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FCC Limits Use of Confidentiality Requests

The U.S. Federal Communications Commission (FCC) has issued a reminder that it does not and will not grant unnecessarily broad requests regarding the confidentiality of information submitted in response to FCC letters of inquiry (LOI).

According to a Public Notice issued by the FCC's Enforcement Bureau, the agency is receiving an increasing number of requests from LOI respondents and their legal counsels to treat their entire response as confidential. In many cases, these requests fail to provide what the Bureau calls a "substantive explanation" for the request.

In its Notice, the Enforcement Bureau says that such overboard requests for confidentiality are "unacceptable" under the Commission's rules "and will be dismissed if not appropriately narrowed in a timely manner." Instead, the Bureau continues, "parties requesting confidential treatment of materials they submit to the Commission are required to identify the specific parts of the submission to which the confidentiality request applies."

The Notice cites Sections 0.459(a)(1) and (b)(1) of the Commission's rules as the basis for this policy.

EU Commission Amends Annex II of REACH

The Commission of the European Union (EU) has implemented modified safety data sheet requirements under its regulation addressing the registration, evaluation, authorization, and restriction of chemicals, or REACH Regulation (EC) N 1907/2006.

Published in the *Official Journal of the European Union*, Commission Regulation (EU) 2020/878 replaces the text of Annex II of the REACH regulation, "Requirements for the Compilation of Safety Data Sheets."

The revised safety data sheet requirements apply as of January 1, 2021. However, safety data sheets that comply with the requirements presented in the current version of Annex II can continue to be provided until the end of 2022.

FCC Report on Robocall Blocking Tools Released

The U.S. Federal Communications Commission (FCC) says that tools available to block unwanted robocalls are "now substantially available" to consumers at no or low cost.

In a staff report prepared by the Commission's Consumer and Governmental Affairs Bureau, the Commission found that billions of unwanted calls are now being blocked each year. The report also says that the available no or low-cost tools have few reported instances of "false positive" blocking (that is, when a potentially wanted call is blocked) and that there are no reported instances that the tools have blocked an emergency call or a call-back from a public safety official responding to a 911 emergency call.

Appendix B of the report provides details on the call blocking and call labeling options currently available from 12 major voice service providers operating in the U.S., as well as the estimated number of calls blocked or labeled by the provider.

"Tools are available today to help consumers block robocalls, spoofed calls, scam calls, telemarketers, and other unwanted calls," said FCC Chair Ajit Pai upon the release of the staff report. "We will continue to prioritize the protection of consumers from scams and unwanted robocalls."

FDA Issues Guidance on Enforcement of Non-Invasive Remote Monitoring Devices

As the impact of the COVID-19 pandemic continues to challenge the nation's healthcare system, the U.S. Food and Drug Administration (FDA) has taken steps to ease its enforcement of certain types of remoting patient monitoring devices.

It is important to note that the easing of the FDA's enforcement policy remains in effect only for the duration of the COVID-19 health emergency.

The Guidance, "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," is intended to support efforts to expand the availability and capability of suitable monitoring devices that can remotely monitor patients. Remote monitoring is essential in limiting the need for patient-provider contact and can also help provide monitoring support for patients in remote locations.

Specifically, the Guidance states that:

"… FDA does not intend to object to limited modifications to the indications, claims, functionality, or hardware or software of certain non-invasive remote monitoring devices that are used to support patient monitoring (hereinafter referred to as "subject devices"), during the declared public health emergency…without prior submission of a premarket notification…"

It is important to note that the easing of the FDA's enforcement policy regarding non-invasive remote monitoring devices as detailed in this Guidance remains in effect only for the duration of the COVID-19 public health emergency. Further, Guidance documents issued by the FDA and other federal agencies are intended solely to provide interested parties with information on the current views of the agency with regard to a specific issue and do not have the force of law.

Health Canada, U.S. CPSC Issued Guidance on Human Factors

The U.S. Consumer Product Safety Commission (CPSC) and Health Canada have published a joint guidance on the application and use of human factors principles in the product development process.

Issued earlier this year by the CPSC's Division of Human Factors and Health Canada's Risk Assessment Division of its Consumer and Hazardous Products Safety Directorate, the "Guidance on the Application of Human Factors to Consumer Products" is intended to help developers and manufacturers of consumer products take into account four separate human factors considerations, as follows: 1) the intended product use environment; 2) the intended product user; 3) the product design or user interface; and 4) the tasks to be accomplished by the user.

The Guidance also proposes the adoption of human factors considerations in each of the six separate stages of product design, including product planning, idea and concept generation, design and development, testing and validation, production, and post-production evaluation.

According to the Guidance, developers, and manufacturers who adopt the four human factor principles throughout the six stages of product design, developers and manufacturers are more likely to produce consumer products that are safer and easier for consumers to use, while also reducing product lifecycle cost and risks.

FCC Denies Huawei's Request for Extended Reply Time

The U.S. Federal Communications Commission (FCC) has denied a request from Huawei Technologies to extend the reply period in connection with the company's final designation as a national security threat under the U.S. National Supply Chain Proceeding.

As we previously reported, the FCC issued a Report and Order that bans the use of monies from the federal Universal Service Fund (USF) to purchase telecommunications equipment and services from companies that pose a national security threat. The Commission initially designated Huawei and ZTE as "covered companies" under the scope of the ban.

According to the FCC, Huawei submitted more than 5000 pages of documentation during the public comment period following the issuance of the Report and Order. Now the FCC denied a Motion for Extension of Time filed by Huawei that would have given the company an additional week to review and comment on information submitted to the Commission by the National Telecommunications and Information Administration (NTIA) in support of that final designation. The Commission originally granted Huawei 10 days to respond.

In its Order, the FCC noted that the documentation submitted by the NTIA "reflects facts about Chinese law or Huawei's operations that ought to be within the knowledge of officers of the company and readily available, and have been echoed in other submissions throughout this proceeding." Under the circumstances, the Commission argued, "an extension of time is not warranted given the programmatic and national security interests at stake."

FCC Grants Speech Recognition IP Captioned Telephone

The U.S. Federal Communications Commission (FCC) has granted conditional certification to a second telephone captioning service using automatic speech recognition (ASR) technology.

In a Memorandum Opinion and Order issued in early June, the FCC's Consumer and Government Affairs Bureau granted conditional certification to CaptionMate, an internet protocol captioned telephone service (IP CTS) application developed by Clarity Products, LLC. CaptionMate functionality is based entirely on the use of ASR technology and does not require human communications assistance to support IP CTS services.

The CaptionMate application can be downloaded for use on iOS and Android smartphones and is also accessible through the company's website.

The conditional approval of Clarity Products CaptionMate application is based on the FCC's 2018 determination that automatic speech recognition is a permissible means of delivering captioned telephone services and follows the Commission's conditional approval in early May of an IP CTS application by MachineGenius.

The Commission's conditional certification serves to verify that the CaptionMate application meets or exceeds the standards required for compensation under the FCC's Telecommunications Relay Service (TRS) Fund, subject to further verification against TRS standards.

MEASURING DIFFERENTIAL- AND COMMON-MODE CURRENT RADIATION FROM CABLES

By Bogdan Adamczyk

This article discusses the common-mode and differential-mode radiation from cables and presents the measurement results from the SMPS connecting wires.

DIFFERENTIAL-MODE AND COMMON-MODE CIRCUIT MODEL

Consider a typical circuit model shown in Figure 1.

If the fields generated by the forward current cancel the fields of the return currents and no other circuits, or sources, or coupling paths are present, then the forward current equals the return current. In virtually any practical circuit a different scenario takes place, as shown in Figure 2.

$\hat{I}_D$ is referred to as the *differential-mode (DM) current* while $\hat{I}_C$ is referred to as the *common-mode (CM) current*. The DM currents are usually the functional currents, they are equal in magnitude and of opposite directions. The CM (unwanted) currents are equal in magnitude and of the same direction (See [1] for the discussion of the CM current creation).

In the analysis of the DM and CM currents, we often utilize the *total* currents $\hat{I}_1$ and $\hat{I}_2$ flowing in the same direction. The reason for this is that it is easier to apply the classical circuit theory to the total currents than it is to the individual currents. Once the equations are developed for the total currents, we simply substitute the differential or common-mode currents for the total currents in the derived expressions. This approach will be demonstrated in the next section.

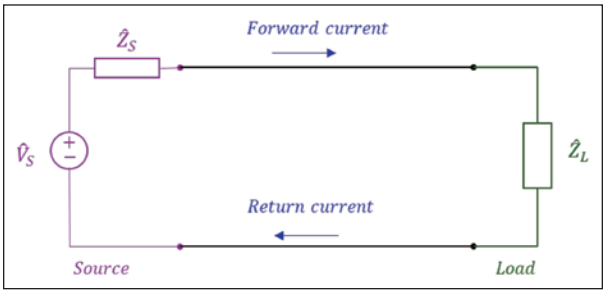

Figure 1: Typical circuit model

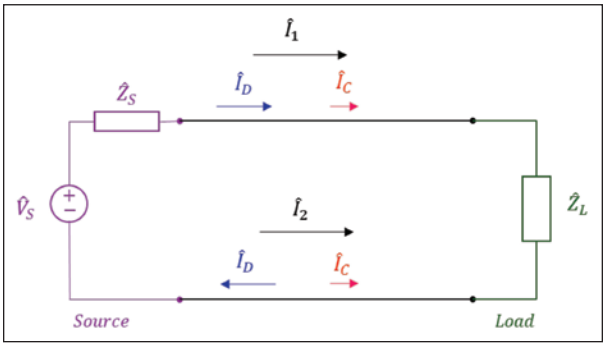

Figure 2: Circuit model showing the CM, DM, and total currents

Dr. Bogdan Adamczyk is professor and director of the EMC Center at Grand Valley State University (http://www.gvsu.edu/emccenter) where he regularly teaches EMC certificate courses for industry. He is an iNARTE certified EMC Master Design Engineer. Prof. Adamczyk is the author of the textbook "Foundations of Electromagnetic Compatibility with Practical Applications" (Wiley, 2017) and the upcoming textbook "Principles of Electromagnetic Compatibility with Laboratory Exercises" (Wiley 2022). He can be reached at adamczyb@gvsu.edu.

The total currents $\hat{I}_1$ and $\hat{I}_2$ flowing are related to the DM and CM currents by

$$\hat{I}_1 = \hat{I}_C + \hat{I}_D \quad (1a)$$

$$\hat{I}_2 = \hat{I}_C - \hat{I}_D \quad (1b)$$

RADIATION FROM DIFFERENTIAL- AND COMMON-MODE RADIATION

Differential- and common-mode radiation can be modeled as the radiation from two Hertzian dipoles driven by a noise voltage.

Let's begin with the DM radiation. Consider the scenario shown in Figure 3. where two linear antennas (conductor 1 and conductor 2) placed along the *x*-axis, carry the differential-mode currents along the *z*-direction.

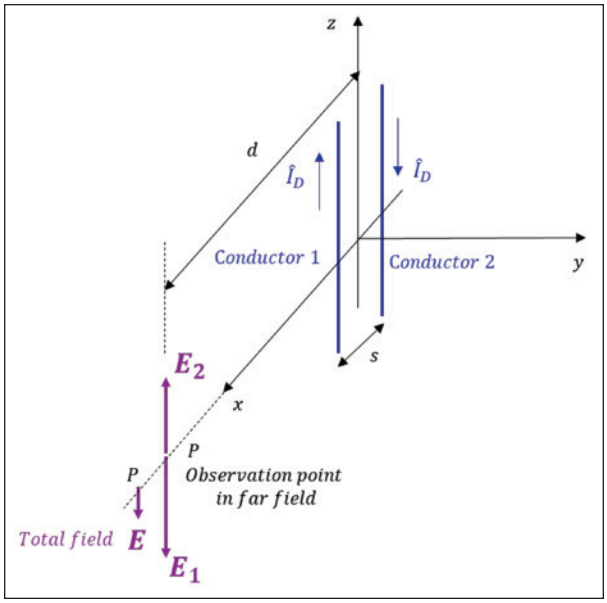

Figure 3: DM currents and the associated fields

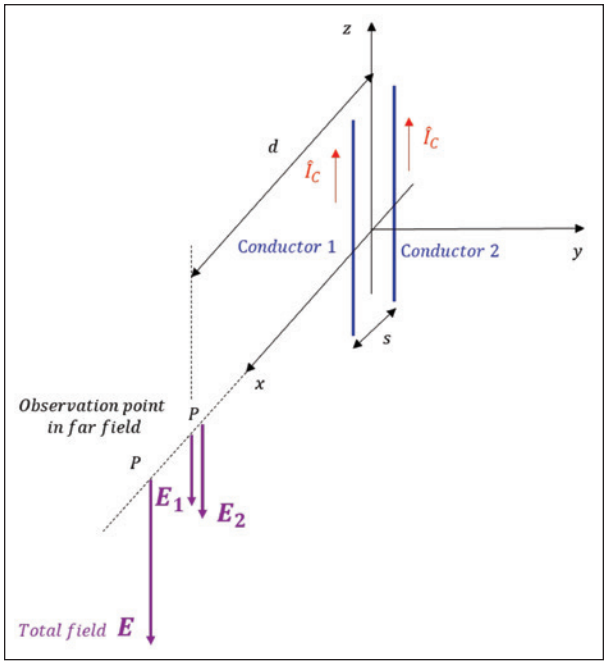

Figure 4: CM currents and the associated fields

The maximum radiated field is broadside to the antenna (in the *xy*-plane, where $\theta = 90°$ and in the *z*-direction, as shown. Note that the radiated fields due to both conductors are of opposite directions, giving a small total radiated field as shown. This total radiated field at the observation point in the *far* field can be obtained by superimposing the fields due to each antenna.

Treating each antenna as a linear dipole of length *l*, the magnitude of the total field at a distance *d* from the antennas is, [2],

$$E_\theta = 131.59 \times 10^{-16} f^2 I_D \frac{ls}{d}, \left[\frac{V}{m}\right] \quad (2)$$

where *f* is the frequency of the current carried by the antennas.

Now, consider the scenario shown in Figure 4. where two linear antennas carry the common-mode currents.

The radiated fields due to both conductors are of same directions, thus reinforcing each other to give the total radiated field as shown. The magnitude of the total field at a distance *d* from the antennas is

$$E_\theta = 125.66 \times 10^{-8} f I_C \frac{l}{d}, \left[\frac{V}{m}\right] \quad (3)$$

It should be noted that the CM currents could be several orders of magnitude smaller than the DM currents, yet the radiation from them could exceed the regulatory limits.

For instance, it takes only 8 µA of the CM current to exceed the FCC Class B limit of 100 µV/m at a distance of 3m, as the following calculations show. From Eq. (2) we can calculate the expression for the CM-current in terms of the maximum allowable field strength, [3].

$$I_C = \frac{(E_\theta)10^2 d}{125.66 fl} \cong \frac{0.8 E_\theta d}{fl} \; [\mu A] \quad (4)$$

Letting, l = 1m, d = 3m, f = 30 MHz, E_θ = 100 µV/m, we obtain I_C = µV/m.

It is, therefore, no surprise that the CM current is of great interest (or fear) to the EMC engineers. Next, we will discuss the DM- and CM-current measurements from the cables connecting a SMPS.

DIFFERENTIAL-MODE AND COMMON-MODE CURRENT MEASUREMENT

Figure 5 shows the test setup to measure the differential- and common-mode currents.

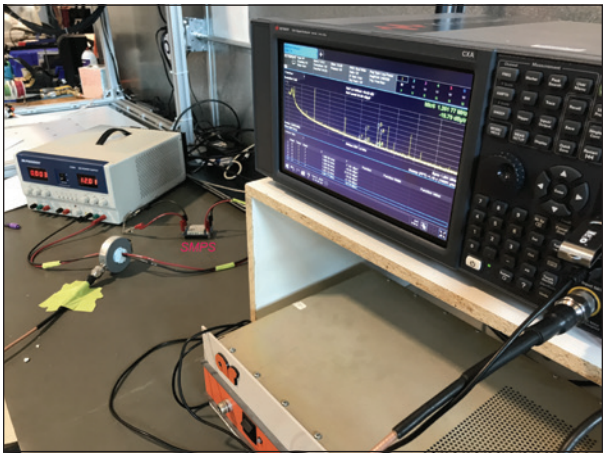

Figure 5: Measurement setup

The current probe used is shown in Figure 6.

