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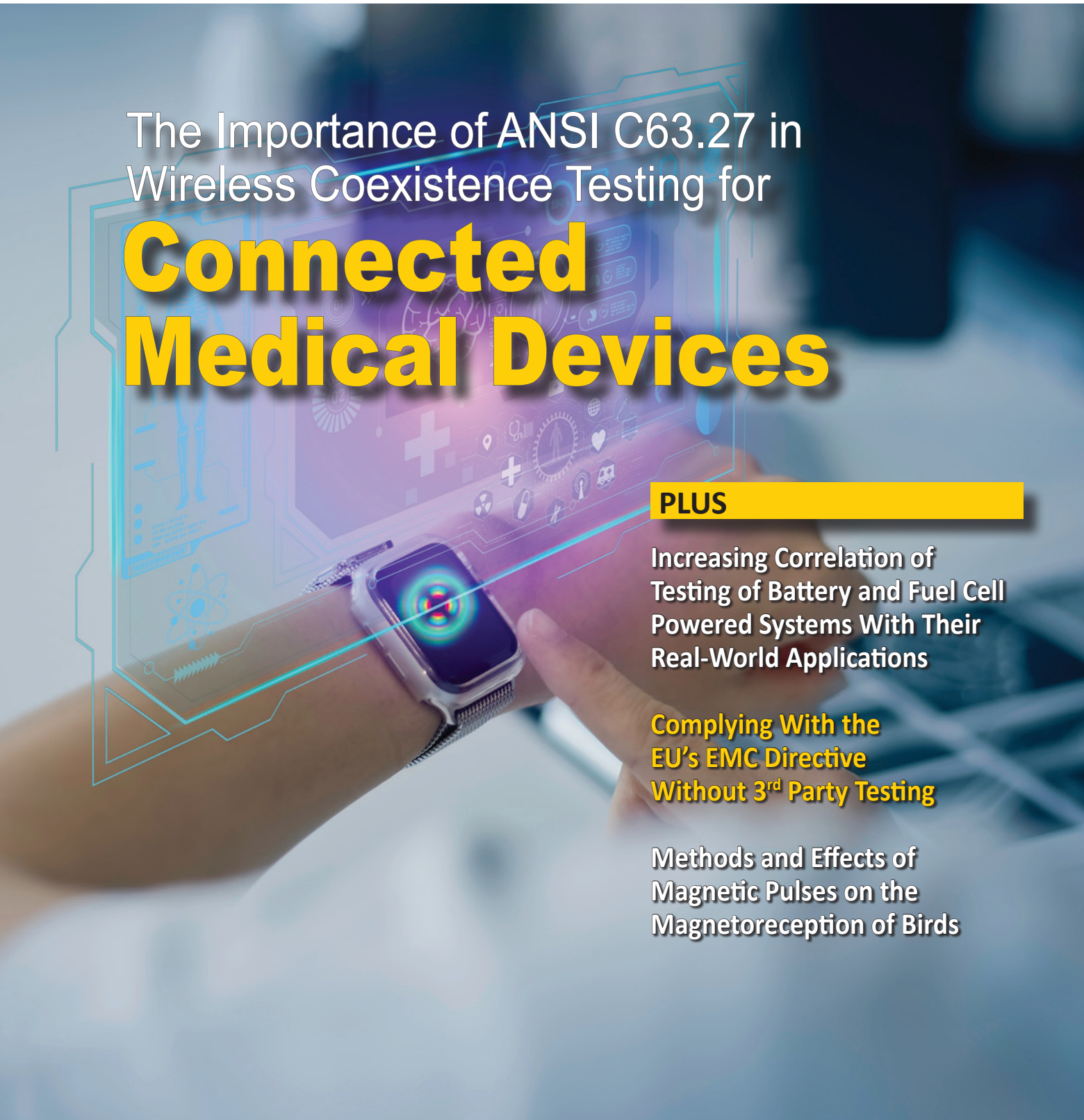

The Importance of ANSI C63.27 in Wireless Coexistence Testing for Connected Medical Devices

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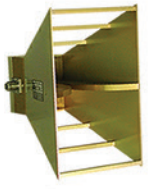

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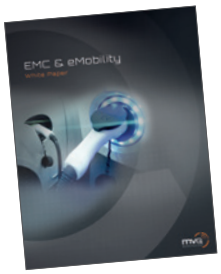

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FDA Warns Manufacturers to Scrutinize Third-Party Testing Data

The U.S. Food and Drug Administration (FDA) is reminding medical device manufacturers to independently verify testing results generated by third parties that are included in premarket submissions to the agency.

In a Letter to Industry, the FDA notes that it has observed an increase in recent years of contracted third-party testing laboratories fabricating test data, duplicating test data used in other device submissions, or providing unreliable characterizations of their testing. Although the Letter does not identify specific testing laboratories that have generated fabricated test data, it does point to "numerous such facilities based in China and India."

In such cases, says the FDA, the inclusion of false or fabricated data in a premarket submission undermines the integrity of the entire premarket submission application. It leaves the agency no alternative but to reject the marketing authorization request.

The FDA advises device manufacturers to work with third-party testing laboratories that have been accredited under the voluntary Accreditation Scheme for Conformity Assessment (ASCA) to help reduce the likelihood of being provided fraudulent testing results. However, the FDA also warns that even using accredited testing laboratories does not completely eliminate the possibility of fraud and that a careful assessment of third-party test data is still strongly advised.

FCC Makes AI-Generated Robocalls Illegal

In a landmark decision, the U.S. Federal Communications Commission (FCC) has unanimously ruled that robocalls made with voices generated by artificial intelligence (AI) tools are illegal.

In a Declaratory Ruling issued in early February, the Commission summarized its determination that calls that include AI-generated voices are "artificial" under the Telephone Consumer Protection Act (TCPA) and, therefore, illegal. Under the TCPA, violators are subject to FCC enforcement authority, including fines and actions to block calls from telephone carriers that facilitate illegal robocalls. In addition, individual consumers are empowered under the TCPA to bring lawsuits against robocallers.

The Declaratory Ruling, which takes immediate effect, is based in part on a Notice of Inquiry issued by the Commission in November 2023 to solicit public input on how AI and AI-influenced technology can or will impact calling and texting processes and the extent to which such technology could compromise consumer privacy under the TCPA.

The FCC's decision to make AI-generated robocalls illegal also has the support of a coalition of 26 State Attorneys General across the U.S., who urged the FCC earlier this year to restrict the use of AI in marketing phone calls.

U.S. and EU Sign Joint Cybersafe Products Action Plan

The U.S. and the European Union (EU) have signed an agreement to work collaboratively to strengthen the cybersecurity of Internet-of-things (IoT)-capable hardware and software products used by consumers.

According to a joint press statement issued by the European Commission and the White House National Security Council, the Joint Cybersafe Products Action Plan is intended to foster technical cooperation between the U.S. and the EU in an effort to align their respective cybersecurity requirements. The ultimate goal of the Joint Action Plan is for the signatories to achieve mutual recognition of cybersecurity labeling programs and regulations for IoT devices.

The Joint Cybersafe Products Action Plan was immediately endorsed by Jessica Rosenworcel, Chair of the U.S. Federal Communications Commission (FCC). In a separate statement, Rosenworcel referenced the FCC's efforts to establish its own cybersecurity labeling program, building on work by the National Institute of Standards and Technology (NIST), and welcomed the opportunity to actively collaborate with its counterparts in the EU to reduce unnecessary cyber risks for consumers.

FCC Adopts Rules to Enable Consumers to Stop Robocalls, Robotexts

As part of its ongoing effort to stem the rise in unwanted robocalls and robotexts, the U.S. Federal Communications Commission (FCC) has adopted new rules that give consumers more tools to fight back.

According to the Report and Order, the new rules required that originators of robocalls and robotexts comply with "do-not-call" and consent revocation requests received from consumers within 10 business days of receipt of the request. Originating parties may send a one-time text message to the consumer confirming the opt-out request as long as the text does not include any marketing information.

The Report and Order also seeks public comment on whether the scope of the Telephone Consumer Protection Act (TCPA) applies to unwanted robocalls and robotexts received by consumers for their own service providers and whether consumers should have the same ability to stop unwanted calls and texts as they do with other service providers.

FDA Amends Quality System Regulations for Medical Devices

In an effort to stay current with new and updated international standards, the U.S. Food and Drug Administration (FDA) has amended its quality system regulations applicable to the manufacture of medical devices.

In a Final Rule published in the Federal Register, the FDA amended its current good manufacturing practice (CGMP) requirements for its quality system (QS) regulation applicable to medical device manufacturers. The amended requirements now incorporate by reference ISO 13485:2016, *Medical devices—Quality management systems—Requirements for regulatory purposes.* The FDA says that the change is part of its effort to harmonize its quality management systems requirements for medical devices with those adopted by other regulatory agencies.

The FDA's final rule regarding the changes to its current CGMPs takes effect on February 2, 2026. Until then, device manufacturers must continue to comply with the FDA's QS regulation.

THE IMPORTANCE OF ANSI C63.27 IN WIRELESS COEXISTENCE TESTING FOR CONNECTED MEDICAL DEVICES

Understanding How Radios Affect Medical Device Compliance

David Schaefer is an EMC Technical Manager for Element Materials Technology's Connected Technologies and Mobility business unit. He is active in ANSI C63 subcommittees 1, 5, 6, and 8, and served as a member of the working group that developed the second edition of ANSI C63.27 on wireless coexistence. David can be reached at david.schaefer@element.com.

By David Schaefer

Communication has advanced at an unbelievable pace in the 150 years between the Pony Express and the advent of the internet. The shelf life of information has drastically decreased, from weeks to seconds, and the distance we are willing to travel for information has shrunk to virtually nothing. We demand instantaneous access to a massive range of data, no matter where we may be in the world. Companies are spending billions of dollars for faster access to information, and consumers spend more each year on faster devices. Cellular carriers, aware of this trend, have shifted from voice-only networks to data-centric services and are relying more heavily on spectrum sharing.

The first recognizable iteration of Wi-Fi launched in 1999. Prior to 2008, about two billion Bluetooth devices had been sold. But, in 2022 alone, 4.9 billion Bluetooth devices were shipped in the span of a single year. There are now Wi-Fi access points in planes, dog collars with GPS, and toothbrushes with Bluetooth connectivity. Radio devices are everywhere, and there are more users, more devices, and greater saturation of frequency bands.

Beyond the proliferation of the devices themselves, multiple radio technologies are also being combined into single devices. Many cell phones now have seven different radio technologies, including: 1) Bluetooth, 2) Wi-Fi, 3) global navigation satellite system (GNSS), 4) wireless power transfer, 5) nearfield communication, and 6) ultra-wideband for location sensing; and of course 7) 4G or 5G cellular radio.

The radio spectrum is a valuable and finite resource that needs to be shared across all applications, so efficient spectrum utilization is critical as well as a growing focus of regulators. New technologies such as smart antenna systems and orthogonal frequency-division multiplexing (OFDM) are being developed to try to optimize the use of the frequency spectrum. Optimizations such as cognitive radio, which is programmed to select the least congested nearby channels to try to minimize interference, are mandated by trade groups such as the Wi-Fi Alliance and regulatory bodies including the U.S. Federal Communications Commission (FCC) and the Commission of the European Union (EU) are following suit.

WIRELESS COEXISTENCE RISKS AND CHALLENGES FOR MEDICAL DEVICES

Connected medical devices monitor patient health and make crucial health information accessible when it is needed. Such devices are often instrumental in saving lives but they rely on proper operation in their electromagnetic environment. Unfortunately, thousands of incidents of electromagnetic interference (EMI) occur in healthcare every year.

The U.S. Food and Drug Administration (FDA) has a database called MAUDE (Manufacturer and User Facility Device Experience) that tracks medical device malfunctions. It currently contains more than 250,000 reports of issues related to electromagnetic compatibility (EMC). Between 2010 and 2019, there were more than 170 reports of deaths attributable to EMC, electrostatic discharge (ESD), or wireless malfunctions.

Because of the way in which the reports are compiled and recorded, it is not possible to determine how many of these incidents are specifically related to wireless coexistence. But these figures obviously raise concerns about the adequacy of wireless device testing and how such risks can be reduced or eliminated.

HOW MEDICAL TECHNOLOGIES USE RADIO BANDS

Manufacturers are increasingly relying on wireless technologies for functions that are critical to patient

well-being, using a variety of radio technologies and frequency bands. Some of these are exclusive to medical devices, but many are shared with other applications or entities. Examples include:

- Inductive radio, which is typically below 200 kHz
- Medical Device Radiocommunication Service (MedRadio) 401-406 MHz, including medical micropower network (MMN) devices
- Medical Implant Communication Service (MICS) 401-406 MHz
- Industrial, scientific, and medical (ISM) bands are various specific bands shared by medical devices, industrial devices, and various scientific devices.
- Medical body area networks (MBANs) are adjacent to the 2.4 gigahertz ISM band and allow multiple sensors on a patient's body to communicate with a control unit.
- Wireless Medical Telemetry Service (WMTS) is a safe, proprietary band also used for sensors, like MBANs, but is typically limited to critical care in healthcare facilities.

Medical micropower networks (MMNs) are a subset of MedRadio specifically for implanted nerve stimulators. Thanks to extensive negotiations with the military and the FCC, MMN bands can only be used for these implantable nerve stimulators.

Some bands used by medical technologies are not exclusive to such devices. For example, Wi-Fi is ubiquitous in medical facilities. Most facilities use a secure network to transmit patient data both within the facility and to other medical facilities. MRI, X-ray, and other screening or diagnostic devices may transmit images or data through the secure Wi-Fi network, and it can also be used for tracking patient or staff movements through the facility.

Off-the-shelf technologies like Wi-Fi have both pros and cons: widespread use of Wi-Fi makes interoperability easier and using a tried and tested technology like Wi-Fi in a new medical device reduces development time. However, Wi-Fi technologies have generally poor product support, can quickly become obsolete due to consumer technology churn, and operate on very crowded bands (2.4 and 5 GHz).

The use of Bluetooth is also becoming more widespread in healthcare. In fact, there is a new use case called the Bluetooth Health Device Profile that has been specifically developed for use in transferring medical data. Common current uses for Bluetooth include inventory tracking, sensors, and glucose monitoring. An emerging application uses 2.4 GHz Bluetooth to send a wake-up signal to an implant, and the implant then uses inductive or MedRadio to transfer data. Additionally, ZigBee, a mesh networking protocol, is used for real-time monitoring systems, similar to MBANs.

Radio frequency identification (RFID) technology is also widely used in medical facilities. It covers multiple unlicensed bands and is primarily used for tracking everything from million-dollar pieces of equipment to single doses of drugs.

Cellular technology in medical applications faces similar hurdles to Wi-Fi. It is used for data transfer, step counters, and even in some diagnostic imaging. The high-bandwidth capabilities of 5G are also prompting more explorations of its use in medicine, such as in remote robotic surgery or in ambulances connected directly and continuously with a hospital.

