The
Product Safety Engineering Newsletter

IEEE PSES
Product Safety Engineering Society

What's Inside

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President's Message

The IEEE Product Safety Engineering Society is kicking off a new season of chapter meetings, and we have our conference in Boston (www.pses-symposium.org/) on October 18–20. As a member of the PSES, you can participate and benefit from what the society offers. But, really our professional IEEE society can be much more for you. The IEEE PSES can be the venue that provides technical and moral support as you move through your career. It can be a platform for you to build leadership skills to enhance your "regular" job abilities. The PSES board of directors is dedicated to nurturing resources to serve you as an engineer, technician or manager involved with product safety engineering. We continue to build a structure that will be all that an IEEE society can be for you.

It's the regular, monthly chapter meetings that most members enjoy that are relevant to many of our members. I know from my own experience that attending meetings and getting more involved is satisfying and rewarding from a personal and a professional standpoint. It's nice to have one evening a month where you can sit down with familiar colleagues, discuss topical issues, and get a sense of how things are going in your industry. This awareness can only benefit your company; without getting involved with proprietary issues, you build tools that can be brought back to your day job. As we go through the normal industry cycles, you have access to other professionals looking for work and you can gain a sense of the opportunities that may develop in other companies. I know first-hand how this is helpful from the roller coaster we ride in the Santa Clara Valley aka Silicon Valley.

I know that some companies are reluctant to have their staff exposed to the opportunities presented by participation in a professional organization. Companies putting such limits on their staff are not the leading companies with the leading opportunities. And in the high tech, global marketplace, such companies are doomed in the long run. Especially in our field. Product Safety Engineers need to be aware of what is going on around them. This is

Continued on Page 3

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IEEE PSES Web Sites

http://www.ieee-pses.org/
http://psessymposium.org/
http://product-compliance.oc.ieee.org/
http://www.ieee-pses.org/emc-pstc.html
http://www.ieee-pses.org/newsletters.html
http://www.ieee-pses.org/pses.html

in the best interest of their company. During my career at UL, exposure to the multitude of product categories and environments handled throughout UL gave me a perspective that helped me evaluate products and give advice on a regular basis. I expanded this background with our regular TC-8 meetings that evolved into the PSES. (Technical Committee No. 8 of the EMC Society was the "committee" from which PSES evolved.) I think this made me more effective at my job and more valuable to my employer. Progressive companies take the risk of exposing their employees to opportunities because the companies know it takes such awareness to maintain their competitive edge.

In the global, competitive marketplace that we live in nowadays, it takes a professional society to provide the background to be knowledgeable and effective. I suppose it would be possible to get some of the background by searching the internet and independently building a network. But it would be difficult and limited in its reach. Our society is the resource that's available for you. The neat thing is that a professional society is, by definition, a synergistic combination of the talents of its membership. That's you and me! We make the society, and its effectiveness is determined by how we can all impart our current skills and grow with the benefits of this association. When you go to our chapter meetings and attend our conferences, you can meet and develop a professional relationship with the leaders in our field. Step by step, you can become one of those leaders. The PSES is the single venue where we can do this.

Once again, this year we've put together what should be a great conference! As many of our conference "regulars" know, this is "the" IEEE PSES event of the year. Each year, as we move through the conference there is an excitement buzz that we all feel. We have some very timely topics as well as some foundation material to present. This year, we will have an expanded group of exhibitors. As those of you who have attended in the past know, our conference centers around the exhibit area with refreshments and tables for relaxed conversation. It's YOUR conference and your opportunity to build relationships with experts in our field. Whether your interest is technical - how the latest innovations involve safety hazards - or regulatory - what the various committees are doing - or political - what the trends are in the Far East or Latin America, you can get your answers here, and develop a network for getting answers to future issues.

This year's conference is very special because it's in Boston, the home of the Northeast Product Safety Society (NPSS) . I hope that we get a great turnout form the Boston/New England area so that we can meet everyone from the NPSS. The NPSS has a long history going back to the very beginning of TC-8 in the mid 1980's, and it will be great to put faces on the names that we've heard of over the years.

Our Conference Committee, under the leadership of Steve Brody, has done everything possible to make the Boston event memorable and worthwhile. This event exists for our membership, and also provides resources for our society. Our annual conference is one of the society's key sources of funds. The proceeds go to support our society, so please encourage all your colleagues to attend. A high attendance will ensure that we can move ahead to plan future conferences and workshops, and work towards developing a Distinguished Lecturer Program, and build the PSES Newsletter into an expanded magazine format. Proceeds from the conference will enable us to provide more chapter support and to build more technical committees. These are all resources for you.

It's hard to believe that this will be our seventh annual conference. Santa Clara, Chicago Area, Southern California, Denver, Austin and Toronto. Now, with Boston, we'll have made it fully to the East Coast. By having the conference at a different location each year, we hope to help build the local chapters. Ideally, each year's event is an opportunity to build teamwork for an active and dynamic chapter. Next year, we will be in the San Diego area and in 2012 we will be in Portland, Oregon. Each chapter is encouraged to make a proposal for a future conference. While challenging to put together, we do have some pretty good templates to work with, and also work with conference professionals to handle the various elements of a conference.

