



CE Marking and Legal Risk Management-Simply Good Business

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Disclaimer

This paper is intended to provide interesting and useful information regarding the subjects covered. It is not meant to supply company specific direction on how to handle legal or regulatory compliance issues, nor is it intended to take the place of expert advice. Because of the wide scope of the subjects addressed in this paper, those responsible for the design and placing on the market of products in the EU should conduct their own independent evaluation to assure that each such application and use meets the requirements of all relevant directives, as well as other local and regional codes, laws and regulations.

Key Words: CE marking, risk management, ISO 9000, preventive law, design review, contract review, manufacturers' liability prevention

Abstract

This paper discusses methods manufacturers can employ to effectively meet CE marking requirements and simultaneously minimize their liability exposure through systematic quality and risk management strategies. These strategies include the performance of effective contract reviews, design reviews and hazard analyses/risk assessments. Optimally, a firm should have documented procedures for such activities, as described in the ISO 9000 Quality Management Standards, and involve different departments in the process including senior management, sales, legal, design and quality. Companies that understand their liability exposure and effectively execute CE marking and risk management strategies can increase customer satisfaction and reduce costs, disputes, claims and litigation.

Introduction

The purpose of this paper is to show ways companies can save money and increase productivity through effective quality and risk management strategies by involving multi-functional personnel in areas such as quality, legal, sales, engineering and senior management. The strategies discussed in this paper focus on prevention activities which can lead to reduced liability claims. Companies selling their machinery in the European Union (EU) must ensure their equipment is intrinsically safe. If the work associated with ensuring this can be viewed proactively and as a process, benefits can be realized.

The scope of this paper covers industrial goods sold from business to business and does not include consumer products since product safety requirements and applicable laws tend to differ in this regard.

For companies that are exporting certain products to the EU, compliance to the applicable EU requirements is mandatory; however firms that may not be currently exporting should also assess the need to implement these strategies in an effort to reduce the risk of unexpected cost, delays, and potentially damaging law suits, and to improve the safety of their equipment. To the extent that machinery sold in the EU is considered safer than machinery sold in the U.S., a manufacturer runs the risk of providing a plaintiff with proof of an alternative design that could be used against the manufacturer in U.S. litigation.¹ Too often, exporters view compliance as a “paperwork” exercise to some highly technical or legal requirements – but if viewed in a different manner, compliance to the requirements can be the beginning of a program that helps to define ways in which the company can minimize its risk and improve quality. Management should be interested in such strategies as ways to increase shareholder value, minimize accidents and add customer confidence and loyalty.

During the design process, most engineers focus on designing a product that meets its intended use. While a product must meet the customer's needs, it must also be safe. Indeed, it is a good practice to design safe products using industry adopted practices, however typically only in firms that supply equipment where safety standards have long been established (such as farm equipment) do such practices get systematically utilized. Beyond this, most firms do not have the management support, resources, and knowledge base to institute a regimented and structured program for accomplishing this objective. Compliance with the applicable EU requirements requires that the designer implement a disciplined approach to designing in safety.

Ultimately, manufacturers must ask themselves does the product provide the safety that the user and other exposed persons are entitled to expect and does it comply with applicable statutory and contractual requirements. If either question cannot be answered with a yes, the product may be considered to be defective or may not fulfill legitimate expectations breeding disappointment and negative surprises, which could lead to claims and litigation. This article explores ways in which manufacturers can avoid defects and negative surprises in the sales/contracting, design, and manufacturing process.

Fear among US managers towards defects in their firm's products may be justified as there continues to be a trend in the US towards higher financial awards in product liability cases. Liability claims, litigation and awards are increasing in the EU, as well. In addition to the monetary loss (if a case is tried and lost) companies must also be concerned with the waste (in management time) involved in going through a legal case as well as the negative publicity associated with such an action.