A critical advantage for all these technologies, and a large part of the reason they are now so in demand, is wireless mobility. Healthcare providers and patients need to be able to move freely, whether across the world or simply from one room to another, without losing access to their data. These applications of radio technologies is not only convenient but can lead to better health outcomes due to faster communication and fewer geographic barriers to accessing the best possible care.

REDUCING THE RISK OF INTERFERENCE THROUGH COEXISTENCE TESTING

But radios also pose a special challenge as medical device manufacturers must use wireless communication in a crowded spectrum. The more users there are on a single band, the greater the risk of interference. There are now billions of Wi-Fi, Bluetooth, and cellular devices in use, with still more added every day. Device manufacturers must manage risks and work proactively to prevent interference with their products. Interference may be inconvenient for consumer products, but it has potentially much more serious consequences for medical devices.

Unfortunately, although risks to the proper operation of safety-critical devices have been widely acknowledged, methods for quantifying those risks have been varied and not comprehensive. This lack of information highlights the importance of widespread wireless coexistence testing for medical devices.

So let's take a step back to answer an important question. How is coexistence testing different from normal EMC testing?

Electromagnetic compatibility (EMC) is the ability of electronic systems to function acceptably in their electromagnetic environment. Essentially, EMC testing evaluates whether a product will work in the field despite potential interference. Coexistence testing can be thought of as a subset of EMC testing specifically for radio products that demonstrates whether the presence of in-band or out-of-band radios have any impact on functional wireless performance, basic safety, or essential performance.

It is a common misconception that standard EMC tests developed by the International Electrotechnical Commission (IEC) are sufficient to evaluate the risk of interference from nearby wireless sources. However, the specific exclusion bands that are part of most standards eliminate the assessment of in-band interference. And, with standard EMC testing, there is no way to quantify the risk of interference from other users of the same frequency band, such as other nearby wireless medical devices. As such, EMC testing in accordance with the technical requirements of familiar standards will not directly address coexistence for the radio.

In the EU, the Radio Equipment Directive (RED) cites several standards with requirements similar to coexistence testing, but they are not comprehensive. Tests such as receiver blocking, adjacent channel selectivity, and adaptivity are similar to coexistence tests, but they use continuous wave (CW) or additive white Gaussian noise instead of a representative real-world signal. Additionally, these tests focus only on radio performance, not host performance. When a radio is incorporated into a host, such as a medical device, it may change the radio performance in a way that is not addressed by these tests.

Another factor to consider is that in-band interference is more likely to emerge as a problem for devices that operate in the same band over a long period. Wireless products in a healthcare environment, like a hospital, are likely to be operating simultaneously for very long periods of time.

In 2007, the FDA issued a guidance document that included consideration of coexistence for wireless devices. This FDA guidance document recommended a risk analysis, which is a key part of any medical device

evaluation for compliance. Although this document was a recommendation when first published, the FDA now requires an evaluation of coexistence for nearly every product that implements wireless technology. Today, it is a growing area of interest for the FDA, and medical device manufacturers are facing questions during the product review and approval process of whether coexistence has been adequately evaluated through risk analysis or testing.

HOW COEXISTENCE TESTING IS PERFORMED

Historically, some testing laboratories have performed coexistence testing by purchasing off-the-shelf radios and operating them in a shielded room in proximity to the equipment under test (EUT). However, this type of testing has limitations. Some devices, like cell phones, will jump between multiple bands while in use, and there is no way for the technicians conducting these tests to control what band or bands these off-the-shelf devices are using during the test. This means that repeatability is, in some cases, impossible.

Furthermore, the results of the tests can only be applied reliably to the exact off-the-shelf devices used in testing and are not necessarily applicable to other types of devices that use similar radio technology. This also presents an unknown level of risk whenever new radio devices enter the market.

Currently, the recommended testing approach is to thoroughly test and ensure device compatibility in the intended electromagnetic environment using the following steps:

- Perform a risk analysis to determine failure modes and thresholds for wireless communications that occur due to interference, using medical device standards relevant to application and geography.
- Satisfy the requirements for ANSI C63.27 for co-channel interference, adjacent channel interference, and adjacent band interference.
- Supplement with additional testing as new technologies enter the market and new threats emerge.

WHAT IS ANSI C63.27?

ANSI is the American National Standards Institute, a U.S.-based standards development organization, and C63 is a standards development committee focused on EMC and radio testing. The standard C63.27, *American National Standard for Evaluation of Wireless Coexistence*, was first published in 2017 and provides a method for evaluating device coexistence, with a focus on mitigating risk. The second edition of C63.27 was released in 2021 with a few significant changes.

C63.27 provides the methods for evaluating devices, specifies test plan requirements, and offers guidance on how risk analysis and the results can be used to estimate the likelihood of coexistence. It is a generalized test method for any wireless product, but the primary focus of its use has been in connection with the evaluation of medical devices.

The standard does not provide pass/fail parameters because they will be specific to each radio and application. Instead, it provides testing guidance and indicates how to evaluate the risk presented by interference from other radios. This will be based on key performance indicators (KPIs) for the functional wireless performance (FWP) – essentially, a combination of monitoring radio performance and how it relates to overall device performance. For example, a KPI might be a bit error rate, while the FWP is a function of the EUT that depends on a wireless link and will be affected if the bit error rate drops. The 2021 edition of C63.27 requires a determination of whether the EUT passed or failed based on its FWP while the 2017 edition only required reporting of results.

The overall methods in the standard apply to any type of radio, but the standard is intended to test the performance of the end device as a whole, not just the radio modules within the device. The same radio module can be used in either a medical device or an entertainment device, but the functionality, failure thresholds, and potential errors will differ significantly in these different applications.

While C63.27 provides generalized methods for testing coexistence, it currently only contains guidance for a limited number of technologies and frequency bands (Bluetooth, Wifi, and digital enhanced cordless telecommunications (DECT)). The methods described can be used for any radio, and with the FDA's increased scrutiny of wireless in medical devices, device manufacturers should investigate testing to C63.27 for any radio in their product.

The standard contains three potential levels for evaluating a device. Level three is the least rigorous, testing the fewest signals and providing only very general insight into devices in which potential performance errors are undesirable but will not cause serious consequences. Level one is the most rigorous and is used for devices where the absence of coexistence can cause unacceptable consequences.

TEST SETUP UNDER C63.27

The setup for testing contains three items – the EUT, a companion device communicating with the EUT, and an interference source. Four test methods are described in C63.27. The choice of the test method is up to the user of the standard and should be chosen in partnership with your chosen test laboratory. The four methods are:

- *Conducted (wired) method:* Performed by using a mixer to combine the intended and unintended signals and connecting to the antenna port or the EUT. This excludes the antenna itself from testing and is the most repeatable but least realistic test method.
- *Chamber/hybrid method:* The EUT and the equipment generating signals are each placed in a separate chamber to control how the equipment under test is exposed to the signals.
- *Radiated-anechoic method:* Places the EUT in a chamber with both intended and unintended signal emitters. This creates an environment that does not necessarily replicate the deployed environment but removes environmental variables that would decrease repeatability.
- *Radiated open lab method:* This method involves no chambers or shields and usually attempts to replicate the deployed environment. This testing may be affected by ambient signals and limits the interfering signal to those legally allowed by spectrum regulators.

Not all medical products containing a radio necessarily need to be tested in accordance with the requirements of C63.27. But a risk analysis does need to be conducted to evaluate potential effects and failure modes. AAMI TIR69:2017 is a technical information report that offers a process to assess and categorize the risks associated with the wireless functions of a medical device. If the risk assessment shows that the device's wireless technology presents no significant

With a well-designed test plan, test data will help determine crucial coexistence parameters for the device and form the basis for proper risk analysis.

risk, the manufacturer can choose not to test for wireless coexistence. However, many manufacturers choose to do so anyway. C63.27 provides a more comprehensive risk assessment and specifies tests for both basic safety and essential performance.

CREATING A WIRELESS COEXISTENCE TEST PLAN

ANSI C63.27 specifies that, prior to testing, the manufacturer must create a test plan that includes key performance indicators, the intended functional wireless performance, and how these factors will be monitored. The manufacturer will need to provide information that includes the test methods to be used, the intended signals for the device, and the interfering signals to be tested.

A common misconception is that the testing laboratory will make these decisions. Yes, testing labs can help discuss test needs and provide guidance. But manufacturers are ultimately responsible for the development of the risk analysis and for identifying what needs to be monitored during testing.

To determine appropriate coexistence parameters, manufacturers must have a good understanding of what radiofrequency signals may interfere with their device, based on when, where, and how the device will be used. Because there are a finite number of frequencies, different methods have been devised so that the same frequencies can be used in multiple ways:

- FDMA stands for frequency-division multiple access. An example of this is FM radio. The FM band is split into multiple channels that can be used simultaneously, but one channel cannot be used by two stations at the same time and in the same location.
- TDMA stands for time-division multiple access. This means that different radios use the same frequency band but at different times to avoid interference – essentially, taking turns.
- CDMA stands for code-division multiple access. CDMA uses transmitter coding and spread spectrum techniques to allow multiple transmitters to share channels and bands.

The goal of coexistence testing is to determine if a given device, considering its output power, can reliably operate in its intended frequency band without interference, either from within the same band or from adjacent bands. There are three primary values that testing will focus on:

- Maximum separation distance between interference and EUT
- Maximum duty cycle of interfering signals
- Maximum frequency separation of signals in the adjacent channel/band

Interference can come in multiple forms:

- *Adjacent interference:* When two channels are close to each other, there can be overlap between them, decreasing the overall signal quality in both bands.
- *Co-channel interference:* When two different transmitters using the same channel can be picked up by the same device, creating crosstalk.
- *Harmonic interference:* Out-of-band transmitters can sometimes cause a harmonic signal to show up in a different band.

With a well-designed test plan, test data will help determine crucial coexistence parameters for the device and form the basis for proper risk analysis. Manufacturers will be able to evaluate both the point at which the equipment's key performance indicators begin to degrade and at what point the equipment becomes nonfunctional. These values can be used to calculate minimum signal strength, the minimum separation distance from other transmitters, and other technical and safety parameters.

It's important that manufacturers and their testing partners be familiar with the updated version of ANSI C63.27 when creating their test plans.

EXPERT OBSERVATIONS FROM THE TESTING LAB

Many medical devices use off-the-shelf Bluetooth, cellular, and Wi-Fi technologies. Fortunately, these well-established technologies already have certain protections against interference, like cognitive radio, built in. This reduces some risks that need to be tested for custom-built radios. Manufacturers can make some modifications to off-the-shelf radio modules or systems to improve their performance in medical devices, such as changing frequency bands, adjusting radio sensitivity, or improving antenna performance, But off-the-shelf technology typically can't be significantly modified. Even so, any results from testing can be used to benchmark future module purchases, as well as adjust the radio parameters.

Cellular technology has the added advantage of higher transmit power, more frequency bands, and frequency division duplexing, that is, where transmitting and receiving are on separate channels. These features can help prevent unintended signals from affecting the intended signal.

For purpose-built radios, manufacturers must include some sort of collision avoidance programming. Manufacturers must also be mindful of the firmware or software controlling the radio. In testing, we have found firmware in Bluetooth or Wi-Fi devices that unintentionally negates the cognitive radio functions or the collision avoidance functions, reducing the device's resistance to interference.

THE FUTURE OF WIRELESS COEXISTENCE

As previously noted, the second edition of ANSI was published in 2021. The primary changes included in this edition offer further clarification on the interfering signal parameters and additional testing for LTE-LAA equipment. The requirements for the test of Level one devices have also been updated with additional tests now required for that category.

This version of the standard also includes a new Annex F, which lays out parameters for estimating the likelihood of coexistence. This is an important component of risk management.

It's important that manufacturers and their testing partners be familiar with the updated version of this standard when creating their test plans. A working group is being formed to release a corrigendum covering some minor fixes to the 2021 edition.

Future editions of the standard will likely address some limitations in the current edition. For example, the output power of the interfering signal or intended signals could be varied over time to simulate movement around a facility, reflections, or channel utilization. The duty cycle of these signals could also be increased or decreased during testing.

As new technologies develop and the use of radio bands changes, the devices that rely on these technologies will also need to undergo coexistence testing. The FCC has opened the 6 GHz band for unlicensed use, and there are now many 5G bands in use. Other new bands are being opened for different applications, and the use of radios in medical facilities continues to grow.

With the rapid pace of technological development, the ever-changing regulations surrounding radio devices, and the high stakes associated with medical technologies, manufacturers must fully understand the requirements and best practices associated with their products and must have a reliable, well-informed, and communicative testing partner to guide them through the testing process.

Ask the Expert

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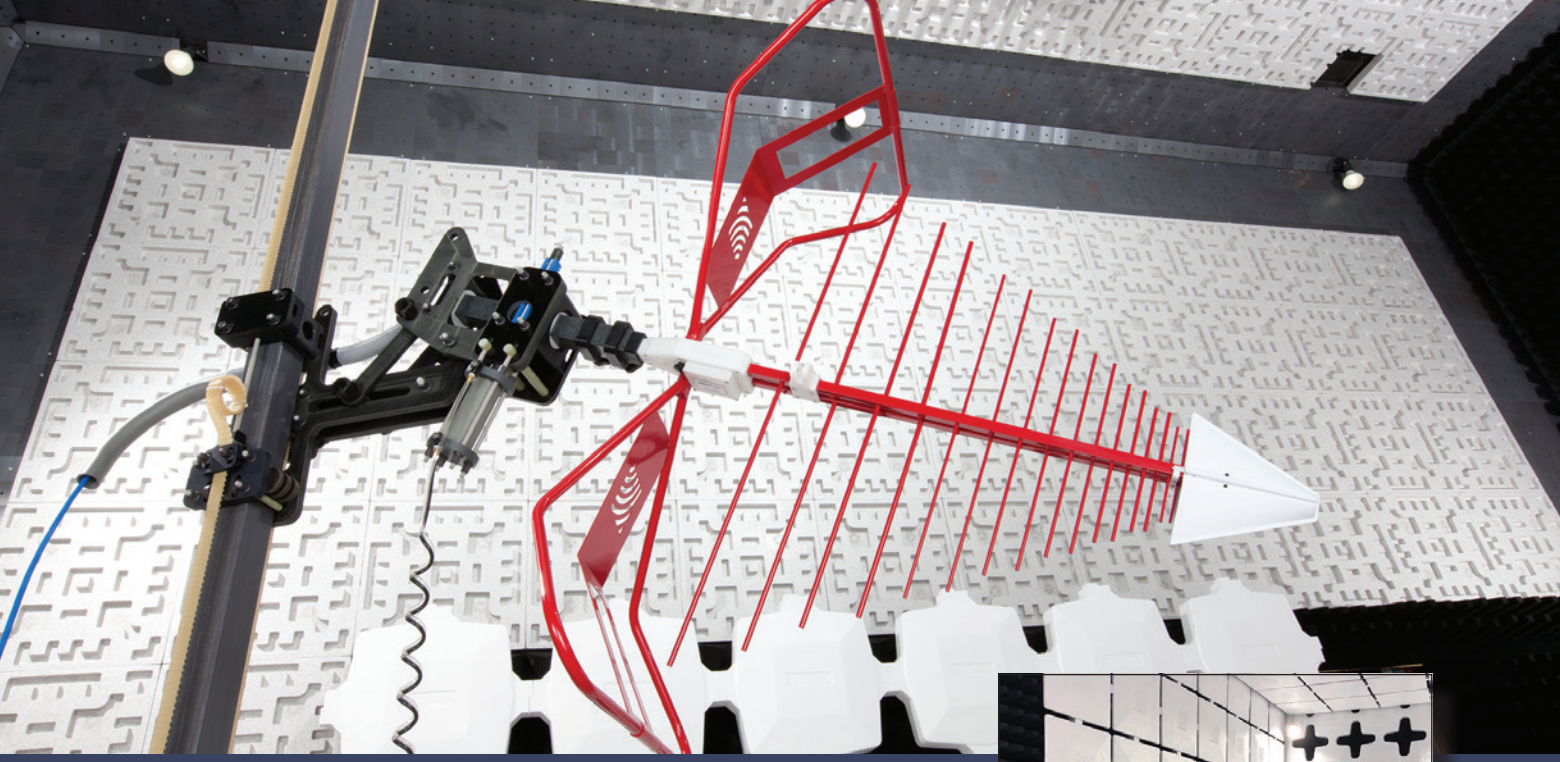

