The
Product Safety Engineering Newsletter

Vol. 2, No. 2 June 2006

IEEE PSES
Product Safety Engineering Society

What's Inside

President's Message

It is exciting to see the evolution of what we expect to be a great IEEE Society. It may not be the biggest or the most lucrative. In fact, it is presently the smallest with approximately 550 members. However, it is growing at the fastest rate of any of the IEEE Societies. The PSES Board is working to promote greater membership. We all need to get the word out to others in the product safety and product compliance disciplines that we exist. Your help with this will help the Society grow and be able to provide more benefits to the membership.

One benefit we are working on is the development of a PSES exclusive publication such as a PSES Journal or Magazine. We are currently accepting technical papers for publication. These will be peer reviewed for publication in an IEEE journal or magazine.

PSES is presently in its third year of existence. An international symposium on Product Safety and Product Compliance will be held in

Anaheim, California, October 23-24, 2006. More information is available on the following website:

http://www.ieee-pses.org/symposium/

We expect to have more exhibitors and attendance than last year, as the scope of the symposium has expanded to include product compliance. Product compliance covers product safety, electromagnetic compatibility

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The
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and environmental aspects. The San Diego PSES Chapter is providing active involvement in making this a great technical symposium. Bansi Patel, Eaton Corporation, is Chairing this event. Richard Georgerian, Carrier Access, is Co-Chairing this conference. Richard is also the Vice-President of Conference for PSES.

Rich Pescatore, Vice-President of Technical Activities, is developing an impressive number of technical committees to support PSES. Look for more discussion on this in subsequent issues.

I invite all of you to visit the IEEE PSES website at:

http://www.ieee-pses.org/

There is a lot of information on the website including past editions of the PSES newsletter and member benefits information. Please keep in mind that we are always looking for feedback from the membership to try to maximize PSES benefits to you.

The PSES Board meets several times a year. Our meetings are open to all PSES members. The next meeting is June 25 in Minneapolis, Minnesota. I invite you to attend and contribute ideas to the continued positive evolvement of the IEEE Product Engineering Society.

Sincerely

Henry Benitez
President,
IEEE Product Safety Engineering Society
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Get the *eDJ*!

New section debuts with this issue.

Our new peer-reviewed papers section, the *eDJ*, debuts with this issue. "*eDJ*" stands for "*e*lectronically *D*istributed, *J*ournal-quality" papers plus more.

The papers are those originally submitted for the Journal on Product Safety Engineering, whose launch has been postponed until we develop a stronger paper flow. These papers promote, recognize and archive work that advances the theory and practice of product safety engineering.

The "more" are value-added discussion threads and web conferences associated with each paper for the weeks immediately after the newsletter's release (see the *eDJ* section for more details). With these resources, you can participate and "get the *eDJ*" for your job!

IEEE PSES Needs Volunteers

Please contact any Board Member on page two and find out how you can help!

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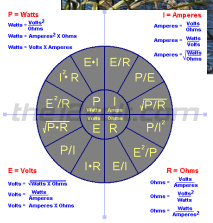
IEEE PSES needs Volunteers
Please contact any Board Member on page two and discuss how you can help!

Explore Your Practical Side

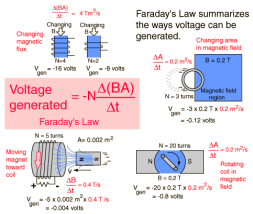
$\mathcal{E} = I R$

Ohm's Law



Kirchoff's Law

$0.2 < \mu < 0.3$ where μ = coefficient of friction



Put Theory into Practice.... Designing Safe Products for your World

2006 IEEE Symposium on Product Safety & Compliance Engineering

Product Safety Engineering Society

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Sponsored by the IEEE Product Safety Engineering Society

Irvine, California **23 – 24 October 2006**

http://www.ieee-pses.org/symposium

Meeting Standards in One Country Can Prompt Suits in Another

by Sheila T. Kerwin

Today's globalizing marketplace can bring great opportunity to product manufacturers, but unfortunately it can also add great complexity. The different-and sometimes more stringent-product standards required by non-U.S. countries can adversely affect product protection here in the United States, because plaintiffs' attorneys can use these discrepancies to their advantage in litigation against product manufacturers. American companies seeking to gain a larger market share by adapting their products for use in other countries may end up paying serious prices when the plaintiff's bar use the different international designs and standards to make a case. It's imperative, therefore, that manufacturers who sell in other countries understand those countries' standards in detail and make good safety decisions in all venues.

Overview of Product Liability Law

A manufacturer has a duty to design defect-free products. Legally, a product is deemed defective if the manufacturer could reasonably foresee that it could cause injury. In product litigation, the focus of the manufacturer's defense is to ensure a jury understands that the manufacturer is thoughtful and takes steps to create safe products.

This is accomplished by showing reasonableness throughout the "life of a product," which refers to the design, manufacturing, sale and post-sale phases of the product life cycle. The manufacturer wants to be able to show concern about safety at each of these phases.

- Design Phase - When developing a product, a manufacturer must consider the DESIGN, GUARD, WARN hierarchy. This means that any hazard in a product must be designed out of the product if at all possible. If the hazard cannot be designed out of the product, then the product must be guarded to prevent interaction with the hazard. Finally, if the hazard cannot be guarded, then the product must warn of the danger. Safe design evidence that a jury will review includes the product manual, warning markings, manufacturer's engineering documents, what similar companies are doing, and compliance with industry standards.

- Manufacturing Phase - Product safety during the manufacturing process can be illustrated by the manufacturer's quality control documents-both its own as well as incoming and outgoing QC documents from suppliers and from distributors who purchase the product.

- Sale and Post Sale Phase - The manufacturer should also ensure it is selling to qualified vendors who know how to safely install the product. Most states now impose post-sale duties which require the manufacturer to stay on top of the state of the art for safety and perform recalls or retrofits of products that are no longer safe.

Relevance of Industry Standards in Litigation

The most prevalent claims in product liability litigation relate to improper or negligent designs. One of the main ways a manufacturer

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can defend itself in such litigation is to show a jury that it complied with industry standards, so it is critical that a manufacturer know and adhere to the industry standards that apply to its products.

These standards are derived from governmental agencies, industry organizations, and independent standards developers. In the U.S., examples of governmental agencies that create standards are the Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA) and National Highway Traffic Safety Administration (NHTSA). Examples of industry organizations are American National Standards Institute (ANSI), American Gas Association (AGA) and American Society of Mechanical Engineers (ASME) as well as, of course, the IEEEE. Examples of independent standards developers are CSA and UL.

Compliance with industry standards is strong evidence that the manufacturer is concerned about safety, but it alone is not enough. A manufacturer must understand that compliance with industry standards is only a minimum expectation and that the manufacturer can go beyond the minimum standards to create products even safer than required. A manufacturer should be prepared for plaintiff's counsel to argue that even if the product is in compliance with an industry standard, the manufacturer could/should have done more to create a safer product.

Effect of Different International Standards on Products Cases

Non-U.S. countries also have industry and governmental standards that require compliance, and while there has been some effort to harmonize these differing standards (for example the ISO and IEC standards across Europe and other member countries) many countries are not as coordinated. Moreover, there are additional standards beyond ISO that can create difficulty for manufacturers. For example, while Canada and Mexico are members of ISO they can have differing standards from the U.S., and manufacturers who sell products in these countries must understand the implications should litigation transpire.

U.S. courts have wide discretion to admit safety standards as evidence. If a product is designed, manufactured, or sold in the U.S., a court in this country would typically admit American standards, finding them relevant.

Whether or not another country's standards would be found admissible, however, is far less predictable. The manufacturer would want to make a strategic decision on whether admission of the standards would be helpful to the defense of a product liability action. Such a decision can be highly dependent on case details. Suppose the case is pending in the U.S., and the manufacturer complies with even higher standards in another country.

- In some instances, the manufacturer should seek to have the foreign standard admitted, arguing that it shows the extreme safety consciousness of the manufacturer.

- In other instances, such as if the plaintiff were trying to argue for compliance with another country's standard, the manufacturer would argue that the other country's standard is not relevant to products manufactured for sale in the U.S.

- The risk in either situation is that if the other country's higher standard is admitted, it could be very damaging evidence to a jury that the manufacturer does not really care about product safety but is only complying with the most minimal standards. A battle may ensue as to what constitutes the current, generally accepted state of the art regarding safe design for the product in question.

The Bottom Line

It's common for manufacturers to produce different versions of a product for different national markets, each version complying with the standards of a country. Manufacturers need to keep an ever-watchful eye towards how another country's standards can affect any litigation, ensuring they request the court either limit or include another country's standards, whichever will be helpful to the defense of the product.

Sheila T. Kerwin is a shareholder and trial lawyer who chairs the products liability practice group at Halleland Lewis Nilan & Johnson in Minneapolis. She is a member of the coordinating counsel team for product manufacturers nationwide. Kerwin can be contacted at 612-204-4128 or skerwin@halleland.com.

