

# The Product Safety Newsletter



**EMC**  
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## Chairman's Message



We're beginning to receive a steady stream of responses to our recent announcement of impending organizational/defiliation changes to TC-8. The upshot of replies is that there is little consensus except on one point: the vast majority of respondents believe striking out as an independent society is not a good idea. Almost all proposed some form of affiliation with an existing organization, be it IEEE or some other organization.

While these organizational issues are necessarily very important and must be addressed, it is even more important that our organizational structure reflect what the emerging Product Safety group intends to accomplish (form following function). This vision for our future should be reflected in our choice of affiliation but must also reflect our constituency, addressing demonstrated and perceived needs and anticipating the future of product-related safety practice.

As I have shared in previous articles, the practice of product safety is continuing to evolve. Part of our constituency will stay in product certification activities although in time growth in this area may stabilize as multinational systems mature. Others will integrate product technical risk management where issues are not so black

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# The Product Safety Newsletter

*The Product Safety Newsletter* is published bimonthly by the Product Safety Technical Committee of the IEEE EMC Society. No part of this newsletter may be reproduced without written permission of the authors. All rights to the articles remain with the authors.

Opinions expressed in this newsletter are those of the authors and do not necessarily represent the opinions of the Technical Committee or its members. Indeed, there may be and often are substantial disagreements with some of the opinions expressed by the authors.

Subscriptions are free and may be obtained by contacting "Subscriptions", below.

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# Mexico Changing Standards Systems

*by Erin McLaughlin, Engineering Team Leader,  
Underwriters Laboratories*

The Mexican certification system has continued to evolve and change over the past year since the passage of the North American Free Trade Agreement.

An example of some of the changes taking place is the standards system. Basically, the Mexican government eliminated the existing standards or Normas Oficiales Mexicanas (NOM) and began to publish new standards in October of 1993. Since that time, several new NOM's have been adopted and, numerous draft standards are out for comment now.

Shortly after the restructuring, four basic appliance standards were published that cover quite a few electrical and electronic products. These are:

NOM-SCFI-001-1993, Electronic apparatus-electronic apparatus for domestic use supplied by different sources of electrical energy-safety requirements and test methods for type approval.

NOM-SCFI-003-1993, Safety of household and similar electrical apparatus for use in the office supplied by different sources of electrical energy- safety requirements and methods.

NOM-SCFI-019-1993, Safety of Data Processing Equipment.

If a product is covered by an adopted NOM standard, then NOM certification must be obtained to legally import or sell the product in Mexico. Products that need certification must



first be taken to a Mexican testing laboratory accredited to perform the tests required for the particular product. Approximately 140 Mexican labs are accredited to perform test in specific product categories. (As an alternative to submitting directly to Mexican

laboratories, manufacturers can utilize non-Mexican intermediary organizations to handle the submittal process for them.)

Upon completion of the investigation, a report containing test results is issued by the testing laboratory. This report must then be submitted to an appropriate certification agency for the NOM certification.

There have also been significant changes in the bodies responsible for certifying products in Mexico. Certification indicating compliance with NOMs used to be carried out exclusively by the Mexican government agency known as Direccion General De Normas (DGN). Under the new product safety certification scheme, the Mexican government has accredited the Asociacion Nacional de Normalizacion y Certificacion del Sector Electrico (ANCE) to certify electrical products and the Normalizacion y Ce tronica, A.C. (NYCE) to certify electronic products. Therefore, the applications for certification may presently be submitted either to ANCE, NYCE or DGN depending on the product category.

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# Area Activities



by John Reynolds

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## Santa Clara Valley Chapter

The January 24th meeting of the Santa Clara Valley Chapter PSTC was covered by our newsletter editor Roger Volgstadt. The following are his notes.

Larry Todd of ETL, Laslua Hasenau of TUV Rheinland of N.A. and Gene Ranger of TUV Product Services each gave a short presentation on the requirements for applying the CE marking.

Larry spoke first and noted that in the European Community (EC), there are many directives related to the CE marking. Only three are of interest during this presentation:

1. Machinery Directive, effective 1/1/95\*
2. EMC Directive, effective 1/1/96\*
3. Low Voltage Directive, effective 1/1/97

(\*The effective date on the directives is before the transition period on each ends. So to be precise,

the above dates are the close of each transition period.)

Larry defined a Directive as a general EC law that requires member states to pass laws that implement the requirements of the Directive. The Directives do not tell how to implement or determine compliance with the requirements of the Directive.

The reason for the directives is as a result of the following:

1. The treaty of Rome in March of 1957 prevented member states from blocking trade. (There were exceptions to what laws the member states could and could not pass.)

2. The Single European Act of 1987 removed all barriers to trade by the end of 1999.

Larry then gave guidelines to determine which directive to use.

1. Use the Machinery Directive if machinery is an assembly of linked parts, at least one of which moves. The exception is that for machinery in which the risks are mainly electrical in origin, such machinery shall be covered exclusively by the Low Voltage Directive. (The judgment of which directive to use is to be made by the manufacturer.)

2. The EMC Directive applies to apparatus liable to cause EM disturbance or the performance of which is liable to be effected by such disturbance.