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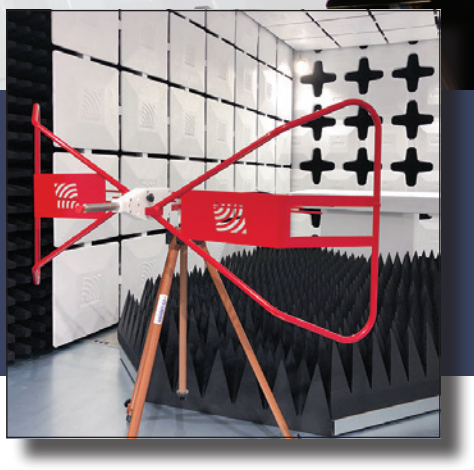

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Rooted in the legacy of Ray Proof from the 1930s, ETS-Lindgren has been serving the RF Shielding and Test and Measurement needs of our customers for nearly a century. Our commitment to innovation remains steadfast as we continuously evolve to address the changing needs of our customers. From electromagnetic pulse (EMP) solutions safeguarding critical infrastructure to MRI shielding systems facilitating life-saving patient imaging, and from electromagnetic compatibility (EMC) test solutions enabling the delivery of cutting-edge consumer, medical, and automotive products to market, to wireless test systems driving the development of the latest wireless technology, ETS-Lindgren empowers our customers' success through an extensive product and solutions portfolio and access to our knowledgeable industry experts.

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At ETS-Lindgren, we are Committed to a Smarter, More Connected Future.

INCREASING CORRELATION OF TESTING OF BATTERY AND FUEL CELL POWERED SYSTEMS WITH THEIR REAL-WORLD APPLICATIONS

Using Established Circuit Analysis Techniques and New Capabilities in Modeling/Simulation Tools Can Improve the Understanding Of Battery and Fuel Cell Powered System Performance

Today's communication, transportation, and power delivery systems all depend on the extensive use of batteries to keep them functioning in a safe and reliable manner. Battery cell technology has its origins in the late 1700s, while fuel cells were not available commercially until the mid-20th century. But today's batteries and fuel cells are an amazing combination of the application of principles of chemistry and electrical engineering.

The standard approach today is that when a battery is the only power source of an electrical system (referred to as the primary power source), analysis techniques are normally applied to characterize the battery as being able to supply constant input voltage to its load. As we have all experienced in our daily lives, constant input voltage conditions do not really exist unless there is an additional power source to maintain the battery's state of charge.

Unfortunately, this results in a potential divergence of the expected results of electrical and electronic system performance when using the theoretical model compared to what may be experienced in actual real-world

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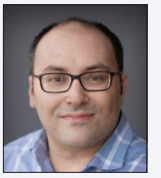


By Nicholas Ingarra and Mark Steffka

Mark Steffka is a faculty member and the Director of International Programs for the University of Detroit – Mercy Electrical Engineering & Computer Science department, with almost 40 years of industry experience with military, aerospace, and automotive electrical/electronic systems. He can be reached at steffkma@udmercy.edu.

applications. For example, when an electrical motor is tested at a constant input voltage, the performance of that motor will vary if the input voltage is changed.

To help engineers better replicate these conditions, this article describes the methods that can be used to increase the correlation of the testing of battery and fuel-cell-powered systems with their actual applications.

THE IMPORTANCE OF TEST DESIGN

Linear circuit analysis (LCA) is typically a standard methodology used in electrical circuit design, development, and testing for electrical systems. With recent developments and the widespread global production of electric propulsion methods for transportation systems, a comprehensive test design approach that complements LCA can be valuable.

There are many benefits of having up-front test data that has a high correlation to a system's actual performance. These new methods can be based on the fundamental principles of the conservation of energy when a battery is used as a system's primary power source. It turns out that, instead of a battery having an unchanging constant energy delivery rate (with a constant current and voltage depending only on the load's power demand), a battery's behavior will be impacted due to the type of load to which it is supplying energy, which will then change the characteristics of a battery's discharge conditions.

There are two types of electrical loads, passive and non-passive. If a load is a passive load, there is no power required. A non-passive load is an electro-mechanical load like a motor connected to a pump or fan. The pump or fan has power that is required from the mechanical domain, and the motor must provide the required mechanical power. The mechanical power must come from the electrical domain. Note the electro-mechanical coupling could be direct or indirect LCA as an applicable methodology.

When a battery is delivering energy to non-passive loads, the power demand must be satisfied, such as with a motor driving a pump. With this insight, battery modeling can be designed to also provide test results that have a higher correlation with other types of electrical components, such as common power electronics, such as capacitors and inductors.

Both batteries and fuel cells are electro-chemical systems, but a battery is an energy storage device, while a fuel cell is an on-demand power supply that provides power as long as the fuel cell is supplied with hydrogen and oxygen. The fuel cell is considered a current-controlled voltage source (CCVS) and its output voltage is a function of its output current.

As a result, batteries and fuel cells are electro-chemical components that convert chemical energy into electricity and heat. Their energy is stored chemically, and their characteristics will be different from other electrical energy storage devices.

BATTERY CHARACTERIZATION

A battery is typically characterized by a constant current discharge. What is actually happening is that, as the discharge current increases, there will be an energy loss within the battery itself, as shown in Figure 1 on page 20.

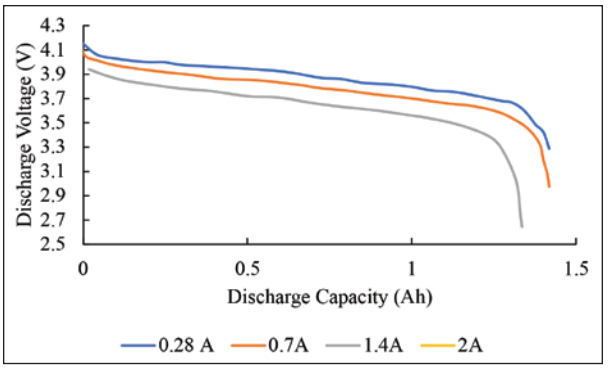


Figure 1: Battery discharge characteristics

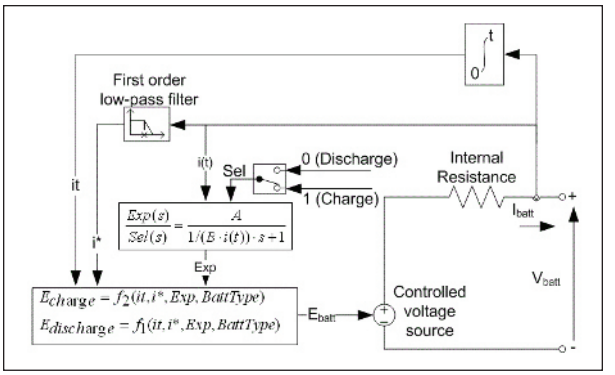


Figure 2: SIMULINK battery model

Based on the behavior shown in Figure 1, a battery is sometimes believed to have an unchanging effective resistance. However, the battery discharge voltage will change based on its state of charge as well as the current it is delivering. The consequence is that, as energy is extracted from a battery, the amount of stored charge in the battery decreases.

The SIMULINK model in Figure 2 shows a battery model that correlates discharge voltage, current, resistance, and the battery's state of charge (SOC).

What the model in Figure 2 (with the coefficients that have been obtained from experimental data) shows is that a generic battery model can be used that will incorporate the ability to determine the battery charge, as well as the computation of discharge voltage and resistance.

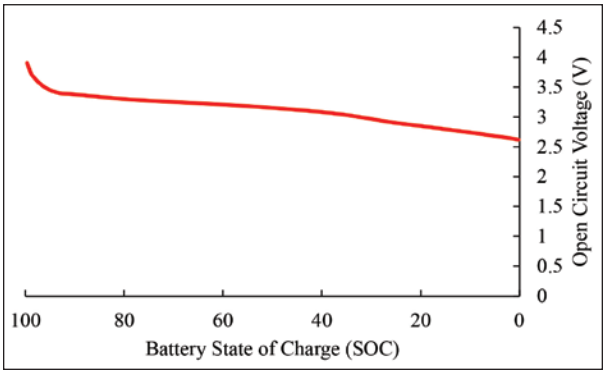
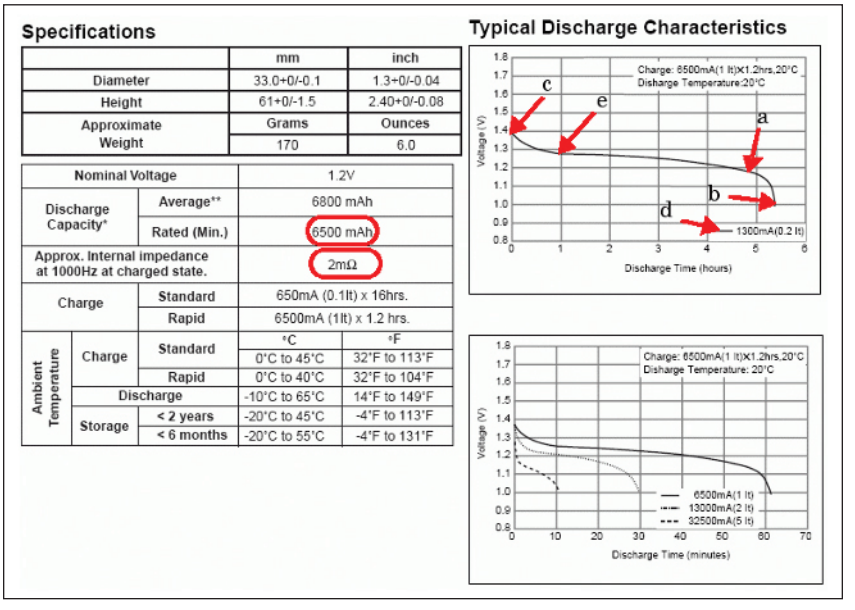


Figure 3: Battery open circuit voltage vs. state of charge [1]

As we see in Figure 3, the battery is considered a controlled voltage source, where its open circuit voltage will reduce as the state of charge decreases. As a result of the SOC decreasing, the discharge voltage will also decrease.

This information then gives us the ability to create a generic battery model that is dependent on certain points in the discharge curve, as shown in Figure 4. The points can be used to determine varying battery SOC and will then yield a quantifiable battery discharge function.



Specifications

		mm	inch
Diameter		33.0+0/-0.1	1.3+0/-0.04
Height		61+0/-1.5	2.40+0/-0.08
Approximate Weight		Grams	Ounces
		170	6.0
Nominal Voltage		1.2V	
Discharge Capacity*	Average**	6800 mAh	
	Rated (Min.)	6500 mAh	
Approx. Internal impedance at 1000Hz at charged state.		2mΩ	
Charge	Standard	650mA (0.1It) x 16hrs.	
	Rapid	6500mA (1It) x 1.2 hrs.	
Ambient Temperature		°C	°F
Charge	Standard	0°C to 45°C	32°F to 113°F
	Rapid	0°C to 40°C	32°F to 104°F
Discharge		-10°C to 65°C	14°F to 149°F
Storage	< 2 years	-20°C to 45°C	-4°F to 113°F
	< 6 months	-20°C to 55°C	-4°F to 131°F

Figure 4: Characterizing a battery [2]

EVALUATING BATTERY POWER SOURCE BEHAVIOR

Does the battery behave the way it is characterized or does it behave as a constant power source? This could be answered depending on whether the load is passive or non-passive.

Since a battery is a component that stores its energy chemically, it can have two types of discharge characteristics, either constant current or constant power. In Figure 5, we see that, during constant current discharge, the battery discharge voltage is also continuously decreasing. As a result, the power delivered by the battery will also decrease due to the falling voltage.

With constant power discharge, the battery discharge voltage decreases faster than the constant current discharge. In this case, the battery discharge power will meet the demands of the load.

In constant current discharge, the discharge voltage decreases along with the SOC. If the electrical is passive, then it can accept a constant current discharge. However, if the load is non-passive, it will require constant power discharge.

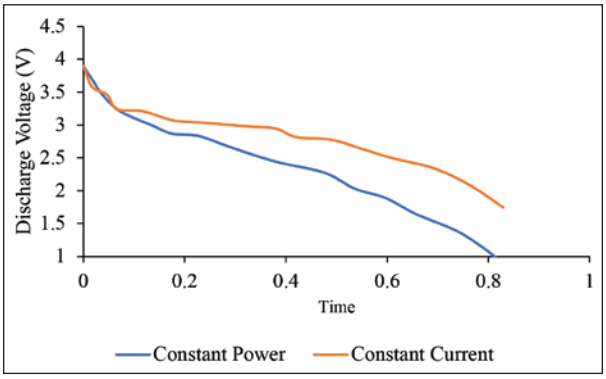


Figure 5: Discharge voltage impact based on discharge mode [1]

In Figure 6, we see how the battery discharge current is influenced by constant current and constant power discharge.

During constant current discharge, the current remains constant and does not change with time. In the case of constant power discharge, the current is low initially when the voltage is high and the current increases as the battery discharge voltage decreases to maintain the power. Note that during constant power, the power discharge is constant at the expense of decreasing voltage and increasing current. Also, the capacity of the battery will decrease more rapidly during constant power discharge and must be sustained by integrating the current.

In Figure 7, we see how power delivery is impacted by battery discharge. In the case of constant current, the battery power delivery is decreasing due to the fall in battery voltage. In the case of constant power, the discharge power remains constant, but voltage and current are also continuously changing. As the voltage decreases, the current increases, which results in the rapid loss of SOC and increased heat generation.

