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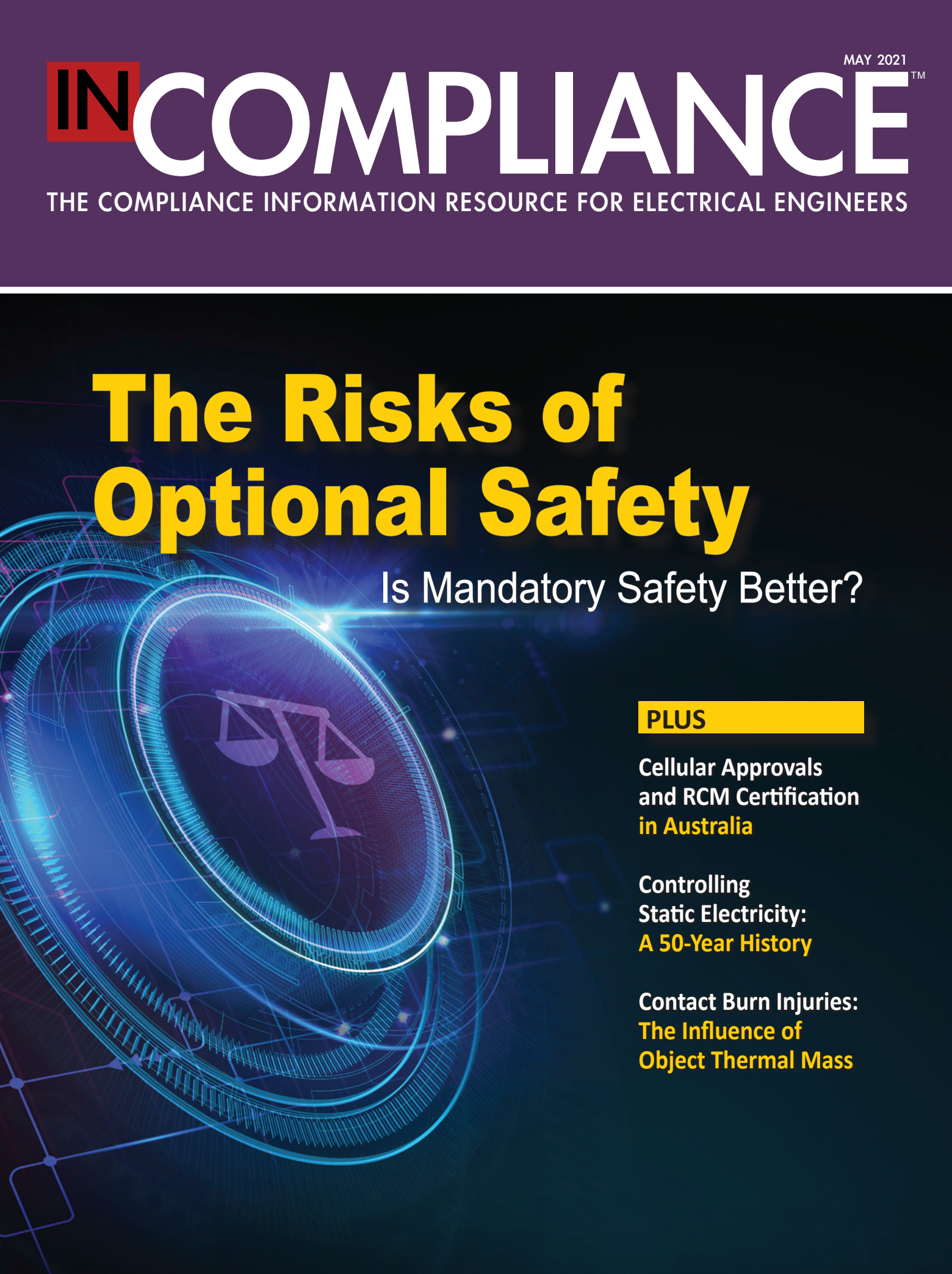

The Risks of Optional Safety

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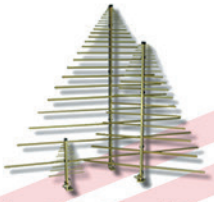

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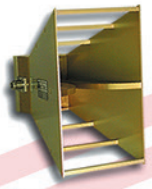

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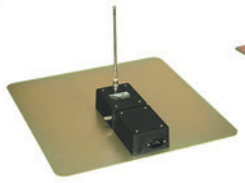

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CONTENTS

FCC Publishes Pirate Radio Enforcement Provisions

The U.S. Federal Communications Commission (FCC) is slated to substantially increase fines against unauthorized radio operations later this month, following the publication of its final rules in late March.

Under the provisions of the "Preventing Illegal Radio Abuse Through Enforcement (PIRATE) Act," the FCC now has the authority to levy fines against unauthorized radio operations of up to $100,000 per violation per day and $2 million in total. The rules cover not just illegal broadcasters themselves but also property owners and managers that house illegal broadcast operations on their premise or that knowingly facilitate those operations.

The final FCC rules under the PIRATE Act were published in the U.S. *Federal Register* on March 25th and took effect on April 26th.

FCC Moves Forward with Efforts to Revoke Authorizations Issued to China Telecom Carriers

The U.S. Federal Communications Commission (FCC) is continuing with its efforts to secure the nation's telecom networks by initiating proceedings that would revoke the decades-old authorization of three telecommunications carriers with ties to China from operating in the U.S.

In a press release issued by the FCC, the FCC named three carriers, China Unicom Americas, Pacific Networks, and ComNet, which it says are owned and controlled by the government of the People's Republic of China.

In response to the substantial evolution of security threats in the past few years, the Commission has raised concerns about the vulnerability of Chinese state-owned enterprises to direct control by the government. Last year, the FCC requested that each of the three companies show cause why the Commission should not revoke their authorizations under its Section 214 authority.

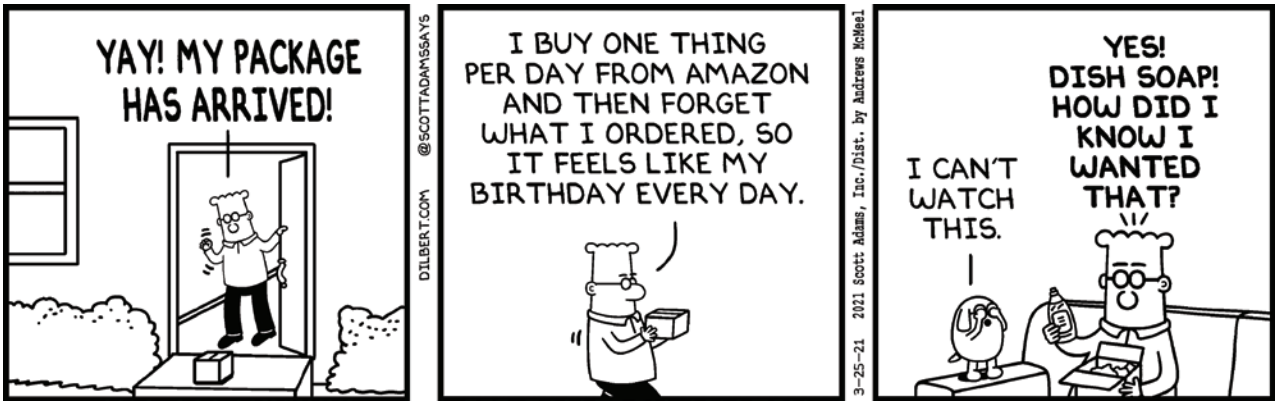
Because each company failed to fully address the FCC's concerns in their respective responses, the Commission decided that, consistent with national security interests, to begin proceedings to determine whether "present and future public interest, convenience, and necessity" justify the revocation of the authorizations previously granted to each company.

Upward Radar Device Submitted to FCC for Approval

A drone technology company has filed a request with the U.S. Federal Communications Commission to approve a new "upward radar" device that can potentially be used in advanced drone-related scanning operations.

According to an article posted on the Drone DJ website, the upward radar device is based on a new technology developed by DJI, an established drone company based in Guangdong, China. It is described in the company's FCC filing as "DXX – Part 15 Low Power Communication Device Transmitter," which operates on the 24.15 GHz frequency.

An FCC test report of the device confirms the basic information contained in the Drone DJ website article, stating that the device is "an Upward Radar…(that) contains a 24 GHz compatible module enabling the user to detect the object from the blindside through a radar detector."



Cell Tower Upgrade Faces Opposition

Some residents in the town of Harvard, MA are opposing a planned upgrade to a cell tower in the town, citing concerns about the safety of electromagnetic radiation.

According to a recent article in the *Harvard Press*, the town's local newspaper, opposition is focused on a special permit requested by a contractor to AT&T to replace old radio equipment on one of the cell towers located within the town and replace it with more up-to-date technology. The company's permit application filed with the town's Planning Board says that the new equipment will not significantly change the appearance of the tower and would not generate any vibrations, noise, or fumes.

However, during a hearing at the Board's February meeting, a number of residents expressed concerns about the increased potential for radiation stemming from the upgrade, as well as the dangers of 5G technology. According to the *Harvard Press* article, one resident claimed that "the FCC approval doesn't mean anything because they aren't doing any health studies, and if they are, they are swaying them in their favor." Another resident implored members of the town's Planning Board to read the arguments against 5G technologies posted on an anti-5G website.

Planning Board Chair Justin Brown, a trained nuclear scientist, reportedly took the opportunity during the hearing to explain the science behind electromagnetic radiation and why the cellphone communications technologies do not pose a risk. He also argued that the basis for the opposition on the part of some town residents was a 2018 study of the effect of radio waves on rats, a study Brown says was severely flawed in its design and its findings.

The Planning Board was expected to vote on the special permit request at recent meeting. As of this writing, there is no information regarding the Board vote. Stay tuned!

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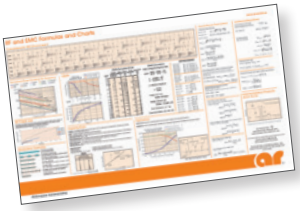

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FDA Releases Catalog of Regulatory Science Tools for Medical Devices

To facilitate the expanded use of innovative science techniques in the development of new medical device technologies, the U.S. Food and Drug Administration (FDA) has published a collection of regulatory science tools that can be used to assess emerging medical technologies for compliance with its requirements.

The Catalog of Regulatory Science Tools was assembled by the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Laboratories (OSEL) and posted to the FDA's website. The Catalog includes details on dozens of methods, computational models and simulations, and phantoms that medical device manufacturers can use to assess their devices for safety and performance.

The FDA says that the Catalog will be expanded and updated as new tools become available. Importantly, the agency also notes that the tools in the Catalog do not replace FDA-recognized standards or qualified medical device development tools.

EU Commission Updates Harmonized EMC Standards for Certain Equipment

The Commission of the European Union (EU) has taken steps to update the versions of certain harmonized standards used to evaluate the electromagnetic compatibility of certain devices and equipment.

In an Implementing Decision (EU) 2021/455, the Commission moved to replace the 2010 edition of EN 55024, *Electromagnetic compatibility – Product family standard for audio, video, audio-visual and entertainment lighting control apparatus for professional use – Part 2: Immunity*, with EN 55035: 2017, *Electromagnetic compatibility of multimedia equipment – Immunity requirements*.

The Implementing Decision also replaces the 2007 edition of EN 60947-5-2, *Low-voltage switchgear and control gear – Part 5.2: Control circuit devices and switching elements – Proximity switches*, with the edition of the standard issued in 2020.

The date of withdrawal for both EN 55024:2010 and EN 60947-5-2:2007 is mid-September 2022.

FDA Posts Biocompatibility Resource Center

The U.S. Food and Drug Administration (FDA) has collected a variety of resources to assist medical device manufacturers in their evaluation of their products for biocompatibility considerations.

Biocompatibility assessment and testing are required for medical devices that come in direct or indirect contact with the human body to determine the potential for an adverse biological reaction to device component materials that could lead to injury or death.

The FDA's new Biocompatibility Assessment Resource Center provides device manufacturers with a step-by-step approach that addresses: 1) biocompatibility basics; 2) evaluation endpoints; 3) test articles; and 4) test reports. The Resource Center also provides links to additional information regarding each of these steps.

The FDA's Biocompatibility Resource Center is intended to supplement the FDA's own guidance on biocompatibility, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'." The FDA also welcomes the submission of general questions about biocompatibility issues, which can be emailed to CDRH.Biocomp@fda.hhs.gov.

FCC Updates Wireless HAC Requirements

The U.S. Federal Communications Commission (FCC) has amended its rules regarding the standard to be used to assess hearing aid-compatible (HAC) telephone handsets.

The Commission adopted the 2019 edition of ANSI C63.19, *American National Standard Methods of Measurement Compatibility Between Wireless Communications Devices and Hearing Aids*, as the standard to be used in assessing HAC-compatible handsets. The revised version of the standard incorporates volume control specifications consistent with HAC certification requirements that were scheduled to take effect on March 1st.

In addition to volume control specifications, ANSI C63.19-2019 also harmonizes its testing methodologies with current available international standards and applies to a wider range of frequencies.

In its Report and Order, the FCC provides for a two-year transition period for manufacturers to adopt the requirements in the updated standard. It also extended the volume control deadline to match this transition period.

THE RISKS OF OPTIONAL SAFETY

Is Mandatory Safety Better?

Kenneth Ross is a Senior Contributor to *In Compliance Magazine*, and a former partner and now Of Counsel to Bowman and Brooke LLP. Ken provides legal and practical advice to manufacturers and other product sellers in all areas of product safety, regulatory compliance, and product liability prevention, including risk assessment, design, warnings and instructions, safety management, litigation management, post-sale duties, recalls, dealing with the CPSC, and document management. He can be reached at (952) 210-2212 or kenrossesq@gmail.com. Other articles by Ken can be accessed at http://www.productliabilityprevention.com.