The SMPS used in this experiment is a step-down (buck), 12V to 5V DC, switching at 420 kHz.

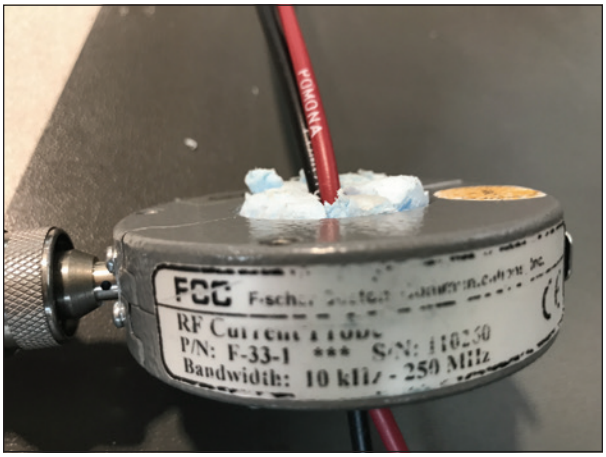

Figure 6: Current probe for DM- and CM- measurements

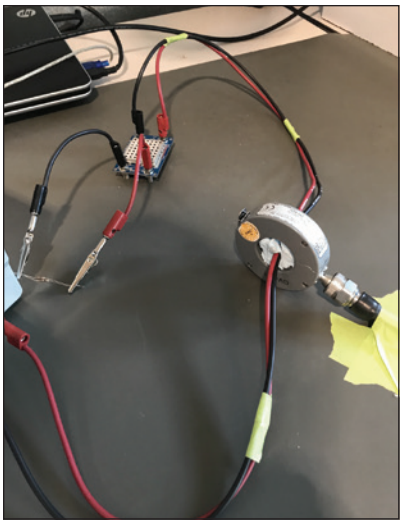

Figure 7: CM-current measurement setup

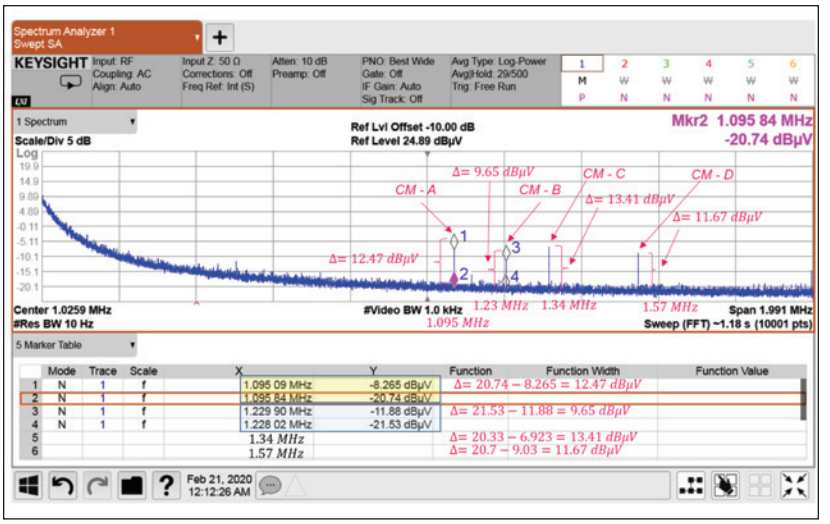

Figure 8: CM-current measurement results

The CM currents were measured with the current probe, where both the power and ground wires were placed inside the current probe, as shown in Figure 7.

With both wires inside the probe, the differential current fields (ideally) cancel each other, and the current probe measures only the common-mode currents. To be precise, it (ideally) measures twice the value of the CM current, i.e., $2I_C$. The measurement results are shown in Figure 8 and summarized in Table 1.

Common-Mode Current	Frequency (MHz)	Magnitude (dBµV)
CM - A	1.095	12.47
CM - B	1.23	9.65
CM - C	1.34	13.41
CM - D	1.57	11.67

Table 1: CM-current measurement results

Next, let's measure the differential-mode currents. The DM currents were measured with two different setups: current probe over the ground wire and the current probe over the power wire, as shown in Figure 9.

The measurement results with the probe over the ground line are shown in Figure 10, while the results for the power line are shown in Figure 11. Both results are summarized in Table 2.

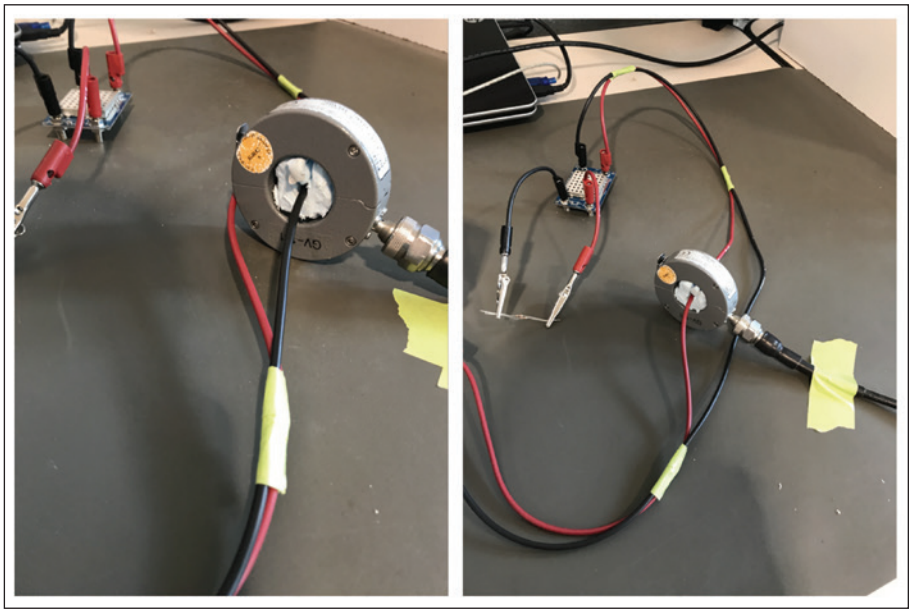

Figure 9: DM-current measurements

OBSERVATIONS

The magnitudes of the differential-mode currents on the ground and power wires are very close (within 2 dBμV), as they are supposed to be. Both the ground and the power wire differential-mode measurements also capture the common-mode currents. These currents and their magnitudes are not as predictable as the DM currents. Note that the ground-wire CM-current is present at point A in Figure 10, but it is not present at that frequency on the power wire in Figure 11. Another CM current at a lower frequency, at point K, appears in Figure 11, and it was not present at that frequency in Figure 10.

REFERENCES

1. Bogdan Adamczyk, *Common-Mode Current Creation and Suppression*, In Compliance Magazine, August 2019.
2. Bogdan Adamczyk, *Foundations of Electromagnetic Compatibility with Practical Applications*, Wiley, 2017.
3. Henry W. Ott, *Electromagnetic Compatibility Engineering*, Wiley, 2009.

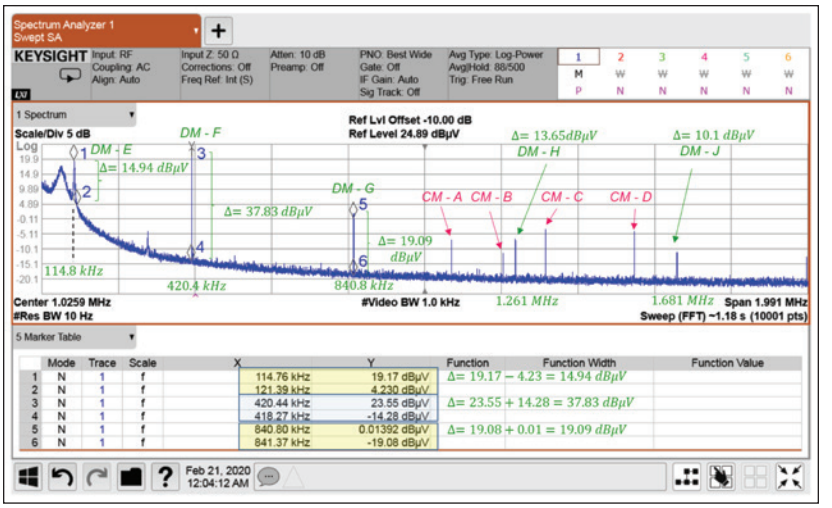

Figure 10: DM-current measurement results – ground wire

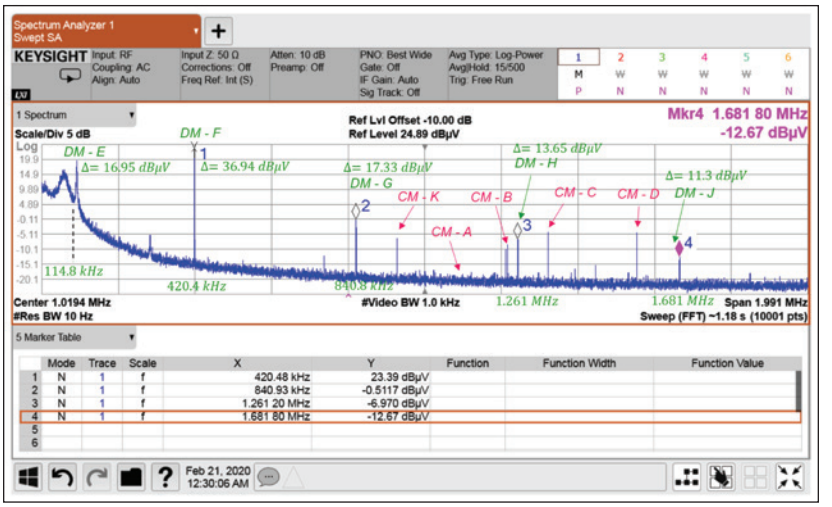

Figure 11: DM-current measurement results – power wire

Differential Mode Current	Frequency	Magnitude (dBμV) Ground wire	Magnitude (dBμV) Power wire
DM - E	114.8 kHz	14.94	16.95
DM - E	420.4 kHz	37.83	36.94
DM - F	840.9 kHz	19.09	17.33
DM - G	1.261 MHz	13.65	12.51
DM - J	1.681 MHz	10.1	11.3

Table 2: DM-current measurement results

NEWLY RELEASED ESD STANDARDS

By EOS/ESD Association, Inc.

WHAT'S NEW IN STANDARDS?

In the past six months, EOS/ESD Association, Inc., the only organization accredited by ANSI to write and produce standards on electrostatics, released eight new or revised documents on electrical overstress (EOS), grounding, packaging materials, seating (chairs), footwear, hand tools, gloves, and human metal model.

EOS is an area that has long been overlooked by the industry, not because of any limited importance, but rather because of its complex definition and multiple root causes. Indeed, it has proven difficult to find complete agreement among experts on even the fundamental definitions. Thus, the language of EOS, EOS threats, and responsibility remains open for discussion. ESDA's newest technical report, *ESD TR23.0-01-20 - ESD Association Technical Report for the Protection of EOS/ESD Susceptible Items – Electrical Overstress in Manufacturing and Test*, is the first in a series of documents intended to provide information that promotes the reduction of EOS damage in manufacturing and test, and provide the knowledge base for on-going mitigation and monitoring for possibly damaging electrical stresses. The document will be revised and expanded as others in the industry come forward with additional best practices used in their facilities. The content in this version represents best practices that have been shared and reviewed up to the time of publication.

The most critical concept in the field of static control is grounding. Attaching all electrically conductive and dissipative items in the workplace to ground allows built-up electrostatic charges to equalize with ground potential. A grounded conductor (includes dissipative items) cannot hold a static charge. Electrically interconnecting all electrically conductive and dissipative items (bonding) allows charge to equalize across these items without actual contact to ground. This provides static control in areas where an actual connection to ground may not be accessible, such as in a field service environment. Electrically bonded conductors and dissipative items share stored electrical charge and therefore have no difference in electrical potential between them. Many types of ESD susceptible parts can be handled within a bonded system without causing damage. Users of ESDA's grounding document, *ANSI/ESD S6.1 - ESD Association Standard for the Protection of Electrostatic Discharge Susceptible Items – Grounding*, need to consider the National Electric Code or other applicable laws and electrical system designs and specifications in the country where an ESD control program plan is being implemented. During the recent five-year review of ANSI/ESD S6.1, clarification language was added for use in countries outside of North America. User's were directed to reference their country's local electric code, if available, and common international terms were included for AC equipment ground (protective earth) and auxiliary ground (functional ground).

Packaging is necessary to protect electronic items from physical and environmental damage during manufacturing, transportation, and storage. While most packaging (not for static sensitive items) provides physical and environmental protection, some forms of packaging also may harm static sensitive electronic items by allowing the accumulation or the discharge of static electricity. Packaging for ESD susceptible (ESDS) items are commonly derived by modifying existing packaging to prevent the packaging itself from causing static damage. The packaging generally retains its physical and environmental protective

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

qualities. Some forms of ESD protective packaging have been modified further to prevent other sources of static electricity from damaging a packaged item. *ANSI/ESD S541 - ESD Association Standard for the Protection of Electrostatic Discharge Susceptible Items – Packaging Materials* describes the packaging material properties needed to protect ESDS electronic items and references the testing methods for evaluating ESD protective packaging and packaging materials for those properties. Where possible, required limits are provided. Guidance for selecting ESD protective packaging with protective properties appropriate for specific applications is also provided. In a recent revision, the marking requirement was changed from a shall to a should because not all packaging can be marked due to material and design.

One source of electrostatic charge generation in a work environment is the separation of personnel from chairs, stools or other types of seating along with the movement of seating across the floor. This results in the generation of electrostatic charge that can accumulate on the seating and on personnel. The effect of this generation and accumulation of electrostatic charge can be minimized with the appropriate selection of seating. To effectively control electrostatic discharge, seating must be used in combination with an ESD controlled floor or mat. Seating is not a primary means of controlling electrostatic charge buildup on personnel in an ESD protective work area. Wrist straps or other means of personnel grounding should be used for this purpose. In the current revision of *ANSI/ESD STM12.1 - ESD Association Standard Test Method for the Protection of Electrostatic Discharge Susceptible Items – Seating – Resistance Measurement*, an alternative test methodology has been introduced that allows a significant reduction of the qualification measurements. Instead of measuring the resistance of all test points against all groundable points, if the groundable points are electrically connected, one groundable point can be selected as representative for all measurements.

An update was recently released for *ANSI/ESD SP9.2 - ESD Association Standard Practice for the Protection of Electrostatic Discharge Susceptible Items – Foot Grounders – Resistive Characterization*. The document describes the electrical resistance test methods for qualification of foot grounders (for example, heel straps, toe grounders, sole grounders, and booties). ANSI/ESD SP9.2 is intended for testing foot grounders used for grounding personnel engaged in working with ESD sensitive items. It does not address static control footwear (shoes) as those are covered in *ANSI/ESD STM9.1 - ESD Association Work in Progress*

for the Protection of Electrostatic Discharge Susceptible Items – Footwear – Resistive Characterization. The recent updates include removing the foot grounder system section, Figure 3, Annex A - Tester Voltage Influence on High/Accept/Low Indications, Annex C - Parallel Ground Paths, and Annex E - Foot Grounder Classification. Round robin testing to verify repeatability and reproducibility of the test method was successfully completed in the last 12 months. ANSI/ESD STM9.1 and ANSI/ESD SP9.2 will be merged into one document within the next two years.

EOS and ESD can damage or degrade certain electronic components and assemblies in repair, debug, and rework stations. The intent of *ANSI/ESD S13.1 - ESD Association Standard for the Protection of Electrostatic Discharge Susceptible Items – Electrical Soldering/Desoldering Hand Tools* is to provide test requirements for soldering/desoldering hand tools used in ESD safe work areas or on materials that are deemed to be ESD sensitive. The methods described can be used during procurement, qualification, and verification of soldering/desoldering hand tools to verify that electrical integrity has not been compromised which could result in EOS/ESD damage. There is no attempt to define how the soldering irons are to be used. The current version is a reaffirmation of the 2015 version with only minor editorial changes.