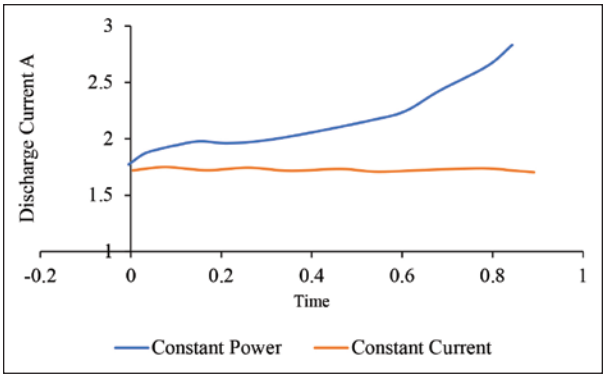


Figure 6: Discharge current impact based on discharge[1]

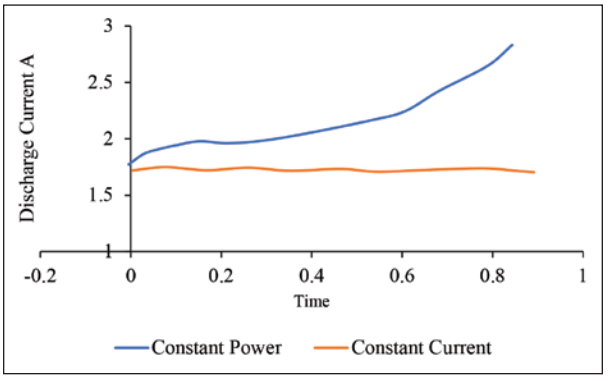


Figure 7: Sample output power based on battery discharge[1]

Unlike a fuel cell that is capable of providing a constant voltage and current, a battery is limited in that it can provide constant power but not constant voltage.

EVALUATING SYSTEM SOURCE AND LOAD

The constant current discharge and constant power discharge may impact the applicability of LCA and need to be assessed to confirm whether that is applicable or not. This is answered by looking at the characteristics of the system source, load, or both.

This theory can also be applied to a DC motor and a resistor, inductor, and capacitor (RLC) circuit. The circuit model of the DC motor is shown in Figure 8.

An electric motor can be mathematically represented by the use of two differential equations, as shown in Equation 1 and Equation 2:

$$J\ddot{\theta} + b\dot{\theta} = Ki \qquad \text{Eq. 1}$$

$$L\frac{di}{dt} = Ri = V - K\dot{\theta} \qquad \text{Eq. 2}$$

In the current model, the voltage of the source is known and kept constant. If a battery is discharging constant power, the voltage and current will ***not*** remain constant. Therefore, we need to reexamine the motor model with variable input voltage, starting with the conservation of energy in its raw form, as shown in Equation 3:

$$V_B(t)I_B(t) - V_R(t)I_B(t) - LI_B(t)\frac{dI_B(t)}{dt} - P_m = 0 \qquad \text{Eq. 3}$$

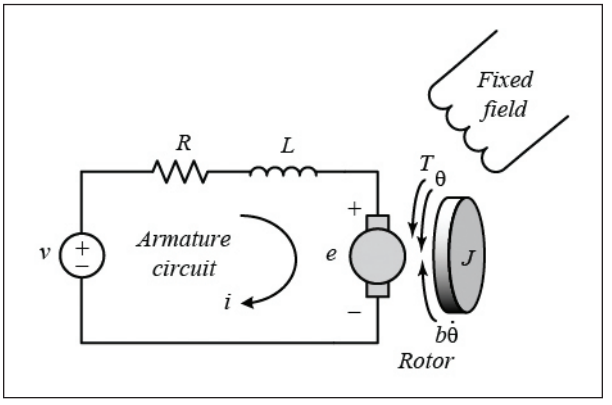


Figure 8: Circuit schematic of a motor[3]

Note that the differential equation is not homogenous, and current (I_b) only appears in three terms. The required power comes from the mechanical domain. To simplify the process, we divide the equation by I_b, as shown in Equation 4:

$$V_B(t) - V_R - L\frac{dI_B}{dt} - \frac{P_m}{I_B} = 0 \quad \text{Eq. 4}$$

The resistor voltage can be further simplified through Ohm's Law, as shown in Equation 5:

$$V_B(t) - I_B(t)R - L\frac{dI_B(t)}{dt} - \frac{P_m}{I_B(t)} = 0 \quad \text{Eq. 5}$$

In the case of the electric motor, the load will be non-passive due to the motor having to provide power to satisfy the mechanical load. As the current changes, the required voltage will also change. As the voltage decreases, the required current will increase, and the increasing current will also reduce the battery state of charge.

The last term of the equation contains power and current. The required power is known, but current and voltage are changing. Therefore, we cannot solve the equation for voltage and current at the same time. First, we must solve for the current. Then, we can solve for the voltage.

To further complicate the issue, the efficiency of electronics changes with input voltage is shown in Figure 9 and Figure 10.

With the change in the efficiency of electronics, the input voltage and current need to be known to compute the power so that, as input voltage drops, the input current will increase along with the power needs. This makes the power required further dependent on voltage and current.

Equation 5 and Equations 1 and 2 are not the same, but Equation 5 can be simplified by using Equations 1 and 2 and assuming a constant voltage. In the case of Equation 5, LCA cannot be used. But the insights derived by the current in the denominator can help explain inrush current.

The new equation is non-linear and non-homogenous and would give a different solution to the existing model.

EXAMINING A BATTERY IN AN RLC CIRCUIT

The next step involves examining a battery in an RLC circuit. The current equation obtained from Kirchoff's Voltage Law (KVL) is shown in Equation 6:

$$V_s(t) - \int_0^t \frac{i(t)}{c}\,dt - iR - L\frac{di}{dt} = 0 \quad \text{Eq. 6}$$

The conservation of energy is applied to the RLC circuit, as shown in Equation 7:

$$V_s(t)i(t) - V_c i(t) - V_R i(t) - V_l i(t) = 0 \quad \text{Eq. 7}$$

Note the current is in each term, and the equation is homogenous and linear. The current can be factored out of each of the terms as shown in Equation 8:

$$V_s(t) - V_c - V_R - V_l = 0 \quad \text{Eq. 8}$$

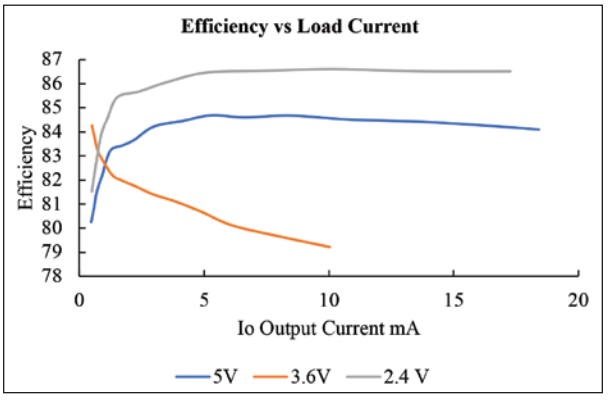


Figure 9: Electronic module efficiency based on load current[4]

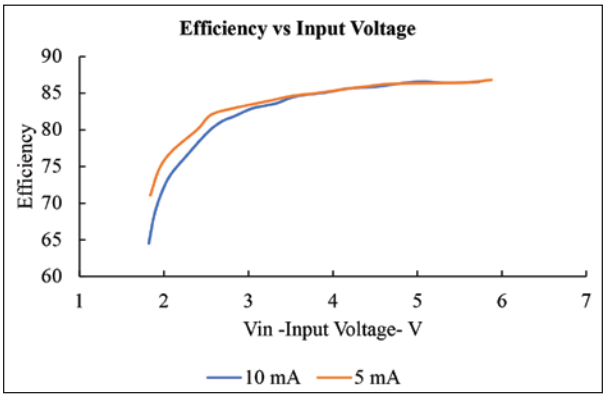


Figure 10: Electronic module efficiency based on input voltage[4]

The equations for voltage and current for capacitors, resistors, and inductors can be substituted into Equation 8, resulting in Equation 9:

$$V_s(t) - \int_0^t \frac{i(t)}{c}\,dt - iR - L\frac{di}{dt} = 0 \qquad \text{Eq. 9}$$

Note that the conservation of energy shown in Equation 9 is the same as in Equation 6. Therefore, linear circuit analysis can be used, which is the reason we propose the use of the electrical matrix since it shows the typical approach for all source and load characteristics (see Figure 11).

It can be seen that LCA is a special case of the conservation of energy.

The next step involves examining where we are with our current circuit analysis, as shown in Figure 11. Based on our dynamic motor modeling with a battery as the main power source, we are proposing adding an additional tool to the toolbox and limiting the use case of LCA. The new proposed matrix is shown in Figure 12.

Like the battery, the other source of electro-chemical energy is the fuel cell. Unlike a battery, a fuel cell is an open system in which hydrogen and oxygen are delivered to produce voltage and current. The next question that comes up is where the fuel cell fits within the electrical matrix and whether it will follow the battery or go elsewhere.

Source	Load	Linear Circuit Analysis
Steady State	Passive	Yes
Steady State	Non-Passive	Yes
Dynamic	Passive	Yes
Dynamic	Non-Passive	Yes

Figure 11: Typical use cases of linear circuit analysis

Source	Load	Linear Circuit Analysis
Steady State	Passive	Yes
Steady State	Non-Passive	Yes
Dynamic	Passive	Yes
Dynamic	Non-Passive	

Figure 12: Proposed change for applicability of linear circuit analysis

One of the differences of the fuel cell is that it provides power-on-demand in which its discharge voltage is a function of current. The fuel cell is considered a steady-state load. A steady-state load can provide constant current and constant voltage. A fuel cell can provide a constant voltage and current as long as hydrogen and oxygen are provided to the fuel cell. A sample polarization curve of a fuel cell is shown in Figure 13.

Note that the voltage drops as more current is drawn, but the system can reach a steady-state solution. In this case, Equation 4 can be solved since the power source is considered a current-controlled voltage source:

$$v_d = r * i_c \qquad \text{Eq. 10}$$

If Equation 10 is substituted for Equation 4, the differential equation will only contain current as shown in Equation 11:

$$r * I_B - I_B(t)R - L\frac{dI_B(t)}{dt} - \frac{P_m}{I_B(t)} = 0 \qquad \text{Eq. 11}$$

As a result, we can solve for the current and then obtain the voltage. The battery is considered a dynamic source since it cannot provide constant power with constant voltage and constant current.

DEFINING PASSIVE AND NON-PASSIVE LOAD

The next point involves defining a passive and non-passive load. The main components integral to passive loads are capacitors, resistors, and inductors. In each of these cases, a voltage-current relationship can be applied to the electrical power equation, as shown in Equations 12, 13, and 14.

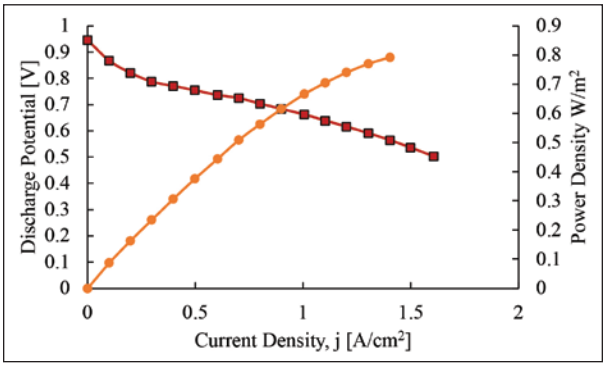


Figure 13: Sample of fuel cell polarization curve[5]

IEEE PSES 20TH ANNIVERSARY

IEEE ISPCE 2024

IEEE International Symposium on Product Compliance Engineering

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Annually, the IEEE International Product Safety Engineering Society (PSES) hosts a premier symposium (ISPCE) on current topics relevant to people who are challenged to make products safe and compliant with ever-changing global codes, standards, & regulations.

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Our Keynote Speaker

PETER SHEARSTONE

VP, Global Quality Assurance & Regulatory Affairs

Peter Shearstone joined Thermo Fisher Scientific in 2018 as Vice President, Global Quality Assurance and Regulatory Affairs (QARA), and is responsible for leading the company's global, corporate QARA team to ensure our products are safe and comply with their intended use. Headquartered in Waltham, Massachusetts, Thermo Fisher is the world leader in serving science; our mission is to enable our customers to make the world healthier, cleaner and safer.

Prior to joining Thermo Fisher, Peter worked in executive-level quality and regulatory roles for 30 years, most recently at Sysmex America, where he served as Vice President, RA/QA/Clinical and Medical Affairs. Prior to that, he held QA leadership roles at Abbott Diagnostics and Siemens Healthcare.

Peter holds a bachelor's degree in biology from Salem State University in Salem, Massachusetts.

Topics for ISPCE 2024

The IEEE international Product Safety Engineering Society seeks original and unpublished formal papers, presentations without formal papers, tutorials, and workshops on any and all aspects of product safety and compliance engineering - including, but not limited to:

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- Importance of Ethics for Effective Compliance
- Field Inspections & Evaluations
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- Global Market Access
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- Instrumentation and Laboratory Equipment
- Introductory or Advanced Design for Compliance
- Laboratory Safety
- Legal Regulations, Directives & Consumer Protection
- Medical Devices
- Product Labeling
- Safety of Education and Healthcare facilities

Important Dates

February 15, 2024
Formal Paper/Reviewable Presentation Submission Deadline

March 15, 2024
Acceptance Notification Deadline

April 1, 2024
Final Paper/ Presentation Submission Deadline

Conference Dates

April 30 - May 2, 2024

The first case that is examined is the capacitor. The electrical power is computed by the voltage and current, as shown in Equation 12:

$$P = V * I \quad \text{Eq. 12}$$

In the capacitor, there is a relationship between current and the derivative of voltage with respect to time, as shown in Equation 13:

$$I = C\frac{dV}{dt} \quad \text{Eq. 13}$$

By combining Equation 12 and Equation 13, a relationship between voltage and power can be obtained. This function is continuous everywhere:

$$P = CV\frac{dV}{dt} \quad \text{Eq. 14}$$

The next component that falls into the passive load is the resistor. The resistor has a voltage and current relationship, as shown in Equation 15:

$$V = IR \quad \text{Eq. 15}$$

If Equation 15 is combined with Equation 12, two equations can be obtained for the resistor power, as shown in Equation 16:

$$P = I^2R = \frac{V^2}{R} \quad \text{Eq. 16}$$

Like the capacitor, the power can be related to either voltage or current and is continuous everywhere.

The last component is the inductor, and the voltage and current relationship for this component is shown in Equation 17:

$$V = L\frac{dI}{dt} \quad \text{Eq. 17}$$

The voltage relationship of Equation 17 can be placed into Equation 12 to obtain Equation 18:

$$P = IL\frac{dI}{dt} \quad \text{Eq. 18}$$

Like the capacitor and resistor, the inductor power can be expressed in terms of one variable and is continuous everywhere.