The biggest benefit - in my opinion - of our conference is the exchange of ideas. If every chapter is represented at the conference, they can take the ideas back to their respective chapters. Topics for monthly chapter meetings are much easier

Continued on Page 4

to identify. Speakers are easier to find with the network built at the conference. Given the lively discussions at the conference, I am a bit frustrated when a chapter says they have no ideas for topics. So please, please, every chapter send a delegation to our conference! Then come back to the chapter and tell the folks about the experience. Our membership needs to have a real feeling for the value of our conference, that only past attendees can express. Many of our attendees come year after year. Why? Because it's a great experience, and well worth the expense. Written ads just don't carry the true feel of our conference.

When I first joined IEEE as a student, it seemed the natural thing to do. As an electrical engineering student, I got a sense of the profession and its offerings by attending meetings. Although I am now far removed from student status and there are a plethora of ways to communicate now that didn't exist back then, face-to-face meetings still convey a depth of information that is rewarding. The expanded venue for that is our annual conference. With successful conferences, we can have local workshops and colloquia and serve the local areas. That is our future.

As I moved through my career at UL, the meetings of various societies were of interest to me (at one time or another Communications Society, Power Society, Management Society, and of course the EMC Society), but it wasn't until the formation of TC-8 as part of the IEEE EMC society that I felt that I had found my "home." Home with a group of people I either knew or would come to know, and who shared a common background and interest in product safety engineering and regulatory issues. Here in the Santa Clara Valley, the industry had its ups and downs, but regardless of where we were in the "cycle" you could get a perspective that was helpful. Generally, our business is a leading indicator of where things are going, and that proved very helpful in anticipating workload and trends. We had a unique roll of maintaining a balance between the need to hire more engineers and the need for engineers to find work. We also provided opportunities for exposure into related areas that were both interesting and potentially a source of future business.

For product safety engineering in particular, regulatory and political trends are critical for getting products to market. Our meetings are a direct and indirect source of information not easily found. So far as I can tell, our society is unique within IEEE in its focus on applied engineering and regulatory issues. IEEE is a great organization, and there are many IEEE societies that delve into state of the art issues of new technologies. But the emphasis is generally on the academic and theoretical realms. I remember scanning the various journals that I received as a member of different societies in the past. The information they contained was interesting, but not really relevant for me.

The IEEE PSES is the professional society that is doing its best to be relevant and of value to everyone interested in product safety engineering. Please make our society an active part of your life!

Murlin Marks
President IEEE PSES

News and Notes

News from Technical Committees

RATC Activities Report - September 2010
Daren Slee - Chair

The Risk Assessment Technical Committee meets monthly to discuss Risk Assessment topics that relate to Product Safety Engineering. We recently set an agenda for our activities and goals we wish to accomplish over the next year. We also identified specific action items for our immediate attention. If this agenda sounds interesting to you, please come to our next meeting!

Work Program
The first items on our agenda are:

1) Terminology - work on developing guidance on the correct terminology relating to risk assessment.
    1) Research terminology already in use for risk assessment in various venues and compare to develop a master list including multiple definitions. Determine a preferred definition from the perspective of our committee.
    2) Will provide comments for the ISO/TC199 revision effort currently underway. This standard already defines several risk terms and can provide a starting point for our terminology effort.
2) Risk assessment tools – determine acceptable methodology to review tools for their strengths and their applicability to specific risk assessment problems. Items to consider:
    1) The variety of tools available
    2) Review of tools and reporting the positives for any given tool (confidence in tool output)
    3) An initial list of tools we as a group are aware of.
    4) Put this list on our website.
    5) Invite the greater risk assessment community to add to this list to help it become as complete as possible.
    6) An eventual discussion of what is and is not present in each tool.
    7) The list of tools addressed should be tools appropriate to product safety risk assessments, consistent with our role in the PSES.
    8) -The upcoming PSES symposium in Boston will be used as a forum where we can identify people outside the RATC that can contribute to this.
3) Author a white paper for publication and presentation at the 2011 PSES symposium, where some common tools are described and discussed using some of the criteria above. This will give us another opportunity to get feedback on our approach to tool review.

If you are interested in working on any of these topic areas, please contact the committee and volunteer your expertise! If you would like to see other items added to the future work program, the committee wants to hear from you. Please contact us!

IEEE PSES TSTC
Peter Tarver - Chair

The Telecom Safety Technical Committee has been having regular monthly meetings covering numerous discussion topics. The committee is also currently at work on several proposals.

1. Proposal to modify CSA/UL 60950-21

    Provide a North American deviation in 60950-21 so that –21 aligns with GR-1089-CORE Issue 4 and UL-2444. This deviation would only apply to equipment that is located on the service providers' side of the demarcation point, or for equipment that makes up the point of demarcation. This equipment is covered by the scope of the proposed UL 2444 standard, and will not be subject to these extra requirements following the publication of UL 2444. Therefore no reduction in safety occurs. Since this has no impact on the ITE world or for consumer equipment, this is the least controversial route to correcting the

Continued on Page 6

problems with –21. This proposal only requires adding a couple sentences to the scope and adding a normative annex. This leaves the remainder of the document "as is" for equipment not used by service providers or under the proposed scope of UL-2444.