Compliance requires involvement from all

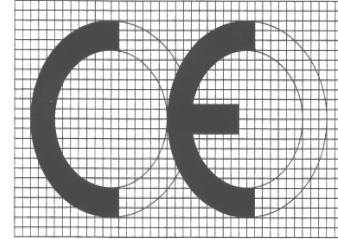
As with any other program initiated in an organization, senior management must understand and take an active role in the process of risk management, loss prevention and compliance. Ultimately, if senior management is not involved, adequate resources will not be assigned and short-cuts will likely be taken because personnel will simply not have the time to perform the amount of work required to effectively comply with these requirements. Senior management's role should be one of understanding the requirements, the overall compliance program outlined for the company including cost and resource requirements, and ways in which the program will be reviewed and evaluated for improvement. There is significant downside potential to a company if management is not fully knowledgeable regarding ways to minimize the company's risk.

For illustration purposes, a chronological, customized one-of-a-kind machinery sale between a US manufacturer and an EU industrial purchaser is depicted. The content focuses on how the US manufacturer can minimize company risk and comply with legal requirements by planning, predicting, preparing and being proactive. Indeed, effective risk minimization strategies are not possible without quality management and assurance. While the primary EU Directive discussed in this article is the Machinery Safety Directive (MSD), a reader interested in complying with other Directives should also be

able to learn valuable information about the compliance process and make appropriate comparisons and extrapolations.

What is CE marking?

In the mid 1980's the EU embarked on a strategy to align the member state regulations in order to enhance the free movement of goods. As a result, certain new Directives were issued and laws were rewritten using a "New Approach" of focusing on broad safety objectives applying to a wide scope of products rather than including detailed technical requirements. EU New Approach Directives were developed to harmonize conflicting national laws and regulations. The primary purpose of these Directives is to ensure that products placed on the market are safe for use and that all reasonable efforts in terms of technology and management have been utilized to prevent exposed persons from hazards associated with the use of the products.



These New Approach Directives (19 currently exist – refer to Attachment 1), contain general safety objectives outlined in "Essential Health and Safety Requirements"(EHSR). Following publication, these Directives are then incorporated or rewritten into existing law, Regulation, or Government Decision in each EU member state. ⁱⁱ

Manufacturers should note that their product may be covered by more than one Directive and it is the responsibility of the entity which affixes the CE marking to ensure that all applicable requirements have been complied with. A technical file must exist that contains evidence, e.g., documents and records, that the specified requirements were met. When, after taking the steps necessary for the product in question, a manufacturer (or his authorized representative in the EU) has declared that the product is in conformity with the applicable requirements, then the product can be affixed with a CE marking. The CE marking, together with an accompanying Declaration of Conformityⁱⁱⁱ, and instructions, is a requirement for the majority of all machinery, both individually and series-produced, sold or used in the EU. The CE marking ensures the machines free movement throughout the EU.

Technical standards developed by standards writing bodies (such as ISO, CEN and CENELEC) play an important role in compliance with EU requirements and at preventing defects in the design process and in the product. However, due to the length of time required to develop and write standards, standards may not always reflect current state of the art and alone may not provide an adequate defense against a liability claim. Although technical standards define the minimum safety, if an injury occurs the manufacturer may still incur liability if it can be proven that more should have been done by the manufacturer to prevent hazardous situations. It is also important to note that technical standards are voluntary and not mandatory.

ISO 9000 and the EU Directives

The relationship between the ISO 9000 series of Quality Management and Quality Assurance Standards and the EU Directives is not well understood. ISO 9000 is a series of international standards which provide guidance for quality management and models for quality assurance. For the EU Directives discussed in this article, the existence of a documented quality management system or compliance with the ISO 9000 series standards is neither an option for compliance nor a requirement. However, an implied reference to a documented quality management system is made in the MSD Annex V specifying i.a., the requirements for a technical file, which requires among documentation available for inspection purposes, “for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive”. This requires the manufacturer to have some system of documented controls in place to ensure consistent manufacturing practices. While this clause does not explicitly refer to the ISO 9000 series of standards, ISO 9001 contains several fundamental principles that can greatly assist a company towards compliance, including those related to contract review and design control.