3. The Low Voltage Directive applies if the product is designed to be operated from a source in the range of 50 to 1000 Vac and 75 to 1500 Vdc,

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# Technically Speaking

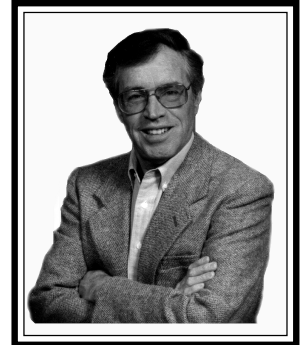
## Two Measures, Two Levels

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The Introduction to IEC 950 states, “It is normal to provide two levels of protection for OPERATORS to prevent electric shock caused by a fault.”

A colleague states, “The basic principles for protection against electric shock in IEC standards is to provide two measures of safety. This means, if one fails, then the product or installation still is safe.”

These phrases have been used for many years in many other publications. What is a “level of protection”? What are “measures of safety”? Why do they apply only to electric shock and not to other injuries?

\*\*\*\*\*

I’m afraid that these phrases don’t mean much to me. I don’t know what a “level” is as used in this context. Likewise, I don’t know what a “measure” is. These words are vague and abstruse in these contexts. We must discuss something much more concrete if we are to understand the idea of two “levels” or two “measures.”

Let’s examine various sources for electric shock. If we consider the common flashlight battery, we find that we are dealing with an ELV (extra-low voltage) source. As a general rule, ELV is defined as a value of voltage which is not likely to render an electric shock. The value of the voltage is the protection against electric shock. Because the voltage source is a battery, there is no means by which the voltage can exceed ELV as a result of failure of the battery. No other protection against electric shock need be provided. The battery terminals can be accessible.

Therefore, in the case of the battery, there is but one “level” or “measure” of protection. We can now generalize this idea. Any conductive part whose potential does not exceed ELV is “safe” because it is ELV.

For the purposes of equipment construction, the world can be divided into two parts, ELV and non-ELV. Every conductive part of the equipment can be assigned into one of two classes. A grounded part is ELV. An isolated conductive part is non-ELV. A 3.2-volt, or 5-volt, or 9-volt, or 12-volt circuit is ELV.

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# News and Notes

by Dave Edmunds  
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## LEDUpdate

A proposed amendment is working its way through the IEC process which, if passed, will relax the LED Class I limits essentially to the Maximum Permissible Exposure (MPE) level. This would allow continuing sales of safe LED's and LED-based products in compliance with CENELECEN60825-1.

The amendment proposed a test condition which treats divergent sources less than the present one. A second test prevents decreasing safety margins for collimated lasers, but this would not affect LED's. Note, for LEDs not exceeding the MPE under non-magnified conditions, no labeling is required! There is one additional condition. If the power to the cornea exceeds the MPE when a magnifier of 2.5x or higher is used, then the product literature must contain a statement concerning this. (Remember, the MPE level is approximately 10% of the level which will produce damage in 50% of subjects.)

This was decided at an IEC TC76 Working Group I meeting in Washington, D.C. in February. Still to happen:

1) WG I must send the proposed amendment to IEC Geneva, for translation into French and distribution as a CDV to the TC76 member countries. (By early April)

2) Assuming a generally positive vote and no serious comments, TC76 should vote to proceed with a Draft International Standard (DIS) at the October 1995 meeting. The voting period should allow the results to be in and the amendment in force by 1 March 1996,

3) CENELEC has a parallel voting process which, we hope, will approve the use of IEC TC76's amendment for an amended EN60825-1 by 1 March 1996.

There is no guarantee of easy passage (or passage at all) of the CDV. Those of us (including, especially, the author) favoring passage will be working over the next several months to facilitate it. Again, stay tuned!

Dr. Joseph Tajnai, Hewlett-Packard Company Member of the US National Committee, IEC TC76 (408) 435-6331  
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## “International Product Safety News”

IPSN can be sampled via the Internet. Using the “gopher” client, point your gopher to: [gopher.eneews.com/Emagazines/alphabetic/all/ispn](http://gopher.eneews.com/Emagazines/alphabetic/all/ispn)

If you have World Wide Web access, point your browser to: <http://www.eneews.com/magazine/ispn>

Once there, you will be able to view the IPSN's current index and a sampling of articles as well as search and/or view the archives for articles of interest in back issues.

IPSN is the newsletter devoted to international product safety compliance. Founded in

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# Machinery Safety

## International & European Requirements

by Werner W. Paster, EUROCONSULT, INC.

### Introduction

Exporting firms face tremendous challenges to compete in today's global market place. Especially the manufacturers of industrial machinery who must meet the requirements of international standards such as the IEC (International Electrotechnical Commission) and the ISO (International Organization for Standardization). These standards are applied to equipment sold in Asia, Australia, the Mid East, Russia and Europe. It is crucial for an exporter to be knowledgeable of these standards, because compliance is enforced on a national level and imports may be held at the port of entry if they are not in compliance with the requirements.

### European Machinery Directive

As of January 1, 1995 the laws of the member states relating to machinery commonly known as the "European Machinery Directive 89/392/EEC" go into effect. Standards supporting the Machinery Directive have been harmonized to enable the proper application required for CE-marking.