After the successful completion of round robin lab testing to verify repeatability within single labs and reproducibility between labs, the ESDA's gloves and finger cots document was re-designated from a standard practice to a standard test method. *ANSI/ESD STM15.1 - ESD Association Standard Test Method for the Protection of Electrostatic Discharge Susceptible Items – Methods for Resistance Measurement of Gloves and Finger Cots* provides test procedures for measuring the electrical resistance of gloves or finger cots and personnel together as a system. In addition, a procedure for measuring the intrinsic electrical resistance of gloves and finger cots is included. ANSI/ESD STM15.1 applies to all gloves and finger cots used in an electrostatic discharge (ESD) control program. The procedures described in this document provide data that are relevant in a specific environment and application. The system test uses a constant area and force electrode (CAFE) specifically designed for resistance measurements at the thumb and fingertips. A further advantage of the CAFE is that it can be used to test finger cots as well as gloves using an identical procedure. A normative annex was added on the intrinsic testing of gloves and finger cots using ANSI/ESD STM11.11; ANSI/ESD STM11.12 and ANSI/ESD STM11.13, as well as an informative annex describing the differences between in-use and intrinsic resistance measurements.

The name human metal model (HMM) is derived from the anticipated ESD stress that could be generated from a person holding a metal tool. The current pulse delivered to the component in this test is intentionally the same pulse as defined in the IEC 61000-4-2 testing method. Customers of IC manufacturers have begun requesting that ICs be evaluated for their ability to withstand the IEC 61000-4-2 stress pulses. However, because this IEC specification only describes testing a complete system, that specification cannot be directly applied to devices such as ICs and discrete components. This document provides IC manufacturers and IC customers with testing methods applicable to devices that utilize the current waveform of IEC 61000-4-2. The technique described in this document is termed human metal model testing to differentiate it from the system level IEC 61000-4-2 and from human body model testing of integrated circuits, ANSI/ESDA/JEDEC JS-001. Many companies have developed their own testing techniques using IEC 61000-4-2 pulses from hand-held gun generators for device and circuit design evaluation. This technique or practice is being utilized on products in packaged configurations. Development of *ESD SP5.6 - ESD Association Work in Progress for Electrostatic Discharge Sensitivity Testing – Human Metal Model (HMM) – Component Level* is in response to the need of the industry for consistent testing methods. Significant changes during the recent update include extensive editing to account for the default stress being pin to ground rather than pin to pin, language added for stressing pin to pin with an HMM pulse source, adding test procedures to be followed when using an ESD gun during HMM testing, adding information on the use of an HMM pulse source with a wafer prober, and removing references to qualification.

If you have specific questions about these documents or any of ESDA's other currently published documents, please send an email to info@esda.org.

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Banana Skins

286 Electronic organ manufacturer fined for EMC non-compliance

The Enforcement Bureau of the Federal Communications Commission (FCC) has fined a Dutch company for importing and marketing in the United States electronic organs which radiated emissions in excess of U.S. limits. The company, Johannus Orgelbouw b.v. of the Netherlands, was fined US$7000 and ordered to submit to the FCC for the next two years verification records for each model of organ which it imports into the U.S.

The matter of the emitting digital electronic organ was brought to the attention of the Enforcement Bureau in early 2003 by a competitor who claimed that other organ companies were suffering competitive harm because the company, by not complying with FCC regulations, was able to produce products less expensively. In a subsequent investigation by FCC agents, the company acknowledged that it had imported and marketed at least one model of organ that did not comply with FCC emissions limits, resulting in the Commission's action.

(From "FCC Fines Importer of Non-Compliant Electronic Organs", *Conformity, News Breaks, February 2004, pp 42-43.)*

287 False alarm in the Bahamas, caused by inadequate immunity of field meter

Once upon a time, when the Bahamas telephone toll center transactions were only $175,000 US per day — and EMC engineers made a great deal less — our facilities safety manager was attending to his appointed rounds with his brand-new, brand name RF field intensity meter in hand. He wanted to make sure that the electric fields within the facility were less than the allowed maximum of 10mw/sq.cm (194 V/m). After all, our company didn't want to accidentally cook anyone that worked there. It wouldn't look good come time to renew their management contract.

Much to the safety engineer's surprise, the fields being presented by the video display units (VDUs) at the operator consoles were way above the maximums. A quick calculation disclosed that the measured field intensities were in excess of 300 V/m. Did he call anyone? Did he ask how that was possible? Of course not! Being a good safetyman, with genuine concern for the workforce, he immediately shut down the toll center. Then, he called to report his findings. Then, his boss called corporate headquarters and they called my boss and also those of six other EMC facilities that we had scattered around the world. Then seven EMC engineers, myself included, immediately reported to the Bahamas to solve this serious problem. At $175,000 per day there was a lot of incentive to get there quickly.

We were prompt, but still didn't arrive at the same time. But when we did, we found that the first EMC engineer on the scene had already discovered that the brand-new, brand name RF field intensity meter was susceptible to the 15kHz VDU raster sweep frequency, and the toll center was back on-line. Of course, this required an appropriate celebration at a little place nearby… but that's a different story!

("A really short 'vacation' in the Bahamas", *Ron Brewer, IEEE EMC Society Newsletter, Spring 2004, 'Chapter Chatter' section, page 8.)*

Numbers 288 - 290 are taken from the Appendix to MIL-STD-464A dated 18 March 1997. *(MIL-STD-464A is entitled "Department of Defense — Interface Standard —Electromagnetic Environmental Effects — Requirements for Systems".)*

288 From MIL-STD-464A A.5.2 "Intra-system electromagnetic compatibility (EMC)"

When appropriate controls are implemented in system design, such as hardening, EMI requirements on subsystems and equipment, and good grounding and bonding practices, there are relatively few intra-system EMC problems found. Most problems that are found involve antenna-connected transmitters and receivers. Receiver performance has been degraded by broadband thermal noise, harmonics, and spurious outputs coupled antenna-to-antenna from transmitters. Microprocessor clock harmonics radiating from system cabling and degrading receivers have been another common problem. Electromagnetic fields radiated from onboard antennas have affected a variety of subsystems on platforms.

Typical non-antenna related problems have been transients coupled cable-to-cable from unsuppressed inductive devices and power frequencies coupling into audio interphone and video signal lines. Problems due to cable-to-cable coupling of steady state noise and direct conduction of transient or steady state noise are usually identified and resolved early in the development of a system. Generation of broadband EMI on ships from electrical arcing has been a common source of degradation of antenna-connected receivers and must be controlled. Sources of the arcing have been brush noise from electrical machinery and induced voltages and currents between metallic items from antenna transmissions. Intermittent contact of the metallic items due to wind or ship motion is a contributor.

289 From MIL-STD-464A A.5.3 "External RF EME"

(EME means electromagnetic environment, used in this document to mean only the radiated environment)

High-powered shipboard radars have caused interference to satellite terminals located on other ships, resulting in loss of lock on the satellite and complete disruption of communication. The interference disables the satellite terminal for up to 15 minutes, which is the time required to re-establish the satellite link. Standoff distances of up 20 nautical miles between ships are required to avoid the problem.

A weapon system suffered severe interference due to insufficient channel selectivity in the receiver's front end. Energy originating from electronic warfare systems and another nearby "sister" channelized weapon system (operating on a different channel but within the same passband) coupled into the victim receiver and was "processed," severely degrading target detection and tracking capability. Installation of an electronically tuned filter immediately after the antenna countered the off-channel interference problem by: 1) eliminating receiver front-end amplifier saturation and 2) reducing overload of the system processor with extraneous in-band signals.

An aircraft lost anti-skid braking capability upon landing due to RF fields from a ground radar changing the weight-on-wheels signal from a proximity switch. The signal indicated to the aircraft that it was airborne and disabled the anti-skid system. An aircraft experienced uncommanded flight control movement when flying in the vicinity of a high power transmitter, resulting in the loss of the aircraft. If the mission profile of the aircraft and the anticipated operational EME had been more accurately considered, this catastrophe could have been averted.

Aircraft systems have experienced self-test failures and fluctuations in cockpit instruments, such as engine speed indicators and fuel flow indicators, caused by sweeping shipboard radars during flight-deck operations. These false indications and test failures have resulted in numerous unnecessary pre-flight aborts.

Aircraft on approach to carrier decks have experienced interference from shipboard radars. One such problem involved the triggering of false "Wheels Warning" lights, indicating that the landing gear is not down and locked. A wave-off or preflight abort could occur due to this EMI induced condition.

Aircrews have reported severe interference to communications with and among flight deck crew members. UHF emissions in the flight deck environment caused interference severe enough that crews could not hear each other for aircrew coordination. This problem poses a serious hazard to personnel with the potential for damage to, or loss of, the aircraft and aircrew during carrier flight deck operations.

290 From MIL-STD-464A A.5.4 "Lightning"

The effects of lightning can cause physical damage to personnel and equipment. In one of numerous documented lightning incidences, lightning appeared to enter a Navy aircraft nose, travel down the right side, and exit on top of the right vertical tail. The pilot suffered from flash blindness for 10-15 seconds. Upon regaining his vision, the pilot noticed all cockpit electrical power was gone. After another 15 seconds had elapsed, all cockpit electrical power returned on its own, with no cockpit indications of any equipment malfunction.

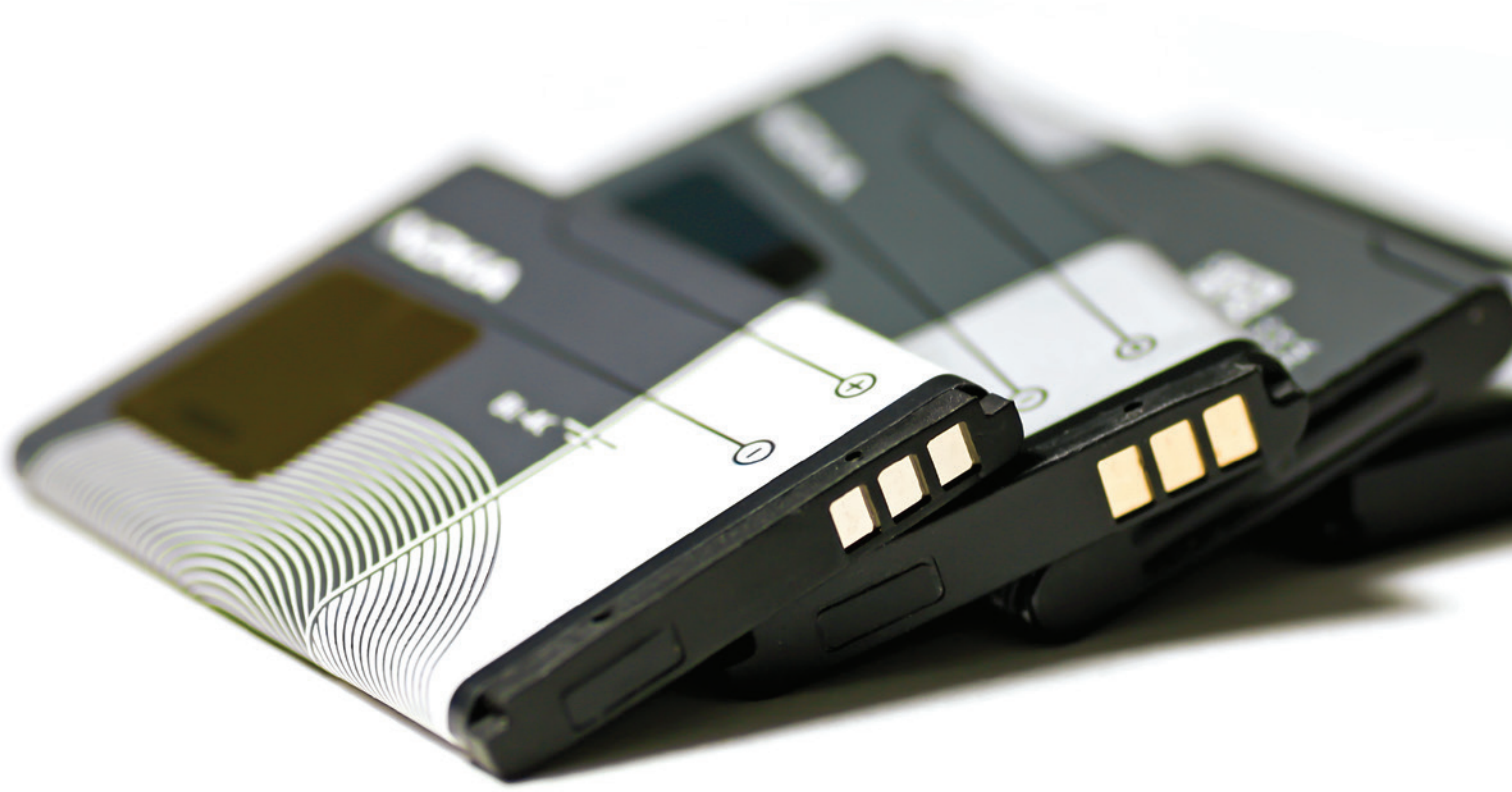
In another case, lightning attached to the nose pitot tube, inducing transients that damaged all 28 volt DC systems. The pilot, disoriented, broke out of a cloud bank at 2000 feet above the ground, at 600 knots and a 45 degree dive. Nearly all cockpit instruments were dysfunctional - compass, gyrohorizon, and so forth. A secondary effect occurred but was not uncovered for several months. The lightning current path that carried the direct effects lightning current did what it was supposed to do, but the path was not inspected on landing.

Over 800 man-hours were expended to correct electrical (28 volt DC) problems but no effort went into inspecting for direct effects damage to ensure the lightning protection system was intact. The rigid coax from the front of the radome to the bulkhead had elongated and nearly torn away from its attachment point at the bulkhead due to magnetic forces involved. This damage reduced the effectiveness of the designed lightning protection. Another secondary effect was the magnetization of all ferrous material which caused severe compass errors. The entire aircraft had to be degaussed.

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

SAFETY CONSIDERATIONS FOR LITHIUM AND LITHIUM-ION BATTERIES

Compliance with Applicable Standards Supports the Safety of These Essential Technologies



Rich Byczek is the global technical director for electric vehicle and energy storage at Intertek, and has more than 20 years of experience in product development and validation testing. He is active on several battery-related technical panels, including the UN 38.3 Working Group, UL STPs for battery and charging equipment standards, Testing Taskforce Chair for CSA-340 Battery Management System Standard, US TAG to IEC SC21A and 125, ANSI C18, and the ANSI EV Standards Panel. Byczek can be reached at rich.byczek@intertek.com.

By Rich Byczek

Lithium and lithium-ion batteries are an integral part of everyday life. They are small, lightweight and, due to a high energy density, offer a long life. Across industries, from medical to consumer electronics, industrial applications to transportation, the small, lightweight energy sources pack quite a punch, making them a popular choice for manufacturers everywhere.

Most lithium batteries used today are safe when designed, manufactured and used properly. However, if they have design defects, are comprised of low-quality materials, are assembled incorrectly, are used or recharged improperly, or become damaged, they can pose a risk. Additionally, because of their high energy density, lithium batteries are susceptible to overheating and can become a fire hazard. For these reasons, there are several safety standards that manufacturers need to apply when developing and using devices incorporating lithium batteries.

UN 38.3

Since lithium batteries can present a fire hazard during transport, they are classified as a dangerous good. To be transported, they must meet provisions laid out in UN 38.3, within the "UN Manual of Tests and Criteria." Section 38.3 applies to batteries transported on their own or within a device. It applies to all points in the battery's transportation process, including from sub-suppliers to end-product manufacturer, from manufacturer to distributor, from in or out of the product; in the field, or during product return or within non-original packaging. It is important for the manufacturer to be familiar with these requirements as the use of these batteries becomes more prevalent.

UN 38.3 has been adopted by regulators and competent authorities around the world, making it a requirement for global market access. The protocol includes identifying/classifying lithium batteries, testing/qualification requirements, design guidance/conditions, and packaging/shipping obligations.