Case histories on next page

Case histories…
Three examples in which varying international standards created litigation complications for manufacturers

1. Case History: Sale of pool heaters in Canada affects stricter standards regarding blocked-vent switches

Both the Canadian Standards Association and the American Gas Association have standards for the design of pool heaters. Interestingly, the Canadian standard was stricter with regarding to safety devices on these heaters in the past. Specifically, the CSA standard

Three Tips for Manufacturers Who Sell to Multiple Countries

1.) Manufacturers need to understand the standards for all countries in which they sell products. More importantly, they need to understand that the standards in any country are only "minimal standards" and might want to have internal safety policies exceeding those standards. A jury will be looking for evidence that the manufacturer was considering safety and going beyond the minimal standards as evidence of the manufacturer's intentions.

2.) When a manufacturer sells into other countries with differing standards that relate to its products, the best policy is to design the product for all countries the same and to the highest standard. In that case, the plaintiff's bar will not be able to use the fact that the product differs depending on what standard applies. Moreover, the manufacturer can use the highest standards as a sword and not a shield to aggressively defend itself in litigation. In such situations, evidence that the company is concerned about safety can be developed in any country.

3.) Finally, if the manufacturer has designed products differently for multiple countries as a result of varying standards, manufacturers should defend lawsuits with an eye toward transferring those cases to the country with the lowest industry standards. Again, knowledge of all the relevant international standards is critical to defend product liability litigation.

required a blocked-vent switch to be on pool heaters that are sold in Canada. At the same time, the AGA standard did not require such a blocked-vent safety switch to be installed on pool heaters sold in the U.S.

A pool heater manufacturer sold heaters to both Canada and the U.S. The company, being very familiar with the applicable standards, designed the pool heaters sold to Canada with a blocked-vent switch and heaters sold in the U.S. without blocked-vent switches. Litigation was pursued in the U.S. where plaintiff claimed there should have been a blocked vent switch on the unit. The manufacturer argued that such a device was not required under the AGA standard and it wouldn't have made a difference anyway. Plaintiff was unable to convince the court to admit the Canadian standard as evidence of a safer way to design the product. A defense verdict was achieved in the case.

2. Case History: Circular saw manufacturer encountered different standards in U.S. and Europe on requirement of a kerf guide

Standards relating to circular saws in the U.S. do not require saws to be sold with a "kerf guide," which guards the area that has already been cut with the saw in the event the saw kicks back towards the operator holding the material to be cut. In Europe, the kerf, or area that has been cut, is required to be guarded with a plastic guide. In the event of a kick back, the guide will be pinched and not the operator.

In a case venued in the U.S., plaintiff's counsel attempted to admit the European standard relating to kerf guarding. The court allowed the evidence claiming it was relevant to alternative design theories. A jury found liability in the case.

3. Case History: Boiler explosion in Mexico calls product manual into question

A boiler manufacturer sold boilers both in the U.S. and Mexico. In the U.S., the applicable American National Standards Institute (ANSI) standards required certain warnings regarding the risk of explosion, but there are no similar standards in Mexico. The manufacturer sold to Mexico through a Mexican distributor who was contractually obligated to provide the relevant safely manuals. Since there are no relevant Mexican standards requiring specific warnings on explosions, the manual did not contain the same language that the manuals used in the U.S. contained. After a significant explosion in Mexico, the plaintiff's counsel succeeded in having the case venued in the United States. The manuals used with the product obviously did not comply with the ANSI warnings required in the U.S. The manufacturer fought hard to have the case transferred back to Mexico, to no avail. Moreover, the defendant was unsuccessful in getting Mexican law or standards to apply to the case. As a result, the case settled for more money than it was worth.

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Tony Robertson
Manager – Customer Training

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Membership: The society ID for renewal or application is "043-0431". Yearly society fee is US $35.

ANSI Z535.6: A New Standard for Safety Information in Product Manuals, Instructions, and Other Collateral Materials

by Steven M. Hall

A new standard, ANSI Z535.6, Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials, is being added to the ANSI Z535 series. To date, the ANSI Z535 Accredited Standards Committee has published five American National Standards:

- ANSI Z535.1: Safety color code
- ANSI Z535.2: Environmental and facility safety signs
- ANSI Z535.3: Criteria for safety symbols
- ANSI Z535.4: Product safety signs and labels
- ANSI Z535.5: Safety tags and barricade tapes (for temporary hazards)

The new standard was approved by letter ballot and comments were resolved at the ANSI Z535 committee's September 2005 meeting. It is scheduled to be published by June 2006, around the same time as the next editions of the existing Z535 standards (excluding Z535.5).

The Need for the New Standard

The five existing Z535 standards contain recommendations regarding the formats, colors, and symbols for safety signs used in environmental and facility applications, product applications, and accident prevention tags/tape, but do not address safety messages in product manuals, instructions, and other collateral materials. The absence of standardized formatting systems, combined with the increased awareness and use of ANSI Z535.4, has led to attempts to apply various aspects of ANSI Z535.4 to safety information in collateral materials. However, ANSI Z535.4 was not intended for and is not well suited to this purpose.

Different standards are needed for product signs and labels and collateral materials due to the differences between these two types of media. For example, collateral materials typically contain more information than a sign or label, address multiple hazards and contain multiple safety messages, provide longer and more detailed safety messages, contain multiple pages of information that cannot be viewed simultaneously, and can provide information that would be impractical on product safety signs, such as definitions of the safety alert symbol, signal words, and safety symbols. Also, unlike safety signs and labels, safety information in collateral materials must often be integrated with surrounding, non-safety information. Collateral materials are typically not attached to the product, so issues related to reading conditions, distinctiveness, placement, expected life, and maintenance are different. In addition, the concept of a safe viewing distance is not generally applicable.

The New Standard—ANSI Z535.6

To respond to this need, the new standard provides a hazard communication system devel-

oped specifically for product safety information in collateral materials. It provides a common design direction intended to provide product safety information in an orderly and visually consistent manner. Certain graphical elements used in the other Z535 standards are included in Z535.6:

- signal words (i.e., DANGER, WARNING, CAUTION, NOTICE);
- the safety alert symbol;
- safety colors (i.e., red, orange, yellow).

However, in order to adapt these graphical elements for use in collateral materials, the standard includes some unique features, such as different safety message formats depending on the relationship between the safety message and other information in the document, and provisions for presenting safety messages without safety colors. The following summarizes, in general terms, the contents of the new standard.

Scope

The standard sets forth requirements for the design and placement of safety messages in collateral materials. Like existing ANSI Z535 standards, such as Z535.2 and Z535.4, this standard is intended to apply to a broad range of products. Collateral materials include a variety of documents, such as owner's manuals, instructions, user's guides, maintenance or service manuals, assembly instructions, and safety manuals. Collateral materials may take the form of a single sheet of paper, a multi-page document, instructions on a package or container, or a printable electronic document.

Signal Words

Many of the safety message formats in the standard use signal words to call attention to the safety message. Signal words are often used with the safety alert symbol to form a signal word panel (Figure 1).

Figure 1: Signal word panels (with optional color).

The standard includes signal words that are used in other ANSI Z535 standards: DANGER, WARNING, CAUTION, and NOTICE. As with other Z535 standards, signal words are selected based on degree or level of hazard seriousness, specifically, the probability and severity of harm associated with not following the safety message.

The signal word definitions in all of the ANSI Z535 standards' 2006 editions have been updated. The definitions of "DANGER," "WARNING," and "CAUTION," when used with the safety alert symbol, have been edited for clarity, but the intended meaning has not changed. The definition of "NOTICE" has been updated in all standards, and the signal word has been added to Z535.4 and Z535.6. This signal word replaces "CAUTION" without the safety alert symbol for use with messages not related to personal injury, such as messages related to

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property damage only.

In addition to the updated definitions, a detailed annex regarding risk assessment and signal word selection has been added to ANSI Z535 standards including Z535.6.
The Safety Alert Symbol
The proposed standard includes formats that use the safety alert symbol (Figure 2).

Figure 2: Example of the safety alert symbol.

The safety alert symbol indicates a potential personal injury hazard; it is not used for messages related to property damage only. The safety alert symbol may be used alone or in conjunction with a signal word in a signal word panel.

When presented as a black triangle with yellow fill, a black exclamation mark and, optionally, a yellow border (Figure 3), the safety alert symbol is identical to the general warning sign defined in ISO 7010 – 2003, Graphical symbols — Safety colours and safety signs — Safety signs used in workplaces and public areas.

Figure 3: Examples of the safety alert symbol when formatted like the ISO general warning sign.

This optional form of the safety alert symbol is being added to the ANSI Z535 standards' 2006 editions to allow greater harmonization with ISO standards. For example, ANSI Z535.4 - 2006 will allow the use of this optional yellow and black safety alert symbol in signal word panels. Such a signal word panel is essentially identical to the optional hazard severity panel defined in ISO 3864-2 - 2004, Graphical symbols - Safety colours and safety signs - Part 2: Design principles for product safety labels.

While there is no ISO standard that is directly comparable with ANSI Z535.6, inclusion of this optional safety alert symbol allows safety messages in collateral materials to be visually similar to signs, labels, and tags that are formatted according to other ANSI Z535 standards and also to ISO standards.

Safety Colors
The use of color is not mandatory. However, if color is used with signal words, the same safety colors that are specified in the other Z535 standards are recommended. ANSI Z535.1 provides specifications for safety colors.