The Directive is intended to cover all types of industrial machinery which it defines as "an assembly of linked parts, at least one of which moves....". Manually powered equipment, motor vehicles, passenger lifts and medical machinery are not covered by the Directive. The Machinery

Directive also states "where, for machinery, the risks are mainly of electrical origin, such machinery shall be covered exclusively by Council Directive 73/123/EEC (Low Voltage Directive)".

The Machinery Directive is a very comprehensive document containing all the essential requirements but it does not replace the need for individual standards, e.g., Electrical Equipment of Industrial Machines, IEC 204-1 1 EN 60204-1. In Annex I the Directive covers the essential health and safety requirements relating to the design and construction of machinery. It gives very specific requirements in the areas of controls, protections against mechanical hazards, required characteristics of guards and protection devices, protection against other hazards (e.g. fire, explosion, noise, vibration, radiation, laser and emissions).

One section which goes above and beyond of most of the requirements are the instructions. A detailed list of required instructions is provided in the directive and it is also required that this information is made available in the language of the country where the equipment is sold, as well as in the language of the country of origin. Included must be start-up, user, and maintenance instructions, which include servicing and repair.

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# Laser Safety Standards in Europe

**B.A. Tozer**  
**Lasermet Ltd. and City University, London, UK**

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## Continued From Vol. 8, No. 1, January-February Issue

### **INITIATION OF STANDARDS WORK IN EUROPE**

#### **Initiation by national bodies**

Each national standards body remains free to draft and publish its own national standards, subject to three provisos:

- a) the proposed work does not encompass a subject already covered by an existing Euronorm
- b) the proposed work is not already the subject of work in one of the three European standards bodies
- c) that, on notifying other member countries of the organization concerned, no other national committees express an interest.

If a European technical committee, or even one other member national committee, expresses an interest, then work will proceed on a European basis.

The effect of these provisions is that, to an increasing extent, new standards work is being initiated at the European or the international level, although it may well transpire for one reason or another that much of the drafting work will be carried out within one country.

#### **Initiation by European standards bodies**

The freedom of CEN, CENELEC and ETSI to start new work is in turn limited by agreements with ISO, IEC and CCITT/CCIR respectively, which are intended to prevent duplication of effort. Further agreements have been entered into between the European and the international bodies which are intended to speed up adoption of new standards internationally and to

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and white, but where decision nonetheless are. Additionally, the realm of product safety will continue to expand to include environmental and other issues and encompass complete cradle-to-grave product life; it is possible that historical emphasis on "traditional" mechanical and electrical hazards related to fast and relatively large energy transfers will diminish with advances in technological improvements in efficiency, etc. My perception is that most product safety practitioners are not on the cutting edge of these changes and may be ill-equipped for the future. It is important that an organization of professionals devoted to the improvement of the profession continue and grow.

We have been fortunate in that to date we have been free to allow any and all interested people to enjoy most of the benefits of TC-8 with no mandatory contribution on their part. Those of you who are fortunate to affiliate with a local chapter benefit from the face-to-face networking and relevant presentations that are valuable to your continued professional development. Our future plans will address the need to maintain and improve existing services while continuing to develop new and valuable ones.

Regardless of our affiliation, it is highly likely that there will be fundamental changes in our operations including the suspension of certain services (such as this newsletter) except to dues-paying members. However, human nature being what it is, if continued benefits will require additional commitment, the relationship of perceived benefit to cost will be an important factor in membership decisions. There is a broad range of

needs that could conceivably be met by a product safety professionals group. In light of this, I'd like each of you to consider the following and respond according to the instructions below:

1. What are the important features that you would expect of an organization of dues-paying product safety professionals?
2. Which of the features or activities of the organization would you be most willing to support with your time and energy?
3. To what extent would you actively support the creation and growth a local chapter of interested safety professionals in your area?

We are continuing to explore our options and will direct our emphasis toward alternatives involving affiliations with an existing organization. With regard to ongoing IEEE EMC Society affiliation, we are still negotiating with Society leadership to maintain as much continuity as possible; with regard to this newsletter, publication will continue otherwise unaffected except that, for the near term, it will not be an official IEEE publication.

Please provide your comments to one of the following:

- Brian Claes (fax: (510) 770-5548) or e-mail: (BClaes@aol.com)
- Product Safety E-Mail Forum: (emc-pstc @ ieee.org), or
- Roger Volgstadt, Newsletter Editor via e-mail: (volgstadt-roger@tandem.com) or fax: (408-285-2553)

-Brian Claes □

## Area Activities Continued from page 4

Larry noted that a manufacturer may have to comply with more than one directive (ie: the machinery and LVD.)

To get into Europe, a manufacturer may want to consider three levels of compliance when selling in Europe:

1. Get the CE marking to satisfy legal requirements.
2. Determine what the customer wants, i.e.: special reqmts. (just need a CE marking, but customers may require more.)
3. Product Certification, i.e., 3rd party backing.

The CE Marking requirements state that the manufacturer

1. must be compliant with all required directives.
2. some directives for allow self-certification or self-declaration
3. can use standards to determine compliance with the standards. If not comfortable self-declaring, a manufacturer can get 3rd party certification.

Laslau Hasenau of TUV added to what Larry said by saying that the Machinery Directive is applicable if a machine's hazard is not covered by any other directive.

Second, the CE marking is not for the entire world, but as an outcome from the treaty of Rome, the CE marking is addressing the internal affairs of Europe.