In the ISO 9000 series standards, safety is one of the aspects of quality. ISO 9004-1:1994 contains an entire element on the topic (19 Product Safety) mentioning among the steps that can be included: identifying relevant safety standards in order to make the formulation of product specifications more effective; carrying out design evaluation tests and prototype (or model) testing for safety and documenting the test results; and analyzing instructions and warnings to the user, maintenance manuals and labeling and promotional material in order to minimize misinterpretation, particularly regarding intended use and known hazards; developing a means of traceability to facilitate product recall; and considering development of an emergency plan in case recall becomes necessary. While the ISO 9000 series standards are voluntary, it is recommended that a manufacturer interested in compliance and prevention considers these requirements and incorporates them into their management system and procedures. For manufacturers who export machinery within the scope of the MSD into the EU, part of the above steps are now a mandatory requirement, as will be discussed later. It is emphasized that the ISO 9000 series standards deal with quality system requirements that can be used for external quality assurance purposes. They are complimentary (and not alternative) to the product related EU requirements.

A Proactive Compliance Process

Step 1: Determine, Identify and Document Customer and Market Requirements, Needs and Expectations.

Benefit: Increased customer satisfaction and improved relationship and risk management result from understanding customer’s needs.

Regardless of the product sold, achieving quality requires a fundamental understanding of the customer's needs. These needs can either be expressed in terms of a request for proposal, purchase order, or referenced specification, or they can be implied or hidden. Many times the customer does not know the equipment half as well as the manufacturer and does not know what questions to ask, particularly regarding safety features. Manufacturers must educate their customers in machinery safety – being proactive and explaining the process for complying with the requirements will go far towards helping the manufacturer understand what the customer's needs and expectations are for the equipment. Often, this requires the involvement from the design and engineering function and product safety department.

It is in the interest of both the supplier, purchaser and end user that these requirements be recognized as early as possible: the customer – while geographically closer to the information – might not know what is expected of it and its suppliers regarding CE marking and other requirements. Early research into the applicable standards and requirements, internal and external collaboration and communication, and active interaction between the parties' representatives become crucial. A manufacturer, working together with the customer, can best determine what requirements and technical standards apply to their equipment.

Step 2: After defining the requirements, review capability to meet the same; resolve any incomplete, ambiguous or conflicting requirements (and communicate and forge a long term relationship with the customer).

Benefit: If a manufacturer has confidence that the requirements are clearly defined and mutually understood and that it has the ability to meet the requirements, both statutory and contractual, there is less chance of disappointing the customer and simultaneously less likelihood of claims and litigation.

When the requirements, needs and expectations are identified and defined they need to be reviewed before a commitment to supply is made to the customer. It is very important that all such information that is relevant to an order is reviewed “up-front” prior to submitting a tender or quotation and prior to order acceptance so that negative surprises and conflicts can be avoided. Effective contract reviews (Element 4.3 of ISO 9001: 1994) ensure that the requirements are understood and agreed upon early on. Implementing a well thought out contract review process is particularly important in international sales.

Because of the relative newness of the EU requirements, sales personnel involved in proposal submission are typically not familiar with what, e.g., the CE marking requirements entail. A contract between the manufacturer and purchaser may have been entered into with the understanding that the manufacturer will easily meet “all applicable requirements” for their product. These “requirements” are then typically passed along to the manufacturer's engineering concern after the fact, which often leads to a hurried compliance process that is less than optimal, and situations where all costs associated with compliance cannot be recouped. Contract review, when conducted pro-actively,

improves planning and implementation and helps uncover the factors that are important to the customer in its purchasing decision and future safety of use, etc. Throughout, one needs to make sure to bridge any gaps between the actual needs, requirements, etc., and the understanding of those needs as expressed in the documents – the earlier, the better!

In the field of international sales, contract reviews can be successfully used as an umbrella for integrating quality and risk management. While contract reviews are carried out as part of the day-to-day operations within the framework of existing quality management systems and while manuals, documented procedures, instructions and forms exist, the opportunities offered by them as risk management tools are often overlooked. When used proactively, contract review checklists, forms and instructions can guide management and line personnel safely through the contracting process. In this way, potential problems can be detected early enough to take action, leading to certainty as to the parties' rights, duties, costs and risks – in the essence: predictable outcomes with minimal surprises.