By Kenneth Ross

We all remember when Sears sold products as "good," "better," and "best." Many times, the more expensive products had better quality and, sometimes, better safety. When airbags were first sold on U.S. automobiles, they were optional. They didn't become mandatory until the U.S. government required it. And even today, you can buy a car with two airbags or some with in excess of ten airbags. It is a rational assumption that the more airbags your car has, the safer it is.

Some reasons for differences in the safety of products include multi-functional uses of the product where some safety devices are not necessary, different price points, requests by customers, adoption of safety improvements, and inconsistent regulations and standards between the U.S. and foreign countries.

The issue of the level of safety to which your products must be designed is intertwined with the two issues that will be discussed in this article. First, is it permissible to sell similar products with different levels of safety? Second, if you do, how do you minimize risk and is it permissible to sell one product with optional safety features? Both issues have generated quite different answers from the courts, making it difficult to decide what to do.

LAW OF DESIGN DEFECTS

The *Restatement Third, Torts: Products Liability (1998) (*hereinafter "Restatement"), which is a good general description of product liability law in the U.S., said that "[t]he emphasis is on creating incentives for manufacturers to achieve optimal levels of safety in designing and marketing products." However, it also said that "[s]ociety does not benefit from products that are excessively safe… any more than it benefits from products that are too risky. Society benefits most when the right, or optimal, amount of product safety is achieved."

The Restatement then sets forth tests that apply to defects in design, and warnings and instructions. The focus is on a "reasonable alternative design" or "reasonable alternative warnings and instructions" that were available at the time of sale or distribution at a reasonable cost, and that their omission rendered the product not reasonably safe.

Since the focus is on a "reasonable alternative," the fact that the manufacturer has or is contemplating selling its products with different levels of safety raises big questions for the manufacturer to ponder.

What is the "right" or "optimal" level of safety? Can I sell safer products within the U.S.? Can I sell safer products in foreign countries because foreign standards require it and sell a less safe product in the U.S.? Can I offer safety devices as options, either in the U.S. or in foreign countries? These are all difficult questions to answer. And, as with many legal questions, there is no clear answer in most situations. Sometimes the answer is based on how much risk the manufacturer is willing to assume.

SELLING PRODUCTS WITH DIFFERENT LEVELS OF SAFETY

In general, many manufacturers and even entire industries sell products with different levels of safety. The automotive industry is the first one that comes to mind.

Small automobiles with the minimum number of required air bags are not as safe as bigger, stronger cars that have many more air bags. In fact, the

Is it ever acceptable for a manufacturer to have a safer alternative design and to offer it to the customer as an option?

safer cars are sometimes marketed as being safer. Considering the general law, isn't this risky?

If these small automobiles comply with all applicable governmental safety regulations, then the manufacturer can argue that the product is reasonably safe. The fact that this manufacturer or other manufacturers can and do make safer products does not diminish the argument.

However, despite compliance with government regulations, a plaintiff can still argue that mere compliance (or, in the case of other products, industry standards) did not result in a reasonably safe product and that it should have been made safer. And proof of the feasibility of the safer design is based on the fact that this manufacturer or another manufacturer sold a safer product in the U.S. or elsewhere.

Any manufacturer needs to anticipate this argument and be prepared to prove that its product was reasonably safe even though there were safer products being offered in the marketplace. Some manufacturers don't want to run the risk of having to defend the adequacy of the less safe product, so instead, they sell the safest version of their product in every market where they do business. This can be difficult if customers do not like the additional safety features, are unwilling or unable to pay for them, or if the safety features are not always required or make the product less usable.

OPTIONAL SAFETY

Taking this one step further, is it ever acceptable for a manufacturer to have a safer alternative design and to offer it to the customer as an option? In a sense, the scenario outlined above involving selling different levels of safety is analogous to an option. With safety options, the consumer is confronted with products that have different safety features and gets to pick which one it wants, needs, and can afford.

But in the relevant cases in this area, the facts are a little different. The manufacturer offers a safety device as an option and puts the burden on the customer to decide whether to purchase it. There are many well-known examples of such products:

- Chainsaws with an optional chain brake
- Table saws with an optional lower blade guard
- A motorcycle with highway bars
- Vehicles with back up alarms
- Vehicles with rollover protective structures
- Safety devices that protect against crane contact with power lines

And the issue could even arise when the consumer can purchase safety accessories made by other manufacturers. Should the manufacturer of the main product be required to include safety accessories such as a bell and light for a bicycle, goggles for a power tool, and a variety of helmets for motorcycles, bicycles, ATVs, skis, etc.?

Who has the responsibility to provide a reasonably safe product – the accessory or product manufacturer, the retailer, the consumer, or the user? When should the option be mandatory? And how far do these entities have to go to inform the purchaser when it is advisable to purchase the option or feature?

The cases arise when the customer is offered, either directly or indirectly, the optional safety device and

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According to the case law, the main rationale to allow a safety feature to be sold as an option is that it only provides safety in certain uses or environments.

rejects it. An accident occurs, and the argument is that the injury would have been prevented if the safety device had been sold with the product and that its omission rendered the product defective and not reasonably safe.

The case law has been fairly fact-specific, but some of the decisions do offer a basis for analyzing the facts after an incident occurs and before sale when a manufacturer decides on whether to make a device mandatory or optional.

According to the case law, the main rationale to allow a safety feature to be sold as an option is that it only provides safety in certain uses or environments. So some purchasers should be able to decide if the option is necessary for their intended use. Making it optional also prevents the purchaser from paying for safety that they don't need and to allow the purchaser to use the product in more situations than it can be used with an option that is mandatory. An example is a crane that is not used near power lines and, therefore, does not need an insulated device to protect against power line contact.

Another way for the manufacturer to deal with the situation is to make the safety device mandatory but removable. The problem with doing this arises when purchasers/users are likely to remove it and never replace it. Then the injured party could argue that there was a defective design and that the guard should have been permanent or at least difficult to remove.

CASE LAW

Unfortunately, the law is "muddled and quite sparse." There are cases on both sides – safety devices can be optional and safety devices should be mandatory – but they provide some useful insights.

An early case on this subject is *Bexiga v. Havir Mfg. Corp.,* 290 A.2d 281 (N.J. 1972) involving a punch press. The New Jersey Supreme Court ruled that the manufacturer was in the best position to install available safety devices on industrial machinery and that these decisions should not be left to purchasers. Therefore, this case has stood for the proposition that manufacturers may not delegate design decisions relating to safety to purchasers.

The key issue, in this case, was that the court believed that the safety device, a two-button on/off switch, was necessary for safety and was feasible and did not make the machine unusable for its intended function. While this switch was not offered as an option, this case started the doctrine that safety is mandatory and that you cannot delegate to the purchaser the responsibility to make the product safe. However, the court would allow a safety device to be optional where the device made "the machine unusable for its intended purpose." A number of courts followed this doctrine.

In 1978, two cases were decided, allowing the manufacturer to offer safety devices as options and placing the burden on the purchaser to determine whether the device was necessary for their use. See *Biss v.Tenneco, Inc.*, 409 N.Y.S.2d 874 (App. Div.1978) (garbage truck without a back-up alarm) and *Verge v. Ford Motor Co.*, 581 F.2d 384 (3d Cir.1978) (V.I. law) (rollover protective structure for a loader). Both cases relied on the expertise of the purchaser in deciding whether the optional devices should have been purchased.

Despite the different conclusions, *Biss*, *Verge* and *Bexiga* held that a safety device can be optional on "multi-functional products if there is no standard

Unfortunately, the law is "muddled and quite sparse." There are cases on both sides – safety devices can be optional and safety devices should be mandatory – but they provide some useful insights.

safety feature that will allow each function to operate unimpeded." Over the years, the courts have enunciated additional factors such as whether the purchaser could install the safety device, whether the hazard was obvious, whether the cost of the safety feature was high, and whether other manufacturers provided the feature as an option.

In 1999, the New York Court of Appeals decided *Scarangella v. Thomas Built Buses,* 717 N.E. 2d 679. The court held that a product that does not incorporate available safety devices is not defective as a matter of law if:

- The buyer is thoroughly knowledgeable about the product and its use;

- The buyer is aware of the availability of the safety device;
- In some normal uses, the product is not unreasonably dangerous without the safety device; and
- The buyer can balance the benefits and risks of not having the safety device during its intended use.

In effect, it is the buyer, not the manufacturer, who is performing the risk assessment that should be performed when designing a product.

The New York Court of Appeals addressed this issue and considered the *Scarangella* factors in *Passante v. Agway Consumer Products, Inc.*, 2009 NY Slip Op. 03588 (May 5, 2009). *Passante* dealt with an optional device that attached a tractor-trailer to a loading dock and provided a warning indicating when it was safe to enter the trailer and when the truck could be safely driven away. The purchaser refused to buy this option, and the plaintiff in the case was injured.

The Court of Appeals ruled 4-3 that the *Scarangella* factors had not been met and that summary judgment was not appropriate. The dissenting judges said that the majority was basically overruling *Scarangella* without specifically saying so and that this would have economic consequences for manufacturers selling into New York who now no longer had a roadmap for dealing with optional safety devices before sale.

PRACTICAL CONSIDERATIONS

Since one tenet of product liability prevention is to try and prevent an accident from happening in the first place, let's see if we can come up with some good practices when dealing with additional safety devices and whether they should be mandatory or optional. The decision should be based mostly on safety, commercial considerations, customer relations, and other non-legal rationales. However, some of the criteria cited in the cases above can help shape a legal rationale for the decision.

First, the manufacturer needs to employ all necessary safety analytical tools before deciding on the original design and warnings and instructions. The base product, without any potentially optional equipment or safer design, must be arguably reasonably safe for its intended use. If there is additional safety equipment that would be operable in most foreseeable uses, then it is probably better to provide it as mandatory equipment and provide a way to remove it or move it out of the way during some aspect of operation. And then, clearly describe in the manual when the safety equipment should be used.

An example of this is passenger-side airbags with on/off switches so that the airbag can be switched off if, for example, you place a child in a car seat in the passenger seat.

When considering making safety devices optional, the manufacturer must consider, in part, industry standards and what other manufacturers of similar products do. Therefore, if all other manufacturers sell a certain safety feature as standard, it would be very hard to justify offering it as an option. And if all offer it as an option, the manufacturer should consider how these other manufacturers are providing information to the purchaser on when it is appropriate to purchase and use the option.

While this may not be the last word on this issue – other manufacturers may not be doing an adequate job of describing the option and when it is to be used – it should be a good place to start the analysis. Another good rule of thumb is to do better than your competitor in providing information about the option and when it is to be used. In that way, if the competitor is not doing enough, at least you can say that you tried to do better.

If the device is going to be optional, the manufacturer wants to be able to point to the factors in *Scarangella* and other cases in establishing a basis for arguing that the purchaser is sophisticated, knowledgeable about the option and the uses of the product, and can make an educated, rational decision as to whether it should be purchased. To help prove that the typical purchaser is sufficiently sophisticated, it might be a good idea to do a random survey of some purchasers to see if they understand the information you have provided and that they have made the "correct" decision on whether to purchase the option and when to use it.

CONCLUSION

Optional safety devices can be tricky. Purchasers don't want to spend money on a device that they don't need in most situations in which they will use the product. And you don't want to make your product cost more than your competitor's product by making the option mandatory out of an overly conservative calculation of potential risk and liability.

Given the sparseness of the case law, it is imperative that you consider the leading cases and what guidance they provide, and also look at when and how such options are handled in applicable standards or by competitors within your industry. Finally, it is imperative that you document the facts and criteria you used to make a final design decision so that it confirms that you considered the ultimate safety of the product during normal intended uses and reasonably foreseeable misuses.

CELLULAR APPROVALS AND RCM CERTIFICATION IN AUSTRALIA

In Australia, all electrical and electronics devices, including cellular modules, need to comply with the requirements of the Regulatory Compliance Mark (RCM). The RCM is of two parts jointly owned by the Australian Communications Media Authority (ACMA) and the Electrical Regulatory Authorities Council (ERAC). Cellular approvals are technically complex and involve all aspects of the ACMA regulations and the ERAC Electrical Equipment Safety System (EESS) RCM certification process.

ACMA RCM REQUIREMENTS

Most recently amended in 2018, the ACMA's standard *TLN: Telecommunications (Labelling Notice for Customer Equipment and Customer*

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By Shaun Reid

Cabling) Instrument 2015 mandates that cellular devices intended for connection to the public mobile telecommunications service (PMTS) must comply with *Telecommunications (Mobile Equipment Air Interface) Technical Standard 2018*, which in turn references AS/CA S042.1, *Requirements for Connection to an Air Interface of a Telecommunications Network – Part 1: General.*

All telecommunications devices, including those utilizing 3G, 4G, 5G, or satellite communications technologies, must comply with the requirements of the latest updated version of the standard issued in 2020. 3G and 4G devices must also comply with the requirements of AS/CA S042.4, *Requirements for Connection to an Air Interface of a Telecommunications Network—Part 4: IMT Customer Equipment.*

The Communications Alliance (the "CA" of AS/CA) Working Committee 94 (WC94) has been established and is currently discussing an update to the scopes of AS/CA S042.1 and AS/CA S042.4, and the introduction of a new Part 5 to the S042 series to address the requirements of 5G technologies. The new and updated standards are likely to be published in the last quarter of 2021.

Compliance requirements for the current AS/CA S042.1 (2020) and AS/CA S042.4 (2018) vary depending on device functionality and the technologies used. Devices such as remote dataloggers, where the cellular and/or satellite functionality are only used for data transfer, are the simplest devices to assess for conformity. But requirements for even these simple devices vary depending on technology (i.e., satellite, 3G, 4G, Cat M1, or NB-IoT) and the frequency bands used (e.g., Band 5 devices must comply with U.S. Federal Communications Commission (FCC) Part 22 requirements).

