

The



EMC SOCIETY

Product Safety Newsletter

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Chairman's Message



One of the goals of TC8 is to more actively associate with other IEEE societies. We're beginning to explore this opportunity and would like your perspective on the matter.

Why is this "expansion" important?

1. We can serve as the product

safety focus for interested individuals in other IEEE societies. Several societies have a substantial interest in product safety but have not had the critical mass to develop and support a dedicated function whose focus is safety. However, with the growth of quality consciousness and customer expectations driving safety requirements, the need is there.

2. We can look at product safety from new viewpoints. For the most part, our emphasis to date has been on hardware and "containment" of certain forms of potentially hazardous energy or chemicals within that hardware (electrical energy and fire for the most part). But are we addressing hazards arising from the system malfunctioning or operating in an undesired manner (undesired output creating risk of hazard)?

Some IEEE groups are already addressing some of these issues, such as the Software Safety working group of the Computer Society.

Who's addressing malfunctions not mentioned in product safety standards that could create hazards within the product? How are we avoiding these hazards not covered in our standards?

Who's addressing safety aspects of the human-machine interface. We have operated for many years with a simple "innocent" operator/ trained serviceman model. In reality, the relationship is much more complex. Some IEEE societies, such as the Systems, Man and Cybernetics Society, address human and system safety issues. We could benefit from their perspective.

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The Product Safety Newsletter

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News and Notes



by Dave Edmunds
News and Notes Editor

ITE Normalization:

A Bi-National group has been formed to harmonize the safety standards for Information Technology Equipment (ITE) and Telecommunication Equipment between Canada and the USA.

This group will be using UL 1950 (2nd edition draft), CSA 950 (2nd edition draft), UL 1459 2nd edition and CSA 225 1st edition as the basis for this work. The coupling between UL 1950, CSA 950 and IEC 950 will keep this effort in sync with the IEC TC 74 work.

The objective is to have a single standard published in 1994 that will replace the four standards currently used in Canada and the US. Projected is an effective date in the year 2000, but product certifications available in 1995.

We are pleased to announce that Rich Pescatore, the PSTC Vice-Chairman, is one of the 12 people on this bilateral group. Rich will be officially representing CBEMA in this task, but he will be interested in hearing from PSN readers.

If your product line (computers or other ITE that connects to the telecommunications network in Canada or the US) will be affected by the new standard, and if you can provide comments to assist Rich in his role representing the ITE industry, please send him a message. Include your name, telephone number and mailing address.

E-Mail Directory-

Members of the Northeast Product Safety Society would like to develop a directory of email addresses for use to contact other Safety professionals from time to time. Please send an email message confirming receipt of this message to verify access to you with the proper user email address.

This proposed electronic network can hopefully be used as an open forum on various subjects relative to the agency and regulatory compliance field or for specific discussions to a relatively small defined audience.

This network works best as more and more users get on to it. Therefore if anyone has other email addresses which can be shared with the safety network, please forward them to be summarized and made available to others.

Since the list of email addresses has only just recently been compiled, please do not just assume that they are 100% accurate.

Please contact:

Paul J. Smith
at the E-mail address
smith_pj*corp_st@msm.cdx.mot.com

CSA To Be NRTL:

CSA has made application to OSHA to become a Nationally Recognized Testing Laboratory. A notice in the June 3rd Federal Register requests comments by August 3, 1992. (Text of the application is reproduced starting on page 7.)

AT&T Introduces Export Hotline:

AT&T, in conjunction with several multinational corporations, unveiled a new information service called The Export Hotline. A fax information retrieval service, the service is designed to help U.S. businesses, especially small and growing

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Technically Speaking

ON LIMITED-CURRENT CIRCUITS

copyright 1991 by Richard Nute

In the March-April Issue of the product Safety Newsletter, a reader asked about where limited-current circuits are required (by IEC 950, Sub-clause 2.4. 1).

He noted that a 5-volt DC circuit will give 2.5 milliamperes into the 2 kohm test resistor. 2.5 milliamperes DC exceeds the allowed 2.0 milliampere limit.

The PSN editor then asked when it is helpful to use a limited-current circuit rather than a SELV circuit.

Let's see if we can answer these questions.

Unfortunately, IEC 950 is not quite clear on the nature of a limited-current circuit and its role in preventing electric shock. Furthermore, it appears that various certification houses likewise are not clear on the nature of limited-current circuits and their role in preventing electric shock.

On the other hand, IEC 1010 presents the idea of a "limited-

current" circuit in a different light: In Sub clause 6.3. 1. 1, IEC 1010 specifies that if the voltage exceeds 30 volts rms AND the current exceeds 0.5 milliampere rms, then the circuit is considered hazardous.

Note that we must have two, simultaneous conditions: first, the voltage must be greater than 30 volts rms, and second, the current available from that voltage must be greater than 0.5 milliampere (for IEC 1010). If both of these conditions are met, then the circuit is considered hazardous.

However, if only one of the conditions is met, the circuit is considered not hazardous.

Let's look at this in graphical form, in Figure 1, below.

In most cases, where the voltage exceeds 30 volts rms, we PRESUME the available current exceeds the 0.5 milliampere criterion. For example, we do not measure the available current from a mains circuit because we KNOW that the available current exceeds 0.5 milliampere.

Normally, we simply identify all voltages exceeding 30 volts rms as hazardous. We don't look at the other dimension, current.

Note the region below 30 volts. There is no current limit. In this region of the graph, any voltage

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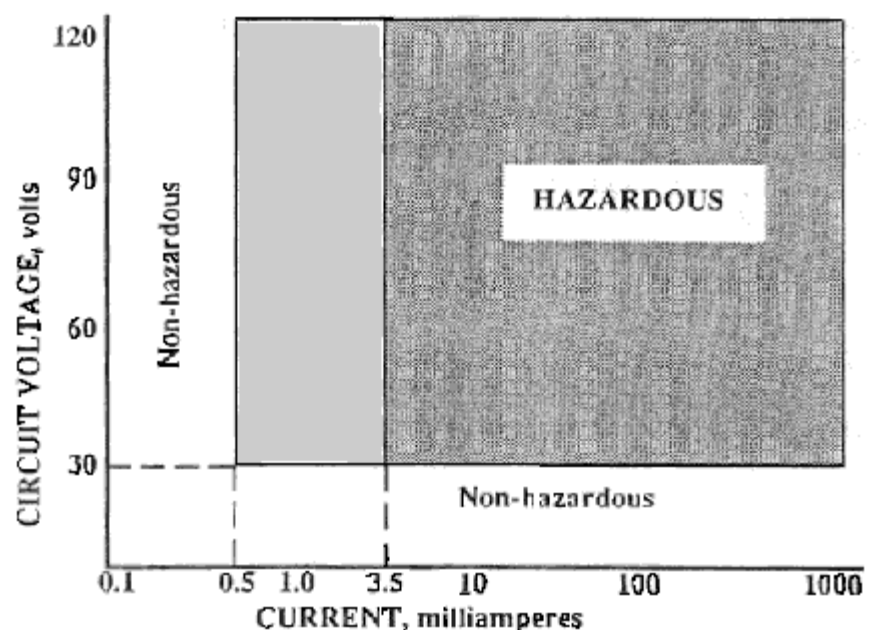


Figure 1

Conference on Environmentally Friendly Fire Retardant Systems

[The following information is provided by the conference organizer, Intertech Conferences, in their advertising brochure. The conference was held September 22-23 in Cleveland, OH -Ed.]