Types of Safety Messages
Unlike safety messages provided on signs or labels, safety messages in collateral materials can be classified based on their relationship to other information in the document. The standard defines four types of safety messages: supplemental directives, grouped safety messages, section safety messages, and embedded safety messages.

Supplemental Directives—
Supplemental directives are messages that refer to other safety messages. They can be used to:
- Direct users to new, unique, unusual, or particularly important safety information;
- Direct users to product safety information in the document, in another document, or in some other source (e.g., product safety signs and labels);
- Make users aware of the safety-related nature and importance of an entire document or section within a document (e.g., a section of grouped safety messages);
- Reduce the need to repeat consequence information, especially generic consequences (e.g., "severe injury or death"), that may be associated with failure to read the document or refer to other sources of safety information.

Some typical supplemental directives include messages like:
- "Read all instructions before use to avoid injury."
- "To avoid serious injury or death, follow the safety information in this document."
- "Keep this manual."
- "Read all product safety labels."
- "Refer to local building codes for installation requirements."

Recommended formats for supplemental directives use the safety alert symbol (Figure 4) and, in cases where hazards and consequences can be determined with enough specificity to assign them, signal words.

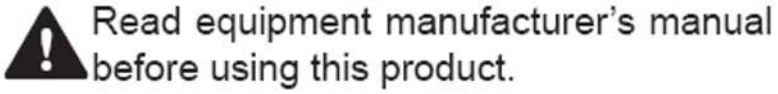

Figure 4: Example of a supplemental directive with the safety alert symbol.

Grouped Safety Messages—
Grouped safety messages are presented in their own separate section or document, for example an "Important Safety Information" chapter in a document or a separate "Safety Manual." When provided in a section within a document, these messages are typically placed at the beginning of a document, before any procedural information to which they apply. A separate section or document of grouped safety messages must have a title or heading indicating that the information is safety-related. Signal words and the safety alert symbol are

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often not used with grouped safety messages, since there is no need to distinguish safety messages from other information in an all-safety section or document.

Section Safety Messages—
Section safety messages apply to an entire section of a document. These messages can be used to:

- Provide safety information that applies throughout a procedure;
- Provide safety information that pertains to the topic of a particular section but that is not related to any particular procedural step or message in the section;
- Avoid unnecessary repetition of information about the hazards, consequences, or avoidance that applies to an entire section, paragraph, procedure, group of procedures, or other unit of text within the body of a document;
- Allow users to access procedural and other product-use information more easily and efficiently by reducing the extent to which a safety message interrupts or interferes with the access or flow of information.

Section safety messages are typically located at the beginning of a section, before the information to which they apply. A signal word panel (Figure 5) or a safety alert symbol (Figure 6) typically precedes these messages.

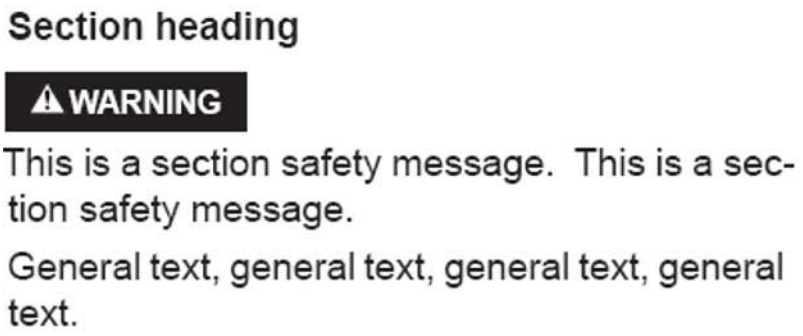

Figure 5: Example of a section safety message with a signal word panel.

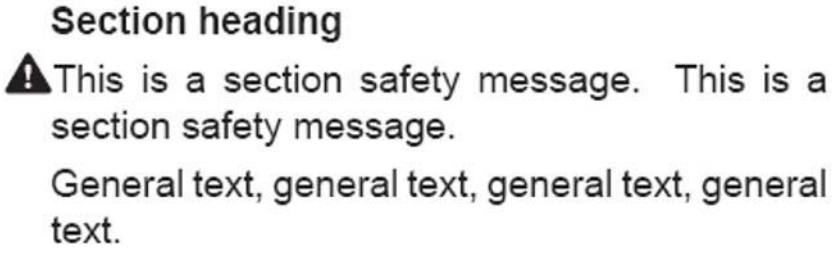

Figure 6: Example of a section safety message with a safety alert symbol only.

Embedded Safety Messages—
Embedded safety messages are integrated into procedures or into other non-safety information. Integrating safety messages into procedures can be particularly helpful, as the safety message can be placed at the step in the procedure when it should be followed. A variety of formats are permitted for embedded safety messages in order to allow them to be better integrated with the surrounding information in a particular situation. Formats include use of signal words (Figure 7), the safety alert symbol, consistently applied text treatments (e.g.,

bold or italics), or, when the content and context of the message make it clear that it has to do with safety, no special formatting.

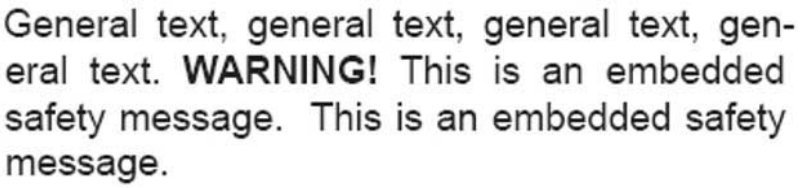

Figure 7: Example of an embedded safety message with signal word.

Conclusion

Because ANSI Z535.6 provides a completely new scheme for classifying different types of safety messages and a variety of options for formatting safety messages, applying the standard to collateral materials will initially be more complicated than, for example, applying ANSI Z535.4 to product safety labels. However, the additional effort required to initially apply the standard can provide valuable benefits. The process of identifying and classifying safety messages provides an opportunity to reevaluate the content and location of safety messages, and to develop a consistent approach regarding when and where warnings are provided, both in collateral materials and via other media. The relative flexibility in formatting safety messages provides an opportunity to develop a custom style that is appropriate for the particular documents and that also is consistent with the new standard. Once this style has been established, developing future collateral materials should be significantly easier.

The experience of many different industries applying the standard to a wide variety of collateral materials will likely expose areas of the standard in need of modification or refinement as time goes along. Users of the standard are encouraged to provide feedback to the Z535 committee and propose changes to improve the next edition of the standard.

Steven Hall, M.S.E., C.P.S.M. is a Senior Human Factors Specialist and Director of Hazard Communication Consultations with Applied Safety and Ergonomics, Inc., a consulting firm based in Ann Arbor, Michigan, and serves as vice-chairperson of the ANSI Z535.6 subcommittee. Mr. Hall is regularly involved in the development and evaluation of product warnings and manuals, and provides technical support in complex litigation involving warnings and hazard communication issues. Mr. Hall can be contacted at shall@appliedsafety.com or 734-994-9400.

Editorial Note — The IEEE PSES bought a copy of the ANSI standards on Safety Colors. We changed the colors of our logo to use the ANSI safety colors and most of the colors we use in the IEEE PSES Newsletter are the Pantone equivalents listed in the standard.— JB

News and Notes

Society

• **Figures of Society:** By 2006.4.30, IEEE Product Safety Engineering Society has ??? full members, including about 25% outside United States. 10 Chapters (including 3 international chapters) are active in their regions, while 2 Chapters are calling for members.

• **Launching of first Journal on Product Safety Engineering (JPSE) has been postponed.** The cited reason was that the current rate of paper submissions is not high enough to ensure a viable IEEE journal at this time. However, responsible IEEE TAB (Technical Activities Board) also expressed the clear desire to publish the papers within the IEEE family of archival journals, and to stimulate the necessary paper flow for a stand-alone journal in the future. Towards that end, BOD of the PSES will contact other IEEE societies to consider publishing under their umbrella. (For more detail, contact Mike Sherman, the Editor-in-Chief of JPSE)

What's new

• **"WHO-IS-IN-WHAT" project will be kicked off very soon.** In order to enhance networking among PSES members, PSES will send all society members a survey by email shortly. The survey will focus on what standards committees/national committees each member serves on. Those who choose to have this information published should reply to this email. PSES will publish a listing/directory of survey result, under the relevant IEEE privacy policy. All members are encouraged to take part in. (For more detail, contact Jim Bacher, VP of Communications)

• **Sri Lanka joins IEC.** IEC welcomed Sri Lanka as its 67th Member (Associate) in March 2006. IEC's family now numbers 135 in total. Located in the Indian Ocean off the south-eastern shores of India (about 30km), the island of Sri Lanka currently has a population of 19 million. (See http://www.iec.ch/news_centre/release/ nr2006/nr0606.htm)

• **China re-invokes mandatory certification for WLAN product.** In bulletin No.4 of 2006, AQSIQ invokes CCC certification scheme for WLAN product, after suspension since 2003. The certification rule is subjected to CNCA-11C-048 which can be download from the CNCA website. Three certification bodies, including CQC, and one testing lab were designated under this scope. (See http://www.aqsiq.gov.cn/cms/template/item.html?did=8&cid=2038\17889)

• **TÜV Rheinland acquired MEEI and LGA.** With the privatization procedure of Hungarian testing laboratory MEEI, one of the most famous labs in Eastern Europe, becomes a 100% subsidiary under TÜV Rheinland. Meanwhile, TÜV Rheinland acquired 49% of LGA holding company in Nuremberg, which comprises LGA Bautechnik GmbH, LGA QualiTest GmbH, LGA TrainConsult GmbH and LGA InterCert GmbH. The acquisition of LGA is subjected to the agreement of the cartell authorities yet.