Classification

There are four classifications based on battery type (lithium or lithium-ion) and how they are shipped (alone or in a device):

- *UN 3090 for lithium batteries and UN 3480 for lithium-ion batteries:* Apply to cells shipped alone, batteries shipped alone, consignment of cells and batteries, modules or other incomplete battery sub-assemblies, power banks, powerpacks, and batteries shipped in a separate package from the device they power (even if the device and batteries are on the same consignment or shipment).
- *UN 3091 for lithium batteries within a device and UN 3481 for lithium-ion batteries within a device:* Apply to devices with batteries installed; devices packed with a battery in the same package, but not installed in the product; up to two spare batteries shipped in the same package as the device (i.e., one installed, two spares).

Testing and Qualification

UN 38.3 requires several tests to ensure the relative safety of the batteries during transport. These tests vary based on the battery and components, as well as the characteristic they are intended to assess:

- Tests T1-T5, conducted on the same samples for all battery types in sequence:
  - Altitude simulation (Test T1)
  - Thermal properties (Test T2)
  - Vibration (Test T3)
  - Shock (Test T4)
  - External short circuit (Test T5)

Recent transport regulation updates include new labels to illustrate the risk of fire associated with the batteries in the package more simply and effectively.

- Test T6, conducted on the primary and secondary cells, evaluates impact and crush
- Test T7, conducted on secondary batteries, assessing overcharge
- Test T8, conducted on the primary and secondary cells, assessing forced discharge

Published in November 2019, the 7th Edition of the Manual includes several key changes regarding testing:

- *Integrated batteries:* Updated to allow testing of batteries within equipment.
- *Disassembly:* Allows for additional test criteria. We recommend any cases that may be considered "borderline" disassembly to be treated as test failures.
- *Rechargeable batteries considerations:* Changes to the cycling requirements reducing to 25 charge/discharge cycles prior to test, from 50 previously. Also updates testing tables to reflect these changes.
- *Test summary:* Now clearly defines "battery test summary," as well as the requirement that the test summary "shall be made available." Additionally, it notes the requirement for the name and title of the signatory as an indication of validity.

Other than clarifying the contents of the test summary, the 7th Edition of the Manual contains no additional changes to the test conditions, criteria or sample requirements as stipulated in the 6th Edition.

It is important to remember to get or create a test report summary, based on successful completion of UN 38.3 testing. These summaries must be made available to the shipper upon request. Obtain the test reports from cell vendors and subcontractors to complete the test summary for shipments, and maintain the supporting information.

Design Guidance and Conditions

UN 38.3 also includes several sections related to design, which includes adherence to the testing and qualification requirements, as well as incorporating a safety venting device or design elements to preclude a violent rupture. Design guidance also includes an effective means of preventing external short circuits, parallel connected cells/cell-strings equipped with a way to prevent dangerous reverse current flow, and the use of a quality management system during manufacturing.

Packaging and Shipping

Recent transport regulation updates include new labels to illustrate the risk of fire associated with the batteries in the package more simply and effectively. Passenger aircraft restrictions have also been updated to prohibit transport of lithium-ion cells/batteries as cargo on passenger planes, requiring that these items be labeled for cargo aircraft only. Lithium-ion batteries shipped alone must be set at or below 30% state of charge (SOC) for cargo air shipment. To meet this requirement, the method used should be documented, as well as how the shipment was verified. Competent authority approvals may be sought and granted for certain medical device batteries that must be shipped at greater than 30% SOC. This will allow for air shipment of such batteries at higher charge levels.

IEC 62133

IEC 62133 is one of the most important lithium-ion battery standards for global markets. It specifies requirements and tests for the safe operations of portable sealed secondary cells and batteries made from them. There are currently two versions of the standard in effect, IEC 62133 2nd Edition and IEC 62133-2 1st Edition. The names look quite similar, but the versions are different. And the requirements for a battery will vary depending on the market you wish to enter.

It is important to understand the difference between the two standards and how you can determine which is best to use. Some (but not all) of the changes in IEC 62133-2 1st Edition include:

- Separate nickel (IEC 62133-1) and lithium (IEC 62133-2) chemistries

- Inclusion of coin cells, if internal AC impedance is <3.0 Ohm
- Inclusion of single fault conditions
- Changes to cell level requirements
  - External short circuit now performed at +55˚C ambient
  - Thermal abuse hold times have been changed
  - The crush test 10 percent deformation condition has been removed
  - End conditions changed for forced discharge, so they are not only time-based.
- Adjustments to battery level requirements
  - External short circuit should be performed with single fault condition
  - Different overcharge charge conditions than before
  - Vibration and mechanical shock tests have been added back to standard
- Incorporation of vibration and mechanical shock testing, based on UN 38.3, with UN 38.3 tests moved to reference Annex E.

The European Union (EU) adopted 62133-2 1st edition in March 2020. Now, all new portable lithium-ion batteries marketed or sold in the EU must comply with these new requirements. Existing batteries and systems generally only need to be recertified if there is a design change or an update to the end-product standard, as batteries are generally considered as components rather than stand-alone end products. Additionally, the U.S. and Canada have adopted ANSI/ UL 62133-2 and CSA C22.2 NO. 62133-2:20. Transition timelines for enforcement of these versions may vary between testing organizations.

Lithium batteries play an important role in the design and manufacture of products that fit consumer demands. The very properties that make them desirable—potency, portability, size—present risks and hazards that any manufacturer must address.

Other countries and markets may adopt the new standard with different timelines. Ultimately, the intended market and end-product will determine which standard to use. When in doubt, partner and consult with experts who can help determine the best path forward.

UL 1642 AND UL 2054

UL 1642, "Standard for Lithium Batteries," is a U.S. standard to ensure the safety of lithium batteries. It covers both rechargeable and non-rechargeable batteries used as a power source in products. In practice, this standard is typically used for certification of component cells, while the resultant batteries are certified according to more application-specific standards.

There are several testing requirements under the standard. For both user- and technician-replaceable batteries, requirements include electrical, mechanical and environmental tests. Specifically, they include assessments for short-circuiting, heating, temperature cycling, forced-discharge, impact, humidity, shock, vibration, drop tests, abnormal changing and altitude simulation. There are also considerations for fire-exposure, flaming particles, projectiles and explosion for user-replaced situations.

UL 2054, "Standard for Safety of Household and Commercial Batteries," is a performance and safety standard for household and commercial batteries, covering portable rechargeable and non-rechargeable batteries in products. Specifically, the batteries covered in this standard consist of either a single electrochemical cell or two or more connected cells that create electrical energy through a chemical reaction, like lithium and lithium-ion batteries.

UL 2054 is specific to the battery. The safety of the product is covered by its applicable standard. The standard is intended to reduce the risk of fire or explosion when batteries are used in a product and when batteries are removed to be transported, stored or discarded. It includes testing requirements for performance, electrical considerations, temperature, mechanical assessments, battery enclosure and pack evaluations, and environmental tests.

Both UL 1642 and UL 2054 have marking requirements related to warnings about risk of fire, explosion and burns, and require the inclusion of instructions not to recharge, disassemble, crush or heat above certain points or to incinerate. The warning statements should also include instructions on disposal and instructions to call physicians or poison control if ingested. Products should also be marked regarding the use of lithium batteries and their risk, and instructions should include guidance on replacing and disposing of batteries.

CONCLUSION

With a growing prevalence in multiple industries, lithium batteries play an important role in the design and manufacture of products that fit consumer demands. The very properties that make them desirable—potency, portability, size—present risks and hazards that any manufacturer must address. It is important to familiarize yourself with the applicable standards, their requirements and needs. Knowledgeable teams and partners can make a huge difference in product success, global market access, building brands and ensuring safety.

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CHALLENGES AND DIRECTIONS FOR LIFECYCLE PROCESSES SUPPORTING CONFORMITY ASSESSMENT OF INTEROPERABLE MEDICAL PRODUCTS

Dr. John Hatcliff is a University Distinguished Professor and Lucas-Rathbone Professor of Engineering in the Computer Science Department at Kansas State University. His research addresses challenges in safety- and security-critical systems, interoperable medical systems, component-oriented and platform-based development, and static analysis & verification of critical systems. His recent research has been funded by US Army, US Air Force, DARPA, US Department of Homeland Security, Collins Aerospace, and the Software Engineering Institute.

By John Hatcliff

Editor's Note: *The paper on which this article is based was originally presented at the 2019 IEEE International Symposium on Product Safety Engineering in San Jose, CA. It is reprinted here with the gracious permission of the IEEE.*

INTRODUCTION

Medical devices are increasingly designed with network interfaces to support interoperability. Interoperability interfaces enable medical devices to be composed into larger medical systems that include infrastructure components supporting networking, composite displays for operators, and software applications providing workflow automation, etc. In addition, work in the research [11], [28], [8], [22], [36] and standards [1] communities is laying the foundations for safety, security, and risk management approaches for "systems of systems" of medical devices built using "medical application platforms" (MAP). As defined in [11], a MAP is a safety- and security-critical real-time computing platform for (a) integrating heterogeneous devices, medical IT systems, and information displays via a communication infrastructure and (b) hosting application programs ("apps") that provide medical utility via the ability to both acquire information from and update/control integrated devices, IT systems, and displays. Consortia [29], [17] are being organized to help support ecosystems of manufacturers [21] that cooperate to build asset bases of reusable components and rapid system development approaches aligned with a particular architecture.

It is sometimes difficult for manufacturers and regulators to use existing safety/security standards to adequately address the above development approaches and device/system characteristics. The primary medical device standards, such as ISO 14971 (risk management), ISO 13495 (quality management), IEC 62304 (medical device software lifecycle processes), and IEC 60601 (safety and essential performance for medical electrical equipment), are focused on conventional monolithic devices and don't explicitly address the unique challenges of interoperability, systems of cooperating components or platform-based engineering approaches. More recent medical device security technical reports, such as AAMI TIR 57 standards and security standards for connected devices such as UL 2900-1, address single devices with connectivity but do not explore system-of-system or platform concepts.

An overall challenge is that well-established concepts of risk management, quality management, security, lifecycle processes, and safety/security/essential performance objectives all need to be extended and integrated to address medical device interoperability, interoperable medical systems, and medical application platforms. However, these concepts are for the most part addressed in stove-piped fashion in individual standards (i.e., ISO 14971 address risk management, ISO 13485 addresses quality management, etc.), and it is difficult for manufacturers and regulators to see (a) how interoperability issues cut across the current standards space and (b) how existing standards should be brought together to address interoperability-related features.

Figure 1 illustrates the theme of this paper: we argue that to support conformity assessment of safety/security of interoperable medical products, lifecycle process concepts should be enhanced to (a) address the unique aspects of planning, specifying, designing, realizing, and assuring interoperable products, and (b) guide manufacturers in weaving together concepts from existing standards on risk management, quality management, security, etc. Moreover, we argue that concepts such as architecture specifications (e.g., as found in ISO/IEC/IEEE 42010), managed reuse (e.g., as found in ISO/IEC 12207 Section 7.3), and

product line engineering concepts (e.g., as found in the ISO/IEC 26550 series) must be utilized in lifecycle processes for interoperable products and that these concepts should receive greater attention in medical device standards development efforts. Multi-organization development (including risk management and assurance), lifecycle activities that guide interactions between organizations, and integration and reuse of components at arbitrary levels of abstraction in the system hierarchy are additional concepts that need to be supported in interoperable product lifecycle processes.

Some justification for our proposed approach is that safety standards such as IEC 61508 and its specialization in the automotive domain ISO 26262 use a development lifecycle approach for supporting conformity assessment for safety, where the flow of lifecycle activities indicates how many issues in the preceding paragraph should be addressed in a phased fashion as a product is developed.

The specific contributions of this paper are as follows:

- We discuss concepts for designing lifecycle processes for interoperable medical products that can guide standards development activities, design of regulatory guidance, and conformity assessment bodies in developing lifecycle process concepts for this space,
- We identify a general structure for individual lifecycle activities that we believe is useful for supporting conformity assessment of interoperable medical products,
- We illustrate why the presentation of lifecycle activities (which tend to follow a "waterfall" or "V-model" order in existing standards) may need to be presented in an alternative phasing to better support the topology of interoperable systems,
- We summarize aspects of managed reuse and product line engineering processes that should be considered to address medical application platform concepts.

This paper does not propose a specific set of lifecycle activities. Rather the goal is to raise awareness of issues that might guide the development of lifecycle approaches in current standards efforts such as the AAMI/UL 2800 interoperability safety/security standards family, the AAMI HIT 1000 series, and ongoing efforts in the international standards community to address interoperable products. This goal is similar in spirit to our earlier paper [15] on challenges and directions for addressing risk management in interoperable medical devices and systems.

LIFECYCLE STAGE STRUCTURE

As discussed in the introduction, lifecycle process descriptions are not prominently featured in medical device standards. ISO 13485 simply requires that the manufacturer "plan and develop the processes needed for product realization." (Clause 7.3.2). IEC 62304 requires the manufacturer to document "the PROCESSES to be used in the development of the SOFTWARE SYSTEM" and "the DELIVERABLES of the ACTIVITIES and TASKS" (Clause 5.1.1). Then, the majority of the normative content of IEC 62304 consists of requirements to include various activities within the documented processes. In this way, IEC 62304 does not dictate a particular (set of) processes or development model, but it does require processes to be documented and it constrains the content of the processes (i.e., it requires certain elements to be included). This allows freedom for manufacturers to follow their own processes as appropriate for their products and organization, but it normalizes aspects of the processes deemed important for achieving safety and for supporting safety reviews.

We suggest that emerging interoperability standards take a similar approach to that of 62304 (require

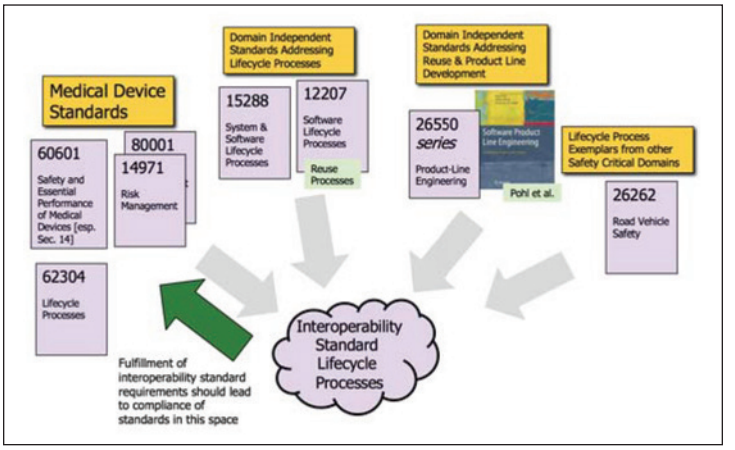

Figure 1: Interoperable product development lifecycle integration concepts

processes to be documented, don't mandate particular processes, require certain activities to be accounted for in the documented processes). However, we advocate a more rigorous capture of activities, deliverables of each activity, and traceability between deliverables.

Figure 2 captures some of the important aspects of these suggestions based on the Process Reference Model (PRM) of ISO/IEC 12207 ("Software Lifecycle Processes") Annex B. The black non-italicized text of Figure 2 is taken from Annex B of 12207; our proposed concepts are captured in the purple italicized text. The ISO/IEC 12207 PRM indicates that each primary activity within a process should have its purpose (not shown) and outputs described. Outputs can include production of an artefact (e.g., a software requirements document, an integration testing plan), a significant change of state (i.e., a security source code vulnerability has been performed on the software and all found vulnerabilities have been removed), and meeting of specified constraints (e.g., release criteria for the software has been satisfied, testing has achieved coverage goals).

The extent to which existing medical and safety standards format their lifecycle activities according to the PRM varies significantly.