This conference presents a balanced, comprehensive outlook for market development of fire retardant (FR) additives and polymers, emphasizing rational discussion between end users, additive suppliers, resin producers, formulators and regulatory experts.

Recently in Europe a draft directive banning polybrominated diphenyl ethers (BrDPOs) was rejected by the Environmental Committee of the European Parliament. Other bodies have taken similar action. However, as a result, individual countries are now considering independent action. Germany currently restricts chlorinated dioxins and furans and may add brominated analogs. Holland is studying restriction of the sale, import or use of BrDPOs.

In the U.S., the EPA issued a test rule in 1987 which requires toxicity and environmental rate testing of a number of halogenated fire retardant additives including BrDPOs. This testing is underway. In June 1991 the EPA proposed additional testing of brominated FRs. If implemented,

such testing will require a minimum of five years and \$18 million to complete.

Currently, no regulations exist anywhere restricting the use of BrDPOs or other halogenated fire retardant materials. The situation is politically charged and may change when testing is complete. More importantly, the mood of environmentalists and certain users is clearly in the direction of restricting use of halogenated systems.

Producers are developing new environmentally friendly FR systems. Use of alumina trihydrate, borates, magnesium hydroxide, organophosphates and molybdenum compounds is accelerating, as is development of silicones and other inherently fire retardant polymers.

Issues addressed at this conference will include:

- * The current status of regulatory initiatives affecting halogenated fire retardants in Europe, USA, Far East
- * Effects of new FR additives on polymer processing and physical properties
- * Whether the costs and process economics of the new halogen-free fire retardants can compete with conventional systems

- * How the U.S. is harmonizing its FR regulations with the rest of the world
- * What direction R&D on halogen-free fire retardant is taking in Japan, Europe and the USA. ☸

Chairmen's Message
Continued from page I

3. We can help reintegrate the product safety practices with related disciplines such as reliability. These have somehow gotten separated over the years, but are actually inseparable from safety. For example, continued correct functionality of components -part of reliability -is frequently essential for safety.

Consider how familiarity with, or increasing expertise in, one or more of these areas can be of value to you. Does your company or do your clients look to you for answers that go beyond IEC 950? If they do, how do you respond? If they don't look to you, who are they looking to for help?

I believe the PSTC must take a leadership position in restoring the broader scope of product safety practice without necessarily "reinventing the wheel". What do you think? I'd like to hear from you ((408) 578-5035). ☸

UL 1950 IAC Report

by Richard Peseatore

[Following is a synopsis of the UL 1950 Industrial Advisory Conference (IAC) which took place May 20 and 21, 1992. The official Meeting Report is available from UL. -Ed.]

Direction of UL 1950 -

A Bi-National (Canada and U.S.A.) task force was established to discuss a future strategy for the UL and CSA Information Technology Equipment (ITE) and Telephone Equipment standards. This committee met on February 11, 1992 in San Diego, CA.

Agreement was reached to pursue a long term goal of developing a single standard that would be used in both countries by both industries. (This harmonizes with IEC TC 74's approach in which requirements for both ITE and Telecommunications Equipment appear in a single standard, IEC 950, Second Edition.) In the mean time, the four existing North American standards will remain in effect.

It is anticipated that the single standard will be harmonized to the Second Edition of IEC 950 with a minimum of national deviations. While deviations are anticipated to account for Canadian and US National Electrical Code guidelines, other deviations

must be based on adequate safety-based rationale.

Both the UL and CSA versions of the standard are to be identical except for the covers and no revisions will be made unless they are supported by both organizations' Standards Committees.

The bi-national task group that will develop the standard is planned to be made up with two members each from UL, CSA, ITAC, CEENIA, TIA, and EEMAC.

It is planned that the standard will be available in late 1994, with the first product submittals beginning in 1995. The standard will become effective (mandatory) in the year 2000, at which time the other ITE and Telecommunications Equipment standards will cease to exist.

A discussion then followed regarding the format of the new single standard. Should it be published as a complete standard showing all of the original text of IEC 950 along with deviations, or should it simply refer to IEC 950 and then list the deviations?

This same discussion took place when UL 1950 was developed and the result was to publish the standard both ways. No final decision has been made.

Another question that was ad-

ressed: Should UL publish a revision to UL 1950, (1) to add requirements for interconnection of ITE to public telecommunications networks and (2) to bring UL 1950 in line with the second edition of IEC 950 editorially? There was general consensus to do both (1) and (2).

IECEE CB Scheme -

UL has applied for acceptance under the IECEE CB scheme (at least for ITE). The vote on the application is June 1. An audit of UL was recently conducted and UL was requested to reduce the number of deviations to IEC 950 in UL 1950. This was done largely by "reclassifying" many of the D2 deviations as "interpretations." This allowed UL to reduce 30 pages of deviations down to two. (CSA went through the same exercise last year.) Other US laboratories have applied as well.

If UL is accepted into the CB scheme (as anticipated), manufacturers should be able to submit UL test data to any other CB recognized certification house and have that data accepted at face

value, thereby allowing for multiple certifications with only one set of testing.

K-Factor Rating -

Some manufacturers of computer power centers have requested UL

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NRTL Application from CSA

[This excerpt is reprinted from the Federal Register, Vol. 57, No. 107, Wednesday, June 3, 1992, page 23429 -slightly edited by PSN. All you ever wanted to know about NRTL applications and CSA. -Ed.]

Agency: Occupational Safety and Health Administration (OSHA), Department of Labor

Actions: Notice of Application for Recognition as a Nationally Recognized Testing Laboratory (NRTL), and Preliminary Finding

Summary: This notice announces the application of the Canadian Standards Association (CSA) for recognition as a NRTL under 29 CFR 1910.7, and presents the Agency's preliminary finding.

Dates: The last date for interested parties to submit comments is August 3, 1992.

Addresses. Send comments to: NRTL Recognition Program, Office of Variance Determination, Occupational Safety and Health Administration, U.S. Department of Labor, Third Street and Constitution Avenue NW, room N3653, Washington, DC 20210.

For further information contact: James J. Coneannon, Director, Office of Variance Determination.

NOTICE OF APPLICATION:

Notice is hereby given that CSA has made application pursuant to section 6(b) of the Occupational Safety and Health Act of 1970, Secretary of Labor's Order No. I-90, and 29 CFR 1910.7 for recognition as a NRTL.

The address of the laboratory covered by this application is: Canadian Standards Association, Toronto Facility, 178 Rexdale Blvd., Rexdale (Toronto), Ontario M9W 1R3, Canada. By letter dated December 20, 1991, CSA amended its application for recognition as follows:

1. The initial phase of the recognition is to be limited to the Toronto facility, and
2. The scope of the application relating to certification services is to be limited to in-house testing only.

