What's Inside

Highlights from the Net

The Product Safety E-Mail forum provides a tremendous platform to ask questions of fellow safety engineers and voice your opinion on a variety of safety related topics. In this column, we’ll attempt to highlight just a few of the many informative messages showing up every day. If you’re not already a participant, read the instructions at the end of this column for getting on and getting educated. [Please note that the questions and answers have been edited to fit in the space available - Ed.]

LV Directive

Q: My products are considered “ITE”. Does anyone have any information on what test standards I will need to pass in order to demonstrate compliance to the LVD?

A: EN60950 ... is the European version of IEC950. If you are going to claim compliance with the LVD purely by virtue of compliance with the harmonised standards, you will need to comply with all standards whose title has been listed in the Official Journal under the LVD and which are relevant to your equipment. If you choose not to comply with any of these standards then after 1-Jan-97 you will have to have, before you can place the product on the market, a written justification that lists the standards that would apply and show, point by point, how the steps you have taken provide equivalent safety. This documentation must be lodged in Europe and available to the authorities on demand.

So far, over 400 titles have been listed in the OJ under the LVD, but this list is not as daunting as it first appears. There are a large number of

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The subject article was written in the beginning of 1995. In the mean time many new things have happened. This letter is just to update your readers on the subject CB Scheme.

The following three new publications by the CCB are now available.

1. **Revised Publication IECEE 002 (Draft):** Rules and Procedures of the Scheme of the IECEE for Recognition of Results of Testing to Standards for Safety of Electrical Equipment (CB Scheme).
   
   This document is being revised to include “Testing at Manufacturer’s Premises” (TMP), and “Supervised Manufacturer’s Testing” (SMT) as the MC has already approved them.


CCB has already announced that IECEE 03 will be published during 1996 as the MC has already approved the Full Certification Scheme (FCS) type programs. This publication describes details of the FCS. A questionnaire will be sent to all the NCBs concerning adherence to the new FCS scheme during 1996.

Following is a brief description of TMP, SMT and FCS:

- Under the TMP, all tests are carried out by the staff of the NCB or CBTL at the premises of the manufacturer. Manufacturer’s staff can not be used to perform any of the tests.

- Under SMT the staff of the NCB or CBTL witnesses tests conducted by the manufacturer’s staff. In the beginning 100% of the tests are witnessed. As the NCB gains confidence in the capabilities of the staff of the manufacturer, tests can be conducted by the manufacturer’s staff without the supervision of the staff of the NCB. In this situation, the NCB may spot check some of the tests if it so desires. The
Derivation of Ground Impedance

Copyright 1995 by Richard Nute
voice: (34) 3-582-13-89; fax: (34) 3-582-25-15
e-mail: richn@hpbpq6.bpo.hp.com

Did you ever wonder why we use 0.1 ohm (and sometimes 0.5 ohm) for the ground impedance value for plug-and-socket connected equipment? For years I wondered where that number came from. I asked all the experts I knew. I was referred here and there, but I never found the answer.

So, I started studying the grounding circuit. As with any such problem, I needed to put some bounds on the problem, state some operating parameters, and make some assumptions. For the purposes of this analysis, I assumed that the ground circuit of the equipment was truly connected to the ground system of the building installation. (This discussion does not consider the situation of the open ground.)

The grounding circuit, for the purpose of analysis, has three operating modes. The first mode is normal operation. In this mode, current through the body is prevented by the grounding circuit returning the leakage current directly to its source, thereby making the leakage current “inaccessible.”

The second mode is the first fault condition. In this mode, we presume a direct, zero-impedance short from the “live” conductor to the grounded parts of the equipment. The grounding circuit returns the fault current to its source, thereby causing the operation of an overcurrent device such as a fuse or circuit-breaker. Note that during the fault, the voltage on the grounded parts with respect to the local ground is one-half the mains voltage. This value of voltage is hazardous, either 60 volts for 120-volt systems, or 115 volts for 230-volts systems. For this mode, electric shock is prevented in the same manner as a GFCI, namely by very fast operation of the fuse or circuit-breaker to disconnect the voltage.

