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## Display

## LED Safety Regulations

# A Comparison of High Level European and U.S. Product Safety Requirements

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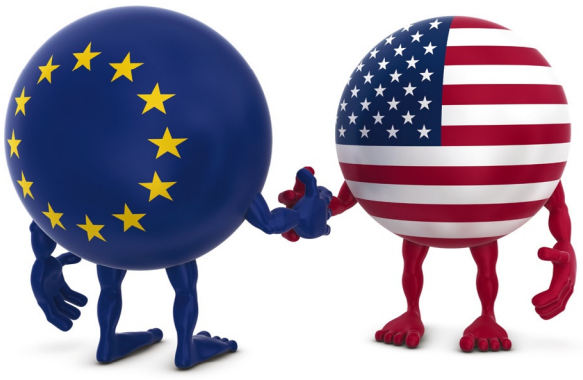
LED lighting product manufacturers have many challenges to face in getting new product designs launched into the marketplace. Apart from the many technical challenges and problems that must be solved to arrive at a commercial quality product fit for release to customers, in an industry which is consistently making very rapid advances in technology, it can be easy to overlook perhaps what may be considered by some as the less glamorous area of meeting the mandatory regulatory requirements of the countries targeted for product launch. Larger established companies are likely to be well versed in regulatory requirements and may even employee specialist conformance engineering staff but the nature of the LED lighting industry and the opportunities arising is leading to many new start-up companies that may not be sufficiently aware of requirements and safety engineering practices. A challenge still exists for the larger companies for example with training new design engineers, entering new markets and addressing the expanding product liability risks and possible product recall probability which increase with product range and production volume. Some of the largest companies will employee a legal professional and develop strategies and contingency plans in the case of a voluntary or mandatory product recall.



Importance of the EU & US markets.
EU & US market trade statistics:

| Zone | GDP $(Trillion, import) | World rank |
|---|---|---|
| US | 13.8 (2007) | 1 |
| EU | 13.5 (2006) | 2 |

Source: WTO

*Figure1: EU/US handshake, istockphoto ref # with brief WTO data on the GDP of the EU & US.*

It is the intention of this article to explain key regulatory requirements in the compliance engineering field of product safety, for the European and U.S. marketplace. Armed with a knowledge of these key requirements, manufacturers can decide how best to design their product safety compliance strategies and processes to ensure a smooth transition of the product from concept stage through to delivery to customers and volume production.

## High Level Safety Regulations

Design for product safety must encompass a firm understanding of higher level safety regulations for the target markets and once this is achieved, manufacturers can confidently manage and execute a safety design process which will ensure timely and cost-effective attainment of mandatory and desired safety approvals.

### European high level safety regulations

Most manufacturers will have some familiarity with the high level safety requirements for the European Union – namely CE marking to the Low Voltage Directive – LVD (2006/95/EC). The relevant content of the LVD should be reviewed for new product designs especially with regard to new or unusual applications. It is useful to keep in mind that application of the harmonised standards is the preferred way to achieve the goal of complying with the high level requirements of the LVD (see Table 1).

Techniques traditionally originating from safety-critical industries such as energy (e.g. oil and gas production) and transport (e.g. railway signalling) are increasingly being used in the consumer and related product industry sectors. Such techniques include fault tree analysis (FTA), event tree analysis (ETA) and failure mode effects and criticality analysis (FMECA). Also safety-critical functions are increasingly finding their way into products which did not originally provide this functionality. In the world of industrial automation for example, some electronic variable speed drives for motor control now feature a 'safe stop' ability complying with a recognized functional safety standard such as EN 61508-1 – Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 1: General requirements. We are likely to see similar trends with LED lighting products increasingly being used in safety critical applications such as airport runway lighting systems. LED product designers for such applications will need to become aware of how to calculate Safety Integrity Levels (SILs) and add this as a new skill to the more traditional safety related knowledge such as calculating electrical spacings to withstand mains borne transient voltage surges (in the case of TVS, needing to be sufficient for the actual application demands but also to meet mandatory requirements for safety purposes). Certainly the application of the safety analysis techniques discussed above could be helpful to LED lighting manufacturers in performing initial and follow-up product hazard analyses to supplement the more rigid application of individual product safety standards and even identify hazards that are simply not envisaged or addressed by meeting the product safety standard requirements alone. A case comes to mind whereby the product in question fully met the relevant UL standard yet a subsequent safety hazard analysis

