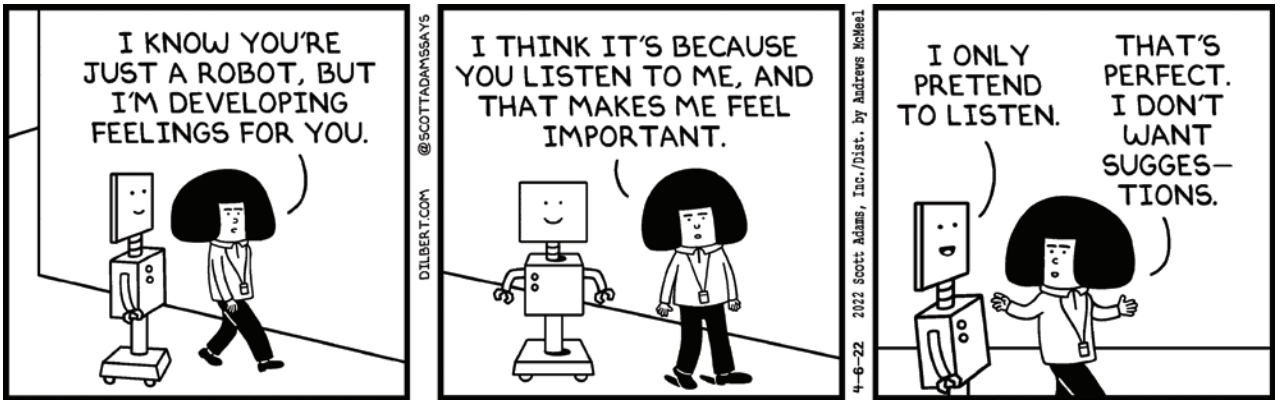
The three companies join Huawei Technologies, ZTE Corporation, and other China-based technology companies whose telecommunications equipment and video surveillance technologies have been banned from use in federal information systems.

EU Commission Initiates Public Consultation on RoHS

The Commission of the European Union (EU) has launched a public consultation on the EU's Directive on the use of certain hazardous substances in electrical and electronic equipment to solicit input on potential changes to improve this landmark legislation.

The consultation seeks input on Directive 2011/65/EU (also known as the RoHS Directive) specific to several potential policy options, including supplementing the Directive with informal guidances, replacing the Directive with a Regulation to provide uniform application across the EU, or repealing the RoHS Directive altogether and integrating its key provisions into the EU's REACH Regulation.

The Commission is seeking input from a wide range of stakeholders, including authorities in EU Member States, business associations and companies, workers associations and trade unions, and individuals. Comments must be submitted by not later than June 2, 2022.



FDA Warns of Medical Device Cyber Vulnerabilities

The U.S. Food and Drug Administration (FDA) has issued an alert to medical device manufacturers and users regarding a cybersecurity vulnerability identified in connection with a widely used web-based software technology.

The FDA alert follows an advisory issued by the federal Cybersecurity and Infrastructure Security Agency (CISA) that identified several specific areas of vulnerability to cyberattacks related to the use of Axeda agent and Axeda Desktop Server. The Axeda agent and Axeda Desktop Server are remote connectivity software applications used to allow multiple parties to securely view and operate the same remote desktop through the Internet and are reportedly used in connection with numerous medical devices across several different device manufacturers.

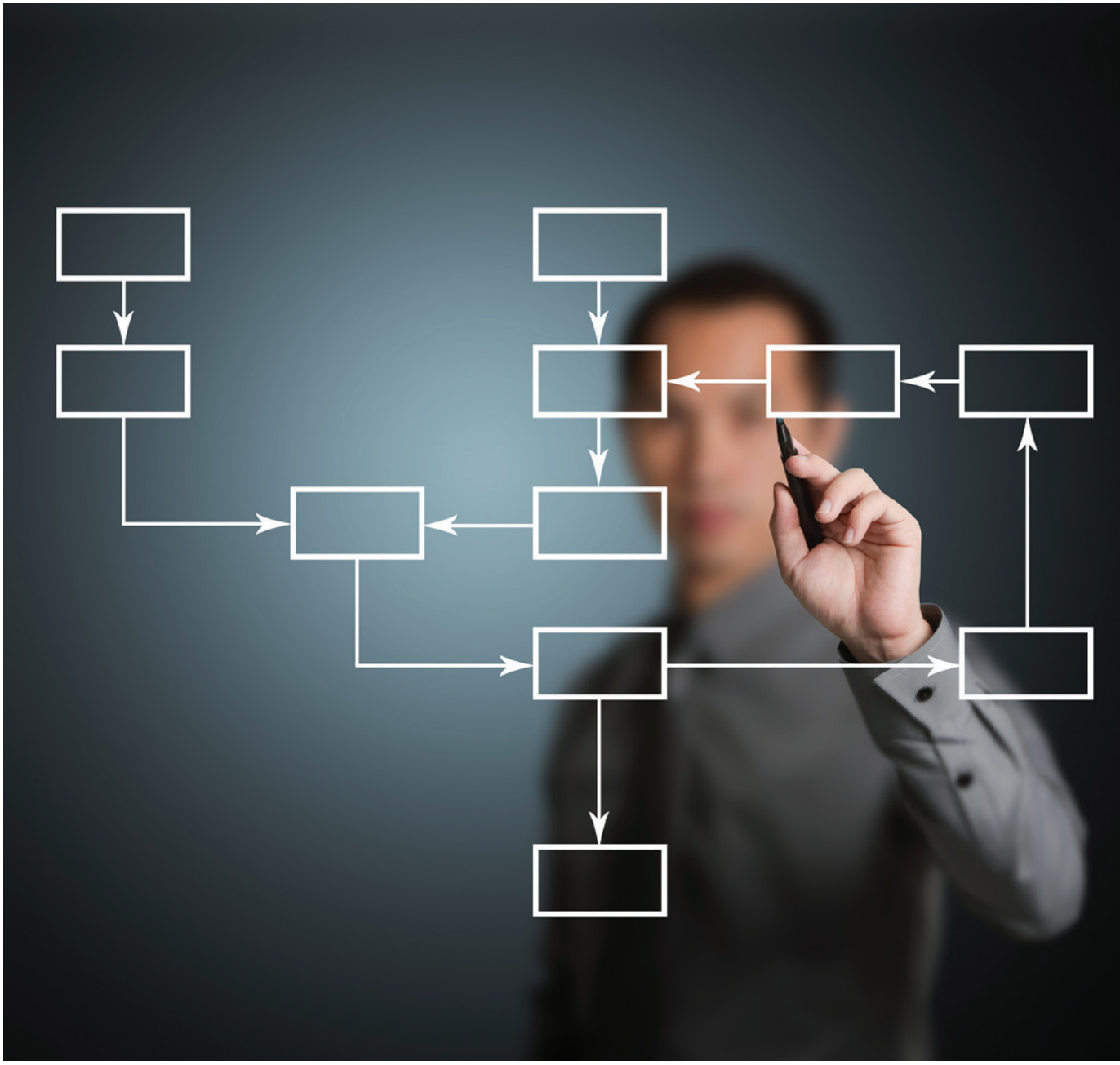
The specific vulnerabilities in the Axeda software identified in the CISA advisory include:

- Use of hard-coded credentials
- Missing authentication for critical functions
- Exposure of sensitive information to unauthorized parties
- Improper check or handling of exceptions conditions

According to the FDA Cybersecurity Alert, PTC (the company that owns and supports the Axeda agent and Axeda Desktop Server) recommends that manufacturers whose devices utilize the software take several specific steps to mitigate the cyber vulnerability risk, including upgrading to the latest version of the Axeda agent and providing a unique password for each unit running the Axeda Desktop Server.

PRODUCT REGULATORY COMPLIANCE:
DEFINITION, SCOPE, IMPORTANCE, AND IMPACT

A Rigorous Process to Achieve Core and Global Market Access



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Cyril Mecwan is the CEO of OnRule, with over 30 years of experience in the fields of new product introduction (NPI), supply chain management, and product regulatory compliance.

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By Thomas Killam and Cyril Mecwan

According to the U.S. Consumer Product Safety Commission (CPSC), at least 41 Americans were killed and about 133,000 injured between 2017 and 2019 in incidents tied to e-scooters, e-bikes, and hoverboards.[1] Ten companies were forced to recall approximately 500,000 hoverboards after the CPSC received about 100 reports of the lithium-ion battery packs that power hoverboards overheating, sparking, smoking, catching fire, or exploding.[2]

While these examples may represent a small segment of concern, their occurrence highlights the importance of product regulatory compliance and the consequences of failing to integrate compliance considerations into the design, development, production, and distribution of a wide range of products.

BACKGROUND AND DEFINITIONS

The world is full of regulations. Local, state, national, and international jurisdictions have in place a variety of regulations and regulatory compliance requirements addressing user safety and health, energy use, environmental issues, and other product-related considerations.

The product regulatory compliance process encompasses all of these aspects in the regulation of end products, components, materials, systems, and processes. It chiefly consists of testing an end product to assess its compliance with applicable requirements and receiving certification from a regulatory agency or a self-declaration by the manufacturer that the end product meets these requirements.

Typically, these requirements apply to products that utilize modern electronic technologies. However, many product regulatory requirements address various health, environmental, and safety issues specific to other types of products, including foods and grains, drugs, oils, chemicals, fabrics, cosmetics, etc.

An original equipment manufacturer (OEM) is obligated to test its products to determine their conformity with the applicable standards mandated by the regulatory authority of the country in which the products will be sold or marketed. In many cases, OEMs are also required to obtain independent verification of conformity and receive certification or other form of approval prior to shipping the product to that market. A copy of the certification or other evidence of product approval is generally required to accompany the product when shipped.

Product regulatory compliance is achieved at the product or stock-keeping unit (SKU) level, and marking verifying that compliance is generally required to be visible on the product. In some cases, product regulatory compliance requirements are also applicable to critical components within the product or spare parts that accompany the product when sold. Generally speaking, achieving compliance with component level regulations is the responsibility of the component supplier, and test data verifying component compliance is included in documentation submitted in compliance declarations covering the actual end product.

Relevant regulatory requirements can vary based on a country or jurisdiction, the industry, or the technology used. For electrical and electronic systems, devices, and components, requirements may include, but are not limited to, issues related to safety, electromagnetic compatibility (EMC), radio, telecommunications, energy efficiency, environmental, quality, performance, etc. Further complicating the compliance picture, individual technical requirements can vary from country to country, contributing to the challenges of achieving global regulatory compliance.

In addition to compliance certifications and approvals issued by regulatory authorities, several industry special interest groups (SIGs), consortiums, and

alliances, such as the Wi-Fi Alliance, the Zigbee Alliance, and the LoRA Alliance, offer product or technology-specific approvals that allow the use of their logo or other identification on products that have been reviewed and verified for compliance with their technology-specific requirements.

Medical devices and instruments used for important functions are also held to rigid performance standards. A few examples of devices and instruments that must meet performance-related standards include pulmonary and respiratory systems, ventilators, blood pressure measurement devices, intravenous instruments, pediatric tracheostomy tubes, feeding systems, culture media used in microbiology laboratories, certain materials used in the practice of dentistry, patient transfer chairs, and sterile containers, etc.

Many government agencies, including those overseeing aviation and military systems and applications, may also require conformity with specialized performance and quality standards that may not fall within the typical definition of product regulatory compliance but which must be addressed nonetheless. For example, "The U.S. Internal Revenue Service released Notice 2015-4 which specifies the performance and quality standards that small wind turbines must meet in order to qualify for the 30% investment tax credit, and which requires that small wind turbine models be certified ……" [3]

Consumer and enterprise products requiring access to telecommunications networks operated by mobile phone carriers may have to comply with the requirements developed by Telcordia, a telecommunications standards body. In addition to the Telcordia requirements, carrier-specific requirements are often imposed by network providers like Verizon, AT&T, T-Mobile, Vodafone, Orange, Telstra, etc. Typically, collaborating with the network providers to conduct tests and satisfy such requirements also becomes the responsibility of compliance engineers.

Finally, large e-commerce retailers and distributors may have their own requirements applicable to the products that they procure for sale or distribution that might be more stringent than those imposed by local, regional, or national regulatory authorities.

SCOPE

Product regulatory compliance touches on every aspect of the product lifecycle (from concept to retirement) and for the entire value chain (from critical components suppliers to the end customers) and is an important and omnipresent function impacting all other functions and stages (see Figure 1).

Concept to Launch

In the NPI phase, a product design is validated for product regulatory compliance through the testing process. Design-related issues, weaknesses, and defects identified during the testing of early prototypes are then incorporated into the next iteration of the product design to make the product more robust and compliant. Testing of the final product is then conducted to produce the test reports that are submitted to the relevant authority to obtain regulatory approval. Once approval has been received, the product is ready for general availability and for release in those core market(s) where approvals have been granted.

This process usually follows the following trajectory:

- *Core Market Access (CMA):* Companies generally first launch new products into their core or primary markets. Meeting the relevant compliance and

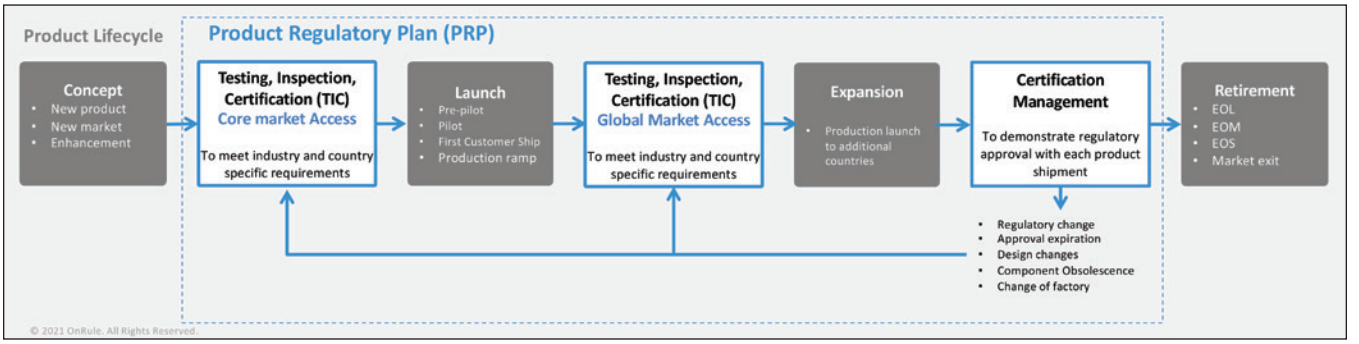

Figure 1: Product regulatory plan

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testing requirements applicable in the EU and/or U.S. and Canada helps to validate the integrity of the product while also establishing a generally accepted baseline conformance to compliance.

- *Global Market Access (GMA):* Following a successful launch and acceptance of its new product into its core markets, companies then launch their product globally into other countries in succession. Some countries, such as China and India, typically require in-country testing, which requires shipping product samples to a local testing lab for the purpose of testing. Even in those countries where in-country testing is not required and in which regulatory authorities accept test results and approvals obtained in the EU or the U.S., companies may still be required to go through a time-consuming regulatory process, submitting applications and other forms to the relevant government agencies.