For example, IEC 62304 lifecycle requirements do not adhere to the PRM in any significant way – they

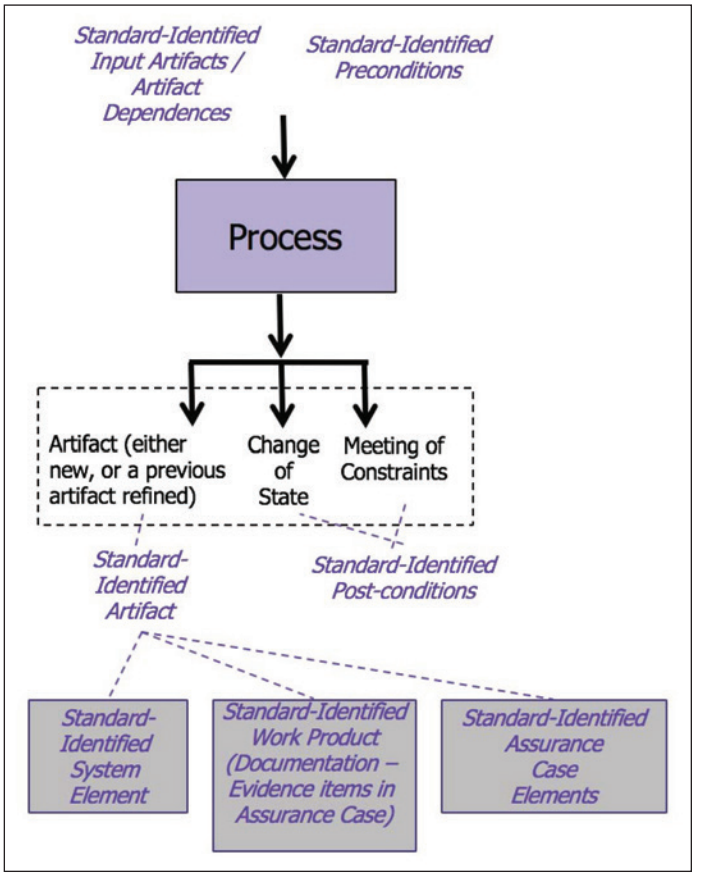

Figure 2: Structure of presentation of lifecycle activity

simply state tasks to be performed in each lifecycle phase (for example, see IEC 62304 Section 5.3 Software Architectural Design). In contrast, Figure 3 presents the template structure of ISO 26262 lifecycle phases, which illustrates a closer alignment with the PRM. ISO 26262-4 Section 7 *System Design* is a good example instantiation of the template, and it provides a nice point of comparison to the presentation style of a similar topic in IEC 62304 Section 5.3 mentioned above. For each subphase of the lifecycle phase (e.g., a "specification of the technical safety requirements" within the "Product Development: System Level" phase), the "Objectives" section provides a crisp statement of the subphase objectives (usually 2-3 objectives, each written in 1-2 sentences). The "Inputs to this clause/Prerequisites" lists the ISO 26262 work products from other activities that are required for the current subphase (establishing dependences between subphases which partially constrains their temporal ordering). "Further supporting information" identifies other optional ISO 26262 work products that might inform the current subphase. The "Requirements and recommendations" has subsections that give the standard's normative requirements for the different activities/tasks within the subphase. Finally, "Work Products" lists subphase outputs, i.e., the ISO 26262 work products that the subphase initiates, extends, or completes (accompanied by clause numbers of the section that pertain to each work product).

While in the past it may have been considered "overkill" to adhere to the ISO/IEC 12207 PRM, there are several reasons why we advocate that emerging standards presenting lifecycle processes

x.1	Objectives
x.2	General
x.3	Inputs to this clause
x.3.1	Prerequisites
x.3.2	Further supporting information
x.4	Requirements and recommendation
x.4.1	[. . . Task 1 requirements . . .]
x.4.2	[. . . Task 2 requirements. . . .]
. . .	
x.4.n	[. . . Task n requirements . . .]
x.5	Work Products

Figure 3: Structure ISO 26262 clauses for lifecycle processes

for interoperable systems adhere to an enhancement of the ISO/IEC 12207 PRM. First, we suggest an enhancement to include an explicit statement of inputs required for the activity (i.e., reflecting dependence on other activities) as done in ISO 26262 (see the section x.3.1 in Figure 3). The inputs would typically be work products that result from earlier activities, along with any other preconditions that need to be met before the current activity could be carried out. In addition, Figure 2 indicates that the work products produced should be explicitly listed among the outputs of each activity. Other explicitly identified outputs might include the specific system element be addressed (e.g., the item, component, system, etc.) along with assurance case elements (discussed later).

It may be useful for the standard being developed to provide a summary enumeration of the various work products or information content that is expected to be produced and controlled across all of the development lifecycle phases. This is the approach taken by AAMI/UL 2800-1 (see Annex C) which also states traceability relationships between the artifacts. Some work products will be proprietary to the manufacturing organization (e.g., planning documents or the details of risk analysis) and evaluated during the conformity assessment process. Other work products (i.e., interface specifications, risk management summaries, or qualifying tests) will be disclosed to other organizations that use the product (e.g., as in AAMI/UL 2800-1 disclosures – see Annex D, or information needed to support IEC 80001 Responsibility Agreements).

Explicit statement of input and output work products is more important in the interoperability space due to the need to coordinate the exchange information between organizations; the input to an activity carried out by one organization may depend on a work product produced by another organization (e.g., risk analysis of a component being produced may depend on error propagation risk analysis of a platform that the component is being deployed on or that of a service component being relied on by a present component, design of a component's interoperability interface may depend on an interfacing specification of another component with which it intends to interoperate). Hand-offs of information between organizations is a theme of both AAMI/UL 2800-1 (referred to as Disclosures – Annex D) as well as AAMI HIT 1000-1.

It is important to note that in many standards that present lifecycle processes, it is explicitly noted that the activities/tasks within the stated processes can occur in any order (or in parallel) as long as the dependences between the activities are observed. Thus, this relaxed order approach accompanied by an explicit statement of inputs and outputs allows manufacturers to map the required activities on to their own processes in a flexible way while achieving the rigor indicated by the input/output dependences.

Assurance cases are increasingly being required by standards as a means to provide arguments supported by objective evidence that a product achieves its assurance goals. The explicit argument structure of assurance cases aims to make a manufacturer's product assurance presentation easier to understand and evaluate in conformity assessment. AAMI HIT 1000-1 recognizes the additional utility of assurance cases for communicating product assurance properties between different stakeholders (e.g., a component manufacturer provides an assurance case for the component to an organization integrating the component into a HIT system). The component assurance case is incorporated into and used to justify the HIT system assurance case (see AAMI HIT 1000-1 Section 6 Figure 3). Similarly, AAMI/UL 2800-1 requires release criteria (see AAMI/UL 2800-1 Annex F) to be specified to summarize the primary assurance claims about a product. Accordingly, when designing process activities for interoperable products, it seems useful to consider how each activity contributes to the product assurance case (either in producing part of the argument claims or, as is more often the case, producing objective evidence for previously established claims).

ISO/IEC 15026-1 *Systems and software engineering Systems and software assurance* Section 9 states the following:

> *Management of life cycle activities includes handling both the activities directly involving the assurance-related information and the effect that the assurance-related information has on other activities. This management is best performed when the top-level claims are considered from the beginning of concept development, used to influence all activities and systems [...] and became an integral part of the overall engineering process. These activities could all be done only if the system and the body of information showing achievement of those claims were being developed concurrently.*

That is, ISO/IEC 15026-1 argues that assurance cases should be built incrementally throughout the lifecycle. To support this approach, when defining lifecycle activities for interoperable products, we advocate some explicit accounting of the portions of an assurance case that are produced as an outcome of carrying out a lifecycle activity (see bottom right of Figure 2).

Additional concepts beyond those listed in Figure 2 may prove important. For example, it might be useful to explicitly list possible cross-organization interactions (categorized according to stakeholder type) needed to carry out an activity.

TOPOLOGY-ORIENTED LIFECYCLE FLOW

In [14], we noted that existing medical device standards often adopt a simple "topological vocabulary" to describe the abstract architecture of a medical product. For example, IEC 62304 uses the term *software item* to refer to "any identifiable part of a computer program", and then has terms for the special cases of *software system* (an "integrated collection of software items organized to accomplish a specific function or set of functions" – note that the software system itself is a software item) and *software unit* (a "software item that is not subdivided into other items"). ISO 26262 uses the term *item* to indicate the units to which conformity assessment will be applied (i.e., items may have further internal structure, but if internal elements are not treated separately in the conformity assessment process then the item is not further decomposed into sub-items). These terms are also used to indicate the granularity at which *development lifecycle processes* are described, e.g., the development phases recognized by AAMI/UL 2800-1 include the "(software) item development phase", and the "(software) item integration phase".

We discussed in [14] that documenting and planning for hierarchical/containment relationships is made more challenging in modern medical systems because a product may be conceived as an interconnected collection of constituent sub-products, but the product itself may be incorporated as a component in a larger product context – sometimes in ways that were not anticipated when the product was produced. In some cases, these notions can be understood using concepts related to "systems of systems", nested to an arbitrary depth. Accordingly, topological vocabulary for interoperable products needs to be recursive in nature

to support the characterization of products with nesting of interoperable components to an arbitrary depth – enabling what may be considered a "system" at one level to be viewed as a "component" at another level.

We, therefore, suggested [14] that for conformity assessment purposes, the term *interoperable item* or simply *item* be used for an interoperable product that is either (a) a *unit* element with respect to assessed interoperability (i.e., it is not decomposed further into interoperable components) or (b) it is an integration of interoperable items with a specific purpose (e.g., it is an integration of interoperable components to form an interoperable medical system). Notice that this definition of *item* is recursive: an item can include (sub)-items, which in turn can include other items to an arbitrary level of nesting.

Conventional presentations of development models such as the V-model, even though they may actually support decomposition to an arbitrary depth, tend to emphasize two levels: a component level and a system level, where the complete functionality to be assessed for safety is known at the system level. Based on the reasoning presented above, we believe that for interoperable products it is more effective to take a slightly more abstract approach and present lifecycle development activities in terms of "item development" (where the item may be occurring at an arbitrary level in an architectural hierarchy) and then consider as options in the lifecycle activity descriptions the special cases where an item is either comprised of (sub)-items or is a unit (no further decomposition). This contrasts with the approach of IEC 62304 (see Section 5) which organizes activities in terms of software units and the software system as a top-level concept (i.e., IEC 62304 does not emphasize a recursive structure, though a careful reading and creative interpretation could accommodate it).

Figure 4 presents one possible arrangement of lifecycle activities that follow the recursive structure of the interoperable item concept described above. Several important activities such as planning, etc. do not show up explicitly here because the intent for this diagram is to emphasize the key activities of specification,

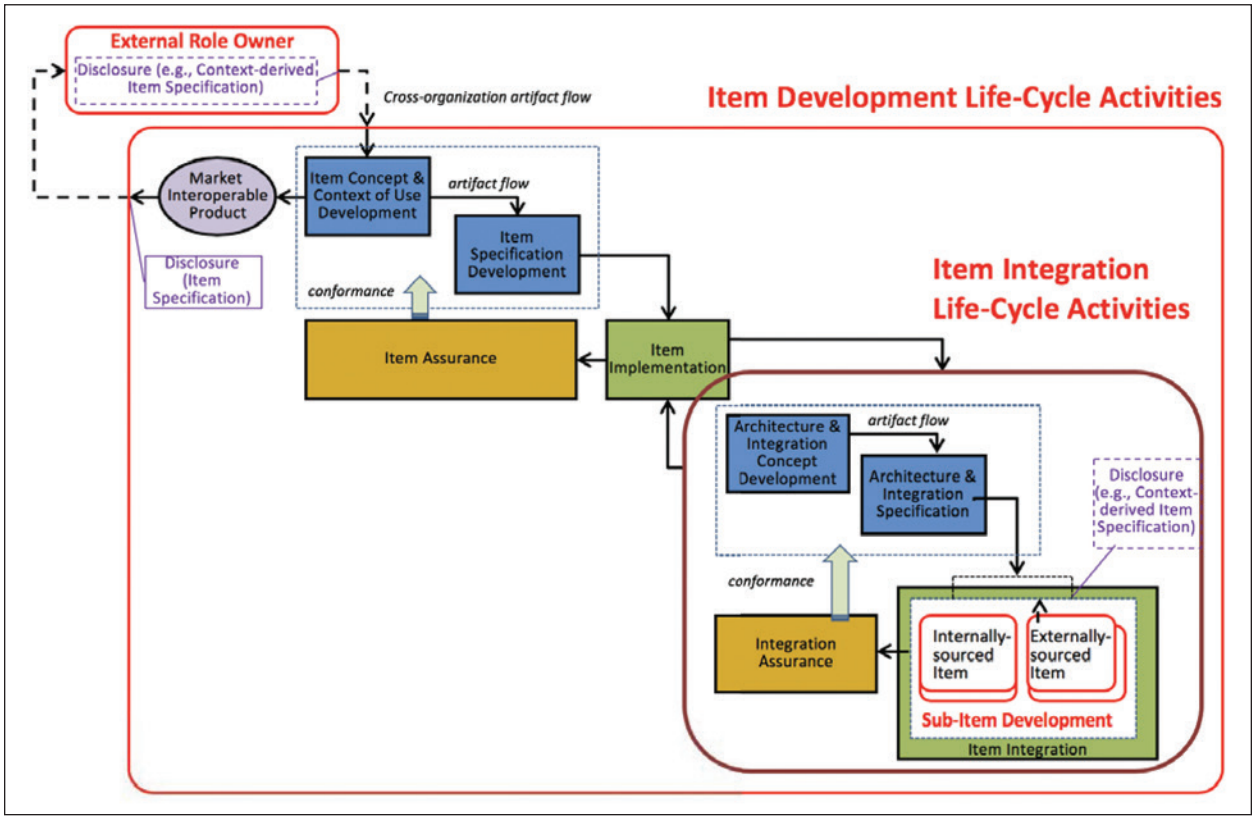

Figure 4: Lifecycle activity flow oriented to abstract interoperable product topology

implement/realization, and assurance. The outer level of the diagram presents item development activities. In the case where an item is an interoperable unit, the inner (sub)-item integration activities are not relevant. However, when the item is comprised of sub-items, then the inner item integration activities are followed.

Note that in interoperable products, getting things to "plug together correctly and talk to each other" is often viewed as an engineering activity distinct from the concept of integrating components to achieve some combined system functionality. For example, one may simply aim to get an interoperable product communicating with a hub or platform without concern to the medical use case (system purpose); indeed, there may be multiple medical use cases supported by the connected components. The suggested treatment of item integration activities (right bottom of Figure 4) as a first-class concept rather than just a subactivity of "system integration" supports these observations.

Within the item development activities, a concept activity and a specification activity lead to the development of a specification of an item's interoperability capabilities and associated safety and security properties. This includes the conventional concept phase (e.g., see IEC 61508-1 Table 1 and ISO 26262-3) notions of gathering user needs and requirements engineering, but it places a greater emphasis on specifying the interface architecture of the product and decomposing requirements to contracts (interaction constraints) on interfaces. In addition, risk analysis information should also be captured on (or traced to) product interfaces to enable integrators of the product to leverage the risk analysis and risk controls of the product. As noted above, the item implementation phase consists of two cases – the case where the item is a unit or the case where the item consists of sub-items. In either case, the goal of the implementation phase is to produce a product whose behavioral properties and functional safety characteristics conform to the item specification. The item assurance activity demonstrates that an item implementation meets its specification. Ideally, the demonstration is supported by structured arguments and objective evidence in the form of an assurance case.

Within the item integration activities, a concept for the integration and an engineering-oriented architecture description for the internal interoperability contained in the item is developed. This includes developing testing/verification plans for the integration of the sub-items. Sub-items may originate within the manufacturing organization of the item or they may be acquired from external sources. In the case of an externally sourced item, information exchange between the item manufacturer and the sub-item manufacturer is necessary. Internally sourced sub-items are developed by recursively following the item development activities. In both cases, confirmation that the sub-items meet their specifications and that the specifications align with the integration specification of the enclosing item is necessary, but this is especially important for externally acquired sub-items due to the greater potential for misalignment of specifications when products cross organizational boundaries. Finally, the integration assurance activity demonstrates that interactions between sub-items can be carried out as required by the integration specification. As with item assurance,

this demonstration is ideally supported by arguments and objective evidence in the form of assurance case elements. The elements of the assurance case presented in the integration activity may be incorporated into the assurance case for the enclosing item.

