Product Safety Perspective

The liability crisis of the early 1970s sparked an interest in the application of sound safety principles.

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INTRODUCTION

A common thread of interest weaves between the product safety and EMI activities of any product. In both areas, the goal is protection from some unwanted event. As this goal focuses on protecting a user, the issue is defined as safety related, whether it presents a direct or indirect threat. In either case, the user is indifferent to the source of the problem, and holds the manufacturer liable. This article is not meant to distinguish these areas; the focus will be on specific activities that are usually of mutual interest.

LIABILITY ISSUES AND INTERESTS

The liability crisis of the early 1970s sparked an interest in the application of sound safety principles as a defensive measure. Today, a variety of interested parties are at work. Consumers and other users want to limit injuries and other liability losses. Insurers want to limit liability losses and encourage manufacturers to develop defensive measures. Regulators are pressured to protect the workers and the public from harm. Manufacturers work to limit their liability and the resultant expenses, which can be extraordinary. At the same time, manufacturers do not want to limit design freedom or manufacturing processes, especially those cost-effective improvements that keep them competitive.

A variety of approaches have been developed in response to these pressures. Some requirements are mandatory:

- Medical devices are closely regulated in every industrialized country.
- EMI emanations are regulated to some degree almost everywhere.
- Third party certified electrical consumer products are required in many areas. Some jurisdictions require the same for industrial products (e.g., the city of Los Angeles and the Canadian Provinces).
- The EC Directives require compliance, but allow for a variety of methods to show it.

Some requirements are voluntary:

- Voluntary use of third party certification for safety (e.g., used by manufacturers of commercial and industrial goods).
- Manufacturers' declaration of conformity (as outlined in some of the EC Directives).

MEETING THE REQUIREMENTS: SYSTEM OR STANDARD?

The evaluation of devices in accordance with safety and regulatory requirements has been a closely held discipline for many years. Although engineering students are taught the use of safety factors in some college courses, safety as a

product criteria has not generally been taught at the undergraduate level.

Within the last decade or more, the aerospace industry has fostered a comprehensive system safety methodology at the graduate level. Generally it has worked quite well, but as evidenced by the Challenger disaster, even the best of systems requires management involvement at the highest levels to be effective. The value of systematic methods of evaluation for safety continues. These methods are now becoming better known.

At the other end of the spectrum, independent third-party test laboratories (such as UL or CSA) have a long history of product evaluation against a standard. The numerous UL standards, although developed with industry advisors, are proprietary standards. They are developed along product lines to meet the needs of a particular industry. Individual standards are developed similarly, but, using good marketing acumen, are adapted to solve the particular needs of each industry. This is a good approach in that it moderates the issues in dealing with manufacturers. On the other hand, it does not clearly follow any delineated principles of safety or work to ensure uniform requirements in a comprehensive way.

This lack of uniformity has been particularly troublesome to manufacturers who have moved digital equipment techniques into many new product areas. The common design techniques - which were acceptable in one equipment classification - were not accepted under another classification and the corresponding safety standard. One common issue related to the isolation of the equipment from the line, especially with transformers. Historically, isolation techniques used by various industries are quite different. Differences between some applications are certainly legitimate; medical equipment isolation should be better than general industrial, for instance. Perhaps several categories of isolation should be developed; medical, commercial and industrial, and consumer appliances. The categorization should not be overly complicated however.

The U.S. standards system, which

depends entirely on voluntary activity, is not well suited to correcting this problem.

The IEC has taken the lead in moving toward a clearly delineated system by assigning basic, pilot level activities to several committees to develop fundamental requirements which will be used across the IEC standard system. These committees have promulgated basic requirements for: insulating material evaluation; use of colors as lights or on wires; standardized actuator movement directions; insulation coordination in low voltage equipment; fire hazard testing; protection against electric shock - in installations and in equipment; protective enclosures; leakage current measurement; and EMI compatibility between equipment and in networks.

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In North America, CSA, and now ANSI and UL, are starting to adopt some of this philosophy. But North America is behind Europe in this regard. The U.S. standards system has less direction and this makes the development of a comprehensive approach more difficult. Americans are therefore left in a reaction mode in dealing with the IEC rather than proposing current practices, as reflected in the standards, to the IEC. The recent hearings to develop a standards council for the USA (SCUSA) pursued the possibilities of devising a system which could have provided leadership in standards development. Most of the testimony rejected any government role in standards development in the U.S. Apparently, the U.S. will continue to react to the directed implementation of the IEC and the European Community.

BIFURCATED ACTIVITY: HOLDING IT ALL IN CHECK!

Like the product safety field, EMI has developed as a discipline in two directions at once. Legal, mandatory requirements are on the one hand and the technical discipline that has developed to meet these demands on the other.

In the U.S. and Canada, computers must meet the FCC Part 15 requirements and be appropriately labelled. The German approach is more general; it regulates any digital switches that operate at 10 kHz or more. These will be the European community requirements, in accordance with the Common Market program. Manufacturers who market worldwide are expected to meet these more general and more difficult requirements.