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| LVD article number | Key requirement | Comments |
|---|---|---|
| 1 | 'Electrical equipment' operating at 50 – 1000Vac, 75 – 1500Vdc is in the LVD scope. | Although an LED light module rated for a supply voltage under 75Vdc would be exempt using this voltage criteria, the LVD may still offer relevant advice regarding other hazards to be considered. Clearly, complete end-products with e.g. 240Vac supply voltage rating will come within the scope. For instances where the LVD does not apply, consider also application of the General Product Safety Directive 2001/95/EC, though the CE mark cannot be applied with reference to the GPSD. |
| 2 | The equipment must not endanger humans, animals or property when used and installed as intended. | A high level hazard analysis to the LVD articles may reveal issues to be addressed that may be overlooked when using detailed product specific standards documents. This hazard analysis may be included in a Technical File to assist demonstrating conformity with the LVD. |
| 5 | Equipment complying with the safety requirements of harmonised standards satisfies article 2. | Identifying the correct harmonised standard or standards is crucial to creating a robust safety case. High level hazard analysis can help to determine standards or parts of standards that may be applicable. |
| 6, 7 | If a required harmonised standard is not yet available, alternative safety standards such as IEC may be applied, or use other suitable standards published by the member state to achieve equivalent safety levels. | Gives a route for developing a safety case e.g. for very new technology, aspects of which may not be envisioned or addressed by an existing harmonised standard. |
| 8 | The CE mark should be affixed to the product before it is placed on the market. It indicates all relevant directives have been complied with. | It would be acceptable to demonstrate a pre-production non CE marked unit for example at an exhibition, with adequate safety measures put in place. |
| 10 | The CE mark may be placed on packaging or product documentation if not able to be placed on the product. | This article also has a procedure to deal with discovery of CE marks placed on equipment when there should be no CE mark applied. |
| Annex II | Lists types of specialised equipment not inside the scope of the LVD. | Examples include products for use in explosive atmospheres, products for use on ships, aircraft and railways. |
| Annex III | Contains CE mark graphics requirements and what should be in the Declaration of Conformity (DoC) | DoC should include manufacturer or representative name and address, reference to harmonised and any other standards or specifications for which conformity is declared, signature of authorising person, last two digits of year of CE marking. |
| Annex IV | The manufacturer must create technical documentation to show the equipment conforms to the LVD, and put in place an adequate process to ensure ongoing conformity. | The Technical File must be available to authorities up to 10 years after cessation of production. It should contain details including description of equipment, product electrical and mechanical design data, operation instructions, list of standards applied, and how safety has been addressed if standards not used in any instance, results of calculations , examinations and tests assuring safety. An ISO 9000 manufacturing quality system can help to demonstrate ongoing LVD conformity. |

*Table 1: Summary of the key high level requirements paraphrased from the LVD. Refer to the full LVD text for complete guidance (Remark: A harmonised standard is one that has been adopted and agreed by EU member states and its title recorded in the Official Journal of the European Union).*

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revealed hazards in the product that were not covered by the UL standard and a design change was required. So simply complying with the relevant industry-recognized standard for a particular product category may not be enough to assure a safe product or defend successfully against a potential lawsuit.

Be sure to enquire whether your product liability insurer will give you discount from the insurance premium in recognition of having performed the analysis and documented any corrective measures. Prudent manufacturers will consider whether they should print specific legal disclaimers in their product manuals for example stating that the LED product is not suitable for use in a safety critical application - if it is not designed for that purpose (or unless designing safeguards into the system against failure). It is advisable to take the advice of a specialist Attorney when developing additional safety related warnings to ensure they are legally effective.