• **The famous blueprint for electrical fire safety – the 2005 edition NFPA70: National Electrical Code ® is valid now.** New features include Expanded requirements for ground-fault circuit-interrupters (GFCI) for wider use in homes, businesses, and public spaces, and new requirements for arc-fault circuit-interrupters (AFCI). (See http://www.nfpa.org)

Notes

• Irv Engelson, IEEE Fellow, a member of the TAB Management Committee (TMC), was named 2006 Mentor to the PSES. Engelson who served on the IEEE Board of Directors, and on virtually all other major IEEE boards, has expertise in most IEEE organizational activities. He is a Charter Member of the PSES and is assisting our board and society leadership while we are sailing thought the largely unknown waters of the IEEE organizational and procedural routes.

Dr. Irving Engelson, Ph.D. (EE) and IEEE Fellow, is the immediate past-President of the IEEE Engineering Management Society. He heads Isinglee Associates, a Strategic Planning activity. Previously he held leadership positions in industry, academe, and the not-for-profit sector. He speaks seven languages and was a linguist with the US Army; Representative to the United Nations Economic and Social Council; Member, NJ Higher Education Master Planning Committee; and Member, Omaha NE Chamber of Commerce Free Enterprise Task Force. Engelson held elective positions in AAAS, ASEE, and Eta Kappa Nu. He is the second foreigner to be named an Honorary Member of the Russia Papov Society, and holds other honors. He gave US congressional testimony on international technology transfer.

• Want to know more members and known by more members? You may publish your short profile and proposal projects or interested topics on the Newsletter to call for fellows to work together. All members are encourage while no advertisement is welcomed.

• Needs Volunteers as Editors Lingfeng Chen will resign News & Notes Column from PSES Newsletter issue #4. We need volunteers for this column. Please contact Gary Weidner if you are interested. He can be reached at gweidner@ieee.org.

• U.S.-OSHA Considering Product Safety Self-Declaration Proposal

At the other end of the spectrum from *Consumer Reports'* cry for U.S. government supervision of product safety (see Editorial), the powerful Information Technology Industry Council (ITIC) has submitted to the U.S. Occupational Safety and Health Administration (OSHA) a proposal to allow IT manufacturers to bypass OSHA-mandated Nationally Recognized Testing Laboratories (NRTLs) and self-certify that their products meet safety standards.

OSHA posted a public notice and request for information and comments in the Federal Register, with a February 13, 2006 deadline for comments. OSHA included 14 questions in the notice, hoping to gain insight from the answers received. The relevant documents, including all comments received by OSHA, can be accessed by going to www.osha.gov and entering the Docket Number (NRTL03-SDOC) in the home page search box.

Comments posted by OSHA appear to run about two-to-one in favor of the present NRTL system. Predictably, NRTLs such as CSA, ETL, UL, and the American Council of Independent Laboratories—their trade association—unlimbered heavy artillery for their comments opposing self-certification. Also predictably, several European trade groups weighed-in in favor of the self-certification proposal.

OSHA received a lot of material, so it's unclear how long it will take before the next step. An OSHA spokesperson told PSEN, "OSHA will decide what to do next after reviewing all comments, which will probably take a few months."

• NEMA Launches Project to Create Uniform U.S. Voltage Standard

Under ANSI auspices, the National Electrical Manufacturers Association is beginning work on a revision and expansion of the U.S. standard for supply voltages, ANSI C84.1. The new version will set voltage ratings and tolerances for 60 Hz supply systems from 100 V to 1200 kV. It will also recommend voltage ratings for "utilization equipment" connected to the power system. PSEN is an observer in this group so we'll keep you posted.

• ANSI Works on Implementing Standards Strategy

The American National Standards Institute (ANSI) is now guided by a *Framework for Action* document that is updated annually. The document, accessible at www.ansi.org/about, articulates strategies, initiatives, and tactics. One of the functions of the *Framework* is to implement the *U.S. Standards Strategy* adopted by the ANSI Board of Directors on December 8, 2005.

ANSI has been taking a more aggressive stance in bringing the U.S. positions on standards matters before the rest of the world. Currently, the U.S. holds 156 memberships on IEC Technical Committees and Subcommittees.

• North American Appliance Safety Standard Group Nearing End of Job

A three-day Technical Harmonization Committee meeting of CANENA was held in conjunction with the annual meeting of CANENA in Puerto Vallarta, Mexico, on March 7–9. The purpose of the meeting was to continue work on 60335-1, a single, harmonized Part 1 (general requirements) appliance safety standard to be used throughout Canada, Mexico, and the U.S.

CANENA (www.canena.org) is the organization responsible for coordinating the harmonization of standards throughout North America. Canada, Mexico, and the U.S. fielded 16 representatives to the meeting from standards organizations, trade associations, and manufacturers. PSEN Editor Gary Weidner participated, presenting an analysis of differences in wire size requirements in North American electrical codes compared with IEC requirements.

After having had a series of three-day working meetings during 2005, the group has reached agreement on most of the content of the standard, with remaining efforts aimed at cleaning up open items. Another meeting is scheduled for July in Washington, DC. The goal is for the new standard to pass through all processes and be published by the end of 2007.

• Next generation Holds the Key to the Future

The March 2006 *PSEN* reported that the PSES is developing a letter to go to the deans of engineering schools, inviting participation in the PSES. At present the letter remains under development.

We are looking for Product Safety Articles!

Please send proposeals for articles to:

Gary Weidner
Editor, IEEE PSES PSE Newsletter
GW Technical Services Inc.
2175 Clarke Drive
Dubuque, IA 52001-4125
phone = 563-557-0717
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2004 / 2005 IEEE-PSE Symposium

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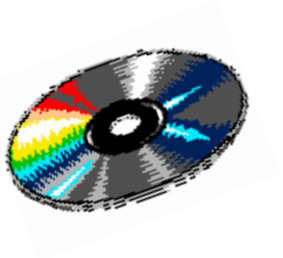

SYMPOSIUM PAPERS ON CD:

The Product Safety Engineering Society continues to offer the 2004 IEEE PSES records for sale. The cost for the CD is $35 plus shipping and handling for IEEE members; $50 plus shipping and handling for non-IEEE members. At this time, check or money orders are the means for payment. Please provide the following information:

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c/o Richard Georgerian, PSES Board of Directors
7103 Sioux Court
Longmont, CO 80504
U.S.A.

Depending on stock availability allow 2 to 3 weeks for delivery.

IEEE Member-Get-A-Member Program

When you experience something good, you want to share it with others. It's the natural thing to do.

This is the idea behind the IEEE **Member-Get-A-Member (MGM) Program.** Most members know how beneficial IEEE membership is in their professional lives and what it has meant to their technical and career development. With this campaign, IEEE members themselves can get the word out about IEEE's membership benefits.

Beginning 1 September 2005 and running through 15 August 2006, the IEEE will conduct the MGM Program to encourage members to recruit their colleagues to join IEEE. In return, the person who recruits a member will earn a US$5. credit voucher for each member recruited. The voucher can be used toward 2007 IEEE dues, IEEE Society fees, or the purchase of IEEE products and services.

Rules of the Program

- IEEE members may recruit members above the grade of Student for the MGM program. Society affiliates, non-members and past members are not eligible. *See MGM Recruiting Tips below*.

- Completed applications, with full dues payment, must be submitted with the recruiter's name and membership number—both are required—in the recruiter box on the prospective member's application.

- Applications received without a recruiter's membership number will be disqualified, and there will be no retroactive qualifying of recruiters.

- The MGM Program may not be combined with other membership incentive programs such as discounted Society conference promotions.

- Applications may be submitted in hard copy or online. To request a hard copy application, please send your request (with your fax number and/or mailing address) to application-request@ieee.org.

- Prospective member applications must be received at IEEE before 15 August 2006. Cash award vouchers will be mailed to qualified recruiters prior to 1 October 2006 and will be valid through 31 December 2006.

MGM Recruiting Tips

1 Invite at least one non-member colleague to attend an IEEE Section or Chapter meeting.

2 Follow up a discussion about IEEE membership with a note emphasizing membership benefits; be sure to provide an application.

3 Have IEEE membership applications available for prospective recruits.

4 Keep issues of IEEE Spectrum and Society publications on display to attract the eye of non-member employees.

5 Publish an article in your company newsletter telling how the IEEE helped you in your career or helped the company.

6 Post announcements of IEEE meetings and IEEE conferences, seminars, and educational programs on company bulletin boards.

7 Welcome your company's newly hired technical employees and use the opportunity to discuss the benefits of IEEE membership.

8 When discussing membership with a prospect, listen for clues as to what they look for in a professional society. Stress those member benefits that meet their needs!

9 Suggest they check out the IEEE Website and apply online. Whether your recruit applies using a hard copy or online, make sure they fill in your name in the recruiter box with your membership number to become eligible for this program.

10 Coordinate an IEEE event at your place of employment.

For more information about MGM, contact Dyana Barnosky of IEEE Membership Development at d.barnosky@ieee.org.