Design engineering, in particular, must be actively involved in the contract review process in order to perform an adequate review of a firm's ability to meet all applicable technical requirements. This research/capability assessment will probably entail obtaining actual copies of the Directives, implementing Regulations, Decisions and standards and reviewing the compliance process to understand whether self-certification is an option or whether a third party must become involved. A manufacturer should not commit to a project too early (or blindly). The statutory and contractual requirements affect costs, price, delivery time, performance, liability exposure, etc., and should be reflected in the quotation (or tender, proposal or offer) and contractual documents. Thus design related activities must be an integral part of contract review related activities and vice versa.

Opportunities, problems and risks seldom come pre-labeled "legal". In everyday dealings, legal professionals can train design and sales personnel and other non-lawyers to identify such opportunities, problems and risks at an early time – and in knowing when to consult a lawyer. The key to success lies in the hands of line management and employees. Sales, design and purchasing professionals need a working knowledge of the legal principles related to their functions – and ongoing system support to make informed decisions, the first time and every time.

Step 3: Execute the defined requirements through an accurate and complete design process.

Benefit: Designing equipment costs money. Designs that result in manufactured product that meets the customer's needs and applicable requirements lead to safer products, less last-minute changes, reduced causes of claims, and long-term customer satisfaction.

The design process is where the requirements defined during the earlier steps are engineered into the product. The resultant output from the design process will be

documents (drawings, calculations, etc.) that should meet the applicable requirements. Quality management and quality assurance place emphasis on ensuring that the design process yields output that meets the customer's requirements as well as all applicable legal requirements. Issues to be addressed during the design process of machinery within the definition of the Machinery Safety Directive (MSD), when desiring to meet the applicable EU requirements, include:

Design and Development Planning

For the design process to go smoothly, design activities should be planned with milestones, timelines and responsibilities. For its own benefit and to benefit its customers, a firm will need to determine who has sufficient background knowledge to ensure that the design meets EU requirements. The applicable design personnel must have a clear understanding of the relationship between the EU Directives, technical standards and other applicable requirements as well as knowing which of them apply to the product at hand. The designers must have required skills, including an understanding of how to perform a Failure Mode and Effects Analysis (FMEA) on the reliability of the electrical control system, where necessary. To the extent that the applicable requirements are not understood, external consulting assistance may need to be sought and it should be determined what type of other external resources, such as testing firms, will be required to comply with the requirements.

Design Input

ISO 9001:1994 4.4.4 states: "Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy." Certainly in this context, 'statutory and regulatory requirements' refers to the requirements laid down in the MSD as well as other applicable Directives and provisions, including the technical standards or other methods that are being used to demonstrate conformance to the Essential Health and Safety Requirements (EHSR). For effective, efficient quality and risk management, a firm must have a method for "identifying and documenting" these requirements and to develop evidence that the selection and contents of these requirements have been reviewed by appropriate personnel in the company.

At this stage, any unclear requirements must be resolved. Questions may arise regarding the meaning of a certain requirement or who will pay to meet a certain requirement. A review and amendment of the terms of the contract may be required, and the design input shall take into consideration the results of any such contract review activities. For personnel reading the EU Directives, implementing Regulations or Decisions and technical standards for the first time, the language and requirements may be difficult to follow and appear disjointed. In order to avoid problems at a later stage, it is important that the firm's personnel understand how these requirements apply to their specific equipment.

Design Development

The MSD, in the Preliminary Observations of Annex I, states explicitly: “The manufacturer is under an obligation to assess the hazards in order to identify all those which apply to his machine; he must then design and construct it taking account of his assessment”. According to Annex V of the MSD, before drawing up the EC Declaration of Conformity, the manufacturer (or his authorized representative in the Community) “shall have ensured and be able to guarantee that the documentation listed below is and will remain available on his premises for any inspection purposes: a technical construction file comprising: ...a list of: the essential requirements of this Directive; standards, and other technical specifications, which were used when the machinery was designed; a description of methods adopted to eliminate hazards presented by the machinery, ...”