### U.S. high level safety regulations

We have seen that high level safety regulations for Europe are encompassed in the Low Voltage Directive. So what are the equivalent high level safety regulations in the U.S.A. and what are the key differences?

Main high level regulations:

- The Occupational Safety and Health Association (OSHA) 29 CFR (Code of Federal Regulations) 1910 Subpart S (Electrical) regulations. OSHA is a section of the U.S. Government's Department of Labor.
- The National Fire Prevention Association (NFPA) standard number 70 – the "National Electrical Code (NEC)".
- The NFPA standard number 70 E – the "Standard for Electrical Safety in the Workplace".

These regulations address the health and safety aspects in U.S. law relating to the use of electricity and electrical equipment in the workplace. It is proposed in this article that the above regulations cover much of the safety goals the EU Low Voltage Directive is intended to. In fact the above U.S. regulations address general health and safety requirements and practices in much more detail than does the LVD, as there are separate regulations in the EU for workplace health and safety.

It can be seen that the LVD directly refers down to the lower level regulatory requirements – the harmonised standards themselves - and for example EN 61347-2-13:2006 Lamp control gear — Part 2-13: Particular [safety] requirements for d.c. or a.c. supplied electronic control gear for LED modules – is a harmonised standard listed in the Official Journal of the European Union.