PRODUCT LINE AND REUSE PROCESSES

When a manufacturer designs a component such as a medical device for interoperability, an implied goal is that the component should be (re)usable in different system contexts. This is especially true in the platform approach to system development, in which domain-relevant infrastructure and services are also designed for reuse across multiple system contexts. The software and systems engineering communities have developed lifecycle processes and development paradigms that specifically target planning and designing for reuse as an activity that is distinct from developing a specific application/system from a collection of reusable assets (see, e.g., [4], [31]).

- Activities associated with planning for reuse and developing reusable platforms and components are typically referred to as *domain engineering*. These activities are typically undertaken by a manufacturer of a platform or by a consortium of manufacturers that jointly agree to cooperate to build a platform and to contribute to the collection of reusable assets.
- Activities associated with using those reusable assets to develop a specific system are called *application engineering*.

Unfortunately, the distinction between domain engineering and application engineering is not explicitly recognized in most safety standards, including those within the medical device community. As one example of the many gaps that this leaves, the absence of such standard content means there are no standard guidelines for performing hazard analysis, designing risk controls, or developing assurance arguments for platform components that by themselves have no specific medical intended use, but would benefit from having these tasks done once and for all and then shared and instantiated in system integration activities across different products built within the platform. In addition, the regulator pathway for systematic reuse of platform assurance is currently not clear – leaving regulators in doubt as to how much "credit" should be given for a previously-used and regulatory-approved platform. Moreover, manufacturers and regulators are unclear about processes to be followed to ensure that platforms assurance is being reused properly and not "mis-reused" in a manner that would lead to safety/security problems (See Section 6 in [16]).

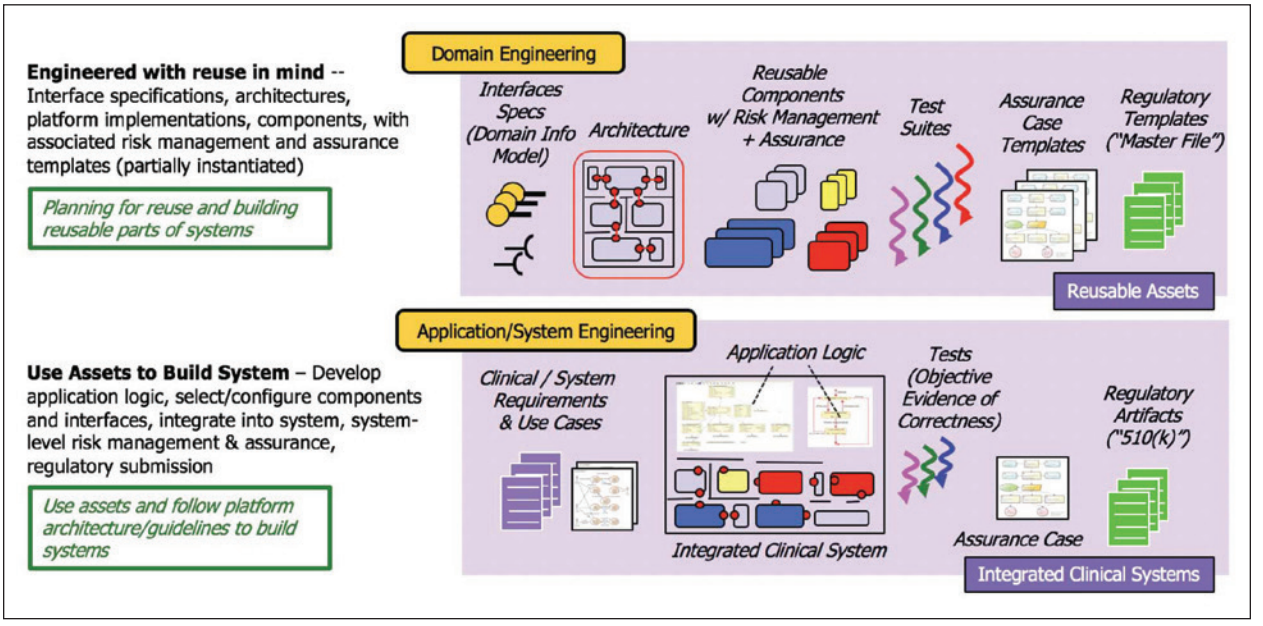

Figure 5: Structure of presentation of lifecycle activity

Figure 5 (inspired by diagrams of [31]) illustrates the distinct processes of domain engineering and platform engineering. Domain Engineering processes are associated with planning for reuse including the development of a platform and its associated reusable asset base. The family of systems to be built using the reusable assets is called the *product line*. Within the product line, some system components and functions will remain the same across all systems. For example, for a product line associated with a particular medical application platform [11], all systems might be built using the same middleware, the same communication hub, the same process for defining interfaces, etc. These are called the product line *commonalities*. On the other hand, the systems may differ according to the specific medical devices they include, the specific application logic, the specific intended use, etc. These are called the product line *variabilities*. The systematic documentation of the commonalities and variabilities of a product line is referred to as the *variability model* of the product line. In the interoperability context, the points in an architecture at which systems can vary are typically the points where interoperability is designed. For example, to enable the platform to easily support varying sets of medical devices across different systems, the platform will be designed to support network-based interoperability interfaces for medical devices that enable medical devices to be plugged and unplugged from the platform.

We argue that adequately addressing safety and security in the context of platform-based reuse and interoperability depends on clearly distinguishing the above concepts in lifecycle activities.

One important justification for this point of view stems from the fact that application engineering directly aligns engineering activities with a system's medical intended use – and the intended use drives the identification of safety/security-related hazards associated with the intended use as well as much of the top-down risk management process. These "single system intended use" concepts connect easily with the processes and goals of existing medical safety and risk management standards. In contrast, domain engineering involves planning for not just one system with a single intended use, but an entire family of systems with possibly different intended uses that may eventually incorporate the reusable components or infrastructure. Keys aspects of domain engineering in a safety/security-critical context include (a) identifying the scope of system intended use across many possible systems, (b) within this scope, identifying generic forms of hazards associated with system contexts and generic forms of faults that arise from the platform and component infrastructure, (c) designing and assuring architectural approaches and safety services that provide general fault identification, fault containment, fault notification, and mitigation solutions, and (d) defining methods and processes by which these general safety/security-related approaches are instantiated so that the previously generated generic assurance can be reused in the context of a specific system.

A second important argument for explicit domain engineering and variability modeling is that it is typically the variabilities in a product line that lead to unanticipated emergent properties as different systems are built. For example, if a common middleware or hub is used across all systems, that middleware can be tested once and for all and the assurance that specific communication capabilities are supported can be reused. However, when the middleware is configured with various medical devices or applications in different systems, one must be careful to assess whether unanticipated interferences between devices and applications arise and contribute to hazardous situations related to the overall system behavior. In particular, the domain engineering safety analysis process should seek to analyze the variability model to determine the possible ways in which unanticipated interferences might arise in different system variations and to design architectural and implementation approaches for the platform that either eliminate or notify of unanticipated inferences via dynamic checking. Here are some example strategies (that vary according to assurability and effectiveness of controls): the middleware may be designed to ensure that communication associated with one device doesn't interfere with that of other devices, the possible combinations of devices could be constrained (i.e., the variability reduced) by whitelisting individual devices or sets of devices that can be used together, the current communication latencies on the network could be monitored dynamically to raise an alert if the quality-of-service requirements for application-to-device communication are not being satisfied, etc.

In the standards context, simple notions of reuse processes are presented in Clause 7.3 Software Reuse

Processes of ISO/IEC 12207, which defines three different lifecycle processes that address many of the aspects of domain engineering described above: 7.3.1 Domain Engineering Process,7.3.2 Reuse Asset Management Process, 7.3.3 Reuse Program Management Process. A much more expansive presentation of product line and reuse concepts is given in the ISO/IEC 26550 series. Neither of these sources addresses safety and security issues, nor are they oriented to conformity assessment. However, they provide valuable standardized content that can form the basis of introducing (a) standardized lifecycle concepts for interoperability-based reuse and medical application platforms and (b) safety and security concepts within product line development.

We advocate that lifecycle concepts in the previous sections (in particular, those sketched for item development/item integration) be complemented by and linked to standardized lifecycle activities, artifacts, and assurance objectives for platform-based interoperable medical systems, drawing on the existing standard sources above for resources. In some areas in this space, there is already a good foundation of work. For example, Habli, Kelly, Oliveira, Braga, Papadopoulos, and colleagues have a sustained line of research related to safety analysis and assurance cases in the context of product lines and platform-based development (e.g., see [9], [6], [5]).

GOALS FOR DEVELOPMENT OF LIFECYCLE PROCESSES FOR INTEROPERABLE MEDICAL DEVICES

In this section, we summarize the discussions in previous sections in a list of goals for the development of lifecycle processes for interoperable medical products. Not all of these issues need to be addressed in detail in the specification of process steps; notes, rationale, and other forms of guidance may be used to lead stakeholders to fully explore/address supporting issues.

Presentation of Process Phases

- Consider a presentation of lifecycle stages that explicitly identifies information (work products) that are produced in the process of carrying out stages. Indicate how specific clauses/tasks contribute to (initiate, extend, complete, etc.) specific work products (consider ISO 26262 as an example).
- Consider a presentation of lifecycle stages that explicitly captures work product *inputs* and *outputs* to clarify dependences between stages and information that may flow across organizations. Link work products to *disclosures* and *responsibility agreements* that indicate the sharing of information across organizations.
- Consider a presentation of lifecycle stages that explicitly identifies assurance case elements (claims, evidence) planned or produced in each stage. Tie work products to evidence needed to support claims in assurance cases.

Architecture Issues

- Support the organization, flow, and decomposition of lifecycle stages with vocabulary appropriate for a high-level description of topological relationships between products in an interoperable medical system [14]. The vocabulary should enhance the conventional notions of software *system* and *item*, as presented in IEC 62304. Organize lifecycle stages for products and their decomposition based on that vocabulary.
- Ensure that lifecycle stages and flows are presented in such a way that enable products to be addressed at an arbitrary level of an architectural hierarchy (e.g., supporting notions of *systems of systems* and the idea that when a product is released there may be no way of knowing how deeply it will be nested in a broader interoperable medical system context).
- Incorporate steps leading to the development of a detailed architecture description that captures the details of interoperability interfaces and the structure of internal interoperability in terms of architecture views (e.g., as presented in ISO/IEC/IEEE 42010). Consider concepts from the architectural views defined in ISO/IEC 10746 standard series on the Reference Model for Open Distributed Process (RM ODP) [27].
- For platform-oriented products [11], [18], [3], [30], incorporate steps leading to the notion of a *reference architecture* [31, Chapter 11], and steps for establishing traceability from products that are instantiations of the platform to the platform reference architecture.
- Work to identify and normalize patterns of interaction between interoperable products (e.g., [33], [27, Section 4.4], so that process steps related to interaction risks, behavior specification,

and testing can speak to interaction types with a shared understanding of those interaction types across stakeholders.

- Incorporate steps that decompose system/product requirements down to interface contracts that capture constraints on interactions between products and indicate the behavior of a product's interoperability functions and interface-related risk controls. Consider incorporating guidance on using behavioral interface specification languages [13], [26] to precisely capture interaction constraints.
- Incorporate consideration of design and risk control principles that use resource partitioning (e.g., the emerging use of micro-kernels and hypervisors [3], [10]) and safety architectures [25] to avoid unanticipated interference and emergent properties when individual products are integrated to form a system (an idea that goes back almost forty years to the foundational work of Rushby [35]).
- Provide guidance on the use of architectural modeling to more precisely characterize medical product architectures (e.g., [12]).

Risk Management Issues

Some of the biggest needs are to help the community develop a better awareness of how the proliferation of interoperable products will necessitate risk management activities to be *distributed* across organizations [15] and how to address products that may not have a specific medical purpose. Better descriptions of lifecycle processes for interoperable medical products can clarify how distributed risk management tasks are interleaved with other tasks through the product lifecycle.

- Include steps that address the development of product *medical purpose* and *technical purpose* as well as the product's role in supporting interoperability (i.e., one needs to move beyond the conventional

and limited focus on a product's medical intended use – an infrastructure product may not have a specific medical purpose, but will be (re)used in system(s) with medical purposes – which necessitates risk management of the incorporated infrastructure product). Such information should feed into an expanded version of the product's intended use description as required in ISO 14971 Section 4.2.

- Include steps that specify the boundaries of the product and the scope of the product risk management in terms of the product's architecture description and variability model.
- Include steps that support risk analysis (including various forms of hazard analysis) for an interoperable product to be performed by the product manufacturer and then results shared (e.g., focusing on risk-related aspects of the interoperability interfaces) to other organizations that integrate the product into an interoperable medical system. Tie the interface-related risk analysis information to interoperability interfaces as documented in the product's interoperability architecture description. Include steps that help evaluate the extent to which some risk information may be held as proprietary while ensuring that information needed by integrators is not omitted in sharing.
- Include steps guiding system manufacturers in the use of the risk analysis results of incorporated subproducts, the assessment of the completeness and trustworthiness of those results.
- Include guidance that aids stakeholders to develop a common understanding of common faults and errors associated with interoperability and variability mechanisms. Provide guidance on how these notions might drive bottom-up risk analysis of interoperable products and their integration.
- Include steps leading to the identification of the product's contribution to risk controls. In the case of platform infrastructure, this may include *partial* elements of risk controls (e.g., mechanisms for monitoring the timely delivery of data) that are then integrated with application-specific risk controls (e.g., monitoring data delivery information to ensure that a particular control signal for actuation of a patient's state is carried out in a timely fashion, where the acceptable latencies are determined by the application requirements).
- Include steps leading to the identification of how an interoperable system's risk controls may be dependent on the risk controls of subcomponents and the assessment of the reliability specification of the subcomponent risk controls upon which the system depends.
- Include steps that lead to an assessment of how all the different variabilities within a product (as indicated by its architecture description and variability specification) are addressed in the risk management process.
- Include guidance on how risk analysis and risk control information may be captured in or traced to the interoperable product's architecture description [32], [24].
- Provide an approach that either integrates *safety* and *security* risk management into a unified risk management process or that clarifies the dependences and information flow between distinct safety risk management and security risk management processes.
- Develop steps to ensure the trustworthiness and integrity of the shared risk management information (e.g., in the presence of product evolution/updates – the update cycle of the system may proceed at a different tempo than the update cycles of the incorporated interoperable products).

Quality Management Issues

- Includes steps leading to how safety management for the interoperable product and all of its variabilities is linked to quality management goals (e.g., in ISO 13485 Section 5).
- Includes steps leading to appropriate defect reporting and monitoring for interoperable products, tied to the architecture description and variability specification of the interoperable product. This includes a "reporting out" to stakeholders that may include the product and monitoring of reports from manufacturers that supply constituent products on which the interoperable product depends.
- Includes steps linking the planning of the development process (e.g., in ISO 13485 Section 7) to the development of interoperability architecture descriptions, the planning of assurance case construction, the tracking of shared risk management information, and other aspects distributed development issues as discussed previously.

Assurance Case Construction

- Includes steps throughout the development lifecycle (as suggested by ISO/IEC 15026-1 Section 9) leading to the planning of assurance case structures, the development of assurance case claims, and construction of objective evidence supporting those claims. Tie the production of evidence to the work products indicated in lifecycle stage inputs and outputs.
- While AAMI HIT 1000-1 indicates that assurances cases may be used to share safety/security-related information between stakeholders in integrated medical systems, this may create tension with a manufacturer's need to protect proprietary information. Develop concepts that help manufacturers identify assurance case elements that need to be disclosed versus information that may be kept private.
- Distributed development of assurance cases for interoperable products (especially across multiple organizations) inevitably leads to the need for a manufacturer to explicitly identify (a) that specifications/assumptions about other products that the product under consideration is relying on and (b) the guarantees that a product is providing to other products that incorporate it. Lifecycle processes should include steps that explicitly identify these assumptions/guarantees (and ties to the notion of Information for Safety in ISO 14971), the representation of assumptions/guarantees in assurances, and steps that ensure that assumptions made by products are discharged (i.e., guaranteed satisfied) when products are composed into a system (see [19], [20], [7], [34]). The notion of "safety element out of context" in ISO 26262-10 Section 9 may also provide inspiration.