The third mode is the second fault condition. In this mode, we presume a finite-impedance short from the “live” conductor to the grounded parts of the equipment. The impedance of the fault is just slightly less than the maximum-time trip-current of the fuse or circuit-breaker. Recall that at twice rated current, fuses can take up to one minute to operate, and at four times rated current, circuit-breakers can take up to two minutes to operate. For this mode, electric shock is prevented by
Happy New Year to all! I hope everyone has an exciting and prosperous 1996!

The following is an overview of recent or planned activities for the various Local Groups around the USA. If you have any ‘activities’ information that may be of interest to readers, please forward it to the above address and I will try to include it in the next issue.

December Meeting:
The December meeting was held jointly with the Santa Clara EMC Society. A Test Methodology for the EMC Directive was discussed.

January Meeting:
Philosophy of meeting the Low Voltage Directive - Dave Adams, Hewlett Packard

February Meeting:

March Meeting:
HazOps and System Safety - Charles Hoes, Hoes Engineering
For additional information contact:
Murlin Marks
voice: 408-985-2400
fax: 408-296-3256
e-mail: 743141.3433@compuserve.com

Central Texas

December Meeting:
The December meeting was actually for November and December and was held at Seimens Rolm Communications in Austin, TX. The munchies and social were provided by the attending members.

The program consisted of a presentation on the European Union Machinery Directive by Charles Goertz. A questions and answer session followed the presentation.
“Vehicle Short Circuit Fires and Their Prevention”, was published in the August, 1993 issue of “Professional Safety”.

The author, Frederick F. Franklin sites NFPA statistics comparing vehicle fires (447,500) vs building fires (745,000) in 1989 as happening frequently. The use of fuses is discussed in relation to short circuit fires. He goes on to suggest replacing rubber hose sections with a coiled, expandable metal line tubing and reducing the size of fuses would likely prevent most accidental vehicle fires.

“The Role of the Canadian Standards Association (CSA) in Standards and Conformity Assessment”, was published in the January, 1994 issue of “ASTM Standardization News”.

John E. Kean, P.E., president of CSA traces the early years after World War I and the need for Canadian engineers to progress as an industrial nation. He further discusses CSA’s expansion of services, the move to quality, back to basics, and future trends.

“Can Your Dielectric Withstand the Test?”, was published in the December, 1994 issue of “Test and Measurement World”.

The author, Walter F. Hart, P.E., of Fluke Corporation discusses dielectric voltage withstand tests used to verify the safety in electrical and electronic products. The article references IEC 1010-1, IEC 664-1, IEC 60-1, and UL 840.

“Electrical Standards Go Global”, was published in the January/February, 1994 issue of the “NFPA Journal”.

The author, Edward R. Kelly, AMP Incorporated, discusses change on a global level in the electrical field. He covers geographical groups such as the European Community (EC), the European Free Trade Association (EFTA), the North American Free Trade Agreement, the North American Electrotechnical Standards Harmonization Council (CANENA), the International Standards Organization (ISO), and the International Electrotechnical Commission (IEC). The roles of governments clustering together to ensure reserved access to each others’ marketplaces is covered.

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Defining Basic Activities of Product Safety

by Paul W. Hill & Associates
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[We are grateful to the author for providing a series of condensed installa-
tions from his book "Managing Product Safety Activities", 1st Edition 1993. This text is a registered copyright of Paul W. Hill & Associates, Inc., and is reproduced with permission. Details about the book may be obtained by calling (407) 368-2538 - Ed.]

Before any effort is expended to establish, restructure or modify a product safety function it might be well to review exactly what such a function should be doing. If a product safety function is to have any real influence on the safeness of a product it must have a respectable capability in all of the following eight activities as a minimum effort.

1. **Formulation of minimum product safety requirements.**

This activity identifies the safety standards which must be met to satisfy mandatory safety certification requirements in the product’s marketing areas. The design objectives must always incorporate these safety requirements if the product is to be certifiable. In addition, the safeness attributes of the product addressed in the Section “How Safe Is Safe Enough?” must be considered.

2. **Communicating product safety requirements to product developers.**

If safety requirements are to be incorporated into a product some methods of communicating these requirements to product developers must be established. It is unreasonable to expect product developers to be knowledgeable about current safety regulations, test agency interpretations of requirements or regulatory agency demands. Without this communications link the necessary safety attributes may well be lacking in the finished product. It is essential that these requirements be made known early in the product development cycle to avoid certification delays and costly retrofits.