Lastly, Laslau noted that there are risks with putting the CE marking on a product that has not been fully evaluated. Specifically,

I. Rapid exchange of information regarding dangerous products.

*Consequences:*

1. The product is out of the market in all member states, i.e., would be rejected, not just one.
2. The Official Journal will publish identification of the offending product, resulting in negative PR.

II. Product Liability.

*Consequences:* Strict liability in tort gives the person who put the product into the market only a few defenses.

Laslau stated that the Competent or Notified Body has the responsibility to comply with the quality and competency requirements of:

-Accreditation  
-Testing  
-Certification  
Surveillance  
requirements



Requirements  
contained in  
EN 45000

The manufacturer can either do type testing or have ISO 9000 certification (if the manufacturer is within the EC) or do self-certification.

The product must comply with the quality (including safety) and reliability of the EN/HD product standards.

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in 1988, ISPN is relied upon by product safety consultants and professionals around the world, for timely updates.

Published 6 times a year, ISPN features news, information and resources about UL, CSA, and other NRTLs as well as updates about the international compliance scene including news of IEC, VDE, the TUVS, the CB Scheme, and the European Community.

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**July Safety Seminar  
in San Jose, CA**

The Northern California Chapter of the System Safety Society has announced its 1995 International System Safety Conference in San Jose California. "System Safety; The Hazard Control Methodologies for the Future" will be the theme of the 13th International System Safety Conference occurring July 12 through the 16th, 1995. This major event will congregate safety specialists from national and international companies and governments for five days to attend the technical sessions, exchange ideas, and make new acquaintances. For conference information call Michael Scannell at 408-742-9581.

Technical Sessions include an interesting variety of safety and safety-related subjects: Safety Analysis for Cleanup of a Super fund Site, Root

Cause Analysis for Failure Investigations, Safety of Quality Assurance Testing and Verification Programs, Facility Safety During Integrated System Testing, Safety Risk Management in the Mining Industry, Safety Analysis for the Transit Industry, Safety of Liquefied Natural Gas Fueling Facilities, Repetitive Trauma in the Workplace, Indoor Air Quality (Sick Building Syndrome), Laboratory Safety, Experimental Aircraft Safety, Safety of Commercial Space Launch Vehicles, Construction, Crane Society. To discuss technical material or submit a paper, call Terry Osborn at Phone 408-742-2310, FAX 408-756-4220. Final papers are due by June 1, 1995.

Any company interested in exhibiting please contact the Exhibit Coordinator: Glenn Koehler at Phone 408-756-2096, or FAX 408-756-1399.

To obtain further conference registration information, call Larry Fistolera at Phone 408-756-1657 or FAX 408-756-1399. Cost is noted below:

|                  | Before<br>April 1 | Before<br>June 1 | After<br>June 1 |
|------------------|-------------------|------------------|-----------------|
| Non Members      | \$200             | \$225            | \$250           |
| Members *        |                   |                  |                 |
| Co-Sponsors      | \$175             | \$200            | \$225           |
| Authors          | \$100             | \$225            | \$225           |
| Students         | \$50              | \$50             | \$50            |
| Walk In, Per Day |                   | \$75             |                 |

\*Member price also includes members of IEEE/EMC

(The following information comes from Chris McGough, Head of Approvals Group, KTL, in Hull, United Kingdom- Ed.)

**Continued on page 19**

Gene Panger began by trying to dispel some misunderstandings about the CE marking. His foil had the following quote:

***“The CE marking is only intended as a passport- a sign to market surveillance authorities “***

- Evangelos Vardakas of the European Commission’s DGHIIB- legislation and standardization: telematic networks.

Gene stated that the CE approach is simple

- Meet the requirements
- create and complete the documentation
- the person with the ability to bind a company to European liability signs the European Union Declaration of Conformity
- the manufacturer applies the mark.

For the LVD, Gene dispelled the following Myth:

Myth: “Now, self certification is available for the first time.”

Wrong! Self declaration has been around since 1973.

Question: “Why have companies been getting 3rd party marks for 22 years”

Answer: Liability, market differentiation and uncertainty.

Gene stated that the liability issue drove the GS mark. But we shouldn’t focus on this. The TUV’s of the world are in an Assurance market; a kind of “who says” business.

For the EMC Directive:

Directive written to accommodate manufacturers. There has been wide clamoring for competent backing- Independent and corporate labs.

Question: Why? Self Declaration is enough.

Answer.- Liability, market differentiation and uncertainty.

A brief question and answer period followed. Hand outs were provided.

### **Northeast Product Safety Society**

The January 1995 newsletter featured articles on “The Risk of Non-compliance in the European Union (EU) by David Lohbeck of TUV Rheinland and on ISO/IEC Guide 25 revision. In addition Page 1 of 5 the International harmonized standards published by CSA was reprinted in this issue.