A non-passive load involves loads in which power requirements must be satisfied, and the voltage and current respond to the power needs. Power is known in the case of electrically generated power. But voltage and current are not known in cases in which the battery is the primary load.

If KVL is applied, the power is divided by the current to convert into the voltage domain, as shown in Equation 19:

$$V = \frac{P}{I} \quad \text{Eq. 19}$$

In this case, the voltage function from Equation 19 is not continuous everywhere. So as the current increases, the required voltage decreases until it hits the asymptote. The element introduced is a power-based element in which the element requires constant power.

The proposal for electrical circuit analysis involves the transition from the matrix shown in Figure 11 to the matrix shown in Figure 12. To proceed, the load and the source need to be examined to determine whether linear circuit analysis is applicable. For instance, in a case where the source can provide a constant voltage and current, such as with a fuel cell or a power supply, the input voltage to the system will be constant. In this case, we can solve for the voltage and current at the same time and LCA can be used.

The next step of the process involves examining the sources to see how they will impact the proposed electrical matrix. In addition, all four cases will be tested to validate the theory.

CONCLUSION

Today's electrical and electronic systems depend on portable sources of energy to be able to meet the demands (and expectations) of customers and users of those systems. LCA, as used in our circuit analyses, identifies issues with the broad applicability of the model due to interactions between the power source and the load and has been shown to be valid in only three of the four usage cases we evaluated. Accordingly, to meet the challenges of creating systems with the highest value, lowest mass batteries and fuel cells, a new approach can be used, one that involves using the conservation of energy to develop a

relationship between voltage and current required by both passive and non-passive loads.

The raw form of the conservation of energy can use LCA when passive elements are present. But there are limits to the use of LCA, and a new tool is needed to solve new problems. Our hope is that new insights resulting from our research will help size batteries for existing needs, size electronics components to minimize conduction and switching losses, and improve electronic efficiency.

In addition, battery evaluation needs to include the connection between the source and the load. For instance, a motor used in a battery electric vehicle should be tested with a variable input versus a constant input load to get an accurate representation of how the motor and electronics will actually behave in the real world.

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COMPLYING WITH THE EU'S EMC DIRECTIVE WITHOUT 3RD PARTY TESTING

Keith Armstrong is a senior contributor to *In Compliance Magazine*, and the founder and principal of Cherry Clough Consultants Ltd, a UK-based engineering firm that utilizes field-tested EMC engineering principles and practices to help companies achieve compliance for their products and reduce their potential risk. He is a Fellow of the IET and a Senior Member of the IEEE and holds an Honors Degree in Electrical Engineering from the Imperial College, London (UK). Armstrong can be reached at keith.armstrong@cherryclough.com.

By Keith Armstrong

A common path to achieving compliance to the European Union's (EU's) EMC Directive 2014/30/EU (which I shall call the EMCD here) takes many manufacturers down the route of utilizing a third-party EMC test laboratory to obtain EMC test reports for their products. This process was detailed in the article "IT Server Hardware Compliance, Part 1," which appeared in the December 2023 issue of *In Compliance Magazine* [1].

However, it is important to understand that the EMCD *contains no legal requirements for performing any EMC laboratory tests*. This was equally true for the original EMCD, 89/336/EEC, and its 2nd Edition, 2004/108/EC.

Manufacturers are required to affix the CE marking to their products, and to do that, they must first have created and signed an EU EMC Declaration of Conformity (DoC), which is based on the evidence of EMCD compliance contained within a Technical Documentation File (TDF).

As I will show later, there are two routes to declaring EMC compliance (sometimes called conformity to the EMCD), and it is the manufacturer's choice whether his DoC relies entirely on all relevant harmonized standards (the "Standards Route") or uses just a few or none of the relevant harmonized standards (the "EMC Assessment Route").

Either way, a DoC is effectively a legal statement by a manufacturer that "if my product was tested to these harmonized standards, it would probably pass."

CE-marking plus a DoC is a requirement for crossing customs borders into and within the EU. For the official "chapter and verse" on this, see my January 2024 blog "No tests are required for CE-marking to the EMCD[1]."

1. Available at https://www.emcstandards.co.uk/no-tests-are-required-for-ce-marking-to-the-emc.

How a manufacturer obtains sufficient confidence to make this legal declaration is entirely up to that manufacturer and should be documented in the TDF. But compliance with the EMCD certainly does not require any test reports from third-party EMC test labs. This makes it possible for manufacturers of electronic products to save time and money by testing in their own EMC labs.

This also makes it possible for individual entrepreneurs who might be working out of their garages (like Mr. Hewlett and Mr. Packard!) to sell their products in the EU without the high costs associated with EMC testing to standards. In fact, the same is true for most of the so-called CE Marking Directives – third-party testing is only a legal requirement in a very few EU Directives, and only when dealing with especially dangerous products, such as certain kinds of medical equipment, machinery such as chainsaws, bandsaws, etc.

I have often heard the EU's single market described in the United States (U.S.) as "Fortress Europe," when the exact opposite has always been true. The EU's single market does not present any significant barriers of cost or delay to any equipment from anyone, anywhere in the world.

APPLYING THE EMC DIRECTIVE

OK, that's enough background. Let's get into the details!

To see how it is that manufacturers can comply with the EMCD [2] without third-party testing, even without any testing at all, we need to understand how the EMCD works. When we understand this, we will also understand that even passing third-party laboratory tests to all relevant EU-harmonized EMC standards might not, on its own, ensure compliance with the EMCD.

The EMCD applies to both *apparatus* and *fixed installations*, with special legal meanings for both of these otherwise commonplace terms. Figure 1 shows that apparatus is treated very differently from fixed installations.

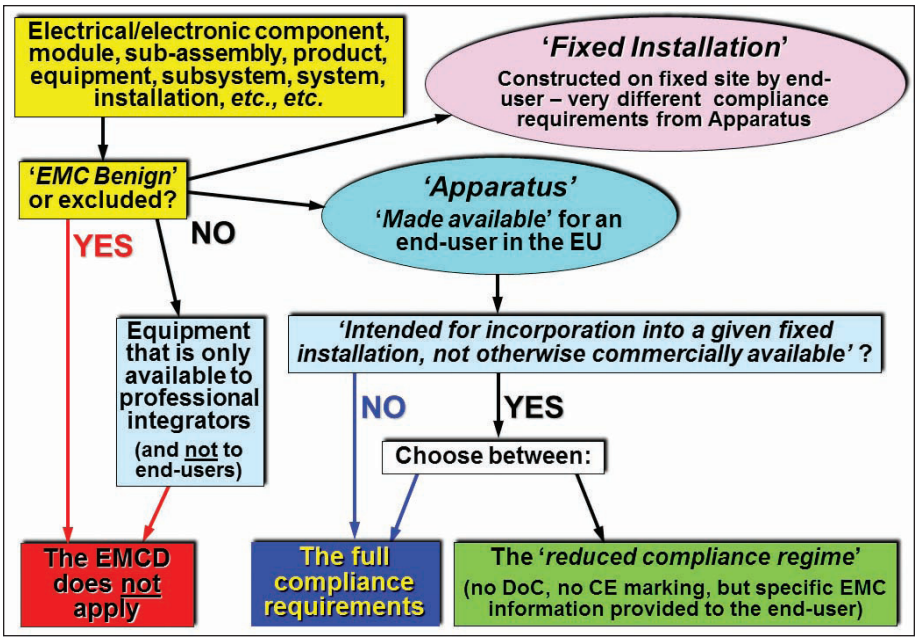

Figure 1: Applying the EMC Directive

Apparatus is any electrical/electronic item that could cause or suffer EMI *and* which is "made available for an end-user in the EU" for the first time (see later). It is important to understand that the EMCD applies to every individual unit of manufacture (e.g., individually serial numbered items), and Chapter 2.2 in [4] and Chapters 1.2 and 3.2.2 in [5] provide much more detail on this.

The EMCD also has a special category of apparatus "…intended for incorporation into a given fixed installation, and not otherwise commercially available" (which most of us would call *custom*, *bespoke*, or *one-off* equipment), which can avoid having to be CE marked for EMC, although it then has to comply with other EMC activities.

Inherently benign equipment is excluded from the EMCD's scope, and the official guide [5] contains a list of what is currently considered to be EMC benign. As a general rule, inherently benign equipment never contains any operational semiconductors (rectifiers, transistors, ICs, etc.) or thermionic valves or makes sparks.

Equipment that is only made available for the exclusive use of professional integrators in the construction of their own products and which is not made available for end-users (even by distribution) is also excluded from the scope of the EMCD. However, such equipment will almost certainly have to be CE marked for compliance with an EU safety directive, such as the Low Voltage Equipment Directive (the LVD) [6], Machinery Directive [7], etc. This is one reason why a manufacturer should never assume EMC compliance when purchasing a CE-marked third-party product for incorporation into another product, system, or installation.

I have seen many large projects suffer greatly from main contractors making two big errors regarding EMC:

1. Mistakenly assuming that every item of equipment that carries a CE marking must perforce comply with the EMCD. This article describes three ways in which this assumption can be wrong, all of which are shown in Figure 1.
   a. When the equipment is *inherently benign*;
   b. When the equipment is only supplied to professional integrators, whether it is manufactured in volume or custom-designed (e.g., as a subcontract); or
   c. When the equipment is custom-made for a particular end-user's fixed installation
2. Mistakenly assuming that an EMC-compliant final system merely needs EMC compliance for its constituent parts, often mistakenly called the CE + CE = CE approach (see later).

Also exempt from the EMCD are: a) radio amateur equipment that is not commercially available;

b) aeronautical equipment covered by Regulation 216/2008; c) "custom-built evaluation kits destined for professionals to be used solely at research and development facilities;" and d) equipment covered by the Radio Equipment Directive (2014/53/EU), typically referred to as the RED[2].

For any equipment that has one or more functions that use radio wave communications or propagation (even simple broadcast receivers), the RED has very important implications for complying with the EMCD [2] and the LVD [6]. (See a video of my presentation at the 2020 IEEE EMC+SIPI Symposium, "Who's Afraid of the Big Bad RED," available at https://vimeo.com/469763677.)

Equipment that has EMC aspects addressed in specific product Directives (e.g., medical devices, automotive, etc.) is only exempt from the EMCD to the extent covered by those other Directives. Unfortunately, this is widely misunderstood to mean they are totally exempt from the EMCD.

Apparatus that must comply with the EMCD when made available for an end-user in the EU may be advertised or exhibited before it is EMC compliant as long as it is clearly marked as being non-compliant with the EMCD and as not (yet) being available to end-users in the EU.

EMC CONFORMITY OF APPARATUS

The EMCD requires all apparatus to:

1. Comply with the Essential Requirements
2. Undergo a conformity assessment procedure
3. Have a TDF prepared and readily available for inspection by enforcement officials
4. Be supplied with specified User Information
5. Have a signed EC Declaration of Conformity
6. Carry the CE marking

Items 1-5 in the above list must be complete before the CE marking is applied (item 6).

All of the items 1-6 must be complete before the apparatus is "made available" for the first time in the EU (see 2.2 and 2.3 in [4]). It is important to note that being made available for the first time in the EU does not only mean new products. Used or second-hand products that are brought into the EU are also covered and have to comply with the EMCD, no matter how old or how large they are.

As already mentioned, there is an exclusion to compliance with the EMCD for apparatus intended for incorporation into a given fixed installation and not otherwise commercially available (see later).

THE PROTECTION REQUIREMENTS

The Essential Requirements (Clause 1 of Annex I in [2]) state the essential legal requirements for compliance with the EMCD, using simple terminology in the (probably vain) hope that this will

2. See https://single-market-economy.ec.europa.eu/sectors/electrical-and-electronic-engineering-industries-eei/radio-equipment-directive-red_en

make it difficult for lawyers to interpret them in ways other than what was intended:

> *"Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:*
>
> *(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;*
>
> *(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use."*

Who would ever want their products not to comply with these Essential Requirements? The costs of dealing with the resulting complaints (and the loss of possible future sales) would eat into the financial bottom line, making a manufacturer less profitable.

So, even if there was no EMCD, the Essential Requirements above should still be applied to help reduce financial risks.

CONFORMITY ASSESSMENT IN GENERAL

Conformity assessment is specified in Annex II of [2] and requires an EMC Assessment that results in a TDF that demonstrates how it is that a product can claim compliance with the Essential Requirements. A TDF should cover all operational modes and all intended use configurations, and the amount of verification work required can be reduced by first identifying the worst-case combinations of configuration and operational mode, i.e., the ones that would cause the highest emissions or are the most susceptible to interference.

As I said earlier, there are two routes to conformity with the EMCD:

1. The Standards Route, which uses harmonized EMC standards; and
2. The EMC Assessment Route, which can use any standards or none.

CONFORMITY ASSESSMENT BY USING HARMONIZED STANDARDS

When following the Standards Route, the product's DoC must list all of the relevant harmonized EMC test standards that apply to the product, which can be found on the official listing website at [8]. This route to EMC conformity requires that all these harmonized standards are correctly applied. But what does "correctly applied" actually mean?

Clearly, one way is to have a third-party test lab perform all of the tests exactly as described in the relevant standards, with the EMC test reports forming the bulk of the TDF. If the test lab is accredited by a national accreditation body to perform a particular test, there is more confidence that the test will be done correctly. Unfortunately, my experience (and that of many others) is that not all national accreditation bodies are equal.

Third-party testing has been very well described in [1], so I don't need to go into it here.

Some manufacturers (and not only the larger ones) have their own full-compliance EMC testing labs, and some of them even have some/all of their testing labs accredited. These labs are generally best used just as if they were third-party labs.

(Interestingly, in-house testing labs located in the same building as the design teams can pay back their original investment much more quickly than the usual business case predicts. I have seen one such lab achieve full payback in four months!)

However, as stated early on in this article, using the services of a third-party accredited testing lab to correctly apply a harmonized standard to test exactly to the standard is not the only option when following the Standards Route.

The correct application of a harmonized standard actually means that a manufacturer has done enough homework to have sufficient confidence that if the product was fully tested in an EMC laboratory that was accredited to test to that standard – it should pass.

Let's be perfectly clear on this. Correct application does not mean that the product has actually been tested to that standard but only that, if it were tested at some future time, it would probably pass.

Unfortunately, even when full testing is done in a lab that is accredited for that test and passed, it might not ensure compliance with the Essential Requirements in real-life operation.

The EMCD leaves manufacturers totally free to decide on the amount and quality of EMC testing they do themselves or have done for them to have sufficient confidence to sign their DoC when using the Standards Route.

(It is important to understand that there are no absolute guarantees in the world of EMC, even with fully accredited third-party testing. A product that passes in one testing lab can fail when tested in another lab, even though nothing has changed in the product and the exact same cables are used with it. Some manufacturers take advantage of this by always using test labs that they find are more likely to give them a pass result!)

Here are four examples of when laboratory testing might not be required to correctly apply a harmonized radiated emissions standard such as EN 55022:

A. When the product emits a certain amount of radio frequency (RF) power spread in a particular way over a particular frequency spectrum, and calculations/simulations show that, if this emitted power was measured according to the relevant EMC test standard, it would be almost certain to pass (even when taking measurement uncertainty into account). For examples of this approach, see [9] [10] and [11].