Launch to Retirement

Once a product has been released into production, it enters the sustaining mode. To support the growth of sales in new markets, fulfillment of testing and certification requirements applicable in additional countries is required. Global market access (GMA) is achieved through the fulfillment of the testing and certification needs of additional countries. In this phase, certification management of a company's current product portfolio becomes critically important, and several events can occur that require a company to review existing product certifications for continued compliance. These events can include:

- Changes in an underlying standard (or standards) in a given country or jurisdiction may require retesting of the product to the new or revised requirements to either retain approval or receive a new approval.
- In cases in which a country or jurisdiction does not grant lifetime approval for a given product, renewal of an existing certification may be required. Typically, the frequency of such renewals can be anywhere from one to five years from the original approval date.
- A significant change in an existing product design can trigger the need to retest and/or recertify the product.
- A change in a critical component such as a power supply may also require a company to retest and/or recertify the end product.
- In cases in which regulatory authorities require follow-up inspections of the factory (or factories) where a product is produced, the use of a new or different factory may require a review of current product certifications and retesting.

As mentioned earlier, product regulatory compliance is evaluated at the product or SKU level. However, an OEM is required to disclose the list of critical components used in the final product. As part of the overall evaluation of the end product, some regulatory authorities may require evidence of safety testing and certification of those critical components. If a critical component is sourced from more than one supplier, (typically is the case for the purpose of managing the supply chain risk), evidence of safety testing and certification from all suppliers may be required.

IMPORTANCE

If a product's compliance with applicable regulatory requirements cannot be demonstrated, a company may be legally prohibited from shipping that product to their customers and may risk seizure of their product by customs officials at border crossings. This is not an uncommon occurrence, and many regulatory compliance engineers experience this situation multiple times during their careers.

Product regulatory compliance requirements play a significant role in your ability to ship your company's products to foreign and domestic customers. Having sufficient evidence demonstrating your product's compliance with applicable regulations to support a factory audit or to accompany your product when shipped requires verifying the validity, quality, and availability of your regulatory compliance documentation. Organizing that documentation and designating a secure location for it is also an obvious and commonplace practice that is essential to support the uninterrupted shipment of goods.

Engineering, NPI, and Product Management

During the new product development process, the product regulatory function must provide guidance to the design engineers as to the particular technical requirements that will apply to that product. The individuals or team responsible for product regulatory compliance should develop a test plan and testing methodologies to assess the new product. Doing so will help sharpen everyone's focus on the particular

regulatory requirements that will apply to the product when formal regulatory testing is conducted. It can also help the compliance team understand the potential compliance issues that might arise during the design and testing phase. Providing this guidance at an early stage in the product development process can reduce or prevent time-consuming iterations of the product design itself in order to comply with regulatory requirements. This early involvement in the design can also help the product to be designed so that the technical boundaries affecting the performance and safety around many critical parameters are taken into account.

In many cases, early testing on product prototypes against the limits set forth in applicable technical standards will pinpoint issues that may lead to non-conformity. Waiting until the product design has been completed to conduct testing almost always results in the need to redesign the product and to conduct regression testing on the updated design to verify its compliance. This inevitably leads to delays in bringing your product to market and increases the overall development cost for the product.

Product Management and Marketing

Obtaining product regulatory approvals is typically the last step before a product launch and represents a critical milestone in the NPI schedule. By this point, your product management and marketing teams should have a clear plan for the markets in which they want to launch the product, including a country-by-country sequence for market deployment. It is extremely difficult to launch a product in all targeted global markets in the same time period due to variations in the approval process among individual regulatory authorities in different markets and the amount of time required in individual jurisdictions. This is why a global product rollout is generally broken into different market segments to provide staggered availability dates for the product.

The best approach involves the development of marketing waves, that is, segmenting individual countries into groups to be given priority in the initial product rollouts to customers. The success of this wave approach ultimately requires the product regulatory group to develop a clear plan that accurately accounts for the time required for the testing and approval phases in individual jurisdictions so that product approvals coincide with the planned market availability. This regulatory compliance plan should be fully transparent to the entire product development team and the marketing team so that the necessary distribution channels can be established or verified as operational.

Sales

The ability to sell any new product depends on obtaining the required regulatory approvals to ensure the product's legal availability to customers. The order management process in place in most companies

typically will not authorize acceptance or shipment of an order for a new product until the required regulatory approval has been secured. Further, selling a new product in a new country or a region will first depend on the company's ability to secure regulatory approval for the product in that country.

Distributors and System Integrators

Conforming with regulatory compliance requirements and obtaining independent verification of compliance is the responsibility of the OEM. Third-party distributors and system integrators who have a presence in a local market or country are often required to serve as an importer of the product into that country. As a result, most third-party distributors typically require documented proof of compliance before assuming responsibility for making a company's product available to their end customers through their distribution channels.

Operations, Logistics, and Quality

The product regulatory compliance process is often part of the quality metrics that are presented during the product readiness review that takes place before the launch of a new product. At the same time, at the point of shipment, operations and logistics personnel need the required compliance documentation (approval certificates, manuals, packaging labels, etc.) in hand to avoid having products held up or denied at customs checkpoints or delayed at shipping docks and failing to reach the end customer as promised.

Customer Support

Existing end customers, channel partners, and field sales personnel will often contact customer support teams for compliance documentation that verifies that the requirements of the product regulatory approval process have been met. In some cases, this request can be for the approval documentation required for spare parts and critical components scheduled for shipment by the service department to existing customers.

Legal

Lastly, in several companies, the legal department gives the final nod to the product launch upon reviewing the completion of all regulatory milestones. Evidence that the product regulatory compliance process has been completed and that regulatory approval has been received is one of the important metrics reviewed and signed off by the legal team. In some companies, the product regulatory compliance team reports to the legal department.

Figure 2: The importance of product regulatory compliance

THE IMPACT OF NON-CONFORMANCE

The failure to ensure product conformity with regulatory compliance considerations may have important impacts on several fronts, including on communities and on the business. Here are just some examples:

- *Safety and well-being:* A lack of conformity may result put the safety and well-being of people at risk. According to the CPSC, in 2019, there were an estimated 22,500 treadmill-related injuries treated at U.S. emergency departments among all ages (of which around 2,000 were children under eight years of age).[4]
- *Revenue impact:* It is all too common for companies to miss quarterly or annual revenue targets because they could not ship orders on hand from available inventory due to a lack of compliance documentation availability. We know of incidents in which a distributor could not bring inventory into a target market because the products were being delayed at customs due to a lack of compliance approval documentation. As a result, the OEM

could not register the necessary revenue recognition during a fiscal quarter, falling short of both the company's and investors' expectations.

- *Customer satisfaction:* Missing an order commitment date due to lack of regulatory approval directly impacts customer satisfaction, a critical metric to business success. Note that an OEM customer may be a reseller, distributor, system integrator, or end customer.
- *Brand impact:* Recalls from the market due to poor quality and performance may adversely impact the OEM brand. The bad press from an incident can be devastating to a company's reputation, from which it may never recover. In the infamous hoverboard issue cited previously in this article, more than ten companies were forced to recall 100,000 hoverboards after the CPSC received about 100 reports of the lithium-ion battery packs that power hoverboards overheating, sparking, smoking, catching fire, or exploding.
- *Legal impact:* Typically, good business practices dictate that a company secures product liability insurance prior to placing the product on the market. Generally speaking, product liability insurance premiums for a product that meets all of the applicable regulatory requirements will be significantly less than that paid for a non-compliant product or a product that has no proof of compliance. If a non-compliant product is introduced into a market and an event occurs that brings a safety issue to light, there can be many ramifications that directly affect the company, including fines and possible jail time for those responsible.

CONCLUSION

The emergence and importance of product regulatory compliance as a formal discipline in governing and ensuring the release of safe, environmentally sustainable, and energy-efficient products in the global markets have now been established and recognized. CE, FCC, UL, etc. marks are understood and regarded by consumers and businesses at large. But the scope and impact of product regulatory compliance in safeguarding our universe, planet, and human beings through the introduction of compliant products are much broader and deeper. Products, whether used underwater, on earth, or in space, are all subjected to and benefit from this ubiquitous discipline. As technologies evolve and as mankind races to explore far space, it is imperative that this discipline be further promoted, developed, and implemented.

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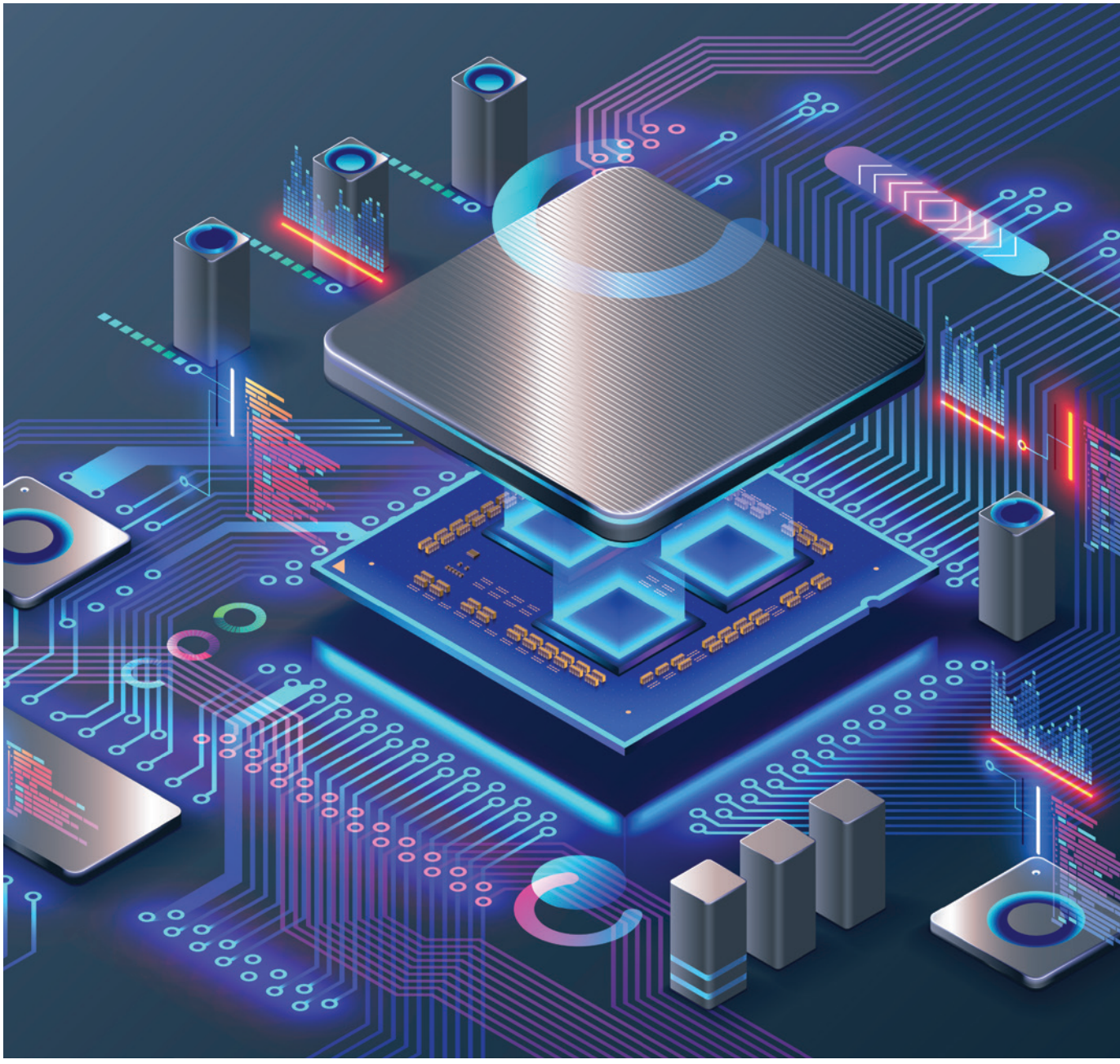
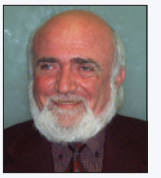
HIGH-INTEGRITY COMPONENTS IN ELECTRICAL EQUIPMENT, PART 1

Achieving Safety Integrity Through the Selection of Components



Steli Loznen has over 40 years of experience in compliance issues associated with electrical equipment and participates in the IEC standardization as WG Convener and Project Leader. In 2017, he received the IEC's *1906 Award* in recognition of his efforts to advance the work of the IEC. Loznen is also a member of the Experts Evaluation Team of the European Commission, a member of the Board of Governors of the IEEE-PSES, and a vice-president for IEEE-PSES technical activities. Loznen is co-author of *Electrical Product Compliance and Safety Engineering* – vol.1-2017; vol 2-2021, published by Artech House. He can be reached at sloznen@ieee.org.



By Steli Loznen

In today's increasingly complex and competitive world, the compliance and safety of electrical equipment have become a top management challenge for fulfilling all of the demanding regulations.

The safety of electrical equipment raises an important question, who is responsible for prioritizing safety above all when equipment is designed, implemented in production, installed, operated, and maintained? Manufacturing "safe" equipment has come to be a catchphrase, affecting and influencing the minds of many designers and manufacturers. But this is no longer enough. Instead, building a safety culture at the organizational and professional levels has become a must.

The present article (Part 1 of a two-part series), is intended to make a small contribution toward this goal of building a safety culture around electrical equipment.

A TERMINOLOGY ISSUE: SAFE, SAFETY, AND RELIABLE

Before discussing safety in electrical equipment, we must first clarify what it means for electrical equipment to be safe and reliable.

Safe and Safety

The term safe is used to represent the state of being protected from identified hazards that are likely to cause physical harm. In real life, there is no such thing as being absolutely safe or achieving a total elimination of the risk of harm. Because of this reality, safe equipment is equipment that poses an acceptable risk of the occurrence of harm. This goal of safety requires the implementation of knowledge, adequate construction, and a correct selection of the components.

Unsafe equipment may be the immediate cause of most accidents, and companies should not leave that door open for such unwanted events. They should strive for ways to promote safe equipment development and manufacturing. Very often, safety programs call for a change in attitude; as attitudes change, equipment safety will increase. At the same time, focusing directly on the attitudes that lead to unsafe products may not be enough. Sometimes people tend to maximize gain instead of minimizing risk. And this attitude is a real danger. Applying risk management requires a clear understanding of what constitutes unnecessary risk, and when benefits actually outweigh the costs.

The term safety is used to represent a state in which hazards and conditions leading to physical or material harm are controlled to protect the health and well-being of individuals and the community. Safety is both objective and subjective as it deals with both perceptions of being safe and the status of the surrounding conditions. Safety is achieved by reducing the risks of harm to an acceptable level.