Complexity increases when voice functionality is introduced. The least complex assessment is for walkie-talkie type devices, where the device is restricted to a preconfigured call group and does not operate in a standard telephone service (STS) access mode. STS access mode allows devices to make cellular or satellite calls to other devices (cellular, satellite, or landlines).

Additional requirements apply to the devices operating in an STS access mode. Cellular and satellite devices must be assessed to confirm their emergency service access and their handling of emergency calls to the national emergency service numbers 000, 112, and 106. Test calls for satellite services are limited to 000 (the general emergency service number), whereas cellular devices additionally include 112 (the alternative emergency service number for digital mobile phones). Test calls are performed with the device in multiple configurations, such as various lock states, with and without SIM, and using manual and/or soft keys.

Devices capable of both satellite and cellular functionality are required to comply with the requirements of each service. Additionally, if a device is incapable of operating in STS access mode but can provide these services to another device through a local port and/or RF interface, the gateway device is subject to the requirements of each provided service.

AS/CA S042.1: 2020 introduced advanced mobile location (AML) testing. Test calls made to the emergency service numbers 000 and 112 by a device supporting AML and GPS functionality now require contacting the emergency call person (ECP) to confirm that the device information and location data was received correctly.

Devices used in close proximity to the ear for voice communications in a typical handset style or a headset are also required to comply with the maximum sound pressure level output requirements to confirm that the device will not cause acoustic shock to the user. Devices used in a speaker phone or walkie-talkie style where the device is not used near the ear in a typical handset style are not required to undergo this testing.

To reflect the importance of emergency service access and acoustic safety, AS/CA S042.1 for devices that are used to supply a standard telephone service (STS access mode) is treated as a high-risk standard, and the test report must be endorsed by an accredited facility.

The requirements of Part 4 do not vary as much as those in Part 1. Most devices coming to market are integrating pre-certified modules from well-known manufacturers. The test reports and declarations for these modules are usually available from the module manufacturer and passed on to testing laboratories for use in the telecommunications assessment. These reports are used to demonstrate the RF compatibility, network integrity, and interoperability with the STS of the module and host device.

A common misconception with host device manufacturers is that these module reports are enough to establish conformity for their device to AS/CA S042.4. However, the standard refers to the device undergoing assessment as "customer equipment," not the cellular module itself.

It is understood that the ACMA's position is that device manufacturers integrating a pre-certified module (with suitable evidence of conformity for Australian requirements) are not expected to re-establish the RF compatibility, network integrity, and interoperability with the STS conformance of the module. However, the integrated host device must be assessed for radiated spurious emissions to determine that integration into the host device and antenna configuration used has not caused any unintentional emissions from the module that exceed the limits.

AS/CA S042 Part 1 and 4 assessments mainly requires gathering documentation, including the following information:

S042.1:2020 General

- Testing for emergency service access and AML (if applicable)
- Testing for audio acoustic safety (if applicable)
- Manufacturer's Declaration of Conformity (DoC) for mobile identity requirements
- Warning notice requirements

S042.4:2018 3G/4G Devices

- The cellular module test reports to FCC Part 22 Rules; or FCC/TCB Grant of Equipment Authorization based on FCC ID/Manufacturer's DoC.
- The cellular module test reports to ETSI EN 301 908, Parts 1, 2, and 13 (as applicable); or EU-type examination by a Notified Body (NB)/ Manufacturer's DoC, based on conformity assessment procedures described in the EU's Radio Equipment Directive (2014/53/EU, also referred to as the RED).
- Manufacturer's DoC stating compliance with mandatory requirements of the core protocol specifications as per applicable ETSI technical standards.
- Radiated spurious emissions test report on the final integrated/composite customer equipment.

A National Association of Testing Authorities (NATA)-accredited report is largely accepted as proof of compliance by the ACMA and the Australian telecommunications industry. NATA is a signatory to the ILAC Mutual Recognition Agreement (MRA). Therefore, a report accredited by an equivalent accreditation body is also acceptable. A Certification Body Statement (CBS) by an ACMA Certification Body is not mandatory but a NATA (or equivalent) endorsed report may be used to obtain one.

OTHER ACMA REQUIREMENTS

The ACMA requirements also include EMC, EMR/SAR, Radiocommunications, and Electrical Product Safety as follows:

EMC Compliance

For most telecommunication devices, the most common standard is CISPR 32, *Electromagnetic compatibility of multimedia equipment – Emissions requirements*. As the title suggests, this standard relates to multimedia equipment (IT, audio, video, broadcast receivers, entertainment lighting control equipment, or any combinations). EN/IEC 61326-1, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*, is another common standard as it relates to measurement, control, and laboratory equipment (e.g., dataloggers).

For equipment used in vehicles, UN ECE R10, *Electromagnetic Compatibility*, is usually applicable.

Where multiple standards are applicable, the ACMA advises selecting the standard that best matches the main purpose of the product.

EMR/SAR Compliance

The ACMA standard, *Radiocommunications (Electromagnetic Radiation – Human Exposure) Standard 2014*, is the applicable standard for electromagnetic radiation (EMR) and specific absorption rate (SAR) compliance. If the integral antenna of the device is greater than 20 cm from a human body, e.g., a wireless router, compliance with the ACMA EMR standard requires an assessment of the radio frequency (RF) exposure levels performed in accordance with AS/NZS 2772.2:2016, *Radiofrequency fields – Principles and methods of measurement and computation – 3 kHz to 300 GHz*.

International human exposure assessments (FCC Part 2.1091, RSS-102, EN 62311, etc.) provide useful information for the AS/NZS 2772.2 assessment, but only AS/NZS 2772.2 is accepted as evidence of conformity for the ACMA EMR standard.

For the ACMA standard, the human body includes only the torso, neck, and head, and not limbs such as arms and legs.

If the device has an integral antenna and is normally used within 20 cm of a human body, a NATA (or equivalent)-endorsed SAR test report is required. SAR must be measured in accordance with methods described in EN 62209-1 (at the ear) and EN 62209-2 (at the body). All bands and all radio transmitters must be assessed. If simultaneous

operation via telecommunications (3G/4G), and/or radiocommunications (Wi-Fi/Bluetooth) is possible, SAR measurements must be conducted with the device in a simultaneous transmission mode.

The exposure levels are assessed against the reference limits for occupational and general public exposure (as applicable) as defined in the recently released ARPANSA RPS S-1 (February 2021).

European EN 62209 SAR reports must state compliance with the performance requirements of the ACMA EMR Standard 2014. FCC SAR reports are not acceptable for ACMA compliance purposes.

Radiocommunications Compliance

Bluetooth, Wi-Fi, and NFC transmitters must comply with ACMA Radiocommunications (Compliance Labelling – Devices) Notice 2014 as per the short-range devices (SRD) standard, AS/NZS 4268:2017, *Radio equipment and systems – Short range devices – Limits and methods of measurement*. EU RED reports showing compliance with EN 301 893 (5 GHz Wi-Fi), EN 300 328 (Bluetooth and 2.4 GHz Wi-Fi), EN 300 220 (25 MHz to 1 GHz), and EN 300 330 (9 kHz to 25 MHz) can be used to show compliance with AS/NZS 4268. In most instances, a CE RED radio report or an FCC radio report may be used to show compliance to the requirements of AS/NZS 4268.

Electrical Product Safety Requirements

The ACMA TLN requirements mandate that satellite/3G/4G devices must comply with the Telecommunications (Customer Equipment Safety) Technical Standard 2018 (AS/NZS 60950.1:2015, *Information technology equipment – Safety*, or AS/NZS 62368.1:2018, *Audio/video, information and communication technology equipment – Safety requirements*). The Customer Equipment Safety standard is classified as a high-risk standard, and test reports must be NATA or equivalent endorsed.

AS/NZS 60950.1 has been superseded by AS/NZS 62368.1 and the transition period ends on 15 February 2022. For those targeting CE marking compliance as well, AS/NZS 62368.1 with EN variation testing is the preferred option as EN 60950-1 is no longer accepted for CE marking.

For devices where the intended application is such that the ingress of water is possible, the electrical safety standards require an ingression protection (IP) test report to IEC 60529:2004, *Degrees of protection provided by enclosure (IP Code)*, to a declared IP rating.

Although the Telecommunications Customer Equipment Safety standard mandates AS/NZS 60950.1 or AS/NZS 62368.1, there may be additional relevant electrical safety product standards. The EESS defines products as being in-scope and not in-scope. Suppliers of electrical safety equipment that are not in-scope still have a responsibility to ensure their products are electrically safe. AS/NZS 3820, *Essential safety requirements for electrical equipment*, provides the essential safety criteria for electrical equipment and requires evidence of conformity to the relevant product standard to be held.

In-scope products are classified as risk level 1, 2, or 3. Risk levels 2 and 3 are defined in AS/NZS 4417.2, *Regulatory compliance mark for electrical and electronic equipment – Specific requirements for particular regulatory applications*. Products not defined in the standard are classified as Risk Level 1 and are low or unknown risk.

One point of note for international suppliers or manufacturers is that the ACMA requires a local Australian representative such as the supplier, importer, or an agent (someone in Australia who acts on behalf of a manufacturer or importer) for their RCM compliance declaration. However, agents cannot be registered as Responsible Suppliers under the ERAC/EESS.

ERAC EESS RCM REQUIREMENTS FOR CHARGER/POWER ADAPTERS

The applicable standard for electronic or ferromagnetic power supplies or chargers for use with IT, audio, and video equipment is AS/NZS 60950.1:2015 as per the in-scope electrical equipment definitions and risk levels for

the Electrical Equipment Safety System (EESS) document published by the EESS. This document is a freely available alternative summary of the class 2 and 3 applicable standards available in AS/NZS 4417.2.

An accredited test report (NATA or equivalent) to the applicable Australian safety standards is required to obtain electrical authority approval and certification for chargers/power adapters. Assuming an Australian approved plug and cord set is provided, the local supplier or importer into Australia must prepare and submit for electrical authority approval, application, and certification, pay fees, obtain approval number, and register the charger/adapter on the ERAC national database.

It is recommended that an Australian-approved (ERAC registered) OEM charger be used (must be sourced in Australia) to eliminate testing, certification, and registration costs. An EMC report to AS/NZS CISPR 32 or EN 55032 is also required for the charger if sourced separately.

An external power supply used as a charger is required to meet the minimum energy performance standards (MEPS) and needs to be tested to AS/NZS 4665.1:2005, *Performance of external power supplies – Part 1: Test method and energy performance mark*, and registered in the Equipment Energy Efficiency (E3) database.

Existing report to AS/NZS 60950.1:2015 or AS/NZS 62368.1:2018 will be suitable if the report of the testing is NATA- (or equivalent-) accredited. CB reports or reports to IEC 60950 or IEC 62368 that include Australian variations are also acceptable.

CONCLUSION

The compliance requirements for cellular devices that connect to the mobile phone networks in Australia involve all aspects of the ACMA technical regulations including EMC, telecommunications, electrical safety, radiocommunications, electromagnetic radiation (EMR/SAR), and the ERAC regulations for chargers and power adapters. Most information on the technical requirements is readily available on the respective regulatory body websites.

CONTROLLING STATIC ELECTRICITY: A 50-YEAR HISTORY

The recognition and control of static electricity today has benefitted from a continuously evolving approach

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By David E. Swenson, John Kinnear, and the ESDA

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It is well understood that static electricity has been with us forever. Our awareness of problems associated with static electricity probably originated with the invention of gun powder when, no doubt, there were some mysterious ignitions that took place during chemical blending operations that could not be explained at the time.

The manifestation of static electricity problems in an industrial setting likely began with Gutenberg's invention of the automatic printing press in 1440.[1] Paper and velum (two different materials) sticking together had to be an issue. Somewhere along the line, it was likely observed that a fire burning in the vicinity of the printing press could magically make the paper less sticky. Flame treatment was used in industrial printing presses back then and in newspaper printing presses well into the 1950s, and perhaps even longer in some areas.

Static control has been practiced in munitions, modern pyrotechnics, petroleum processing, and other industries dealing with explosive and flammable materials for a long time. The grounding of process tools, equipment, and personnel has been practiced since Ben Franklin's time.

The industry we are primarily dealing with today, electronics, did not report any significant static electricity-related issues until the later stages of the 1960s. Changes in the resistance values of some shipments of carbon resistors appear to be the first reported issue associated with static electricity in any electrical or electronic-related products. The development of metal-oxide-semiconductor (MOS) devices caused many issues in the early days of modern electronics manufacturing. Early advances in disk drive technology and the manufacture of read-write heads were almost brought to a stand-still in companies due to the fallout from static damage.

THE ORIGINS OF MODERN STATIC CONTROL EFFORTS

Our review of the history of modern static control begins in the late 1960s. The first materials used for static control then were carbon-filled conductive plastics and organically treated plastics that created low charging materials (known as antistatic materials at the time). These materials were distinctly different in performance and application requirements. When these material types were used in combination for packaging electronic parts for storage and shipment, they made a highly effective static control packaging product. But this happened infrequently due to the competition between the companies that made these materials.

Grounding systems for people were already available, with innovators coming up with new concepts in wrist straps and shoe grounding devices. Varieties of these systems and concepts had been used for a long time in munitions and chemical processing facilities, but they were somewhat cumbersome and uncomfortable to use in the typical electronics assembly operation. The new designs were lighter in weight and easier to use, so they became the first line of static control in the growing electronics industry.

Special worksurfaces and flooring materials began to enter the marketplace in the middle 1970s and helped to establish what we know today as the electrostatic protective area.

Special worksurfaces and flooring materials began to enter the marketplace in the middle 1970s and helped to establish what we know today as the electrostatic protective area or EPA. At about the same time, standards for military and defense-related applications entered the market, which helped support the development of industry specifications for the workplace and packaging materials. Damage to electronic parts was becoming a significant reliability issue in the later part of the 1970s. In fact, the first EOS/ESD Symposium was convened in Denver in 1979 to discuss the issues of the time, predominantly those dealing with military electronics.

