

# The Product Safety Engineering Newsletter

## What's Inside

President's Message .....	1
Officers of the IEEE PSES .....	2
Chapter Activities .....	20
A New Approach to Product safety .....	5
Medical Electrical Safety Under Attack .....	11
News and Notes.....	7

Vol. 6, No. 2 June 2010

## President's Message

This has been an exciting time for me! And a frustrating time, as I would like to be in a better position to provide much more for our members. Our situation is not quite or the same magnitude as a Dickens novel, but we are in a critical phase in our development into a successful IEEE Society.

First, the high points of the past few months: In April, I went to Beijing for our first Beijing Product Safety Engineering Workshop. It was a great culmination of a number of meetings to try to get a Beijing PSES chapter up and running. Thomas Ha, our VP of Membership, and Paul Wang our IEEE PSES Region 10 Representative were great hosts, introducing me to a number of potential leaders for the Beijing Chapter. China Quality Certification and CQC Testing Technical Services did a great job hosting the event.

We were very fortunate that a TC-108 meeting in Beijing had some of our preeminent speakers in Beijing. Bob Griffin, A. Hessami, Peter Keller, Rich Nute, Peter Perkins and Rich Pescatore gave presentations of their work. A lot of material was covered! Mark Montrose, IEEE Division VI Director

and first president of the PSES told the attendees about the history of PSES. Thomas Ha went over the benefits of IEEE PSES membership.

The 120 attendees seemed intrigued by the wealth of information. Our hosts provided nourishment during breaks and the luncheon. So it was a very productive day!

As I write this, the Beijing Chapter is in its formative stages. As I told anyone who would listen, our society is here to serve the product safety professional—engineers, technicians, administrators and managers: anyone whose career involves product safety and regulatory issues. It's a forum for professional development that exists only to serve its members.

Part of the PSES success will be due to leadership and leadership development, which I think is an important part of our profession. With a num-



## Newsletter Committee

**Editor:**

Gary Weidner 1-563-557-0717 (v) 1-563.557.0725 (fax) gweidner@ieee.org

**Co-Editors:**

Michael S. Morse Ph. D. mmorse@sandiego.edu  
 Richard Nute richn@ieee.org  
 Nosh Medora nmedora@exponent.com  
 Lal Bahra Lal\_Bahra@Dell.com  
 Lingfeng Chen gzclf2-ieee@yahoo.com.cn

**News & Notes:**

Your name here

**Chapter Activities:**

Your name here

**Page Layout:**

Jim Bacher 1-937.865-2020(v) 1-937.865.2048 (fax) j.bacher@ieee.org

## IEEE PSES Officers

Executive Committee	Name	Term
President	Murlin Marks	(10-11)
Past President	Jim Bacher	(10-11)
President Elect	TBD	(11)
Secretary	Daniece Carpenter	(09-10)
Treasurer	Jan Swart	(10-11)
Vice President - Communications	Dan Roman	(09-10)
Vice President - Member Services	Thomas Ha	(09-10)
Vice President - Technical Activities	Jack Burns	(09-10)
Vice President - Conferences	Dough Nix	(10)

**Directors At Large**

Term Expires 12/10	Term Expires 12/11	Term Expires 12/12	Ex Officio (without vote)
Jim Bacher	Jack Burns	Daniece Carpenter	Chapter Chairs
Silvia Diaz Monnier	Jim Pierce	Richard Georgerian	Standing Committee Chairs
Doug Nix	Richard Pescatore	Elya Joffe	IEEE HQ
Peter Tarver	Ivan Vandewege	Rich Nute	IEEE TAB Division VI Director
		Douglas Kealey	Gold Member: Open

## IEEE PSES Web Sites

- <http://www.ieee-pses.org/>
- <http://www.ieee-pses.org/symposium/>
- <http://www.ieee-communities.org/emc-pstc>
- <http://www.ieee-pses.org/emc-pstc.html>
- <http://www.ieee-pses.org/newsletters.html>
- <http://www.ieee-pses.org/pses.html>



---

ber of leaders in China and in Beijing in particular, we can build active chapters that will provide meetings, workshops and other activities for its members. Having a number of leaders also means that the workload can be broken down to manageable levels.

On my return from China, I stopped in Osaka, Japan to discuss setting up one or more IEEE PSES chapters in Japan. I discussed our society with several executives; I hope this discussion helps to get things started in Japan. I do think that the PSES offers product safety engineers in Japan the opportunity to participate in a professional forum, but it's up to a few key leaders who have the vision and access to industry to set things in motion.

I also attended Santa Clara Valley Chapter meetings. The last one was particularly good. It was a joint meeting with the IEEE Reliability Society, with about 50 attendees. It was a great meeting; the kind of stimulating discussion with chapter regulars and a number of individuals with a somewhat different perspective. The topic was probably the safety issue of the day—How to Avoid Being the Next Toyota. You can find the presentations at [www.ieee.org/r6/scv/pses/ieee\\_scv\\_pses\\_apr10.pdf](http://www.ieee.org/r6/scv/pses/ieee_scv_pses_apr10.pdf). All PSES chapter meetings may not be quite as much in the public focus, but they do offer a unique opportunity to consider wider aspects of product safety issues. It was particularly satisfying to me to know that one of our Technical Committees (Risk Assessment) had helped get access to engineers at the forefront of the issue.

The excellence of the April Santa Clara Chapter meeting leads me to my present frustrations. We haven't yet convinced IEEE that PSES serves a vital engineering discipline worthy of IEEE society status. My frustration is that I see our potential as a vital IEEE society, but I don't see us functioning that way yet. Even with a number of people making significant efforts, I don't think we are currently "viable" as IEEE sees it – and, perhaps not as important but not as I see it either. There, I said it.

I know everyone has to earn a living, and there just isn't any time left. That's why it's crucial until PSES is large enough, with conferences and jour-

nals to bring in the funding to support a staff to do the leg work, that we have many people sharing the load. Each chapter needs at least a half dozen people willing to plan and coordinate meetings. Conferences need to be planned and budgeted, with a flow of papers, exhibitors and sponsors. Technical Committees need to stimulate an adequate conference and Newsletter paper flow and provide chapter meeting presenters so that chapters can plan out meetings well in advance and build a solid attendance. We need active dissemination of all this "stuff" going on.

Right now, we are functioning on a single cylinder. A few folks are spending a lot of their time trying to do certain tasks. But things for the most part aren't falling in place. Others for whatever reason haven't done what they said they would do. Others have said they are interested, but they haven't taken on any tasks.

The irony is that we are nearly there. We have a number of chapters, we have the Newsletter, we have a tradition of successful conferences, and we know how to put technical papers together. We can operate in the black within the IEEE structure. But those of us who are putting the effort into the PSES cannot hold it together. We need to have most of our chapters running with planned out schedules to have well-attended meetings—I believe that the biggest value to PSES and potential PSES members is having regular meetings covering timely topics. We need conferences that have enough margins to keep the society in the black. We need a technical operation that supports a paper and presentation flow. I don't think it's really very difficult, but it does require the many hands of a "society."

I remember back when I was an assignment engineer at UL. Back in those days, our main effort was to close out projects, not to get to compliance and certification. I was pretty successful, but very busy going back and forth with my clients. Some got certification; some didn't. Those that didn't always knew what the issues were. Many engineers back then often extended due dates (promise dates as we called them). They generally said that they had done what they needed to do, but were waiting for information or samples – the ball was in the client's court. They had done their part. The point is that those of us who made

---

most of our commitments always figured that we had to go more than half way to get the job done. That's where we are with the PSES. We all need to do a bit more than the minimum. If you join PSES and think that the society will be everything you want it to be if you nominally participate, we won't make our promise date.

Our vision is for a professional society. That means that we, as "professionals" (and that doesn't mean you have to be an engineer – just someone who has a serious career related to product safety engineering; you could be a technician or an administrator or an engineer) must build our society to help our profession, our careers and our companies. A few of us can't do that for you.

In late June, I will sit down with the IEEE Society Review Committee and make the case of why PSES should continue in its present structure within IEEE. I want to present the best case I can, but I need your help. Please look at where you have a good fit in your local chapter, in a technical committee, a conference committee, or supporting the VPs (Membership Services, Technical Activities, Communication, and Conferences). I do ask that if you take on a task, you get it done within the necessary parameters. If all members do their part, we will make it.

Finally, please let me know what I can do to provide support. I have some time for supporting PSES, but rather limited resources. I am willing to do a bit more than what is "reasonable," but cannot pull a society together on my own or even with the help of a few as we are currently operating.



Murlin Marks  
President IEEE PSES

***Tip: Best way to get your boss to approve your trip to the 2009 Symposium on Compliance Engineering is to submit a paper that gets accepted for the symposium! Or volunteer and tell him you have to be there!***

# A NEW APPROACH TO PRODUCT SAFETY

The narrowing distinction between IT (information technology) at home and as professional entertainment products has created a need to harmonize related safety requirements. The increasing proliferation of audio, video, information, and communication technology equipment also means that safety needs of children, the elderly and the disabled must be taken into consideration. In addition, the safety requirements must keep up with the rapid advancement in technology for these products. All of this has changed the way the IEC looks at safety standards for these products.

In the past, an IEC standard was typically prescriptive, describing specific constructions. For example, the traditional standard would indicate exactly the size for a ventilation opening in a product for it to comply with safety requirements. Today, such guidelines can prove limitative to new product designs and may become obsolete when technology evolves.