Risk acceptance is not as straightforward a matter as it may appear at first glance. Acceptable risk is determined by searching for the optimal balance between the ideal of absolute safety and the requirements with which a product must comply, and other factors such as the benefit to the user, its suitability for its intended purpose, its cost-effectiveness, and conformity with the conventions of society. This means that the acceptable level of risk must be continually reviewed, especially when developments in both knowledge and technology can lead to economically feasible improvements that attain the risk compatible with the use of equipment. But it is important to always remember that "safe" and "safety" are never an absolute assurance of risk of harm [1].

Reliable

I want to discuss a few details about safety concepts in the context of reliability [1].

Safety and reliability are not only different product characteristics. Sometimes, they even conflict with each other. A reliable product is not necessarily safe, and a safe product is not necessarily reliable. Reliability engineers often assume that reliability and safety are synonymous, but this assumption is only true in particular cases. In general, safety has a broader scope than mere failures, and failures may not compromise safety in every situation. A reliable component (for example, one with a high mean time between failure) is not necessarily safe, and a safe component does not have to be reliable. In some instances, increasing reliability can actually decrease safety. For example, if equipment continues to operate even though that behavior is unsafe in its current environment, the safest behavior under certain conditions may be to stop operating and switch to a fail-safe mode.

There is obviously an overlap between reliability and safety, but many accidents occur without any component failure. That is, individual components were operating exactly as specified or intended. The opposite is also true that components may fail without an accident.

Reliability engineering is concerned primarily with component failures and failure rate reduction. Thus, the approach to safety is focused on failure as the cause of hazards and/or accidents. While these techniques are often effective in increasing reliability, they do not necessarily increase safety. In fact, their use under some conditions can actually reduce safety.

Most accidents are caused not by the product ceasing to fulfill its intended use (reliability deficiency). Rather, most accidents are caused by the product operating while doing something unsafe (i.e., producing electrical shock, fire, unwanted radiation, etc.). Serious accidents have occurred while all equipment components were functioning exactly as specified.

The Intersection of Safety and Reliability

If only failures are considered in a safety analysis, many potential accidents will be missed. In many situations, failing is not the most important safety issue with a component. Most accidents are caused not by the component discontinuing operation; rather, most accidents are caused by the component operating in an unsafe mode. In addition, the engineering approaches to preventing failures (increasing reliability) and preventing hazards (increasing safety) are different concepts and sometimes conflict with each other. It is relatively easy to protect the equipment against total failure, but it is much more difficult to protect it against intermittent unsafe component operation. In fact, within a given piece of equipment, accidents are much more likely to result from dysfunctional and unsafe interactions among normally operating (not failed) components.

Accidents may be caused by equipment operation outside the parameters and time limits upon which the reliability analyses are based. Therefore, equipment may have high reliability and still have a high risk of accidents. In addition, accidents are often not just the result of a simple combination of component failures.

Safety is an emergent property that arises at the equipment level when components are operating together. The events leading to an accident may be a complex combination of equipment failure, faulty maintenance, instrumentation and control problems, human actions, and design errors. Reliability analysis considers only the possibility of accidents related to failures. It does not investigate potential damage that could result from the successful operation of the individual components.

Reliability uses a bottom-up approach (e.g., failure mode and effects analysis, or FMEA) to evaluate the effect of component failures on equipment function. Safety requires a top-down approach that evaluates how hazardous states can occur from a combination of both incorrect and correct component behavior, such as proper behavior of a component at an improper time or under the wrong environmental conditions.

Care must be taken when applying reliability assessment techniques to safety. Since accidents are not necessarily caused by events that can be measured by reliability assessment techniques, reliability should not be used as a measure of risk. Reliability assessment measures the probability of random failures, not the probability of hazards or accidents. Also, if a design

error is found in equipment, safety will be more effectively enhanced by removing the design error than by measuring the design error to convince someone that it will never cause an accident. High reliability numbers do not guarantee safety, and safety need not require ultra-high reliability.

COMPONENT SELECTION FOR SAFETY

Now that we have clarified what we mean by "safe" and "safety," we turn to the application of these concepts to component selection.

The business of electrical equipment requires evidence of compliance with appropriate safety standards focusing on component selection, construction requirements, and testing. For electrical equipment to be safe, the materials and components used in the construction of that equipment also need to be safe. To achieve this goal, these materials and components should be selected and arranged to perform reliably for the anticipated (expected) safe service life of the equipment. That is, the selected materials and components are to remain within their manufacturers' ratings without generating any hazard during normal operating mode and even in foreseeable fault conditions. When the components have not been previously investigated, the probability of failure is much higher and may generate unacceptable risks of harm.

SAFETY-CRITICAL COMPONENTS

While safety is important in the selection of all components of electrical equipment, it is especially important in safety-critical components.

Safety-critical components are components whose failure could result in a hazardous situation. As their name suggests, safety-critical components are critical to the safety of equipment. Generally speaking, these are components that are intended to prevent (along with the design, manufacturing, packaging, transportation, installation, use, maintenance, and service of the equipment) any injuries or damages due to identifiable hazards which may arise during the life of the equipment.

Safety-critical components include, but are not limited to:

- AC and DC motors and fans
- Appliance inlets/outlets

- Batteries
- Battery protection and management circuitry (BPM)
- Battery charging circuitry
- Capacitors (high voltage)
- Circuit breakers
- Conductive coatings
- Contactors
- Crimp connectors
- DC-DC converters
- DC-AC inverters
- Fuses and fuse-holders
- Heating elements
- Internal wiring
- Interlock switches for safety purposes
- Isolating devices (non-optical)
- Laser modules
- LEDs (non-laser)
- Line EMI/RFI filters
- Main switches
- Main transformers
- Motor start capacitors
- NTC and PTC (thermistors)
- Optical fiber cables
- Optocouplers
- Overcurrent protective devices
- Power entry modules
- Power supply assemblies
- Power supply cords
- Printed wiring boards
- Protective devices on USB
- Programmable controllers
- Pulse transformers
- Relays
- Sensors
- Heat shrink tubing
- Strain relief for power supplies cords
- Surge suppressors
- Software
- Terminal blocks
- Thermal cut-off devices
- Thermoplastic materials
- Thermostats
- Transducers
- Triple insulated wires
- Varistors
- Voltage selectors [2]

Such components are those that have been evaluated against relevant national or international component standards and are provided with a third-party/ certification body approval, such as UL Listing or Recognition, CSA certification, VDE, IMQ, PSE, etc., and are normally marked with the mark of the certification body. In some situations, due to limitations on dimensions, the marking is done on the packaging. (Note that CE marking, the Mark recognized by the European Union, is not required by law for components.)

The regulatory compliance and approval of critical components should be documented with a copy of the approval certificate or by the license for the component (the use of catalog data sheets is not the proper way to prove compliance).

Particular attention needs to be paid to the Conditions of Acceptability for correct application and use of the components in the end-use equipment. Specified electrical ratings (included in the test reports of certification bodies) shall be taken into account and should never be exceeded.

In situations when there is no published component standard for specific safety-critical components, components identified as critical can be tested for compliance with the end-use product safety standard.

Each test report template based on a product safety standard shall include safety-critical components in a table designated as List of Critical Components or List of Components and Circuits Relied Upon for Safety. In addition, details should be provided for each critical component, including component

name, manufacturer/trademark, type/model, technical specifications, applicable standard, a mark of conformity (approval status), and the approval file number.

Technical specifications should be considered as relevant technical information that may influence the safety features, such as flammability class, maximum operating temperature, maximum voltage, maximum current, breakdown voltage, insulation resistance, electric strength voltage, minimum thickness, dimensions, color, drawing numbers, etc.

In general, in electrical equipment, the failures of safety-critical components are manifested by electrical/electronic performance deficiencies depending on the type of component (e.g., short circuit; open; passive components not meeting their tolerance or temperature coefficient specifications; analog components not meeting the frequency response specifications; digital devices not meeting rise time specifications; etc.). These failures may lead to harmful effects on humans and the environment.

To prevent such situations, some safety-critical components are designed, manufactured, and tested in a special way that includes these components in a special category, referred to as high-integrity components.

HIGH INTEGRITY COMPONENTS

High integrity components (HIC), also considered as infallible, are designed not to fail in such a way that failure could be dangerous or detrimental. Such claims are made where the probability of failure must be so low as to be effectively discounted from further safety analyses [3].

High integrity components are components where one or more characteristics ensure that the component function is fault-free ("Incredibility of Failure" claim) in relation to the safety requirements of a standard during the expected service life and reasonably foreseeable misuse of the equipment. When a failure occurs, an HIC always works the same as in normal operation, and additional protection is not required. When a fault in a particular safety-critical component can generate an unacceptable risk of harm, it is recommended that this component be switched out in favor of one with high-integrity characteristics.

In the case of HIC, it is required to prove that the probability of failure over the lifetime of the equipment is less than that required to reduce the risk to acceptable. As an example, suppose a piece of equipment could generate moderate severity thermal harm. To reduce the risk of harm to an acceptable level, a component "T" is used for which the acceptable probability of failure might be around 1/10,000 per year. If the lifetime of the equipment is seven years, the probability of failure of the T component should be less than 1/100,000 per year. If the reliability assumption for the component T is such that T will meet this requirement without problems, the component T could be considered a valid high-integrity component. The use of reliability engineering techniques such as highly accelerated life testing (HALT) or highly accelerated stress screening (HASS), average expected functional life (with random failures), the point of expiration (wear-out failures), etc., will help with the estimation of the component's probability of failure.

CONCLUSION

In Part 1 of this article, we've provided a detailed explanation of the differences between safe, safety, and reliability and focused on aspects related to component selection. We've also worked to clarify the differences between safety-critical components and high integrity components. In Part 2 of this article, we'll address the issue of high integrity components in greater depth.

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PRODUCT Showcase

SAFETY PROGRAMS AND CPSC MANDATES

Some Best Practices for Product Safety Management

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By Kenneth Ross

Since its inception in the early 1970s, the U.S. Consumer Product Safety Commission (CPSC) has encouraged companies to implement active product safety management programs. This article will examine the CPSC's previous guidances on safety programs, describe the requirements imposed on companies, and discuss what they might mean.

These guidances and mandates are important since they can help a company determine if its safety program would be deemed sufficient by the CPSC or even by a jury in a product liability case and help identify areas where its program could be improved.

PRIOR GUIDANCE ON SAFETY PROGRAMS

The CPSC first published the *Handbook for Manufacturing Safer Consumer Products* in the 1970s, shortly after the CPSC was created. The last edition of this Handbook came out in 2006 and discusses product safety policies, organization, and training as well as all aspects of design, manufacturing, quality, corrective actions, etc. In other words, it discusses safety procedures that it believes are appropriate for any company making consumer products in all aspects of design, production, sales, and post-sale.

The text of the Handbook begins by stating:

> *"Manufacturers must assure the safety of consumer products. This is achieved through the design, production, and distribution of the products they manufacture. It is best accomplished by a comprehensive systems approach to product safety, which includes every step from the creation of a product design to the ultimate use of the product by the consumer. The basic concepts for a comprehensive systems approach for the design, production, and distribution of consumer products are discussed in this Handbook."*

In addition, the CPSC's Recall Handbook, in existence for many years but last updated in March 2012, includes sections on the appointment of a Recall Coordinator, development of a company recall policy and plan, and extensive suggestions for the creation and retention of records to support a recall.

The safety processes advocated in these handbooks are just suggestions and not legal requirements. In addition, they are similar to those procedures employed by companies that have a well-functioning safety effort. So, there is nothing particularly onerous here that a company shouldn't already be doing.

More recently, the CPSC's Small Business Ombudsman posted a list of recommendations and links to safety-related resources on how to make safe products.[1] It is a concise yet informative list with links to CPSC and other documents that can be helpful to small business owners who don't have the resources for full-time safety and compliance personnel.

And, in November of 2018, the CPSC hosted a Compliance Program Seminar featuring four separate panel discussions. There was a good discussion of the CPSC's list of ten steps to developing an effective compliance program. Slides from the Seminar are available at https://www.slideshare.net/USCPSC/compliance-program-seminar-panel-1-develop-a-compliance-program.

REQUIREMENTS FOR SAFETY COMPLIANCE PROGRAMS

Since the publication of the Recall Handbook, requirements for safety compliance programs have been inserted by the CPSC into various documents.

First, on March 31, 2010, the CPSC published in the *Federal Register* a final rule laying out the factors that

The CPSC has made it clear that a compliance program is important and will be considered in determining whether civil penalties are appropriate. This is very important since the CPSC has great discretion over whether to levy civil penalties and, if so, how much.

the CPSC staff will consider when deciding whether the CPSC should seek civil penalties. The rule (16 CFR §1119.4(b)(1)) clearly states that product safety programs are one of the factors to be considered by the staff in assessing civil penalties:

> *"The Commission may consider, when a safety/compliance program and/or system as established is relevant to a violation, whether a person had at the time of the violation a reasonable and effective program or system for collecting and analyzing information related to safety issues. Examples of such information would include incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns. The Commission may also consider whether a person conducted adequate and relevant premarket and production testing of the product at issue; had a program in place for continued compliance with all relevant mandatory and voluntary safety standards; and other factors as the Commission deems appropriate. The burden to present clear, reliable, relevant, and sufficient evidence of such program, system, or testing rests on the person seeking consideration of this factor."*

In addition, the Commission released a statement dated March 10, 2010, concerning these new factors, which said in part:

> *"The safety/compliance program factor takes into account the extent to which a person (including an importer of goods) has sound, effective programs/systems in place to ensure that the products he makes, sells, or distributes are safe. Having effective safety programs dramatically lessens the likelihood that a person will have to worry about the application of this civil penalty rule. Any good program will make sure that there is continuing compliance with all relevant mandatory and voluntary safety standards. This is not the same as saying if one's product meets all mandatory and voluntary standards that the Commission will not seek a civil penalty in appropriate cases. The Commission expects companies to follow all mandatory and voluntary safety standards as a matter of course."*

Then, in September 2015, the CPSC issued a Staff Guidance on enforcement of civil penalties. This guidance states that:

> *"If a violation appears to have occurred, staff will evaluate potential civil penalty enforcement, including the need for remedial action, such as the implementation of internal controls and a compliance program. Depending on the facts and circumstances as well as other considerations, OGC may take a variety of approaches. Staff may decide to seek a civil penalty, determine that other actions are appropriate, or conclude that the matter should not be pursued at that time. In some situations, calling for remedial action where applicable factors may not compel civil penalties, staff may consider closing the matter without any civil penalty if the potential defendant formally agrees to implement appropriate remedial action."*

Therefore, the CPSC has made it clear that a compliance program is important and will be considered in determining whether civil penalties are appropriate. This is very important since the CPSC has great discretion over whether to levy civil penalties and, if so, how much. In addition, if there is product liability litigation, the existence of a comprehensive product safety program can help to lessen the chances that the plaintiff's attorney might seek punitive damages.