For further discussion of assurance case considerations in interoperable medical systems see [37], [23]. The work of Birch al. on assurance case structures for ISO 26262 may also be useful [2].

Product Line Concepts

The overarching challenge for this topic is that both product line process concepts and safety process concepts are very well-developed, but to date there has been very little integration of the two in general (and almost no integration in medical product domain). Therefore, the primary objective can be simply stated: take product line processes and inject into them the different process concerns from the medical space including quality management and risk management (for both safety and security).

- Synchronize medical domain product topology vocabulary [14] with vocabulary from the product line space including reference architecture, variability model, commonalities, variabilities, and product instances.
- Assess how concepts from each medical development lifecycle phases such as concept, requirements, design, implementation, verification & validation, etc. should be generalized to obtain domain engineering activities in which one is aiming to address not a single product but a family of products.
- Include lifecycle steps that establish refinement and traceability links between a product line reference architecture and the architecture of a product instance. Include steps that address criteria for the domain engineering assets (e.g., risk management and assurance artifacts and results for the generic product family) to be instantiated and reused in a particular product. Specifically, platform assurance must not be reused in situations where that is not warranted – one must show that a product properly aligns with a platform before reuse of platform assurance is appropriate.
- Develop specific risk analysis techniques for reusable assets that can address the issue that a specific intended use may not be known.
- Develop steps leading to the development, specification, and verification of general-purpose risk controls in platform infrastructure and appropriate instantiation/configuration of those controls for product instances.

CONCLUSION

This paper has argued that including content related to interoperable product development lifecycle activities in emerging standards on interoperability can be a useful means to convey to manufacturers and conformity assessment bodies how cross-cutting issues (currently addressed independently in separate standards) such as quality management, risk management, usability, security controls, architecture specifications, cross-organization information disclosure, and assurance arguments/evidence should be integrated to address

safety and security of interoperable components, systems, and reusable platform-based infrastructure. This paper has focused on development lifecycle issues, but clearly other lifecycle dimensions across the entire use lifecycle such as deployment, operation, and maintenance need to be addressed.

We have identified several issues that interoperability standards development activities should consider carefully:

- Presenting lifecycle activities in a manner that supports the interoperability challenges including (a) more deliberate tracking of information and work products and dependences that arise between activities and organizations due to production/consumption of work products, and (b) increased emphasis on incremental production of assurance case content throughout lifecycle activities;
- Rethinking the phasing and flow of lifecycle activities to better accommodate the recursive structure of solution topologies as things trend more towards "systems of systems";
- Explicitly incorporating notions of domain engineering and product line engineering to support significant trends to platform-based engineering approaches to medical systems.

Throughout the discussions, we have indicated existing standards content in other domains that may be useful as resources for developing lifecycle-related normative content and conformity assessment concepts for interoperable medical products.

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REFERENCES

1. *ASTM. F-2761: Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model.* Standard, 2009.
2. J. Birch, R. Rivett, I. Habli, B. Bradshaw, J. Botham, D. Higham, P. Jesty, H. Monkhouse, and R. Palin. "Safety cases and their role in ISO 26262 functional safety assessment." In F. Bitsch, J. Guiochet, and M. Kaâniche, editors, *Computer Safety, Reliability, and Security*, pages 154–165, Berlin, Heidelberg, 2013. Springer Berlin Heidelberg.
3. T. Carpenter, J. Hatcliff, and E. Y. Vasserman. "A reference separation architecture for mixed-criticality medical and IoT devices." In *Proceedings of the ACM Workshop on the Internet of Safe Things (SafeThings)*. ACM, November 2017.
4. P. Clements and L. Northrop. *Software Product Lines*. Addison Wesley, 2002.
5. A. L. de Oliveira, R. T. V. Braga, P. C. Masiero, Y. Papadopoulos, I. Habli, and T. Kelly. "Model-based safety analysis of software product lines." *IJES*, 8(5/6): 412–426, 2016.
6. A. L. de Oliveira, R. T. V. Braga, P. C. Masiero, Y. Papadopoulos, I. Habli, and T. Kelly. "Variability management in safety-critical software product line engineering." In *New Opportunities for Software Reuse - 17th International Conference, ICSR 2018*, Madrid, Spain, May 21-23, 2018, Proceedings, pages 3–22, 2018.
7. E. Denney and G. Pai. "Towards a formal basis for modular safety cases." In *International Conference on Computer Safety, Reliability, and Security*, pages 328–343. Springer, 2015.
8. L. Feng, A. L. King, S. Chen, A. Ayoub, J. Park, N. Bezzo, O. Sokolsky, and I. Lee. "A Safety Argument Strategy for PCA Closed-Loop Systems: A Preliminary Proposal." In V. Turau, M. Kwiatkowska, R. Mangharam, and C. Weyer, editors, *5th Workshop on Medical Cyber-Physical Systems*, volume 36 of *OpenAccess Series in Informatics (OASIcs)*, pages 94–99, Dagstuhl, Germany, 2014. Schloss Dagstuhl–Leibniz-Zentrum fuer Informatik.
9. I. Habli and T. Kelly. "A safety case approach to assuring configurable architectures of safety-critical product lines." In H. Giese, editor, *Architecting Critical Systems*, pages 142–160, Berlin, Heidelberg, 2010. Springer Berlin Heidelberg.
10. S. Harp, T. Carpenter, and J. Hatcliff. "A reference architecture for secure medical devices." *Association for the Advancement of Medical Instrumentation (AAMI) Biomedical Instrumentation and Technology*, September 2018.
11. J. Hatcliff, A. King, I. Lee, M. Robkin, E. Vasserman, A. MacDonald, S. Weininger, A. Fernando, and J. M. Goldman. "Rationale and architecture principles for medical application platforms." In *ICCPS*, 2012.
12. J. Hatcliff, B. R. Larson, J. Belt, Robby, and Y. Zhang. "A unified approach for modeling, developing and assuring critical systems." In T. Margaria and B. Steffen, editors, *Leveraging Applications of Formal Methods, Verification and Validation. Modeling*, pages 225–245, Cham, 2018. Springer International Publishing.

13. J. Hatcliff, G. T. Leavens, K. R. M. Leino, P. Müller, and M. Parkinson. "Behavioral interface specification languages." *ACM Comput. Surv.*,44(3):16:1–16:58, June 2012.

14. J. Hatcliff and E. Vasserman. "Topological vocabulary for supporting conformity assessment of interoperable medical products." 2019. Submitted for publication.

15. J. Hatcliff, E. Y. Vasserman, T. Carpenter, and R. Whillock. "Challenges of distributed risk management for medical application platforms." In *2018 IEEE Symposium on Product Compliance Engineering (ISPCE)*, pages 1–14, May 2018.

16. J. Hatcliff, A. Wassyng, T. Kelly, C. Comar, and P. L. Jones. "Certifiably safe software-dependent systems: Challenges and directions." In *Proceedings of the on Future of Software Engineering (ICSE FOSE)*, pages 182–200, 2014.

17. ICE Alliance. http://www.icealliance.org.

18. M. Kasparick, M. Schmitz, B. Andersen, M. Rockstroh, S. Franke, S. Schlichting, F. Golatowski, and D. Timmermann. "OR.NET: A service-oriented architecture for safe and dynamic medical device interoperability." *Journal of Biomedical Engineering/ Biomedizinische Technik*, 2018.

19. T. Kelly. "Concepts and principles of compositional safety case construction." *Contract Research Report for QinetiQ COMSA/2001/1/1*, 34, 2001.

20. T. Kelly. "Using software architecture techniques to support the modular certification of safety-critical systems." In *Proceedings of the 11th Australian workshop on Safety critical systems and software*-Volume 69, pages 53–65, 2006.

21. Y. J. Kim, S. Procter, J. Hatcliff, V.-P. Ranganath, and Robby. "Ecosphere principles for medical application platforms." In *IEEE International Conference on Healthcare Informatics (ICHI)*, 2015.

22. A. King, S. Chen, and I. Lee. "The MIDdleware Assurance Substrate: Enabling strong real-time guarantees in open systems with openflow." In *IEEE Computer Society symposium on Object/component/service-oriented real-time distributed computing (ISORC)*. IEEE, 2014.

23. A. L. King, L. Feng, S. Procter, S. Chen, O. Sokolsky, J. Hatcliff, and I. Lee. "Towards assurance for plug & play medical systems." In *Proceedings of the 34th International Conference on Computer Safety, Reliability, and Security - Volume 9337*, SAFECOMP 2015, pages 228–242. Springer-Verlag New York, Inc., 2015.

24. B. Larson, J. Hatcliff, K. Fowler, and J. Delange. "Illustrating the aadl error modeling annex (v.2) using a simple safety-critical medical device." In *Proceedings of the 2013 ACM SIGAda Annual Conference on High Integrity Language Technology*, HILT '13, pages 65–84, New York, NY, 2013. ACM.

25. B. R. Larson, P. Jones, Y. Zhang, and J. Hatcliff. "Principles and benefits of explicitly designed medical device safety architecture." *Biomedical Instrumentation & Technology*, 51(5):380–389, 2017. PMID: 28934584.

26. B. R. Larson, Y. Zhang, S. C. Barrett, J. Hatcliff, and P. L. Jones. "Enabling safe interoperation by medical device virtual integration." *IEEE Design Test*, 32(5): 74–88, Oct 2015.

27. P. Linington, Z. Milosevic, A. Tanaka, and A. Vallecillo. *Building Enterprise Systems with ODP*. Chapman and Hall, 2011.

28. MDPnP Program. "Openice – open-source integrated clinical environment." 2015. https://www.openice.info.

29. OR.NET e.V. OR.NET e.V. – safe, secure, and dynamic networking in the OR, 2017.

30. J. Plourde, D. Arney, and J. M. Goldman. Openice: "An open, interoperable platform for medical cyber-physical systems." In *2014 ACM/IEEE International Conference on Cyber-Physical Systems (ICCPS)*, pages 221–221, April 2014.

31. K. Pohl, G. Böckle, and F. van der Linden. *Software Product Line Engineering: Foundations, Principles, and Techniques*. Springer, 2005.

32. S. Procter and J. Hatcliff. "An architecturally integrated, systems-based hazard analysis for medical applications." In *2014 Twelfth ACM/IEEE Conference on Formal Methods and Models for Codesign (MEMOCODE)*, pages 124–133, Oct 2014.

33. V. Ranganath, Y. J. Kim, J. Hatcliff, and Robby. "Communication patterns for interconnecting and composing medical systems." In *37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, EMBC 2015, Milan, Italy, August 25-29, 2015, pages 1711–1716, 2015.

34. J. Rushby. *Modular certification*. Technical report, Computer Science Laboratory, SRI International, Menlo Park, CA 94025, US, September 2001.

35. J. M. Rushby. *Design and Verification of Secure Systems*. *Operating Systems Review*, 15, 1981.

36. E. Y. Vasserman and J. Hatcliff. *Foundational security principles for medical application platforms*. In *WISA*. 2014.

37. Y. Zhang, B. Larson, and J. Hatcliff. "Assurance case considerations for interoperable medical systems." In B. Gallina, A. Skavhaug, E. Schoitsch, and F. Bitsch, editors, *Computer Safety, Reliability, and Security*, pages 42–48, Cham, 2018. Springer International Publishing.

PRODUCT LIABILITY LITIGATION AND ITS EFFECT ON PRODUCT SAFETY REGULATORY COMPLIANCE

(And Vice-Versa!)

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By Kenneth Ross

Product liability litigation and regulatory activities in the U.S. and elsewhere often become intertwined. Product liability claims and lawsuits can generate investigations by the government and recalls. And, on the flip side, investigations and recalls can generate product liability and other lawsuits and contribute to findings of liability.

Reporting a safety issue to the government and undertaking a recall can certainly make defending a product liability case much harder. And, while it doesn't amount to absolute liability, reporting and recalling a product, at a minimum, increases the interest of plaintiff's attorneys and can serve as the basis for a plaintiff's verdict and possible award of punitive damages.

As a result, plaintiff's lawyers and their retained experts can try to use the government as leverage to force a recall or use the argument that the manufacturer should have reported to the government who would have most likely forced a recall. And, on the other side, the government can argue that a product liability lawsuit or expert's opinion triggered a duty to report, and that the company's failure to report in a timely fashion should result in a fine.

The U.S. Consumer Product Safety Commission (CPSC) has various regulations requiring manufacturers to consider what goes on in litigation in determining whether a report needs to be filed with them about a potential safety problem. The increased risk of being sued in product liability and increased need to report to U.S. and foreign government agencies has made product safety regulatory compliance a very complex and risky global endeavor.

The result of this increased complexity is that companies who sell regulated products are well advised to coordinate claims and litigation management and regulatory compliance, either by using the same law department personnel or by at least having the responsible in-house and/or outside personnel coordinate closely over strategy in both areas.

CPSC REGULATIONS REGARDING LITIGATION

The Consumer Product Safety Act (CPSA), section 15(b), requires manufacturers, importers, distributors, and retailers notify the CPSC immediately if they obtain information that reasonably supports the conclusion that a product distributed in commerce: 1) fails to comply with a consumer product safety standard, rule regulation, or banning regulation; 2) fails to comply with any other rule, regulation, standard, or ban under this chapter or any other Act enforced by the Commission; 3) contains a defect that could create a substantial product hazard to consumers; or 4) creates an unreasonable risk of serious injury or death.

The most important basis for reporting to the CPSC is section 15(b)(3), which requires reporting if there exist both a defect *and* the possibility of a substantial product hazard. The first question is whether a product has a defect. Under section 15(b)(3), a product without a defect is not necessarily subject to the reporting requirements even if injuries occur. Many products are reasonably safe and are not defective, but people still get hurt.

The CPSC regulations say that the term "defect" used in this section is not necessarily the same as the term "defect" as interpreted in product liability law. But the CPSC regulations require product liability in general to be considered in connection with a determination of whether a product is defective. They say:

> *"In determining whether the risk of injury associated with a product is the type of risk which will render the product defective, the Commission and staff will consider, as appropriate: ….* ***the case law in the area of products liability;*** *and other factors relevant to the determination."* (Emphasis added)
>
> 16 CFR §1115.4

The factors contained in these regulations track pretty closely the factors that a jury must consider when performing a risk-utility analysis to determine if a product is defectively designed.

The factors contained in these regulations track pretty closely the factors that a jury must consider when performing a risk-utility analysis to determine if a product is defectively designed.

The regulations also require that the firm consider the following to determine whether there is a substantial product hazard:

1) Information about engineering, quality control, or production data
2) Information about safety-related production or design change(s)
3) Product liability suits and/or claims for personal injury or damage
4) Information from an independent testing laboratory
5) Complaints from a consumer or consumer group

16 CFR §1115.12(f)

Therefore, plaintiff's expert's opinions, articles in consumer magazines, or reports by testing laboratories indicating that your product failed some *voluntary* testing protocol could serve as a basis for reporting to the government and recalling your product.

The regulations make it clear that the reporting company may deny that its product is defective when it reports. Therefore, while the manufacturer can submit a report and deny that the product is defective and creates a substantial product hazard, or deny that the defect creates an unreasonable risk of serious injury or death, the fact that a report was made might be admissible in a trial to support an expert's opinion. And, at a minimum, the manufacturer would have to explain why it reported and recalled the product if it wasn't defective or had a substantial risk of injury.

Another ground for reporting is if the product presents an unreasonable risk of serious injury or death (section 15(b)(4)). This regulation does not require that a product be defective before a reporting responsibility arises. However, for such reports, the regulations require firms to consider "reports from experts, test reports, product liability lawsuits or claims, consumer or customer complaints, quality control data, scientific or epidemiological studies, reports of injury, information from other firms or governmental entities…" The regulations then go on to say:

> *"While such information shall not trigger a per se reporting requirement, in its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA, the Commission* ***shall attach considerable significance*** *if such firm learns that a court or jury has determined that one of its products has caused a serious injury or death and a reasonable person could conclude based on the lawsuit and other information obtained by the firm that the product creates an unreasonable risk of serious injury or death."* (Emphasis added)

16 CFR §1115.6(a)

It is interesting that this regulation makes it clear that it will attach "considerable significance" to a plaintiff's verdict in a product liability case, although it specifically says that it is not a per se reporting requirement. The manufacturer and possibly the CPSC will need to decide what that language means in the context of making a matter reportable. And it is interesting that this language only applies to the "unreasonable risk" reporting requirement and not the one based on defect and substantial product hazard.

