

Xenon Light Sources and the European Union

Steve Reames

Introduction

Selling light sources into Europe has changed over the last few years with the formation of the European Union (EU). Ironically, the EU was designed to make it easier to ship products into Europe. By becoming a member of the EU, each country agrees to make no laws restricting the free trade of goods among member countries.

To make the idea of free trade a practical reality, it became necessary to develop a uniform set of regulations regarding such things as product safety and electromagnetic interference. Prior to the EU, each country had its own rules, which made shipping into Europe nearly impossible for all but the largest of corporations. Now the EU has a set of regulations called European Norms to which all products must adhere. These apply to both products manufactured in Europe and products imported from other countries.

This paper highlights the European Norms that usually apply to xenon light sources used in medical applications. What follows is a much simplified interpretation of EU rules and regulations. Although an expert in the field may argue over the details, the basic concepts are accurate.

How Do I Get a CE Mark?

The CE mark is the symbol of approval that allows your product to be shipped into EU member countries. A frequently asked question is “How do I get a CE mark?” The answer is simple: you put it on yourself.

This answer deserves a little more explanation. In the U.S., the UL mark is a trademark owned by Underwriters Laboratories. In order to use the UL mark you must pass a set of tests, pay a licensing fee, and then Underwriters Laboratories will grant you permission to put their trademark on your product. If you put this mark on your product without their permission, you are guilty of trademark infringement and can be prosecuted accordingly. This is how the UL mark is controlled in the U.S.

Setting up the same kind of control for the CE mark would have been difficult considering the complexities of international law. So the EU took a different tack—self certification. Each company decides whether or not they meet the appropriate specifications and then they put the CE mark on their product. The EU has guidelines for how this should be done.

The process is conceptually simple. First you read through all of the European Norms and decide which ones apply to you. You’ve probably seen these

before; all of the European Norms start with “EN” and usually have five digits. For example, EN60601, EN55011, and EN61000-3-2. Make a list of the applicable standards. Then you perform the necessary tests for each of the Norms. The tests can be done by you, or by a certified testing lab. For the safety and EMI standards, almost everyone uses an accredited lab. The results from all of these tests are put into one big folder. This folder is very important as we will see later.

Once you are satisfied that you meet the relevant standards, you can put the CE mark on your product. You must also sign a one-page form that essentially says “We hereby declare that we passed all the tests that apply to this product.” Ready? Now box up your product and ship it.

Normally your product is received with no problems. But let’s suppose that you cheated just a little, and you didn’t quite meet one of the specifications. Most likely no one will notice. The customs agent, say in France, might be suspicious because you claim to meet the medical standard, yet there is a gaping hole in the sheet metal where someone could touch the power lines.

The customs agent would hold your shipment and request a copy of your technical folder. Remember that big folder you put all your test result into? That’s the one. You have 48 hours to get a copy of that folder to the requesting country. If you don’t supply the requested information, they go to the form you signed that says “We hereby declare blah blah blah.” The name at the bottom of the form is the person that gets thrown in jail. If they can’t find that person, then they grab the head of your sales office in France, or whoever they can get their hands on. Your product is seized, and an alert message is sent to all member nations telling them to freeze the shipment of your product. As you can see, the Europeans are serious about their regulations.

Regulations experts that have experience with the EU say that they are actually very reasonable. If someone in Germany reports that your product interferes with their TV set, then VDE or some other agency will test your product. If they find that you’re 2 dB over the limit, they’re not going to throw someone in jail. They will politely ask you for your technical folder, then open discussions with your company as to how many units in the field have the problem, how you plan to address the problem, etc. If a competitor complains that your product doesn’t meet some specification, the EU will examine the evidence before taking action. The EU won’t make you jump through a bunch of hoops based on hearsay from a competitor.

The bottom line is that the CE mark is self-certified, but you better have solid documentation in the form of a technical folder before shipping product to Europe. Does this make you nervous? It makes lots of people nervous. That is why the EU provided for an extra feature on the CE mark. On some CE marks you will see a small four or five digit number following it. This is the code number of a testing agency that has registered with the EU. Many testing agencies will sit down with your company and review your technical folder. They can provide suggestions and ideas based on their experience, and they will let you know if there is a regulation that you overlooked. Once the testing agency has thoroughly

reviewed your technical folder and agrees with its findings, they will let you put their code number after the CE mark. Now if anyone challenges your product, they will look up the code number and contact that lab. None of this comes for free, but the confidence that comes from having an independent lab review your work is often worth the cost.

The European Norms

Where did the European Norms come from? When the EU was formed, they didn't have enough time to invent all kinds of new standards. So they essentially stole standards from reputable organizations and put their own numbers on them. They used a logical renumbering scheme so you can tell where the standard originated. The old IEC 601 specification became EN60601. The CISPR-11 and CISPR-22 standards were turned into EN55011 and EN55022 respectively.

