DESIGNING AND TESTING PRODUCTS TO MEET THE REQUIREMENTS OF REGULATORY AGENCIES

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Abstract *– Conventional Engineering and Engineering Technology courses may teach students how to design functional products, but almost never address the very practical problem of meeting regulatory requirements. This paper discusses actual Instrumentation and some of the design specifications and modifications that were implemented to meet the requirements of various regulatory agencies. Both hardware and software considerations are discussed. Requirements to gain approval from the following agencies are considered:*

1. *Underwriter Lab Listing (UL)*
2. *Third party testing agencies*
3. *FDA for Laser Safety*
4. *Compliance Engineering (C. E. Marking)*
5. *R.F. and EMI testing*
6. *FDA Premarket Notification - 510k*

An understanding of the requirements from regulatory agencies leads to better product design and reduces product development time. Case histories of actual products that were submitted by the author and approved by various regulatory agencies will be presented.

INTRODUCTION

The objective of this paper is to describe design and test requirements to meet the requirements of various regulatory agencies. This paper will describe the author's experiences over a career period of about eighteen years and provide current references pertaining to these examples. While these products pertain mainly to Biomedical Instrumentation, similar regulatory standards exist for almost all products. A listing of the standards for UL can be found on the following web page: http://ulstandardsinfonet.ul.com/. A sample of these listings is as follows:

Title	UL Standard No.
Mechanically and Electrically Operated Fuel Pumps for Marine Use	1130
Mechanisms, Burglary-Resistant Electric Locking	1034
Medical and Dental Equipment	544
Medical Electrical Equipment, Part 1: General Requirements for Safety	2601-1
Medical Equipment, Refrigerated	416
Medium Heat Appliance Factory Built Chimneys	959
Medium-Pressure, Acetylene Generators, Portable	297
Medium-Voltage Power Cables	1072
Message Type Electric Signs, Control Centers for Changing	1433
Metal Conduit, Intermediate	1242
Metal Container Assemblies for Butane, Nonrefillable (Disposable) Type	147B
Metal Containers, Special-Purpose	1347
Laboratory Equipment	1262
Laboratory Centrifuges	3101

The examples discussed in this paper will include the regulatory agencies pertaining to the following products: Pacemakers, Hematology Analyzers, and Centrifuges. The agencies that will be discussed include: UL, Third party testing agencies, FDA for Laser Safety, C. E. Marking to sell products in the European Community, and the FDA - 510K.

PACEMAKERS

Although the length of time that I worked at a company that developed and manufactured pacemakers was short, and my involvement did not deal directly with regulatory agencies, I still wanted to include some information as to how these devices are viewed. Additional information can be found on the following FDA web page: http://www.fda.gov/search.html. Pacemakers fall under the category of Class III devices.

Class III – Premarket Approval:

Implanted and life-supporting or life-sustaining devices are required to have FDA approval for safety and effectiveness before they can be marketed unless FDA determines that premarket approval is not necessary [1].

UNDERWRITERS LABORATORY

LABORATORY EQUIPMENT

The next experience that I had with regulatory agencies involved the submission to Underwriters Laboratory of an analyzer for measuring sodium and potassium electrolytes in the blood. This product was designed to be used in the doctor's office, or in the operating room, for measuring these components. This instrument was designed to meet the requirements of UL Standard No 544, Medical and Dental

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Equipment [2]. These topics are areas that UL evaluates according to this standard:

- Construction
- Protection against injury to persons
- Performance
- Manufacturing and Production Tests
- Ratings
- Markings
- Cautions and warning notices

A prototype of this equipment was taken to UL for guidance during its early design stages to provide initial input. These are some of the areas that needed to be modified as a result of this initial visit.

- Indicator lights had to follow the proper color requirements. For example: red could not be used for a power-on switch. The color of this power-on indicator needed to be changed.
- Material had to meet the required flammability rating. One of the materials used for a barrier inside the instrument needed to be changed.
- The temperature of the inside of the instrument had to be within a certain range when the instrument is operating in an environment at the maximum specified value. Additional ventilation holes were added to the instrument.
- Circuit boards had to made of UL listed material. The circuit board material was changed.
- Transformers had to be UL listed or submitted for testing. A vendor that had transformers of the same rating with UL listing was found.
- Any openings in the instrument had to be within certain limits. For example: if there was an opening for ventilation with a fan behind it, UL defined dimensions of a probe that could not reach a specified distance into the opening. One opening had to made smaller.
- Proper labels had to be affixed to the product. UL required labels warning against possible explosion in the presence of flammable anesthetic since this product could possibly be used in the operating room.
- High Potential Testing. We had to test this product at the recommended high potential and also measure leakage currents.

The above is just a sample of the some of the design considerations that needed to be considered before submitting the product to UL.

Submitting a product to UL

The process of submitting a product to UL consisted of the following [3]:

- Determining which standard your product falls under.
- Obtaining the proper standard.
- Design the product and labels in accordance with the standard.