Regarding the merits of the application, the applicant contends that it meets the requirements of 29 CFR 1910.7 for recognition in the areas of testing which it has specified.

The applicant states that for each item of equipment or material to be certified, it has the capability (including proper testing equipment and facilities, trained staff, written testing procedures, and

calibration and quality control programs) to perform testing and examination of equipment and materials for workplace safety purposes to determine conformance with appropriate test standards.

CSA's application contains sections dealing with background and history; the Certification and Testing (C&T) Division structure; affiliation including a statement of independence; personnel, including experience and expertise, training, and list of key personnel, position descriptions and resumes; the certification process, including testing and evaluation, certification, reports and records and the service agreement; the field services program, including follow-up inspections, re-examination testing and field monitoring; certification services, including prototype (model) certification; testing experience, including recognition by other bodies; control programs, including the quality assurance program, control of technical and quality records, handling and storage/packaging and shipping, and test procedures; laboratory test equipment and calibration of this equipment; facilities; and, finally, CSA's appeal process, the comprehensive system for handling complaints and ultimately providing an unbiased review of any controversial matter.

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1992 EMC Symposium Reports

Product Safety Workshop

by Mark Montrose

The Product Safety Technical Committee (TC-8) of the IEEE EMC Society conducted a workshop, "Product Safety Considerations for EMC Engineers", on August 17, 1992, at the International EMC Symposium in Anaheim, California. This well-attended workshop was aimed at informing EMC engineers about concerns of

product safety engineers when designing products for safety agency approval. This was not a "how to" design workshop.

Speakers discussed a variety of topics, including:

- * Liability
- * Items commonly overlooked during product safety certification
- * Current state of regulatory affairs in Europe, 1992
- * Component selection for EMC engineers

All attendees received handouts as well as participating in extensive question and answer sessions. The workshop was co-chaired by Mark Montrose, Consultant, and Murlin Marks, Underwriters Laboratories Santa Clara.

The TC-8 committee has decided to conduct another Product Safety Workshop at the 1993 International EMC Symposium in Dallas, Texas, during the week of August 9-13, 1993. Suggestions for topics of interest are requested



TC-8 Annual Meeting

by Brian Claes

Every year at its International Symposium, the EMC Society provides an opportunity for each of its technical committees to meet. Most of these committees are composed of ten or fewer members who, because of geographical separation and other factors, may only be able to meet together as a group once a year at the symposium.

The PSTC, on the other hand, is the exception. Because of our size and other characteristics, we function more like a society with most of our business being handled in local chapters and functional subcommittees. Our annual meeting has become a time

to report progress and to develop and review plans. Attendance at four annual meeting is open to I anyone attending the Symposium with an interest in product safety.

This year, half of the meeting was spent dealing with issues on the formal agenda:

Space does not permit in-depth reporting here on each of the agenda items discussed

- Five year plan review (including technical council progress)
- Subcommittee reports (Standards, Newsletter, '92 Symposium workshop)
- Local chapter support
- 1993 Symposium planning

However, articles on the technical council effort, '92 Symposium workshop and the '93 Symposium 'Call for Papers' appear elsewhere in this issue of the Newsletter. In

future issues we will review the five-year plan and provide progress reports from the other functional subcommittees.

The remainder of the time spent in open discussion convinced me that I had greatly underestimated the potential of the annual meeting in catalyzing future PSTC direction and energy. While we did not have a large turnout, the enthusiasm and contribution of each attendee was exciting. Some of those attending had not heard of the PSTC before, but came because of an interest in product safety. There was a very encouraging affirmation of the value of the PSTC: everyone that attended asked to take on some type of role or added responsibility because each believed in its importance and that the PSTC was in a unique position to help make it happen.

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ISO 9000 Perspectives

By Brian Claes

(Editor's Note: The June meeting Santa Clara Valley Chapter featured two speakers on ISO 9000. Grant Schmidbauer of CSA led off with an excellent presentation of the structure and content of ISO 9000 and the registration process. Brian Claes followed with an insightful presentation of ISO implementation perspectives. The following is a synopsis of Brian's presentation -Ed.)

There has been a lot of excitement in the business world regarding ISO 9000. While opinions vary as to its impact, one thing is clear: it will have an increasing impact on the competitive marketing of goods and services. Let's briefly examine some aspects of its impact and, where helpful, compare and contrast it with common experience in product safety certification.

The ISO 9000 Standards

ISO 9000 series of quality management standards and guidelines represents a very traditional approach to quality control (it is a direct descendent of a 35-plus year-old US military quality standard). Its scope falls within a subset of modern "Total Quality Management" thinking. For instance, it can be argued that ISO

9000 substantially addresses only one (Quality Assurance) of the 7 Malcolm Baldrige quality criteria categories .

The focus of ISO 9000 is on selected quality-related processes rather than on product quality characteristics. The standard specifies in very broad terms which basic processes must be in place and describes some basic attributes of these processes. However, it is non-prescriptive in that it does not describe how they are to be implemented. This general nature of ISO 9000 requirements leaves much room for judgment and interpretation and ISO has not yet provided formal guidelines for interpretation.

The central theme is the demonstration that contractual quality-related requirements are met by the supplier. As for quality improvement, it encourages reduction of defects (deviation or variation from specified or contracted goals), but does not address raising or improving these goals.

Compliance effectively imposes certain process management disciplines with the intent of minimizing deviation from the company's intended quality system processes.

Regulatory Impact

For purposes of this discussion, "regulatory" refers to those government-imposed and administered (involuntary) business constraints applicable to a company because of the nature of its business rather than to the particular requirements of any given customer. To illustrate from the product safety perspective: there is no fundamental regulatory requirement for manufacturers to obtain UL safety approval. The requirements, instead, come from that manufacturer's customer base who, depending upon the type and application of the product in question, may face regulatory requirements in their environment (local electrical or building code inspectorates or possible OSHA requirements) that can be satisfied by UL approval. FCC EMC compliance, on the other hand, is a regulatory requirement for equipment addressed by its requirements and, with few exceptions, is customer independent (other than intended environment).

With very few exceptions, compliance and/or formal registration to ISO 9000 is not a legal or regulatory requirement to do business in any given country or multi-national economic alliance (such as the EC). One such exception is the US Food and

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Area Activity Reports

Santa Clara Valley PSTC Meeting (9/22/92):

by Murlin Marks (from notes by D.W.)

The Santa Clara Valley Chapter had a presentation delivered by Dan Weinberg, Ph. D., that was entitled "American National Standard for Leakage Current in Appliances -A Perspective". Dr. Weinberg was at Duke University in the 1960S when interest was raised about the „startle reaction” in which a person moves involuntarily following a sensation of electric shock. This could cause injury if a person were carrying hot liquids or standing on a ladder. Dr. Weinberg showed a film of research done on women at UL in the 1960s. The film shows the calibrated setup used to gauge reaction levels to carefully controlled currents applied to women test subjects, At the 1-2 ma (available current) range, the woman in the movie reacts by flinging the metal rice cup across the room. These tests were the basis for the leakage current requirements in ANSI C101.1. The requirements generally cover cord-connected appliances and assume that there is not a reliable ground path.