TC (Technical Committee) 108: *Safety of electronic equipment within the field of audio/video, information technology and communication technology*, addressed this challenge by moving from a product-driven safety analysis to a systemic identification and analysis of hazards using an approach commonly referred to as Hazard-Based Safety Engineering (HBSE).

TC 108 developed a new standard, IEC 62368-1, *Audio/video, information and communication technology equipment - Part 1: Safety requirements*. It clearly states the risk being addressed and its principles for compliance. To the extent practicable, compliance statements are performance-based. However, to minimize testing, acceptable constructions are also provided for a designer's use, if they so choose.

From reactive to proactive

Typically, the differences can be illustrated by comparing the approach in a standard such as IEC 60065, *Audio, video and similar electronic apparatus – Safety requirements*, which is incident-based and product-specific, with that of the new IEC 62368, which is technology-independent and based on

performance as opposed to construction. The former takes a reactive approach while the latter is proactive in its direction.

No longer product-specific

Being technology-independent, the standard is based on sound engineering principles. It is destined to be used by engineers who designed the product and evaluated its safety requirements. It is also intended to be used by first, second or third parties assessing conformance of products.

Scope for innovation

Says Richard L. Pescatore, Global Product Safety Standards Development and Certification Manager at Hewlett-Packard Company and Convenor of TC 108/WG HBSDT, "From now on, the designer, when going through the engineering and safety analysis of a product, will understand what is needed to make that product safe. He will no longer be bound by specific required constructions. Instead, he will understand the hazard being addressed and the criteria for mitigating the hazard. This will give him tremendous design freedom."

IEC 62368-1, is different from anything the IEC has written to date in the area of product safety. The hope is that 10 years from now, a design engineer will understand the objective of a given safety guideline so that the intent of the requirements is not lost over time. Tremendous work has been expended in developing this standard. TC108 started working on this generic approach back in 2002. The result is that now a new separate standard will not have to be developed every time the technology changes in the market.

Safety is paramount in conformity assessment

IEC 62368-1 is a very important standard too for Conformity Assessment (CA). Seventy per cent of all IECEE CA certificates issued each year concern safety in the three major industries under the scope of IEC 62368-1: communication technology, information technology and consumer electronics. IECEE is the System of Conformity Testing and Certification for Electrotechnical Equipment and Components. TC 108 has also adopted a proactive role in reducing potential negative impact of

technology on the environment, while preserving product safety properties. Another area of intensive work is related to energy efficiency.

**Change in approach**  
**From reactive to proactive, product-based to generic, the systems approach**

<p><b>Current product safety standards:</b></p> <p><b>Incident-based standard</b> This type of standard takes into account particular incidents that analysis has shown can be prevented provided certain safety measures are taken. An example would be the case of an external power supply that overheats, or where there's a risk of it catching fire. An incident-based standard therefore includes particular requirements to prevent mechanical movement of the connector and thus recurrence of the particular incident.</p> <p><b>Product-specific standard</b> The standard is written for a specific product or product group. IEC 60065 is specific to consumer electronics such as TVs, audio systems, etc. IEC 60950-1, <i>Information technology equipment – Safety – Part 1: General requirements</i>, is written for computers and related equipment.</p> <p><b>Construction-based approach</b> The standard specifies the actual constructions that make the product safe. Other constructions (which may be equally safe) are prohibited. An example of this could be a ventilation opening that must be of a specific size.</p> <p><b>Reactive approach</b> The requirements of the standard mean that it provides for reactions to incidents or near-incidents, much in the way of an "incident-based" standard. An example here might be a reaction to field complaints that results in a mechanical securement of the power input connector on external power supplies.</p>	<p><b>IEC 62368:</b></p> <p><b>Hazard-based standard</b> The standard is based on the energy sources within the equipment. The publication classes the energy sources as either hazardous or non-hazardous. Example: Voltages above a certain level are hazardous, while those below a certain level are non-hazardous.</p> <p><b>Technology-independent</b> The standard addresses safeguards against specific energy sources, independent of the function of the product. In today's world, computers and TVs are becoming complementary equipment, so the safety standard must be written to account for technology, not specific products. Example: The principles for protection against any energy source are applicable to any technology existing today and any future technology.</p> <p><b>Performance-based</b> It is the safety performance of the equipment that is specified, not the construction. For example concerning the assembly of a power input connector of an external power supply, it is specified that it shall not stress the electrical connections.</p> <p><b>Proactive approach</b> The standard addresses the sources of energy contained in the equipment. This allows hazardous energy to be anticipated and safeguards to be designed to prevent future safety incidents. This can be illustrated by solder which, under stress, is subject to cold-flow. If the connection were to fail and result in a hazardous condition, then the failure would need to be prevented, or the consequences of a failed connection mitigated.</p>
--	--

**Reprinted with permission from the January-February 2010 issue of IEC E-TECH.**

# News and Notes

## EN 60950 Deadline is Approaching

The date of withdrawal/date of cessation for EN 60950-1:2006 is 1 December 2010, so products manufactured and declared in conformance with it will not be permitted on the EU market after that date. Certificates issued after December 1<sup>st</sup> must include EN 60950-1:2006 (Ed. 2) + A11. The modifications caused by A11 particularly relate to components.

(Information provided by Nemko. For more details, visit [www.nemko.co.uk/node/136](http://www.nemko.co.uk/node/136).)

## University of Wisconsin Annual Product Liability Conference

The University of Wisconsin (Madison, Wisconsin, USA) has scheduled its 22<sup>nd</sup> annual product liability conference for 28–30 September, 2010. Topics to be covered include:

- Product liability lawsuits;
- Consumer products safety improvement act
- Avoiding development of a “defective” product;
- Liability and risk assessment of materials;
- Liability and nanotechnology;
- Finding, selecting, and utilizing an expert witness;
- Principles for analyzing product defects;
- Managing warnings and instructions;
- What to do when learning of adverse information about suppliers’ products or processes.

For more information, visit:  
<http://epd.engr.wisc.edu/emaL451>.

## Call for Papers—2010 PSES Symposium

A call for papers has been issued for the 2010 PSES Product Compliance Engineering symposium. Requested are original, unpublished papers and tutorials on all aspects of product safety and compliance engineering, including topics such as these:

- Product-specific topics;
- Hazard-specific topics;
- EMC/RF;
- Components;
- Certification;
- Standards activities;
- Research;
- Environmental;

- Demonstrations.

The symposium will be held 18–20 October, 2010 at the Boston Marriott Burlington hotel. The schedule for authors is as follows:

- Submission of intent to present, and topic, 30 June, 2010;
- Draft e-paper, 30 June, 2010;
- Notification of acceptance, 30 July 2010;
- Complete e-paper submitted, 30 August, 2010.

Prospective authors should submit e-papers using the on-line submission system provided at the symposium web site, [www.psessymposium.org](http://www.psessymposium.org). Comprehensive submission instructions at the web site include paper templates.

## News from Technical Activities Committees (TAC)

As you may have read in the previous issue, PSES has a secret—or maybe that should be HAD a secret—and that is its Technical Activities Committees. We now have five Technical Activities Committees up and running and several more in progress. We have room for as many as there is an interest in forming and we welcome suggestions for new ones. These committees serve the purpose of providing the connection of PSES to each of the many industry and technical groups which have an interest in product safety. It is beyond the capability of the PSES Board of Directors to know what is going on everywhere and where we need to focus attention. The Technical Committees serve that purpose for us and ensure that their industry groups are getting what they need from the Society. At present the following committees are active with monthly leadership conference calls and email lists either active or forming:

- Medical Product Safety TC (Dr Sandy Weininger, Chair);
- Forensic and Failure Analysis TC (Ivan Vandewege, Chair);
- Risk Analysis TC (Doug Nix, Chair);
- Telecom Safety TC (Peter Tarver, Chair);
- Computers and ITE TC (Gary Schrempp, Chair).

Continued on Page 8

---

In addition, interest has been shown for the following TCs which are now trying to form and become active: Laser Product Safety, Consumer Products, and Industrial Equipment and Control.

In case you didn't know, all it takes to form a TC is for a couple of leaders to step forward (only one needs to be a member of PSES) and find at least two others for a total of four—not all from the same organization or geographical area. Send me an email or give me a call and I'll set up an organizational conference call, and we'll go from there. It's really very easy and simple, and it provides an excellent way to hone your leadership skills, meet other leaders, and do something good for the PSES and your industry. We've got lots of help to give you and we'll get enough people involved so that no one has too great a burden. For my contact information and that of the TC Chairs, and for more information about Technical Committees, click on "Technical Committees" on the PSES home page ([www.ieee-pses.org/technical.html](http://www.ieee-pses.org/technical.html)).

Jack Burns  
PSES VP, Technical Activities  
[jburns@ieee.org](mailto:jburns@ieee.org)

### **TAC for ITE/Computers is Being Formed**

Any parties interested in contributing to the formation of this group should contact Gary Schrempp ([gary\\_schrempp@dell.com](mailto:gary_schrempp@dell.com)).

### **Medical Safety TC**

The Medical Safety Technical Committee implemented a listserv to share discussions regarding medical device issues. We were successful at the last PSES conference in assembling a dedicated track with topics on design, hazard analysis, and the standards landscape. Our current efforts are trying to get useful information into the listserv.

### **Risk Assessment TC**

Activities Report—May 2010  
Doug Nix, Chair

The Risk Assessment Technical Committee meets monthly to discuss risk assessment topics that relate to product safety engineering. We recently set our Field of Interest and our Mission. If these

areas of work sound interesting to you, please come to our next meeting!