The topic of the January 25th meeting was “International Compliance- Mexico and Europe”

### **Central Texas**

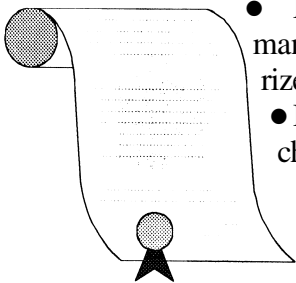
The December 7th meeting of the Austin Texas TC-8 Committee was held at International Compliance Corp., 2540 Brockton, Ste. 110 (Aus-

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## CE-Marking

The Declaration of Conformity is covered in Annex 2 and the CE-marking is covered in Annex 3 of the Machinery Directive. The CE-marking must be affixed to the equipment to demonstrate compliance with the Machinery Directive and its related standards. CE-marking will allow free movement of machinery between the member states of the EU (European Union), but a noncompliant product will be removed from the market. Equipment sold after January 1, 1995 must carry the CE-marking, must be accompanied by a Declaration of Conformity and a complete technical file must be available at the manufacturer or its authorized representative in the European Union.

The Declaration of Conformity must contain the following information:



- Name & address of the manufacturer or its authorized representative.
- Description of the machinery.
  - Year of manufacture
  - All directives applied to the machinery
- All applicable standards applied to the machinery.
- If required, all applicable approvals by a notified body.
- Identification of the person empowered to sign on behalf of the manufacturer or his authorized representative.
- Type approval by a notified body for more dangerous classes of machines such as presses and saws.

Notified bodies (national test houses) located within the EU are inspected by their national governmental authorities and upon approval they are “notified to the EU”. Only EU member states can qualify notified bodies within their countries. To be certain that machinery complies with the applicable standards we strongly recommend that a consultant with a European background become involved with the creation of the technical file and performs or supervises the necessary testing to the applicable standards.

## What Standards Must Machinery Meet

There are numerous standards published in conjunction with the Machinery Directive. These standards are identified as EN (European Norm), many of them are based on IEC standards which are often adopted with or without minor modifications. They will be published in English, German and French and will be adopted as national standards in the European Union and EFTA member states. There is a hierarchy of standards as follows:

Type A Standards (Fundamental Safety Standards) give basic concepts, principles for design and general aspects which can be applied to all machinery.

### Examples of Type A Standards are:

EN 292: Safety of Machinery - Basic concepts, general principles for design.

EN 292-1: Basic terminologies, methodology.

EN 292-2: Technical principles and specifications.

Type B Standards (Group Safety Standards) deal only with one safety aspect or one type

**Continued**

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of safety related device which can be used for a wide range of machinery.

Type B I Standards deal with a particular safety aspect, e.g. safety distances, surface temperature and noise.

Examples of Tyl2e B I Standards are:

EN60204- 1: Electrical equipment of industrial machines.

EN 418: Emergency stop equipment.

EN 954- 1: Safety related control systems.

Type B2 Standards deal with safety related devices, e.g. two hand controls, interlocking devices, pressure sensitive devices and guards.

Examples of Type B2 Standards are:

EN 574: Two hand control devices.

EN50100- 1: Electro sensitive protection devices, e.g. light curtains and safety mats.

Type C Standards (Machine Safety Standards) give detailed safety requirements for a particular machine or group of machines, identify the different types of machinery, itemize their hazards and risks and dictate which risk category shall be applied. The equipment manufacturer, not covered by a Type C Standard, will be required to conduct his own risk assessment and decide which risk category to apply to his machinery.

Example of a Type C Standard:

EN 60204-3-1: Particular requirements for sewing machines, units and systems.

The same principles are true and the requirements are nearly identical for other markets than Europe. The requirements applied are the IEC and ISO standards instead of their EN counterparts but the safety philosophy remains the same.

### **Risk Assessment**

There are basically two factors to be taken into account when assessing a risk.

1. The probability of the occurrence of an injury or damage to health.
2. The highest foreseeable severity of this injury or damage to health.

The analysis of the technical and human elements on which each risk factor is dependent is very useful for the selection of the appropriate safety measures, when designing the machine. There are numerous methods for conducting the risk assessment and they are invaluable tools for identifying the hazards, limit the risks and design safeguards against remaining risks.

### **Risk Reduction by Design**

The European and the international requirements and their safety philosophy rely heavily on the idea of risk reduction by design. This means avoiding sharp edges and corners, making machines inherently safe, limiting exposures to hazards through mechanization and automation of loading/unloading operations, and limiting exposures to hazards through location of the majority of setting and maintenance points outside the danger zones.

**Continued**

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EN292-2 states that "Risk reduction by design consists in following actions, used separately or combined:

- avoiding or reducing as many of the hazards as possible by suitable choice of design features, and
- limiting exposure to hazards by reducing the need for operator intervention in danger zones."

### **Precautions in View of Emergency Situations**

Each machine shall be fitted with one or more emergency stopping devices to enable hazardous situations to be averted. In machines where an emergency stopping device would not lessen the risk, an emergency stopping device is not required. Handheld portable machines and hand guided machines are also exempted.

Emergency devices shall have clearly identifiable, clearly visible and quickly accessible manual controls. They must stop the dangerous process as quickly as possible without creating additional hazards and where necessary trigger or permit the triggering of certain safeguard movements. After having been actuated, the emergency stop control shall remain engaged and only after disengaging it is permitted to restart the machinery.

To provide for the escape and rescue of trapped persons, precautions must be considered which include, e.g. arrangements for reversing the movements of some motors, and the moving of some elements by hand after an emergency stop has occurred. This would allow the freeing of a trapped person immediately after the emergency stop has been engaged.