Dr. Weinberg discussed various exceptions that have been added to the requirements over the

years. For example, a small, but significant percentage of electric skillets unavoidably have higher leakage current during warm up and cool-down than permitted by the standard. The standard includes an appropriate exception. As computers moved from industry to the home they came under the standard. To meet FCC rules for conducted emissions, computers often have capacitive filters between the power line and ground. This can cause leakage current exceeding the standard's limits. An exception was added.

Dr. Weinberg also discussed some of the politics of committees, in particular how the NFPA's committee on hospitals worked to develop a standard for safe use of electrical equipment on patients. It set very strict limits on electrical leakage during medical procedures when there is a direct electrical path to the patient's heart. The chairman of the committee, a physician, insisted on extremely stringent requirements without consideration of the injury record or of cost. These medical requirements were considered untenable and never adopted by ANSI or the medical equipment industry.

In addition to the interesting presentation, the Santa Clara Valley Chapter implemented a new practice at their September meeting, Henceforth, an informal

dinner will be held at a local restaurant just prior to the presentation. Hopefully, this will provide added depth to meetings by allowing those interested to meet the speaker and to exchange the latest news. September's dinner was a great success! Watch for meeting announcements or contact any chapter officer for details. ❀

1992 EMC Symposium Reports
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Some final observations from the annual meeting:

- The PSTC is just scratching the surface in terms of addressing the span of product safety interest embodied within the IEEE
- We will take even better advantage of the annual meeting as both a planning tool and a forum for exploring new opportunities and developing new contacts.
- Key decisions are made at the meeting; it's another opportunity for each of you to express your point of view and influence the course of the PSTC.

I'm looking forward to even greater things at the 1993 Symposium in Dallas. While you're there, plan on attending the TC-8 Annual Meeting. ❀

source less than 30 volts is non-hazardous, including a 100-ampere car battery. (I am ignoring the concept of energy hazard, which has been discussed before in this column.)

Now note the region below 0.5 milliamperes. There is no voltage limit in this region of the graph, the circuit is said to be current-limited.

A current-limited circuit is one where the open-circuit voltage exceeds 30 volts, but the available current (through an appropriate resistor) does not exceed either 0.5 milliamperes or 3.5 milliamperes, depending on the standard.

For example, if we connect one end of a 240 kilohm resistor to 120 volts, the other end now constitutes a limited-current circuit. The maximum available current is:

$$I = \frac{120 \text{ volts}}{240 \text{ kilohms}}$$

$$I = 0.5 \text{ milliamperes}$$

But, we need not have a resistor to develop a current-limited circuit. In some cases, insulation provides the current-limiting.

Consider the measurement of leakage current. If you open the ground and measure the voltage with a high-impedance voltmeter, you will measure about one-half the mains voltage (about 60 volts

on a 120-volt system). (Try it!)

So, we have 60 volts rms, which exceeds our 30-volt limit. We next measure the available current, and determine that it is less than 0.5 milliamperes (or 3.5 milliamperes, depending on the standard).

What we have done is to show that the open ground is a current-limited circuit!

Another example of a current-limited circuit is the voltage source for some electroluminescence panels. The voltage may be in the neighborhood of 300 volts dc, but the current, when measured with an appropriate resistor, is less than 2 milliamperes (depending on the appropriate standard). If you were to touch such a circuit, you would not likely have any sensation of current or electric shock.

Another “use” of the limited-current circuit is the “floating” circuit. A floating circuit is one where neither pole of the circuit is connected to ground.

Consider the case of a 5-volt circuit which generates the power for a floating power supply whose output is 150 volts. In this case the 150 volts is not current-limited pole-to-pole. However, because it is “floating”, it is current-limited from pole to ground.

Thus, one need only provide basic insulation on each pole of the power supply to provide adequate protection against electric shock,

including that of failure of one basic insulation.

A brief note about SELV, Safety Extra-Low Voltage, and how it differs from ELV, Extra-Low Voltage, and its relation to Limited-Current circuits.

A 9-volt battery is ELV. It is considered safe by virtue of the value of the voltage being low.

A 9-volt battery-eliminator plugged into a wall outlet is also ELV. The 9-volt output voltage is considered safe by virtue of the value of the voltage being low (i.e., less than 42.4 volts dc).

However, for a 9-volt battery eliminator, the voltage is derived from a hazardous voltage source. The low voltage must be isolated from the hazardous voltage. Therefore, the output voltage must be SELV.

The difference between ELV and SELV is that SELV is derived from a hazardous voltage source AND is suitably isolated from that source.

An ELV source can also be derived from a hazardous voltage source BUT need not suitably isolated from that source.

The 9-volt battery cannot be SELV because it has no hazardous voltage source from which it need be isolated.

The point is, that, for Extra-Low Voltage, safety is provided by the low voltage itself. Indeed, be-

cause the voltage is low and therefore non-hazardous, we can consider the conductors to be accessible parts which just happen not to be grounded (as is the case for most other conductive parts).

However, where the ELV is derived from a hazardous voltage source, and where that ELV may constitute accessible conductive parts, the circuit must be suitably isolated from the hazardous voltage just as any other accessible conductive part must be isolated from the hazardous voltage.

Usually, we simply install double or reinforced insulation between the ELV and the hazardous voltage, and verify its adequacy with measurement of spacings and testing for hi-pot.

This insulation between the ELV and the hazardous voltage is analogous to the insulation between the ground and the mains (hazardous voltage) circuits. Consequently, we can measure leakage current from the ELV conductors just as we would from the grounded conductors: open the ELV ground and insert the leakage current meter. This

measurement shows that the insulation between the ELV and the hazardous voltage is a LIMITED-CURRENT CIRCUIT with respect to the hazardous voltage!

Therefore, an SELV is an ELV with a Limited-Current Circuit between it and its hazardous voltage source.

SELV has TWO voltage sources. One is the low voltage itself. The other is the hazardous voltage from which the low voltage is derived. With respect to the low voltage source, the magnitude of the voltage renders the circuit conductors safe. With respect to the hazardous voltage, the insulation between the ELV and the hazardous voltage renders the circuit conductors safe.

The insulation between the ELV and the hazardous voltage is an insulation between two conductors. Two conductors separated by insulation constitute a capacitor. The capacitor makes the path between the ELV and the hazardous voltage a limited-current circuit. Neither spacings measurement nor hi-pot testing evaluates the current through the capacitance.

Therefore, to complete the evaluation of the adequacy of the separation, we should test the SELV circuit for limited current from the hazardous voltage. We don't normally do this because, usually, the capacitance is very low and can be neglected. Nevertheless, a product can be built which passes the spacings and hi-pot criteria, but does not pass the limited current criterion.