3. **Safety test and evaluation of products.**

It is never advisable to have the certification agency conduct the only safety evaluation of the product. The safety function will always face the testing agency query, upon failing a requirement, “What did you observe when you conducted this test?”. It is also well to remember that it is unrealistic to expect testing agencies to test each and every standard requirement, leaving open the risk of overlooking a latent defect which them makes its way into the user environment. Many safety tests are common to product development...
NEW PUBLICATIONS AVAILABLE

UL has a new publication “Practical Application Guideline for the Standard for Safety Information Technology Equipment including Electrical Business Equipment- UL 1950 second edition”. Copies may be ordered from UL offices.

A new publication IEC 825-3 Guidance for laser display and shows is available from ANSI for $61.00

ELECTRICAL SYMBOLS ON THE INTERNET

The following is extracted from the “Approvals Review” newsletter Vol. 8, No. 1, Winter, 1995, published quarterly by M.A. Lamothe and Associates, Georgetown, Ontario, Canada (Phone: 905-877-2203) and Ultratech Engineering Labs Inc., Mississauga, Ontario (905-569-2550):

Chiba University in Japan has all of the IEC 417 symbols available for download, either in graphical form or as a postscript file. The also list postscript file readers that are available for download or you can use a program such as Corel Draw to import the file as ‘Interpreted Postscript’. Point your browser to: http://www.hike.te.chiba-u.ac.jp/iec417/ver2.0/html/index.html

LASER LIGHT SHOWS FORBIDDEN

The US FDA has forbidden all outdoor laser light shows within 20 miles of any of the three major airports serving Las Vegas, NV. This prohibition will be in effect until the agency assures the displays will not impact aircraft safety. The levels for exposure is from a FDA recommended Guideline from titled Recommended Interim Guidelines FAA Order 7400.2D, Chapter 34.

PRACTICAL GUIDE TO ELECTRICAL PRODUCT SAFETY

New European rules ensure the safety of electrical products. The Low Voltage Directive applicable to most electrical equipment was amended to include CE marking.


The guide is in workbook format of 150 pages in a ring binder. Modules cover different aspects of electrical safety with quick guides and information on each topic.

The Guide is produced in association with APPROVAL magazine, covering all European Directives which affect the engineering industry. Call Technology International at 804-560-5334 for information about the Approval Guide.

From “European Community Quarterly Review”, 4th Qtr. ’95.

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The July/August issue of Microwave News had an article describing the draft report of the NCRP Scientific Committee 89-3, on Extremely Low Frequency Electric and Magnetic Fields (EMF), which will not be officially released until 1996. The USEPA funded the study, after criticism of its own 1990 report on the potential carcinogenicity of EMFs. This is probably the first time a draft NCRP report has been leaked prior to its official release. The current draft report has not completed the normal NCRP review process. This means that the conclusions and recommendations of the final report could be somewhat different.

According to Microwave News, the NCRP proposes a phased approach using the principle of "As low as reasonably achievable" (ALARA) often used in regulating other toxic agents such as ionizing radiation or chemical exposure. The phased approach would consist of three steps.

1. An interim exposure guideline of one microTesla (1 uT or 10 mG) would be adopted to reduce exposure in homes, schools, and offices over a period of three years.

2. After six years, there would be an option to reduce the guideline to 0.5 uT or 10 mG, based upon the availability of new scientific evidence.

3. After ten years there would be an option to reduce the guideline to 0.2 uT or 2 mG.

Other recommendations include use of a 0.2 uT exposure guideline for schools and for new transmission lines near existing housing, with a less strict guideline for new housing and offices.

This may be a good approach from a technical viewpoint, due to the uncertainty in risk estimates, but it is unlikely to be accepted by, or understood by the general public. Given the reaction of the public to other technical issues such as nuclear power, toxic and hazardous waste disposal, or other issues receiving extensive media coverage, the NCRP recommendations for a phased approach are not likely to be favorably received.

As various experts on risk perception have shown, the general public reacts more by how they feel about an issue, rather than by how they think or reason about the issue. The logical
tests and with preplanning many tests can be combined to save time, units of product in destructive tests and capital equipment. Some tests may be required during the agency certification and the ability to evaluation the item in question must be available.