B. When the product is housed in a well-shielded and well-filtered enclosure that has been proven by shielding effectiveness testing and/or simulation to provide more than sufficient RF attenuation to ensure that, if its emitted RF power was measured according to the relevant EMC test standard, it is certain to pass (even when taking measurement uncertainty into account).

   Many manufacturers purchase well-shielded/filtered overall enclosures, then ruin them with modifications, completely wasting their high cost (see Chapter 5 of [12]). So an expert assessment is usually required to have sufficient confidence in the final assembly.

C. When a product fails in a test lab and a simple modification applied by hand makes it pass, and the same modification is applied on production units, there can be sufficient confidence that, if a new production sample was retested, it would pass.

   In this context, "the same modification" means physically and dimensionally the same – for example, an additional shield bond made with a screw-fixing is not the same for EMC as an additional bond made in a different place or made in the same place with a braid strap or piece of green/yellow wire instead of a screw.

D. When a product has passed an equivalent or tougher radiated emissions test and has not been changed (either in its hardware, software, or components). A typical example is a product that has passed MIL-STD 461 radiated emissions tests, which set lower emissions limits than the relevant harmonized test standard (see [13]).

4.3 in [5] provides very good guidance on EMC assessment and makes it clear that the EMCD contains no legal requirements for testing.

Unfortunately, even when full testing is done in a lab that is accredited for that test and passed, it might not ensure compliance with the Essential Requirements in real-life operation. This is, of course, what really matters for compliance with the EMCD and also (more importantly) for financial success. This is because no harmonized test standards cover all of the EM disturbances that could occur in real life. Also, it is because the tests have been specifically developed to ensure repeatability in testing, which can often mean they are simply not representative of real-life EM disturbances.

Also, given the inevitably slow pace of international standardization, most published standards are behind the times. For example, none of the harmonized immunity standards cover the very close proximity of

cellphones, e-book readers, Wi-Fi transmitters, RFID transmitters (including active RFID tags), etc., even though such proximity is now a normal "… electromagnetic disturbance to be expected in its intended use…".

Immunity to the near-fields (see [14]) that can be created by portable RF transmitters in very close proximity is arguably now a necessity for legal compliance with the Essential Requirements, even though not tested by any harmonized standards.

"Big deal," you might say, "but I don't want to spend any more on legal compliance than I have to!" OK, but think for a minute about what I said earlier in the section on Essential Requirements. If products don't comply with them, they are less likely to be financially successful. If they have big problems with EMC in real life, they could even do irreparable damage to a manufacturer's brand image and future profitability. Some companies have actually been bankrupted by real-life EMC problems.

The real reason we need to achieve EMC compliance is to have products that work well enough in real life and don't upset customers. Achieving this is important to help control financial risks, and so what if we have to produce a few pages of legal documentation for EU sales, when it merely covers EMC work we have already done?

For these reasons, when following the Standards Route, in addition to correctly applying all relevant harmonized standards, I always recommend performing a full EMC assessment as detailed below, then doing whatever else it takes to ensure conformity with the Essential Requirements. This can sometimes be as quick and easy as a check for emissions or immunity using a homemade near-field probe with a low-cost spectrum analyzer [15].

Please note that, when following the Standards Route, the DoC should not state that the product has been tested to the listed harmonized standards and has passed those tests (unless they have been, of course!). Generally, it is better for the DoC to say something like, "The following standards have been applied...".

CONFORMITY ASSESSMENT BY NOT USING HARMONIZED STANDARDS

The EMC Assessment Route is the other route to EMC conformity permitted by the EMCD. When following this path, a manufacturer declares the EMC conformity of his apparatus directly with the Essential Requirements of the EMCD, using just some of the relevant harmonized standards, or just some parts of some harmonized standards, or even ignoring all harmonized standards completely. The EMC Assessment Route must follow a specified technical methodology to ensure that the Essential Requirements are met.

According to [5], the EMC Assessment Route is usually more appropriate than the Standards Route in the following situations:

- Where the Essential Requirements are not entirely covered by the application of the harmonized standards that are relevant for the product;
- Where the apparatus uses technologies incompatible with, or not yet taken into account by, any harmonized standards;
- The manufacturer uses test facilities not yet covered by harmonized standards;
- The manufacturer prefers to apply other standards or specifications (even in-house specifications) that are not harmonized under the EMC Directive; or
- The apparatus is physically too large to be tested in the type of facility specified by a relevant harmonized standard or where "in-situ" testing is necessary (e.g., for systems or installations that are first assembled on the end-user's site) and is not adequately covered by a harmonized standard.

Of course, a manufacturer may choose to follow the EMC Assessment Route simply to save time and money, which is often the case for start-up companies that cannot afford the cost of laboratory testing.

This alternative conformity route is essentially the old TCF route under the first EMC Directive (89/336/EEC), but with the significant difference that now there is no legal requirement for any TDFs to be assessed by a third party (see Notified Bodies, later).

Non-harmonized methods of demonstrating conformity with the Essential Requirements, which may be able to be used, either singly or in suitable combinations, as part of an EMC Assessment Route, include (but are not limited to):

1. Non-EU-harmonized but published EMC test standards (e.g., FCC, military, automotive, etc.);
2. In-situ/on-site EMC tests [16];
3. EMC tests or checks developed by the manufacturer that are not compliant with the harmonized test methods listed in [8]. These are often called "pre-compliance" EMC tests and can vary from full-compliance tests that are just done a little more quickly than they should be, to near-field probing and a variety of other low-cost methods e.g., those described in [15], which might bear little resemblance to harmonized tests;
4. Calculations (e.g. [9] [10] [11]);
5. Validated computer simulations;
6. Comparisons with known EMCD-compliant products made by the same manufacturer, which use the same technologies, devices, and construction methods. (But beware. Hardware and software technologies, and devices, change very rapidly. And so do their EMC characteristics!)

The EMC Assessment Route's technical methodology includes (but is not limited to):

A. Assessing the EM environment(s) normally expected at the user(s) location(s), taking into account (see [17]):
   i. The likely proximity to sensitive equipment that the product's emissions could interfere with;
   ii. The likely EM "threats" that could interfere with the product, plus the degradation of functional performance that the user will accept when it is interfered with.

B. Create the EMC specifications for the product. To help make life easier, these often use modified versions of harmonized standards, basic IEC test methods (see [1]), other EMC standards (automotive, military, aerospace, etc.), and/or guidance for systems and installations such as [12] [18] [19] or some of the many references they contain.

C. Verify and/or validate the product's design against the EMC specifications. Verification and validation techniques include, but are not limited to, EMC testing.

THE 3RD EDITION OF THE EMCD, 2014-30-EC, APPLIES FROM 20 APRIL 2016

All of the technical compliance issues discussed in this article, and in [1], were previously published in *In Compliance* Magazine in December 2014 (see [20]) and are unaffected by the third edition of the EMCD [2]. The changes in [2] are more to do with adapting the existing EMCD to the EU's New Legislative Framework (NLF, see [4]).

The changes wrought by the NLF are mostly concerned with extending legal compliance requirements to all economic operators through whose hands EMCD-compliant products pass, including the manufacturer of the products (obviously), appointed agents, distributors, importers, etc.

CE + CE DOES NOT EQUAL CE

Constructing systems only from items that are CE-marked, and mistakenly assuming that this alone takes care of the EMC compliance of the overall system or installation, is often (mistakenly) called the CE + CE = CE approach. I say "mistakenly" because it simply doesn't work!

This incorrect approach is very widely used by system integrators, installers, and major contractors. However, it is easy to show that, technically and/or legally, this approach should never be relied upon, and Chapter 1.2.2 in the official guide [5] contains a specific warning against using it. More detailed information on this is given in Chapter 1.5 of [12], Chapter 2.3.4 of [18], and Chapter 2.3.3 of [19].

Note that the so-called CE + CE = CE approach is also incorrect technically and/or legally for most, if not all other, EU Directives, including [6] and [7].

CONCLUSION AND ADDITIONAL INFORMATION

There's a great deal more I could write on complying with the EMCD, but I've covered the main issue of how to comply without using laboratory testing and wandered off into some related issues as well.

To find out more about related issues, here are some sources of free information:

- Employing Notified Bodies (see [21]);
- Creating and maintaining the TDF (Technical Documentation File) (see [21]);
- The EU EMC DoC (Declaration of Conformity) (see [21]);
- Correctly affixing the CE Marking (see [21]);
- The EMC information legally required to be provided with each apparatus (see [21]);
- Maintaining EMC compliance in serial or batch manufacture (see [21]);
- Maintaining EMC compliance when the harmonized standards change (see [21]);
- EMC compliance of custom-designed "apparatus intended for incorporation into a given fixed installation, and not otherwise commercially available" (see Chapter 2.5 of [18]); and
- EMC compliance of "Fixed Installations" (see [18]).

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METHODS AND EFFECTS OF MAGNETIC PULSES ON THE MAGNETORECEPTION OF BIRDS

Exploring Magnetic Sensing Mechanisms in Avian Navigation

The Earth's magnetic field is a dipole that acts like a large magnet, with its poles relatively near to the geographic (rotational) poles. Although the magnetic north pole is really in the geographic south position and vice versa, the magnetic north pole is typically referred to as the end of the dipole closest to the geographic north pole, and the magnetic south pole is similarly referred to as the end of the dipole closest to the geographic south pole. The geomagnetic field lines of force leave the magnetic South through Antarctica, circle the Earth, and re-enter through the magnetic North's surface, through the Arctic pole, creating vectors of these ascending lines of force in the Southern Hemisphere and descending lines of force in the Northern Hemisphere, which are parallel to the earth's surface at the equator.

As one moves closer to the equator, the strength of the lines of force steadily declines, reaching maximum values of around 60,000 nT at the poles

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and around 30,000 nT at the Equator [1]. These characteristics make the magnetic field a very reliable and omnipresent source of information, in which the magnetic vector (the vector between the line of force of the magnetic field and the line of force of gravity) provides directional information that the bird can use as a "compass." Further, the spatial distribution of other factors, such as intensity or inclination, can be components of the "map," providing information on the geographic position of the bird as they vary between the poles and the equator. [2, 3].

METHODS OF MAGNETIC SENSING IN BIRDS

Although it is not completely understood how migratory birds are capable of sensing the orientation and intensity of the geomagnetic vector field generated by the Earth, behavioral experiments indicate that they use a combination of sensing methods and that the combination of these senses provides migratory birds with the ability to successfully migrate [4]. Referred to as the avian magnetic compass, migratory birds determine their position and direction with two separate measurements, which consist of inclination (or deviation) from the magnetic field lines for determining orientation with the poles and magnetic field intensity for determining direction [4]. The two primary methods of detecting inclination and intensity are the radical pair mechanism and the magnetite hypothesis.

Radical Pair Mechanism

A likely mechanism for an axial magnetic compass in migratory birds, the radical pair mechanism relies on unpaired electrons with parallel (T) and antiparallel (S) spins [5]. Sets of unpaired electrons result in differing chemical properties based on what spin combination the set has. This, in turn, alters the reaction rate and yield of chemical processes that occur. A weak external magnetic field can modify the relative alignment of the electrons, thereby altering the reaction rate and yield, and is dependent on the intensity and the orientation of the external field.

For migratory birds, this process usually occurs on the surface of certain cell membranes. The direction of the external field lines produces arrays of protein oriented in the same direction, and the varying density of the synthesized protein enables the bird to determine the orientation of the field lines [5].

In order to produce these radicals, cryptochrome photoreceptors located in the eyes of the bird use photons from external light, such as the sun [4]. Behavior experiments determined that the photoreceptors and the bird's ability to navigate are impacted by the wavelength of perceived light. Further, short wavelengths of light from UV to about 560nm were necessary for radial pair production [4]. Tests that involved birds in total darkness displayed a 90-degree shift in the preferred direction, which suggested that the radical pair sensing mechanism was not activated. Instead, a separate magnetic sensing mechanism behaves as a backup [5]. Although it is uncertain what the backup mechanism is, it likely relies on the magnetite-based magnetoreception mechanism.

Magnetite Hypothesis

The biomineralization of magnetite in animals that migrate, such as certain birds and fish, leads to the hypothesis that the ferrous ferrite may play a role in magnetoreception [5]. Crystals of magnetite roughly 50nm in size are attached to mechanoreceptors within specific cells and behave as small compass

needles within the cells of the bird or fish. The torque produced by the crystal under an external magnetic field triggers the receptor, thereby providing a method of sensing the field. This behavior has also been studied in magnetotactic bacteria, which orient themselves with external magnetic fields [5].

Studies conducted on homing pigeons have determined that magnetite-containing dendrites are located at six locations on the upper beak. Clusters of the dendrites have been found to deform under weak magnetic fields, producing a torsion on the dendrite. We hypothesize that this torque behaves in the same manner as the radical pairs, and provides a complementary sensing method for magnetic fields [5].

MAGNETIC PULSE GENERATION WITH HELMHOLTZ COIL

In order to further investigate the behavior and functionality of magnetoreception in birds (or other animals), the application of magnetic pulses with specific direction and intensity are used to study how the bird's flight behavior is affected. The application of magnetic shielding techniques may be used to block Earth's existing magnetic field. But in order to generate a uniform magnetic field with specified direction and intensity, the application of a Helmholtz coil (see Figure 1) is employed [6].

Figure 1: An example of a Helmholtz coil two-system for uniform magnetic field creation

Two coils placed in parallel along the same axis can produce a relatively uniform magnetic field between the coils, This configuration is known as a Helmholtz coil, named after the German physicist Hermann von Helmholtz. Three pairs of Helmholtz coils can be configured on the X, Y, and Z axis, allowing for complete control of the magnetic field in the center of the configuration.

A configuration of a 3D Helmholtz coil system enables the ability to cancel Earth's magnetic field, as well as produce a static, rotating, or alternating field [6].

EFFECTS OF MAGNETIC PULSES ON BIRDS

The application of 500mT pulses for a few seconds on passerine migrants (bird) initially produces a shift in orientation during flight [5]. As expected, by 4 to 10 days after the treatment, the passerine migrants that had experienced the pulses had recovered their normal orientation and returned to their expected migration path. Another important note made in the experiment was that young birds that had not yet migrated were not affected by the pulse treatment. The shift in orientation due to magnetic pulses indicates that there is involvement with magnetic material for migratory and targeted-location flight [5].

A similar experiment was conducted on homing pigeons [5]. It was determined that pigeons treated with pulses deviated from the untreated control group path, a deviation that became more substantial as the distance between home and the release point was increased. Overall, this indicated that the magnetic pulses would affect the internal avian compass but left the navigation map relatively unaffected, as the pigeons were still capable of returning home.