### **Field of Interest**

The PSES Risk Assessment Technical Committee Field of Interest is the development and application of risk assessment methodology in the theory, design, development and implementation of electronic and electromechanical equipment and devices and the embedded control software and firmware used in those devices.

### **Mission**

The Risk Assessment Technical Committee is committed to becoming a center of excellence in risk assessment. The committee will pursue this goal by creating a core group of experts in the field to guide the activities of the Committee.

The TC will provide guidance and information to anyone who needs this information, including other PSES TCs, IEEE Societies, Standards Development Organizations, Regulatory Authorities, Certification Bodies, Producers of electronic and electromechanical products, and users of those products.

The TC will disseminate risk assessment knowledge to users through publication of papers and reports through the PSES, and by providing a source of speakers for Society and Chapter meetings.

### **Membership**

The Executive Committee of the TC is a fairly small group of individuals who are responsible for setting the tone and the agenda for the committee as a whole. I have been Chair of the TC for the last few months, but my recent appointment to VP Conferences means that I have had to give this role up. At our June meeting, Daren Slee from Exponent graciously agreed to take the Chair from me. I want to welcome Daren to this role. He is very experienced in forensic engineering and failure analysis and will bring much to the RATC in coming months.

RATC Chair: Daren Slee ([dslee@exponent.com](mailto:dslee@exponent.com))  
RATC Secretary: Tom Doyle ([tj.doyle@isafetyi.com](mailto:tj.doyle@isafetyi.com))  
RATC Communications: Steve Lawrence

---

(stelawre@cisco.com)

### Calendar

Our calendar is posted on the TAC page within the PSES Society site at [www.ieee-pses.org/technical.html](http://www.ieee-pses.org/technical.html). You can subscribe to the calendar to keep our activities updated in your personal calendar too.

### Work Program

The committee is drafting their initial work program now. Currently being considered for inclusion are:

1. Terminology—work on developing guidance on the correct terminology relating to risk assessment.
2. Scoring Tools—develop criteria for judging the effectiveness and usefulness of various scoring tools that are available (i.e. PHA, FMEA, FTA, HazOP, etc.), and then develop a list of reviewed and recommended tools for members to consider for use.
3. Develop guidance on selection of qualitative, semi-quantitative and quantitative risk assessment methods. How can you decide which approach to take? What are the implications of choosing one method over another?
4. Develop guidance on the output from the risk assessment process, and the communication of that information to the user.
5. Develop guidance on how to relate statistical measures of probability, i.e.  $1 \times 10^{-6}$  occurrences per year = ? in layman's terms?
6. Develop a link guide for risk assessment resources on the web.
7. Develop guidance on how to set risk assessment criteria based on the target market, i.e. consumer products vs. industrial products (workplace OHS) vs. medical products.

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!

This will be my last report as Chair, as my new duties as VP, Conferences are absorbing all the time I can make available this year. Thank you all

for the opportunity to get this important committee off to a flying start. I look forward to continuing to work with the group as my time permits. Please offer your support to Daren Slee as he takes over this strong group!

**The Telecom Safety Technical Committee (TSTC)** website and email list are being set up. TSTC meets the third Wednesday of every month at 8:00 AM Pacific time. Contact Peter Tarver ([peter.tarver@ericsson.com](mailto:peter.tarver@ericsson.com)) for details. Join our TSTC Subgroup of PSES on LinkedIn. Topics currently being worked on include:

- Cell phone base stations using inadequately vented VRLA batteries that have led to batteries overheating and exploding
- Safety of SmartGrid equipment
- Lightning strikes and ground potential rise
- Lightning strikes and equipment failures

### **VP, Conferences Report: Q2-2010 Doug Nix**

As many of you know, Richard Georgerian has been the VP, Conferences for PSES since the Society's inception in 2004. Richard was one of the key players in the EMC Society's TC-8, the forerunner of the PSES and was instrumental in the many events run by TC-8 and the PSES.

This year, Richard was forced to give up this important role in the Society for work and family demands, and the Board asked me to step in for the remainder of Richard's term. After organizing last year's Symposium in Toronto, I couldn't say no! I am taking on this role with excitement, and also with a deep awareness of the shoes I need to fill. I look forward to working with everyone who has been involved with our conferences over the years.

We had two main events planned for this year: Our first ever Summer Colloquium in conjunction with the EMC Society Symposium in Fort Lauderdale, Florida in July, and our Annual IEEE Symposium on Product Compliance Engineering (ISPCE) in Boston this October.

Unfortunately, we were forced to cancel the Colloquium due to a very low number of paper submissions. We did not feel that it would be reason-

---

Continued on Page 10

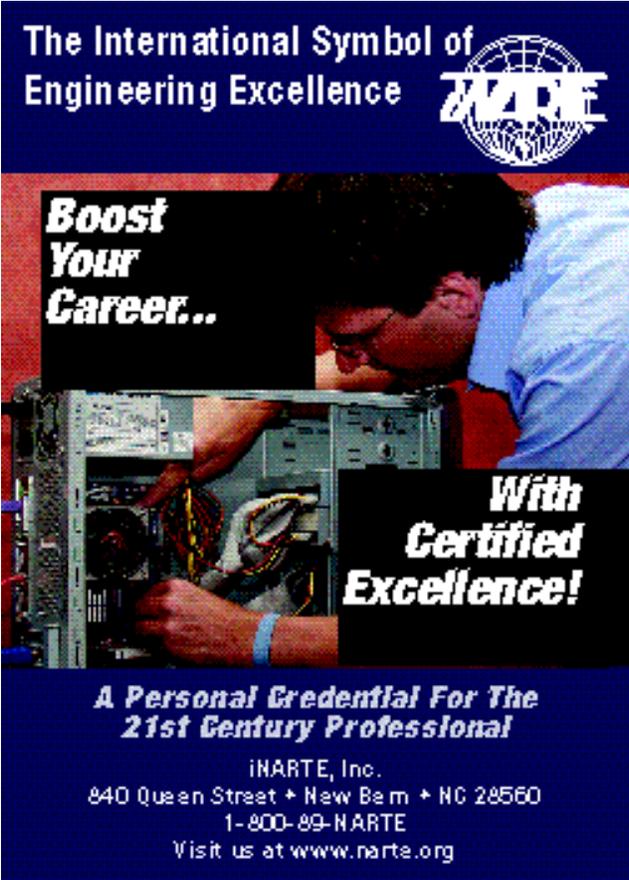
able to charge a significant entry fee and then provide only a very few presentations. Papers that were accepted for this event will be presented at the Symposium this fall.

Our Symposium Steering Committee is going full blast on the organization for this fall's ISPCE. They have chosen a great venue in the Burlington Marriott hotel in Burlington, MA, on the outskirts of Boston.

We currently have more than 30 papers registered with more coming daily. We are anticipating presenting 48-55 papers, tutorials, workshops and demonstrations this year. Deadlines for submissions of abstracts and drafts is midnight, 30 June, 2010.

In addition, our exhibit area has grown, and there will be more exhibitors and new vendors this year than ever before.

This coming year promises more challenges and more opportunities for exciting growth in our Society. Make this the year to get involved!



The International Symbol of  
Engineering Excellence 

**Boost  
Your  
Career...**

**With  
Certified  
Excellence!**

*A Personal Credential For The  
21st Century Professional*

iNARTE, Inc.  
840 Queen Street + New Bern + NC 28560  
1-800-89-NARTE  
Visit us at [www.narte.org](http://www.narte.org)

# MEDICAL ELECTRICAL SAFETY TESTING UNDER ATTACK IN THE U.S.A.

by Greg Smith

You're on the operating table, the surgery is almost over. The procedure has gone well. The doctors and nurses are walking in liquid on the floor covered with antiseptic, your blood, and other fluids. As your doctor is making the final repairs, a nurse is at the computer typing in some data; then she turns to assist the doctor, steadying herself with one hand on the computer monitor. As she touches the doctor, the faulty PC sends its stray current through both of them and directly into your heart. They feel almost nothing, but you are especially vulnerable, and in a few seconds, it's too late, the damage has been done.

How could this happen? Let's examine the situation more closely and try to determine what might have gone

as the *only* required evidence of product safety. (This is equivalent to the CE mark declaration of conformity). A national healthcare organization had worked hard to have leakage current requirements stripped from NFPA 99 (*Standard for Health Care Facilities*).

The hospital administration and the IT department had forced purchasing to order regular consumer-type computers for the operating rooms (ORs). The IT department had put a regular computer in a patient area, and the cord became pinched, causing the ground wire to contact a metal frame.

It's possible there were people on consensus document committees who allowed this to happen for "political"



Computers are everywhere in our healthcare facilities.

wrong. In this unfortunate scenario, a number of things happened because of what people and organizations did and did not do. A special interest group of foreign computer manufacturers had succeeded in pressuring the Occupational Health and Safety Administration (OSHA) into accepting a "manufacturer's declaration,"

or other unknown reasons. Some other people in healthcare safety knew what was going on, but were afraid to act against these organizations. So now, the healthcare provider's biomedical engineers were not allowed to test the computer. The doctors and nurses did not even think to consider whether they might not

Continued on Page 12

---

be safe to use in the OR environment. You had checked into the hospital not worrying about electrical safety of the equipment. In this story, you are now a victim of negligence and careless tampering with safety requirements. Too late.

This article discusses safety issues surrounding electrical equipment in U.S. medical applications from the perspectives of standards development, regulatory agencies, and healthcare provider safety engineering departments.