4. Product certifications.

Safety certifications require assembling a considerable amount of documentation such as proof of listing or recognition of parts and materials, test data, photographs documenting construction, product changes, requirements imposed by follow_up services, and other paper work chores. The product safety function must be in position to provide these administrative tasks.

5. Maintenance of certification status.

Once certification has been granted the certification status of the product must be preserved as the product matures or changes. Upgrades, added features, materials modifications and engineering changes, or remanufacture will nearly always occur during the manufacturing life of the product. A procedure must be in place, acceptable to the certifying agency, which maintains the certification status throughout its production life.

6. Assessment of residual risks.

The product safety function plays and important role in providing management with assessments of residual product safety risks. It is most likely that management will rely on product safety test data, safety investigations, recommendations and proposals detailed in the section on “Acceptance of Safety Risks”.

7. Field safety incidents and product recall.

A field safety incident handling and product recall plan is essential to every safety function, particularly so if the product is accessible to or marketed to the general public. The product safety function will be deeply involved in any field incident or recall situation and should be fully aware of the regulatory agency requirements in this area. These requirements are detailed in the section “Regulatory Agencies Which Influence Product Safety”.

8. Professional development.

Product safety activities continuously grow in complexity as new technologies are introduced into products, new safety standards issued, and events that require more than a conversational knowledge in advanced materials, toxicology, ergonomics, environmental issues and ISO 9000 participation. Product safety practitioners can quickly lose professional competence unless an effort is made to remain technically competent in the profession. Several courses of action for maintaining professionalism are outlined in the section “Staffing”.

Having established these eight items as the minimum for a product safety function the next section will address the development of an operating plan which channels these capabilities to development of reasonably safe products.
The Product Safety Newsletter is looking for volunteers for the following:

- Administrative Assistance
- Newsletter Layout

If interested contact Roger Volgstadt, Editor, at (408) 285-2540.

UL now participates in the CB Scheme for IEC 601 (Medical Equipment), IEC 950 (IT Equipment) and IEC 1010 (Test, Laboratory, and Control Equipment). UL has already been pre-assessed for IEC 335-1 (Household Appliances). UL has recently requested an expansion of its application to cover IEC 730 (Appliance Controls) and IEC 745 (Hand-held motor operated tools) and will be requesting a pre-assessment for IEC 65 (Audio/Video Equipment).

Thanks and best Regards,

Lal Bahra

**HELP WANTED**

**URGENT**

The Product Safety Newsletter is looking for volunteers for the following:

- Administrative Assistance
- Newsletter Layout

Publication IECEE 04 (1995):

IECEE 04 describes the procedures of the CB Scheme as they apply to equipment for use in explosive atmospheres. A questionnaire on adherence to the IECEx scheme has already been circulated by the CCB. A start of the IECEx scheme is foreseen in 1996.

- Under the FCS, the manufacturer runs a compliance control program for his test equipment according to ISO Guide 25 and a product safety evaluation and manufacturing control program according to ISO Guide 53. A quality control program registered to ISO 9000 is an acceptable alternative. Here the NCB prepares a compliance control report in addition to the CB Test Report. The NCB generating these reports must sign contractual agreement with the NCB who accepts these reports and may conduct follow up inspection if the latter NCB so desires. Under the FCS there is no need for providing a sample to the NCB accepting the reports.
January Meeting:

The January meeting was held January 24, 1996 and consisted of a presentation on high voltage insulators and lab tour at 3M in Austin, TX.

For more information, contact:

Vic Baldwin  
voice: 512-990-6342  
fax: 512-990-6145

January Meeting:

The January meeting was held at CalComp in Anaheim, CA. Ercell Bryant, Compatibile Electronics made a presentation regarding CE Markings for the 90’s.

February Meeting:

Same location, no program scheduled at this time.

For information or comments, please contact:

Charlie Bayli  
voice: 714-367-0919

January Meeting:

The meeting was held in the Jackson’s Hole Bar & Grill in Thornton, CO. Some great activities for 1996 were discussed, including meeting date changes. Meetings will now be held on the first Wednesday of every other month. Activities planned so far are:

Feb: No meeting/activity  
Mar: Possible Coors Field Tour  
Apr: No meeting/activity  
May: Tour of Telsa in Colorado Springs

Other meeting ideas discussed and in the works are a speaker from OSHA discussing safety awareness in the office and a tour of a local poewr plant.