Packaging innovations eventually led to the invention of transparent static shielding films used to make protective static discharge shielding bags. By the early 1980s, these film materials became ubiquitous throughout the electronics industry, and the need for further electronics packaging standardization became more obvious. In response, several industry groups emerged around that time. Leading the way was the Electronics Industry Association (EIA), which established the Packaging of Electronics for Shipment committee (PEPS). The EIA PEPS Committee ultimately drafted EIA-541–1988, *Packing Material Standards for ESD Sensitive Items*, the first commercial standard devoted to packaging materials used in the storage and shipment of ESD susceptible electronic devices.

THE ROLE OF THE ESDA IN STANDARDS DEVELOPMENT

The EOS/ESD Association, Inc. (ESDA) was formed in 1982, following the success of the initial EOS/ESD Symposiums. The founding members of the ESDA naively believed that the Association and its annual Symposium would be needed for just a few years, after which it could be disbanded. But this turned out not to be the case, and plans are now in the works for the 43rd EOS/ESD Symposium, currently scheduled for September 2021.

The ESDA formed its own Standards Committee in 1982 and immediately started work on Standard #1, *Wrist Straps*, since that was viewed as the front line of protection at the time. That standard served as the foundation for the development of other standards, standard test methods, standard practices, and advisory documents over the ensuing 40 years that have helped establish specifications for most of the products used for static protection and mitigation. And the emergence of automated handling and assembly operations has required the development of new ESD control standards and test methods to manage static electricity developed within such equipment.

The period from the late 1980s to the late 1990s saw a massive amount of work in standardization. Just about all the static control products available today were the subject of some level of standards activity during that period. Over time, many of the ESDA's standards, test methods, standard practices, and technical reports have been reviewed and revised several times since their original release. Today, the standards development effort within the ESDA is still going strong, with the participation of 200 active members worldwide.

THE SHIFTING LANDSCAPE OF STATIC CONTROL EFFORTS

During the same period, the electronics industry shifted major portions of its manufacturing activities to locations around the world. Large factories employing thousands of people for manual assembly operations were established. But there was

As the electronics industry created standards and materials to control static electricity, measurement tools were needed to validate the materials and to evaluate the manufacturing processes.

a steep learning curve in efforts to produce high reliability in device fabrication (wafer fabs), circuit board assembly, and equipment assembly. Large offshore factories with huge numbers of employees required extensive training, massive installation of electrostatic protection products and materials, and frequent travel by corporate-based management and technical staff to oversee product control and maintain quality.

The development of local expertise to manage static control issues became a priority in the late 1990s to the early 2000s, and many of the current members of the ESD Association represent companies and operations from outside of the U.S. Arguably, the most far-reaching static control standards activity occurred in 1995 when the U.S. Department of Defense (DoD) formally asked the ESD Association "to take the lead" in the development of a new, state of the art, ESD control program standard for commercial and military users. That effort ultimately led to the introduction of ANSI/ESD S20.20–1999, *Protection of Electrical and Electronic Parts, Assemblies and Equipment (Excluding Electrically Initiated Explosive Devices)*, which was quickly adopted by the DoD and several branches of the military.

Around 2000, DNV, an ISO 9001 Certification Body, proposed that the ESDA adopt a facilities audit program in connection with ANSI/ESD S20.20, eventually leading to the ESD facility certification program. Today, there are several hundred certified facilities around the world. Other certification programs were developed subsequently to that initial effort, most notably the ESD Certified Professional Program Manager certification and the ESD TR53 Certified Technician certification.

THE EMERGENCE OF STATIC CONTROL MEASUREMENT TOOLS

As the electronics industry created standards and materials to control static electricity, measurement tools were needed to validate the materials and to evaluate the manufacturing processes. Original validation equipment typically consisted of a high resistance meter, called a megger, and an

electrostatic field meter. The megger was designed for measuring the electrical system to ground (or insulation) resistance. The typical voltages first used for measurement were 500 to 1000 volts. As materials to control static electricity and the standards to measure them were further developed, resistance measurement voltages were revised to 10 and 100 volts to create more measurement sensitivity and to help ensure that the materials and products could perform their intended function in an EPA.

The evaluation of static control materials at low relative humidity also has become a requirement to make sure the product maintains its specifications and performance attributes at the lowest environmental moisture condition expected. Electrostatic voltmeters were developed along with a device called a charge plate monitor to measure ionization.

THE CHALLENGES OF AUTOMATED PRODUCTION

The emphasis today in comparison to the early days relates to automated electronics processing. It is well understood that personnel must be grounded all the time when handling unprotected susceptible items. The most significant change in the grounding of personnel has been the increased reliance on footwear and flooring. Wrist straps are still used by the millions every year since they are a requirement for seated operations in the ESD Control Program development standards ANSI/ESD S20.20 and IEC 61340-5-1, *Electrostatics-Part 5-1: Protection of Electronic Devices from Electrostatic Phenomena – General Requirements*.

Footwear and flooring test methods now have significant importance since mobile personnel are required to operate and maintain automated process equipment and assembly lines. The electrical resistance to ground and voltage of personnel while in motion are important considerations for the modern EPA. The instrumentation for measuring and recording voltage on people has become arguably the most essential tool in the ESD control practitioner's toolbox.

Testing device susceptibility to ESD events has been the subject of standardization for well over 50 years. For a long time, separate industry standards existed for the evaluation of the human body model (HBM). Today, the HBM requirements and specifications have been harmonized into a single harmonized HBM standard through a joint effort between the JEDEC Solid State Technology Organization and the ESDA.[2]

Similarly, the susceptibility of devices during automated handling have been harmonized in a joint charged device model (CDM) standard.[3] The ESD susceptibility test method known as machine model (MM) has been dropped as a device qualification standard since the damage mechanism is much the same as HBM, only at a lower threshold.

Over the last 5-8 years, there has been further development to connect device testing specifications and susceptibility levels to what happens in the factory during production. What is called "process assessment" has become one of the important activities of the ESDA standardization activity.

The effort is providing test methods and techniques for the evaluation of electrostatic charging and ESD events within automated handling equipment. One technical report is now available,[4] and a standard practice[5] will be released in early 2021.

These documents, along with new measurement tools such as the high impedance contact voltmeter and event detector devices, will provide knowledgeable practitioners with valuable tools and insight for the evaluation of automated handling equipment capabilities. The question "what device sensitivity/susceptibility level can my process handle?" will be easier to answer using the new documents and new tools.

CONCLUSION

The physics of electrostatics has not changed over the decades, but the ability to measure and protect from the phenomenon certainly has. Materials science and innovation have led to vast improvements in products used to control static electricity in the workplace. ESD standards and test methods have brought a level of understanding into an area that was once considered "black magic."

ENDNOTES

1. Childress, Diana, *Johannes Gutenberg and the Printing Press*, Minneapolis: Twenty-First Century Books, 2008
2. *ESDA/JEDEC Joint Standard – For Electrostatic Discharge Sensitivity Testing – Human Body Model (HBM) Device Leve*l, ESD Association, 7900 Turin Road, Bld. 3, Rome, NY 13440, 315-339-6937, http://www.esda.org
3. *ESDA/JEDEC Joint Standard – For Electrostatic Discharge Sensitivity Testing – Charged Device Model (CDM) Device Level*, ibid
4. *ESD TR17.0-01-14 ESD Association Technical Report – For Electrostatic Discharge Process Assessment Methodologies in Electronic Production Lines – Best Practices Used in Industry*
5. *ESD Association Standard Practice – For the Protection of Electrostatic Discharge Susceptible Items – Process Assessment Techniques*, ibid (not published at time of this writing but coming soon)

CONTACT BURN INJURIES

The Influence of Object Thermal Mass

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

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, where it received recognition as the Symposium's Best Paper. It is reprinted here with the gracious permission of the IEEE. Copyright 2021 IEEE.*

Part II of this paper, "The Influence of Object Shape, Size, Contact Resistance, and Applied Heat Flux", *is available through the IEEE Explore archives at http://www.ieeexplore.ieee.org.*

The skin is made up of three distinct layers. The top layer of the skin that does not contain blood vessels and functions as the protective barrier of the skin is called the epidermis. The layer underneath the epidermis is called the dermis and contains blood vessels and nerve endings. Under the dermis is the subcutaneous fat also known as the hypodermis. Basal skin cells are located underneath the epidermis and are responsible for the generation of new tissue.

A first-degree burn occurs when there is partial necrosis of the epidermis, which presents itself as a reddening of the skin due to dilation of superficial blood vessels near the epidermis. A second-degree burn occurs when there is complete necrosis of the epidermis without damaging the dermis and presents itself as blistering of the top layers of skin. A third-degree burn is when there is necrosis of the epidermis and at least 75% of the dermis. In order for a contact skin burn to occur, heat from the contracting hot object needs to travel through the epidermis and dermis and increase the tissue temperatures for a sufficiently long period of time in order to reach the dosage threshold for a burn.

The seminal work of Henriquez and Moritz [1] and Stoll and Green [2] summarized the relation between contact temperatures and contact durations to cause human skin to become necrotic. They also defined mathematical functions that can be used to assess thermal damage to the human skin.

The regulatory standards [3,4,5] provide guidance on burn threshold surface temperature and contact duration limits. The ISO 13732 standard assumes the surface temperature of the object remains constant after contact with the tissue while the ASTM standard recognizes that the temperature at the surface- skin interface drops when it comes in contact with tissue; however, all the standards assume the temperature of the touched object distal to the contact point stays constant. This means the skin-object interface temperature is transient only during the initial time of contact and then is constant for the duration of the contact. This results in a time vs. burn threshold curve as shown in Figure 1 on page 32 from the ISO standard.

The ASTM standard leverages a similar burn threshold curve, only allowing for an offset of the curve to account for internal resistance between the heat source and surface of the device. For short contact durations, touching objects of different materials with the same surface temperature cause burn injury at different times. Materials of high thermal conductivity such as metals produce burn injury in shorter contact durations due to high heat conduction rates causing the skin to exceed the threshold thermal dose.

The standards ascribe that the curve needs to be modified according to surface finish and material; however, according to the standards, at long

contact times burn injury is always predicted regardless of material, finish, or other factors such as the size of object; 43°C is the "infinite" contact touch temperature limit. This "infinite" 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 which are becoming more common in the consumer electronics industry and wearable devices.

The determination of the thermal damage to the skin depends on tissue temperature and the duration of the thermal exposure. One of the commonly accepted methodologies relies upon the concept of cumulative equivalent minutes at 43°C (CEM43°C) [6]. 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 summarize the relation between CEM43°C values and 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 [1]. The skin of humans and pigs has been shown to have a CEM43°C thermal damage threshold ranging between 300 and 600 minutes [1]. That is, the thermal damage of the skin is likely to occur when the basal layer of the skin experiences temperatures of 43°C for a time duration ranging between 300 and 600 minutes.

MODEL

In order to understand the influence of the thermal mass of an object and its propensity to cause a skin

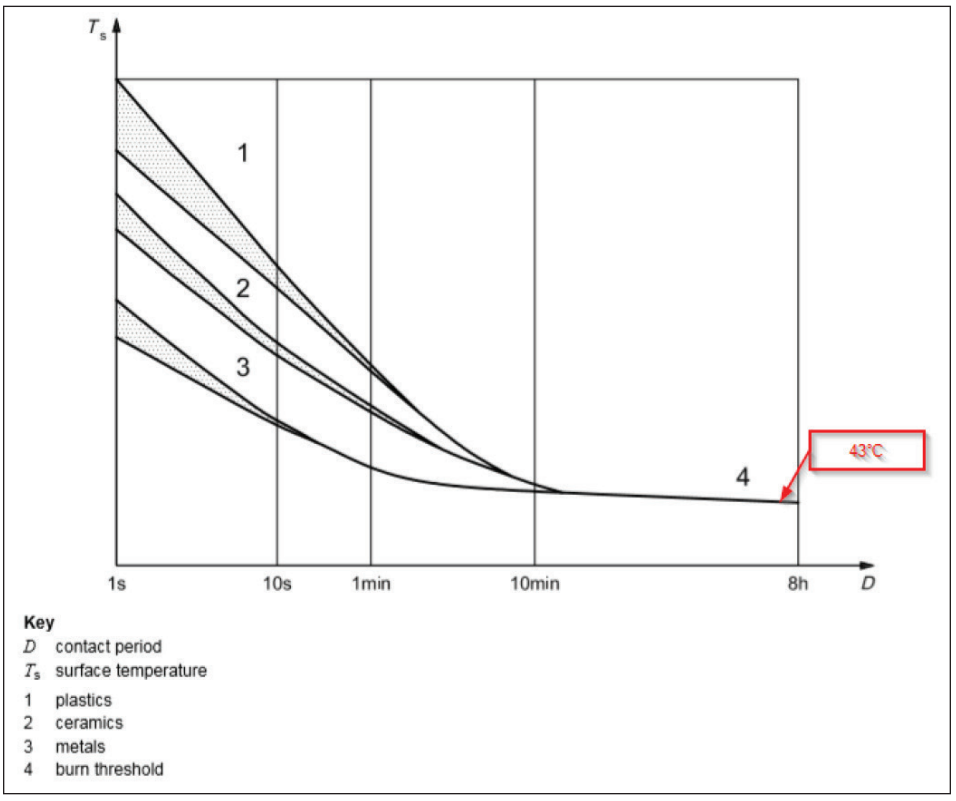


Figure 1: General relationship between burn threshold and contact according to the ISO 13732 standard [3]

burn, a 2D heat transfer model was developed. This model solves for the conduction of heat from a hot contacting object into human tissue layers. The Pennes bioheat equation [7] seen 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 seen in Equation 1. The threshold for burn injury is defined by when the tissue reaches a critical CEM43°C of 600 minutes, based upon validation with the human skin burn data of Henriquez and Moritz and the Stoll and Green data [1][2].