The concept of the limited-current circuit is extremely valuable as it is a necessary piece of protection from electric shock. In Figure 1, we usually only think of the voltage axis when we think of electric shock. Add to your understanding of electric shock by thinking also of the current axis and limited-current circuits.

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, Loc 55-53, Cupertino, California 95014-0708. ☼

UL 1950 IAC Report
Continued from page 15

- Use a UL Recognized fuse that is also certified by another agency to an IEC standard. This option may require the end product manufacturer to assume responsibility for additional follow-up testing, depending upon the completeness of the UL Recognition.

- Short the fuse during all testing (thereby relying on the branch circuit protection). Then use an IEC fuse as in the first scenario mentioned above.

Polarity Control -

One industry member suggested modifying the standard to specifi-

cally require polarity control for auxiliary receptacles that are non-NEMA standard (for example, a special receptacle on the rear of a PC intended for connection of a monitor). The issue was discussed at length, but no consensus was reached. UL will solicit comments in the Meeting Report. ☼

to allow the use of a K-factor rating on their equipment. UL will publish their requirements to allow the use of this marking. At this point, this is an entirely optional program that has only been requested by computer power center manufacturers. A number of issues surround this proposal, for example, how to measure the K-factor of equipment. However, there are techniques to calculate the expected K-factor, just as there are techniques to calculate the branch circuit loading, for example.

The K-factor is defined as the sum for all harmonics of the product of the square of the per unit rms current at each harmonic and the square of the harmonic order. $[K = \text{Sum of all values of } \{I_h(\text{pu})^2\} \{h^2\}]$, where h = the harmonic frequency order number, and $I_h(\text{pu})$ = the per unit rms current at harmonic order h . Refer to the standard IEEE C57.110 for more information.]

Rack Mounted Equipment -

Several months ago, UL distributed a proposal (which was called an interpretation) of requirements that should be applied to equipment intended for general use in racks. As a result of comments from industry, UL discussed a new set of ideas with the IAC. (UL is trying to work with industry to get rack mounted equipment Listed without specific knowledge and control of the final rack and assembly.)

Most of the IAC members felt the proposal was either reasonable or not comprehensive enough (because it did not consider total leakage current, overcurrent protection, or stability). Some members believed that each of these topics could be handled by providing the user with adequate instructions for proper insulation. UL will solicit comments in the Meeting Report and will formulate their final decision based on the responses they receive.

48 Volt DC Supplies -

Traditionally, UL has treated unknown 48 VDC supplies (usually encountered in telecommunications applications) as being derived from a circuit with a transformer having a 240V, 60 Hz. primary winding and with basic insulation between primary and secondary. This approach requires the equipment manufacturer to incorporate additional insulation to achieve SELV where needed.

UL has surveyed the telecommunications industry and, based on the input received, is willing to assume that the 48 VDC provided by the telecommunications industry (in the U.S.) is indeed derived from a circuit containing an isolation transformer with at least basic insulation and that the secondary circuit is grounded (earthed) in a reliable manner. Based on this assumption, they will treat equipment intended to operate from a 48 VDC supply as having a 48 VDC SELV input

(usually with battery backup provided).

UL also proposed that the equipment be provided with instructions stating that the 48 VDC input must be grounded or SELV. UL will make this interpretation known in the Meeting Report and if no strong objections are received, it will be implemented.

One industry member expressed concern that the integrity of the ground was not assured. UL reminded industry that, in North America, ELV has been viewed as safe to touch and that the only reason we are concerned with SELV is for harmonization with the IEC.

Component/ Accessory Program

UL presented the notion of expanding the information available in the Recognized Component Index (the Yellow Book) to include a complete listing of parameters (needed to judge the suitability of the component in the end product) for those components where this might be feasible. The intent is to allow the manufacturer easier substitution of components without having to modify the UL Procedure.

One example cited was a small disk drive intended for use in personal computers where commonly only the input voltage, current, status of motor protection, and flammability of the front bezel are of concern. Presently, the UL Procedure specifies the exact drive submitted by the end

product manufacturer. If the end product manufacturer wants to use a different drive, he must notify UL and have the procedure updated.

Under the proposed scheme, the Procedure would specify the critical parameters, which would be indexed in the Recognized Component Directory. The manufacturer would be free to substitute any UL Recognized drive complying with the specified parameters. An example of the Procedure description might be "Recognized Component Disk Drive (NWGQ2), rated 12 VDC, max. load 0.2 amps, min. 94-VI bezel, provided with Locked Rotor Protection."

Industry was supportive of this concept and an ad hoc group will be formed to explore candidate component categories and make recommendations regarding the safety critical parameters that UL should control.

UL Classification to IEC 380/435 -

UL currently has products Classified to IEC 380 and 435. They will survey the industry via the Meeting Report for a need to continue to offer this service (in light of the wide acceptance of IEC 950) and how long current Classifications should be maintained.

Class E Insulation Systems -

UL now has a program to Recognize Class E insulation systems. The deviation excluding these systems from UL 1950 will therefore be deleted.

NEC 645-5(d) -

The 1993 National Electrical Code (NEC), Article 645-5(d), will require most cables under raised floors in electronic computer/data processing rooms to be "...listed as Type DP cable having adequate fire-resistance characteristics UL currently has no Listings or requirements for DP cables. An ad hoc committee (to be made up of cable manufacturers and users) will be formed to develop appropriate requirements.

NOTE: Once UL Listed DP cables become available, UL will require their use if shipped with ITE. Furthermore, an effective date will be established and a file review for this item is planned.

NEC 645-11 -

The 1993 NEC, Article 645-1 1, will require a disconnecting means for uninterruptible power sources (UPS) capable of delivering more than 750 VA, whether the source is derived from a separable UPS or battery circuits integral with electronic equipment.

UL will therefore require ITE to have provision for connection to the Emergency Power Off (EPO) circuit in the electronic computer/data processing room.

One major issue to be resolved is the interpretation of "capable of delivering more than 750 VA."

UL will suggest that this value either be calculated by multiplying the battery voltage and overcurrent protector ratings or by measuring the VA into a resistive load for one minute. If industry

agrees, the options will likely be written into UL 1950.

It is recognized that more precise means of defining 750 VA can be established. However, since that number was selected arbitrarily, the determination method should be as simple and liberal as possible.

NOTE: This will also require a UL review of existing Listings once it becomes effective.

NFPA 75 -

NFPA 75 requires larger Automated Information Storage Systems (AISS) to be sprinklered internally or fitted with a fire extinguishing gas system. UL will propose requiring such AISS to have provision for sprinklers or a gaseous extinguishing system as a condition of Listing. The only manufacturer of this type of equipment represented at the meeting said that this is already common practice in the industry so such a requirement by UL would not create a burden.

Component Recognition -

UL has received requests from industry to add reference to the Standard for Across-the-Line, Antenna-Coupling, and Line-by-Pass Capacitors (UL 1414) and the Standard for Optical Isolators (UL 1577) to Supplement A of UL 1950.

Adding UL 1414 would reflect a change in practice and require a UL file review. After discussion, it was determined that a general need to require UL Recognized X and Y capacitors in ITE does not

exist and UL will not recommend that this standard be added to Supplement A of UL 1950. However, adding UL 1577 would reflect current practice and therefore will likely happen.