### **Can non-certified computers and equipment in hospitals kill patients?**

Product safety and biomedical engineering experts know the answer is “yes,” and so do designers and manufacturers of safety-certified medical equipment. Many injuries and deaths have been caused by non-certified equipment, no matter the location or the type of equipment. Computers are only one category. Why then would an organization like the American Society for Healthcare Engineering (ASHE) attempt to potentially cripple U.S. safety standards and pressure The Joint Commission (TJC) to have product safety testing stopped? At the same time, when it comes to the subject of inspection of equipment for U.S. certification and enforcement of existing laws, ASHE is silent. Why are ASHE and The Joint Commission not aggressively encouraging the proper testing and deployment of computer equipment in hospitals under existing regulations and safety standards?

The following is a quote from a letter written in February 2009 by ASHE to TJC. “This is a rather timely subject as ASHE is working hard to debunk a lot of legend behind leakage current and with it remove it from NFPA 99...Our proposal has passed the public comment stage and has been accepted by the technical committee. So we anticipate a significant reduction in requirements for the 2010 NFPA 99 ...and hope for elimination in the 2013 edition.” Clearly, this shows ASHE’s intention to reduce the present level of safety. It’s important to consider that ASHE likely has *no* electrical product safety professionals in their “working groups.” For now, the ASHE proposals have been rejected, but it’s likely this issue will come up again soon.

The Joint Commission, formerly The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), has also never taken a firm position on certification and testing of medical equipment; instead,

relying on each organization to police itself and attempt to identify and maintain safety-certified equipment. A search of the JCAHO website ([www.jointcommission.org](http://www.jointcommission.org)) reveals that there are no references to safety of electrical equipment, UL standards, certification or listing of equipment, or leakage current. Also, there is no mention of 29CFR 1910 Subpart S, which requires all equipment in the workplace to be listed or labeled by a Nationally Recognized Testing Laboratory (NRTL). The term *listed equipment* means that equipment is certified by a U.S. NRTL for compliance with applicable standards, in this case Underwriters Laboratories standard UL 60601.

If a piece of equipment is designed with improper grounding or the grounding is compromised, there is a possibility of harm to high-risk and other patients. Normal use of portable, cord-connected equipment can lead to the risk of leakage current due to wear and tear on cords and plugs. Also, if a connection plug is incorrectly re-attached, exposure to leakage current may result. Such conditions and the resulting leakage current can cause cardiac arrest.

Studies on the effects of leakage current on humans show that leakage current causes cardiac arrest in certain patients, especially high-risk patients. However, everyone involved with patients or present in these areas is exposed. For example, if a healthcare worker touches a piece of equipment with higher-than-safe leakage current and also touches the patient, both the patient and the healthcare worker will be put at risk. If a piece of equipment is worn or damaged, the likelihood of shock or energy hazard increases.<sup>1</sup>

### **Electrical safety standards for medical equipment**

For medical equipment, the primary U.S. standard for many years was UL 544, *Safety of Medical and Dental Equipment*.<sup>2</sup> This standard requires that power supplies be certified as protecting any low-voltage output circuits, and often sets requirements for medical grade cords, plugs and other components. UL 544 was a consensus product safety standard, and it was created with cooperation from product safety engineers, design and manufacturing specialists, medical/biomedical, and inspection authorities.

Products that met this necessarily strict standard became the best performers in healthcare in U.S. and international safety certification agencies. In the last edition of UL 544, leakage current for ground-to-chassis

---

was limited to 300 mA. Depending on the specific medical device, leakage current limits in this standard are as low as 10 mA. For example, a non-patient-connected device like a spirometer (connected to the patient by a plastic air tube only) is required to have a maximum of 300 mA leakage current from chassis to ground. With an electrosurgical generator on the other hand, the patient is in direct contact with applied voltage, so the limits are extremely low, in some cases as low as 10 mA.<sup>3</sup>

UL 60601 is the “harmonized” U.S. version of an international standard, IEC 60601. The U.S. version contains national differences to account for differing voltages and national regulatory requirements for the U.S. The leakage current limits and electrical safety requirements are very similar to the UL 544 limits. The Association for the Advancement of Medical Instrumentation (AAMI) standard,<sup>4</sup> used by biomedical technicians, is similar to IEC 60601, and requires a chassis-to-ground maximum of 500 mA. The advantage of harmonized standards is that they enable testing laboratories to more readily certify products for both U.S. and international requirements in a single evaluation. Despite some differences, the requirements for leakage current are now similar worldwide. Another result of this harmonization is that X-ray equipment, including portable X-ray units, is now subject to the 60601 requirements. NFPA99 has similar testing requirements and leakage current limits.<sup>5</sup>

### **Why is certain equipment not suitable for medical use?**

Why does medical equipment undergo different and more rigorous evaluation and testing than other categories of equipment, and why would unsuitable equipment be used in ORs, intensive care units (ICUs) and other patient care areas?

*Medical grade* equipment needs to be used in ORs, emergency rooms, ICUs, and all patient care and exam rooms. For medical equipment, added safeguards and testing are required. Listed medical equipment often has special markings, such as “Do not use in the presence of flammable anesthetics,” and “Grounding reliability can only be achieved with the use of a hospital grade receptacle.” When you see this kind of equipment and hospital grade receptacles in the facility, then it is likely that the facility management has required other equipment in these areas, such as computers, computer monitors, X-ray film viewers, etc.

to meet the requirements for medical use.<sup>6</sup>

Many pieces of equipment, such as microscopes or other laboratory equipment, regular “consumer” computers, office furnishings, or lights not listed for medical use, and many other products do not belong in these areas.<sup>7</sup> Still, there are many healthcare facilities that have no incoming inspection for equipment, or no one on staff who would recognize a *non-certified* piece of equipment. Many distributors do not even know the difference; while some do know and try to pass off CE marking as a certification mark. (CE is not a certification mark). Sometimes, physicians request very new or prototype equipment directly from a distributor or manufacturer, thus bypassing any purchasing procedures or incoming inspection by biomedical engineering that might be in place. Much of this new/prototype equipment has never been tested for safety, and can put the physician and the healthcare provider in the unfortunate position of potentially harming the patients they are trying to help.

In addition to more rigorous requirements for electrical safety, NRTL-certified devices have to meet requirements for electromagnetic interference and compatibility (EMI/EMC). This means that these devices have to be designed and tested to receive interference from other devices without malfunctioning, and have to function without interfering with other devices. Equipment not certified for medical use may not have to meet these requirements. Also, many devices not certified for medical use do not meet the requirements for enclosure construction, and they can be easily damaged by fluids commonly used in healthcare facilities. This compromising of a device with fluid ingress can lead to short circuits and shock, even electrocution.

### **Examples**

There are many examples of medical equipment suitable for use in patient areas. For instance, Cybernet ([www.cybernetman.com](http://www.cybernetman.com)) makes a medical grade computer, and Maxant Technologies ([www.Maxant.com](http://www.Maxant.com)) manufactures medical display workstations and equipment for healthcare patient and operating room environments. Both of these companies have their products listed to UL 60601. These manufacturers understand the certification requirements for products intended for use in healthcare facilities.

The following questions and answers are based on an interview with Brud Sturgis, President of Maxant

Continued on Page 14

---

Technologies.

**Q.** How does your experience and expertise differ from a computer manufacturer?

**A.** Unlike a manufacturer of general-purpose computers, we work closely with medical end-users to define use parameters and identify the proper product to meet specific needs. We have to understand in depth the nature of the healthcare delivery systems and how one modality differs from another. Our quality and design characteristics need to be of a higher standard in order to function in heavy use and lengthy periods of 24/7 use. We need to have the ability to communicate effectively with doctors and IT professionals to identify needs and configure the features of each product built.

**Q.** Are there companies selling non-medical grade product into this market in competition with you?

**A.** Yes there are...however most of the major computer manufacturers are issuing disclaimers in their product literature that their product does not and is not intended to meet medical use standards in patient care areas. These disclaimers and warnings are most often ignored in IT and purchasing decision making. Regardless, non-compliant equipment invariably finds its way into patient care areas, thus putting patients at risk.

**Q.** How do you ensure regulatory compliance?

**A.** We had to develop in-depth knowledge of all relevant regulations and requirements, then design and build units which are capable of meeting or exceeding these regulations. Every unit is tested prior to shipment to ensure that all rules and regulations are met.

**Q.** How does the added requirement of meeting rules and regulations (UL 60601 and others) affect costing and pricing decisions?

**A.** To navigate the quagmire of higher standards required in hospital, we work closely with federally approved nationally recognized testing labs. Considerable added component costs and manufacturing expenses are incurred to meet these requirements. For example, we are required to acquire and maintain sophisticated testing equipment and establish procedures to ensure that each product built meets all appropriate standards. Also, the quality and reliability of costly components must be ensured to meet the demands of high-use healthcare environments.

All these factors add considerable expense to the cost of goods sold, yet we still have to keep in mind severely limited end-user budget requirements.

### **Federal Law (OSHA) 29CFR1910**

This law requires that all electrical equipment in the workplace be listed or labeled by a nationally recognized testing laboratory. Some claim that it is OSHA's responsibility to police safety in the workplace. Electrical safety groups such as the American Council on Electrical Safety (ACES) have been working with OSHA to promote training of OSHA inspectors to enforce current laws, but it is an uphill battle for several reasons. Due to budget and personnel limitations, OSHA most often visits a workplace after someone has already died. The fact that OSHA does such minimal enforcement leaves the workplace owner with heavy liability for injuries and deaths. When there are incidents of this nature, the workplace owner is forced to bring lawsuits against equipment manufacturers and distributors, and anyone else responsible for bringing or allowing this equipment in the workplace. This can include inspectors, contractors, hospital safety committees, risk management directors, and others.