This deviation is consistent with current practices, aligns with other ANSI standards such as T1.337-2003 that was developed by NEP, aligns with GR-1089-CORE, and captures the intent of the letter NIPP-NEP sent to UL in 2003. It also helps alleviate the discontinuity between UL-2444 and UL 60950-21.

In addition, this proposal would prevent RFT-C voltages that are not allowed in North America per GR-1089-CORE from be applied to service providers' networks or facilities. It would not prevent the use of RFT-C circuits in private or campus networks, or on the customers' side of the demarcation point (provided a connection of the RFT-C circuit is not made to the public telecommunication network).

2. Proposed actions on battery strings

Draw attention to the need for ventilation of hydrogen gas and separation from arcing parts in electrical enclosures, construction guidelines and testing for ventilation, drawbacks in the use of venting tubes in un-vented enclosures, battery charging, wire sizing and insulation in light of high energy faults, wet cells vs. arrested electrolyte cells, and avoidance of thermal runaway hazards.

Request to revise IEC 60950-22:2006, Clause 11, to correct a common ventilation deficiency that can result in the buildup of hydrogen gas inside of an outdoor enclosure under fault conditions, such as thermal runaway.

3. Proposed actions on wiring simulators

Past studies suggest that the "worst case" customer premises wiring is the so-called tinsel wire that is sometimes used in modular phone cords. The current standards have in place limits to prevent this type of cord from presenting a safety hazard. Wiring simulators presently in use sometimes fail to limit the current to these levels however.

The next step is to define a wiring simulator curve with a true RMS current.

Chapter Safety Probes

Chapter Info

There was a joint Central New England Chapter and Northeast Product Safety Society meeting on September 22nd in Boxborough MA. A social hour with light refreshments and a technical meeting featuring speaker Brad Bombardier, Senior Project Engineer at Intertek, Boxborough was held. Brad's topic concerned product safety compliance for hazardous locations. These are compliance requirements that stem from the Canadian National Electrical Code, The Directives governing commerce in Europe and the United States National Electrical Code (NFPA 70). In addition, Brad discussed the differences between the Zone systems of hazardous (classified) locations.

On Sep. 16th, 2010, the IEEE-PSES Asia-Pacific chapter held its first meeting at CQC-TS in Beijing. Sixteen people from CQC, CQC-TS, NEMKO (Korea), COSMOS (Japan), CTI (Shenzhen, south China), SAMSUNG (Tianjin), and G&M Compliance attended the meeting.

IEEE-PSES Asia-Pacific chapter first meeting attendees

Mr. Limingming held the meeting; Paul Wang introduced IEEE and PSES history, development, structure, member benefits, and the coming symposium in Boston this October. All the officers were confirmed and signed the chapter petition form. All the attendees discussed the plan for member development as well as activities in the future with plans to build the most active chapter in PSES!


IEEE Product Safety Engineering Society
A Safer Tomorrow Through Technology Today
Paul Wang
PSES


IEEE-PSES亚太地区分会
执行委员会，筹备会
IEEE-PSES Asian-Pacific Chapter
Executive Committee, Preparatory Committee

After the meeting, CQC-TS arranged a dinner party for all attendees.

The Santa Clara Chapter held their most recent meeting on September 28th at El Torito on Lakeside Drive in Santa Clara, CA. The topic was "What's in your electronic product, where does it come from, and why should a Product Safety Engineer be concerned?"

The speaker was Rick Row, currently consulting on energy efficiency and low-carbon energy generation and use, and on compliance with environmental regulations.

Three trends make mineral sourcing an issue of potentially compelling interest to product safety engineers. First, many more minerals are used today in manufacturing electronics than just a couple of decades ago. For example, Intel estimates that, whereas computer chips contained 11 mineral-derived elements in the 1980s, potentially up to 60 elements will be used in coming years.

Second, the downstream manufacturer is being held increasingly accountable for the traceability and regulation of materials in his product. Such traceability has commonly been non-existent for many complex electronic products. Section 1502 of the Dodd-Frank Wall St. Reform and Consumer Protection Act, signed into law on July 21, 2010, will require U.S. public companies to disclosure the use of "conflict minerals," such as tantalum from the Democratic Republic of the Congo, in manufacturing their products; and over 60 percent of tantalum used in the U.S. is used in capacitors. This law imposes a social responsibility on manufacturers, and adds to a growing international pattern of laws and regulations with environmental and public health and safety objectives.

Finally, concern is growing in some quarters about the availability, pricing, and sourcing of minerals (some of which are difficult to replace in certain electronic applications) as global demand rises, the grade of mineral deposits decline over time, and competitors such as China threaten to "lock-up" supplies of rare earth minerals. Because earlier material concerns have risen through the need to comply with EHS regulations such as the RoHS, WEEE, and REACH directives in the European Union, product safety engineers are as well placed as any professionals in the electronics industry to take on a key company-wide coordinating role to help their companies and industry remain profitable and resilient in the face of these trends.

To see current chapter information please go to the chapter page at:
http://www.ieee-pses.org/Chapters/index.html

Product Safety Management: Its Time Has Come

by Kenneth Ross

An effective product safety management program can help to reduce accidents, reduce recalls, reduce insurance premiums, increase the safety and quality of products, provide a more defensible product and company in the event of litigation, and minimize the chance of punitive damages. And the techniques have been well-developed for decades.