NOTE: UL will accept UL 1577 Recognized opto isolators that meet the requirements for double protection in applications where reinforced insulation is required. This is an option in lieu of the distance through insulation (DTI) requirements and is viewed as a DC deviation.

Testing Procedures -

The IAC agenda included a presentation by UL regarding a Laboratory Procedure Guide that they preparing. However, UL stated that they were not yet ready to discuss this.

One industry member suggested that UL consider using the work published by Lal Bahra of CSA which describes CSA's test methodology and procedures.

Ball Pressure Test -

Subclause 5.4.10 of UL 1950 requires certain thermoplastic parts to be resistant to abnormal heat. The Compliance portion of the subclause refers to the Ball Pressure Test as the method to evaluate this parameter.

In March, UL received a letter suggesting that the Ball Pressure Test need not be conducted on Listed or Recognized components (such as switches, relays, connectors, plugs, etc.) if those components are used as intended. The letter pointed out that, while these

components may not have been subjected to the Ball Pressure Test, they have been evaluated for their suitability to support live parts. It further was suggested that UL either add a DC deviation to exclude Listed or Recognized components from the test or issue a formal interpretation stating these components are to be exempted.

These suggestions were unanimously supported at the meeting. UL agreed to include a record of the discussion in the Meeting Report, specifically stating that Listed or Recognized components that are used as intended will be accepted without conducting the Ball Pressure Test.

Standardized Appendix Pages -

UL has circulated a proposal for Standardized Appendix Pages to be included in Procedures covering ITE. Comments are due to UL by May 29. UL indicated that comments received to date were mostly editorial, with general agreement for their proposal.

UL was asked to develop a process to automatically update the list of acceptable agencies for power cord certifications under the POCUS program. They agreed to develop a process that would either routinely update the Appendix or keep manufacturers and UL inspectors updated by bulletin. This should resolve any future problems with FUS inspectors.

Agreements with other Agencies

UL passed out some literature discussing agreements they have

with other certification agencies. If you would like specific information regarding such agreements, contact UL's International Compliance Services (ICS) Department.

Acceptance of IEC Certified Fuses -

One industry member asked why UL would not accept fuses certified to IEC standards by other agencies. UL responded by restating their reluctance to accept other agencies' certifications without formal reciprocity agreements in place. It was also pointed out that an industry group was formed several years ago to attempt to resolve some of the differences in blowing time requirements between U.S. standards and IEC standards. However, the group has apparently not yet produced any useful results.

UL said they are willing to work with manufacturers on a case-by-case basis to resolve the dilemma caused by the different fuse requirements by certification bodies throughout the world. Some of the options UL said they have taken include:

- Use a UL Listed fuse in series with an IEC fuse. UL will investigate the product with the IEC fuse shorted. Then they will evaluate the IEC fuse for its ability to remain safe under fault conditions. The IEC fuse must be certified by an agency that UL "recognizes".

Continued on page 12

The Rexdale facility includes the corporate headquarters, a standards division, finance and administration division, and certification and testing division. The laboratory is owned by CSA and consists of a two story building covering 250,000 square feet, situated on ten acres. Approximately 100,000 square feet of floor space are allocated to product testing. The laboratory, established in 1919, has been at this location since 1954.

Natural gas, electric, oil, and water utilities are available in the laboratory for product testing. Environmental conditions in the laboratory are controlled. 'Be temperature and humidity variations throughout the laboratory are recorded as required by specific test requirements. There are rooms and chambers used to control and monitor environmental conditions for specific product testing. The calibration room also has relative humidity control.

The laboratory has a shipping and receiving department for receipt, retention, and disposal of samples for testing. Incoming samples are identified with numbered tags and then delivered to the testing areas with a duplicate numbered tag attached. A secondary numbered tag is prepared in triplicate for sample disposition purposes after testing is complete. A copy of each tag is retained by the shipping and receiving department. One copy of the secondary tag is

routed to the customs department and a second copy is sent to the jobholder. The jobholder completes this copy when all product evaluation is finished and returns it to the shipping and receiving department for sample disposition. The sample information is maintained on a computer data base. All storage locations are secure and pose no adverse environmental conditions on the samples.

Visitors must enter the front lobby area and are issued name tag labels by a receptionist. All visitors are escorted. A card access system is utilized for staff to enter/leave the facility. Separate test and conference areas are available for clients requiring confidentiality. There are 24 hour, 7 day per week security guards. Staff entering the facility outside normal working hours are required to sign an in/out log book. Indoor and outdoor monitoring cameras are provided. Staff must wear name/photo identification badges.

The applicant states that CSA is an independent, not-for-profit membership association, without share capital, incorporated under the laws of Canada in 1919, engaged in developing national standards and providing a certification service for manufacturers wishing to have their products certified as complying with national standards or standards of foreign countries. The applicant states further that the organization has no affiliation with manufacturers or suppliers of

the products submitted for testing and certification. Several documents are submitted as a part of the CSA application to address the issue independence.

CSA claims that it maintains effective procedures for producing creditable findings or reports that are objective and without bias. The C&T Division maintains a quality assurance (QA) system for CSA's world-wide network. The QA Program of the Testing Laboratory is registered by Quality Management Institute (QMI) to ISO 9003 and Z299.3. The Corporate Engineering and QA Group (EQA) has the responsibility and authority for overseeing all activities related to the Quality Program. 'Me object of the QA system is to ensure technical excellence, consistency of interpretation and application of standards, consistency of implementation of certification programs and procedures, the integrity of the CSA Mark, and continuous improvement. In addition, the QA system is designed to meet National and International Accreditation Criteria. The QA system is documented as follows:

* "Quality Assurance Policy Manual" (QAPM). It contains the quality policies for the C&T Division and establishes the responsibilities for implementation of these policies.

* "Quality Assurance Manuals" (QAM). These manuals describe in detail the system and procedures outlined in the QAPM. They are issued by each Opera-

tional Unit after approval by EPA.
* “Divisional Quality Documents” (DQD). They are issued and controlled by EQA and consist of additional operating procedures and guidelines to be used by operations staff.

Permanent records are compiled to document all technical and quality related activities of the C&T Division. The system for controlling all technical and quality records is described in the QAMs for each CSA Office.

CSA claims that it has a comprehensive system for handling complaints and ultimately providing an unbiased review of any controversial matter. All complaints and disputes shall be resolved, whenever possible, by those directly involved with the work contested and/or at the level of authority appropriate for the nature of the complaint/dispute. If the issue cannot be resolved, there are specific steps, including appeals, which may be followed.