THE DAISO CONSENT DECREE

Around the same time that the new civil penalty factors were being finalized, the establishment of a product safety management program was included for the first time in a consent decree that levied civil penalties. In a March 4, 2010 agreement, Daiso Holding, a U.S. subsidiary of a Japanese company, agreed to pay a little more than $2 million in fines for

violating various laws and regulations concerning the sale of toys and children's products.

The consent decree required Daiso to hire a product safety coordinator, who would then be charged with taking the following actions:

- Create a comprehensive product safety program;
- Conduct a product audit to determine which of Defendants' merchandise requires testing and certification of compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC;
- Establish and implement an effective and reasonable product safety testing program in compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC;
- Create guidance manuals for managers and employees on how to comply with product safety requirements;
- Establish procedures to conduct product recalls; and
- Establish systems to investigate all reports of consumer incidents, property damage, injuries, warranty claims, insurance claims, and court complaints regarding products under the jurisdiction of the CPSC that the Defendants imported into the United States.

Daiso retained an independent consultant to certify compliance and the CPSC sent its staff to Daiso facilities to audit compliance. Daiso passed the audit and the monitoring was ultimately discontinued.

SAFETY REQUIREMENTS IN CIVIL PENALTY SETTLEMENT AGREEMENTS

The CPSC did nothing further to impose safety requirements on manufacturers until they were inserted into civil penalty settlement agreements starting in February 2013. In the first agreement,

It is certainly possible for a company with a robust safety program to have information that the CPSC would expect to be reported but decides not to report that information because it does not believe that there is a defect or substantial product hazard.

Kolcraft agreed to pay a $400,000 civil penalty and to adopt a variety of actions to enhance their safety program.

Then Chairman Tenenbaum and then Commissioner Adler issued a joint statement in connection with this agreement, stating that they were concerned that Kolcraft had had a dozen recalls since 1989 and that further action was required. They said:

> *"The failure of a company to have an effective means of detecting and addressing serious or continuous safety issues with its products is contrary to the expectations of consumers and is unacceptable to this Commission. While we certainly understand that even the most responsible companies can make mistakes, the failure of a company to have in place an effective compliance program and internal controls is irresponsible. Thus, going forward, we expect those companies that lack an effective compliance program and internal controls to voluntarily adopt them. If not, we will insist that they do so."*

The commissioners also made it clear in their statement that having an adequate safety program does not exonerate a company for failing to timely report a safety problem.

Then, in May 2013, Williams-Sonoma agreed to pay $987,500 in civil penalties for failing to file a timely report with the CPSC. The requirements in the Kolcraft opinion were inserted into the Williams-Sonoma agreement.

Since May 2013, every settlement agreement for civil penalties has included at least some compliance requirements. This includes the Gree civil penalty in 2016, the Polaris civil penalty in 2018, the Cybex civil penalty in 2021, and the Core Health & Fitness civil penalty in 2022. These compliance requirements include:

- Programs designed to ensure compliance with CPSC requirements including written standards, policies, and procedures; and
- A system of internal controls and procedures concerning documentation, reporting to the CPSC, and reporting to management.

Finally, in 2021, Gree Appliance agreed to a plea deal, thereby deferring prosecution for criminal charges. This agreement included requirements for establishing and maintaining written standards, policies, and procedures to ensure compliance with the CPSA, including UL certification or listing and whether testing to confirm compliance has been conducted. Under the plea deal, Gree also agreed to implement, maintain, and enforce an effective system of internal controls and procedures addressing the reporting of safety issues to the company's management.

The Gree plea agreement also included requirements in the areas of confidential employee reporting, training and enforcement, management responsibility and accountability, and record retention. And last, Gree was required to retain a compliance expert to help set up these programs and to report to the government concerning the company's progress in completing them.

Based on this history, it is virtually certain that future settlement agreements in civil penalty matters will contain some type of requirement for the establishment of more robust safety compliance programs. It is still an open question as to how compliance will be audited and monitored and when the CPSC will require that additional processes and procedures be established. In addition, it is unknown what the CPSC would do if a firm never fully complies with these requirements or complies with all of these requirements but still has a problem with safety and reporting to the CPSC.

CONCLUSION

It is certainly possible for a company with a robust safety program to have information that the CPSC would expect to be reported but decides not to report that information because it does not believe that there is a defect or substantial product hazard. So, reasonable minds may differ. At the same time, it's difficult to justify civil penalties and impose new procedures on a manufacturer who may already have sufficient programs in place.

It will be interesting to see in the future whether companies that have good safety programs are able to keep these provisions out of their settlement agreements and corrective action plans and whether these programs will enable them to escape all civil penalties or negotiate lower civil penalties.

In this context, manufacturers should consider all of these requirements and evaluate their own programs. They should also consider the best practices detailed in ISO 10377, "Consumer product safety – Guidelines for suppliers," which sets forth practical guidance in safety management, as well as other studies and reports on what constitutes an effective product safety management program. (See articles at http://www.productliabilityprevention.com discussing the ISO standard and other product safety management best practices.)

Most companies don't do a good enough job of safety management, especially as they begin to sell globally and have to monitor safety issues and incidents around the world. Therefore, it is prudent for every company to take a fresh look at its current safety program and evaluate what changes could be made to improve its effectiveness.

Being proactive about complying with these requirements before you have a safety problem is the prudent and responsible thing to do. Dealing with these issues after a problem arises increases the risk of it turning into a huge problem for your products and your company anywhere your products are sold. IN

ENDNOTE

1. See https://www.cpsc.gov/business--manufacturing/business-education/business-guidance/BestPractices

CONTACT BURN INJURIES, PART II

The Influence of Object Shape, Size, Contact Resistance, and Applied Heat Flux

Editor's Note: *The paper on which this article is based was originally presented at the 2020 IEEE International Symposium on Product Safety Engineering held virtually in November 2020. It is reprinted here with the gracious permission of the IEEE. Copyright 2020, IEEE.*

Part I of this paper, "Contact Burn Injuries: Part I: The Influence of Object Thermal Mass," was reprinted in the May 2021 issue of In Compliance Magazine *and is available at https://incompliancemag.com/article/contact-burn-injuries-the-influence-of-object-thermal-mass.*

By May Yen, Francesco Colella, Harri Kytomaa, Boyd Allin, and Alex Ockfen

INTRODUCTION

Part I of this series discussed the general aspects of the regulatory guidance for burn threshold surface temperature and contact duration limits [1,2,3]. Part 1 also outlined a number of important aspects associated with the regulatory framework. Specifically, the ISO 13732 standard assumes that the surface temperature of the object remains constant after contact with the tissue. The ASTM standard recognizes that there exists a difference between the object surface temperature, the object-skin interface temperature, and skin contact temperature, which is defined as the temperature at the epidermis-dermis interface. All the standards assume the surface temperature of the touched object remains constant and neglect the surface temperature reduction associated with the transfer of energy from the object to the tissues. Furthermore, only a limited number of contact parameters are considered in the standard. They include the thermal resistance between the heat source and surface of the device and the influence of the surface finish and material.

Part I outlined the limitation of the regulatory framework associated with long contact times where, according to the standards, a burn injury is always predicted regardless of material, finish, or other factors such as the object's size [4]. This "infinite" contact time limit is demonstrably not valid for cases where the contacting object (and its surface temperature) cools due to the heat transfer to the skin. This is particularly true for low thermal mass objects and long-duration exposures. Part II addresses some of the additional limitations of the regulatory standards regarding the impact on the time-temperature contact burn threshold of the object size and shape (i.e., large, circular, elongated), contact resistance with the skin, and presence of an applied heat flux. The influence of object shapes and applied heat flux is of particular interest for the consumer electronics and wearable devices industry.

The methodology followed in this study is largely similar to that discussed in Part I [4]. The thermal damage assessment is based on the tissue temperature and the duration of the thermal exposure and is estimated using the concept of cumulative equivalent minutes at 43°C (CEM43°C) [5]. This model allows time-temperature history to be converted to an equivalent duration exposure at 43°C as:

$$CEM43°C = \int R^{43-T(t)} dt \qquad \text{Eq. 1}$$

where CEM43°C is the cumulative equivalent minutes at 43°C, t is the duration of the thermal exposure, R is a constant (R (T<39°C)=0, R(T<43°C)=0.25, R(T>43°C)=0.5) and T is the temperature at the tissue. Large tissue-specific databases are available in the literature that summarizes the relation between CEM43°C values and the observed damages to the tissues. In the case of the skin, most of the CEM43°C threshold values are based on the work of Henriquez and Moritz [6]. In this study, a 600 min CEM43°C for thermal damage threshold has been used as defined by the scientific literature [6].

MODEL

In order to understand the influence of the object contact conditions on the propensity to cause a skin burn, a 2D heat transfer model was developed. As described in Part I, the model solves for the conduction of heat from a hot contacting object into human tissue layers. The Pennes bioheat equation [7], shown in Equation 2, is numerically solved to simulate the evolution of the temperature distribution through the skin. The Pennes bioheat equation accounts for blood perfusion, in which blood flow through the skin carries heat away from the contact area and metabolic heat generation effects in the dermal and hypodermal layers of the skin. The computational model integrates for CEM43°C as indicated in Equation 1.

The model developed for this study was used to simulate the three geometry configurations shown in Figure 1. The first configuration is that of an infinite plate of a finite thickness which is also referred to as a large contact area. The second configuration is that of a cylindrical object contacting the skin to create a circular contact area. The third configuration is that of an infinitely long rectangular object of finite thickness and width in contact with the skin creating an elongated contact area.

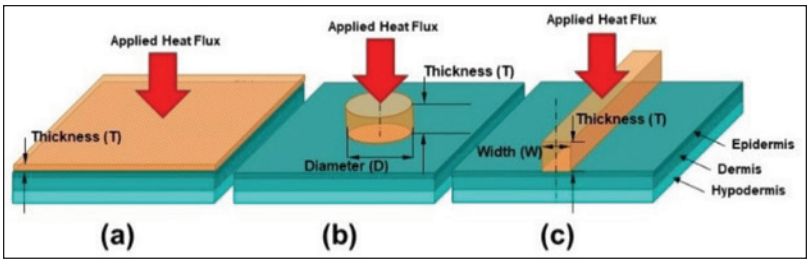

Figure 1: Skin (green) and contacting object (orange) geometry implemented in the numerical model for (a) large contact area, (b) circular contact area, (c) elongated contact area.

	Aluminum	Pyrex	Plastic	Epidermis	Dermis	Hypodermis
Cp [J/kg-K]	872	838	1550	3589	3300	2674
Rho [kg/m³]	2710	2250	1280	1200	1200	1000
K [W/m-K]	203	1.13	0.25	0.235	0.445	0.185
Thickness [mm]	1, 3, 5, 10, 100			0.08 [2]	2	20

Table 1: Material properties and thicknesses

In these computations, an object of finite thickness is placed into contact with the skin which is composed of epidermis, dermis, and hypodermis. The contact between the hot object and the skin is assumed to have zero contact resistance unless otherwise stated. The non-contacting surfaces of the hot object are considered to be adiabatic unless otherwise stated in order to provide conservative results. Multiple computations with varying initial object temperatures are carried out for several materials, object thicknesses, shapes, and sizes. The influence of active components that dissipate energy has been simulated as a heat flux boundary condition that is applied on the object surface that is opposite to the contact surface, as shown in Figure 1. In the heat flux scenarios, at time equal 0 sec, an object of uniform temperature comes into contact with the skin surface simultaneously with the application of the heat flux. Burn injury thresholds based on initial object temperature, exposure time, and thickness are shown and discussed in the Results section.

$$\underbrace{C_p\rho\frac{\partial T}{\partial t}}_{\text{Transient}} = \underbrace{\frac{\partial}{\partial x}\left(k\frac{\partial}{\partial x}\right)}_{\text{Heat conduction}} + \underbrace{w_b\rho_b c_b(T_b - T)}_{\text{Blood perfusion}} + \underbrace{q_m}_{\text{Metabolic heat generation}}$$

Equation 2: Pennes bioheat equation [7]

As discussed in Part I, the model was validated using the experimental data of Henriques and Moritz [6] and Stoll and Green [8]. The model shows that temperature and contact durations that result in a CEM43°C of 600 min, a burn threshold suggested by the literature, are well aligned with all the relevant experimental observations from Henriquez and Moritz [6] and Stoll and Green [8]. The interested reader should refer to Part I of this study for more details on the validation procedure.

SENSITIVITY ANALYSIS

The following variables and corresponding ranges have been considered in the sensitivity studies summarized in this paper:

- **Material of the contacting object:** Aluminum, Pyrex, Plastic (Table 1 summarizes the thermal properties of the plastic material considered in this study)
- **Thickness of the contacting object:** 1 mm, 2 mm, 3 mm, 5 mm, 10 mm, and 100 mm
- **Shape of the contacting object:** large contact area, circular contact area, elongated contact area (see Figure 1)
- **Size of the contacting object:** for circular contact areas: diameters of 1 mm, 3 mm, 5 mm, and 10 mm; for elongated contact areas: widths of 1 mm, 3 mm, 5 mm, and 10 mm
- **Contact resistance:** 0 m^2K/W, 10^{-6} m^2K/W, 10^{-4} m^2K/W, 5×10^{-4} m^2K/W, 10^{-3} m^2K/W [9]
- **Heat Flux from active components:** 0 W/m^2, 50W/m^2, 100 W/m^2, 200 W/m^2, 400 W/m^2

RESULTS

The sensitivity of the burn threshold to various contact conditions is conducted by tabulating the time it takes for the basal layer of the skin to reach a CEM43°C of 600 minutes. The results are presented in a format that is similar to the ISO 13732 standard. The analysis has been performed for a range of initial object temperatures from 130°C-43°C. The isolines of 600 min CEM43°C are plotted on an *initial object temperature* to *time to 600 min CEM43°C* plot.

Effect of Object Material Properties and Thickness

Sensitivity to material properties and contact object thickness is studied using the large contact area configuration. The chosen object thicknesses were 100 mm, 10 mm, 5 mm, 3 mm, and 1 mm. Isolines of CEM43°C equal to 600 min are plotted as functions of initial object temperature and time in Figure 2, showing three sets of curves (1) red curves for plastic objects, (2) black curves for ceramic objects, and (3) blue curves for metal objects. The material properties that were considered for the object and skin are summarized in Table 1.