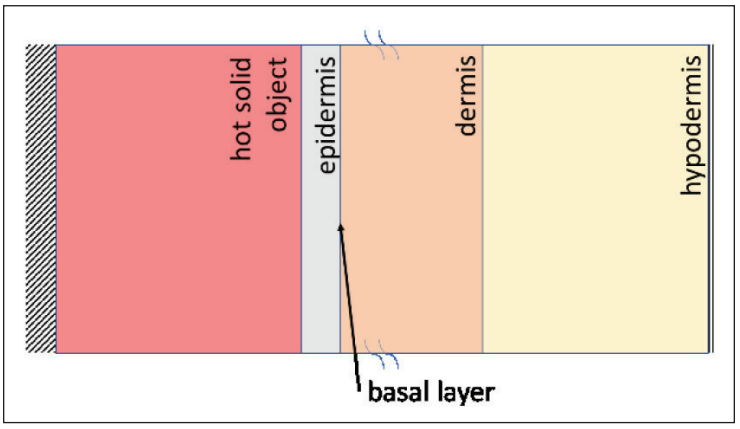
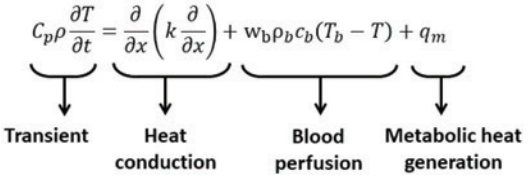


Figure 2: Skin and contacting object geometry implemented in the numerical model

In these computations, a finite thickness object is placed into contact with the skin which is composed of an epidermis, dermis, and hypodermis. The contact between the hot object and the skin is assumed to have zero contact resistance. The non-contacting surface of the hot object was considered to be adiabatic. These two assumptions provide conservative results, that is, higher temperature levels experienced by the tissues provided that there is no heat generation in the contacting object. Multiple computations with varying initial object temperatures are carried out for several object thicknesses. The first set of computations are performed with an aluminum object and the second set using a plastic object. Burn injury thresholds based on initial object temperature, exposure time, and thickness are shown and discussed in the Results section of this paper.



Eq. 2

Pennes bioheat equation [7]

MODEL VALIDATION

The model was validated using the experimental data of Henriques and Moritz [1] and Stoll and Green [2]. The Henriques and Moritz study used a 1" diameter hot water applicator at temperatures ranging from 44°C to 70°C for different durations on human and pig skin. Hot water of a fixed temperature was continuously circulated throughout the applicator in order to keep the water temperature constant – essentially acting as an infinite thermal mass. The level of damage for each of these cases is evaluated to be fully necrotic (third-degree burn) and partially or reversibly necrotic. Stoll and Green [2] irradiated ink-blackened arms of humans and recorded the time and temperature at which subjects felt pain or developed a threshold blister.

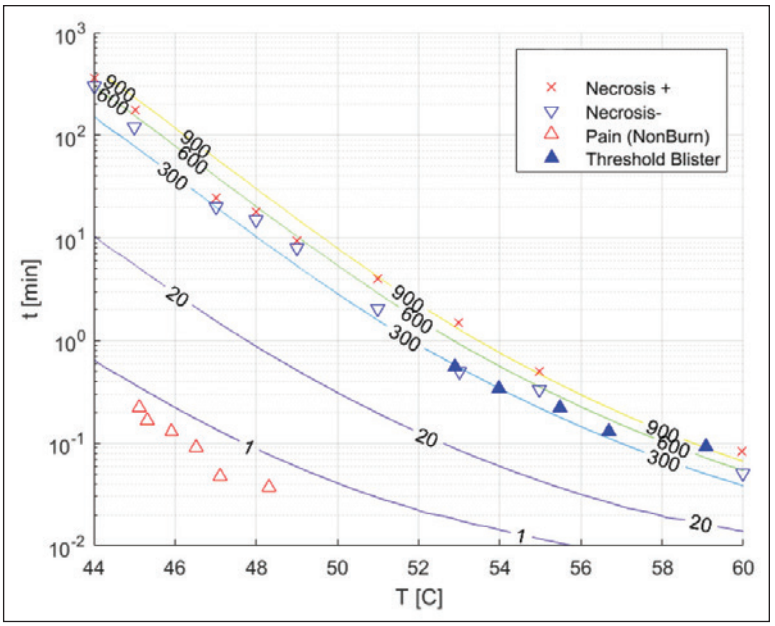


Figure 3: Experimental data [1,2] shown in symbols and isolines of CEM°C obtained from the computational model. Necrosis+ refers to complete epidermal necrosis over the contact area, Necrosis– refers to partial or reversible epidermal necrosis.

The data on human subjects from these studies is shown in Figure 3. The conditions of the Henriques and Moritz experiment are replicated using the 2D axis-symmetric computational model as described in the previous section. In order to replicate the conditions in the hot water applicator used by Henriques and Moritz, a convective boundary condition was used in the region of contact. An

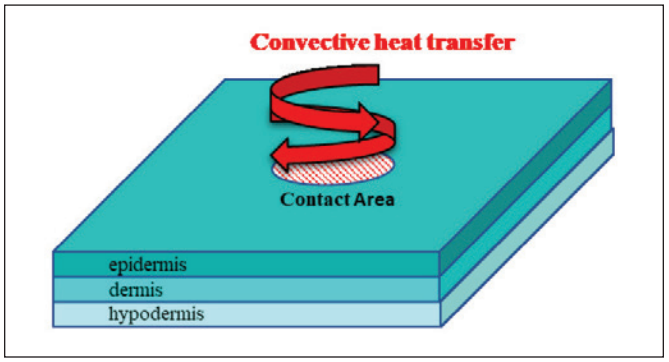


Figure 4: Illustration of computational setup replicating the Henriques and Moritz experimental conditions of a 1" diameter hot water applicator on skin

illustration of the computational setup is shown in Figure 4. CEM43°C isolines are computed using the model and are also plotted with the experimental observations in Figure 3.

The model shows that the threshold of pain without burn injury is predicted to be under 1 CEM43°C. Threshold blisters are observed to occur around where the model predicts a CEM43°C of 300.

First-degree burns characterized as injuries where part of or all of the epidermis had reversible damage is denoted in Figure 3 as Necrosis-. The majority of the first-degree burn observations were predicted between 300-600 CEM43°C. Second- and third-degree burns, denoted as Necrosis+ in Figure 3, are characterized by complete necrosis of the epidermis over the entire contact area. These second- and third-degree burn observations are shown to be mostly predicted by a CEM43°C between 600-900. The model shows that temperature and contact durations that result in a CEM43°C of 600, a burn threshold suggested by the literature, are well aligned with all the relevant experimental observations from Henriquez and Moritz [1] and Stoll and Green [2].

RESULTS

Once validated, the model was used to predict the effect of the thermal mass of the object on the contact temperature thresholds. Two sets of cases with different object materials were analyzed: aluminum and plastic. In order to examine the effect of object size, the thickness was varied from 100mm to 1mm. The material properties that were considered for the object and skin are shown in Table 1.

The initial temperature is 80°C for both the metal and plastic objects. The temperature distributions for four different simulations at 0.1, 1, and 5 seconds are shown in Figure 5, where the temperature is shown on the ordinate and the spatial distance normal to the contact area, x, is shown on the

	Aluminum	Plastic	Epidermis	Dermis
Cp [J/kg-K]	872	1550	3589	3300
Rho [kg/m^3]	2710	1280	1200	1200
K [W/m-K]	203	0.25	0.235	0.445
Thickness [mm]	1, 3, 5, 10, 100		0.08 [4]	2

Table 1: Material properties and thicknesses

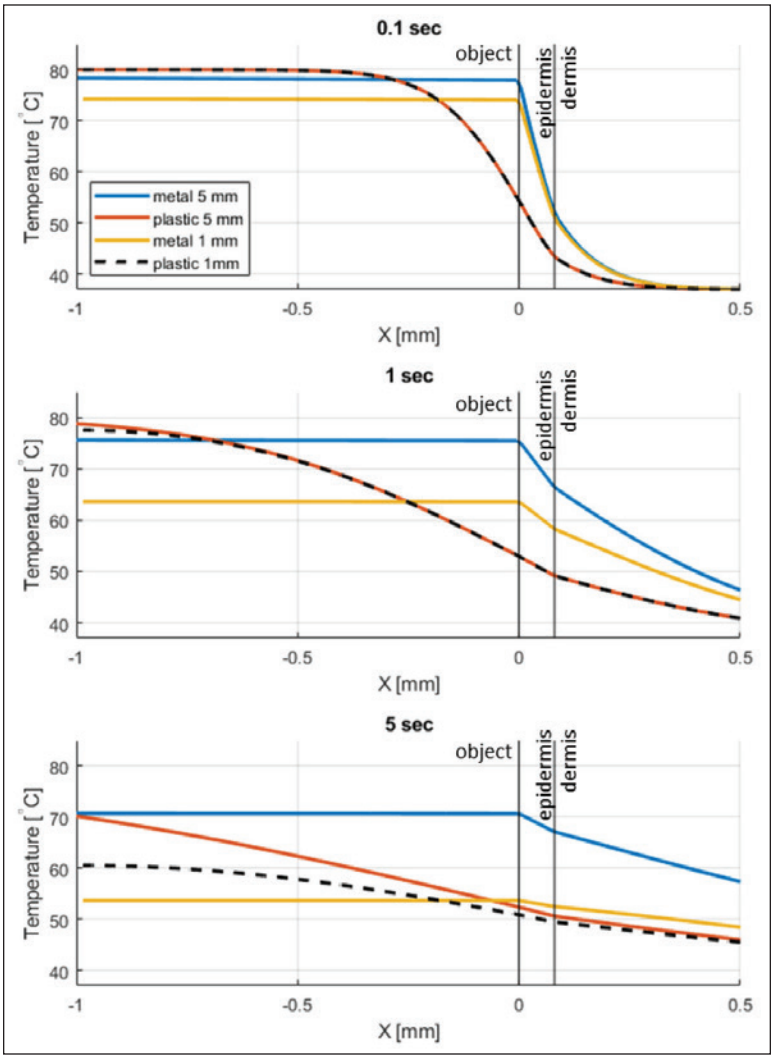


Figure 5: Temperature distributions at 0.1 s, 1 s, and 5 seconds for the four contact scenarios involving 1mm and 5mm thick aluminum and plastic objects at 80°C

abscissa. The object-skin interface, marked by a solid line, is located at an x location of 0 with the object to the left of the origin and the skin to the right of the origin. The basal layer, located between the epidermis and dermis layer, is marked with another solid line at an x location of 0.08 mm.

As expected, the temperature of the skin rises to a higher value when it comes into contact with a metal object due to its higher thermal conductivity when compared to plastics. As a result, the yellow and blue curves in Figure 5 (corresponding to 1 mm and 5 mm thick metal objects) are generally above the red and black curves (corresponding to 1 mm and 5 mm thick plastic objects). The effect of the object thermal mass is evident when comparing the yellow and blue curves corresponding to 1mm and 5mm metal objects, respectively. The higher thermal mass of the 5 mm object results in higher tissue temperatures that persists for longer times.

The effect of thermal mass is less evident for the plastic objects after 0.1 and 1 second exposures, while it becomes more evident after 5 or more seconds. This is due to the low plastic thermal conductivity that causes both plastic objects to behave as thermally thick after at 1 second as the thermal wave has not diffused through the entire thickness of the object. The thermal diffusion time scale is proportional to τ where = L^2/α , L is the thickness of the object, and α is the thermal diffusivity. This leads to diffusion time scales of about 10 s and 200 s for the 1mm and 5mm plastic objects, and 0.01 s 0.3 s for the 1mm and 5 mm aluminum objects, respectively.

The temperature at the basal layer, located between the epidermis and dermis as a function of time, is shown in Figure 6, top. The basal layer temperature is generally higher for contact scenarios involving the metal objects.

As expected, thicker objects also result in higher basal layer temperatures that persist for longer durations. The difference between the basal layer temperature for the 1mm and 5mm plastic objects becomes substantial after about 100 seconds when the two corresponding temperature traces (see purple and orange lines in Figure 6, top) diverge as a result of the difference in thermal mass.

It is worth noticing that the basal layer temperature reaches a peak value immediately after exposure, followed by a decrease due to limited thermal mass of the contacting object that starts to cool down as it transfers energy to the skin. As expected, the peak temperature is much more pronounced for thin objects that have a more limited energy content.