For the last few years, almost every country in the world has noticed the problem with differing standards. To address this issue, most countries have been revising their own standards so they match what other countries are doing. Let's look at the medical safety standard as an example. The original U.S. standard was UL544. The EU took the IEC 601 standard and turned it into EN60601. To make the U.S. specification match the European one, UL created UL2601. Canada's effort to standardize resulted in CSA 22.2.

These three standards, EN60601, UL2601, and CSA 22.2 are called "harmonized." This is another way of saying that if you meet one, you meet them all. Suppose your product has been certified for UL2601. Do you need to re-certify to meet EN60601? No. Remember that bit about self certification? It is perfectly valid for your company to put your UL2601 data into your technical file and declare that you meet EN60601. That's the beauty of harmonized standards. But what if you certified to UL544 instead? Tough luck, you will have to re-certify to one of the harmonized standards in order to claim adherence to EN60601. Remember that key word: harmonized. Either UL544 or UL2601 is fine if you plan to only sell your product in the U.S. If you aspire to ship your product to Europe, you want to make sure that all of your testing is done to one of the harmonized standards. Underwriters Laboratories would be perfectly happy to test your unit to UL544, but the forward-looking designer will insist on UL2601 instead.

Here is a list of the most common European Norms that apply to xenon light sources for medical applications. Included is a brief description of the intent and extent of the standard.

EN60601 – This is probably the best known of the standards in the medical industry. It includes the requirements for building a safe product. From the viewpoint of the standard, safety governs anything that could cause a hazard to either the patient or the operator. Includes are specifications for maximum leakage current, insulation breakdown voltage, flammability testing, and maximum case temperature.

EN55011 – This standard covers the requirements for electromagnetic compatibility (EMC). This is a general term that covers how much energy your product is permitted to radiate, and also how resistant your product is to energy from someone else. There are several sub-groups in this standard:

Class A – Product is used in establishments other than domestic areas.

Class B – Product is suitable for use in domestic establishments.

Group 1 – Laboratory, medical, and scientific equipment.

Group 2 – Industrial induction heating equipment.

Most xenon medical light sources fall in the EN55011, Class B, Group 1 category.

EN61000-3-2 – This standard controls the amount of harmonics that a product is allowed to put on the power line. It essentially dictates that the product must have a power factor near unity.

EN61000-3-3 – The flicker standard regulates the amplitude and frequency of current pulses that a product is allowed to draw from the line. Most people have noticed how the lights flicker whenever the heater inside a laser printer turns on. The goal of this standard is to reduce the annoyance factor that comes from flickering lights.

To PFC or not to PFC

The creation and enforcement of new regulations within the EU has generally proceeded in an orderly manner. But 1996 marked the beginning of regulations that have confused the industry. The issue revolves around EN61000-3-2: Line Harmonics. The problem that the EU was trying to address was the non-sinusoidal current waveform that virtually all electronic devices draw from the power line. Any device that has a full-wave bridge and a filter capacitor is guilty of drawing current spikes at the peak of the voltage waveform. The only practical way to solve this problem, and to meet the standard, is to add Power Factor Correction (PFC) to the product's power supply. Electronic PFC is essentially a pre-regulator that precedes the main regulator in a switching power supply.

In September, 1995, the EU voted to include EN61000-3-2 as a standard. This would essentially require all products between 50 Watts and 600 Watts to add PFC. The enforcement date was set as January 1st, 1996. The power supply industry strongly objected, stating that there was no way to put PFC into all of their products in only three months.

The EU didn't take any action until late 1997 when they postponed the implementation of EN61000-3-2 until January 1st, 2001. The industry is still split on the reality of this standard. Some observers point out that this kind of postponement is not unusual for the EU, but that it is very unlikely that they will delay implementation a second time. Others hold out for the hope that medical

and dental products might get some kind of exception before the 2001 deadline. Still others believe that the standard is impractical and will never be enforced.

Different companies are taking different approaches to the issue. Some companies point out, rightfully so, that PFC is a very expensive addition in a competitive world market. The power supplies in PC's sell to OEMs for \$14 to \$25. Adding PFC would double their cost and most likely add \$100 to the list price of every PC sold in Europe. Laser printers, fax machines, and photocopiers are among the list of cost competitive products that would be adversely affected by adding PFC. This faction argues that manufacturers will push back, and EN61000-3-2 will be repealed before it is implemented. Other companies are accepting the standard and updating their products to be compliant.

This issue is creating a high-stakes gambling situation in the industry. If Company A decides to add PFC to all their products, and EN61000-3-2 is repealed, then they are put at a cost disadvantage to their competition. On the other hand, if Company A decides not to implement PFC, and the EU decides to enforce EN61000-3-2 starting in January, 2001, then they will not be able to ship to Europe and once again are at a competitive disadvantage.

Many power supply companies are pushing the problem off onto the end-product manufacturers. They are making both PFC and non-PFC products available and letting the system integrator decide which path to take. This does not help system designers because PFC supplies are invariably larger than their non-PFC counterparts. The problem is complex, and as of this date, unresolved.

Copyright, 1999, Carsan Engineering

This application note may be copied in full or in part provided proper credit is given to Carsan Engineering.