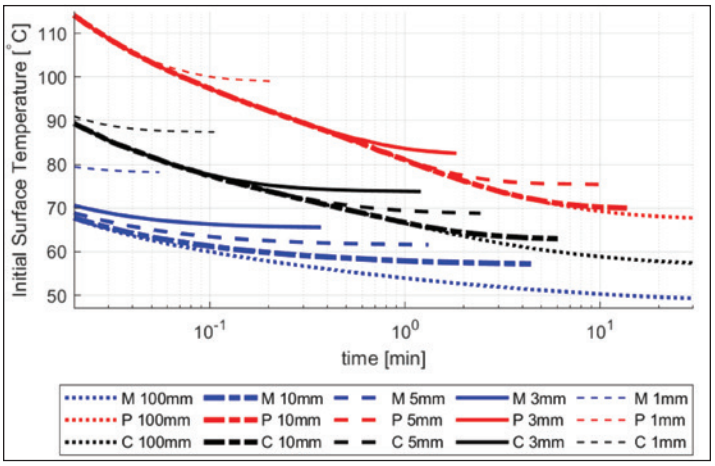

Figure 2: Computed isolines CEM43°C equal 600 min for large contact areas and metal (M), ceramic (C), and plastic (P) objects of varying thicknesses without applied heat flux

For a specified thickness, the plastic objects have the highest burn thresholds, followed by ceramic objects and metal objects. This is due to the thermal conductivity of each material. Higher material conductivity leads to a larger heat transfer into the skin resulting in higher skin temperatures and lower burn thresholds. For a given material, the curves approach one another for short contact duration scenarios where the objects behave as thermally thick. As contact duration increases, the curves diverge, with thinner objects having a higher burn threshold due to their lower thermal mass. For instance, in order to cause a burn for a 1 min contact duration, a 100 mm and a 1 mm thick metal plates must have an initial temperature of 54°C and 78°C, respectively.

The burn threshold curves displayed in Figure 2, and those summarized in the ISO 13732 standard, feature the same trends with respect to the material property and the same general relation between contact duration and initial temperature. That is, when the contact duration decreases, the object temperature required to cause burn injury needs to increase. However, the ISO 13732 standard shows that, as contact duration increases, the curves for metal, ceramic, and plastic converge to a condition where, regardless of the material of the object, a burn injury will occur if the object has a surface temperature exceeding 43°C. In ISO 13732, it is assumed that the "*surface temperature is essentially maintained during the contact period either by the mass of the product or by a heating source*" [1]. This is not a realistic assumption for semi-infinite objects, let alone for objects of finite mass, unless there is a heat source that actively maintains the object surface temperature. Furthermore, it can be noted that the last point in each curve represents a temperature threshold at which an object of that material and thickness is able to cause a skin burn. If the initial object temperature is lower than this threshold, there is not enough energy stored in the object to cause a skin burn, and as a result, the contact time required to incur a burn at that temperature becomes infinite.

Heat transferred from the object into the skin causes the temperature of the object to decrease until the object and skin reach thermal equilibrium. As the object temperature decreases, the heat flux into the skin drops until it reaches a point where the temperature at the basal layer and the CEM43°C does not increase appreciably. This is due to heat diffusion through the skin, heat removal through blood perfusion, and other environmental or object geometry effects. The influence of these parameters is described in the following sections.

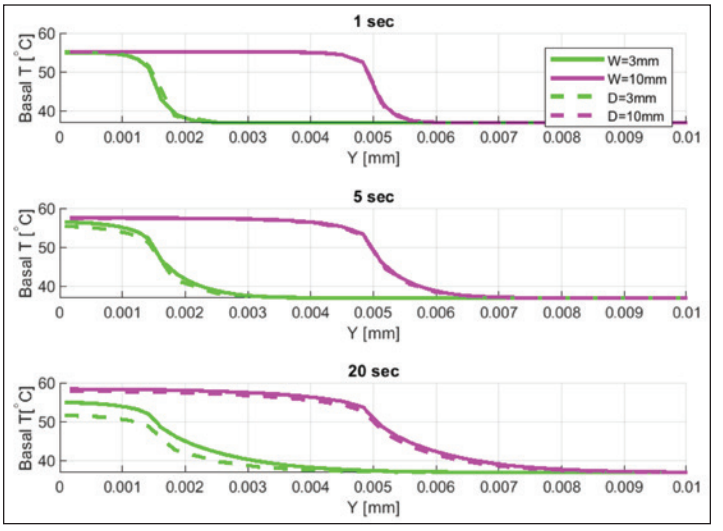

Figure 3: Basal Temperature profiles at 1 sec, 5 sec, and 20 sec for 100 mm thick ceramic objects with an initial temperature of 80°C. Circular contact objects diameters (D) of 3 mm and 10 mm are shown in dashed lines. Elongated contact objects widths (W) of 3 mm and 10 mm are shown in solid lines

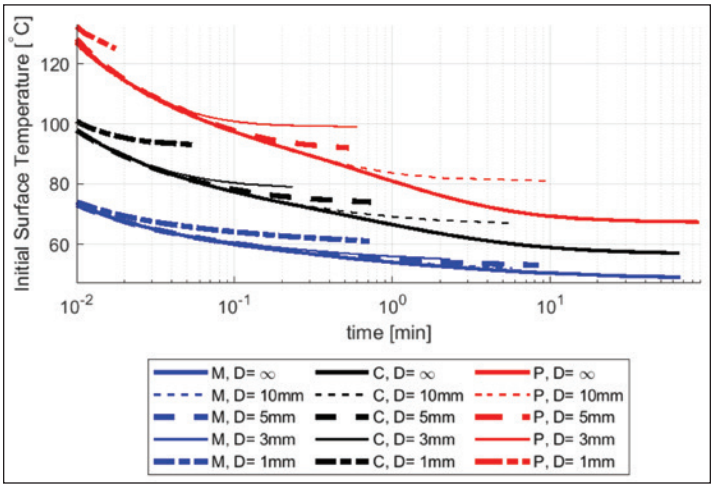

Figure 4: Computed isolines of 600 min CEM43°C for circular contact areas associated with metal (M), ceramic (C), and plastic (P) 100 mm tall cylinder of varying diameters (D)

Effect of Contact Shape and Size

A sensitivity analysis of the contacting object shape and size was performed to understand their effects on the potential for thermal damage to the skin. First, the effect of contact area size is examined by modeling circular contact areas of various diameters. Next, we examine elongated contact areas of varying widths.

Figure 3 shows the basal temperature profiles at three different times for a circular contact area with a diameter of 3 mm and 10 mm and for an elongated contact area with a width of 3 mm and 10 mm. Both contact areas correspond to a ceramic object that is 100 mm thick with an initial temperature of 80°C.

The results for the two circular contact shapes (see dashed lines in Figure 3) at 1 sec indicate a maximum basal centerline temperature of approximately 55°C. The basal temperature immediately outside of the contact area also increases as heat diffuses radially through the skin. At 5 sec, the contact with the 10 mm and 3 mm diameter objects results in a centerline temperature of 57°C and 56°C, respectively. Both basal temperature profiles flatten out as heat continues to diffuse radially into the skin. As expected, these edge effects are more pronounced for the 3 mm diameter object.

Figure 3 shows elongated contact areas with 3 mm and 10 mm widths as solid lines. At 1 sec, the elongated contact area results closely match the circular contact area basal layer temperature data. At this point in time, all objects still behave as thermally thick, and as a result, the influence of the geometric contact parameters is minimal.

At 5 sec, basal temperatures associated with the elongated contact areas are higher than the circular contact area temperatures. At 20 sec, the effects of both the size and shape are even more pronounced with (1) the elongated contact temperatures being higher than the circular contact temperatures and (2) the larger contact temperatures being higher than the smaller contact temperatures. Higher basal layer temperatures are observed for elongated objects in comparison to a circular object of the same characteristic size (i.e., diameter for circular contact area, width for elongated contact area) due to the absence of the heat diffusion through the skin in the direction aligned with the elongated object.

In Figure 4, isolines for CEM43°C equal to 600 min are shown for cylindrical objects with diameters of 1 mm, 3 mm, 5 mm, and 10 mm. The infinite contact diameter scenario (*i.e.*, identical to the large contact area case for a 100 mm thick object seen in Figure 2) is also shown. Decreasing the diameter of the contact area decreases the overall heat transfer into the skin, increasing the burn threshold temperatures.

Figure 5 shows the isolines for CEM43°C equal to 600 min for elongated objects with widths of 1 mm, 3 mm, 5 mm, and 10 mm. The infinite contact width

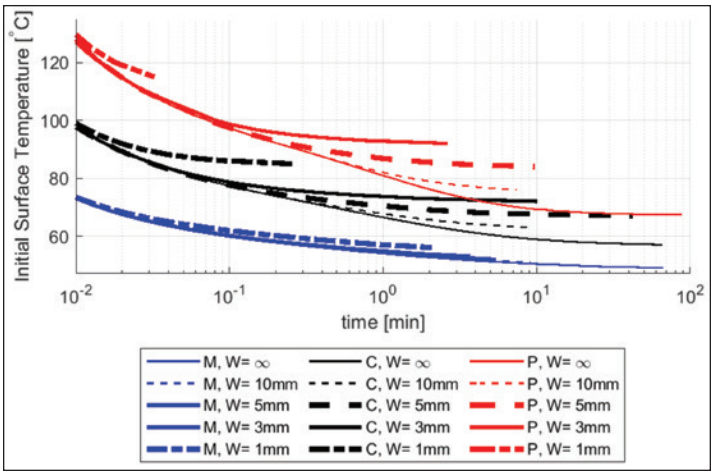

Figure 5: Computed isolines of 600 min CEM43°C for elongated contact areas associated with metal (M), ceramic (C), and plastic (P) 100 mm tall elongated objects of varying widths (W)

It should be noted that a low object thermal conductivity results in lower rates of heat transfer into the skin and, therefore in a slower decrease in the object's internal temperature.

scenario (*i.e.*, identical to the large contact area case for a 100mm thick object seen in Figure 2) is also shown. The results summarized in Figure 4 and Figure 5 confirm that for the same material and characteristic size, the elongated contact area scenarios have lower burn thresholds than their circular counterparts.

Effect of Object Thickness for Various Shapes

The effect of the circular and elongated contact areas was studied by holding the diameter/width constant and by varying the thickness of the object. In Figure 6, isolines of CEM43°C equal to 600 min are shown for circular contact areas with a diameter of 5 mm and thicknesses of 1 mm, 2 mm, 3 mm, 5 mm, 10 mm, and 100 mm. Similar to the trend seen in Figure 2, the curves for a particular material approach each other with decreasing contact duration. For burn thresholds found at shorter contact durations, the dominant factor is the high initial temperature of the object.

Furthermore, as the object thickness decreases, the burn temperature threshold increases due to the lower object thermal mass. This trend can be seen for both ceramic and metal objects, even though it is more pronounced for the former.

It should be noted that a low object thermal conductivity results in lower rates of heat transfer into the skin and, therefore in a slower decrease in the object's internal temperature. For example, in the plastic circular object cases shown in Figure 6, the low thermal conductivity of the plastic limits the heat transfer rate, and the curves fall on top of each other for all objects with thickness larger than 2 mm. In all these scenarios, the rate of heat transfer through the objects bottlenecks the heat transferred to the skin, and only at a thickness of 1 mm or less does the thermal mass of the object becomes small enough to be the limiting factor that controls the burn threshold.

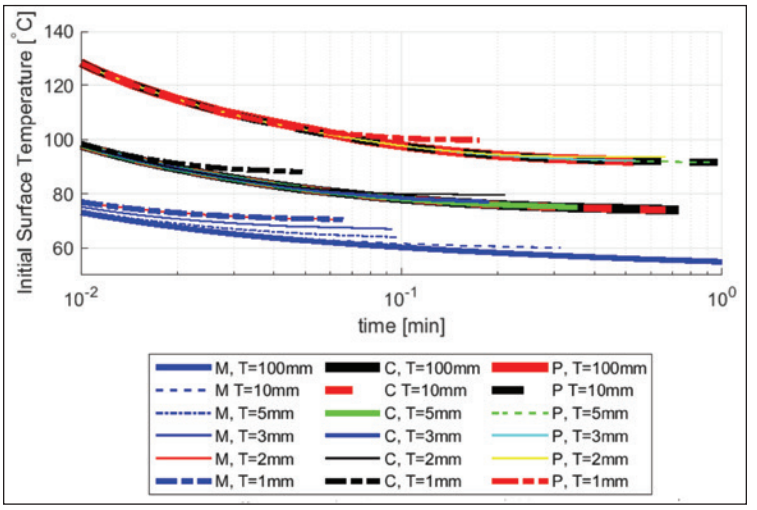

Figure 6: Computed isolines of 600 min CEM43°C for circular contact areas associated with metal (M), ceramic (C), and plastic (P) 5 mm diameter objects of varying thicknesses (T)

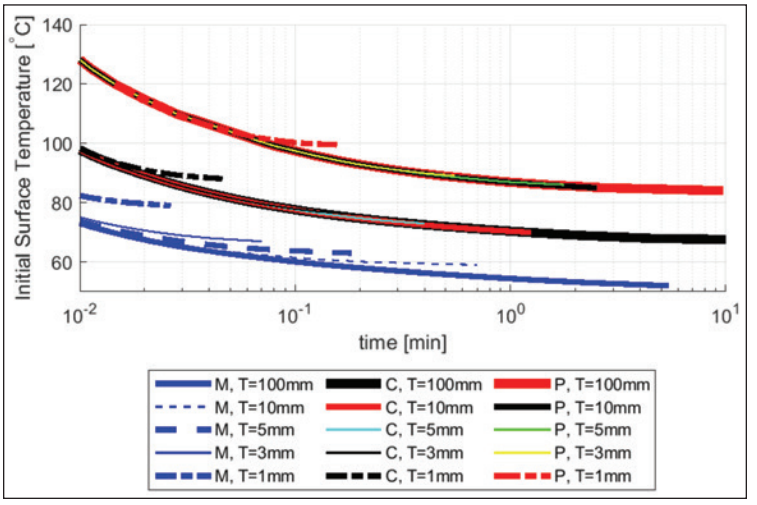

Figure 7: Computed isolines of 600 min CEM43°C for elongated contact areas associated with metal (M), ceramic (C), and plastic (P) 5 mm wide objects of varying thicknesses (T)

Figure 7 shows the isolines of 600 min CEM43°C for elongated contact areas with a width of 5 mm and thicknesses of 1 mm, 3 mm, 5 mm, 10 mm, and 100 mm. The trends are similar to those seen in Figure 2 and in Figure 6.

Effect of Applied Heat Flux

Thus far, only objects with an initial uniform temperature with adiabatic non-contacting surfaces have been discussed. However, objects may also contain a heat source such as a processor, as is now common in consumer electronics. The effect of the heat flux is examined here by imposing a uniform heat flux of 400 W/m^2, 200 W/m^2, 100 W/m^2, 50 W/m^2, and 0 W/m^2 on the face of the object that is not in contact with the skin. Figure 8 shows the 600 min CEM43°C isolines for large contact area metal objects that are 5 mm thick. The case of zero heat flux is the same as found in Figure 2. Increasing the imposed heat flux decreases the burn temperature threshold as it establishes a non-zero baseline heat flux into the skin over time. In the cases analyzed earlier in the paper, the baseline heat flux became zero after the initial transient effects associated with the temperature differential between the skin and the contacting object.