With that said, why are so many manufacturers being sued and fined by government safety agencies? Why are so many products being recalled, many times by well-known and respected manufacturers? Why are legislative bodies here and around the world enacting sometimes oppressive legislation to force manufacturers to do a better job of providing a safe product? And, why are retailers creating a global safety standard that will be imposed on those who sell to them?

Obviously, companies must not be devoting enough resources to these efforts. Why is that?

As someone who has counseled manufacturers on product safety, regulatory compliance, and product liability prevention for over 30 years, I have seen many answers and excuses: We haven't had too many problems yet; it's the cost of doing business; everyone's job is product safety; that's why I have insurance; my foreign supplier will take care of the problem if anything happens; it costs too much and I can't cover the cost in my prices; my competitors aren't doing these things, so how can I justify the effort and expense?

I have written previously about the elements and benefits of such programs. See these articles on www.productliabilityprevention.com. I wanted to report on some recent developments concerning consumer products and industrial products which help solidify my earlier thinking and recommendations concerning the necessity of such a program and its important elements.

RILA/BRC Global Standard for Consumer Products

In 2003, the British Retail Consortium (BRC) published a standard for consumer product manufacturers who were selling private label products to British retailers. Since then, this standard has been extensively revised and updated to reflect the latest thinking in the production of safe and legal consumer products. Its third edition has been released and BRC is now working with members of the Retail Industry Leaders Association (RILA) to finalize and implement the standard.

RILA members include Wal-Mart, Costco, Lowe's, Home Depot, Target, Sears, Walgreens, and Best Buy. BRC members are the leading British retailers.

In the current draft, the standard is described as follows:

> The text of the Standard specifies the safety, quality and operational criteria required to be in place within a manufacturing organization to fulfill obligations with regard to legal compliance and protection of the consumer. It forms a core to the Global Standard for Consumer Products scheme which encompasses a network of approved and accredited certification bodies, employing qualified auditors who audit companies and provide a detailed report assessing the company's compliance with the requirements of the Standard. If successful, the audited company becomes certificated to the Standard and is listed on the BRC Directory of suppliers.

The final draft was published earlier this year with implementation to take place through 2011.

The standard applies to both private labeled products (branded with the name of the retailer or

the retailers' brand name) and branded products (branded with the name of the manufacturer). Each retailer will have to decide which of its suppliers will be subject to the requirements of the new standard. I suspect that most will concentrate first on smaller manufacturers of private label products whose manufacturing facilities are in foreign countries.

Of course, this standard, to the extent it exemplifies the best current thinking on product safety procedures, can be used by anyone, including component part and raw material suppliers to consumer product manufacturers, as well as manufacturers of non-consumer products.

Some of the key elements of the standard are as follows:

- Supplier's senior management shall develop and implement a product safety policy that is communicated to personnel.

- The supplier shall perform a systematic, comprehensive, and thorough risk assessment that is fully implemented and maintained. This will include reference to legislation, product standards, codes of practice, and developments in science and technology.

- All documents, records and data critical to the management of product safety, legal compliance and quality must be in place and effectively controlled.

- The supplier shall have a clearly defined and documented organizational structure with responsibility for product safety, legal compliance, product quality, and management systems. This organization shall have a named individual with relevant experience and qualifications to be responsible for its management. In addition, the company shall audit the management system to ensure that it is being complied with and is appropriate under the circumstances.

- The supplier shall control all purchasing processes which are critical to product safety, legal compliance and quality. This includes an ongoing assessment which monitors performance of suppliers such as subcontractors and component part suppliers.

- Procedures must be in place to record, investigate, analyze and correct the causes of nonconforming products or the failure to meet standards, specifications and procedures which are critical to product safety, legal compliance and product quality.

- The standard requires an extensive traceability system starting with the identification of components and raw materials and ending with finished products and materials. The company must test the traceability system to ensure that products can be traced. This test must be done at least annually. It is also required that subcontractors and component part suppliers must be able to trace their products to a level appropriate for the risk.

- The supplier must have a plan in place to effectively manage product withdrawal and product recall procedures. These procedures shall be regularly tested, at least annually, and results of the tests retained.

The key additional requirement is that suppliers must have their compliance with the standard confirmed by an accredited third party auditor. These auditors will most likely be the same third-party testing laboratories that currently are accredited to certify compliance with the standards issued pursuant to the Consumer Product Safety Improvement Act and with requirements of the EU Machinery Directive to justify a CE mark.

I have a few preliminary observations concerning this standard.

- These requirements are an extensive and comprehensive interpretation of the product safety management procedures that have been around for decades.

- This is not an official consensus standard as you would have from ANSI or ASTM. And the number of retailers that are members of these groups is fairly limited. Therefore, it remains to be seen what effect this will have going forward.

- The inclusion of these requirements in such a document could enhance the acceptability

Continued on Page 12

of these procedures for manufacturers of all kinds of products. This could raise the state of the art in product safety as more and more companies adopt these kinds of procedures and documentation controls. However, there are many different ways to improve product safety and many manufacturers do not have to do all of the things identified in this standard to achieve that goal.

- Those manufacturers who are not required by retailers to comply with this standard may still need to explain why they don't comply with the "state of the art" and may suffer the consequences of non-compliance. However, they still have that task today as these procedures have been well-known for decades.