### **FDA: problems and misconceptions**

The US Food and Drug Administration (FDA) is a government agency concerned with many issues and areas, most having no bearing on safety of equipment. Although there are FDA requirements for medical equipment, these requirements are not generally related to electrical safety of this equipment, rather they focus on correct and reliable operation of equipment.

The FDA has an incident reporting database called MAUDE. While this database is interesting, it has no search parameters for electrical injury and death resulting from causes related to product safety. Additionally, this database is a *voluntary* reporting database for incidents, relying on a variety of sources. Many of these sources are people who have no training in electrical safety and are not even minimally qualified to judge the root cause of an incident, much less to determine if the incident was the result of leakage current. In the end, this database is not a reliable source for any scientific analysis of electrical injury or death from equipment.

The FDA also ignores the matter of electrical safety certification to U.S. standards. Perhaps this is because of the misconception that if a device *functions* correctly, it is thought to be electrically safe. Additionally, The

---

Project on Government Oversight reports that decisions by senior FDA officials in 2006 eliminated critical measures that keep manufacturers of medical devices compliant with high quality standards.<sup>8</sup>

In a regulatory bulletin provided by Bureau Veritas, it was revealed that under the provisions of legislation introduced in 2009 in the U.S. House of Representatives, manufacturers may face liability for medical devices that harm consumers, even if those devices received pre-market approval from the FDA. The proposed H.R. 1346: *Medical Device Safety Act of 2009* would amend the Federal Food, Drug and Cosmetic Act to provide legal recourse to patients who are injured by a medical device that malfunctions.<sup>9</sup>

Why is the U.S. Congress considering a bill that would allow lawsuits against FDA-approved products? Most likely because FDA-approved products have injured and killed, and the Supreme Court decision of 2008 was a grave mistake. As many of us in product safety are well aware, the FDA 510(k) Premarket approval process is a flawed and highly questionable regulatory requirement. As more product recalls are being reported by the media, Margaret Hamburg, the newly appointed FDA commissioner has said “there obviously have been some problems” at the Center for Devices and Radiological Health, and has designated device reform as “a high priority” for the immediate future. Former FDA Commissioner David Kessler described the device center as “dysfunctional” and “in meltdown.” According to the new FDA chief, “Agency scientists have said some devices that received 510(k) approval should have been required to show more data on safety and efficacy.”<sup>10</sup>

In addition to these problems, the FDA has historically ignored the requirements for electrical safety and federal workplace law. Obviously the FDA in its current state is an unreliable source for research or meaningful data on the subject.

### **Healthcare provider technical staff**

Healthcare provider biomedical/clinical engineering departments are a major force protecting our patients and healthcare staff. These specially trained technicians and engineering professionals work to ensure the safety and proper operation of equipment for procedures and operations. Their diligence and commitment to patient safety is generally unseen and under-appreciated, just as is often the case with product safety certification

professionals.

Biomedical engineers and technicians perform preventive maintenance of portable equipment. These duties include repair and maintenance (cords, leads, equipment subject to abuse, and so on), and leakage current, grounding and other tests, depending on the equipment being used. They also ensure equipment is operating properly so that patients will not be put at risk from faulty equipment. Grounding is the weak link and doorway to leakage current injury. Regular tests are critical to ensuring these conditions do not put healthcare workers and patients at risk. Frequency of tests required or recommended by product varies from three months to two years, depending on the type and use of the equipment.

Recent reports from these departments indicate a trend toward the use of regular, non-certified consumer computer equipment in patient areas, but their objections tend to be ignored by hospital administrators.

Scott Trombley is a Certified Biomedical Equipment Technician (CBET) who has been working in this field for over 25 years. He has worked with several hospitals, and is currently on the Agency for Healthcare Administration’s (AHCA) expert list and was a speaker at the 23<sup>rd</sup> AHCA seminar. Scott and his employer InterMed work closely with the biomedical advisory board of Santa Fe College. He is currently vice president of InterMed Biomedical Services where he oversees operations, employee safety and writes policy procedures to comply with authorities having jurisdiction (AHJs). These AHJs include The Joint Commission, Agency for Healthcare Administration, and city and county electrical inspectors. Here Scott provides answers for questions about leakage current and other testing in healthcare facilities.

**Q.** Why are leakage current tests performed and how often are they performed?

**A.** We perform electrical safety inspections (ESIs) routinely as part of an Equipment Management Program. Whether it is on a scheduled device, loaner, rental, patient or physician owned, or post-repair, it is common that our technicians perform this test daily, along with other tests. Each day, equipment fails these tests.

**Q.** What kind of test failures do biomedical technicians

Continued on Page 16

---

see, and what are the causes?

**A.** There are various reasons for the excessive leakage current: Degradation of components, which over time shows up as a relation of leakage to wear when the power supply or other components age or stress; abuse damage due to a variety of neglect or accidents including missing or broken ground pins, spillage from fluids that egress and evaporate leaving excessive current leakage, and defective power cords; instances where beds or other equipment may have damaged the conductors and cords. We see good systems connected by bad or inappropriate power strips, and we see inappropriate equipment for the patient care setting. All too often IT equipment intended for office or business use finds its way into the clinical areas. These conditions can only be avoided by regular testing and inspection.

**Q.** Do hospital IT departments bring in equipment not suitable for patient areas?

**A.** Unfortunately it is a common practice for doctors, purchasing agents, equipment representatives and IT departments to try to bring ordinary computer equipment into healthcare facilities and patient areas. Sometimes it's merely due to lack of knowledge of codes and standards. Sometimes the equipment bought in is certified, but not certified for patient area use—there is a big difference between medical devices and all other equipment. Since some of this non-certified and inappropriate equipment makes it into these facilities, we get a chance to inspect this equipment. What are the differences? Only an expert with the right background and tools can answer that question. OSHA and many states realize this and this is why codes and laws are in place.

**Q.** What about non-certified equipment?

**A.** The situation is the same with non-certified equipment. Most hospital administration departments and purchasing agents don't know the inherent dangers associated with unknown and untested devices. The types of equipment vary from EEG devices to neuro-stimulation devices, computers, printers—the list is extensive. Many of these companies know better and continue to sell uncertified equipment. I can tell you that most of the non-certified equipment I've seen required modification to be made safe. Grounding is a big problem in non-certified equipment, and grounding

problems lead to leakage current exposure.

**Q.** What is the perception of product safety in the healthcare environment?

**A.** I live and work in Florida where state code requires NRTL certification appropriate to the intended use. When we point this out, the responses I receive vary from concern for patients and staff to denial. Some worry about the legal aspects, others are genuinely concerned about compliance to state codes, but many others see no problems and will address problems IF they occur. I hear a lot of comments such as, "Everybody else uses it," or "We had one at the last hospital I worked at, and our biomed there never said anything." Of course, there are also many who will have any non-certified device inspected and tested; and although this can be a challenge, it is a wise and prudent choice and the only way to really protect patients and healthcare staff.

### **Deaths due to leakage current**

Many deaths due to electrical shock and current have occurred since the widespread use of electricity. In the 1960s, the issue of leakage current came to the forefront, resulting in the increased level of safety we now have in place.<sup>11</sup> There are many ways electrical shock can occur in a healthcare facility. Examples are: humidity in the plugs of blood and fluid heaters causing device failure,<sup>12</sup> accidental toppling of a fluid container causing spillage onto a blood pressure monitor,<sup>13</sup> electric shocks to anaesthetists after touching a faulty device and the chassis of another device simultaneously,<sup>14</sup> an anaesthetised patient connected to an ECG device that had been wired wrongly with the earth and neutral connections transposed.<sup>15</sup>

How widespread are cases of death by exposure to leakage current? This information is difficult to obtain due to several factors: Patients simply die of "heart failure" with no further detail provided. Many of these patients are high-risk, and are exposed to electrical equipment in regions of the country where hospitals may not have biomedical engineering departments and equipment. Many deaths go unreported or are incorrectly reported, but may actually be caused by leakage current.

### **U.S. NRTL product safety system, the CE mark, and SDoC proposals**

A U.S. nationally recognized testing laboratory is a third party agency which ensures that electrical products

---

meet a minimum level of safety. Conversely, supplier declaration of conformity (SDoC) and CE mark are not product safety programs. A current issue of serious consequence for healthcare facilities (and also consumers) is the repeated attempts by special interest domestic and foreign computer manufacturing groups to gain OSHA acceptance of SDoC. These special interest groups are again pressuring OSHA to allow these products to be sold on the market as equivalent of a U.S. listed product (UL or equivalent).

SDoC is a self-declaration program similar to the CE mark self-declaration. This means that a company from anywhere in the world can simply declare that their product meets the international electrical safety standards. In the testing laboratory business, we see these self-declared products come in for evaluation and certification for North America on a regular basis. Some of these products are so far away from being compliant that they represent an immediate hazard, especially for fire and electric shock. Recently, the EU has considered an additional product safety mark because of faulty, counterfeit and misrepresented products coming in from Asia. For the U.S., this SDoC program would mean that these cheaply made, non-tested products like computers will end up in our homes and in our healthcare facilities.<sup>16</sup>

*Fortunately, we still have the OSHA federal law for the workplace, 29CFR1910.303 and related sections which requires all electrical equipment in the workplace to be certified by an NRTL.<sup>17</sup> Robert Stickels has worked in electrical product safety for 20 years, including as a regulatory design engineer for NCR. He is currently the director of field evaluations for TUV Rheinland, and has personally inspected a great deal of medical equipment at numerous healthcare facilities.*

**Q.** When you are inspecting a non-certified piece of medical equipment, do you find test failures for leakage current? What kind of failures are you seeing?