At short contact durations, the effect is not as pronounced as the vast majority of the heat flux into the skin is driven by the high object surface temperature differential. Additionally, the effect on the basal layer by the imposed heat flux is delayed by the time it takes to establish the corresponding temperature gradient between the object and epidermis as well as within the object itself. At a contact duration of 10 minutes, the burn threshold for a 5 mm metal plate without applied heat flux is reached with an initial object temperature of approximately 62°C. When a flux of 400 W/m^2 is applied, the burn threshold at 10 minutes is reached when the initial temperature of the object is approximately 60 °C. The influence of the heat flux becomes more pronounced as the contact duration increases past 10 minutes, which is a relevant contact scenario for the consumer electronics and wearable industries.

Figure 9 shows the 600 min CEM43°C isolines for 5 mm thick large plastic plate. Much like the metal counterparts in Figure 8, the effects of the imposed

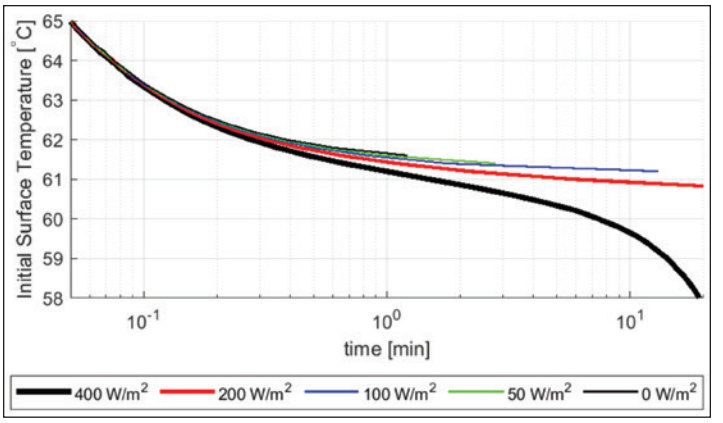

Figure 8: Computed isolines of 600 min CEM43°C for large contact areas associated with 5 mm thick metal plates and varying applied heat flux

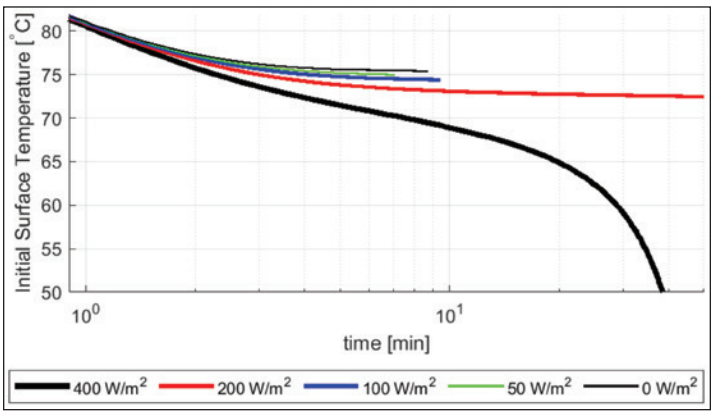

Figure 9: Computed isolines of 600 min CEM43°C for large contact areas associated with 5 mm thick plastic plates and varying applied heat flux

Small gaps in the interface between the contacting objects due to surface roughness cause a temperature drop across the interface. This phenomenon is typically addressed by including a contact resistance between the objects.

heat flux are more pronounced at longer contact durations. At 10 minutes, the 5 mm thick plastic plate without applied heat flux reaches the burn threshold with an initial object temperature of approximately 75.4 °C. The same plate with a 400 W/m^2 heat flux reaches the burn threshold at 10 minutes with an initial temperature of approximately 69 °C.

Effect of Contact Resistance

All the previous results are based on the assumption of perfect contact between the skin and the contacting objects (i.e., zero contact resistance scenarios). However, small gaps in the interface between the contacting objects due to surface roughness cause a temperature drop across the interface. This phenomenon is typically addressed by including a contact resistance between the objects. Generally, lower contact pressure and higher surface roughness result in higher contact resistance. In the context of contact skin burns, contact resistance values as high as 10^{-3} m^{2}K/W are considered possible [9].

Figure 10 shows the centerline temperature profile for 5 mm thick objects with a large contact area, an initial temperature of 70°C, and contact resistances of 10^{-6}, 10^{-4}, and 10^{-3} m^{2}K/W. At 1 sec, the 10^{-6} m^{2}K/W contact resistance case reaches a basal layer temperature of 60°C, whereas the 10^{-3} m^{2}K/W contact resistance case reaches a basal layer temperature of 48°C. This indicates that contact resistance plays a major role in determining the amount of heat that is transferred to the skin.

The effect of contact resistance on the burn injury temperature thresholds is shown in Figure 11. Contact resistances between 0 m^{2}K/W and 10^{-3} m^{2}K/W are applied to the interface between the skin and a 5 mm thick metal object with a large contact area. For an initial object temperature of 80°C, contact resistances

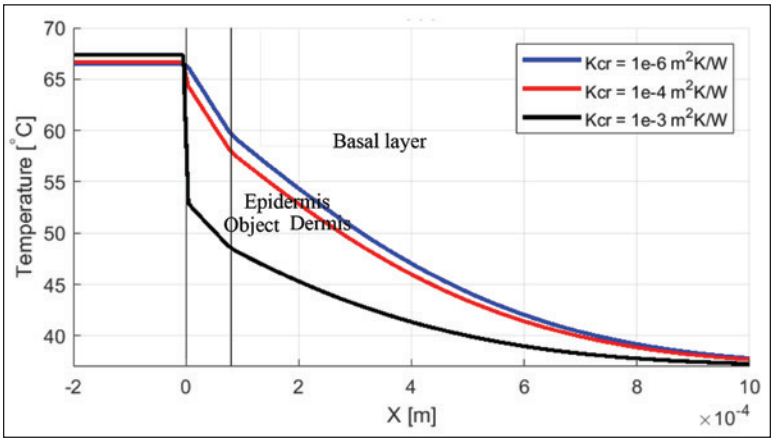

Figure 10: Centerline temperature profile at 1 sec obtained for a 5 mm thick metal plate with an initial temperature of 70°C and different contact resistances

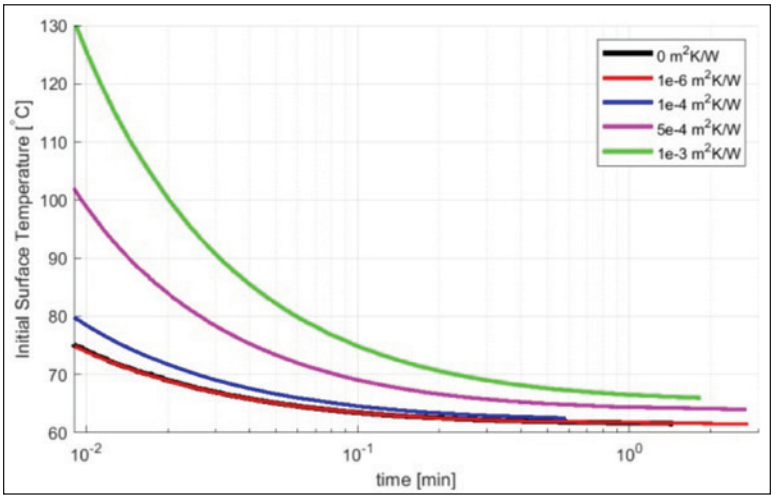

Figure 11: Computed CEM43°C equal to 600 min isolines associated with 5 mm thick large metal plates and varying contact resistances

of 10^{-4} m^2K/W, 5×10^{-3} m^2K/W, and 10^{-3} m^2K/W result in a time to a CEM43°C equal to 600 min of 0.5 sec, 1.5 sec and 3.6 sec, respectively. The analysis also shows that the results obtained for the case with no contact resistance are substantially similar to the $1e^{-6}$ m^2K/W contact resistance case. For long contact durations, the influence of the threshold temperature tends to decrease.

CONCLUSIONS

Guidance on contact burn temperature threshold found in the current regulatory standards fails to account for the importance of thermal mass, geometry of the contact, and the presence of heat dissipation of active components. This paper employs a numerical model that solves the Pennes bioheat transfer equation to predict the contact burn thresholds. This framework was described and validated in an earlier work [4]. This study describes a large set of sensitivity studies for factors that control the burn temperature threshold such as (A) material properties, (B) contact shape, (C) contact thickness, (D) heat flux, and (E) contact resistance. The study shows that there is an initial temperature above 43°C for objects of a finite thermal mass where a burn injury will not occur regardless of the contact duration. This initial object temperature is dependent on the geometry, dimensions, material properties, and contact resistance of the contacting object. Future work will include developing simplified procedures based on regression models or physical scaling that can be used to readily estimate the time-temperature thresholds associated with contact burns and accounts for the effect of the relevant parameters including but not limited to those addressed in this study.

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EVALUATION OF PCB DESIGN OPTIONS ON ANALOG SIGNAL RF IMMUNITY USING A MULTILAYER PCB

Part 1: Top-Level Description of the Design Problem

By Bogdan Adamczyk, Scott Mee, and Bilguun Baatar

This is the first of three articles devoted to the design, test, and electromagnetic compatibility (EMC) immunity evaluation of multilayer PCBs containing analog circuitry. In this study, there are seven design variants that all contain a similar schematic but implement different PCB layout techniques.

All variants were equipped with an analog voltage measurement along with a temperature measurement [1]. Non-conductive and metallic enclosures were evaluated for cases where the design options showed susceptibility issues. Testing was performed according to the ISO11452-11 Radiated Immunity Reverberation Method standard from 200MHz – 1GHz up to 100V/m and ISO11452-4 Bulk Current Injection from 1MHz – 400MHz up to severity level 4. The analog readings were monitored during RF immunity testing to determine the performance of the various design options.

In this introductory article, we present a top-level block diagram description of the design problem under research. The subsequent articles will be devoted to the RF immunity performance of the PCB assemblies.

1. INTRODUCTION

Electronic products that are sold in the marketplace must undergo a series of EMC tests to demonstrate compliance with industry and regulatory requirements. One aspect of the requirements focuses on evaluating a device's conducted and radiated immunity performance. This evaluation begins with developing a prototype design (schematic and PCB layout), then follows with EMC testing a functional part early in the design process. Early test results typically lead to design changes and an understanding of what is required to become compliant. The objective of this study is to provide guidelines for schematic and layout design concerning EMC immunity of analog circuitry.

Many electronic devices use sensors to monitor their environment, interpreting analog signals and quantizing them into discrete values for digital use. For example, temperature and battery voltage are commonly measured in a variety of applications, which is the case in this study.

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2. TOP-LEVEL BLOCK DIAGRAM

The PCB inputs and outputs are shown in Figure 1.

There are three macro inputs to the system which include physical connections (materials), energy (power supply & RF exposure), and signals representing the environment (voltage & temperature). Outputs from the system are the USB connector (electrical RX/TX signals being monitored), heat energy, and unintentional RF emissions. While there are some low-level RF emissions radiating and conducting from the evaluation boards, these will not be considered in this study.

For the purposes of this study, we focused on the electrical interfaces. A 5VDC supply was provided to power the PCB. A separate 12VDC power supply was provided for the analog voltage measurement. Additionally, a thermocouple was connected to the analog measurement port. In response, the PCB provided the measured values of Voltage & Temperature over UART back to the PC through a fiber optic interface. The functional structure of the measurements is shown in Figure 2.

3. PCB VARIANTS

PCB routing design can have a significant effect on analog RF immunity performance. In this study, we evaluated design options such as routing the analog lines as microstrip and stripline configurations. Additionally, the analog traces were routed as single-ended or as a differential pair. Finally, some of the variants utilized either a single PCB ground or a split analog/digital ground. A summary of the various routing implementations is shown in Table 1.

Seven variants were designed, fabricated, and tested to understand the benefits of these various design techniques. The test results led to the identification

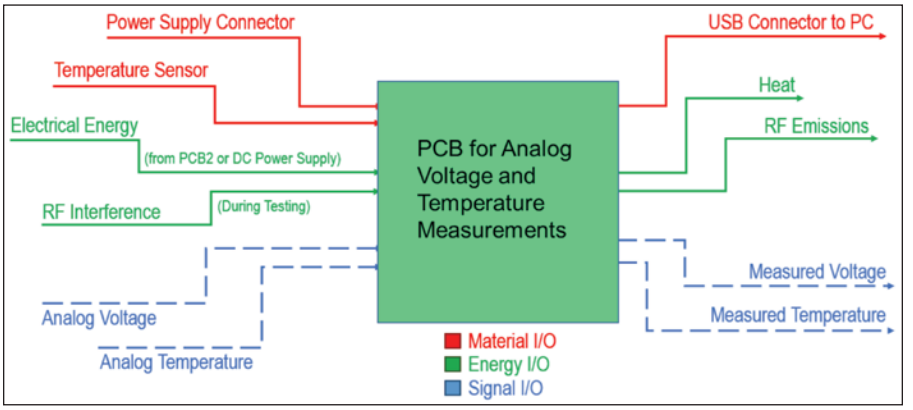

Figure 1: PCB inputs and outputs

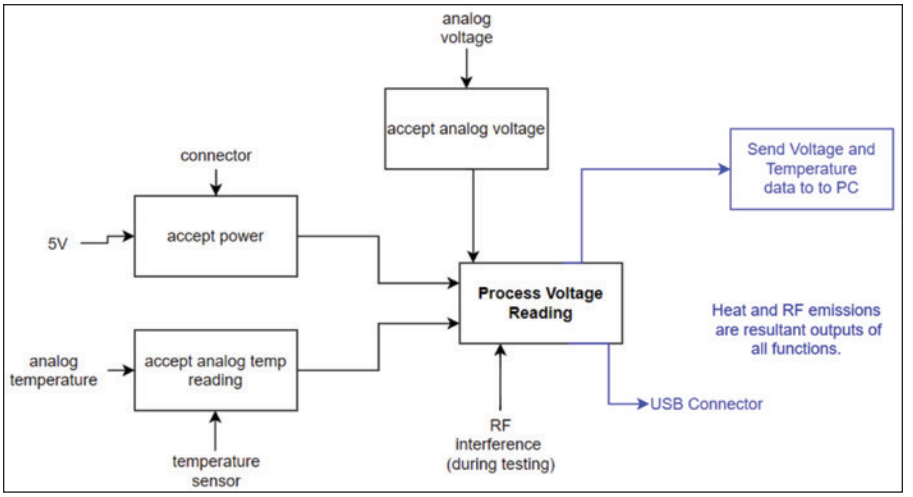

Figure 2: Functional structure of analog measurement PCB

Variant	Analog Trace Routing Style	Analog Trace Routing Layer	Grounding Method	Ground Split Geometry	Ground Split Layers
1	Differential	Microstrip on top layer	Single Ground Reference (GND)	N/A	N/A
2	Single Ended				
3	Differential	Embedded on layer 3			
4	Single Ended				
5	Single Ended	Microstrip on top layer	Split Ground Reference (AGND and GND)	AGND under analog circuitry, adjacent to GND*	All layers
6				AGND under analog traces, surrounded by GND*	Layer 2 only
7		1-3-1-3-1-3-1-3-1			

Table 1: Routing Implementations

of good design practices for similar circuits in a wide variety of industries. All variants of a given board family were designed to be tested using one of two custom-built PCB enclosures. The first enclosure, which is conductive (shown in Figure 3), was machined from 6061 aluminum and uses threaded fasteners for closure.