- There will probably be much more documentation available that will be subject to discovery. The standard should increase documentation on safety and quality between the supplier, the retailer, and the third party auditor before and after sale as well as between the OEM and the OEM's suppliers. Some of these documents may prove challenging to explain if an incident occurs and litigation results. And manufacturers will have to worry about whether business confidential information will be disclosed to retailers and possibly competitors.

- A big question is whether such extensive procedures are necessary for the vast majority of manufacturers who already have product safety management programs of some sort in place. In addition, for those manufacturers who already spend lots of time and money on various certifications such as UL or CSA, do they really need to go through another audit process as required by this standard? Retailers who use this standard will need to make some important decisions as to which manufacturers need to comply and whether they really need to be audited.

This process will play itself out this year and next. RILA and BRC are preparing training programs for potential auditors, retailers and manufacturers to educate everyone about the new standard. At this point, it is safe to say that more organized and comprehensive product safety management procedures of some sort will be the norm in the future for many consumer product manufacturers.

U.S. Consumer Product Safety Commission (CPSC)

The CPSC has always encouraged companies to implement active product safety management programs. It has had available a *Handbook for Manufacturing Safer Consumer Products* for many years. For the current edition of this handbook, see www.cpsc.gov/businfo/intl/handbookenglishaug05.pdf.

However, recently, this has become a bit more official. On March 16, 2010, the CPSC Commissioners approved a final rule of factors that their staff will consider in connection with potential civil penalties. While the final rule has not yet been published in the Federal Register, the last draft (Interim final interpretative rule, *Federal Register*, September 1, 2009) stated clearly that product safety programs would be considered by the staff. The rule states:

> **Safety/Compliance Program and/or System**: The Commission may consider, for example, whether a violator had at the time of the violation, a reasonable program/or system for collecting and analyzing information related to safety issues, including incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns; and whether a violator conducted adequate and relevant premarket and production testing of the product(s) at issue.

In addition, the Chair of the Commission released a statement dated March 16, 2010 concerning these new factors which said in part:

> The safety/compliance program factor takes into account the extent to which a person (including an importer of goods) has sound, effective programs/systems in place to ensure that the products he makes, sells or distributes are safe. Having effective safety programs dramatically lessens the

likelihood that a person will have to worry about the application of this civil penalty rule. Any good program will make sure that there is continuing compliance with all relevant mandatory and voluntary safety standards.

This approach is analogous to the 1992 Federal Corporate Sentencing Guidelines where the existence of comprehensive compliance programs can help mitigate criminal fines imposed by the government against corporations.

Lastly, the establishment of a product safety management program was included in a recent consent decree for civil penalties. In a March 2, 2010 agreement, Daiso Holding, a U.S. subsidiary of a Japanese company, agreed to pay a little more than $2 million in fines for violating various laws and regulations concerning the sale of toys and children's products.

The consent decree requires Daiso to hire a product safety coordinator to do, in part, the following:

- Create a comprehensive product safety program;
- Conduct a product audit to determine which of Defendants' merchandise requires testing and certification of compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC; and
- Establish and implement an effective and reasonable product safety testing program in compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC.

There are many more specific requirements in the consent decree which lead me to believe that this program was instituted at the request of the CPSC. Given the level of the fine and the description of the violations, it is apparent that the CPSC viewed this as egregious. In future penalty cases where the violation is not so significant and the manufacturer already has some safety program in place, it remains to be seen whether such a detailed program would be required.

Despite that, manufacturers and retailers should take these events as evidence that the CPSC will be less likely to impose heavy penalties if the company can show that they had a system in place which evidenced a real commitment to prevention and compliance.

Machinery Safety

There have been some developments in the machinery safety area which also expand requirements for some of the safety procedures we are seeing being mandated for consumer product manufacturers.

In 2006, the European Machinery Directive was modified and applies to all machines sold in the European Union after December 29, 2009. The EU issued in June 2010 a 389 page guide to the new directive. While this directive does not specifically require many of the management procedures in the RILA/BRC standard, such as a product safety policy, it does include some of them. To see the December 2009 guide, go to http://ec.europa.eu/enterprise/sectors/mechanical/machinery/index_en.htm.

Risk assessment is a key requirement in this directive. It was not a requirement in the earlier version of the directive which came out in 1998. There are a number of new provisions where the manufacturer must make important design decisions based on a risk assessment. These can't be educated guesses. The procedures must comply with EN ISO 14121-1:2007 - *Safety of machinery – Risk assessment – Part 1: Principles*. And the risk assessment must be kept as part of the technical construction file.

In addition, the new directive makes it clear that the machinery, especially safety devices, must be designed for reasonably foreseeable and intended use as well as abnormal or unintended uses. And, the requirements for instructions have been expanded. Last, this new directive contains market surveillance requirements mandating that member countries work together to locate non-complying machinery with a goal of taking them out of service or getting them fixed, and preventing their sale. The Guide makes it clear that manufacturers and government authorities are to use risk assessment to determine if machinery violates the essential

Continued on Page 14

health and safety requirements of the Directive and needs to be repaired or replaced. In addition, the authorities can take the machinery out of service by issuing a notice in RAPEX, the safety notification system used for consumer products.