On the technical side, two areas need addressing in every design:

1. Conducted emissions, which result from switching noise generated in the power supply or at any switching device. EMI filters usually are installed at the mains inlet to reduce conducted emissions. The difficulty arises because increasing the filtering also increases the leakage current. As these conflicting requirements intersect, designers must move towards incremental filtering near each source rather than the brute force filtering applied at the mains inlet. This move to reduce the leakage current is also helpful in reducing the conducted emissions when the tests are done both with and without the safety earth ground connected, as done by VDE.
2. Radiated emissions, which are broadcast radiation from any switching devices. Limitation is provided by a grounded screen isolating the source from the receiver. Most modern designs provide a ground plane near the source in the circuit board to limit the radiation. Further screening is provided by the enclosure, or additional shielding within the equipment. Supplementary screening used over ventilation holes must be adequately secured to prevent it from inadvertently being pushed against any part at a hazardous voltage. Conductive coatings on polymeric enclosures must have adequate adhesion to prevent particles from flaking into hazardous circuitry. UL has a specific evaluation for conductive coating on plastics. Finally, coatings must be grounded to the safety earth to prevent a hazard for any situation where the earthing is missing and hazardous voltage shorts to ground; adequate isolation for the user is tested by wrapping the product with foil and applying a high potential between the foil and ground.

The IEEE is currently addressing a number of common issues in their new color book (an Emerald Book) on Power and Grounding of Sensitive Electronic Loads which should be available this year. Among other issues, it has become quite clear that one traditional conflict between

safety and EMI is finally being resolved. Abandoning the safety earth on a product or an installation is not necessary to have good EMI control. It is now understood that a need exists for both a low frequency, safety earth, and for high frequency, EMI grounds. These are not in conflict; good design practice will provide for both. A good large scale example is that of the current practice for computer rooms where both grounds are routinely provided; the third wire connection runs back through the mains for safety and a high frequency grid below the floor controls the EMI reference ground. The FIPS 94 Publication Guideline on Electrical Power for ADP Installations is also a good guide.

MANUFACTURING CONTROL

Maintaining the protection designed into the equipment in an ongoing manner is the responsibility of the manufacturer. This is usually a facet of the manufacturer's quality management. Independent outside inspections are done by various government agencies or certification laboratories. Each approver has their own cycle of inspection, but the test houses such as UL come in on a quarterly basis. In the U.S., most jurisdictions expect quarterly follow-up inspections and base their own approval and acceptance of the marks on these quarterly inspections. The City of Los Angeles and the State of Oregon explicitly expect quarterly visits by the test houses in order to accept their marks on equipment. VDE conducts annual inspections for products which carry either their safety or EMI marks.

Safety and Regulatory managers should be an integral part of the quality team in the factory. Their expectations include clearly defined specifications and requirements; use of approved, qualified suppliers; requalification through a safety and regulatory evaluation at every change; control of changes and modifications; assurances that correct materials are being supplied; defined assembly processes and procedures; and a functional test of all safety systems on a routine basis. Any complete quality system (such as reflected in ISO 9000 series) requires these activities, in a more general sense. The safety and regulatory manager will insist on these steps being performed comprehensively to meet the follow-up requirements of the labs and agencies that are involved with the products. These elements will be reviewed during regular visits of the certifiers and agencies.

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1992: A CRYSTAL BALL GAZE

Multinational manufacturers have seen the EC train hurtling toward the 1992 crossing. Directives covering both safety and EMI are in place to achieve uniform requirements and performance throughout the Common Market by that magic date. Europeans are clear about having a system instituted to prevent inadequate equipment from entering the market. Manufacturers must keep abreast of directives that apply to their products. For most electronics firms, the Low Voltage Directive and the EMC Directive are a minimum set. Detailed technical requirements are just being set into place, such as the CENELEC version of several IEC safety standards and the equivalent for the CISPR EMC requirements. Of special interest are strict conducted emission limits for harmonic currents that will be difficult for switch mode power supplies to meet. Proof of conformity is a somewhat unresolved issue. The directives offer some alternatives:

1. A mark of conformity on the equipment issued by an authorized (European) lab.
2. A certificate of conformity issued by an authorized laboratory.
3. A Manufacturer's declaration of conformity.

It is known that the CE mark cannot be applied unless the equipment meets all the directives that apply to it. It cannot be used to show conformance to the safety or the EMI requirements by themselves; it shows conformance to the safety and the EMI requirements together. Further, European regulators are expecting that manufacturers will move quickly toward registering their quality systems to ISO 9000 as the basis for controlling conformance. Clarification of proof of conformance can be expected to drive manufacturers toward universal use of the quality registration as the principal means.

From this, a recommendation for strategic movement can be presented:

- Manufacturers should clearly understand the directives and the underlying standards that apply to their products.
- Manufacturers should keep abreast of the latest changes in these.

- U.S. manufacturers should acquire some experience with European labs (they quite often take a different interpretation than expected); and
- U.S. manufacturers should participate in American efforts to harmonize requirements.

CONCLUSION

Safety and regulatory managers will be watching the parallel developments discussed here. Although the engineering details somewhat diverge, the need to meet these requirements and to maintain conformance increases in importance as the EC brings their single market together. The technical aspects of safety requirements are being harmonized fairly rapidly on a worldwide basis. EMI requirements within the EC system are quite different than the U.S. requirements and efforts to harmonize them are not moving ahead very rapidly. The manufacturers' challenge is to continue meeting these requirements in a rapidly changing world market environment. Keeping abreast of these changes and apprising the engineering staff of changes needed to maintain compliance continues to be the challenge of the safety and regulatory staff in every company. The '90s will be an interesting time in the safety regulatory field.

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