The second, non-conductive enclosure (shown in Figure 4), was 3D printed using nylon and uses snap hook and lip groove features for closure.

All seven variants used the same PCB stack up, shown in Figure 5.

Figure 6 shows the PCB with analog traces on the top layer. This configuration was used in variants 1, 2, 5, and 6.

Figure 7 shows the PCB with the analog traces buried on layer 3. This configuration was used in variants 3 and 4.

Figure 8 shows variant 7 PCB with the traces jumping between the top layer and layer 3.

Variants 1, 2, 3, and 4 used a solid ground plane on layer 2 (shown in Figure 9a), while variants 5, 6, and 7 used a split ground plane (shown in Figure 9b).

4. IMMUNITY TESTING PLAN

After validating the functionality of all PCB assemblies, radiated immunity (ISO11452-11) and conducted immunity (ISO11452-4) testing

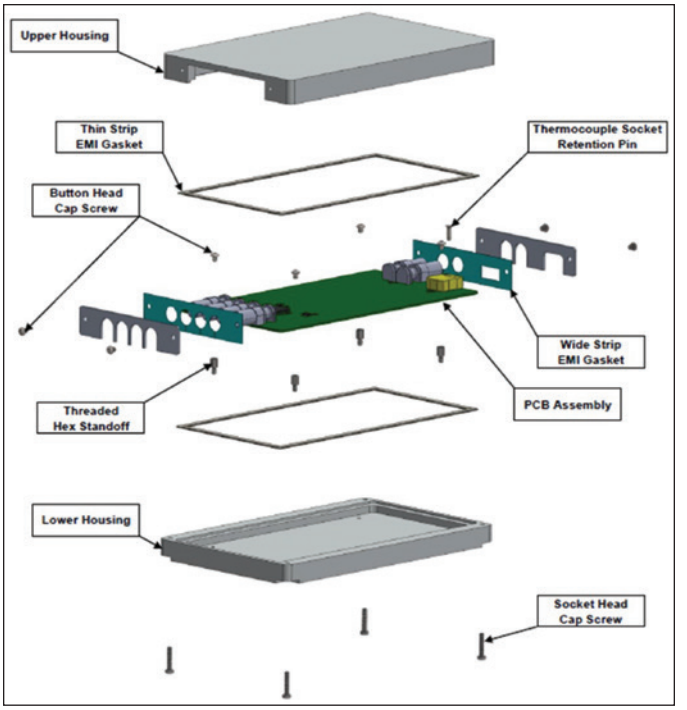

Figure 3: Details of the conductive enclosure

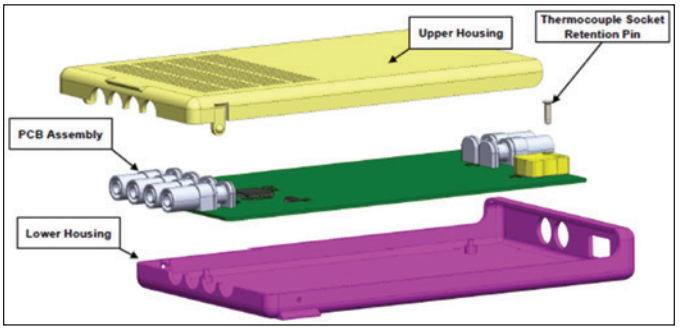

Figure 4: Details of the non-conductive enclosure

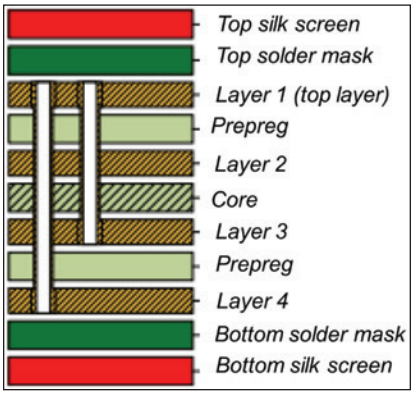

Figure 5: PCB stack up

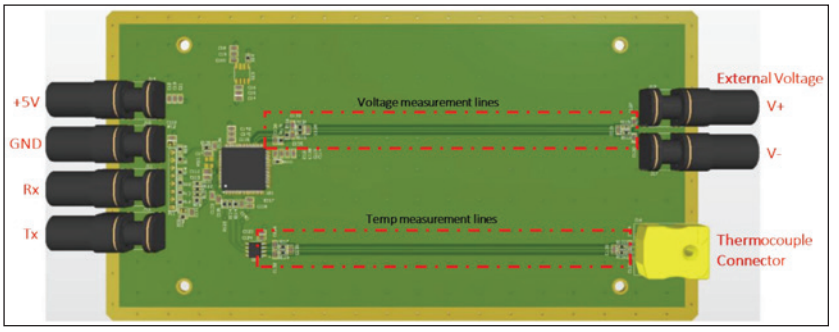

Figure 6: PCB with the analog signals on the top layer (variants 1, 2, 5, 6)

were performed within the frequency range of 200MHz to 1GHz. The test configurations shown in Table 2 represent component placement and enclosure type used during testing to evaluate EMC performance for each design.

Configuration A utilized a non-metallic enclosure. Configuration B utilized a conductive enclosure with non-conductive standoffs to isolate the enclosure from the ground. Configuration C utilized a conductive enclosure with conductive standoffs and two conductive gaskets to improve upper and lower housing bond to the PCB GND. Additionally, selective filtering components were utilized on the analog traces to improve RF immunity.

All seven variants were tested using Configuration A. The three variants which exhibited the weakest RF immunity performance were re-tested in the frequency bands where the failures occurred, using Configuration B (variants 1,5,6). Finally, the worst performing variant from the second round of testing (Configuration B) was re-tested using Configuration C (variant 1), again in the frequency bands where the failures occurred.

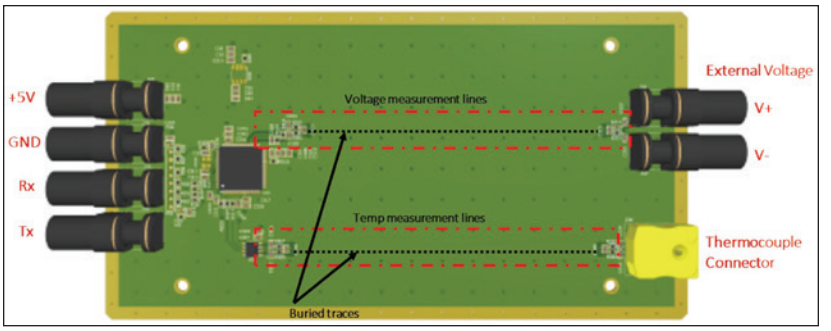

Figure 7: PCB with the analog signals on layer 3 (variants 3 and 4)

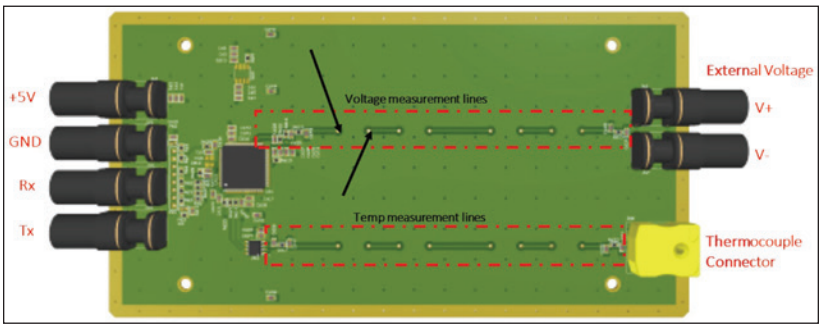

Figure 8: PCB with the analog signals alternating between layers 1 and 3 (variant 7)

5. FUTURE WORK

The next article will discuss radiated immunity testing and results.

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Test Descriptions		
Configuration A	**Configuration B**	**Configuration C**
No filters on measurement signal traces, non-conductive enclosure	No filters on measurement signal traces, conductive enclosure, (4) non-conductive standoffs, no conductive ground ring gaskets	Selective filtering on measurement signal traces, conductive enclosure, (4) conductive standoffs, conductive ground ring gaskets (top and bottom)

Table 2: Description of test configurations

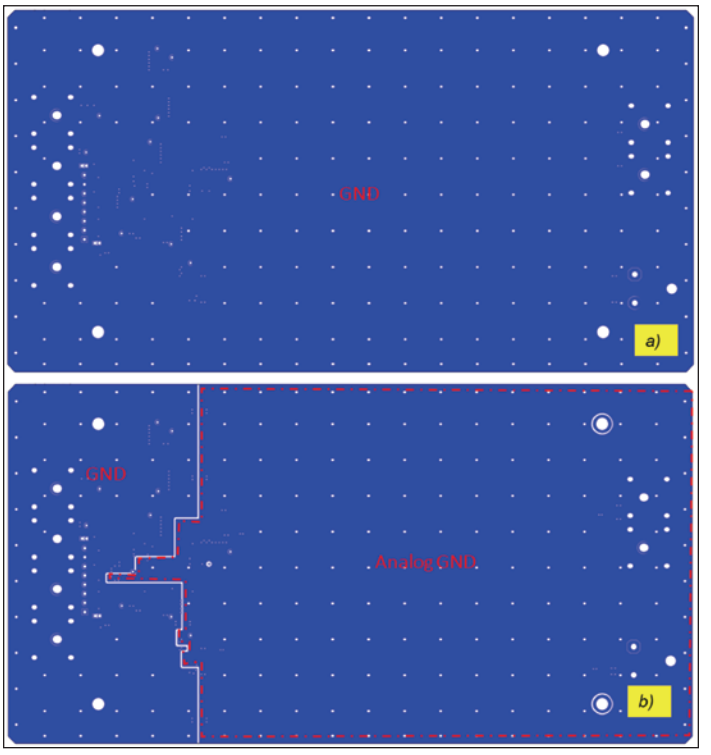

Figure 9: a) solid ground plane (variants 1, 2, 3, 4) b) split ground plane (variants 5, 6, 7)

LOW VOLTAGE CHARGED DEVICE MODEL (CDM) TESTING AT A CROSSROADS

By Robert Ashton for EOS/ESD Association, Inc.

INTRODUCTION

Charged Device Model (CDM) testing is at a crossroads. For the last decade, the Industry Council on ESD Target Levels has recommended that CDM levels of 250 V, as measured with the field-induced CDM test method JS-002[1], are sufficient for high yield manufacture in facilities with basic ESD control [2]. Until recently, integrated circuit manufacturers have routinely provided products meeting the 250 V level and above. This is changing. High-speed interfaces such as 100 Gb/s and above SerDes can no longer meet both the required speed and deliver 250 V CDM levels. ESD protection circuits for 250 V CDM have too much loading capacitance for such high-speed applications. For this reason, the Industry Council has modified its CDM recommendations in the latest update of its CDM white paper [3]. Most devices should continue to meet the 250 V CDM target level but acknowledge that ultra-high-speed pins will no longer be able to reach that level. The Council did not, however, recommend a target of 125 V CDM, the next lowest classification level in JS-002. The Council advised that CDM levels be as close to 250 V levels as practical while meeting performance goals. Dropping CDM levels all the way to 125 V could have severe implications for device yield in manufacture and assembly. This requires a CDM test method providing reliable measurements in the 125 V to 250 V range with an accuracy, repeatability, and reproducibility on the order of 20 V. This cannot be met by JS-002 below 250 V. [4]

BACKGROUND

Most ESD experts consider CDM testing to be the most critical ESD qualification test for modern integrated circuits. CDM testing emulates the fast discharge that a charged integrated circuit will experience if it makes metallic contact to a grounded surface. This is just the kind of ESD stress expected in a modern printed circuit production line. Printed circuit boards automatically and rapidly move from place to place while high-speed robotic arms grab components from trays or off reels and place them on the circuit board. Speed is of the essence, resulting in a multitude of chances for electrostatic charging and discharging. Factory ESD experts work hard to minimize device charging and control discharges, but all components must have some ability to survive the discharges they may be exposed to. The ESD control engineers need to know the charged device ESD robustness of all components passing through their manufacturing line. CDM measurements provide that knowledge.

FIELD-INDUCED CDM TESTING

Field-induced CDM is the most widely used CDM test method today. Figure 1 shows a diagram of the CDM test fixture as well as a circuit diagram overlay for field-induced CDM testing according to JS-002[1]. In field-induced CDM an uncharged integrated circuit is placed on a thin insulator on top of a field plate. The field plate is then brought to a high potential. Capacitive coupling elevates the potential of the integrated circuit to a voltage close to that of the field plate. The integrated circuit is then rapidly grounded by touching a pin on the circuit with a pogo pin tied

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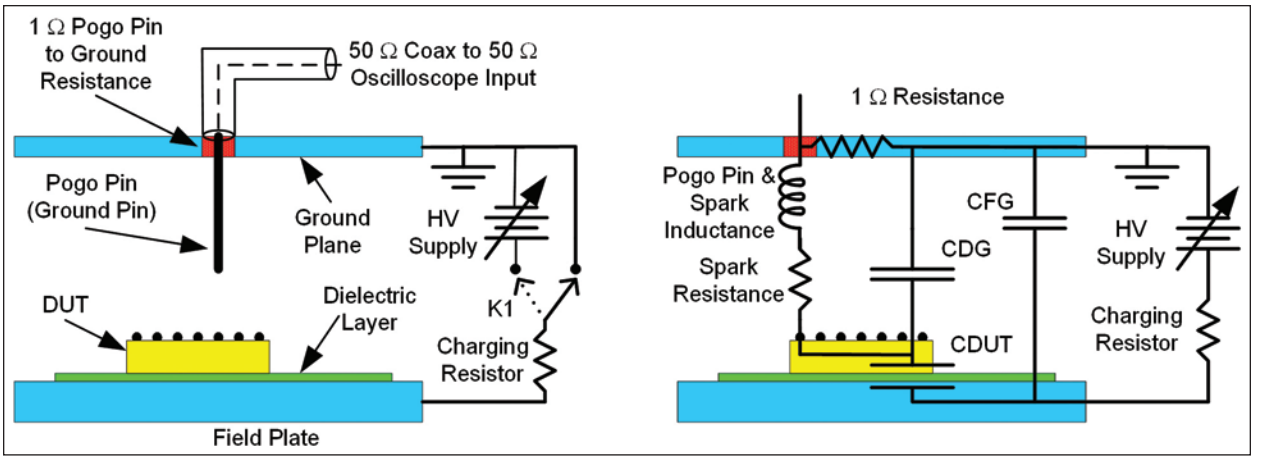

Figure 1: Field induced CDM test fixture and equivalent circuit

to ground with a 1-ohm resistor. The grounding of the integrated circuit often creates a sub ns pulse of up to several amps, replicating the type of stress a circuit could see during manufacture. The test is repeated with both positive and negative field plate voltages for all pins on the circuit. After stressing all pins, positive and negative, the device still needs to meet all datasheet and functional specifications.