Machinery sold in the European Union will need to be redesigned in accordance with new risk assessment procedures and instruction manuals will need to be revised to comply. In addition, manufacturers will have to institute their own market surveillance programs where risk assessment is applied to adverse field experiences. These changes could also impact machines sold in the U.S. To the extent that manufacturers want to sell machinery in the U.S. that is the same as in Europe, they will need to consider this directive as well as U.S.-based machinery standards.

Risk assessment is a concept that has been in U.S. machinery safety standards since 2000. However, these standards are being revised right now to make risk assessment mandatory for compliance. (See the ANSI B11 series of standards.)

Now you might think that requiring risk assessment is not a big deal. However, many manufacturers do not do a formal risk assessment. They design the product to comply with the standards in effect where the product is sold and that's it. Their assumption is that the standards group did a risk assessment and they don't need to. But this guide to the new Machinery Directive raises lots of options in design that need to be resolved by the manufacturer. Therefore, doing a formal risk assessment becomes a necessity.

I have written before about risk assessment and the legal implications of creating those documents. See "Risk Assessment and Product Liability," (with Bruce Main), *For the Defense*, April 2001 (also available at www.productliabilityprevention.com). The more risk assessments that are performed, the more explaining a manufacturer may have to do as to what they mean, how risk was evaluated, and how final decisions were made.

Product Safety Survey

In 2009, a product safety engineer who works in the plastics equipment industry was awarded a PhD in safety engineering. In connection with that effort, he published a dissertation which included a survey of over 30 product safety professionals in the plastics industry.

The engineer, Doug Sten, first reviewed the safety literature and identified the key elements of a safety program as described by those who have worked in the area for many years. He identified 40 key elements of any product safety program and asked these professionals to grade them as Critical, Very Important, and Important. Seventeen elements were described as critical. A review of these seventeen items (as well as all 40) shows that product safety management systems and procedures for consumer products and machinery are pretty similar. Below are the 17 elements viewed as critical:

- Ensure that there is a written corporate product safety policy;
- Provide appropriate communications to all employees;
- Perform design reviews, assessing intended use vs. misuse;
- Perform formal risk assessment as part of design review;
- Apply current, industry safety-related design standards;
- Produce a prototype of a product before going into production;
- Develop a manual that is easy to follow, apply and understand;
- Test product for reliability, quality and safety prior to shipment;
- Provide clear, emphatic warnings where there remains residual risks;
- Design product safety labels that are in compliance with safety standards;
- Provide labels and instructions in the language of users where the product is to be used;
- Assess and communicate to engineering

feedback from customers received from sales and technical service personnel regarding any product safety issue;

- Send certified letters to customers whose machines were found not to be using safety guards as originally designed;
- Sales and technical service personnel must report accidents they are aware of that occurred at a customer's site;
- Perform on-site investigation once informed of an accident;
- Develop a formalized product recall or retrofit program;
- Participate on national safety standards committees, developing requirements in design safety for specific machines or products.

The importance of the above list is that it is consistent with what has been done for decades and what is being included in standards and guidelines issued by various entities for all kinds of products. In addition, the respondents to this survey currently work in the product safety function and, when their individual levels of experience are added up, have many hundreds of years of experience. Therefore, their vote as to critical elements of a safety program should carry some weight.

Conclusion

No matter what a manufacturer does, it is always possible that its product safety program is lacking in some respect and could arguably constitute evidence of a disregard for safety. To combat that possibility, any program must be able to show a high regard for safety, both on paper and in actions. If this showing is made, even if the jury believes that the manufacturer could have done more, it should also believe that the manufacturer tried to do the right thing and may not be inclined to award punitive damages.

As companies better organize themselves for the worldwide challenges of providing safe products, the bar will be raised. Companies who do not follow the lead will be at great risk of further product safety, product liability, and regulatory problems, in the U.S., in Europe, and in other foreign countries.

The techniques are well-known; the difficult part is to analyze what is appropriate for a particular company and then incorporate it into the company's organization, culture, and processes. Doing so should pay for itself, either by preventing future problems that could arise or giving the manufacturer a much better defense if accidents do occur.

Kenneth Ross is Of Counsel to Bowman and Brooke LLP in Minneapolis. Mr. Ross has helped companies develop and implement product safety management programs for over 30 years. This article is adapted from one that appeared in the Spring 2010 edition of Strictly Speaking*, the newsletter for the Defense Research Institute's Product Liability Committee.*

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Absense of Proof is Not Proof of Absense

Absence of Proof is Not Proof of Absence (and the "Proven in Use" Fallacy)

by Keith Armstrong

In my work in "EMC for Functional Safety" over the last decade, I have ventured out of the cozy world of electromagnetic (EM) compliance, where everything is done by EMC testing, into the "wild west" of safety engineering, where affordable EMC testing can *never* be thorough enough to demonstrate that a design will be reasonably safe over its lifetime in its EM environment.[1] [2] [3] [4]

A fallacy

In the safety engineering world I am often told even by the most senior executives and official regulators—who really ought to know better—that, "We have no evidence that safety problems can be caused by electromagnetic interference." What they mean by this is, "Therefore there is no problem. EMI does not cause safety incidents."

This is one example of the fallacious "Absence of proof means proof of absence" argument, widely used by politicians, officials, and other people for whom perception is more important than reality. The purpose of this article is to enable us to recognize and counter this type of spurious argument when we meet it.