The CEM43˚C of these 4 cases is also shown in Figure 6, bottom. The 5 mm metal object heats the skin quickly and the CEM43˚C value of 600 is quickly exceeded, predicting a burn injury immediately upon contact. A similar behavior is observed for the 1 mm metal object where the CEM43˚C threshold is exceeded after 1 second. Interestingly, the decrease in the basal layer

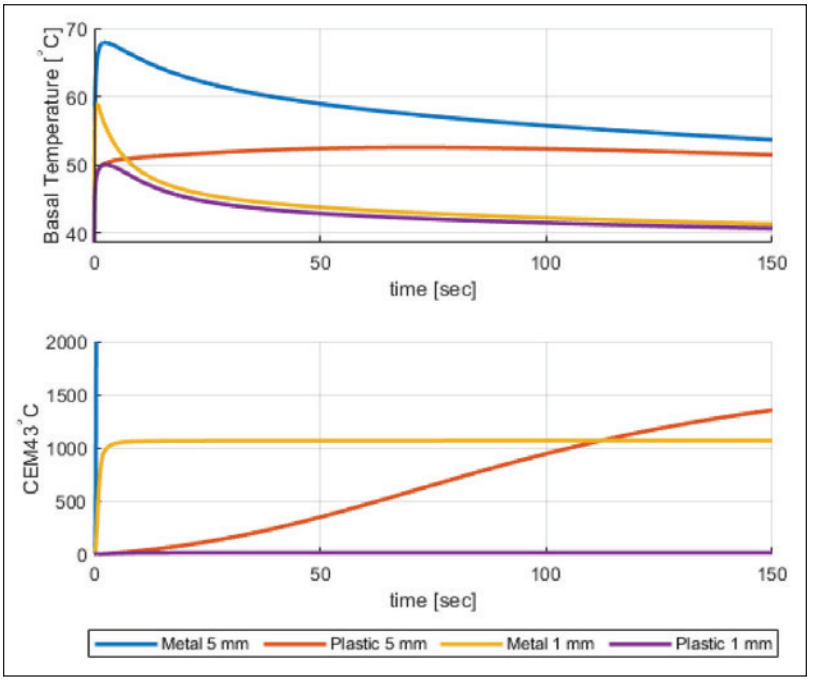


Figure 6: Basal temperature (top) and CEM43°C (bottom) for the four contact scenarios involving 1mm and 5mm thick aluminum and plastic objects at 80°C

temperature after the initial peak (see yellow curve in Figure 6, top) manifests itself in a CEM43°C that reaches a plateau and does not increase further.

The contact with a 5 mm plastic object increases the basal temperature more slowly when compared to the metal object due to its low thermal conductivity. Hence, the CEM43°C threshold is exceeded after about 70 seconds. The 1 mm thick plastic object never causes conditions that exceed the burn threshold of 600 CEM43°C even though its initial temperature was the same as the 5 mm thick plastic object.

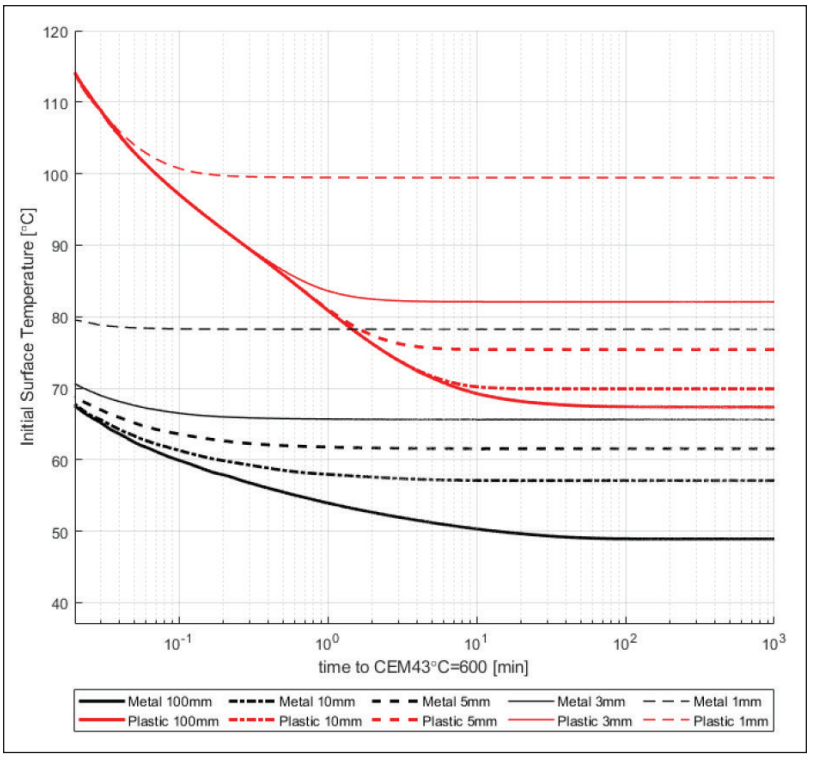


Figure 7: Computed isolines for CEM43°C equal to 600 min for objects of varying thicknesses, materials, and initial temperatures

SENSITIVITY ANALYSIS

A comprehensive sensitivity analysis was performed to understand the effect of the material thermal properties and object thicknesses on the potential for thermal damage to the skin. Specifically, for a given object material and thickness, the model was used to calculate the time to CEM43°C equal to 600 minutes for initial object temperatures ranging between 43- 120°C. The chosen object thicknesses were 100mm, 10mm, 5mm, 3mm, and 1mm. Isolines of CEM43°C 600 min, are plotted as functions of initial object temperature and time in Figure 7.

Figure 7 shows two sets of curves (1) red curves for plastic objects of various thicknesses and (2) black curves for aluminum objects of various thicknesses. Each curve summarizes the relation between initial object temperature and exposure duration required to injure the skin. The curves in each array tend to merge for short duration injurious exposures as, in those scenarios, the objects behave as thermally thick, and their thickness decreasingly impacts the temperature history in the skin (as discussed in the previous sections).

For longer duration exposures, the array of curves diverges resulting in thicker objects having initial temperature thresholds that are lower than those of thinner objects. For example, for a 100 s exposure, the initial temperature of a plastic object required to injure the skin ranges between approximately 68°C for a 100mm thick object and 100°C for a 1 mm thick object. Similar considerations can be obtained when analyzing the results for a metal object.

When compared to the ISO 13732 threshold vs. contact duration plot (see Figure 1), the overall trends are similar. The burn threshold for plastics is higher than that of metals for any given exposure time and for the same object thickness. Consistent with ISO 13732, the higher the initial surface temperature, the lower is the exposure time required to cause a burn.

However, there is a noticeable difference between the present findings and the guidance contained in ISO 13732. Figure 1, obtained from ISO 13732, suggests that, as long as the surface temperature of the hot object is above 43°C, there exists an exposure time long enough that a burn injury will eventually occur. This is due to the inherent assumption in ISO 13732 that the "surface temperature is essentially maintained during the contact period either by the mass of the product or by a heating source" [3]. Even for a semi-infinite object, this is not physical unless there is a source of heat that keeps the surface temperature at the location of the contact constant.

For an object of finite mass, the heat transferred into the skin during contact causes the temperature of the object to decrease until it reaches a thermal equilibrium with the skin. Such thermal equilibrium depends on the thermal properties of the skin, the thermal properties of the object, and other parameters that have not been included in this evaluation, including but not limited to contact resistance, object shape, heat losses to the environment, and heat generation inside the object.

As the temperature of the object decreases during contact, so does the heat flux into the skin. The resulting temperature profile experienced in the skin and consequently the CEM43°C history at the basal layer responds to such variations and, in some circumstances (as discussed in the previous paragraph), the object temperature starts dropping and the CEM43°C ceases to increase.

There then exists, for an object of finite mass, an initial temperature such that CEM43°C never exceeds the burn threshold. Hence, the thickness and correspondingly the thermal mass of the object, are critical factors to understand the potential for contact skin burns.

CONCLUSIONS

The current regulatory standards applicable to consumer products and consumer electronics provide guidance on burn threshold surface temperature and contact duration limits. While the standards provide an estimate of the maximum surface temperatures for burn injury assessments, they fail to recognize the importance of the thermal mass of the contacting object on the likelihood of causing a skin burn.

This paper discusses the limitations of the current regulatory environment and discusses the importance of the thermal mass of the contacting object on the temperature history experienced by the skin and the cumulative degree of thermal damage assessed using a CEM43°C method. The analysis was performed using a numerical model that includes the effect of blood perfusion using the Pennes bio-heat transfer equation that was validated against the seminal experimental work performed by Henriquez and Moritz [1] and Stoll and Green [2]. This model is used to predict burn injury by plastic and metal objects of various thicknesses in contact with human skin. It is shown that for objects of finite thermal mass, there exist initial object temperatures above 43°C at which no amount of contact time is sufficient to cause a burn injury. Such initial object temperatures depend on the object thickness.

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EVALUATION OF EMC EMISSIONS AND GROUND TECHNIQUES ON 1- AND 2-LAYER PCBS WITH POWER CONVERTERS

Part 1: Top-Level Description of the Design Problem

By Bogdan Adamczyk, Scott Mee, and Nick Koeller

This is the first of a series of articles devoted to the design, test, and EMC emissions evaluation of 1- and 2-layer PCBs that contain AC/DC and/or DC/DC converters and employ different ground techniques. 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 specific parts of the design, and subsequently to the RF emissions performance of the PCB assembly. This is a research in progress. The goal of this study is to evaluate the impact of different grounding strategies and the tradeoff with other design constraints that designers often face.

1. INTRODUCTION

Electronic products that are sold in the marketplace must undergo a series of Electromagnetic Compatibility (EMC) tests to demonstrate compliance to industry and regulatory requirements. One aspect of the requirements focuses on evaluating a device's conducted and radiated emissions performance. These two aspects of EMC are important as they measure a device's ability to produce noise that can interfere with the AC or DC mains as well as radiated noise impacting other devices in the surrounding environment. One of the biggest challenges industries face as they design and manufacture electronic devices is EMC performance related to grounding and power conversion circuitry. Most electronic devices have some type of power converter in use. Common examples are converting 240VAC or 120VAC to 24VDC or lower logic level voltages such as 5VDC, 3.3VDC or lower. Linear power converters often have thermal dissipation concerns, and as a result, class D switching converters are used to save on power dissipation and improve the overall efficiency of the converter. Class D switching power converters typically generate conducted and radiated emissions that can be measured during testing from 150kHz to as high as 300MHz or higher. The contributions come from the fundamental switching frequency, the first set of harmonics, and the broadband noise from ringing and oscillations found in and around the switching devices and magnetics. Many industries including Automotive, Consumer, Office

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Environments, Medical, Industrial, Commercial, and Aerospace face these challenges. Some of the EMC specifications that apply to these industries are: CISPR25, Title 47 CFR Part 15, ICES-003, IEC 60601-1-2, EN 61000-6-4, EN61326-1, CISPR11, CISPR22, DO-160, MIL-STD-461.

This article is organized as follows. Section 2 presents the top-level functional block diagram with the EMC considerations. Section 3 is devoted to the individual functional blocks. In Sections 4 and 5, several grounding schemes for 1-layer and 2-layer boards, respectively, are shown. Section 6 provides a brief outline of the next article.

2. TOP-LEVEL SCHEMATIC – FUNCTIONALITY AND EMC

Figure 1 shows the functional blocks of the PCB assembly.

The board will be capable of accepting either an AC or DC input. The AC to DC conversion will take part in Partition A of the board (not drawn to scale). The DC to DC converter in Partition B will accept 24V DC input either from the AC/DC converter in Partition A or from an external source.

In Figure 2 we show the EMC consideration superimposed onto the functionality requirements. These considerations include both conducted and radiated emissions.

The external AC and DC inputs and I/O circuitry provide noise-coupling paths (for conducted /radiated emissions) from the converters. Additional noise paths exist between the two converters themselves, as well as between the converters and the rest of the circuitry in Partition B.

Switching Class D power converters contain switching waveforms that produce harmonic noise and ringing that causes broadband high-frequency emissions. The implementation of EMC design controls and PCB layout will affect the EMC performance of the PCB assembly and associated cabling.

3. FUNCTIONAL BLOCK DETAILS

Figure 3 shows the block diagram of the AC/DC converter.

The converter stage employs a filtering block, full-wave rectifier, controller, and a transformer which provides isolation between the two partitions.

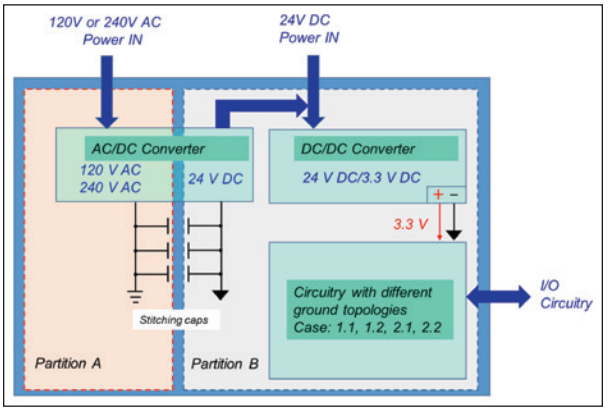

Figure 1: Top-level schematic – functional blocks

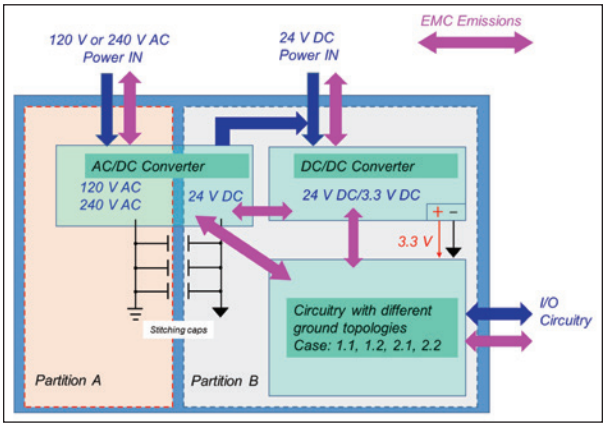

Figure 2: Functional blocks with EMC considerations

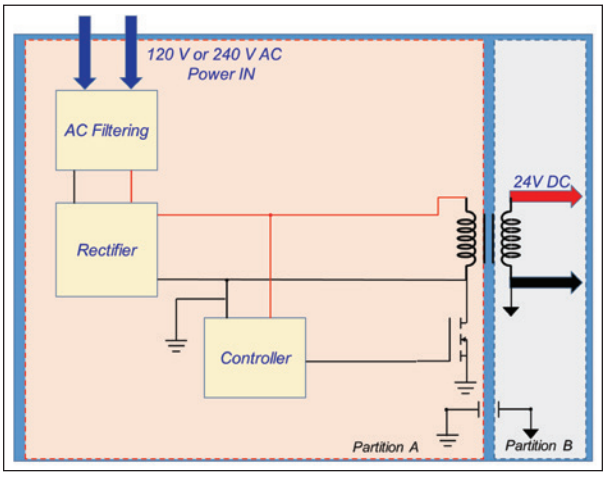

Figure 3: AC/DC Converter – block diagram

Figure 4 shows the block diagram of the DC/DC converter.