### **Conclusion**

With the implementation of the European Machinery Directive by January 1, 1995 compliance to the Directive and its associated standards is mandatory. The CE-marking and the Declaration of Conformity will be a

requirement for all industrial equipment exported to the European Union.

In order to enable U.S. manufacturers to continue to export equipment after the January 1, 1995 deadline, a compliance program must begin immediately. For newly developed equipment it is crucial to apply the applicable EN and IEC Standards during the development phase and to design a universal model with the global market in mind.

Many buyers and distributors of equipment in countries throughout the world require compliance. EUROCONSULT has successfully assisted many companies with the preparation and completion of Declaration of Conformity, Letters of Compliance and third party safety approvals for their equipment.

*Mr. Paster is a registered Professional Engineer at FEANI in Paris, France, He also holds a Master's Degree in Electrical Engineer Telecommunications from Polytechnic University in Karlsruhe, Germany.*

*Mr. Paster has extensive experience with large European safety organizations and moved into a full-time consulting business when he founded EUROCONSULT, Inc. in 1990. EUROCONSULT provides a wide array of consulting services in the technical areas of industrial, medical and information technology equipment. Mr. Paster is also the US representative and authorized safety inspector of the German Notified Body, LGA of Numberg, Germany and a BSI certified lead assessor of Quality Management Systems.*

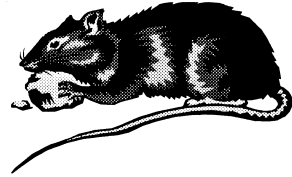
Mr. Werner W. Paster, Managing Partner,  
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## AND ON THE LIGHTER SIDE ...

(Our thanks to Dave Edmunds, News & Notes Editor, for alerting us to the following danger. No attempt has been made to verify the accuracy of the report. - Ed.)

“In retrospect, lighting the match was a mistake. But I was only trying to retrieve my son’s rat.” Dick Stone told doctors in the severe burns unit of San Francisco City Hospital.



Stone was admitted for emergency treatment after an attempt to retrieve the rat had gone seriously wrong. “My son left the cage door open so his rat, Vermin, escaped into the garage,” he explained. “As usual, it looked for a good place to hide and ran up the exhaust pipe of my motorcycle. I tried to retrieve Vermin by offering him food attached to a string, but he wouldn’t come out again, so I peered into the pipe and struck a match, thinking the light might attract him.”

At a hushed press conference, a hospital spokesman described what happened next. “The flame ignited a pocket of residual gas and a flame shot out the pipe igniting Mr. Stone’s mustache and severely burning his face. It also set fire to the pet rat’s fur and whiskers and which, in turn, ignited a larger pocket of gas further up the exhaust pipe which propelled the rodent out like a cannonball.”

Stone suffered second degree burns and a broken nose for the impact of the pet rat. His son was grounded for 6 weeks. (No word on the condition of the rat.)

And I thought I had a problem. ☐

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Mexican Standards, Continued from page 3

It should be pointed out the “NOM” certification can only be obtained by authorized local representatives. A local representative must be a Mexican entity with proven legal responsibility. This means that the certification is often obtained by the distributor or retailer.

Erin McLaughlin is Engineering Team Leader, International Compliance Services, at UL’s Santa Clara Office. UL maintains a staff in Mexico and assists Mexican certification organizations in the development programs and training. She can be reached by telephone at 408-985-2400, ext. 2671; by fax at 985-8653; and by e-mail: 5654376@mcmail.com



In these examples, protection against electric shock is provided by ELV alone. There is no second “level” or “measure.”

Next, let’s consider non-ELV sources such as the mains voltage. A non-ELV source is defined as a source which is Rely to render an electric shock. Electric shock is an insidious event. An insidious event is one that you cannot sense until the event occurs. You cannot sense proximity to an electric shock hazard.

Recall when you have received an electric shock. Most likely, the experience of electric shock was an unexpected event, was a surprising event.

On the other hand, the hazard of being cut by a knife is not an insidious event. It is not an insidious event because you can sense (see) the hazard before it occurs. You can sense proximity to the hazard.

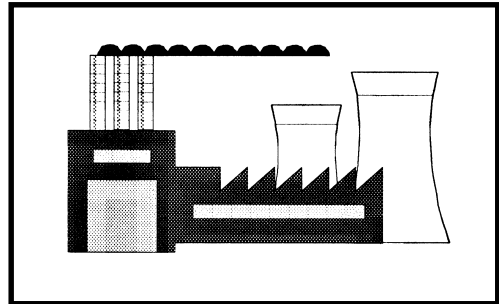
Most people become very anxious about hazardous situations which they cannot sense. This is so because if they cannot sense a hazard, then they cannot initiate any means to avoid the hazard. The situation is out of their “control.”

A good example of an insidious hazard is the ionizing radiation emission of a nuclear power plant. Ionizing radiation cannot be sensed prior to its causing an injury. Therefore, ionizing radiation is insidious. Since we cannot sense a radiation leak, we cannot control our safety. Consequently, we demand extensive safety construction for nuclear power plants.

On the other hand, a good example of an insidious hazard converted to a non-insidious hazard is natural gas. The odor added to natural

gas allows us to sense the presence of gas before its concentration accumulates to a dangerous level. In the event of a gas leak, we can sense the leak and a we can control the situation.