For information, please contact:  
Richard Georgerian  
phone: 303-417-7537  
fax: 303-417-7829  
e-mail: richard@exabyte.com

Still no activity in this area. Any one interested is encouraged to contact:  
Scott Varner  
voice: 360-817-5500 (ext. 55613)  
fax: 360-817-6000  
e-mail: 4777294@mcimail.com

That is it for this month.

Best Regards,
Kevin Ravo
perceived risk is felt to be too high by enough people, large scale opposition is likely to be generated, with consequent pressure on government to immediately reduce the risk, or to prevent the imposition of a new one.

The EMF issue is likely to have high Outrage Factors, and hence have a high Perceived Risk. This has already been seen in pressures to pass ordinances restricting construction of new power lines, or to force rerouting of existing lines. A number of lawsuits have been brought against electric utilities by individuals or groups claiming that their diseases, primarily cancer, have been produced by exposure to EMF at home or at work. Most of the suits have been dismissed by the courts for lack of a scientific basis linking exposure to specific health effects.

The release of an NCRP report containing recommendations similar to the ones listed in the Microwave News would receive wide media attention. Several outcomes can be envisioned;

1. The report might be seen as providing a scientific basis for health effects. This would change the atmosphere in the courts, and probably lead to more litigation about existing or planned power lines.

2. The public may not feel comfortable with a phased approach, but is more likely to want to move to the 0.2 uT guideline now. They prefer a simple safe/unsafe criterion, and in the face of uncertainty will seek more restrictive guidelines.

3. There may be a great demand to measure EMF levels in homes, schools, and workplaces. Levels above 0.2 uT will be per-
ceived as dangerous. Remediation will be difficult, expensive, and time consuming.

4. There may be pressure to pass legislation restricting EMF exposure, which could lead to regulations which are difficult to implement, and which may be ill-conceived from a public health viewpoint.

5. Unlike radon, there is a responsible party, namely the utilities, which includes the US Government. And there are deep pockets in terms of financial assets. This could produce a demand for major resource reallocation.

6. Anything else you can imagine.

Please note that the opinions expressed in the above article are strictly those of the author and do not necessarily represent those of the New York State Department of Health.

Mr. Condon is a Certified Health Physicist with over 30 years experience in radiation protection and environmental radiation monitoring. The Product Safety Newsletter editor wishes to thank Mr. Condon for allowing us to publish his comments in the PSN.

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HELP WANTED!!
The Product Safety Newsletter Committee is looking for someone interested in working on the newsletter layout.
If interested contact Roger Volgstadt, Editor, at (408) 285-2540.

“Building Consensus on International Standards”, was published in the January/February, 1994 issue of the “NFPA Journal”.

The authors, Paul E. Teague and Warren P. Russo explain the difficulty in obtaining consensus on diverse international standards. They discuss how standards can be looked at as business tools and more. Standards can be viewed as global marketing tools; making technology available to distant peoples; and can dramatically upgrade safety. They emphasize standards writing activity in Europe. The article also gives a primer on ISO and CEN. ■
limiting the voltage on the grounded parts to less than 30 volts with respect to the local ground.

So, I stated this mode as a rule:

The IMPEDANCE of the protective grounding circuit shall be of such value that, in the event of a fault, the VOLTAGE at any accessible part with respect to the supply-circuit ground point SHALL NOT EXCEED THE VOLTAGE LIMIT VALUE (30 volts) for longer than the maximum time duration trip-current of the overcurrent device.

The key to solving the circuit equations is knowing the maximum allowable voltage drop in the system. Discussing this with an electrical consulting engineer, I learned that electrical distribution systems are designed for a maximum 6 percent voltage drop at the equipment (i.e., at the socket-outlet) at maximum load. He went on to say that typical voltage drop is more like 2 or 3 percent.

So, now we know all of the parameters necessary to solve the problem. Knowing the allowable voltage drop in the system, we can calculate the resistance of the distribution system. For a 120-volt, 15-amp system, with a maximum voltage drop of 6 percent (i.e., 7.2 volts), the resistance of the system is the voltage (7.2 volts) divided by the current (15 amps). This is 0.48 ohms.