EDITORIAL

A Lack of Understanding

In the U.S., product safety standards are developed by consensus groups working through standards developers such as Underwriters Laboratories, and conformance to the standards is usually voluntary for manufacturers. Not so in many countries and in the European Union, where product safety standards are associated with the government. It is illegal to offer a product for sale in the EU that does not meet the required standards.

In a March 2006 editorial titled, "Product Safety Standards Are No Safety Guarantee," the widely-circulated *Consumer Reports* magazine says, "The CPSC (Consumer Product Safety Commission) relies heavily on voluntary standards developed by organizations such as the American National Standards Institute (ANSI), ASTM International, and Underwriters Laboratories (UL). But that practice is an accident waiting to happen."

Citing a "need for reform," *CR* proclaims that

- "Congress should ensure that the CPSC is allowed to keep unsafe products off the market."(And what, pray tell, will be the new method of determining whether a product is safe?)

- "Manufacturers should be legally required to conduct premarket testing."(This means switching the entire U.S. product safety system to the European government-directed approach.)

- Retailers "Should test or require proof of testing and not sell any products that don't meet safety standards."(What standards? Is the government to develop a whole new set to replace the above-criticized voluntary standards?)

- "Standards-setting groups should monitor market compliance."(Can you imagine organizations like ANSI and UL being held responsible for monitoring all products in the marketplace? To begin with, standards-setting groups often have nothing to do with evaluating products offered for sale-in this country that's done by Nationally Recognized Testing Laboratories.)

Although Europe is not mentioned, the *Consumer Reports* editorial seems to advocate scrapping almost all of the U.S. product safety system and adopting that of Europe (CE Marking, etc.).

This is not to find fault with the European approach. It is probably neither better nor worse than the U.S. approach, simply different. What is really disappointing is *CR*'s lack of understanding of America's product safety system.

The *eDJ*

A Peer-Reviewed Publication
of the
IEEE Product Safety Engineering Society

The *eDJ*
A Peer-Reviewed Publication of the Product Safety Engineering Society

From the eDJ Editor's Desk

June 17, 2006

Dear Fellow Product Safety Engineering Professionals,

To "get an edge" is a phrase that usually implies a gaining a competitive advantage; e.g., if my car goes 5 km/hr faster than yours, I've "got the edge." However, our profession and our Society are marked by a wonderful willingness to share insights and experiences. This is the "edge" that we give each other.

The first issue of *The eDJ* debuts an important member benefit of the PSES, and one that has been part of our vision from our founding—the sharing of insights and experiences via peer-reviewed, journal-quality papers that promote, recognize, and archive work that advances the theory and practice of product safety engineering. The name "*eDJ*" tries to capture this concisely, as an acronym for *e*lectronically-*D*istributed, *J*ournal-quality papers.

I am both humbled and delighted that Carl Schmuland has offered to share for this first issue his risk management insights from 27 years of experience in the critical medical device field. Working with Carl on his paper has already given me an "edge" that improves the product safety engineering work that I do, and I expect and hope that you will similarly benefit.

Two more benefits debut with this issue of *The eDJ*: discussion threads with the authors, followed by web conferences for those interested. Please follow the links inserted at the end of Carl's article to take advantage of these benefits. Please also be patient as we bring these features on-line, and please also be generous with your feedback about their usefulness to you.

Lastly, although we have a number of additional peer-reviewed papers in the pipeline, we need many more, because this member benefit only works if we all embrace the spirit of discovering and sharing. To find out more about how to submit a paper, or to direct a colleague on how to do so, please go to our Journal on Product Safety Engineering website (http://www.ieee-pses.org/journal.html) and follow the information there. A note of explanation: all papers intended for the Journal will instead be published in *The eDJ* section of the Product Safety Engineering Newsletter until we can demonstrate enough paper volume to justify a stand-alone publication.

And of course, you can always reach me via the below contact information.

Get the *eDJ!*

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eDJ Editor
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Overall Residual Risk

Carl Schmuland

***Abstract*—The assessment of overall residual risk is the primary objective of performing risk management activities, and is required by ISO 14971:2000, *Application of risk management to medical devices*. Despite this requirement, much confusion as to what is required remains among medical device manufacturers and the various regulatory approval bodies. Today many medical device manufacturers do not formally address the subject.**

This paper provides practical ideas to allow manufacturers to begin assessing the overall residual risk of their products. These ideas may also be helpful to regulatory bodies in formulating and communicating a consistent set of expectations. The concepts developed in the article should also be applicable to evaluating the safety of a wide variety of other products.

***Index Terms*—risk analysis, implantable biomedical devices, biomedical equipment safety.**

I. Introduction

THE proper evaluation of overall residual risk is the primary purpose of all risk management activities. For the medical device industry, overall residual risk evaluation became a requirement with the release of ISO 14971:2000, *Application of risk management to medical devices* [1]. Despite the requirement to evaluate residual risk, much confusion exists among medical device manufacturers and the various regulatory bodies as to what is required. As a result, many medical device manufacturers do not formally address the subject. Given that overall residual risk is a new requirement for medical devices, there is not a large body of documented theory and practice on the subject. Therefore, this article is based primarily on the author's experience of estimating and evaluating residual risk for over 20 years and at least ten years of estimating and evaluating overall residual risk. While this paper is aimed at medical devices, manufacturers of other types of products may also find the concepts in this paper useful.

II. What is Overall Residual Risk?

To understand what is meant by 'overall residual risk' it is necessary to refer to the definitions given in ISO14971:2000:

—*Residual risk* is the **risk** remaining after **control measures** have been taken.

—*Risk* is the combination of the probability of **harm** occurring and the severity of the harm.

—*Control measures* are all implemented specifications, protective measures, training, and labeling to reduce the risk to an acceptable level.

—*Harm* is physical injury or damage to health of people or damage to property or the environment.

Therefore, 'overall residual risk' is the **combined residual risk** of all the issues associated with a product.

A. Example

As an example, consider the problem of safely negotiating an intersection while driving to work. Many control measures have been implemented to solve this problem such as:

- *design specifications:* intersections have stop signs or stop lights
- *protection:* the passenger compartments of automobiles are designed to withstand impacts from other vehicles
- *training:* drivers must be licensed by passing a written test, a vision test, and a road test
- *labeling:* signs are positioned announcing the approach to a controlled intersection.

Of course there are many other controls, but regardless of all the controls, there never can be a complete absence of risk when passing through an intersection because:

- drivers make mistakes
- brakes fail
- cars can not always stop on icy streets.

So whenever an intersection is encountered, there is some risk that a person could be injured passing through the intersection.

However, the *overall residual risk* of getting to work safely is not limited to passing through intersections. There are myriads of other things that can go wrong outside of intersections, such as:

- a vehicle crosses into your lane
- failing to successfully negotiate a curve
- hitting a deer
- a driver that loses control of their vehicle because they pass out.

Each of these scenarios (called a *hazardous situation*, which is defined as a circumstance in which people, property or the environment are exposed to one or more hazards) has some probability of occurring and resulting in:

- injury to a person (death, broken bone, etc.)
- damage to property (dented fenders, broken windshields, etc.)
- damage to the environment (spilling of hazardous fluids, etc).

As a driver I am interested in avoiding each hazardous situation, but what I really want is to arrive at my destination without being injured in an accident. Notice that there are different harms that could occur. Suppose someone runs a red light and collides with my car in an intersection; I could:

- be killed
- have my leg broken, or
- be bruised.

If we focus on the worst-case harm—death—there is a certain probability that I could be killed in the intersection accident, but there is also a probability that I could be killed by:

- a vehicle crossing into my lane
- hitting a tree because I lost control in a curve, or
- hitting a deer that jumps into the road.

The *overall residual risk* of dying is the **sum** of all the probabilities. In the United States this is roughly 1/6200 on an annual basis. Whether or not I get into a car depends on whether or not I think the risk is justified, namely is it safe

Continued on Page 30

in my judgment.

III. Why is overall residual risk the most important measure of safety?

Using the car analogy, it makes no difference to me or my family if I am killed because a drunk driver runs a red light, or because I lost control in a curve and hit a tree, or a truck crossed into my lane of traffic because the driver fell asleep—I am still dead. Finding the risk of each of these scenarios is the means by which the overall residual risk can be estimated.

What can we learn from this example? Quite a lot!

1) *Harm either occurs or it doesn't occur.* When it occurs, it occurs an integer number of times. It is possible that the residual risk for a given scenario is so low that it is very unlikely that anyone will ever be injured by that scenario. However, risk is cumulative, so if there are many scenarios, each with a similarly low residual risk, sooner or later at least one person will be injured by one of the scenarios.
2) *What people really want is no serious injuries.* The more serious the injuries are, the more they care. Therefore, overall residual risk is heavily biased towards severity, minimizing the most serious injuries.
3) *No matter how low the probability of a particular scenario occurring may be, if the sample size is large enough, the scenario will eventually happen.* So the residual risk (notice this is not overall residual risk!) for a particular harm in a particular scenario is the probability of the harm happening to an individual multiplied by the total number of product uses. This results in the number of occurrences of the harm.
4) *Overall residual risk is best thought of as limited to a particular harm*. It is not the total injuries for all harms. So if the possible harms being considered are death, broken bones, and contusions, there is an overall residual risk for death and an overall residual risk for broken bones, and an overall residual risk for contusions. One does not add the number of deaths to the number of broken bones to the number of contusions, because the severities are different.
5) *Similarly, the evaluation of the acceptability of the overall residual risk is a function of the number of incidents and their severity.* To make good risk decisions regarding the safety of a product in development, it is necessary to quantify the number of injuries for each of the most serious harms that will occur over the life of the product, taking into consideration every product that will ever be produced for the entire life of each product. For example, 1 death, 10 broken bones, and 100 contusions is 111 injuries, which is more acceptable than 10 deaths, 100 broken bones and 1 contusion, but not as acceptable as no deaths, 1 broken bone and 110 contusions.