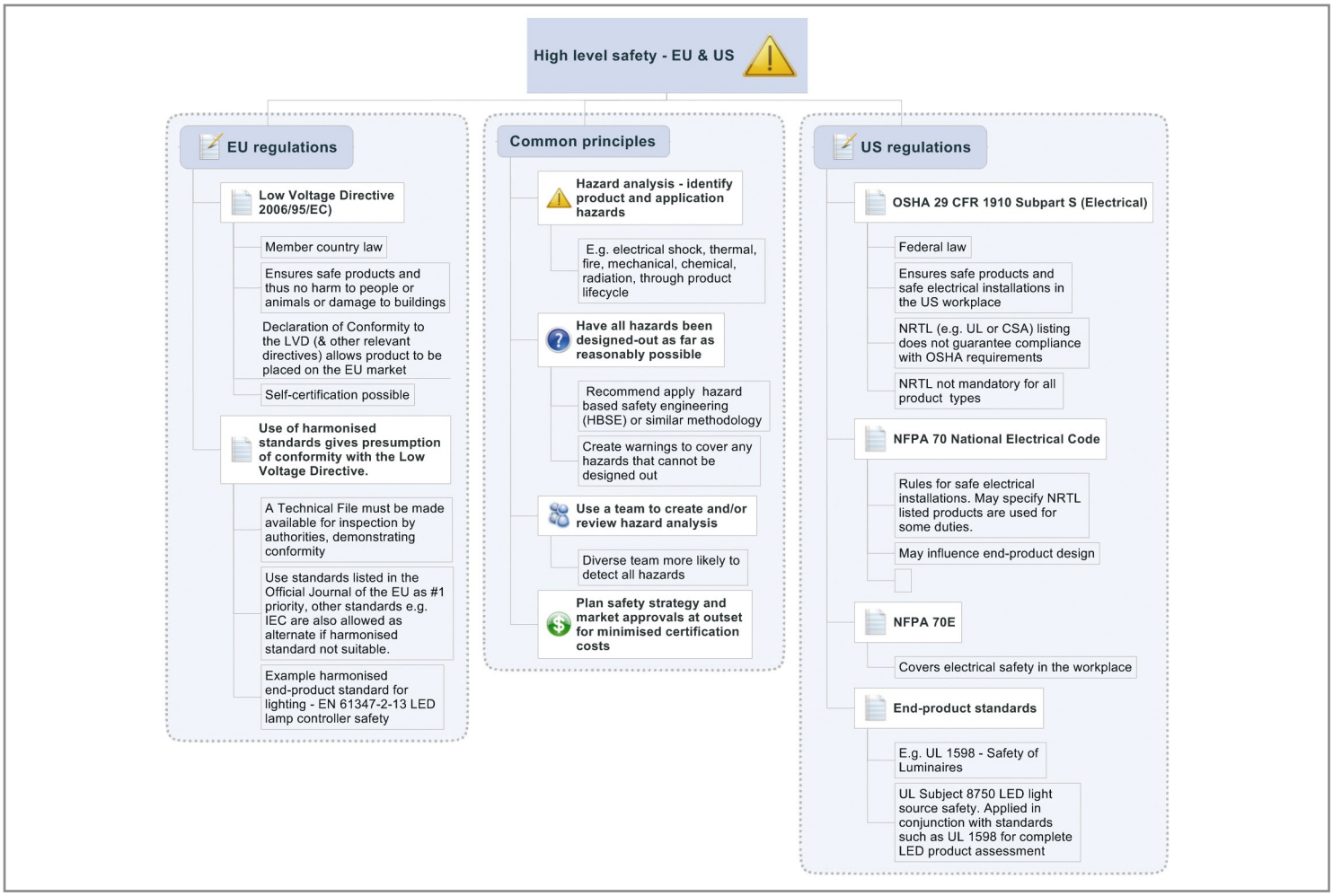


*Figure 2: High-level safety regulations and principles.*

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And as a comparison with the U.S. system the lower level requirements - the standards themselves - are called up by the OSHA and NEC regulations, which require the use of the appropriate American National Standards (ANS). ANS are standards developed by Standards Development Organisations (SDOs) that work to American National Standards Institute (ANSI) guidelines to ensure the quality and consistency of the standard development process and that the standard has been developed by consensus of interested parties.

The ANS covering the electrical, fire and mechanical hazards for the lighting sector are those developed by Underwriters Laboratories (UL). UL has developed many lighting standards as of course this industry sector is one of the oldest in the electrical engineering field. There are currently approximately 27 lighting related product standards published by UL – from somewhat obscure examples such as UL 1230 for the Safety of Amateur Movie Luminaires – to the widely used UL 1598 Standard for the Safety of Luminaires, and of course through to the currently topical Subject 8750 - LED Light Sources for use in Lighting Products - which is under development (and as a side-note is used in conjunction with appropriate existing UL end-product lighting standard in order to fully evaluate the complete LED based end-product).

The OSHA regulations can be considered to be at the centre of the U.S. electrical safety requirements and constitute federal law. The outcome of a lawsuit may end up being decided over the interpretation by experts of a particular federal code requirement. One can locate expert witnesses that specialise in knowledge of a particular OSHA code regulation, and that publicise their expertise and court procedure experience to product liability Attorneys looking for this assistance.

The NFPA 70 (NEC) should be used for its advisory role on implementing safe electrical installations and using safe products (such as when certain products must be listed by a Nationally Recognized Testing Laboratory - NRTL), whilst the NFPA 70E standard will give employers guidance in safe working practices to be observed during equipment installation and ongoing once the installation goes into service and is then subject to normal maintenance and operation procedures.

NEC article 410 lays down many of the requirements for luminaires, lampholders and lamps including for example specific references to installation practices for LED luminaires installed in closets (article 410.16). Article 411 is also worthy of reference as it applies to lighting systems operating at 30Vac or less (30Vac / 42.4Vpk being the limit for a circuit considered not to present a risk of electric shock according to U.S. requirements). Article 411 has important definitions regarding listing requirements (such as UL or other NRTL listing) of low voltage lighting systems.

Nationally Recognized Testing Laboratories

Typically manufacturers may immediately think of obtaining UL (Underwriters Laboratories) 'approval' for their product in order to launch their new product design onto the U.S market – but this is not a sufficient approach on its own because the important higher level regulatory review would have been missed out. In many cases UL or an alternative NRTL evaluation may prove to be needed as established by the high level review but do not assume that NRTL listing is mandatory until this aspect has been researched – other routes may be perfectly permissible. For example installation of a one-off custom designed system to be installed at a fixed end-customer site may not need listing, although it will be wise in such a case to liaise with the local Authority Having Jurisdiction (AHJ) to ensure a non-listing approach is acceptable.