The applicant states that it provides for the implementation of control procedures for identifying the listed and labeled equipment or materials, inspection of the production run of such items at factories for product evaluation purposes to assure conformance with applicable test standards, and the conducting of field inspections to monitor and to assure the proper use of its identifying mark or labels on products. A submitter must enter into a written legal contract (service contract) with CSA to permit the use of the

CSA Mark on the product. This agreement clearly specifies the submitter’s responsibilities and the terms and conditions for maintaining certification, such as the right of access by CSA inspection staff to listed factories, or notifying CSA when changes are made to certified products. These terms and conditions are designed to protect the integrity of the CSA Marks. CSA establishes a comprehensive field services program to ensure that manufactured products bearing any of the CSA Marks continue to meet the applicable requirements. The program consists of three elements:

- * Follow-up Inspection,
- * Re-examination Testing, and
- * Field Monitoring.

Follow-up inspections are conducted at the point of manufacturing and labeling to ensure, among other things, that:

- * The CSA Mark is applied only to certified products;
- * That the terms of the Agreement are met when the CSA Mark is used;
- * Defects noted during previous inspections have been corrected;
- * The manufacturer is aware of any new services, requirements, and effective dates.

The inspections are unannounced and are based on performing a minimum of four inspections per factory per year. The frequency varies with production volumes, the types of products and the manufacturer’s track record.

When products fail to meet the requirements, Field Service Representatives take action to have the manufacturer correct the defect immediately, quarantine the stock until the product can be reworked or reevaluated by certification staff, and remove the CSA Mark from the product.

In cases where it is difficult to determine if a product or component complies with the requirements strictly by visual examination, such products are reexamined and tested on a yearly basis.

CSA has an independent, special investigation unit, the Audits and Investigations Group, to monitor products in the field investigate field complaints, and provide feedback to the standards writing and certification process.

BACKGROUND:

According to the applicant, CSA is an independent, not-for-profit organization governed by a Board of Directors selected by the membership, providing integrated services in the fields of standards development and conformity assessment. The Standards Division of CSA is responsible for the administration of the development of voluntary consensus standards. The C&T Division provides conformity assessment programs including laboratory testing, certification, inspection and quality management services. The organization started out in 1919 as the Canadian Engineering Standards Association (CESA), which was

changed in 1944 to the present name.

The applicant states that during the last 70 years, CSA has developed more than 1400 standards and codes which cover industrial and consumer products and services in a wide range of product areas. In 1940, CSA began to test and certify products and today is an international organization with more than 9000 volunteer members from 20 countries representing consumers, regulators, manufacturers and retailers. They are supported by a staff of approximately 1000 employees, with management staff located in the Far East and Europe.

Again according to the applicant, over 14,000 manufacturers worldwide use CSA's testing and certification services, and the CSA Certification Mark appears on over one billion products a year. CSA processes some 36,000 engineering projects, and the inspection staff makes follow-up visits to some 19,000 factories in almost 60 different countries, each year.

The applicant states that the C&T Division, Toronto facility, of CSA employs approximately 370 staff as follows: 12 Management, 84 Professional Engineers, 139 Technologists (C&T), 24 Technologists (inspection), 71 Support Staff, 40 Other Support Staff (Corporate C&T). Of this staff, some 45 are considered to be key personnel.

The applicant desires recognition

for testing and certification of products when tested for compliance with the following test standards:

[A list of over 300 ANSI and UL Standards follows, including UL 1950 (Information Technology Equipment), UL 1262 (Laboratory Equipment), UL 1077 (Supplementary Protectors), UL 1012 (Power Supplies), UL 817 (Cord Sets and Power-Supply Cords), UL 796 (Printed Wiring Boards), UL 746A,B, CE (Polymeric Materials), UL 544 (Electric Medical and Dental Equipment), UL 508 (Electric Industrial Control Equipment), UL 94 (Tests for Flammability of Plastic Materials), and many more.)

PRELIMINARY FINDING:

CSA addressed all of the criteria which had to be met for recognition as a NRTL in its initial application and in its further correspondence. For example, the applicant submitted a list of its test equipment and instrumentation; a roster of its personnel including resumes of those in key positions and copies of a typical test report, a factory inspection form and an inspection summary; a summary of its listing, labeling, and follow-up services; a statement of its independence as a testing laboratory; and a copy of its Quality Assurance Manual including a description of its documentation, calibration system, appeals procedure, recordkeeping and operational procedures.

Nine major areas were examined in depth in carrying-out the laboratory survey: facility; test equipment; calibration program; test and evaluation procedures; test reports; records; quality assurance program; follow-up listing program; and personnel.

The discrepancies noted by the survey team in the on-site evaluation were adequately responded to by the applicant prior to the preparation of the survey report and are included as an integral part of the report.

With the preparation of the final survey report of CSA, the survey team was satisfied that the testing facility appeared to meet the necessary criteria required by the standard, and so noted in the On-Site Review Report (Survey).

Following a review of the application file and the on-site survey report of the CSA Toronto facility, the NRTL Recognition Program Staff concluded that the applicant appeared to have met the requirements for recognition as a NRTL and, therefore, recommended to the Assistant Secretary that the application be preliminarily approved.

Based upon a review of the completed application file and the recommendation of the staff, the Assistant Secretary has made a preliminary finding that CSA (Toronto) can meet the requirements for recognition as required by 29 CFR 1910.7.

All interested members of the

public are invited to apply detailed reasons and evidence supporting or challenging the sufficiency of the applicant's having met the requirements for a NRTL, as well as appendix A, of 29 CFR 1910.7. Submission of pertinent written documents and exhibits shall be made no later than August 3, 1992, and must be addressed to the NRTL Recognition Program, Office of Variance Determination, room N3653, Occupational Safety and Health Administration, U.S. Department of Labor, Third Street and Constitution Avenue NW, Washington, DC 20210. Copies of the CSA application, the laboratory survey report, and all submitted comments, as received (Docket No. NRTL-2-92), are available for inspection and duplication at the Docket Office, room N2634, OSHA, at the above address.

The Assistant Secretary's final decision on whether the applicant satisfies the requirements for The Assistant Secretary's final decision on whether the applicant satisfies the requirements for recognition as an NRTL will be made on the basis of the entire record including the public submissions and any further proceedings that the Assistant Secretary may consider appropriate in accordance with appendix A of 1910.7. ☸

businesses, learn about worldwide markets, and, as a result, launch or expand expert sales. The database contains up-to-date information on 50 key industries of all major trading partners of the U.S. and can be accessed from anywhere in the country 24 hours a day. By calling the 1-800-USA-EXPORT toll-free number, callers will receive the menu and codes of available countries and industries. They then use their fax machines to send the country/industry codes of their choice to a designated telephone number, and receive by return fax customized reports within minutes. A typical report is 5 to 10 pages long. The only expense incurred by the user is the cost of its fax call. (The above two items from APPLIANCE Magazine, MARCH and APRIL 1992, respectively, via Dave Lorusso at Sequoia Computers. Thanks Dave!)

CB scheme Update

The following information comes from the VDE Test and Certification Institute (VDE-PZI):

The CB-Scheme is an intentional certification agreement. Outside Western Europe it is recognized in Australia, People's Republic of China, India, Israel, Japan, Canada, South Korea, Singapore, and USA. With safety testing passed any one of the authorized test centers, one may obtain the various national certifi-

cations without additional testing.