Finally, a good example of a non-insidious hazard is the burning of a candle in our home. We can see the flame, and we can control its location such that the flame is unlikely to cause a fire. Even in the event of the candle igniting



another fuel, we can usually control the situation before it gets to a non-controllable magnitude.

So, for most non-insidious hazards, we do not require specific safety construction. However, for most insidious hazards, standards require the situation to be safe not only during normal operation, but also in the event of a single fault. Where the consequences of the hazard are extreme, we require the situation to be safe in the event of multiple faults. Examples include the field of nuclear power, and the field of intrinsic safety.

For non-ELV sources, standards require insulation be interposed between such circuits and ELV parts, whether those ELV parts are grounded, are isolated, or are secondary circuits. Further- more, because electric shock conditions are insidious, standards require the construction to account for failure of that insulation.

**Continued**

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Note that the first constructional requirement that gives protection against electric shock is that insulation be interposed between the non-ELV source and the ELV part.

Regardless whether we are considering an overhead power line or a coffeemaker, the constructional requirement is that insulation be interposed between the non-ELV source and any other conductive part or the human body. In the case of an overhead power line, the insulation is primarily air, with solid insulation giving support to the wires. In the case of a coffeemaker, the insulation is comprised of both solid insulation and air insulation.

Let's now look at the issue of insidiousness. The outward manifestation of an operating circuit is its output in a form which a human can sense. This implies an output which can be detected by one of our five senses, seeing, hearing, feeling, smelling, and tasting. Normal operation of many electrical products results in something we can see, feel, or hear. Through these sense we can deduce that an electrical device is energized.

But, this is not always the case. Consider the overhead power line. How do you know if the power line is energized?

(Several winters ago, I was driving across the Oregon desert during a severe cold following a moderate snowstorm. I passed under two sets of big, overhead power lines, suspended from two sets of steel towers. The first set of power lines had snow and ice on the wires. The second set did not. Which set of power lines was surely energized?)

In most cases, there is no outward sign that a power line is energized. If the power line should fail and fall to the ground, how would we know if it was energized (assuming no sparks or other fireworks)?

If a coffeepot is not operating, there is no outward sign that it is energized. Even if it is plugged into an outlet, there is no outward sign that the outlet is energized. If the insulation of the coffeepot were to fail, how would we know?

These situations are insidious. They appear to our senses to be safe, but are not. So, our safety standards demand that products be safe from electric shock even in the event of failure of the insulation that was providing protection against electric shock.

There are three construction schemes for providing protection against electric shock in the event of failure of insulation:

- 1 Equipotential bonding construction.
  - a. Grounding.
2. All-insulated construction.
  - a. Double insulation.
  - b. Reinforced insulation.
3. Automatic disconnection of the source
  - a. Over current device.
  - b. Ground fault circuit interrupter.
  - c. Immersion detection circuit interrupter.

What about SELV (Safety Extra Low Voltage)? SELV is a special case of ELV. The special case is that the ELV is derived from a non-ELV source.

First, the ELV source, being derived from a higher, non-ELV source, must be maintained as ELV. Usually, this is determined by the turns-ratio of a transformer, or by the junction of a photo-transistor, or some other voltage-determining device. Usually, failure of voltage-determining characteristics of this device is ignored.

Continued

Secondly, the ELV must have insulation interposed between it and its higher, non-ELV source. The construction must account for failure of that insulation.

So, SELV actually has at least three and possibly four parameters that must be evaluated in its construction. First, the value of ELV. Second, the insulation between the ELV and the higher non-ELV. Third, the consequences of failure of that insulation. The fourth possibility is the evaluation of a fault that might increase the circuit value to greater than that of ELV.

My point is that the expression “two levels” or “two measures” is rather vague and abstruse. A better expression is that protection against electric shock is provided both for normal operating conditions and for the case of an insulation fault.

Promulgating the idea of “two levels” or “two measures” can lead to ignoring other factors that determine electric shock.

By the way, we apply the same principle to the issue of electrically-caused fire. We determine that the product will not ignite itself, or cause ignition of nearby materials, under both normal operating conditions and in the event of a failure.

\*\*\*\*\*

Your comments on this article are welcome. Please address your comments to the Product Safety Newsletter, Attention Roger Volgstadt, c/o Tandem Computers Inc., 10300 N. Tantau Avenue, Location 55-53, Cupertino, California 95014-0708. Or, e-mail Volgstadt-Roger@Tandem.com.

If you want to discuss this article with your colleagues as well as with the author and editor, e-mail your comments to  
emc-pstc@ieee.org.

### NET 2 Becomes Interm CTR2 for PTT Approvals in Europe

On February 17th, ACTE adopted NET 2, Layer I as the Interim CTR 2 approval for X.25 equipment. This move enables European Notified Bodies to issue pan-European approval for X.25 Packet Switching devices. There are no longer requirements under the Interim CTR 2 to evaluate layer 2 and 3 for European Economic Area approvals. As with ISDN Interim CTR'S, it is likely that full CTR 2 will continue to be developed and will be introduced at some time in the future. For now, under the Interim CTR 2, manufacturers have a choice whether to apply stated that they will upgrade national X.25 approvals to CE mark approvals upon request.