24V DC input to the converter comes either from the AC/DC converter or from an external linear power supply input. The control IC contains the switching transistor and the feedback signal detection.

Figure 5 shows the block diagram of the I/O circuitry.

The I/O circuitry contains a microprocessor powered by 3.3V DC as regulated by the DC/DC converter. A real-time clock is provided so that analog values from the thermocouple can be recorded in memory. An unshielded multi-conductor cable with a length of 1 meter will be connected between Partition B and a thermocouple. This cable is likely to carry some of the common-mode emissions from the converters and the microcontroller.

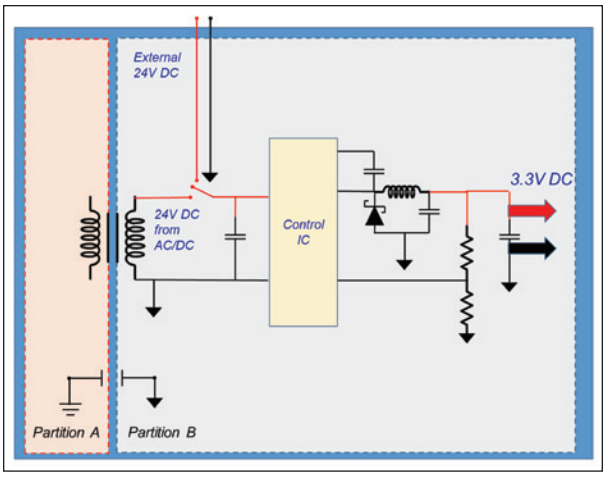

Figure 4: DC/DC Converter – block diagram

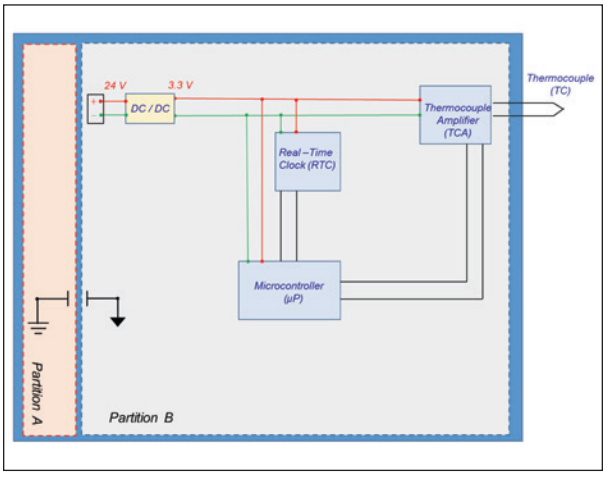

Figure 5: I/O circuitry – block diagram

4. ONE-LAYER BOARD TOPOLOGIES

This Section describes two 1-layer PCB topologies under study, referred to as Case 1.1 and Case 1.2, respectively.

Figure 6 shows the grounding scheme for Case 1.1, where the ground is routed exclusively as traces on the top of the board.

This case represents some of the more challenging designs that are subject to significant cost and space constraints. In this scenario, the designer has very few options to apply EMC rules-of-thumb and best design practices. It is likely that this design will have challenges meeting RF emission requirements and may require additional filtering components to address non-compliances.

Figure 7 shows the grounding scheme for Case 1.2, where ground floods are introduced on the top of the board.

Case 1.2 is similar to Case 1.1, but with fewer space constraints in its application. Here the designer has more opportunities to improve grounding and reference areas. Adding additional ground and/or reference areas improves RF return

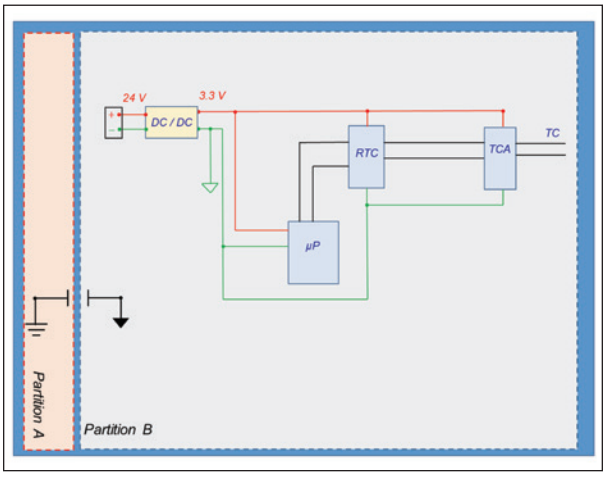

Figure 6: One-layer board – Case 1.1

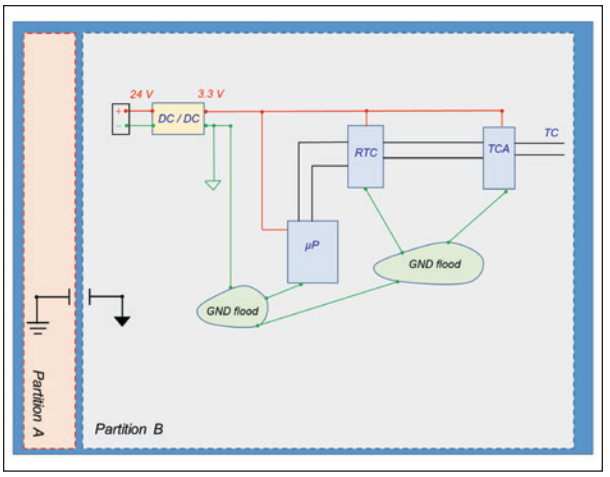

Figure 7: One-layer board – Case 1.2

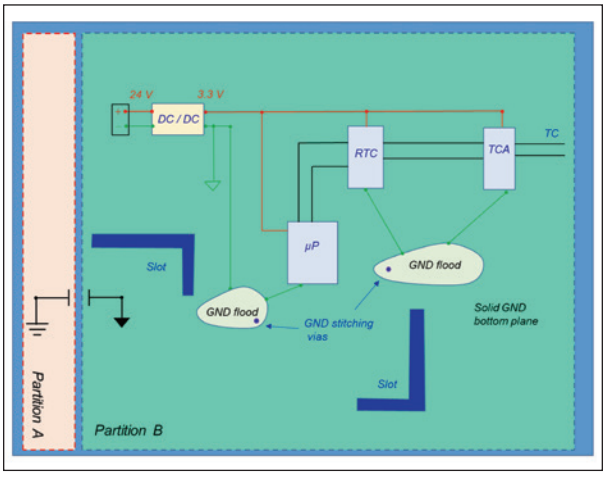

Figure 8: Two-layer board – Case 2.1

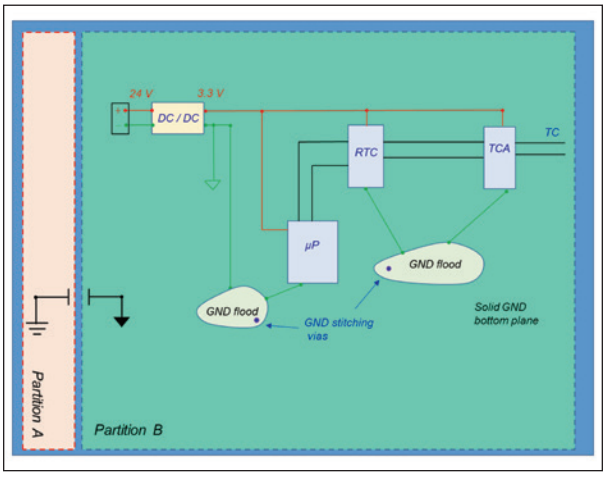

Figure 9: Two-layer board – Case 2.2

paths and can reduce RF emissions. The additional copper areas will likely help with thermal power dissipation, as well.

5. TWO-LAYER BOARD TOPOLOGIES

This Section describes two 2-layer PCB topologies under study, referred to as Case 2.1 and Case 2.2, respectively.

Figure 8 shows the grounding scheme for Case 2.1, where the bottom layer is a mostly solid reference plane with some slots accounting for the need to route signals on the secondary layer.

This design moves closer to the ideal reference plane implementation on the secondary side of the PCB. It has significantly more reference copper to help reduce RF emissions, but the designer requires some use of the secondary side to route power and signal nets. These nets create cut-outs (slots) in the secondary side of the PCB and can negatively impact RF emissions. Stitching vias are used to connect some copper reference areas on top and bottom layers.

Figure 9 shows the grounding scheme for Case 2.2, where the bottom layer is a complete ground flood with via stitching to the top-layer ground areas.

This design implements a solid reference plane on the secondary side of the PCB. Stitching vias are used to connect the reference planes between the top and bottom layers. This design approach can improve RF emissions while potentially reducing the number of filtering components needed for compliance.

6. FUTURE WORK

The next article will provide the schematic details of each functional block for the baseline design. The article will also address some of the EMC design controls that can be implemented on the schematic level.

WHAT EXACTLY IS ESD FOR 3D ICs?

By Harald Gossner for EOS/ESD Association, Inc.

For decades, Moore's law has been driven by the downscaling of transistor dimensions on silicon. When reaching the ultra-advanced integrated circuit (IC) fabrication technologies in the single-digit nm regime (currently 5 nm CMOS is in volume ramp) there is little headroom left, and a different path of packing more functionality into an even smaller volume at the lowest power and cost has to be taken. 3D and 2.5D IC packaging technologies have become primary candidates to serve this purpose [1]. Both packaging technologies, which are often also referred to as 'heterogenous integration', have reached the maturity for volume production and can already be found in products.

A valid question to ask is what is 3D or even 2.5D packaging about? 3D packaging means to stack dies of silicon on top of each other and contact them in large numbers by die-to-die connections (see Figure 1). Today thousands of interconnects are running between a bottom die and a top die. This is predicted to grow into the tens of thousands to millions of interconnects per square millimeter of die area. One essential step in the process is to use so-called through silicon vias (TSVs) to route power and signals from the bottom side to the top side of a die. 2.5D packaging in contrast describes the assembly of silicon dies side-by-side atop an interposer substrate, which serves as a carrier on which the routing lines/connectivity between the dies are implemented (Figure 2).

How is ESD performance affected by these packaging technologies? While for the handling and testing of the finished package there will be hardly any difference, there are multiple challenges in the fields of design and manufacturing of such interconnects. Predominantly, it is about the ESD sensitivity of the die-to-die connections. Do they need to receive a dedicated ESD protection and, if so, what is the targeted ESD robustness? These interfaces are potentially exposed to ESD during a few process steps of singulation of dies, picking of dies from the wafer and die-to-die attach bonding. The process steps need to be carefully ESD controlled, notably from CDM type discharges. While in today's manufacturing lines, CDM robustness of about 30 V is assumed for the die-to-to interconnects, this needs to scale down to 5V or even lower over the next decade to accommodate the massive scaling of the interconnects [2]. Even a 1 μm^2 area of ESD protection per die-to-die IO would consume the full die area in case of the highest interconnect density as predicted. This ESD scaling of interconnects is anticipated to become one of the critical topics of ESD control in the near future.

At the same time, these packaging methods also allow the optimization of the ESD protection design for package balls. Some of the area-consuming IO ESD protection circuits on expensive 5 nm CMOS technology dies might move to the interposer processed in a much less expensive technology. The new ESD protection architectures and the management of the models and parameters for dies manufactured in different technologies and incorporated into one ESD protection network will pose a challenge for ESD and latch-up verification tools and methods. It is definitely not a new challenge, but one that needs to be tackled soon to better address 3D package designs.

Harald Gossner is Senior Principal Engineer at Intel. Harald has authored and co-authored more than 150 technical papers and two books in the field of ESD and device physics. He holds more than 70 patents on the same topics. Currently, he also serves as Senior Vice President of EOS/ESD Association, Inc. and as editor of IEEE Electron Device Letters.

Founded in 1982, EOS/ESD Association, Inc. is a not for profit, professional organization, dedicated to education and furthering the technology Electrostatic Discharge (ESD) control and prevention. EOS/ESD Association, Inc. sponsors educational programs, develops ESD control and measurement standards, holds international technical symposiums, workshops, tutorials, and foster the exchange of technical information among its members and others.

The new ESD protection architectures and the management of the models and parameters for dies manufactured in different technologies and incorporated into one ESD protection network will pose a challenge for ESD and latch-up verification tools and methods.

The EOS/ESD Association is addressing the various vectors of development needed to support 3D packaging ESD integration and manufacturing ESD control. The ESDA Standards Working Group 17 on ESD Process Assessment and Working Groups 18 and 22 discussing EDA ESD tool needs and IP constraints. Volunteers interested in the above topic or an engagement in the working group activities are encouraged to contact the EOS/ESD Association at info@esd.org or visit the Standards webpage within the ESDA website at http://www.esda.org.