A hazard analysis/risk assessment is a systematic approach of analyzing all possible ways equipment could cause or create hazards, designing equipment to minimize or eliminate these hazards, and providing warnings for any residual risk. While the MSD requires a hazard analysis/risk assessment for all “machinery” within the scope of the MSD, it does not provide details for its practical application. Guidance on performing a hazard analysis/risk assessment can be taken from harmonized standard EN 1050: 1996 Safety of Machinery – Principles for risk assessment which describes, in a series of systematic steps, this methodology.

During the design process, sketches and prototypes are developed to conceptually design a product that meets the applicable requirements. Following conceptual definition of the design, a hazard analysis/risk assessment should be performed as it is important to design in the safety requirements early into the process.

Prior to beginning the hazard analysis, efforts should be put forth to obtain an accident history of the equipment. Possible sources could be industry trade societies, customers, or governmental health and safety data. Even if accident history is not available or shows a small accident frequency, the absence of accident history, it cannot be construed by the designer as an automatic presumption of a low (equipment) risk.

When conducting the risk assessment/hazard analysis, design engineers must constantly deal with constraints. Certainly, some of the hazards identified will not be possible to solve either technically or economically. A manufacturer should document carefully what was done in order to solve or reduce the hazard and to eliminate the cause. To the extent possible, these constraints should be documented as part of the hazard analysis – theoretical constraints are always true and based on such things as physical phenomenon while perceived constraints may be based on an engineer’s experience, training, and understanding of the system. By utilizing proven methodologies, these perceived constraints can be minimized.

Design Output

Design output should be documented in verifiable terms. Drawings, instruction manuals, training syllabuses, checklists (based on technical standards) and the Hazard Analysis/Risk Assessment are all examples of design output documents which can demonstrate conformance to the requirements in the MSD.

The engineering measures that were implemented to address a particular hazard are crucial to the safe operation of the machine. These measures, such as a machine guard, should be uniquely identified on a drawing indicating the importance of the particular piece of equipment in meeting overall safety objectives.

Step 4: Conduct design reviews and verify and validate the design. Perform design changes as well as contract amendments, where necessary, in accordance with specified procedures.

Benefit: The design process is iterative meaning the learning process never stops. Because of this, it benefits the company to perform rigorous equipment testing and reviews.

Design Review

Design engineers should be willing to have their work exhaustively critiqued by their peers. ISO 9001:1994 4.4.6 states: “At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted.” Design output documents, such as drawings, calculations and the Hazard Analysis/Risk Assessment, should be reviewed before final release of the design to ensure that they conform to the applicable requirements defined during the earlier steps.

Design Verification and Validation

Design verification involves ensuring that the design output complies with the design input requirements specified earlier in the process. Examples of design verification may include the following:

- Electromagnetic Compatibility (EMC) testing to ensure the requirements for radiated emissions and equipment immunity are met
- Noise testing to determine sound pressure and sound power levels
- Design document reviews to ensure the applicable requirements have been properly addressed and documented.

Design validation is performed to ensure that product conforms to defined user needs and/or requirements. Design validation is the process whereby a manufacturer ensures that the designed (and/or manufactured) product conforms with the applicable requirements. For certain applications, this can be performed using computer simulation where for other applications, it may occur during the installation and commissioning of

the equipment. While designers usually think of other requirements, it is important to also include a safety assessment when performing design validation. Where applicable, it is also beneficial to record the test runs and document the taking over/acceptance procedures for the equipment, following successful commissioning – not only for contractual compliance but also for sound design validation practices.

Design Changes

The hazard analysis/risk assessment and the design process, in general, are iterative in nature due to the fact that knowledge is gained along the way in performing such activities. Because of the incompleteness of information, reexamination, particularly by personnel other than the original equipment designer, at later points in the design process is necessary, hence reviews of the hazard analysis and other output documents must be performed. Once the design is completed, personnel should periodically assess the adequacy of the existing hazard analysis/risk assessment to ensure that it accurately reflects current state of the art and intentions of the designer. While the post-sale duties of industrial manufacturers under the MSD remain largely undefined, and vary from country to country manufacturers should monitor a product's status and consider incorporating their findings in revised warnings and instructions.

The design change process should also incorporate a corrective action procedure, i.e., if an accident is discovered to be caused by a machine, a system should be established to review all existing designs and assess the need to modify the design (based on what was learned to prevent the accident from re-occurring). As a result, a design change may lead to a review and amendment of the terms of the contract.