**A.** Yes, I find test failures during leakage measurements. The equipment's components may or may not be certified. Many times I find components are certified and when combined into the end-use product, the product as a whole does not meet the leakage current requirement set forth in the medical standard. I see many failures between a few ~A to 4 mA.

**Q.** What kind of equipment have you found these

failures in? Patient area? OR? Emergency?

**A.** This equipment is found in all areas. Case in point, Heart Cathlab A/V integrated system failed leakage current tests. The problem was with power supplies. The power supplies were not rated for use with medical equipment, instead they were certified/listed to the ITE standard. A replacement power supply capable of delivering the current required by the monitor was not available. To fix the problem, a medical grade isolation transformer was used to reduce the leakage current to acceptable levels. Other systems of concern are patient beds, light fixtures, new types of procedure equipment, and others.

**Q.** What do the manufactures of this equipment say about these test failures?

**A.** Sometimes little or nothing; often the manufacturer simply states, "We have never run into this before," or "The equipment meets the NRTL requirements for the intended use." System integrators use what is cost effective and meets the immediate need. A/V equipment designed for medical area use typically may not be available; therefore, testing and evaluation by an NRTL is necessary.

**Q.** What do the owners of the equipment say about the failures? Did they know they were buying non-certified equipment?

**A.** It is buyer beware. Typically, the hospital and doctors do not have a clue; they only know what the equipment does as far as the procedure it's intended for. The equipment is tagged for evaluation only when compliance is required by a local AHJ, The Joint Commission, state agency or an internal hospital equipment acceptance procedure. Keep in mind that non-compliant equipment may range from as small as a relocatable power tap to OR equipment to equipment as large as a DI water chiller system used for dialysis patients.

**This fact remains: Equipment that is not suitable for medical use can put patients and healthcare providers at risk for electric shock and death.** To suggest that critical testing, such as leakage current, should be stopped is like arguing that since cars have airbags we can save money by removing seat belts. This is why the ASHE position on leakage current testing is especially troubling and dangerous. In their proposal to cut sections of NFPA 99, the organization

---

states that these requirements are being cut in order to “...manage risks while bringing efficiencies to the regulatory compliance burden faced by healthcare providers.” *In other words, this is being done simply to cut costs. Any “re-engineering” of NFPA 99 should absolutely consider the existing U.S. product safety standards, (e.g., UL 60601) and their scientific basis.*

As research has shown, **ac leakage current can cause complete cardiac arrest at low levels.** When an electrical product or system loses its ground, patients and staff are immediately exposed to the possibility of leakage current. Portable *listed* medical products employ heavy duty cords and plugs to help avoid the loss of ground; however, this condition is inevitable, especially when a piece of equipment is kept in service for many years.

Most people have a healthy fear of radiation, so no one questions the physicist coming in to check equipment that uses radiation. Ironically, since our track record with electrical incidents and deaths has improved because of the correct application of U.S. standards such as UL 60601 and NFPA 99, electricity has indeed become “invisible,” and because of this success the practices of electrical safety are being questioned.

With counterfeit products from Asia, and special interests pushing things like the SDoC program, now is the time for increased vigilance, not for softening or the elimination of time-tested safety standards and product testing. The ASHE attempt to influence JCHAO and dilute NFPA 99 should be closely scrutinized and their vested interest and motivations identified and monitored.

### **The laws of physics cannot be changed to suit a particular purpose**

Lives saved by accomplishments of product safety and hospital biomedical professionals are probably in the tens of thousands, and possibly more. The science behind prevention of death from electricity has guided the requirements of national and international safety standards. The history of electrical safety for medical equipment *is* the history of the U.S. industry, engineering, government, and testing laboratory professionals developing consensus safety standards. These requirements cannot be sacrificed to suit the plans of any special interest group. It’s a formula for disaster: *Politics + Electricity = Death*. Where electrical safety is concerned it’s better to abandon politics and just do the right thing. In the case of medical equipment and

electrical safety testing, we need to be allowed and encouraged to keep doing the right thing to protect our families, friends and communities.

*Greg Smith, NCE is a Product Safety Engineer with MET Laboratories Southeast. He has personally inspected and tested thousands of devices for MET Laboratories (NRTL), and has visited hundreds of healthcare facilities in the course of electrical safety evaluations. He can be contacted by e-mail at gregs@fieldlabeling.com and by phone at 919-524-4555. This article is adapted from one published in the November-December 2009 issue of the IAEI (International Association of Electrical Inspectors) News.*

### **References**

- <sup>1</sup> Swerdlow, C.D., and W. H. Olson, M. E. O’Connor, D. M. Gallik, R. A. Malkin, and M. Laks. “Cardiovascular Collapse Caused by Electrocardiographically Silent 60-Hz. Intracardiac Leakage Current: Implications for Electrical Safety,” *Journal of the American Heart Association*, (1999) 99: 2559–2564.
- <sup>2</sup> UL 544: Medical and Dental Equipment, 4th ed., Underwriters Laboratories, Northbrook, IL, 1998.
- <sup>3</sup> Eisner L, R. M. Brown, and D. Modi: “Leakage Current Standards Simplified,” *Medical Device & Diagnostic Industry Regulatory Outlook*, 2004.
- <sup>4</sup> ANSI/AAMI ES60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, Association for the Advancement of Medical Instrumentation, 2006.
- <sup>5</sup> UL 60601-1, *Medical Electrical Equipment, Part 1: General Requirements for Safety*, Underwriters Laboratories, Northbrook, IL, 2003.
- <sup>6</sup> UL 1950, *Safety of information technology equipment, including electrical business equipment*, 2nd ed., Underwriters Laboratories, Northbrook, IL, 1993.
- <sup>7</sup> American National Standards Institute, ANSI C101-1992: *American National Standard for Leakage Current for Appliances*, Underwriters Laboratories, Northbrook, IL, 1992.
- <sup>8</sup> “The FDA’s Deadly Gamble with the Safety of Medical Devices,” *Project on Government Oversight*, February 19, 2009.
- <sup>9</sup> S-540: *Medical Device Safety Act of 2009*, (HR 1346), 111<sup>th</sup> Congress of the United States.
- <sup>10</sup> Mundy, Alicia. “FDA Chief Eyes Device Group,”

Continued on Page 19

---

*The Wall Street Journal*, June 17, 2009.

<sup>11</sup> Bruner, J.M.R., MD. "Hazards of Electrical Apparatus," *Anesthesiology* 28, March-April 1967:396-425.

<sup>12</sup> Linko, K. "Testing a New In-Line Blood Warmer," *Anesthesiology* 52, 1980:445-456.

<sup>13</sup> Singleton, R. J., G. L. Ludbrook, R. K. Webb, and M. A. Fox. "Accidental Toppling of a Fluid Container Causing Spillage onto a Blood Pressure Monitor," *Anaesthesia and Intensive Care*, 1993.

<sup>14</sup> Singleton, R. J., G. L. Ludbrook, R. K. Webb, and M. A. Fox. "Electric Shocks to Anaesthetists after Touching a Faulty Device and the Chassis of Another Device Simultaneously," *Anaesthesia and Intensive Care*, 1993.

<sup>15</sup> Atkin, D. H. and L. R. Orkin. "An anaesthetised patient was connected to an ECG device that had been wired wrongly with the earth and neutral connections transposed," *Anaesthesiology*, 1973.

<sup>16</sup> *Federal Register* (at [www.osha.gov](http://www.osha.gov)). For more information on SDoC, go to [www.osha.gov](http://www.osha.gov) and type "SDoC" into the search box.

<sup>17</sup> *Federal Register*, 29CFR1910.303a and 29CFR1910.399, Subpart S.

---

## *Advantages of Membership in the IEEE PSES*

*Makes you part of a community where you will:*

- Network with technical experts at local events and industry conferences.
- Receive discounts on Society conferences and symposiums registration fees.
- Participate in education and career development.
- Address product safety engineering as an applied science.
- Have access to a virtual community forum for safety engineers and technical professionals.
- Promotion and coordination of Product Safety Engineering activities with multiple IEEE Societies.
- Provide outreach to interested engineers, students and professionals.
- Have access to Society Publications.



E-Mail List: <http://www.ieee-pses.org/emc-pstc.html>  
Virtual Community: <http://www.ieee-communities.org/emc-pstc>  
Symposium: <http://www.ieee-pses.org/symposium/>

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

---

# Chapter Safety Probes

To see current chapter information please go to the  
chapter page at:

<http://www.ieee-pses.org/Chapters/index.html>

## People Looking To Start Chapters

Denver Colorado

Richard Georgerian  
voice: (303) 833-2327  
e-mail: richardg@ieee.org

Japan

Hiroshi Sasaki  
hiroshi\_sasaki@jema-net.or.jp

Dallas Texas

Mike Cantwell, PE  
Sr. Account Representative  
Intertek ETL SEMKO  
420 N. Dorothy Dr.  
Richardson, TX 75081  
Tel: 972-238-5591 x107  
Fax: 972-238-1860  
e-mail: mike.cantwell@intertek.com  
or  
Bill Paschetag b.paschetag@verizon.net

North Carolina

Warren Fields  
ncps@bellsouth.net

China

Paul Wang  
paulwang@gmcompliance.com.cn

Southern California

Charles Bayhi  
bayhi@cpsm-corp.com

---

## Portland

The Oregon/SW Washington Chapter reports that their speaker for their June 22 meeting was Pete Perkins who discussed developments in standard 60950.