CONCLUSION

The magnetic orienting mechanism in birds has been discovered to be a two-step system. First, utilizing the information offered by variables of the terrestrial

magnetic field, such as strength or tilt, the map allows them to calculate their geographical position, and the compass allows them to decide the direction to follow. It is also known that birds have an intrinsic sense of magnetoreception. It is the primary foundation, along with the internal circadian clock, for establishing the many navigation systems through intricate learning processes. All of this comes together to produce an adult bird's entire navigation system.

The following are two hypothesized magnetoreception models: By converting the strength of the Earth's magnetic field into mechanical force within specialized cells, magnetoreception based on magnetite particles housed in the upper part of the beak function as chains of magnetite particles that interact with the Earth's magnetic field and provide directional information and even geographic position to the birds.

Chemical magnetoreception based on a radical pair model, in which a molecule is energized by the absorption of a photon, produces an electron and forms a pair of radicals, which affects the speed of singlet-triplet interconversion depending on the alignment with the Earth's magnetic field.

Because both magnetoreception models are hypothetical, the current understanding of magnetoreception models is insufficient to identify the magnetoreception model employed. Although a clear picture of how information from the magnetic compass is interpreted is beginning to appear, our present understanding of magnetoreception is constantly evolving.

There are still a lot of questions concerning magnetoreception and how data is processed from these receptors to the brain. Advances in behavior, anatomy, and physiology will aid in the discovery and identification of magnetic reception structures in the future.

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IMPACT OF DECOUPLING CAPACITORS AND TRACE LENGTH ON CONDUCTED EMISSIONS IN A CMOS INVERTER CIRCUIT

By Bogdan Adamczyk and Mathew Yerian-French

The impact of decoupling capacitors and a PCB trace length on signal integrity was discussed in [1], while the impact on radiated emissions was discussed in [2]. In this article, we evaluate the impact of the capacitors and trace length on conducted emissions.

1. CMOS INVERTER CIRCUIT

Figure 1 shows the block diagram of the inverter circuit and the PCB. In this study, trace length varied between 3,000 mils (short trace) and 20,000 mils (long trace). Additionally, the PCB was tested in two configurations: without the decoupling capacitors and with decoupling capacitors by each inverter (0.1 µF and 1 µF).

2. CONDUCTED EMISSIONS MEASUREMENT SETUP

The measurement setup is shown in Figure 2. The measurements were performed in a semi-anechoic chamber, in accordance with CISPR 25 Edition 5 automotive standard.

Measurements were taken on both the battery and ground lines, in the frequency range 150 kHz – 108 MHz. In the frequency range 150 kHz – 30 MHz measurements were taken with a bandwidth of 9 kHz while in the range 30 MHz – 108 MHz the bandwidth was set to 120 kHz. All measurements were taken with the average, peak and quasi-peak detectors.

3. IMPACT OF THE TRACE LENGTH ON CONDUCTED EMISSIONS

In this section, we evaluate the conducted emission results from the PCB with short traces (3,000 mils) and long traces (20,000 mils) without decoupling capacitors by the inverters.

3A. Short trace vs. long trace: 150 kHz – 30 MHz

Conducted emission results are shown in Figure 3 (battery line) and Figure 4 (ground line).

Observations

Both short and long trace showed failures at the same frequencies, on both the battery and ground lines. The failures for the short trace were smaller.

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Mathew Yerian-French is an electrical engineer specializing in EMC design and diagnostic testing. He received his B.S.E in Electrical Engineering from Grand Valley State University. He focuses on preventing EMC issues through design reviews and early EMC pre-compliance testing and diagnostics. Mat participates in the industrial collaboration with GVSU at the EMC Center. He can be reached at mathew.french@e3compliance.com.

3B. Short trace vs. long trace: 30 MHz – 108 MHz

Conducted emission results are shown in Figure 5 (battery line) and Figure 6 (ground line).

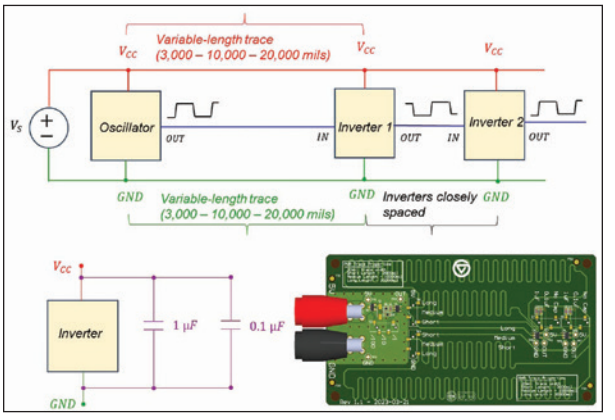

Figure 1: Block diagram of the inverter circuit and the PCB

Figure 2: Measurement setup

Observations

Both traces showed failures over the entire frequency region, with one trace outperforming the other in three frequency subregions.

30 – 42 MHz: Short trace outperformed the long trace, on both the battery and ground lines, using both detectors.

44 – 88 MHz: Long trace outperformed the short trace, on both the battery and ground lines, using both detectors.

90 – 108 MHz: Short trace outperformed the long trace, on both the battery and ground lines, using both detectors.

4. IMPACT OF THE DECOUPLING CAPACITORS ON CONDUCTED EMISSIONS – SHORT TRACE

In this section, we evaluate the conducted emission results from the PCB with short traces, without the decoupling capacitors, and with the decoupling capacitors by each inverter (0.1 µF and 1 µF).

4A: Short trace with and without decoupling capacitors: 150 kHz – 30 MHz

Conducted emission results are shown in Figure 7 (no caps) and Figure 8 (caps) on page 44.

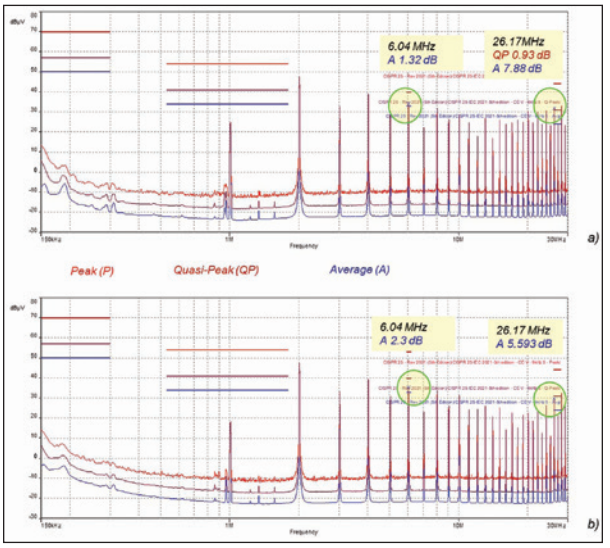

Figure 3: Battery line, 150 kHz – 30 MHz: a) short trace b) long trace

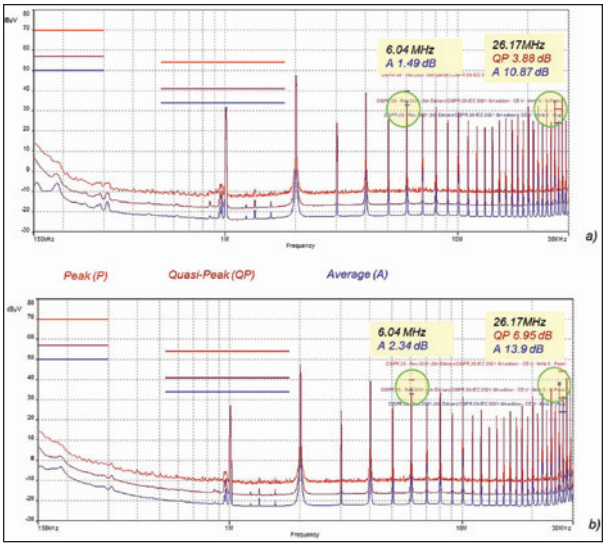

Figure 4: Ground line, 150 kHz – 30 MHz: a) short trace b) long trace

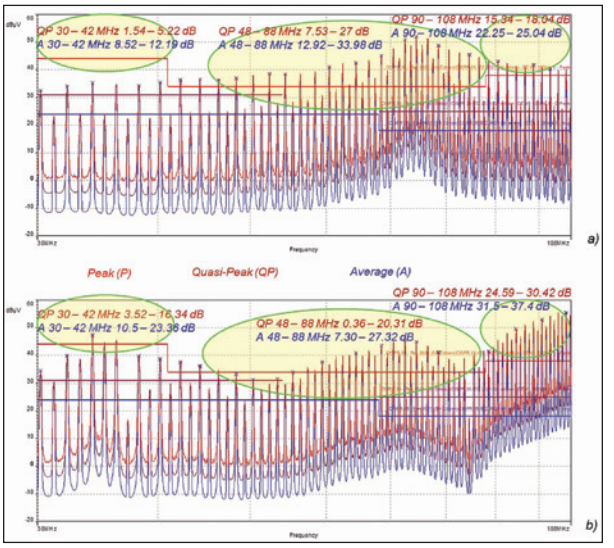

Figure 5: Battery line, 30 MHz – 108 MHz: a) short trace b) long trace

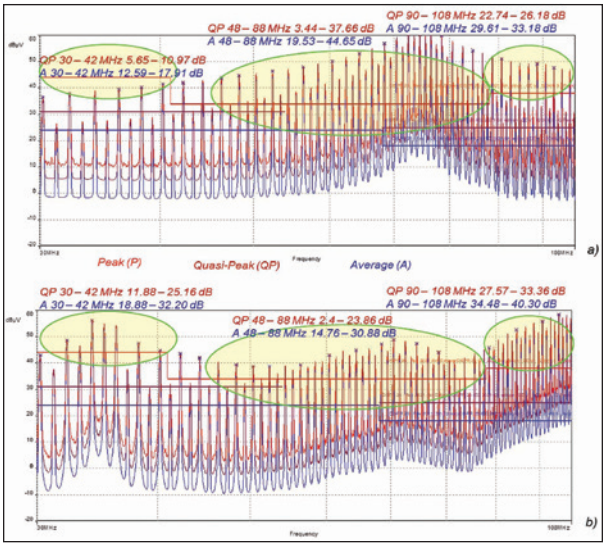

Figure 6: Ground line, 30 MHz – 108 MHz: a) short trace b) long trace

Observations

Battery Line: Capacitors eliminated the failure at 6.04 MHz. At 26.17 MHz, quasi-peak failure was eliminated and the average detector failure was substantially reduced.

Ground Line: Capacitors eliminated the failures at 6.04 MHz and 26.17 MHz.

4B. Short trace with and without decoupling capacitors: 30 MHz – 108 MHz

Conducted emission results are shown in Figure 9 (no caps) and Figure 10 (caps).

Observations

Battery Line: Capacitors eliminated the quasi-peak failures over the entire frequency range except for a single substantially reduced failure, at 107.73 MHz. The average detector failures were eliminated up to the frequency of 73 MHz, and the failures in the range 73 – 108 MHz were substantially reduced.

Ground Line: Capacitors eliminated the quasi-peak failures up to the frequency of 87 MHz, and the failures in the range 87 – 108 MHz were substantially reduced. The average detector failures were eliminated up to the frequency of 73 MHz, and the failures in the range 73 – 108 MHz were substantially reduced.

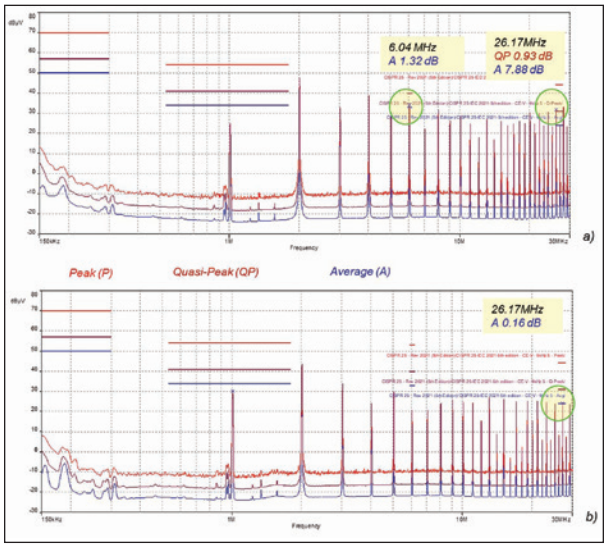

Figure 7: Battery line, 150 kHz – 30 MHz: a) without capacitors b) with capacitors

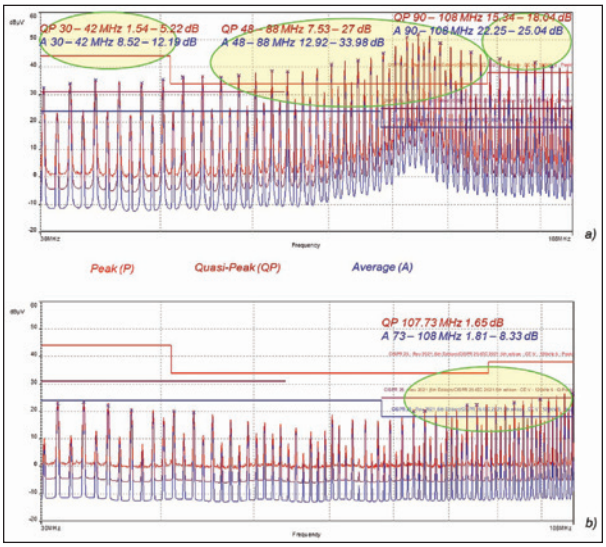

Figure 9: Battery line, 30 MHz – 108 MHz: a) without capacitors, b) with capacitors

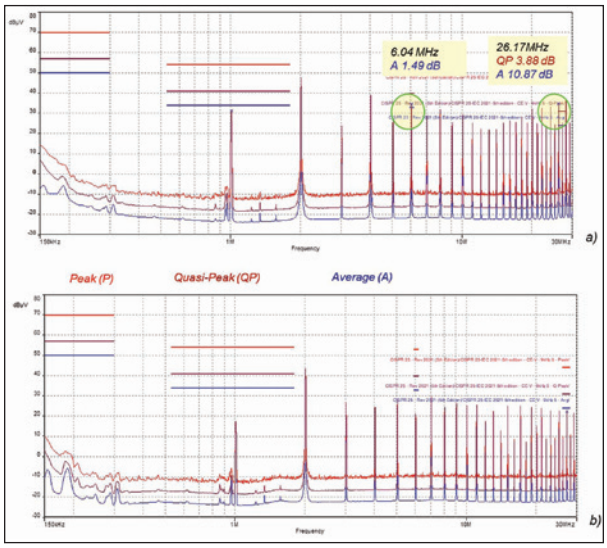

Figure 8: Ground line, 150 kHz – 30 MHz: a) without capacitors b) with capacitors

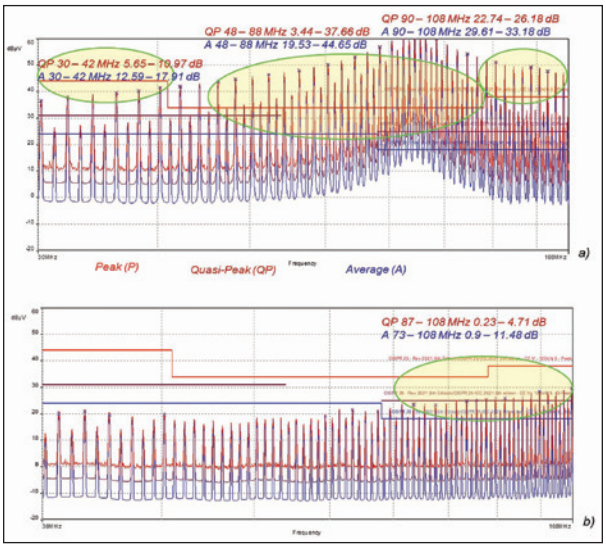

Figure 10: Ground line, 30 MHz – 108 MHz: a) without capacitors, b) with capacitors

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PRODUCT Showcase

THE ESD ASSOCIATION TECHNOLOGY ROADMAP

By Mirko Scholz for EOS/ESD Association, Inc.