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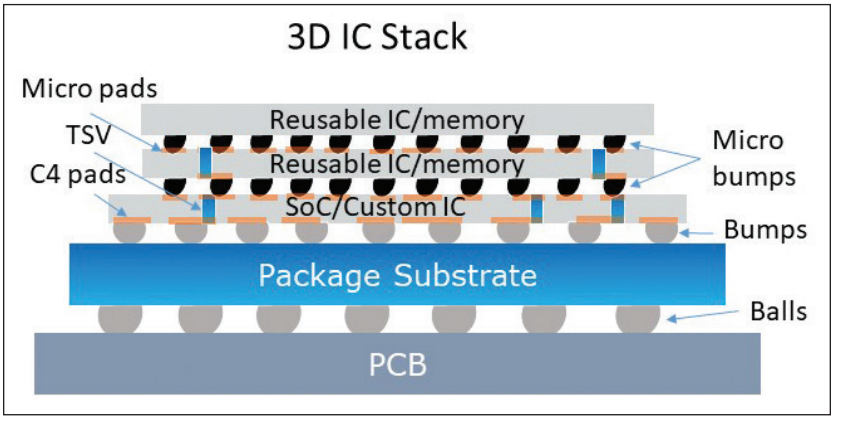


Figure 1: Schematic view of a 3D IC stack [3]

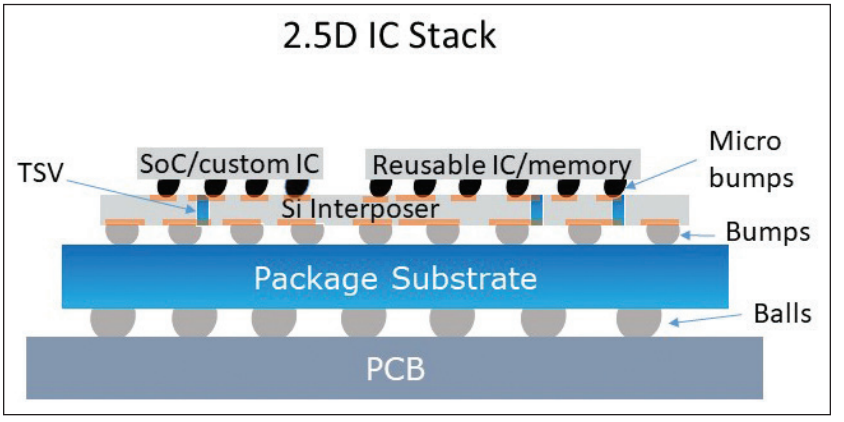


Figure 2: Schematic view of a 2.5D IC stack [3]

Banana Skins

330 VCR/CD/DVC combo TV sends out false distress signals

This October, Chris van Rossman of Corvallis Oregon turned on his do-everything combo TV and got a big surprise—the police, the Civil Air Patrol, and the County Search and Rescue Officers knocked on his door. Apparently, Mr. van Rossman's flat screen, VCR/CD/DVC combo TV had developed some sort of strong emission (a parasitic oscillation, more than likely) at 121.5 MHz, which is a rescue frequency used by aircraft and boat distress transponders and monitored by orbiting satellites. This service uses an uncoded analog carrier detection system, and is therefore rather sensitive to unauthorized transmissions.

When the distress signal was picked up from the satellite, the information was picked up by the Air Force Coordination Center at Langley Air Force Base in Virginia. Langley in turn called the volunteer Civil Air Patrol in Oregon, which in turn contacted Benton Country Search and Rescue for help in locating the signal. Using radio direction finding equipment, the officers were able to narrow the source down to a few possible units in Mr. Rossman's apartment building. When they knocked on his door and he turned off his set to answer, the signal disappeared.

David Mandrell, the CAP squad leader had heard of similar inadvertent interference from consumer equipment, but often it was weak enough to be ignored. This particular instance of interference was unusual because it was abnormally strong. Mr. Rossman was simply warned to keep his TV turned off or face fines of potentially up to $10,000 per day for emitting a false distress signal. He has contacted the set's manufacturer, whose technicians had never heard of a case like this, and has agreed to send him a free replacement.

(Taken from Conformity magazine, Jan *21 2005,* "TV Interference Triggers Aircraft Rescue Satellite Response"*, and published in the Corvallis Gazette-Times, Oct. 17, 2004)*

331 Illegal truck radio transmitters suspected of causing two bus accidents

It has been reported widely in the Japanese press that electromagnetic interference caused by illegally modified transceivers on trucks is suspected of causing two accidents by disabling the braking system of commuter buses. Mitsubishi Fuso Truck & Bus Corporation announced that two models of its buses are adversely affected by high-powered EMI from short distance and its braking system may not function properly under such conditions. Specifically, its braking system that detects the wheel-locking condition falsely triggers due to the EMI and thus the brake doesn't work as intended.

Two accidents were reported last year where the bus drivers reported that the brakes suddenly stopped working. However, after the police investigation, no visible malfunction was found. The manufacturer continued investigation and found that high-powered radio signals emitted by a nearby transceiver (illegally modified and thus 1,000-10,000 as strong as permitted by law for such transceivers) can interfere with its braking control unit, resulting in false information that the wheels locked due to braking. Upon this false information, it seems (my interpretation from what I read various reports) that the control unit decided to release the brakes, and thus caused unintended loss of braking.

It is not known whether such illegally modified transceivers were present nearby in two accident cases. But in other two instances where loss of braking was observed, the bus drivers saw suspicious trucks nearby. The company could reproduce the condition in live experiments, and it will refit the 2200+ cars by replacing the control unit, sensors, pipes, circuit harness, etc. I think the company should be commended for its continued investigation after the accidents.

(An extract from the Risks Digest 5 Jan 04 issue that is posted at: http://catless.ncl.ac.uk/Risks/23.09.html. Sent in by Simon Brown of the HSE, January 2003. The Risks Digest describes itself as a "Forum on Risks to the Public in Computers and Related Systems"*, current issues can be read at: http://www.csl.sri.com/users/risko/risks.txt.)*

332 Concerns about worsening interference in medical and healthcare discussed

Is there enough regulation in the EU to avoid the potentially fatal outcomes for patients that could occur when electromedical or electronic medical devices interfere with each other or with other equipment? And are manufacturers taking enough care to ensure that they are not exposing themselves to the litigious consequences of being negligent in ensuring that such devices operate properly in the environment for which they are intended?

Those were the questions being asked on June 15 in London at the Management Forum Regulatory Update for Electromedical Device and Equipment Manufacturers in London. While actual cases of serious incidents and deaths caused by such interference are difficult to establish given the anecdotal nature of many reports, a UK study dating back to 1993, suggested there had been 23 serious incidents and two fatalities due to electromagnetic interference that year.

Unfortunately, more recent events are "hard to nail down" one regulator told the meeting, although "we know there are causes and effects, and with basic proximity testing you can prove this". Hospitals are generally reluctant to report incidents, delegates at the meeting heard, because of the fear of blame, as was the case when one surgeon answered his mobile phone in the operating theatre, causing the anaesthesia machine to reset.

Without doubt, potential interference is a growing problem and, unless something is done to keep up with the rapidly changing technological environment, manufacturers are going to find themselves increasingly at risk of being accused of lack of due diligence and even negligence.

Consultant Trevor Lewis of Medical Device Consultancy told the meeting: "We know that there is a lot [of interference] going on. Whether it is being reported is another matter. To get more people to report we should avoid apportioning blame and that may move forward the trend to report."

Mr Lewis is adamant that something needs to be done and quickly on an EU level. "I've seen this trend [of electromagnetic interference] moving forward, and I want to be able to advise my clients accordingly to make sure that they are robust from a regulatory and liability point of view," he said.

This not an issue that manufacturers can solve on their own, he insisted, since about 85% of companies operating in this area are small firms and simply cannot afford the resources to analyse the environments in hospitals into which their equipment is placed. Instead, Mr Lewis believes "it would be good if the regulators could characterise safe environments - not only in hospitals, but in homes as well".

To what extent the hospital managers are also responsible for ensuring that electromedical and electronic medical equipment is used in situations where the risk of interference is avoided, seemed unclear at the meeting.

"Very few NHS hospitals are taking this seriously," Chris Marshman, managing director of York EMC Services and chairman of the conference said. Most hospitals, he continued, have medical physics departments that would be capable of the necessary assessments yet it "seems nothing is happening and there is no co-ordination".

It is not only the decisions about where to install products that need to be taken by those in hospitals with a full understanding of the potential interference problem, it is also decisions concerning the management of the maintenance of equipment. Some clinical engineers working on equipment in accident and emergency, for example, may be unaware that if they remove the screws from an item of equipment during maintenance and then fail to put them all back, that this could change the EMC of the equipment and potentially increase risks.

So with all the risks bound up in the use of electromedical and electronic equipment, what can manufacturers do to ensure to prove that they have taken all reasonable steps in terms of addressing issues that arise through a constant risk analysis and management to avoid the risk of interference?

The key here for manufacturers is to ensure instructions for use are clear and readily available, to provide a good installation guide to ensure that the user can safety install the equipment and to use historic good practice to give indications about the careful "zoning" of equipment in the intended environment to avoid interference problems, Mr Marshman said. Also necessary is any further information that will ensure the device is EMC compliant throughout its lifetime, including flagging up in the maintenance file any essential steps, such as putting back all the screws on equipment and explaining why.

"Care is needed on both sides," Mr Marshman insisted. "The manufacturer with the instructions, and users to make sure that they know what they are doing...The duty on users is to make sure that they are doing the best they can."

Finally, a word of warning was given by Ian Cutler, senior medical devices expert and European regulatory affairs consultant to the medical devices industry. Mr Cutler reminded delegates that the healthcare environment is becoming increasingly litigious and asked the meeting to imagine what a prosecuting lawyer would ask, should an incident lead to court action. "Did you consider how X could have had an effect on your product? And, did you have enough technical data to justify your claims on performance?" would be among the likely questions and companies would be found to be totally negligent to ignore potential new sources of interference.

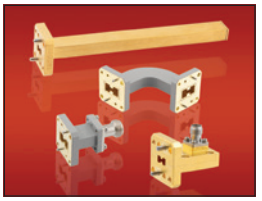
So, it is clear that companies operating in this sector expose themselves to being prosecution unless they are constantly updating their knowledge of potential and changing risks and applying it to products being marketed and in the field. Unless manufacturers perform constant post-market surveillance and risk management and act immediately on their findings, they could face sanctions, including criminal prosecution.

(Taken from "Is the EU underplaying the device interference problem?", *Clinica – World Medical Device & Diagnostic News: Issue 1113, p8 , filed 21 June 2004. Trevor Lewis can be contacted at: lewlink@btclick.com)*

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.

PRESS Releases

WAVEGUIDE COMPONENTS



Fairview Microwave has launched its new line of double ridge waveguide components that are ideal for radar, wireless, and satellite communication devices, and for test instrumentation. The line includes 28 models in a variety of configurations and covering a wide range of frequency bands. Each offers superior RF performance and provides lower cut-off frequencies than comparable rectangular waveguides.

Fairview Microwave,
an Infinite Electronics brand
http://www.infiniteelectronics.com

ELEMENT EXPANDS PRODUCT QUALIFICATION TESTING CAPABILITIES

Element Materials Technology has expanded its product qualification testing (PQT) capabilities at its testing sites in Hull and Hitchin (UK) to address the broader range of wireless technology requirements. This expansion includes CB and UKAS accreditation to test to IEC 62368-1 and IEC 62368-3, which cover a variety of smart and connected technologies, such as tablets, routers, printers, and audio-visual equipment formerly covered under IEC 60950-1 and IEC 60065. The company's Hull testing facility is also UKAS accredited for testing to IEC 17025, and is a Notified Body for the EU's R&TTE Directive.

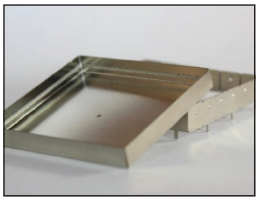
Element Materials Technology
http://www.element.com

CURRENT-COMPENSATED RING CORE CHOKES

TDK Corporation offers a new series of current-compensated EPSOC double-ring core chokes for the suppression of common-mode interferences in switch-mode power supplies, converters, and domestic appliances. The chokes are available in three sizes with current handling capabilities between 10-17 A, and with a rated voltage of 250 V AC (50/60 Hz). The plastic material used in the ring core conforms with UL 94 V-0, and the components offer extremely small dimensions in relation to their current capacity.

TDK Corporation
http://www.tdk-electronics.tdk.com

EMI PROTOTYPE SHIELDING



Orbel has introduced its Groove-LocTM EMI shielding material for use in printed circuit board prototyping. The two-part system is comprised of a bendable, formable fence strip and a locking cover, and is made from a highly solderable nickel silver alloy that provides shielding from medium to high levels of electromagnetic interferences. The design and quick assembly of the Groove-Loc system provides an optimal solution for low to mid-volume production requirements.

Orbel
http://www.orbel.com

SOURCE MEASURE UNITS FOR SPECIALTY POWER SUPPLIES

Rohde & Schwarz has expanded its lineup of test and measurement equipment with the addition of two new source measure units (SMUs) to meet specialized power supply testing needs. The company's new two-quadrant model NGU201 addresses wireless device battery tests and can switch from source mode to sink mode at a defined positive input voltage. The four-quadrant NGU 401 can conduct the same testing at both positive and negative voltages, supporting source measurements for a wide range of power supply types.

Rohde & Schwarz
http://www.rohde-schwarz.com

ISOLATION TESTER FOR SHIELDED ENCLOSURES

Saelig has introduced its new JRE TVK isolation tester, designed to help verify the proper shielding isolation of radiofrequency (RF) enclosure test set-ups. The testing consists of a sensitive, handheld spectrum analyzer and a high power 2.45 GHz test signal source that can measure enclosure isolation down to less than -100dB. The isolation tester also requires no adjustment, eliminating complicated spectrum analyzer adjustment or erroneous readings.

Saelig Company, Inc.
http://www.saelig.com

PRODUCT Showcase

Advertiser Index

Upcoming Events

May 11

Annual Chicago IEEE EMC MiniSymposium

May 11-14

Applying Practical EMI Design & Troubleshooting Techniques

May 13

EMC Fest 2021

May 17-20

IEEE International Instrumentation & Measurement Technology Conference

May 18-20

The Battery Show: Digital Days

May 19

EMC & Compliance International (EMCUK) 2021

June 6-11

International Microwave Symposium (IMS)

June 15-18

Applying Practical EMI Design & Troubleshooting Techniques

June 26

IEC International Special Committee on Radio Interference (CISPR)

June 28-30

Sensors Expo and Conference

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

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