Overall residual risk is the most important measure of safety because it provides an estimate of the total harm that will be done. A good example of applying this concept arose after the September 11, 2001 terrorist attacks on the United States. Concern was raised that terrorists might attack the United States with smallpox. The question was posed whether or not everyone should be vaccinated. The statistics showed that one or two deaths could occur per million inoculations. So from the perspective of an individual this was a very safe thing to do, but if the entire population of the United States was inoculated, several hundred people could die. This was not judged to be prudent. Notice that two different contexts are consider in this example:

- risk to the individual, and
- risk to the society as a whole.

In general risk, risk is usually quantified as a probability when the concern is harm to an individual. However, most of the time medical device manufacturers need to consider the total number of harms that will occur, not the risk to an individual. There are two exceptions to this rule that will be discussed in the section on evaluating overall residual risk.

IV. How Can Overall Residual Risk Be Estimated?

The basic process to be followed in estimating overall residual risk for a given harm is to estimate the residual risk for each possible scenario and then add the residual risks to get the overall residual risk.

Residual risk for a given scenario is estimated by identifying the sequence of events that must occur for the harm to result, and then assigning a probability for each event or factor in the identified sequence. This results in the probability of the harm occurring in an individual use or patient. Multiplying the probability of the harm occurring in one use by the expected total number of uses gives the number of harms that occur for each scenario. The harms for each scenario are added to get the overall residual risk (assuming that each scenario is independent of all the other scenarios). Thus the unit of measure of the overall residual risk is the number of harms that occur over the entire life of the entire product base.

V. Common Objections

When people are first presented with the concept of estimating overall residual risk, three objections are usually raised. They are:

A. The Legal Department Will Never Let You Document the Estimate

For medical device manufacturers, this objection is mitigated somewhat by the requirement in ISO 14971:2000 to evaluate the overall residual risk. By inference this means that the risk must first be estimated and documented. The standard does not say that the risk estimate must be quantified. However, quantification is the best way to estimate the risk, if it can be done with sufficient accuracy. There never really is a slight, moderate or high risk (qualitative measures), because injuries will occur as integer numbers—0, 1, 10, 100, etc.

The key legal concern is not so much the estimate as *the evaluation of the acceptability of the estimate*. In other words, if a company proposes release of a product with an estimated 3 deaths over the entire life of a product, why does the company think that it is acceptable? Further discussion of the evaluation of acceptability is deferred to the next section on what is acceptable overall residual risk.

B. It is Impossible to Estimate Risk Accurately

The operative word is "accurately." Surely it is not possible to distinguish between 9.746 and 9.749 patient deaths. The good news is that it is not necessary to do so. The accuracy needs only to be accurate enough to make a good "go/no go" decision. The evaluation must take the overall residual

risk estimation and decide either that it is acceptable or that it is unacceptable. There are no other alternatives. In all likelihood 9.746 patient deaths is unacceptable, but 1.5 or 0.6 might be acceptable. As a result, extreme accuracy is not that important—order of magnitude is often times accurate enough to judge the acceptability of the risk. This is especially true when the total injuries are very low, for example 10^{-4}. In this case two orders of magnitude could be an acceptable error.

On the other hand, it is not very likely that a company would accept 1.6 patient deaths and not accept 2.5 patient deaths, even though there is a large percentage difference in the two numbers. As a result, knowing that one or two deaths may occur as opposed to knowing that 15 or 20 might occur or that 0.2 or 0.3 might occur is often the goal. The purpose of estimating the risk is not so much to identify exactly the total prevalence of harm as it is to make a good decision about releasing or not releasing a product. In this context, the process comes down to using *quantitative* estimates to make a "yes/no" decision.

C. Human Frailty Will Lead to "Creative Accounting"

This objection plays out as:

- the people preparing the estimate will zealously make it look worse than it is, or
- management will cheat and force the number to be better than it is.

Of course both are possible, but recognize that a credible business made up of professional adults will have to exhibit more responsible behavior than this if the organization is to survive. In fact, if their behavior is this immature, it is unlikely the business could have survived to this point

On the other hand, recognize that some give-and-take on the numbers is inevitable and healthy, in order to arrive at the best possible estimate. The first time an estimate is done, the accuracy may be biased heavily towards a conservative number, but over time an organization will improve greatly in its ability to accurately estimate overall residual risk.

In some cases the review process may result in identification of additional factors that could significantly reduce the risk. In other cases the quantification will show that the risk is so low that quantifying every factor in a given scenario is unnecessary, because additional factors will always reduce the probability of harm. Of course it is possible that the review process will result in a greater number of harms than originally estimated, but this is rare in the author's experience.

VI. How to Estimate Overall Residual Risk

Once an organization gets beyond the objections to evaluating overall residual risk, the next question is: "How?" The following steps outline a basic process to follow.

A. Identify Every Possible Scenario that Could Still Cause Harm after All Control Measures Have Been Taken

This key step has a lot of work lying behind it.

1) Identify every possible scenario that could cause harm.
2) Estimate the risk of each scenario *qualitatively* to eliminate scenarios that either cause minor harm or are sufficiently improbable that they can be disregarded.
3) Subject any scenarios that remain to additional controls to either eliminate the scenario altogether, or reduce the probability of it occurring. Usually, it is not possible to reduce the severity of the harm.
4) If the scenario has not been eliminated, then the residual risk for each scenario must be evaluated. If the residual risk is not acceptable, further reduction is required. *Therefore, the only scenarios that make it through the process have each been reduced to an acceptable level of risk!*

A. How Can You Be Sure You Have Identified All the Scenarios?

Fallible human beings will never identify every possible scenario, but it should be possible to discover the most severe and probable ones. One useful approach is to consider three categories of scenarios and creatively work in a fault tree approach, starting with the most severe harms, to discover the individual scenarios. The three categories are:

1) *Design Input.* If you could consistently build products that meet the design input specification, would they be safe? There are two types of issues to consider:
   - The specification of the product must not have any systemic safety issues designed into the product and must be complete enough that all safety requirements are specified from a "black box" perspective.
   - How could the product be improperly used or misused in a manner that compromises safety?
2) *Design Output.* A perfectly specified product can still be a safety issue if it is not designed correctly. Two questions are important:
   - Have any systemic failure modes been introduced because of the design implementation? In other words, are there scenarios that will always result in harm? Product operation that requires a particular sequence of events and/or logical decisions to result in safe operation is particularly vulnerable.
   - Is the product sufficiently reliable that safety is not compromised because of "random" hardware failures?
3) *Design Transfer.* ISO 14971:2000 does not specifically require a manufacturing analysis. However, a perfectly specified and designed product with no safety issues could result in a serious safety problem if it were manufactured incorrectly. Therefore, it is important to consider how manufacturing the product could introduce product failure modes that result in harm. A good way to proceed is to leverage the manufacturing failure mode and effects analysis (FMEA) to identify scenarios that could compromise the reliability of the product.

A. How Do You Obtain the Probabilities for the Elements in Each Scenario?

Remember that in order for harm to occur, some sequence of events must take place. Once the sequence of events is understood, a probability is assigned for each step in the sequence. Generally there are three categories of events.

1) *Product Specific.* These factors are specific to the operation of the product, but do not include use issues. The device manufacturer will likely have good

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information regarding probabilities for most of these items. Examples include the percent of defective components, and probabilities of encountering known systemic design errors.

2) *Medical Information.* There is usually a wealth of information about patient medical conditions or factors. Examples include the percentage of patients with a specific medical condition in combination with other exacerbating circumstances, or likely medical consequences of exposure to given device failure. This information is likely to be quite accurate.
3) *User Behavior.* Usually, there is limited information available as to how a user might respond in a given situation. For the most part, this comes down to expert opinion of field staff, customer service, or other knowledgeable people. The best guidance is to get many opinions, throw out the high and low and average the rest.

   Recognize that the more improbable an event is, the harder it is to estimate. In these cases it is best to focus the expert opinion by asking questions such as: "Is it 1/1000, 1/1,000,000, etc.?" Examples include the percentage of users who would take specific action in the presence of device failure, or the percentage of users that would recognize a specific anomaly before harm occurs.

A. Add the Residual Risk from Each Scenario and Determine If the Overall Residual Risk Is Acceptable

Addition is by type of harm: death, broken bone, contusion, etc. The addition, of course, assumes that each scenario is independent of every other scenario, which is normally the case.

Figure 1 outlines a high-level procedure for determining the acceptable residual risk for each identified scenario. The resulting risk from each scenario is then combined into the overall residual risk via step D above and evaluated in the next section of this article.