The ESDA technology roadmap is written to support and guide the daily work of ESD and latch-up experts in the worldwide industry and academia. At the same time, it is intended to provide a glimpse into the future ESD thresholds of semiconductor devices and their impact on ESD control practices. It also presents current and future technical challenges in ESD and latch-up. With their expertise vision, the ESDA Advanced Topics Team has completed the most recent edition, published in January 2024 [1]. In this article, we want to highlight some of the changes and look at one key trend in advanced packaging.

Dr. Mirko Scholz is currently a Principal Engineer in ESD Development at Infineon Technologies AG in Neubiberg, Germany. From 2005-2019, he conducted research on ESD at imec, a nanoelectronics and digital technologies research institute in Belgium. He plays an active leadership role within the EOS/ESD Association.

ESD TARGET LEVEL

The evolution of Charge Device Model (CDM) target levels was previously summarized in [2]. As technologies further advanced, it became necessary to reduce CDM target levels from 500 V to 125 V for ultra high-speed IO applications. However, depending on the IC design functions, the achievable level can be 500-125V. Looking forward to the next decade and beyond this can be even below 125 V. Figure 1 shows the device ESD design sensitivity trends based on the main standards used for the ESD qualification at component-level: Human Body Model (HBM) and CDM. The shown sensitivity limits are a projection by engineers from leading semiconductor companies. For both qualification standards, no changes are expected until 2030. The current target level for HBM is kept at 1kV and for CDM at 250V.

In practice, the achievable CDM protection level depends on the IO design or type and on package size effects. Larger packages will experience higher discharge currents at a given stress voltage level. Figure 2 illustrates the impact of application and IC packaging on the achievable CDM robustness for packaged exposed "external" pins and "internal" pins of 2.5D and 3D integrated ICs. In the RF space, there is often a delicate balance between CDM robustness and RF performance. As higher bandwidth RF applications become more widespread in the market, the achievable CDM protection level is likely further decreasing. For internal pins, the provided range is based on the area constraints for internal IO that only allow the use of very little to no additional area to enable minimal CDM robustness.

ESD TESTING

Because of the larger variability when applying low-stress levels and decreasing pin pitches, the commonly used field-induced CDM testing reaches its limitations. Contact CDM testing methods allow the reliable application of low CDM stress levels even to small pin pitches. Two contact CDM stress methods, low impedance-contact CDM (LICCDM) and capacitively coupled TLP (cc-TLP), are currently evaluated by the ESDA JEDEC CDM Joint Working Group. Both methods allow the application of low

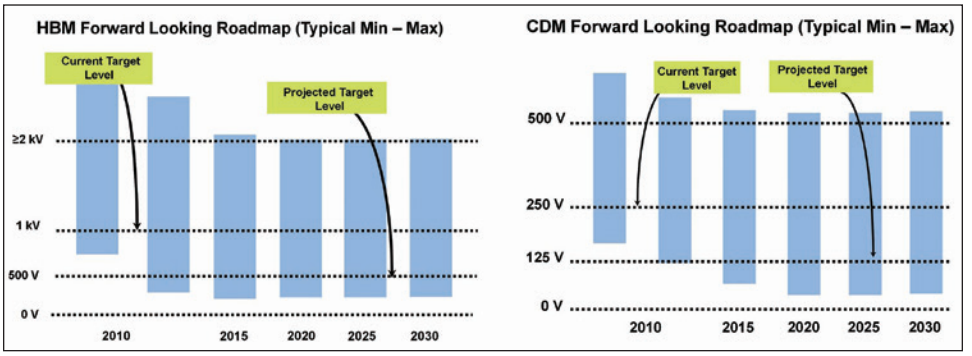

Figure 1: HBM (left) and CDM (right) roadmap.

CDM stress levels and can be used to stress small pin pitches. Thereby, cc-TLP systems have been used for a much longer time compared to LICCDM setups and showed a good correlation with CDM results in many studies.

OUTLOOK

The scaling of CMOS technologies continues, moving from FinFET to nanowire- or nanosheet-based device architectures. Another driver will be the broad use of compound semiconductors such as Gallium Nitride or Silicon Carbide, particularly in energy conversion. This includes the application of photonic technologies to enable the required huge data bandwidths of the digital society. Electronic Design Automation (EDA) tools for design verification will be able to support the ESD and latch-up protection design even more. Always-increasing computational power and new machine learning methods will allow us to simulate and verify complex IC designs.

A strong push will be seen in advanced packaging where separate dies or chiplets that may come from different technologies are connected in a single package. What are the ESD Challenges associated with this advanced packaging? In the next few years, the density of micro bumps increases significantly. It is enabled by reducing the bump pitch from more than 25µm to less than 10µm. A higher die-to-die interface density requires reducing the minimum CDM level for die-to-die interfaces (Figure 3). This is because the typical area allocated to ESD protection of external pins is not available for these internal interconnects [3] and is not necessary for manufacturing. CDM target levels for die-to-die interfaces described in the literature are below 100V [3], for which ESD controls are adequately described by S20.20. Below the CDM sensitivity level of 100V, there are no means of controlling ESD; each case must be carefully analyzed to determine the ESD risk and mitigations necessary to ensure manufacturability. Developing ESD control standards below 100V is a critical need for the industry to improve this situation.

SUMMARY

The ESDA technology roadmap is a guiding document for the daily work of ESD and latch-up experts in the worldwide industry and academia.

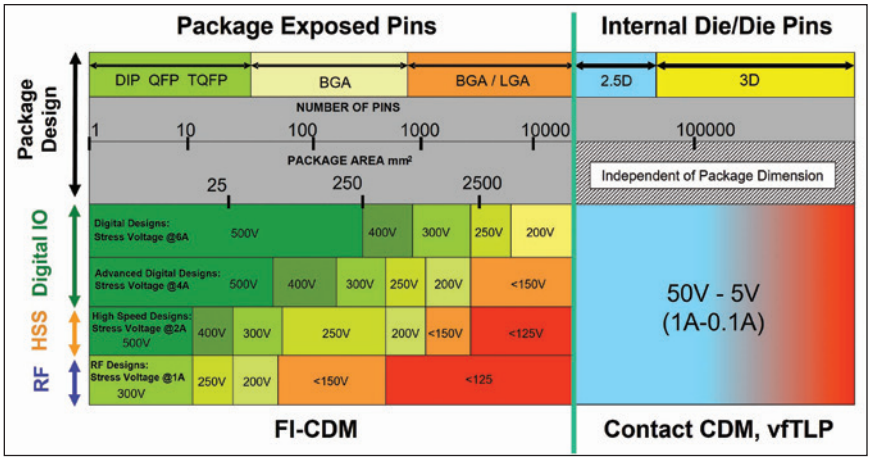

Figure 2: Combined projected effects of IO design and IC package size on achievable CDM protection level

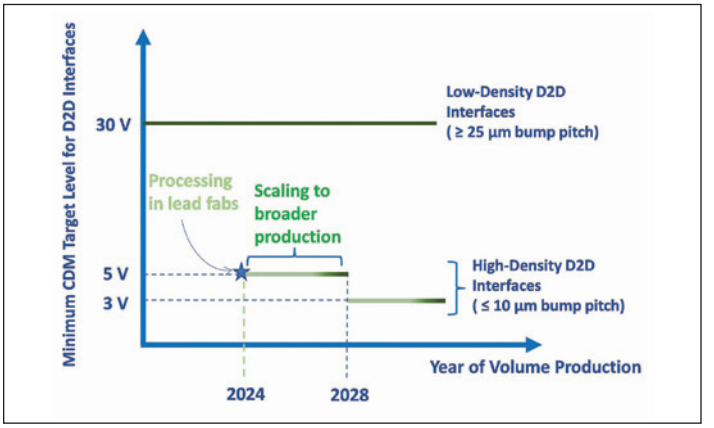

Figure 3: Roadmap of CDM target level of Die-to-Die Interfaces [4]

In this article, we highlighted the ESD target levels and focused on one major trend in our industry. The work on the roadmap will continue. The next edition is already in the works and will be published by the next EOS/ESD Symposium in September 2024.

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ANSI Z535.6 – MANUALS IN FOCUS

By Erin Earley

In our last few "On Your Mark" columns, we've been putting a spotlight on the American National Standards Institute (ANSI) Z535 standards. This family of U.S. voluntary consensus standards was created to enhance safety communication and promote consistent hazard recognition and understanding – making it important for manufacturers and workplaces across the country. These standards create a guide for the design, application, and use of signs, colors, and symbols intended to identify and warn against hazards and for other accident prevention purposes. Our theme of exploring each of these standards individually continues, this month focusing on ANSI Z535.6 – Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials.

Erin Earley, head of communications at Clarion Safety Systems, shares her company's passion for safer products and workplaces. She's written extensively about best practices for product safety labels and facility safety signs. Clarion is a member of the ANSI Z535 Committee for Safety Signs and Colors, the U.S. ANSI TAG to ISO/TC 145, and the U.S. ANSI TAG to ISO 45001. Erin can be reached at eearley@clarionsafety.com.

WHAT IS ANSI Z535.6?

ANSI Z535.6 is a standard developed by ANSI specifically focusing on the inclusion of safety information in product manuals and other related materials to enhance user understanding and safety. This standard – ANSI Z535.6 Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials – provides guidelines for the design and location of product safety messages in collateral materials. Similar to the other ANSI Z535 standards, it's intended to apply to a broad range of products.

The standard offers a communication system developed specifically for product safety information in collateral materials to help manufacturers, consumers, and the general public. It outlines requirements for collateral materials – which means information like owner manuals, user guides, instructions, maintenance or service manuals, and safety manuals – that accompany a product.

THE STANDARDS ORIGIN – AND LATEST UPDATES

According to ANSI, "Historically, there has been a lack of widely available or generally applicable graphic systems for presenting safety information in product manuals, instructions, and related materials. The absence of such systems, combined with the increased awareness and use of ANSI Z535.4 Standard for Product Safety Signs and Labels, has led to attempts to apply various aspects of ANSI Z535.4 to the presentation of safety information in collateral materials." The issue: ANSI Z535.4 was created to apply specifically to product safety signs and labels, not to address collateral materials.

Collateral materials, while related to product safety signs and labels – with a need for cohesiveness between them – have many core differences from labels. That includes their overall purpose, content and depth of content, format, length, how they're published or viewed, and the level of detail on safety messages. To respond to those differences, ANSI determined the need to develop a new Z535 standard to create a communication system designed specifically for product safety information in collateral materials.

In 2002, the ANSI Z535 committee voted to form a new subcommittee, ANSI Z535.6. According to ANSI, the purpose of the subcommittee was to develop a standard, "to complement the existing Z535 standards by addressing various aspects of the provision of safety information on collateral materials." The standard was published for the first time in 2006. Following that, revisions were made periodically, according to ANSI's cycle, in 2011 and in 2017, when it was reaffirmed. The 2011 revision included an update to permit the use of the safety alert symbol in the middle of a line of text, as well as updates to several definitions ("accident", "harm", and "incident"), which were harmonized across the Z535 series to

clearly define physical injury from other safety-related issues, like property damage.

Most recently, a revision to Z535.6 was made in late December 2023, along with updates to the ANSI Z535.4 and ANSI Z535.2 standards. The 2023 revision of Z535.6 incorporates minor clarifications. Notably, the definition of "risk" has been expanded, ensuring consistent understanding and application of this crucial concept. This refinement contributes to the standard's efficacy in guiding effective safety messaging within product manuals, instructions, and other collateral materials. In addition, the German translation of the signal word "Notice" in Annex B was updated.

An example of a best practice, ANSI Z535-formatted 'Read Manual' safety label; the label includes the ISO 7010, internationally-standardized symbol for "Refer to instruction manual/booklet".

USING THE STANDARDS' GUIDELINES TO CREATE EFFECTIVE PRODUCT SAFETY INFORMATION

ANSI Z535.6 is intended to provide guidance to those creating collateral materials containing safety messages.

"The implementation of this standard can be complex. Like its other ANSI Z535 counterparts, .6 is intended to be a guide, not a prescriptive doctrine, and needs to be general enough to be able to be applied across a variety of products," says Angela Lambert, ANSI Z535 committee member and head of standards compliance at Clarion Safety Systems. "In addition to that, developing an effective manual may include incorporating elements of the other ANSI Z535 standards, as well as finding a way to harmonize with standards like ISO 20607: Safety of Machinery – Instruction Handbook – General Drafting Principles."

While the standard does not specify what safety messages to include or what individual safety messages should say, it offers a variety of options for how to format messages. It does that by addressing four types of safety messages that are often present in collateral materials:

1. Supplemental directives: messages about other safety messages.
2. Grouped safety messages: messages that are collected or grouped in a document or section of a document focusing on safety information.
3. Section safety messages: messages that apply to entire sections, subsections, or multiple paragraphs or procedures within a document.
4. Embedded safety messages: messages that apply to a specific part of a section, paragraph, or procedure in a document.

The standard also discusses message components, as well as offers up a common design direction to provide product safety information in an orderly and consistent way. Many of the graphical elements used in the other ANSI Z535 standards are found in .6 – including signal words, the safety alert symbol, and safety colors – but are adapted for use in collateral materials.

"Understanding ANSI Z535.6 and unraveling how to apply it to a specific product and product manual, as well as alongside other national and international standards, may feel complex. However, it's important to keep in mind where this standard came from – how it adapted out of a need for this level of specific information while working together with the original best practice Z535 standards – and how it can truly help to support a comprehensive and effective approach to hazard communication," Lambert says.

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April 21-24

American Association for Laboratory Accreditation (A2LA) Annual Conference

April 23

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April 30- May 2

★ IEEE International Symposium on Product Compliance Engineering (ISPCE 2024)

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Applying Practical EMI Design & Troubleshooting Techniques

Advanced Printed Circuit Board Design for EMC + SI

Mechanical Design (Enclosure & Cable shielding) for EMC

May 14

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EMC TEST AND MEASUREMENT SOLUTIONS: SUPPORTING THE NEXT GENERATION OF MEDICAL INNOVATIONS

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