Under certain earlier conditions, tests by two test centers were required. This situation is now changed.

Also the manufacturer now has the choice to use any of the authorized test centers and is no longer bound to a national test center.

Further, now more than one test center per country may become authorized.

The following test centers recently became authorized:

- India: BIS (Bureau of Indian Standards)
- Singapore: SISIR (Institute of Standards and Industrial Research)
- USA (for IEC 950 only):
 - Dash, Straus & Goodhue Inc.
 - ETL Testing Laboratories
 - MET Electrical Company Inc.
 - UL Underwriters Laboratories Inc.
- France: LNE associated with UTE under the CB
- Slovenia]KM associated with VDE-PZI, unless the new state Slovenia has established a working organization with IEC and IECEE. ☸

Drug Administration's plan to incorporate ISO 9000 requirements into its Good Manufacturing Requirements (GMP's).

Contrary to much of the ISO 9000 hype surrounding the European Community's (EC) planned completion of its internal market by the end of 1992, regulatory impact in the EC is primarily tied only to mandated implementation of particular product directives:

-Regarding effectively, with few exceptions, each of these EC directives has its own implementation schedule that is tied to 12/31/92 (some extend to 1995 or 96 while some have not even been written).

-Product directives generally contain mandatory product assurance requirements. Most of these, including the Telecom Directive, permit several alternative approaches to satisfying these requirements. ISO registration is required in some, but not all, of these alternatives. On the other hand, at least one directive (covering intrusive medical devices) effectively makes ISO registration mandatory.

Customer Requirements

The predominant driving forces behind ISO 9000 registration are customer requirements. Most commonly, customers requiring ISO registration of their suppliers are large quality-conscious companies (particularly in the EC), companies in certain industries (such as telecommunications and

chemicals) or government procurement agencies. From a competitive and market differentiation perspective, being ISO 9000 registered may not make your company more desirable as much as not being registered may make it less desirable. Thus, a critical factor in determining your ISO plan is to know and anticipate your customers' existing and future requirements. **KNOW YOUR CUSTOMERS!**

Registrar Selection

In the case of product safety, there has usually been a single prominent test house or certifier in each country that has played a leading role in developing and testing to standards (examples include UL, CSA, VDE and BSI). These organizations establish and maintain prevailing interpretations of requirements, even when attempts are made to harmonize with internally-developed consensus standards. Thus, the availability of these services eventually drive market requirements.

The history of ISO 9000 is almost the reverse, especially in the case of the United States: the requirements were developed intentionally first and the registrar (approval) industry was created after the fact. This has resulted in many companies trying to fill a lucrative vacuum by going in the ISO registration business.

The key criteria for selecting a registrar include:

-Customer requirements which registrars are recognized by your

customers?

-Accreditation ... is the registrar accredited by its national accreditation body or the appropriate accreditor in another country? is the national accreditation body officially recognized by other countries and multi-national alliances (such as the EC)? As a temporary measure, in the absence of accreditation, does the registrar have effective memoranda of understanding (MOU'S) with accredited registrars? These MOU's permit a type of cross-registration.

-Experience ... how long have the registrar and its auditors been conducting quality system audits? Of the first 225 registrations granted to US companies, only around 10% were performed by US-based registrars. Up until last year, nearly 80% of all registrations world-wide had been granted by a single (non-US) registrar and its licensees.

-Service quality...registrars should be assessed as any other service supplier in terms of accessibility, reputation, timeliness, total true cost of service, flexibility, and so on. To what extent are the registrar's requirements making your company better? If all registrar-required changes aren't for the better (especially from your customers' perspectives), why make the changes?

-Interpretation policy ... as mentioned above, there is great latitude in the ISO 9000 standards for interpretation and judgment. Reasonable latitude is important, particularly when the standard is as dated as ISO 9000. This interpretation issue is so acute that

at least one registrar has separately published its interpretations (at \$50 per copy). Several registrars have developed checklists as audit tools which are useful in understanding approaches and interpretations; some of these registrars make these checklists available upon request. However, even with the checklists there is enormous room for variation. - Pass/fail criteria: many registrars have only two categories for deficiencies: major and minor. If the client company is found to have one major nonconformance or several minor ones, registration will be denied until corrective action is successfully implemented. However, the criteria for differentiating major from minor may not be precisely defined and consistent from one registrar to another. Already, some registrars are beginning to get a reputation for being "easy" while others are considered "hard".

Product Liability

Some have been hyping ISO 9000 compliance and registration as a key product liability defense. To put this into perspective, one must look at two major categories of products liability: negligence and strict liability.

Industry or consensus standards do play a role in determining negligence liability. If a standard requires a business to effectively implement a particular process and failure to properly implement it could be shown to have contributed to a plaintiff's loss or injury, that company may be found

negligent. Since the intent of ISO 9000 is to assure processes are in place to meet specific customer requirements, it stands to reason that implementing ISO 9000 could reduce negligence liability risk to some extent. Failure to implement ISO 9000 may increase a company's negligence risk, particularly if its processes are substandard.

ISO 9000, however, does little to address strict liability in tort, which is the basic product safety measure in the US and the EC (per the 1985 Products Liability Directive, not yet adopted by all EC members.). Manufacturer's conduct is not a major issue in strict liability. -

Traditional product safety practices are most impacted by ISO 9000 in the following areas-

- Product verification per contractual requirements
- Safety-related process description and audits, particularly in development and manufacturing.
- Mandatory process audits and on-going surveillance by third-party registrars and internal auditors.

Business operation and goals

As discussed above, implementing ISO 9000 will have an impact on your business. Process definition, description, discipline and management are central to ISO 9000. Formal registration will involve third-party audits, periodic surveillance and registration renewal audits covering your company's quality systems. Be

especially aware of unnecessarily restrictive or counter-productive requirements.

If becoming compliant with ISO 9000 improves your company's processes, then they were most likely substandard by definition and by accepted practice.

Final Thoughts

By all means pursue ISO compliance. Make sure your quality-related processes conform to requirements, or, if they don't, are demonstrably better. Most importantly, make sure ISO 9000 fits properly into your company's overall quality management scheme and goals.

With regard to formal registration, be very clear about the role of registration in your overall quality goals, particularly from your existing and prospective customers' perspectives. Treat your registrar as a valued key supplier. Remember your company is their customer and as a supplier they should be your ally in satisfying your existing customers and winning new ones. ☸

Institutional Listings

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 the publication of the *Product Safety Newsletter* of the IEEE EMC Society Product Safety Technical Committee. Please direct inquiries to: Ervin Gomez at (408) 447 4070 (phone) or (408) 257 5034 (fax).

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Employment Wanted

As a free service to our readers, the Product Safety Newsletter will periodically list Regulatory Compliance professionals who are available for employment. Those with employment opportunities are encouraged to contact the following individuals directly. Those interested in listing their names should contact the Editor.

Please note that the Product Safety Newsletter staff cannot make any recommendations about the individuals listed.

Product Safety/ Regulatory Engineer:

Carlos A. Ortiz, 884 So. Quieto Way, Denver, CO 80223

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