VII. Evaluating Overall Residual Risk

After the residual risk for each individual scenario has been reduced to an acceptable level, attention turns to the overall residual risk. In principle, the process to be followed for evaluating the overall residual risk is straightforward. The problem is that in a complex product there could be many scenarios that could cause a given harm, each of which is acceptable, but in aggregate could cause an unacceptable risk. For example, if there were a 1000 scenarios that could cause a patient death, and each scenario produced a total of 0.01 patient deaths, then each scenario would likely be judged to be acceptable, but in aggregate 10 deaths would occur which would likely be judged to be unacceptable.

The above example is useful to illustrate the principle, but in practice it is rare that a situation is encountered with a large number of scenarios that each produce a low level of harm. It is more usual that there are a handful of scenarios that each produce a moderate level of harm and a large number of scenarios that produce in aggregate a low-to-moderate level of harm. For example, there may be 50 scenarios that in aggregate produce 0.2 patient deaths, and 4 other scenarios that produce 0.1, 0.4, 0.5, and 0.7 patient deaths respectively. Therefore, the overall residual risk would be 1.9 patient deaths.

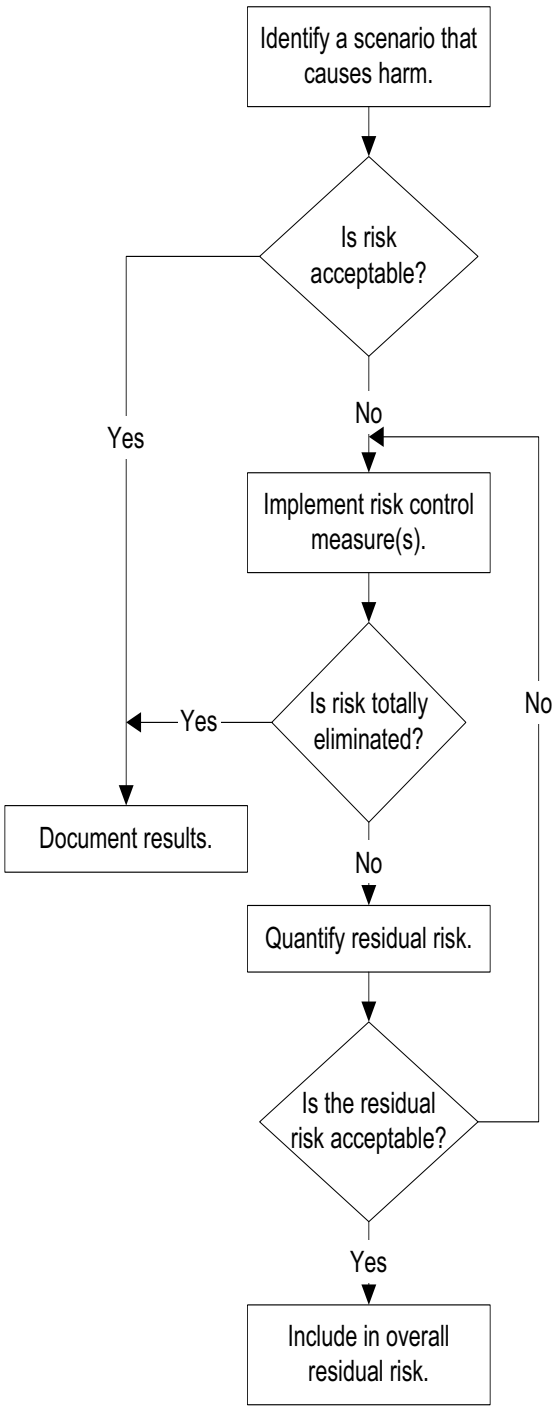

Fig. 1. Procedure for determining residual risk for a given scenario.

A. Strategies for Evaluating Overall Resdiual Risk

While it is possible to come up with an overall residual risk that is a true composite risk, it is often more useful to compare the risk of a new product to an existing comparable product that is judged to have acceptable performance. There are two reasons why the comparative method is generally preferred.

1) No matter how well the overall residual risk has been estimated, real field performance is more accurate than a prediction. If a composite risk were calculated, it would

be most reasonable to use the previous product's actual field performance and add or subtract the differences for the new product, because it is usually easier to understand the difference than the composite.

2) Stakeholder acceptance of the safety of a previous product bodes well for acceptance of the new product if it can be shown to better than or substantially equivalent to the previous product. Though regulatory agencies do not necessarily publicly endorse the comparison method, they generally find the comparison method to be very useful.

A. Example

A common situation is a new product that is an improvement over a previous product. The nature of the new product improvement is usually that the product has some additional feature enhancements that allow it to meet new medical needs or to better address a medical need that is already met. In some cases, the product may also correct a design flaw or reliability issue with the previous product.

Usually, the comparison to a previous product will conclude that the risk is essentially the same as the previous product or slightly increased, because of additional functionality. However, in some cases the risk may actually decrease, because of the correction of a reliability issue or design flaw in the previous product.

As stated previously, it is not so much the *estimate* of the risk that will get a company into trouble as it is the *evaluation* of the risk. Of course, the estimate must be reasonably accurate, and all the factors need to be included. When a final number of injuries is computed, the question becomes, "Is it acceptable?" The following points should be considered in setting the level of acceptability:

1) *ISO 14971:2000 and regulatory agencies do not state what an acceptable level of risk is.* The device manufacturer must determine what is acceptable. Ideally, the goal should be to set a level of acceptability that is low enough to ensure that it is unlikely anyone will experience the most severe harm possible.

2) *Acceptable risk is a perception that will be different for different people.* In general, the more in control a person feels, the more risk they will tolerate. A classic example is that some people would prefer to drive between two points rather than take a commercial flight. They feel more in control when they are driving then when they are sitting in a seat 30,000 feet above the earth going 500 miles per hour. Of course the statistics show that the perception is completely wrong, but statistics are unlikely to be very persuasive in this scenario. The medical application of this concept is that patients often feel, and are in reality, not in control during a medical procedure. Trust and credibility then are of great importance. Not only must the patient trust the medical professional doing the procedure, the patient must trust the equipment used. Trust of the medical professional is often based upon how the patient relates to the medical professional. However, with regard to the equipment, the patient has limited information to judge its trustworthiness. In some case there may be brand recognition, but most of the time the patient is trusting the medical professional to have chosen the best equipment. However, there is the underlying assumption that no stone was left unturned in ensuring that the equipment is safe and effective. This means at least two things for medical device manufacturers:
   - Great care must be exercised in ensuring that medical devices are safe and effective.
   - Health professionals need to know what the medical device manufacturers know about the risks of their products so that the medical professionals can make the best possible decisions for each individual patient.

3) *Generally, it is best to look at acceptability from the perspective of the total injuries by type of harm over the entire useful life of the all the products in question.* There are two important exceptions that can arise:
   - When very few product uses are expected, the probability of harm to the individual is the better measure, since a person could be at a fairly high risk individually even though the total risk is low. For example, if the risk of death from a device is 1/100 uses but only 5 uses are planned, there will be a total of 0.05 deaths, which usually would be acceptable. However, the high risk to the individual makes the risk unacceptable.
   - When tremendous numbers of uses are expected, a very small individual risk could result in a large number of injuries. Suppose the probability of death is 1/1,000,000 but there will be 10,000,000 uses; then the total deaths would be 10, which would usually be judged to be unacceptable. However, with the low risk to the individual, the risk may actually be acceptable if it is the best available technology.

4) *Acceptability is driven to some extent by technology.* Therefore, what is the best available technology today could be unacceptable in five years. Releasing a new product to the field or continuing to produce and market a product that does not have the best available technology is a potentially dangerous undertaking even if the overall residual risk is judged to be acceptable.

5) *Risk-benefit arguments should be used cautiously and infrequently.* Keep in mind that risk-benefit arguments will not be acceptable if someone has a better product, or if an entirely different treatment exists with comparable success but without the risk (for example, medication versus a device). According to ISO14971:2000, risk-benefit can only be used when the risk is *unacceptable* and *cannot be reduced to a normally acceptable level*. Normally risk-benefit will only be applicable with breakthrough products for which there is no other viable treatment for a serious medical condition. In this case, quantify benefit (the number of people helped) by the same method used to quantify risk when making the evaluation. The acceptability of a risk-benefit argument will generally hinge on the advantage of the benefit. A product that results in the death of 5 people and saves 10 lives is not a good risk benefit. On the other hand, a product that could result in the death of 5 people but saves the lives of 1000 people might be a good tradeoff if there was no other viable treatment for a fatal condition being addressed by the device. Generally the severity of the benefit must equal or exceed the severity of the risk. For example, a medical device that totally cures acne but results in a ten fold increase in the incidence of melanoma is not a

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candidate for risk-benefit analysis!