It is an appropriate point to explain some terminology and requirements. Firstly UL 'approval' - a commonly used term but incorrect according to UL definitions – should be clarified as UL listing, recognition or classification. Generally, the UL listing mark (the letters 'UL' in a circle) applies to an end-product such as a complete luminaire ready for wiring to a building electrical circuit, whereas the UL recognition mark (the letters UR written backwards) applies to components that are to be used inside end-products (for example some LED light modules are now appearing with UL recognition). Classification is a less commonly seen UL marking and covers more specialised evaluations such as to a unique set of application requirements. It is much easier to gain UL listing for an end-product if safety related components used are UL recognized. Recognized components have undergone constructional assessment and testing within certain conditions – and provided they are used in an end-product within the recognized conditions (known as 'conditions of acceptability'), then further assessment at end-product level is minimised. Another point which should be made clear is that UL is one of several NRTLs and manufacturers should be aware that product safety listings can be carried out by any NRTL that is accredited by OSHA against the relevant product category and standard so there is choice in the marketplace.

NRTLs are appointed and administered by OSHA which is a section of the U.S. Government's Department of Labor.

Authorities Having Jurisdiction (AHJ) with regard to electrical product and installation safety, may be a number of different organisations at local level, e.g. part of an NRTL, or a staff member employed by a city or municipality department responsible for such duties. An AHJ inspector can 'red-tag' (prevent from use) an installation or equipment if the inspector find a problem - for example with non-compliance to the National Electrical Code, or a deviation from a manufacturer's installation manual or UL/NRTL listing or condition of acceptability violation.

As well as originally being located in the U.S., NRTLs can now be found in many other countries – which involves OSHA staff travelling to the NRTL location to carry out initial qualification of the NRTL and perform regular auditing. With regard to CE marking, for most product categories, including many types of lighting product, self-certification application of the CE mark can be done entirely by the manufacturer without third-party involvement equivalent to an NRTL. Some more specialised markets such as products designed for use in explosive atmospheres, will require mandatory third-party certification by EU accredited laboratories. The official term for such organisations is a 'Notified Body' and they are appointed by each EU member state.

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## Summary

The high level European safety legislation in the form of CE marking to the requirements of the Low Voltage Directive may be considered as giving the manufacturer more flexibility in demonstrating mandatory conformity requirements compared with the higher level requirements of the U.S. system which in many more cases will involve the judgement of a third-party such as an NRTL and/or a local Authority Having Jurisdiction before the item is placed on the market or installed. This is because the European system allows self-certification by the manufacturer for most categories of products. This should not prompt conclusions as to whether products meeting European safety requirements are safer than those meeting U.S. requirements or vice-versa. Such generalisations cannot be easily or reliably made. The important point is to understand the requirements in detail for whichever market is targetted and devise methodologies of ensuring the design process results in a safe product at minimal conformance cost and in the least possible time. Design for safety should be planned at the outset of a development project and not left to the final stages of the project.

The highest level legal requirement with product safety is the expectation of the law that the manufacturer will place a safe product onto the market. This means that the manufacturer must design-out all product hazards as far as possible, and if there are any hazards that cannot be designed out, they must be brought to the attention of the relevant parties – user, installer, service person, repairer, re-cycler (different hazards may be present depending on the usage mode of the product and the lifecycle stage) . This last area is usually addressed by appropriate warnings on the product labels, and in the supplied product documentation. Whilst the safety standards lay down certain requirements and give actual text to be used in some cases, these warnings may not be sufficient and the manufacturer may need to develop additional special warnings particular to the possible hazards presented by the use of the product. Many manufacturers, particularly in the U.S., now routinely engage the service of a specialist Attorney to define the exact wording. This can be crucial to building a robust litigation control scheme to help guard against 'nuisance' or 'speculative' lawsuits, or other potential legal actions that may arise once the product is on the market.