The argument is often used, or accepted, because it seems at first sight to be so self-evident that we do not think about its validity. But in safety engineering we have to be concerned with hard physical realities, so we must be able to recognize incorrect statements and false arguments—like this one—even where we *want* to believe them because they give us a warm and fuzzy *feeling* that everything is alright, or because they *appear* to justify cost savings.

It was William Cowper (1731 – 1800) who first wrote, "Absence of proof is not proof of absence." [5] Unfortunately, even 200 years later, people who we trust to know better are still making this fundamental error.

Where is the evidence?

The simple error in this argument is the implicit assumption that people making the statements have *actually tried to find evidence*. We *assume* that they know what they are talking about, but often they do not. Simply because no one has told them that a specific problem has been found, they try to convey this to us as somehow meaning that therefore the problem does not exist.

So the trick is, whenever someone tries to use the "absence of proof…" argument, simply ask what actual grounds they have for claiming proof of absence.

In almost all cases, their answer will reveal that there has been no attempt at a thorough investigation—often that there has been no investigation at all. The reason there is no evidence, is that nobody ever looked for any! Of course, having no evidence cannot prove anything at all, and so we can say, as William Cowper did over 200 years ago: "Absence of proof is not proof of absence."

Sometimes the reply is that an investigation has been done. But quite often it will be found not to have been a very thorough one, so do not be fobbed off by a reply like "Oh, we did an investigation." Ask to see the methodology and the resulting raw data. I have seen a government report in which the Executive Conclusions (written by an official) stated that there was no evidence of a particular problem, despite being contradicted by the actual data (collected by an engineer)!

And I have seen several reports from the U.S. National Highway Transportation Safety Administration (NHTSA) that state that because no defect could be found in an automobile's electronic speed controller after an accident, it could not have been a defect in the controller that caused the accident – therefore the driver must have been to blame. But in the EMC world we know that interference with an electronic controller can make it misbehave in ways that leave no trace after it has been switched off.

This is an example of an accident investigation

that was not thorough enough. But of course no investigation is ever going to find traces of something that – by its very nature – leaves no traces! So where EMI is concerned we need to do a *different kind* of accident investigation – a risk analysis – to see if the design and construction of the controller, and its use, age and exposure to EM disturbances whilst in service could have resulted in the kind of misbehavior that caused the accident and yet leave no trace. Then at least we would have an alternative possibility to consider, rather than simply blaming the driver.

Effects of ignoring the fallacy

That the "absence of proof…" argument is fallacious is well-known to top safety experts, and I quote from a few of them below. Prof. Henry Petrowski, writing in the *New Scientist*, [6] gives a number of real-life examples of engineering techniques that were "known" to be adequate—until their design flaws were eventually revealed at great cost.

He says [6]: "Success frequently masks latent flaws in a design. The longer those flaws remain undetected—or telltale signs of them ignored—the more robust the evidently successful system will appear to be and it will tend to be pushed accordingly."

This also gives the lie to a common management approach to saving costs regardless of the true consequences for safety, which is known as "Proven in Use." This might have been an acceptable rule in the 19th Century, but in our modern, complex, electronic age, it is just another variation of the fallacious "absence of proof means proof of absence" argument.

One of Prof Petrowski's examples is the Columbia space shuttle disaster, of which he says, [6] "Prior to 2003, virtually every space shuttle launch was accompanied by insulating foam being shed from its external tank. The fact that this caused no significant damage to the spacecraft put that kind of event in a category that did not halt flights."

"That all changed when Columbia suffered a critical breach in the leading edge of one of its wings. Because shedding foam had become a part of normal operations, Columbia was not sufficiently scrutinized before being cleared for re-entry in February 2003. Only its spectacular failure revealed incontrovertibly what some 'overly cautious' engineers had been trying to warn NASA about."

NASA management had assumed that because there was no evidence that chunks of foam hitting the space shuttle during launch had caused a problem, this "proved" that there was no problem with the space shuttle design. They never bothered to do a proper investigation, because the design of the space shuttle was considered to be "proven in use." But when they bothered to do some actual investigations (*after* the Columbia disaster) they found that foam hitting the very brittle thermal tiles could in fact cause a catastrophe.

Prof Petrowski concludes, "It is in the public interest to recognise that the possibility of failure lurks in the dark corners and black boxes of technology, and that it is incumbent upon all those involved in design, construction and regulation to keep this fact high in their consciousness. None of us should become paranoid about engineering failures, but a healthy scepticism about built things, and an awareness that apparent success can mask imminent failure, should always inform those in charge of these structure's condition and in whose hands rests the safety of the people who use them."

My recent reading on Product Liability court cases reveals that lawyers, judges and juries tend to accept "absence of proof means proof of absence" and "proven in use" arguments, because they know no better, so the law is not providing the necessary corrections.

Implications for product designers

Now that we understand the fallacy in the "absence of proof means proof of absence" argument, the question then arises as to what we should do to apply this insight when designing high-technology products and systems so that they are reasonably safe.

If you think that all that is necessary for making a product or system safe is to apply IEC/EN 60950 or IEC/EN 61010-1 or one of the many other published safety standards, then you need to get out more and update your understanding of safety engineering.