How to begin the submittal process:

- Send a letter to UL describing the product and its intended use.
- List all components and materials used in the product.
- Include wiring and mechanical diagrams.
- Include all instruction manuals.
- Indicate whether this is a new or revised design.
- Provide the name and address of the factory where the product will be produced.

Getting the product evaluation under way.
UL's engineers and staff will:

- Plan a test program
- Provide estimates of the testing costs.
- Estimate the amount of time needed to complete the investigation
- Send you application forms.

You will be required to submit the following:

- The required number of samples of certain components to UL for testing, such as transformers.
- Submit the final product for testing.
- Operating manuals and artwork for labels.

What you can expect after the testing:

- You will hear from UL about whether or not your product complies with the UL's requirements.
- You will get a document that describes the construction of the product tested. UL will use this as a guide when conducting their periodic examinations.
- If your product does not meet the UL's requirements, you will receive a letter describing the specific requirements your product did not meet.
- Revisions may be as simple as document changes or as involved as major redesigns.
- Usually the resubmission process takes considerably less time than the initial submission and addresses the areas of noncompliance.

Using components in your design that are UL recognized helps to expedite the process:

Recognized Component Mark for Canada and the United States

This new UL Recognized Component Mark, which became effective April 1, 1998, may be used on components certified by UL to both Canadian and U.S. requirements. Although UL had not originally planned to introduce a combined Recognized Component Mark, the popularity of the Canada/U.S. Listing and Classification Marks among

clients with UL certifications for both Canada and the United States has led to the new Mark [4].

Once you have obtained listing and met other requirements, you can affix the label to your product.

UL Listing Mark

This is one of the most common UL Marks. If a product carries this Mark, it means UL found that samples of this product met UL's safety requirements. These requirements are primarily based on UL's own published Standards for Safety. This type of Mark is seen commonly on appliances and computer equipment, furnaces and heaters, fuses, electrical panelboards, smoke and carbon monoxide detectors, fire extinguishers and sprinkler systems, personal flotation devices like life jackets and life preservers, bullet resistant glass, and thousands of other products [4].

Nationally Recognized Testing Laboratories (Third Party Testing Agencies)

My experience with third party Nationally Recognized Testing Laboratories was with MET Laboratories, www.metlabs.com/, in Baltimore Maryland. The products submitted were Hematology Analyzers that gained approval for UL listing 1262 for Laboratory Equipment and a Centrifuge that gained approval for UL listing 3101. In addition to testing the product, a factory inspection was performed according to ISO (International Organization for Standards) 9000 series [5]. Periodic inspections were made to this Standard. Some modifications had to be made as a result of testing but none had major impact to the product. Any proposed changes to the documents, or to the components, had to be presented to the testing agency.

FDA for Laser Safety

This product was also a Hematology Analyzer, but it had scanning laser diode. Because of the laser diode, this product needed to comply with the FDA compliance for Laser Products [6]. The class for the laser had to be established based on the wavelength and energy output. For this particular instrument, hematology samples were inserted through a door and when the lid was closed a laser beam would scan the sample to analyze it. See Figure 1.
Some of the safeguards that had to met were as follows:

- When the lid was opened, two switches were needed to break the energy source to the laser diode.
- Direct switches were needed to turn off the laser energy source rather than mechanical or electronic relays.
- The microprocessor could not be used as a means to turn off the laser when the lid was opened.
- The laser beam could not escape beyond the confines of the instrument when the lid was open in the event the beam did not turn off.

To meet these guidelines, the lid switch that supplied power to the laser diode was changed and the confines for the laser beam was modified.