A particular safety hazard that should be considered from a high level regulatory perspective before undertaking detailed safety requirements research is that of possible injury to the eye through excessive light intensity that may be emitted by an LED; especially with a rapidly increasing luminous intensity performance being seen in the latest LED technology. Legislation and safety standards are being developed to address this but until guidelines are clear, manufacturers will have to do their own additional due diligence, ultimately to be able to show to authorities if required, that they have considered and addressed such hazards and that eye damage will not result through use of the product. From the hazard analysis point of view, one should consider single component faults (multiple component faults for safety critical applications) and whether for example the expected maximum light intensity could be exceeded e.g. due to a fault in the driver circuit.

Newer standards in development such as IEC 62368 in the consumer electronics field, which is intended to replace EN 60950 for Information Technology Equipment and EN 60065 for Audio/Visual product safety, bring in the concept of Hazard Based Safety Engineering (HBSE) and place the emphasis on hazard assessment over technology specific standards. It will be interesting to see how this standard progresses. If it is successful, the HBSE methodology is likely to be adopted in other product safety standards. HBSE techniques can of course be applied now as a tool to analyze potential product safety hazards.

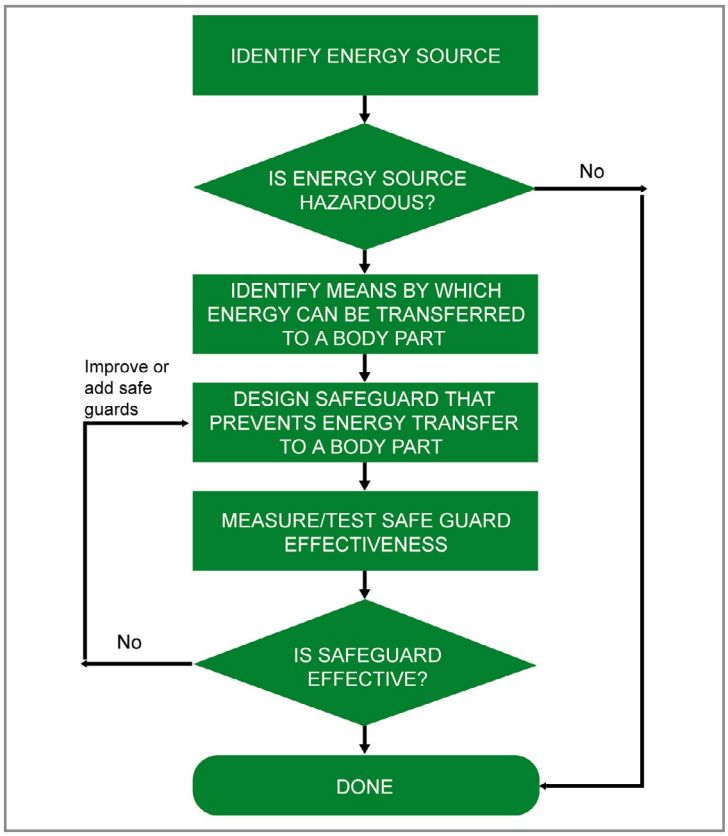


*Figure 3: The hazard based safety engineering (HBSE) process.*

This article has concentrated on the requirements of the European and U.S. marketplace, but meeting regulatory requirements for either, or both of these markets will allow sales to be made in many other counties which accept the CE mark and the U.S. NRTL safety marks. Many other certifications are possible such as the international CB scheme based on IEC standards, but whatever compliance route is taken, it is best to plan the approach early in the development cycle and start compiling the LVD Technical File, list of UL recognized components and other regulatory information early in the development phase. Key safety related tests should be identified and 'dry-run' before submitting the product design for final NRTL witnessed testing to avoid the risk of test failure, re-design and re-test and possible delayed product launch.

It is hoped this article has been thought provoking with regard to the importance of taking a high level view of how best to achieve a safe product design, and also possible ways to innovate in the compliance process just as with innovation in the design of the new LED lighting product itself. ■

***References:***

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