(The following comes from Dave Edmunds, Xerox Corp.-Ed.)

### New Your State Will Accept CDRH approvals

New York State code rule 50 (clause 50.7) has been revised so that laser equipment certified to CDRH Laser Product Performance requirements (21 CFR 1010 & 1040, Classes 1, 2, 2a or 3a) no longer need to be approved in New York State.

Copies of the revised code can be obtained from the following address:

Rita Aldrich  
Principal Radiophysicist  
NYS Department of Labor  
Bldg 12, Room 457  
State Officer Campus  
Albany, NY 12340  
Phone: 518-457-1202

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## Area Activities, Continued From Page 12

tin.) Speaker: Mr. Scott Barrows of International Compliance Corporation.

Program: Status of new Underwriters Laboratories Programs: COMPASS, Client Data, CAP.

The January meeting was a joint meeting of the IEEE Consultants Network at the Austin History Center. Program: "Product Liability from a Defense Attorney's Perspective" Speaker: Mr. Michael J. Crowley, Attorney. Mr. Crowley is name partner in the Austin Law Firm in Maroney, Crowley and Bankston.

The February 22nd meeting of the Austin Texas TC-B Committee was held at 2205 Grand Ave. Pkwy. in Austin. Program: Panel Discussion of the Committee Draft (TC-74) of the Proposed 4th Amendment of the 2nd Edition of IEC 950. Speaker/Moderator: Daniece Carpenter of Dell Computer.

### Colorado Chapter

Here I am pleased to present some more in-depth coverage of a local chapter by one of their own. Thanks to the efforts of Richard Georgian of Exabyte Corp. we have a picture of the activities of the Colorado area PSTC.

The Colorado Product Safety Technical Committee (CPSTC) held their meeting on February 7, 1995. It was hosted by Doug Barrett at IVIDN in Broomfield, CO.

The committee discussed: 1) Changing the meeting day from the second Tuesday to the first Tuesday of the month. 2) The committee is thinking about inviting a UL engineer from the

Northbrook office to give an overview on a yet to be determined topic.

We have suggested the following topics that UL can give:

- a) UL 2601 for medical devices
- b) Shock hazards- some history and research on shock hazards
- c) Implementation of the Bi-national standard
- d) UL 22 for gaming devices
- e) Hi-Pot testing - how repeatable is it after a certain amount of time a EUT has gone through the Hi-Pot station.

3) Randy Anderson of Ohmeda (Louisville, CO) gave the Feb. 7th meeting main topic. He presented an overview as to where EMC is going regarding the Medical Directive. He is involved with the IEC TC 62 group and is primarily working the issues specifically on IEC 601-1-2 (EN 60601-1-2).

The next meeting is being hosted by Ann Marie Doolittle of Qualmark on March 14, 1995. She is the Accelerated Reliability Test Center Manager for Qualmark. Qualmark designs and manufactures thermal/vibration systems; provides accelerated reliability testing services and consulting/seminars accelerated reliability techniques for HALT/HASS. Qualmark is located in Denver, Co.

Thank you Richard, Great coverage!

Well that is what I have from the area groups. Let me hear more from you.

Best regards,

John Reynolds □

The freedom of CEN, CENELEC and ETSI to start new work is in turn limited by agreements with ISO, IEC and CCITT/CIR respectively, which are intended to prevent duplication of effort. Further agreements have been entered into between the European and the international bodies which are intended to speed up adoption of new standards internationally and to minimize differences between international and European standards. These agreements ensure the following actions are taken. The case of EC/CENELEC is quoted

- (a) CENELEC may not start work which is already underway in IEC
- (b) Any new work undertaken by a technical committee of CENELEC must be notified to the IEC and offered to them. A time scale for completion is given
- (c) All work undertaken by CENELEC is notified to IEC and vice versa. On completion, standards developed in one body are offered to the other for adoption
- (d) IEC and CENELEC have harmonized their procedures for preparation and approval of standards. Draft standards are then put through simultaneous voting procedures.


The result of this is twofold: firstly, a dramatic speed-up in the rate at which standards can be adopted and, secondly, a reduction in the extent to which the standards differ at the technical level. Differences can arise, however, because CENELEC may agree to modifications to the IEC standard in order to reach consensus for its adoption as an EN. These developments have had the effect of encouraging the development of standards, first at international levels, with subsequent adoption at European and national levels. A UK view of the flow of laser equipment standards is shown in Figure 1, by way of illustration.

## **DRAFTING AND ADOPTION OF LASER STANDARDS IN EUROPE**

### **Recent trends**

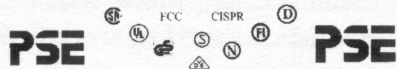
The strengths and weaknesses of the arrangements outlined above have both been illustrated by recent developments in the laser standards field. In 1989 CEN, armed with EC mandates to develop standards to implement a directive on machine safety, formed a technical committee CEN/TC123 with a wide-ranging brief to develop standards for lasers. This is a field which had hitherto been the undisputed territory of IEC, which had behind it the successful introduction of standards for laser safety, medical laser safety and for laser radiation measurement devices. Even a cursory glance at the current membership of the CEN/TC123 and CENELEC/TC76 committees show that the CEN/CENELEC aim to ensure that experts are not obliged to deal with a subject if more than one technical body has not been met.

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