Next, we assume that half the resistance is in the ``line'' conductor, and half the resistance in the neutral conductor. So, each wire has a resistance of 0.24 ohms.

Furthermore, since the building grounding system is wired exactly the same as the line and neutral conductors, we can assume the ground wire is 0.24 ohms.

Now, we can calculate the impedance of the equipment ground. We know that the maximum voltage under a fault condition that doesn't immediately blow the fuse is 30 volts. We will assume that the maximum-time trip-current for a 15-amp branch circuit is 30 amps. The resistance of the grounded part of the equipment to ``real'' ground must be 30 volts divided by 30 amps, or 1 ohm. Since the ground wire is 0.24 ohm, the equipment ground impedance must be 0.76 ohm.

If we repeat the same calculations for a 15-amp branch circuit but with a maximum-time trip-current of 60 amps, then the equipment ground impedance must be 0.26 ohm.

I will leave it to you to calculate the equipment ground impedance for other trip-currents, other system voltage drops (e.g., 3%, 2%), and other voltages (e.g., 230 volts).

If you go through the calculations, you will find that:

1) As the overcurrent trip current increases, the equipment ground impedance must decrease to satisfy the 30-volt criterion.

2) As the system voltage drop decreases, the equipment ground impedance may increase and still satisfy the 30-volt criterion.

3) As the system nominal voltage goes up, the equipment ground impedance must decrease to satisfy the 30-volt criterion.

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Now, will these equipment ground impedances satisfy the short-circuit fault to ground? That is, is the impedance sufficiently low to quickly operate the overcurrent device so as to limit the duration of voltage on the equipment ground?

Let's look at the case of the greatest value of grounding resistance, 0.76 ohms. In this case, the maximum circuit current is the system voltage, 120, divided by the total circuit resistance, 1.24 (the sum of 0.24 + 0.76 + 0.24). The maximum current is 96.8 amps.

As the distribution impedance decreases, the short-circuit current increases. In 120-volt, 20-amp systems, with 3 percent system voltage drop, the short-circuit current will be about 250 amps.

I prepared a spreadsheet with all the variables and looked for the worst-case (least-value equipment grounding impedance) situation. The value of equipment grounding impedance is most critical when the system percent voltage drop is high. For example, for a 120-volt, 20-amp system, with 6% voltage drop, and 80-amp trip-current, the equipment grounding impedance must be no more than 0.2 ohms to hold the voltage to 30 volts.

For a 230-volt, 16-amp system, with 6% voltage drop and 64-amp trip-current, the equipment grounding impedance must be no more than 0.04 ohms to hold the voltage to 30 volts.

So, the equipment grounding impedance is important, and its value, 0.1 ohm, is reasonable. But, in the event of a fault, and until the overcurrent device operates, an electric shock can occur from the grounded parts.

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 56, Cupertino, California 95014-0708.

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

Newsletter
(author unknown)

Getting out this newsletter is no picnic
If we print jokes, people say we're silly
If we don't, they say we're too serious.
If we clip and use things from other papers,
We're too lazy to write our own stuff;
If we stick close to our regular work all day,
We ought to be out hunting up news and
taking pictures.
If we do go out and try to hustle up news,
We ought to be on the job in the office.
If we make a change in someone else's article,
We are too critical; and if we don't we're asleep!
Now, like as not, someone will say we swiped this
from some other paper. We did!
MEXICAN UPDATE

TUV Rheinland has established an office in Mexico and UL has established a working agreement with NYCE that allows them to process Mexican approvals.

All products must be tested in Mexico. Test labs in Mexico can accept testing done by houses like CSA, TUV and UL.

Basic requirements for Mexico are that all products entering Mexico must bear the NOM mark. The NOM mark is issued only to companies resident in Mexico. This means that you must work with an agent in Mexico as no company outside of Mexico can own the approval.

The new Mexican Electrical Code is based upon the US ‘National Electric Code’ and adopted Oct. 1994. Important electrical standards in Mexico are:

NOM-O19-SCFI-1993: Safety of Data Processing Equipment
NOM-003-SCFI-1993: Electrical Equipment - requirements for safety in electrodomestic products and similar equipment.