For the summer, our Chapter will join the EMC Society social event on a date a place yet decided.

The speaker for our September meeting will be Jim Pierce who will discuss grounding issues.

Elections for Chapter Officers will occur at our October meeting.

Future topics for October, November and beyond will be in areas of CE Marking, Product Labeling, PV Safety, PV Grid Intertie, Batteries, Hybrid Vehicles, and Forensics.

The PSES Winter Social will be in December (usually at Who Song & Larry's) to watch the lighted ships in the Columbia River.

IEEE PSES membership applications will always now be available at our meetings to encourage the visitors to join and share in the benefits of membership.

## LONG ISLAND

The Long Island Chapter meeting on Apr 20 was a huge success. Co-sponsored by PES/IAS, approx. 50 attended and many received CEU credit. The presentation slides, "Safety Aspects of Power Distribution Engineering" are now available on our IEEE PSES LI chapter website at: <http://www.ieee.li/safety/index.htm>.

## SANTA CLARA

On June 22, 2010 Meeting Topic was: Safety of Electric Vehicle Charging Equipment

The bold new world of electric vehicles is upon us. You have probably seen advertisements by now for a generation of all-electric vehicles coming to a showroom near you soon. SAE J 1772 will be the configuration for virtually all production electric vehicles allowing North American EV drivers to plug into any manufacturer's EVSE (Electric Vehicle Supply Equipment) and charge in a standards based environment. But what about the safety of electric vehicle charging systems? In North America, EVSE is subjected to requirements from the NEC, and UL standards. There are also IEC standards for electric vehicle chargers, but the connectors in Europe and the rest of the world have not been agreed upon. Find out what it takes to get an electric vehicle charging station certified and into the market place. You will learn what a 'CCID', '2nd neutral ground', 'level 2', and other mysteries of the EVSE world..

Speaker: Gary Eldridge, P.E.

Gary Eldridge graduated from Sacramento State University with a BS in Electrical and Electronic Engineering. Gary worked for Underwriters Laboratories from 1990 to 1997, and worked 2 years at Hewlett Packard. Gary also worked in the network industry for 2 years at Riverstone Networks before joining Apple Inc. where he worked for 5 years. In April 2009 Gary joined start-up Coulomb Technologies. Gary has worked in safety, EMC, forensic engineering and fire investigation.

The Santa Clara Chapter meeting topic for April was "How to avoid becoming the next Toyota" and it was a joint meeting with the Reliability and EMC Society local chapters. A panel discussion was held. They also had a meeting in May and the topic was "EU RoHS changes - What you need to know." Visit the chapter website at: <http://www.ewh.ieee.org/r6/scv/pses/index.html>.

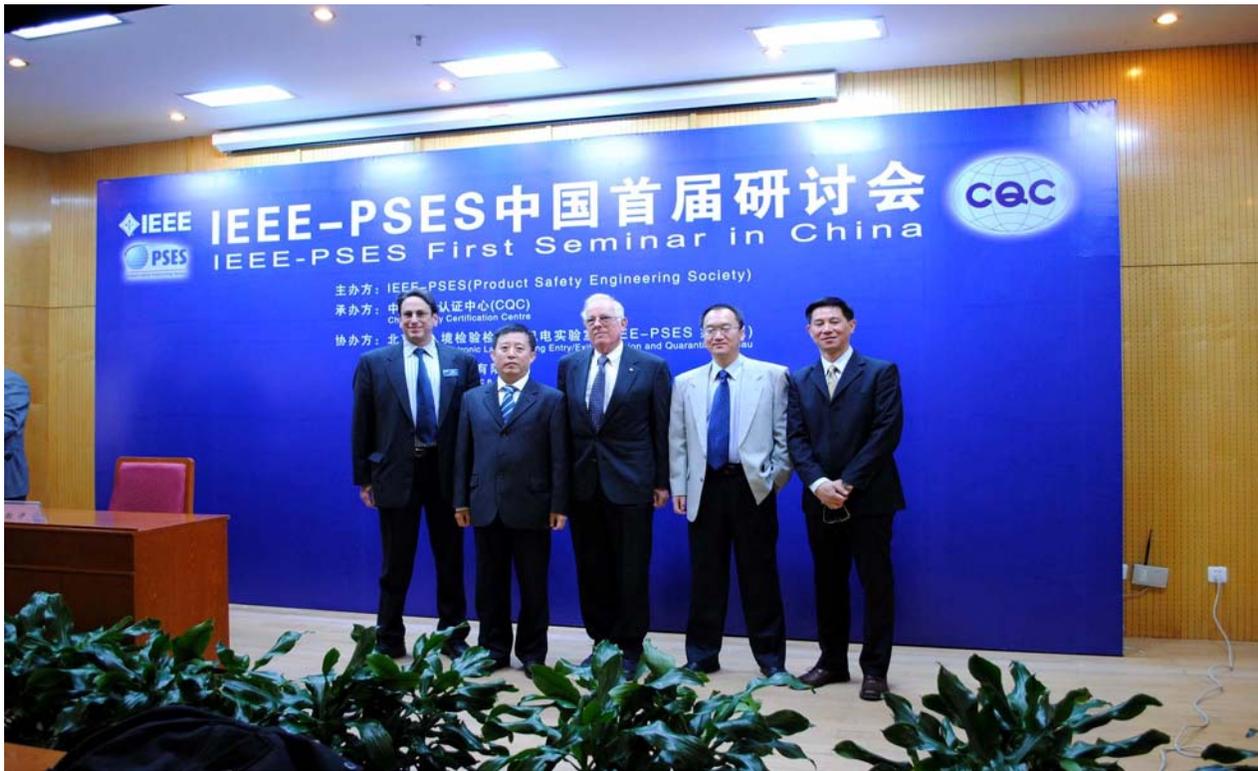
Continued on Page 22

# CHINA

## Workshop Signals Increased Chinese Involvement in PSES

April 17, 2010 marked the first PSES seminar to be held in China. The event was organized through the work of Paul Wang (G&M Compliance, IEEE Region 10 Director of Membership Development), CQC (China Quality Certification Center), and CQC-TS (test lab). More than 120 engineers attended the workshop, and seven topics were pre-

Chapter chair: Mr. Liu Yujun (CQC-TS)  
Vice chair for membership development: Mr. Limingming (CQC-TS)  
Secretary: Ms. Haolijuan (*Certification Technology* magazine)  
Treasurer: Ms. Cathy Geng (G&M Compliance)



From left to right: Mark Montrose (IEEE Division VI Director), Chen Wei (Vice President of CQC), Murlin Marks (President of PSES), Liu Fuguang (former Director of CQC-TS), and Thomas K. Ha (Vice President of PSES).

sented.

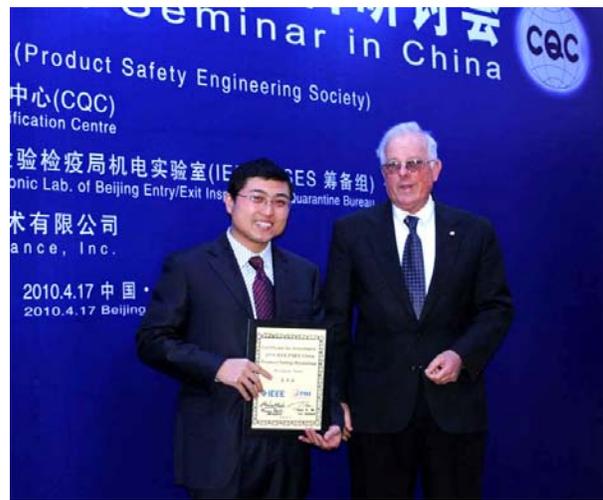
Paul Wang reports that preparations are under way to establish an IEEE PSES China chapter. The PSES bylaws for setting up chapters and chapter organization have been translated into Chinese, and a draft version of chapter regulations has been prepared in Chinese. The following individuals have been selected as candidates, with other positions yet to be confirmed:

Meanwhile, Mr. Mo Xiaofeng (CQC) is recruiting members from the CQC.

“Beautiful conference room, great food for breaks and luncheon, and the presentations were very high quality,” comments PSES President Murlin Marks. “We will submit the chapter petition ASAP,” says Paul Wang.

Contact persons:  
Paul Wang (paulwang@gmcompliance.com.cn)  
Ivy Wu (wuhn@cqc-ts.com)

Information for this article was provided by Paul Wang.



Paul Wang receives volunteer certificate from Murlin Marks.



Excellent facilities contributed to the successful meeting.