Field-induced CDM has worked well for the industry for many years, but the test results become erratic below 250 V due to the erratic nature of air discharges at low voltages. [4] As stated above, there is an urgent need for an improved test method, and it is generally agreed that the air discharge must be eliminated. Fortunately, there are several candidates.

LOW VOLTAGE CDM OPTIONS

Four possibilities will be discussed, two based on direct charging and two based on transmission line pulse (TLP) testing techniques. In each method, the air discharge of field-induced CDM is replaced by discharge in a relay.

JEITA CDM Test

There is already one CDM test standard that does not have issues at low voltage levels, the Japan Electronics and Information Technology Industries Association (JEITA) standard JEITA ED-4701/302A test method 305. [5] This test method, shown in Figure 2, has not been very popular outside of Japan. The JEITA method uses direct charging as opposed to field-induced charging. The electrode touches the pin to be tested, and then the potential is raised to an elevated potential through high-value resistors. A switch then grounds the pin being tested. The use of a switch to initiate discharge removes most of the issues of low voltage testing.

While this method gives useful information, there are several issues with the JEITA CDM test method. The relay geometry will add inductance to the discharge path, slowing the CDM discharge. The method for performing waveform verification inserts a current probe and an additional length of wire, both of which are not present during device testing. This raises the issue of how well the verification waveform matches the waveform experienced by devices being tested. The JEITA test method also calls for a 2 GHz oscilloscope rather than the 6 GHz oscilloscope required by JS-002. This can hide waveform artifacts that could

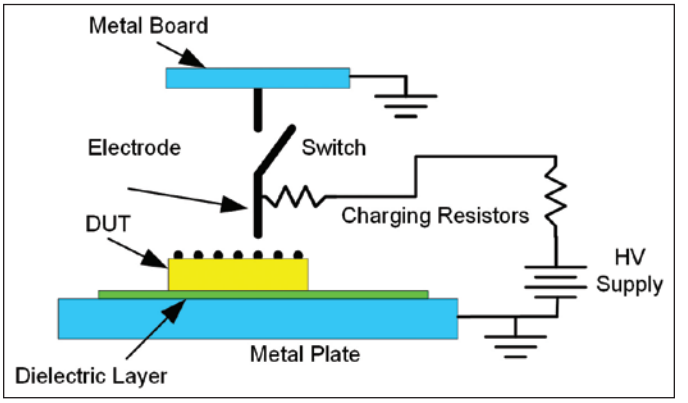

Figure 2: JEITA CDM

affect test results. As written, the JEITA standard does not include a method for measuring device waveforms during device stress, preventing waveform measurement during device stress. Fortunately, at least one equipment manufacturer includes a 1-ohm resistor between the relay and the ground board, similar to JS-002, allowing waveform verification during device stress. The test method's low voltage performance does make it an attractive alternative to field-induced methods at low voltage.

Contact CDM

The contact CDM method [6][7] is shown in Figure 3. Contact CDM uses a test head very similar to that used in JS-002, except that the 1-ohm resistor is removed. The coaxial cable, which in JS-002 connects directly to an oscilloscope through an attenuator, instead connects to a 50-ohm switch. The switch leads to either a resistor and high voltage supply or to an attenuator and oscilloscope. During testing, the device is charged slowly to a high voltage, and the switch is then moved to the oscilloscope triggering a discharge. The device's stress current is determined by subtracting a pulse measured without the device from a measured pulse with the device connected.

Contact CDM produces a very repeatable stress to the device being tested. The 50-ohm characteristics of the relay minimize degradation of the measured waveform. An issue with contact CDM is that the impedance that the device sees is 50 ohms, not the much lower impedance of an air discharge.

Capacitively Coupled TLP

Capacitively coupled TLP (CC-TLP) was introduced almost 20 years ago [8] but has been getting increased attention as a potential extension of CDM testing to lower voltage [9]. In CC-TLP, illustrated in Figure 4 Capacitively coupled TLP. A very fast TLP (vf-TLP) system is used to stress an integrated circuit using a special CC-TLP probe. The probe consists of a ground plane connected to the shield of the coax pulse delivery cable. The center conductor of the cable is connected to a probe that extends through a hole in the ground plane and can touch a pin on the device under test (DUT). The DUT is placed on a thin insulator on top of a chuck. To stress the device, a short TLP pulse is delivered to the probe touching the DUT. The capacitance between the DUT and the ground plane provides the return path from the probe back to the outer shield of the vf-TLP's pulse delivery cable. This system can deliver pulses with similar current levels and time durations as a CDM stress. Since the pulse is started with the closing of a relay, the delivered pulses are very reproducible, even at low voltages. Another advantage of CC-TLP is that testing can be done either at wafer level or on a packaged device.

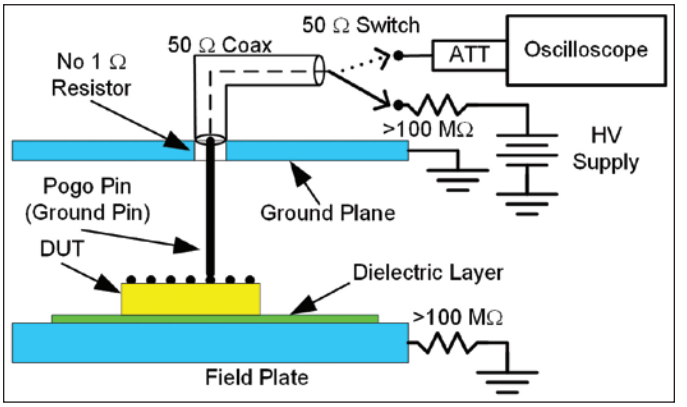

Figure 3: Contact CDM

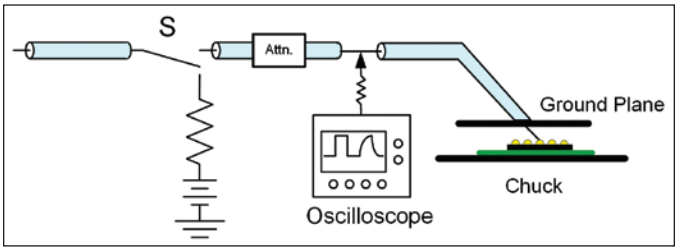

Figure 4: Capacitively coupled TLP

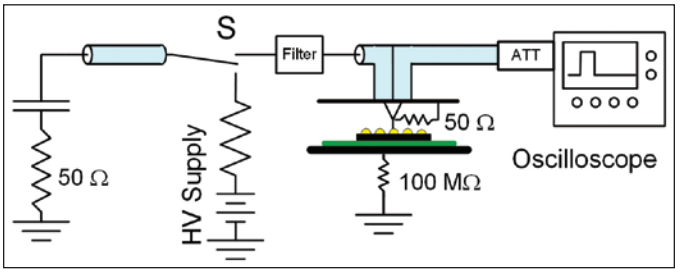

Figure 5: Low impedance contact CDM

Low Impedance Contact CDM

The final candidate for low voltage CDM testing, and one of the most promising, is low impedance contact CDM (LICCDM) [10][11], shown in Figure 5. This system uses a modified version of the JS-002 test head. In this system, a short vf-TLP pulse is passed through a rise time filter which leads to the test head and the device pin being tested. The rise time filter matches the pulse rise time characteristics of JS-002. The capacitor and 50-ohm resistor slow the falling edge of the pulse so that the leading edge dominates the capacitively coupled stress to the device being tested. Also connected to the device pin is a second coaxial cable leading to an attenuator and oscilloscope as well as a 50-ohm connection to ground. Stress pulses are measured by the oscilloscope. Pulses are performed at the same stress levels with and without contact to the device being tested. The stress current to the device can be calculated from the with and without contact pulses and the known 50-ohm impedances of the two coaxial cables and the 50-ohm resistor to ground.

The presence of the two 50-ohm coaxial cables and the 50-ohm resistance to ground means that the device pin sees three 50-ohm impedances in parallel or an impedance of 16.7 ohms. This is very close to the resistance of an air discharge. This implies that the stress to the device should closely resemble a field-induced CDM stress if the peak heights and durations are similar.

WHAT NEEDS TO BE DONE?

In the short term, any of these four methods can provide information for charged device robustness at low voltages, but none of them is universally accepted. The question is how their stress levels compare with the current JS-002 test method. Correlation with JS-002 is important for ESD control engineers so that they understand the level of ESD sensitivity they need to prepare for. The joint JEDEC/ESDA (Electrostatic Discharge Association) CDM Working Group is currently doing extensive comparisons between the JS-002 and the other CDM options, with particular emphasis on LICCDM and CC-TLP.

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Banana Skins

378 Mobile phones can interfere with aircraft systems

Navigation and control instruments can be caused to malfunction. During the approach of an Alitalia aircraft at Turin airport on 31 December, 1995, one of the 160 passengers onboard switched on his mobile phone(picture), thus blocking the plane's autopilot system. There was also interference with the pilot's contact with the control tower.

The conditions were dense fog. The pilot realized what had happened and, displaying a cool nerve, was able to take manual control of the aircraft and land it without further incident. (Source: TT 960103).

(Taken from "Application Areas for MobilePhoneGuard™".)

379 TVs susceptible to the frequency and type of RF modulation

The annex to IEC 61000-4-3 explains that it was decided to use amplitude modulation (of the radiated RF test signal) and not pulse (digital) modulation as the differences were small. However, when testing televisions for immunity to GSM mobile services, the use of a 200Hz modulation was disastrous, and was only solved by using the correct 186Hz signal.

The problem arose because 200Hz was a harmonic of the television frame frequency *(which is 50Hz in the EU – Editor)*. This points to the criticality of such tests, which when viewed in the wider context highlights the impracticability of simulating all digital services during RF immunity testing. So should we be looking at a new approach for RF immunity testing?

(Taken from: "Standards – are we getting what we need" by Peter Kerry, President of CISPR, EMC-UK 05, Newbury, 11-12 October 2005, pages 49-51 in the conference record.)

380 Hunting Radio Howlers – Government Vans on the Track (historical)

The wireless oscillators do not have it all their own way. Re-radiated howls which spoil reception for other listeners are to be tracked down by Government experts employing the latest methods. By the end of this month, the first of the new direction-finding motor-vans will, it is expected, be delivered to the Post Office engineers who are specially concerned with stamping out oscillation. These vans will do their best to work in couples.

The general idea is to listen to any notable howls on frame aerials. A compass bearing is taken of the quarry and the aerial is swung round until the sound reaches a minimum. This gives a still closer reading. Next, the van moves on to another spot and the procedure is repeated. The bearing, naturally, is changed (just as a lamp-post changes it's apparent position as you walk past it).

Finding the 'Lair': When the bearings are plotted out on an ordnance map of the district, you will get two or more lines cutting each other and the spot where they intersect marks the 'lair' of the oscillator, or thereabouts, for an aerial is a length of wire which does not give a very exact 'fix' for this form of land navigation. Two vans, in wireless telephonic touch with each other on a wavelength that does not interfere with broadcasting, can conduct a hunt in quite a short time and the offending listener is eventually run to earth.

(Just to prove that EMI is nothing new, the above item is from the Daily Mail, 21 April 1926, reprinted in Automotive EMC Newsletter 4th June 2006. The problem described was caused by the local oscillators in early 'superhet' radio sets, which could be re-radiated from the antenna or mains wiring and cause interference.)

381 Airport transmissions interfere with some cars on nearby motorway (1)

While towing a caravan south between junctions 24 and 23 of the M1 recently, the turbo of my 29,000 mile Audi A4 TDI suddenly shut down. There were no warning lights or mechanical noises, simply a serious loss of power. I struggled off the motorway and a mobile technician from Audi Assist checked the car the following day. He ran a series of electronic checks but could find no fault other than a "possible" mechanical turbo failure. On

The regular "Banana Skins" column was published in the EMC Journal, starting in January 1998. Alan E. Hutley, a prominent member of the electronics community, distinguished publisher of the EMC Journal, founder of the EMCIA EMC Industry Association and the EMCUK Exhibition & Conference, has graciously given his permission for In Compliance to republish this reader-favorite column. The Banana Skin columns were compiled by Keith Armstrong, of Cherry Clough Consultants Ltd, from items he found in various publications, and anecdotes and links sent in by the many fans of the column. All of the EMC Journal columns are available at: https://www.emcstandards.co.uk/emi-stories, indexed both by application and type of EM disturbance, and new ones have recently begun being added. Keith has also given his permission for these stories to be shared through In Compliance as a service to the worldwide EMC community. We are proud to carry on the tradition of sharing Banana Skins for the purpose of promoting education for EMI/EMC engineers.

the subsequent test run, the turbo was working again and In have completed a further 200 miles without incident. Could the problem have been due to the electronic interference that has previously been mentioned in your column? A.S., Doncaster.

'Honest John' replies: Another reader puts it down to the automatic aircraft landing system at East Midlands Airport. It transmits to planes coming in across the M1 and can apparently interfere with badly shielded car electronics.

(From "South Shields" in the Expert Advice section of the Motoring section of the Daily Telegraph, Saturday August 19, 2006, page 9.)

382 Airport transmissions interfere with some cars on nearby motorway (2)

For many years, automakers have performed electromagnetic compatibility testing of automobiles before their release to consumers. However, as the electronics content of vehicles becomes greater every year, it expands the potential for component or system failure caused by external sources of electromagnetic radiation.

One challenge has come from commercial and military airport radar systems that operate at frequencies from 1.2 to 1.4GHz and 2.7 to 3.1GHz. Cases have been reported in which vehicles near airports and military bases suffered degradation or even failure of critical vehicle systems including braking controls and airbag deployment. As a result, Ford Motor Company and General Motors Worldwide (GMW) have introduced sections in their immunity standards for component testing when exposed to radar pulses, such as those at the 600V/m level.

(Taken from "Required Amplifier Power in Automotive Radar Pulse Measurements" by K. Gove, H-P. Bauer and V. Rodriguez-Pereyra, Evaluation Engineering, *August 2006.)*

Advertiser Index

Upcoming Events

Due to COVID-19 concerns, events may be postponed. Please check the event website for current information.

May 8-11

Asia-Pacific International Symposium on Electromagnetic Compatibility (APEMC)

May 10-13

Applying Practical EMI Design and Troubleshooting Techniques

Advanced PCB Design for EMC & SI

Mechanical Design for EMC

May 10

Chicago IEEE EMC Mini Symposium

May 12

EMC Fest 2022

May 16-19

IEEE International Instrumentation and Measurement Technology Conference (I2MTC)

May 16-19

MIL-STD-810 Training

May 18-19

EMC & Compliance International Workshop

June 13-16

MIL-STD-810 Training

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