From ‘APPROVALS REVIEW’, Vol.7No.4, Fall 1995

LAB DATA--MICROPROCESSOR BASED CONTROLS
SAFETY EVALUATION

Safety related software investigations are not like safety investigations of conventional products. Yet, what UL learns from these investigations is very similar. What are the risks what parts fail and what is component integrity are questions UL asks about products. These questions asked of software may have more difficult answers but UL is answering them.

For software the challenge is to define properties that reduce risks and product failures. Total exercise of software is an insurmountable task. Software investigations include risk analysis, design review, verification and test as well as documentation review. For software these are more abstract and intangible than examination of physical properties. Industry uses standards like UL 1998, IEC 1508-Pt 3, and German DIN VDE 0801 for investigation of software failures.

From UL “On the Mark” Winter 1995

UPDATE ON THE CE MARKING AND ELECTRICAL COMPONENTS

Interim Action for Components

The following guidelines are valid for 1996 and new guides will be needed for 1997

EMC Directive:

- Apply CE to components with an intrinsic function and intended for direct sale to consumers.

Continued
Do not apply CE mark to components without intrinsic function or being sold to manufacturers.

Components that are ambiguous, prepare to apply the CE marking but wait for further guidance.

Low Voltage Directive:

Effectively does not start until 1997. Follow the procedures outlined above for the early years.

[Editors Note: The EC has yet to agree on consistent application of the CE marking for EMC and Low Voltage directives. When this will be completely resolved is unknown. Documents 958/08 and 959/03 published by Single Market Ventures provides some unofficial guidelines.]


WHAT IS AN SIC CODE IN THE USA. AND WHY MUST MY COMPANY PROVIDE THIS BEFORE RECEIVING ISO9000 REGISTRATION?

The Standard Industrial Code (SIC) is ``...the statistical classification standard...[which]...covers the field of economic activities and defines industries in accordance with the composition and structure in the economy.''

The SIC is a manual of codes published by the US Government. It provides a classification in which your business is engaged. All ISO9000 registrations are granted on the basis of specific industry sectors. ISO audits must be conducted by at least one member familiar with the industry under audit.


From ``TUV Rheinland World News'' - NOV/DEC 1995

TELECOMS APPROVALS SET FOR CHANGE

The European Commission is pushing ahead with plans to change the approvals regime for telecommunications. This is likely to entail a new Directive but at the moment, all the proposals are just internal working papers and have yet to be formally adopted by the Commission. The next step is for the Council of ministers to be consulted and agree the proposals. Then the proposed Directive will be put before the European Parliament. If everything goes smoothly, it will be about a year before there is a new Directive on the books.

The latest developments in telecoms approvals will be revealed in a conference sponsored by the Association of Designated Laboratories and Notified Bodies (ADLN) and organised by CommEd. It runs in Brussels on 26 and 27 March 1996 with a series of workshops on 28 March. Call +44(0)171 274 8725 for more information.

From "APPROVAL", Jan/Feb 1996.
standards that will not apply to your equipment such as the many parts of EN60335 that apply to particular types of domestic equipment and quite a few on lighting equipment. EN60950 is the only one that applies to ITE equipment as a whole but there are a fair number that apply to safety related components. If you wish to avoid having to justify the safety of the components, you should ensure that all components, the failure of which could cause a hazard, meet the listed standard. This includes fuses, fuseholders, switches, circuit breakers, power inlets and outlets, RFI power filters, transformers and wiring where these carry hazardous voltages.

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Laser Safety

Q: For the USA, is it mandatory that a CD ROM Drive conform to CDRH (Centre for Devices & Radiological Health) requirements on Laser Safety. Does Europe call for this as well?? What is the standard that CDRH recognizes. Is it IEC 825? If yes, is IEC 825 sufficient to enter Europe?

A: The FDA/CDRH spec. is 21 CFR 1040. The IEC spec. in this case is IEC 825-1 or EN 60825. The two are not the same, but you can run evaluation at the same time and place. One example of the differences is that the IEC spec. includes LED’s, the CDRH does not; but there are many more differences too.