6) *Start with the most severe harm(s).* Focus on hazardous situations that can result in permanent harm (e.g., death), temporarily incapacitate (e.g., paralysis or syncope), or cause harms more severe than the intended medical benefit (e.g., electrocution by an ECG machine). Recognize that as you work down the severity spectrum, at some point safety blurs into the user friendliness of the product. User friendliness may be extremely important from a business perspective, but not at all important from a safety perspective
7) *Establish a value for overall residual risk that is acceptable and proportional to the severity of the risk.* For example, an acceptable overall residual risk for death from a kidney dialysis machine might be 0.1 deaths. When the value is exceeded, responsibility would be given to management to decide what is acceptable. Some form of a system that requires management to sign off is necessary because the possibilities of situations that can arise will certainly outstrip the ability to succinctly document a process that eliminates the need for management decisions. As a side benefit, it also brings management into the process. Notice that in the example of 0.1 deaths, it is unlikely that anyone will actually die since 0.1 means that the probability of an individual dying in a given treatment multiplied by all the treatments that will ever be given by every device ever in use is 0.1 or less.
8) *When a management decision is needed, the best way to make that decision is to put yourself in the position of the person at risk.* If that person was your child, or spouse, or parent, or you, ask if the decision you are making is acceptable. This does not mean that elaborate solutions are implemented when they are not necessary. It simply means that true patient safety trumps cost and schedule. On the other hand, business interest need not be discarded for dubious gains in product safety.

VIII. What If I Do Not Quantify Overall Residual Risk?

The previous discussion is based upon *quantified* residual risk. However, it is quite uncommon that medical device manufacturers actually *quantify* residual risk. More commonly, a risk table based upon *qualitative* probability is used to evaluate the residual risk of each hazardous situation. In this methodology, the goal is to reduce the risk of each hazardous situation to an acceptable level. The problem with such a system is that it can not readily yield useful information about overall residual risk.

For example, suppose a manufacturer uses a risk table with good definitions of severity and probability and identifies traditional evaluations of ***acceptable***, ***as low as reasonably practical*** (ALARP), and ***unacceptable***. Let's say a medical device had 50 hazardous situations that resulted in residual risk with an acceptable evaluation, 5 that resulted in ALARP, and no unacceptable hazardous situations. What can be said about the overall residual risk? Very little!

First of all, ALARP is either acceptable or it isn't! A manufacturer may think they have reached a practical limit in risk reduction but society could easily judge the risk to be unacceptable. "Reasonably practical" may be driven more by schedule or cost than technology. In the final analysis, society rightly expects that the time and effort needed to make a product safe have been expended.

Secondly, a hazardous situation with an acceptable evaluation usually still has some residual risk. At some point the accumulated risk of enough hazardous situations could be an unacceptable risk. So the question is: "How many acceptable and/or ALARP residual risks equal an unacceptable risk?" In a qualitative system, no one knows! Of course a system could be devised that says three ALARP residual risks are unacceptable, but it would be essentially an arbitrary decision, much like saying risk priority numbers (RPN) greater than 20% of the maximum is unacceptable. The reason overall residual risk evaluation was included in ISO14971:2000 was to determine if the combined risk from all hazardous situations is acceptable, and this can not be done nearly as well with a qualitative system as it can be done with a quantitative system.

IX. How Is Overall Residual Risk Used to Manage the Safety of a Product after It Is Released to the Field?

It is necessary for medical device manufactures to reach an acceptable level of overall residual risk prior to releasing a product to the field, not only for the purpose of satisfying regulatory agencies, but also for the sake of conscience. However, once the product is released, the question becomes one of whether or not it is performing at least as well as predicted. The work of monitoring field performance is not of itself a risk management activity. It is addressed by the quality system under complaint handling. The role of risk management is to determine whether or not the actual overall residual risk is acceptable. Therefore, risk management seeks to update the overall residual risk estimate as field information becomes available, and to determine if the actual overall residual risk is acceptable.

Consider the following example: suppose the overall residual risk evaluation resulted in 0.4 patient deaths over the life of a product and this was judged to be acceptable. At first glance it would seem that as long as no patient deaths occurred, performance would be as expected and therefore acceptable, but if a death occurred it would be unexpected performance and therefore unacceptable. Unfortunately, the problem is more complicated than this.

First of all, 0.4 deaths from a simple-minded view can be thought of as a 40% chance of a death or 60% confidence of no deaths. This is much like precipitation probability in a weather forecast. A 40% chance of rain could result in no rain or 2 inches of rain! Therefore, a death could occur in this case and still meet the expectations. In judging 0.4 deaths to be acceptable, the meaning is that for the technology available and the severity of the condition treated and a host of other factors, the risk is acceptable. However, if a death occurred in the first year following market release of an expected ten year product life, the risk estimate is probably flawed and needs to be reviewed in light of the field performance.

Secondly, if a company simply checks monthly to assure no deaths have been reported, it could be setting itself up for a major problem. The better approach is to review field performance on a monthly basis to ensure that no unanticipated safety scenarios have arisen, and that the safety scenarios that have been reported are occurring at a rate less than or equal to the predicted rate in the risk management file. This discussion revolves around the idea that harm does not automatically occur just because a person finds themselves in a hazardous situation. For example, if I drive through a red traffic light I may not be injured at all. Driving through a red light is a hazardous situation, but it

is not absolutely certain that I will be injured. There could be no cross traffic, or the cross traffic successfully avoids a collision, or I am hit by cross traffic but not injured.

Suppose in our estimation of overall residual risk we determined that a particular device failure that could cause a patient death occurs at a rate of one per 10,000 uses, and that 1% of the patients affected by this failure will die. If we expect to sell 1000 devices and that on average they will be used 40 times a year for 10 years, we should end up with 0.4 patient deaths:

1000 devices * 40 uses/year * 10 years = 400,000 device uses.

At a rate of one hazardous situation per 10,000 uses we should see 40 reports of a device failure that could lead to death over the life of the products. One percent of these will result in a patient death or 0.4 patient deaths.

Now if we simply wait for a death to occur and sell 5000 devices instead of 1000, we could expect 5 times as many deaths (5*0.4= 2.0). Likewise, if device failures occur at a rate of 1/1000 uses, we could have 10 times as many deaths (10*0.4 = 4.0). In contrast, careful monitoring of field performance can show that the product is failing at a higher rate than expected before any deaths may occur.

Careful monitoring also provides feedback to refine the risk management system. For example, if the device failures are occurring in scenarios that were discovered during the risk management activities, but they occur at 10 times the expected rate (as in this example), we need to improve our probability estimation. If the 10X rate comes from scenarios not anticipated during the risk management activities, then we need to improve our methods of discovering scenarios ahead of time. If product sales exceed expectations, we can get into trouble even if all our other estimates were perfect!

Despite the necessity of careful field performance monitoring, knowing all the applicable field performance information is of limited value if it is not used to make good decisions. Once the product is in the field it is imperative to communicate the necessary safety information to health professionals and patients. Usually this really means determining when a field action will be taken. There are no established rules of when to take a field action, but the following guidelines are a starting point.

- Generally, health professionals want to know what products are affected, what could happen, and how often is it expected to happen. The health professionals usually want to make the decisions about what to do for each individual patient. They generally are angered when a company waits for severe harm to occur before taking any action, or when it becomes known that the company knew several cases of severe harm could occur, but chose not to disclose this risk information to the society as a whole.
- In light of the first bullet it might seem that it would be best to always defer to taking field actions. However, health professionals usually do not want to know about every minor issue. Taking numerous field actions for minor issues can disrupt health care delivery and could condition health professionals to be cavalier to the point that they do not take seriously the occasional really important field action. As a result, there is no escaping the need to make good decisions on when to take a field action.
- Perhaps the best guideline is to rely on accumulated experience with similar products and allied health professionals as to where the boundary lies between acceptable and unacceptable. The more that field performance and risk have been quantified, the more useful experience becomes, because there is a "harder" basis on which to make comparisons and judgments.

X. Summary

Overall residual risk is the key information that stakeholders need in making good decisions regarding the safety of medical devices and the treatment of patients. Whenever possible, overall residual risk should be quantified as the estimated total number of harm occurrences over the entire life of a product. Estimation of the number of harms requires persistence and experience. However, in the end it is the evaluation of the overall residual risk that determines market acceptance of product safety. It does no good to determine the exact number of patient deaths that will occur, only to rationalize, for the sake of sales revenue or project schedule, that the unacceptable is acceptable. Honest consideration of whether the product could enthusiastically be used on the decision makers' family or self is often the best governor on human frailty that can result in shortsighted rationalization. Finally, medical device manufacturers as a whole need to strive without reserve for the greatest possible safety and efficacy in all medical products. There is no advantage to be gained by a competitor's safety problem, because it casts into question the industry as a whole.

It is my hope that this article has clarified the concept of overall residual risk and that medical device manufacturers will begin quantifying the residual risk of individual scenarios, as well as product overall residual risk. In addition, I hope that this article will form a basis from which a common practice of estimating and evaluating overall residual risk might develop between regulatory bodies and medical device manufacturers, resulting in greater medical device safety for all.

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[1] International Organization for Standardization, C.P.56, CH-1211 Geneva 20, Switzerland, www.iso.ch.

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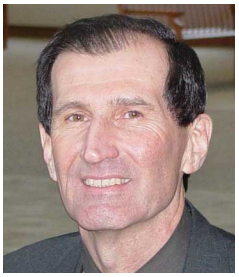

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Online Communities Story

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- Retain IEEE "corporate memory"
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- Accelerate the sharing and delivery of domain-specific knowledge for IEEE Members and Customers which can be utilized to accomplish their work-related tasks

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