The last section of the CPSA dealing with litigation is section 37. This section requires manufacturers of consumer products to report information about settled or adjudicated lawsuits if:

- A particular model of the product is the subject of at least three civil actions filed in federal or state court;
- Each suit alleges the involvement of that particular model in death or grievous bodily injury—

The CPSC makes it clear that a manufacturer does not need to wait for a settlement or an adjudication by a jury saying that its product is defective before they should report.

mutilation or disfigurement, dismemberment or amputation, the loss of important bodily functions or debilitating internal disorder, injuries likely to require extended hospitalization, severe burns, severe electric shock, or other injuries of similar severity; and

- During a two-year period specified in the law, each of the three actions results in either a final settlement involving the manufacturer or in a court judgment in favor of the plaintiff

15 U.S.C. 2084

The CPSC's regulations discuss the Commission's view on the timing of section 15(b) and 37 reports when they say:

"…in many cases the Commission would expect to receive reports under section 15(b) long before the obligation to report under section 37 arises since firms have frequently obtained reportable information before settlements or judgments in their product liability lawsuits."

16 CFR §1115.7

So, the CPSC makes it clear that a manufacturer does not need to wait for a settlement or an adjudication by a jury saying that its product is defective before they should report.

And lastly, the regulations state that information from outside the U.S. must also be considered. Therefore, foreign incidents must be considered and could create a reporting responsibility to the CPSC, even if no incidents occurred in the U.S.

And in these foreign countries where incidents have occurred, their laws concerning reporting requirements are different. Therefore, a duty to report to these foreign governments and undertake a recall could be triggered well before litigation in that country or in the U.S. is commenced. In addition, if litigation occurs outside the U.S., the manufacturer would have to consider the facts of the occurrence and any judge's or expert's opinion (there are generally no jury trials outside the U.S.) concerning the reason for the incident in determining whether there is a duty to report to the CPSC.

WHAT DOES THIS MEAN?

These CPSC regulations can create substantial confusion as they relate to the effect of litigation on the duty to report.

Let's say that there are incidents and the company investigates and determines that there is no defect in the product thus not creating any basis to conclude that the incident was caused by the product. In that case, there should be no duty to report.

Then, a lawsuit is filed, and an allegation is made that the product is defective and caused the injury. Does that create a duty to report? I don't think so. If it did, then every lawsuit would trigger a report. Next, a plaintiff's expert issues an opinion saying that the product is defective and that this defect caused the incident. Now is there a duty to report? If the manufacturer hires a defense expert who reviews the report, sees the product, and then issues an opinion disagreeing with the plaintiff's expert, I would say no. Many things are going on during discovery and there are going to be several competing opinions and a dispute over whether the product is defective and caused harm. Still, I think there is a good argument that there is no duty to report.

But the plaintiff's expert could send their report to the CPSC and argue that the product should be recalled. And, as a result, the CPSC could initiate an investigation and ask the manufacturer to justify why the product should not be recalled. They might conclude that a report was triggered, and a recall is appropriate based merely on the plaintiff's expert report. This seems inappropriate,

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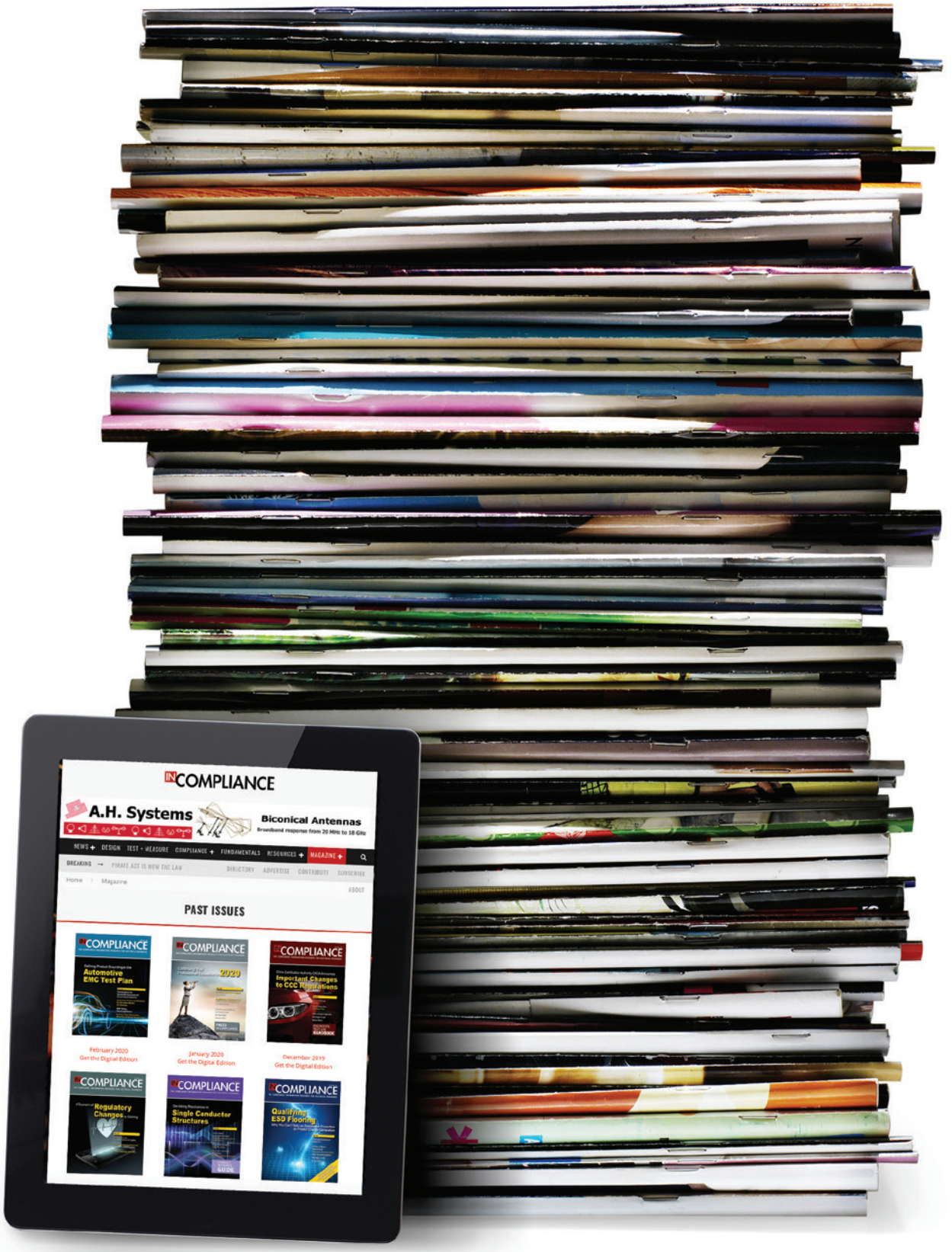

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especially if a defense expert reviews the report and concludes that there was no substantive basis for the plaintiff's expert's conclusions and that it was merely unsupported speculation.

Now let's say that a manufacturer goes to trial and the result is a plaintiff's verdict. Is this per se reportable? The regulations say no, and I agree, especially if this is the first case of its kind and there is no indication that an incident of this type would ever happen again. However, what if the jury renders a verdict specifically saying that the product was defective, was unreasonably dangerous, and caused the accident? Again, there are many reasons why a jury rules in a certain way and the verdict should be evaluated by the manufacturer, but I don't think it should necessarily result in a report.

Certainly, after any verdict by a jury or a judge finding liability, the manufacturer should document the file as to why it believes the jury verdict does not create a reportable matter and a recall isn't necessary. If in doubt, the manufacturer could report to the government, deny defect, and explain why they disagree with the court's ruling or jury's finding. Of course, the risk is that the government might disagree with the manufacturer's opinion.

What about a manufacturer who tries similar incidents to a jury verdict and gets inconsistent results? In one case, the jury says that the product is defective and caused harm. And, in the other case, they rule in favor of the manufacturer. Does the manufacturer have a duty to report? The manufacturer could report and argue that the product is not defective and that a recall or other corrective action is unnecessary. The problem is that the CPSC may disagree, and argue that even though there is no defect, there is an unreasonable risk of serious injury or death and require a recall.

What if the manufacturer loses the first case and then chooses to settle other similar cases so they don't get any further adverse results? Is that some proof that the product is defective? Does that make it reportable under section 15 or section 37? Manufacturers should document in their file the basis of any significant settlement (i.e., anything higher than a nuisance settlement) and discuss why they believe that no report to the CPSC or recall or retrofit program is necessary.

There can be great uncertainty as to the effect of litigation on the duty to report. While the CPSC makes it clear that information developed during litigation must be considered, there is no guidance on how to analyze the evidence and the results, especially when there are a series of cases that have inconsistent results. The manufacturer must consider all the evidence available to it that is required by the regulations, make a decision that is supported by technical analysis and make sure that the basis of the decision is adequately documented.

The manufacturer must manage its litigation and any response to litigation (i.e., safety improvements in new products) in a way that will help them identify when a duty to report might arise or whether it is possible that the CPSC will consider a report to be appropriate. And the manufacturer must also manage its dealings with the CPSC with an eye towards how it will be perceived if it becomes evidence in any current or future product liability cases.

EVIDENCE OF CPSC ACTIONS OR INACTION IN LITIGATION

If there has been a report to the CPSC and a subsequent corrective action, or the CPSC has taken some regulatory action concerning the product in litigation, the plaintiff will try to discover all of this information and use it during litigation. Certainly, evidence of any civil penalty investigation and an award of civil penalties will be sought in discovery. And the plaintiff will be very happy if the CPSC has sent a letter to the manufacturer stating that they have made a preliminary determination that the product contains a defect that could create a substantial product hazard.

On the other hand, if a manufacturer reports to the CPSC and the CPSC agrees that no recall is necessary, the manufacturer could try to use that evidence to support the position that the product is not defective, does not create a substantial product hazard and is not unreasonably dangerous. And, if a corrective action were undertaken, the manufacturer could try to use the CPSC's approval of its efforts as evidence supporting the position that it was not negligent in performing the recall.

It is possible that some or all evidence of this type will not be admissible or will not be persuasive or

determinative to a jury. However, it might be helpful to the manufacturer as the plaintiff's attorney is evaluating the case for settlement or trial.

Clearly, all correspondence in the manufacturer's files between the CPSC and the manufacturer concerning section 15 and 37 reports and any subsequent corrective actions is discoverable, although disclosure by the plaintiff outside litigation might be prevented under a protective order because it contains business confidential information. This information is discoverable even if much of this information in the CPSC's file cannot be disclosed by the CPSC under the Freedom of Information Act. Depending on the court, the information that is produced in litigation could be admissible in a trial or at least be used by the plaintiff's expert to opine about defect and causation and other aspects of the plaintiff's case.

The CPSC's employees are not permitted by the CPSC to testify in litigation about anything done or not done by them in connection with a report and any subsequent corrective action. However, former CPSC employees are free to testify.

Plaintiffs can try to use the CPSC's actions to support their case and manufacturers can try to use the CPSC's inaction to support the defendant's contention that the product did not violate the CPSC's rules or regulations.

EVIDENCE OF RECALLS

Of course, undertaking a recall can generate more litigation. Deserving and undeserving plaintiffs who may have been injured by a particular product are much more likely to sue if there has been a recall of that product. And defending such cases can be difficult. Plaintiffs should be required to prove that the injury was caused by that aspect of the product that caused the recall before they could get testimony admitted on the recall. Also, it is possible that the judge will rule that the recall is a "subsequent remedial measure" and therefore not admissible to prove a defect.

And the manufacturer can retain an expert to defend the adequacy of the recall. The question of recall adequacy is based on negligence and therefore the plaintiff must first show that the manufacturer could have done a better job. However, they then need to prove that if the manufacturer had done a better job, that the plaintiff's product would have been recalled and the accident would not have happened. That would be hard to do.

It is easy to argue that more could be done in a recall. And virtually all recalls are only modestly effective. Therefore, manufacturers rightly worry about a jury ruling that their recall was inadequate. Not only could that result in creating challenging evidence in future litigation, but it might also trigger an additional report to the CPSC because the corrective action the manufacturer undertook has been deemed inadequate. As a result, in my experience, where inadequate recall is alleged, many of these cases are settled before trial.

CONCLUSION

The interrelationship between litigation and regulatory activities is very complex and important. To minimize the risk in all post-sale activities, it is a good idea to seek assistance from lawyers who have expertise in both product liability litigation and regulatory compliance.

If insurance companies are handling a manufacturer's insured litigation, company personnel need to be involved to the extent that they can be made aware of information that may trigger a report to some government agency. And they need to have some input in the resolution or trial of the matter so that it is consistent with the position the company is taking or would take in connection with a possible report to the CPSC and subsequent corrective actions.

Of course, a manufacturer cannot let litigation cloud its judgment in deciding what to do concerning future safety. It must first do what is right for product users and the company. This may result in a company deciding to report to the government and implementing a recall, even though the product can be successfully defended in product liability litigation. It is imperative that a company coordinate both its actions in litigation and regulatory compliance simultaneously. Doing so will result in the best possible result under the circumstances.

PRODUCT Showcase

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IEEE EMC+SIPI Virtual Event

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August 11
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August 17-19
Fundamentals of Random Vibration and Testing with HALT, HASS, ESS and Fixture Design

August 26
5G Antenna Systems

September 13-18
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Power meter resolution	0.1 mVpp
Internal modulation source	sinusoidal / square / triangular wave, 2 mHz - 1 MHz
Pulse duration	1 μs - 500 s
Pulse width	0 ns - 100 s

System Test Setup:

Balun transformer: TBT-200;
HV AMN: TANHV 400;
HV shielded case: HVSE 400;
HV shielded junction box: HVSE 200;
HV battery load;
Load termination: 50 Ω;
Attenuator: 30 dB;
Software: EMC-S 7637-4.

Low Frequency Sinusoidal Disturbances (pulse B) Simulator

LFS 300B

Frequency	3 kHz - 300 kHz
Frequency step	1 kHz for 3 kHz - 300 kHz; 10 kHz for 30 kHz - 300 kHz
Open-circuit voltage	Upp = 0.5 V - 30 V (≤ 30 kHz); Upp = 0.5 V - 20 V (> 30 kHz); Resolution, 0.1 V
Power	max 3 000 W

System Test Setup:

HV AMN: TANHV 400;
HV shielded case: HVSE 400;
HV shielded junction box: HVSE 200;
HV battery load;
Coupling transformer: TPT-7637-4C100;
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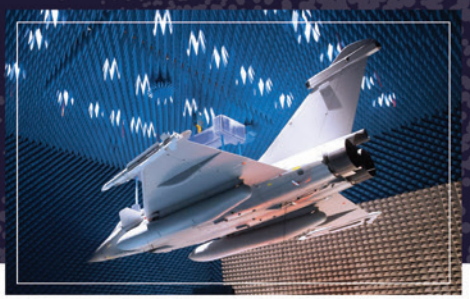

Shielded enclosures, reverberation chambers and anechoic chambers for hi-tech, EMC, military, automotive and aerospace.

Quality turnkey anechoic solutions

Raymond EMC is a leading manufacturer of shielded enclosures and anechoic chambers. In collaboration with Siepel, one of Europe's leading designers and manufacturers of anechoic and reverberation systems, our solutions are guaranteed for quality and performance. A superior commitment to client cares sets us apart, exceeding client expectations on all sizes of projects.

Serving our clients with

- Anechoic Chambers
- RF Shielded Enclosures
- Reverberation Chambers
- Relocation/Modification
- Upgrades
- Chamber Testing
- Deployable Enclosures
- Repair/Maintenance

REMC - Head Office

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