Record retention is an important part of the design process. In addition to the purposes of the MSD, documentation is needed for ensuring that appropriate evidence exists should the need arise for a manufacturer to defend themselves in a lawsuit. The development of the technical file, if prepared in accordance with the MSD, can be a very important tool in this defense. It can also contain information that can be damaging, if insufficient attention is paid to the requirements, product safety and how risks and problems are addressed. Incomplete documentation could be used to show that the manufacturer failed to thoroughly analyze a product's hazards. In the best case scenario, the documentation contained in the technical file can certainly go a long way towards demonstrating compliance.

Legal Risk Management and Proactive Preventive Law

Risk management and preventive law concepts are important for businesses to understand in order to assess both downside and upside potential in their business. Proactive risk management techniques should be used throughout the sales, order entry, contract review and design process in order to help a company identify methods to increase revenue and gain competitive advantage. Conducting a hazard analysis/risk assessment is an important risk minimization method, and for “machinery” within the definition of the MSD exported to the EU (EEA), systematic risk analysis, risk evaluation and risk reduction is explicitly required by the MSD.

In its Memorandum published in the Official Journal in October 1989, the EU Commission discusses, i.a., European standards, conformity assessment, quality systems, ISO 9000 series and the CE mark among elements which, "when carefully and properly assembled, will give the Community as a whole a comprehensive quality policy". When discussing product liability (No C 267/12), it states: "Testing, certification and inspection may diminish the risks and hence the likelihood of damages (which in turn reduces the insurance cost), but do not affect the liability of the manufacturer". The Memorandum then goes on to state: "This [Product Liability] Directive therefore puts responsibility on the supplier to produce safe products, through the pressure which the costs liability places on him after an accident due to a defective product."

Historically, quality, safety, environment and the law have been treated separately. They have been taught, studied and practiced separately, as if they were unrelated. Industry has traditionally managed them as separate functions or entities, employing separate disciplines and professions. While this is still true in many organizations, a few have started to look at the underlying objectives. Those concerned about financial performance, growth and shareholder value have focused on risks, which include failure to comply with laws, regulations and contractual commitments applicable to a given business endeavor. The disruption accompanying major investigations or litigation can be very costly. Large fines and damages, which are increasingly common, can put an organization or individual out of business. The reputation losses suffered due to an offense may be difficult or impossible to cure. For organizations wanting to prosper, it is crucial to spend time and resources in reaching goals and improving performance, not litigating.

Everybody benefits from quality, legal and technical professionals working together, integrating or aligning their efforts. No program or system will work unless it is supported by management and actually accepted into everyday use by the organization as a whole. A manual, program or system is of no use if it does not work. Compliance, quality, risk management and appropriate controls need to be an integral part of business performance, built into processes and everyday actions. The responsibility and accountability needs to move to line management and personnel facilitated by legal, quality and other resources and monitored through self-assessment and interactive control systems.

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Attachment 1: A Listing of Products/Topics Covered by New Approach Directives

Low Voltage Equipment
Simple Pressure Vessels
Safety of Toys
Electromagnetic Compatibility
Construction Products
Safety of Machinery
Lifts
Personal Protective Equipment
Pressure Equipment
Non-automatic weighing instruments
Medical Devices
Active Implantable Medical Devices
Gas Appliances
New Hot Water Boilers
Explosives for Civil Use
Equipment for Explosive Atmospheres
Recreational Craft

ⁱ Kenneth Ross of the Minneapolis firm of Bowman and Brooke in *Managing for Products Liability Avoidance*. Second Edition, 1996, CCH Incorporated, Chicago, IL, Page 31

ⁱⁱ The rules for the free movement of goods that apply to the EU also apply for the European Economic Area (EEA), which, in addition to the EU countries, includes Iceland, Liechtenstein and Norway. Switzerland is not included in either the EU or the EEA.

ⁱⁱⁱ For a machine which cannot function independently and which is designed as a structural part of other machinery or to be connected with other machinery, a different declaration is required, specifically a Declaration by the Manufacturer. A CE marking must not be affixed to such machines.