Almost all of these safety standards specifically

Continued on Page 22

do not cover safety risks due to malfunctions, for which a risk management approach is needed. Mostly, they just deal with "inherent" safety issues such as electric shock and fire hazards.

As electronic devices have become more complex over the years, and the modules and units they are used in, and the software they run, have also become more complex, as items of equipment have been increasingly interconnected to create systems, and as systems are increasingly interconnected to create "systems of systems," the difficulty of ensuring that our electronic technologies do not introduce intolerable safety risks grows exponentially.

This increase in complexity means that we should not blindly assume that safety engineering techniques that used to work well enough will continue to work equally well in the future. When technologies change, past experience is not necessarily a good guide to the future.

But in electronics, technologies are always changing. So even where an "absence of proof…" argument *is* correctly based on real and relevant data, it does not necessarily apply to the next project, because of the introduction of new technologies and increased complexity.

For example, a current development in automotive safety is the use of vehicle-to-vehicle wireless communications so that when vehicles meet a problem, they automatically control the speed of approaching vehicles that can't see the problem because they are around a corner, or in a fog. This is a complex system-of-systems, and because cars are consumer goods they will use lowest-cost technologies. Worried? You bet!

Parting quotations

Here are two additional quotations relevant to the above issues from safety experts.

Nancy Leveson says, [7] "New technology introduces unknowns into our systems and even unk-unks (unknown unknowns)…We no longer have the luxury of carefully testing systems and designs to understand all the potential behaviors and risks before commercial or scientific use…Digital technology has created a quiet revolution in most fields of engineering, but system engineering and system safety engineering techniques have not kept pace. Digital systems introduce new "failure modes" that are changing the nature of accidents. Many of the approaches that worked on electromechanical components—such as replication of components to protect against individual component failure (i.e., redundancy)—are ineffective in controlling accidents that arise from the use of digital systems and software…This situation is not new: Throughout history, inventions and new technology have often gotten ahead of their scientific underpinnings and engineering knowledge, but the result has always been increased risk and accidents until science and engineering caught up."

John McDermid says, [8] using slightly more academic language, "Implicitly, safety engineering assumes that probabilities reflect aleatoric uncertainty, i.e. "randomness," which can be characterised by a stochastic model. Further, we implicitly assume ergodicity—that past failure behaviours are good predictors of the future…However, in many cases we face epistemic uncertainty, i.e. imperfect knowledge of the system or the stochastic model. In other words, we do not know the shape of the probability density function (PDF) or even its mean."

Keith Armstrong is with Cherry Clough Consultants (www.cherryclough.com). *This article is adapted from a previous version published in the September 2008 edition of* The EMC Journal.

[1] "Why EMC Immunity Testing is Inadequate for Functional Safety," Keith Armstrong, *2004 IEEE International EMC Symposium*, Santa Clara, USA, August 9-13 2004, ISBN 0-7803-8443-1, pp 145-149. Also published in *Conformity*, March 2005 pp 15-23.

[2] "Functional Safety Requires Much More Than EMC Testing," Keith Armstrong, *EMC-Europe 2004* (6th International Symposium on EMC), Eindhoven, The Netherlands, September 6-10 2004, ISBN: 90-6144-990-1, pp 348-353.

[3] "EMC in Safety Cases—Why EMC Testing is Never Enough," Keith Armstrong, EMC-UK 2007 conference, Newbury, UK, Defence & Avionics session, Wednesday 17th October 2007.

[4] "Why EMC Immunity Testing is Inadequate for Functional Safety," Keith Armstrong, *2008 IEEE International EMC Symposium*, Detroit, USA, August 18-22 2008, ISBN 978-1-4244-1699-8.

[5] Antony Anderson, presentation to the 20th Conference of the Society of Expert Witnesses, Alexander House, Wroughton, 16th May 2008, www.sew.org.uk. Antony is a forensic engineer and expert witness, antony.anderson@onyx-net.co.uk.

[6] "When Failure Strikes," Henry Petrowski (Alexandar S. Vesic Professor of Civil Engineering and a Professor of History at Duke University, NC, USA) *New Scientist*, 29 July 2006, page 20. Also at: www.newscientist.com/channel/opinion/mg19125625.600-the-success-that-allows-failure-to-strike.html.

[7] "A New Accident Model for Engineering Safer Systems," Nancy Leveson (Professor of Aeronautics ands Astronautics, Massachusetts Institute of Technology, MIT, Boston, USA), *Safety Science*, Vol. 42, No. 4, April 2004, pp. 237-270, http://sunnyday.mit.edu/accidents/safetyscience-single.pdf. Ms Leveson's biography is at http://sunnyday.mit.edu.

[8] "Risk, Uncertainty, Software and Professional Ethics," John McDermid (Professor of Safety Engineering at the University of York, Head of the Department of Computer Science, Head of the High Integrity Systems Engineering Group, and an Independent Safety Assessor), *Safety-Critical Systems Club Newsletter*, January 2008, Volume 17 No. 2, pp 5-8, www.safety-club.org.uk/main.html?opt=Publications.

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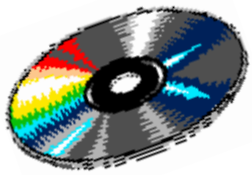

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