# Field Evaluation Services Group



**Providing Complete  
Field Evaluation Services**

Working with  
your every step  
of the way to  
ensure electrical  
equipment  
meets Electrical  
Safety Code  
requirements

**Accredited by the  
Standards Council of  
Canada**

**World Wide Service**



**Safety, Reliability and  
Peace of Mind You Can Trust**



**esaFE  
Services Group**

www.esafieldevaluation.ca  
1-800-559-5356

For scope of accreditation see  
www.esafieldevaluation.ca

www.esafieldevaluation.ca

Phone: 1-800-559-5356 or 613-271-1489

Fax: 1-800-559-5358 or 613-271-6441

field.evaluation@electricalsafety.on.ca



Continued on Page 26



Product Safety Engineering Society



# 2010 IEEE Symposium on Product Compliance Engineering

Sponsored by the IEEE Product Safety Engineering Society

October 18 - October 20, 2010  
Boston Massachusetts

## Call for Papers, Workshops, and Tutorials

### Technical Program

Bob Griffin, bobgriff@us.ibm.com  
Gary Tornquist, garytor@microsoft.com

### Conference Management/Registration

Chris Dyer, cdyer@conferencecatalysts.com

The IEEE Product Safety Engineering Society seeks original, unpublished papers and tutorials on all aspects of product safety and compliance engineering including, but not limited to:

- Product Specific:** Medical, consumer, computer (IT), test and measurement, power supplies, telecommunication, industrial control, electric tools, home appliances, cellular and wireless, etc.
- Hazard Specific:** Electrical, mechanical, fire, thermal, chemical, optical, software, functional safety, control reliability, product reliability, risk assessment, etc.
- EMC / RF:** Electromagnetic emissions, electromagnetic immunity, regulatory, Introduction to EMC/RF for the safety and compliance engineer.
- Components:** Batteries, insulation, optocouplers, capacitors, transformers, current-limiters, fuses, lasers, ferrites, cables, connectors, electromagnetic suppression & protection, surge protectors, printed wiring boards, etc.
- Certification:** Product safety, electromagnetic emissions, electromagnetic immunity, environmental, processes, safety testing, regulatory, product liability, etc.
- Standards Activities:** Development, interpretations, status, interpretations, country requirements, Laboratory Accreditation, etc.
- Research:** Body physiological responses to various hazardous energy sources, unique safeguard schemes, electrically-caused fire, forensic methods, etc.
- Environmental:** RoHS, WEEE, EuP (Energy-using Products), Energy Star, Packaging Directives, REACH (Chemical), CeC, etc.
- Demonstrations:** Demonstrations of product safety testing techniques including mechanical, electrical, fire, etc.

### Author's Schedule

Intent to present and topic	May 30, 2010
Draft e-paper	June 30, 2010
Notification of Acceptance	July 30, 2010
Complete e-paper	August 30, 2010

Prospective authors should submit e-papers using the on-line submission system accessible through the Symposium web site. Comprehensive submission instructions including paper templates are also available.



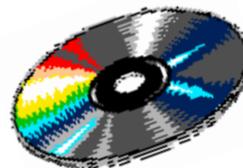
### Venue: □

Boston Marriott Burlington  
One Burlington Mall Road  
Burlington, MA 01803 USA  
Phone: □ 1-781-229-6565  
Fax: □ 1-781-229-7973



## Past IEEE-PSES Symposium Records

### CD Purchasing Information



SYMPOSIUM PAPERS ON CD:

The Product Safety Engineering Society continues to offer past symposium records for sale on CDs. 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:

CDs to be shipped to- ( Please print or type.)

Name: \_\_\_\_\_

Mailing address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

IEEE member number: \_\_\_\_\_

Shipping and handling: \$5 per CD

Payment: Check or money order.

Make Check or money order to: "IEEE Product Safety Society"

Quantity: \_\_\_\_\_ x \$35 = \_\_\_\_\_ for IEEE members

Quantity: \_\_\_\_\_ x \$50 = \_\_\_\_\_ for non-IEEE members

Specify what years you would like (2004 through 2008 are currently available):

\_\_\_\_\_

S&H: QTY \_\_\_\_\_ x \$5 = \_\_\_\_\_

Total = \_\_\_\_\_

Send payment to:

IEEE Product Safety Engineering Society  
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.

---

# New PSES Members from 29 March 2010 Through 16 June 2010

Our new members are located in the following countries: Australia, Austria, Belgium, Brazil, Canada, Chile, China, Costa Rica, Egypt, France, Germany, Greece, Hong Kong, India, Ireland, Italy, Japan, Kenya, Korea (South), Kuwait, Latvia, Malaysia, Mexico, Netherlands, New Zealand, Norway, Peru, Portugal, Singapore, South Africa, Spain, Sweden, Taiwan, Turkey, United Arab Emirates, United Kingdom, Uruguay, USA

Ahmad J Sebzali	Corey Jasper
Ahmed Gamal	Costas Sinanas
Alan Warner	Dale J Gutierrez
Alberto M Munante Aquije REP	Dane E Stone
Alexander Peniazev	Daniel Benta
Amir Geranmayeh	Daniel D Naugle
Andrea Cozza	David A Britton
Andreas Doblender	David C Cassano
Andrejs Romanovs	David H Gapp
Andrew M Terry	David M Mintzloff
Andrew Otieno Nyawade	David W Schreck
Angela P Ferreira	Dimitrios Parsinas Pylorof
Angelo Bruno	Duarte P Goncalves
Anindita Mitra	Fabio A Volonteri
Answer Sung	Felipe A Chacon-Vargas
Antonio Moreno Munoz	Fernando Caballero-Afonso
Antonio Luis Flores-Galea	Fernando Devis
Anurasiri Gamalath	Francesco Muzi
Argirios Tzakas	Francisco Garcia-Juarez
Arthur D Beun	Frank Jenkins
Arthur R Tilford	Fred Song
Ashok Golas	Frezier Anchia
Banadr AbdullAllah Alqahtani	Frieder Endrejat
Bernard C Fong	Gary B Johnson
Bharatbhushan P Joshi	Gee Keong Ong
Bradley C Rowe	Geoffrey A Hofmann
Brendan P Beahan	Geraldo P Caixeta
Brian D Oliver	Gerardo H Paladini
Brian E Bader	Ghislain Remy
Brian R Lamoureux	Giovanni Varasano
Bruce Hanson	Gold Region Tran
Byeong Kwon Park	Gonzalo Martinez
Byron Hamby	Graham J Barraclough
Carlos O Morales	Gregory D Hartzo
Cathy Geng	Gregory F Dix
Chandru J Mirchandani	Haldor T Husby
Cheng-Tsung Liu	Hantian Gu
Chia K Chai	Hector A Avila
Chia-S Shih	Hiram Escabi
Christopher E Kasian	Holger Richter
Christopher J Johann	Hulusi Karaca
Christopher J Murphy	HUNAIN DATTU
CLAUDIU CADAR	Ioannis John Melentis

---

Jack T Rowley  
Jacob McEvoy  
James A Guerry  
James C Smith  
Jan H Richter  
Jan W Vogelaar  
Jared M Gould  
Jean F Joubert  
Jeffrey Schowalter  
Jerry M Ricario  
Jim Kronrod  
Joe S Peeler  
Johan M Van Grootel  
Johann Amsenga  
John A Kay  
John B Rose  
Jonathan R Hinkle  
Jorge Bulcao  
Jorge E Fernandez Daher  
Joseph Wisnewski  
Joseph A Crispino  
Joseph A Kerfoot  
Josh S Zagorski  
Judith E Johnson  
Kevin J Hight  
King Wai Lam  
Koen Meersman  
LIJUAN HAO  
Mahmood Tabaddor  
Mark Keefe  
Md Ashraful Islam  
Mehdi Farrokhrooz

Mehmet T Soylemez  
Melih Pazarci  
Michael A Royer  
Mukhtar Ahmad  
Nallepilly V Mani  
Nataniel R Da Silva  
Nathaniel Candelaria  
R Lloyd A Gorling  
Rammohan V Maikala  
Rathna Kumar Devaraj  
Raymond A McCormick  
Raymond J Bishop  
Renzo Azaro  
Rodney G Parkin  
Roy C J  
Rudolf Haraksim  
San Bun Chu  
SATEESH MARAGANI  
Scott Aldous  
Shirley Cui-Tarantino  
Sik Y Cheung  
Srinivas Golakoti  
Sylvain Demers  
Teruo Azukizawa  
Thomas J Bajzek  
Thomas P Shefchick  
Wade Anthony Munsch  
Wei Wei  
Werner R Drexel  
William L Brown  
Yi Hong

---

The Product Safety Engineering Newsletter is published quarterly during the last month of each calendar quarter. The following deadlines are necessary in order to meet that schedule.

#### Closing dates for submitted articles:

1Q issue: February 1  
2Q issue: May 1  
3Q issue: August 1  
4Q issue: November 1

#### Closing dates for news items:

1Q issue: February 15  
2Q issue: May 15  
3Q issue: August 15  
4Q issue: November 15

#### Closing dates for advertising:

1Q issue: February 15  
2Q issue: May 15  
3Q issue: August 15  
4Q issue: November 15

#### **PSES Jobs Web Page**

PSES has a page on our web site for employers and job seekers at <http://www.ieee-pses.org/jobs.html>. Employers may post jobs seeking regulatory or compliance-related personnel free of charge. Job postings will remain on this web site for a period of 6 months but may be removed earlier by request of the employer.

Society members who are seeking jobs may list a description of the position they are seeking free of charge. A resume in PDF format may also be posted if desired. The listing will remain on this web site for 6 months, but the owner may submit a request to renew the listing every six months, indefinitely. It may be removed earlier by request.

See <http://www.ieee-pses.org/jobs.html> for posting policy and how to submit requests.

# Institutional Listings

We invite applications for Institutional Listings from firms interested in the product safety field. An Institutional Listing recognizes contributions to support publication of the IEEE Product Safety Engineering Newsletter. To place ad with us, please contact Jim Bacher at [j.bacher@ieee.org](mailto:j.bacher@ieee.org)

The Product Safety Engineering Society will accept advertisements for employment and place looking for work ads on our web page. Please contact Dan Roman for details at [dan.roman@ieee.org](mailto:dan.roman@ieee.org).

---

*The*  
**Product**  
**Safety**  
**Engineering**  
**Newsletter**

Gary Weidner  
GW Technical Services Inc.  
2175 Clarke Drive  
Dubuque, IA 52001-4125

**CHANGE SERVICE REQUESTED**