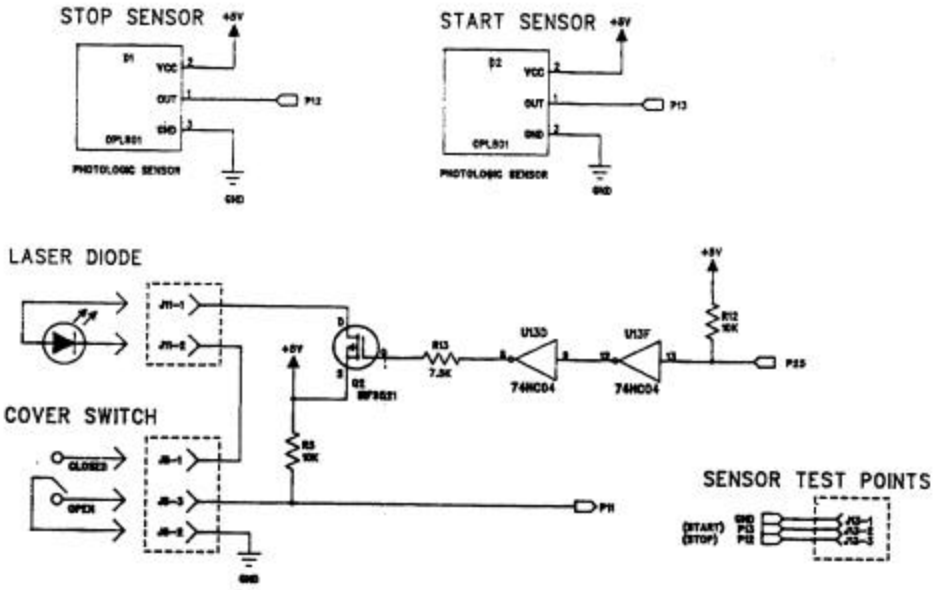

FIGURE 1

The European Medical Device Directive – C.E. Marking

This same Hematology Analyzer was to be sold in Europe Union Countries; therefore it needed to meet requirements to obtain the CE marking. The European Medical Device Directive (MMD) mandates that all medical equipment sold in Europe Union Countries must carry the CE Marking [7]. A third party agency was used for this testing. One of the requirements that was tested was electromagnetic compatibility (EMC). Electromagnetic compatibility or EMC means that the device is compatible with (i.e., noninterference caused by) its electromagnetic (EM) environment, and it does not emit levels of EM energy that cause EMI in other devices in the vicinity. The wide variation of medical devices and use environments makes them vulnerable to different forms of EM energy which can cause EMI: conducted, radiated, and electrostatic discharge (ESD). Further, EMI problems with medical devices can be very complex, not only from the technical standpoint but also from the view of public health issues and solutions [8]. Some items that must be considered to meet these requirements include the following [9]:

- Proper layout of printed circuit boards
- Power Supplies
- Enclosure Shielding
- Filters

This product did not meet the requirements for conducted radiation. Fortunately, a line cord with a built in filter was added to the product without requiring major modifications.

A Model Course in EMI/EMC

A model of a course in EMI/EMC could include the following topics [10]:

1. Introduction to Electromagnetic Compatibility
2. Sources of EMI
3. EMI from systems and circuits
4. EMI Measurements Demands
5. Measurement of Radiated Interference
6. Measurement of Conducted Interference
7. Grounding, Shielding and Bonding
8. EMI Filters
9. Cables, connectors and components
10. Frequency assignment and spectrum conservation
11. EMC Standards

Regulatory Requirements for Medical Devices – 510(k)

This Hematology Analyzer had to be demonstrated to be safe and effective. This had to do more with testing results obtained from this instrument and comparing it to other standards. This involved clinical trials of the product and the submission of data in a process called a premarket notification 510(k) to the FDA. The FDA regulates devices to assure their safety and effectiveness. To fulfill provisions of the FD&C Act, FDA develops and promulgates rules to regulate devices intended for human use. These rules regulate various aspects of the design, clinical evaluation, manufacturing, packaging, labeling, commercial distribution, and postmarket surveillance of devices. These regulations are published in the *Federal Register* [11].

Conclusion

During the initial prototype stage of a design, the Engineer is primarily concerned with just getting something that works for demonstration purposes and proof of principal. Yet, if the designer has an understanding of the regulatory requirements for the particular market for which the product is to be sold, fewer modifications will be needed as the product proceeds through the design process. The Engineering Technician should also have an understanding of these requirements since they will often be involved in the testing of the product to ensure regulatory compliance. Often tooling costs are being incurred before final reports from regulatory are obtained and modifications to products can add significant cost and time to product development [12]. As a result, this subject matter should be included in Engineering and Engineering Technology curriculums. One way that this could be addressed is to obtain actual UL standards and review this information with students. In addition, by having students make actual EMI measurements in the lab and learning actual shielding techniques, they can become better prepared for the work place.

References

[1] FDA, Center for Devices and Radiological Health, Premarket Approval Manual, *HHS Publication FDA 97-4214*.

[2] UL 544, *Medical and Dental Equipment*, Underwriters Laboratory Inc. Standard for Safety. August 1993.

[3] Underwriters Laboratory Web Page: http://www.ul.com/services/submittal.html, "How to submit your product."

[4] Underwriter's Laboratory Web Page: http://www.ul.com/mark/index.html, "UL's Marks – What they look like and what they mean."

[5] ISO 9000, *Handbook of Quality Standards for Compliance.*

[6] FDA, Center for Devices and Radiological Health, *Compliance Guide for Laser Products*, HHS Publication FDA 86-8260.

[7] Schnoll, L, *The CE Mark – Understanding the Medical Device Directive*, Paton Press, 1997.

[8] FDA, Center for Devices and Radiological Health Web Page: http://www.fda.gov/cdrh/emc/, "CDRH Medical Devices Electromagnetic Compatibility Program".

[9] Kerridge, B. "EMC components administer + first aid +", *Electronic Design News*, February, 1994. 54-60.

[10] Lozano-Nieto, A. and Ofosu, W. "Assessing the need to introduce Electromagnetic Compliance and Interference (EMC/EMI) in Engineering Technology programs." *Proceedings ASEE 1999 Annual Conference*, Session 3547.

[11] FDA, Center for Devices and Radiological Health, "Premarket Notification 510(k): Regulatory Requirements for Medical Devices", *HHS Publication FDA 95-4158*.

[12] Wright, J.F., and Foster, M.A., "Integrating Safety Measures into the Design Control Program." *Compliance Engineering, Jan/Feb 2000*.