CDRH has new Reporting Guidelines and Forms for Laser Products. Forms are available from the Division of Small Manufacturer's Assistance (DSMA) in Rockville, MD. DSMA automated system, CDRH Facts-on-Demand at: (301) 827 - 0111 or 1 (800) 899 - 0381

Other DSMA numbers are:

voice: (301) 443 - 6597 or 1 (800) 638 - 2041
FAX: (301) 443 - 8818

Information obtained from 27.Oct.95 letter from Joanne Barron, Regulatory Operations Officer, Office of Compliance, CDRH. [Author unknown]

More on Laser Reporting Guidelines

I prepared the following summary for clients last November, and those of you who are involved in the FDA/CDRH reporting and record-keeping may find it of interest.
REVISIONS TO CDRH REPORTING AND RECORD-KEEPING REQUIREMENTS - OCTOBER 1995

The CDRH published revisions to their reporting and record-keeping for laser products in October 1995. A Federal Register publication described the details of those changes. The CDRH also issued revised reporting guidelines for Product Reports and for Annual Reports. Copies of these documents are available from the CDRH [as noted in Carl Bergard's message earlier today].

REPORTING REQUIREMENTS

The report forms have been revised as follows: Initial Reports and Model Change Reports now use a common term: "Product Report", and that name is applicable for reports on entirely new models. The new reporting guideline is basically unchanged, but there are some minor additions and corrections.

Supplemental Reports are to be used for new products that are in the same model family as one previously reported, but which have somewhat different laser safety characteristics, or products which have been modified in a manner that would affect their laser safety characteristics. The appropriate sections of the Product Report should be extracted in preparing a Supplemental Report.

Products previously reported that have been modified in a manner that does not affect their laser safety characteristics can be listed in the Annual Report or in a quarterly update to the Annual Report. A Supplemental Report would not be needed.

One change that may be helpful is that manufacturers of Class I products which incorporate only Class I, IIa, II, or IIIa lasers need not file Supplemental Reports. Only the Product Report (or previously-submitted Initial Report) on the original product in that model family would be needed. (This was previously permitted only for products that did not allow access above Class I under any conditions.)

The Annual Report guideline has been revised, but it requires essentially the same information.

RECORD-KEEPING

The revisions to the record-keeping requirements are as follows:

The manufacturer or the distributor need not maintain distribution records of shipments for Class I products that contain only Class I lasers. (This was previously allowed under a CDRH Laser Notice but is now in the formal regulations).

For Class I products that incorporate only Class IIa, II, or IIIa lasers, the manufacturer must still keep distribution records, however, distributors no longer must maintain such records.
This is a relaxation of the regulations which will be helpful for some products.

Regards,
Bob Weiner
Weiner Associates
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E-Mail: 71020.734@@compuserve.com

HOW TO USE THE EMC-PSTC E-MAIL FORUM DISCUSSION GROUP:

1. How to Subscribe and Unsubscribe: The only way to subscribe is to send an e-mail message to:

   majordomo@@ieee.org

   and place the following command in the body of the message:

   subscribe emc-pstc your_email_address>

   (Do not include the brackets < or > ).

   The only way to unsubscribe (ie: remove your name from the EMC-PSTC) is to send an e-mail message to:

   majordomo@@ieee.org

   and place the following command in the body of the message:

   unsubscribe emc-pstc<your_email_address>

   (Do not include the brackets < or > ).

2. How to send a message to the EMC-PSTC discussion group: Simply send an e-mail message to the following address:

   emc-pstc@@ieee.org

   All mail sent to this Internet address will be immediately echoed to everyone on the EMC-PSTC list by an automated list server.

3. How to get help: To get more information about using the IEEE's EMC-PSTC discussion group, send an e-mail message to:

   majordomo@@ieee.org

   and place the following command in the body of the message:

   help

   Should you have any questions, you may address them to the following:

   Volgstadt_Roger@@Tandem.com
We are grateful for the assistance given by these firms and invite application for Institutional Listings from other firms interested in the product safety field. An Institutional Listing recognizes contributions to support publication of the Product Safety Newsletter of the IEEE EMC Society Product Safety Technical Committee. Please direct inquiries to:
Ervin Gomez at (408) 553-7684 (phone) or (408) 553-7694 (fax).
ADDRESS CORRECTION REQUESTED