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# Procedures for Documenting Product Safety

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**SUBMITTED TO**  
USAID

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**UNDER CONTRACT NO.**  
PCE-I-00-98-00016-00  
Task Order 827

July 2006

# **Procedures for Documenting Product Safety**

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## **A. Introduction**

Article 69 of Ministerial Decree 770/2005 states that products listed in Annex Eight of the Decree must be inspected by GOIEC in accordance with Section II of the Decree. If relevant mandatory standards have been issued by the Egyptian Government, then GOIEC must conduct the inspection in accordance with those standards. However, GOIEC inspection could be based on standards from other countries if there are no relevant Egyptian mandatory standards. Under Ministerial Decree 180/1996, producers and importers can base product development for goods that are not subject to Egyptian mandatory standards on standards developed in any one of six countries; Egypt, international (ISO/IEC), US (ANSI), Europe (either EU or UK, France or Germany), Japan or the Codex Alimentarius.

This memo will discuss ways to minimize total costs to the foreign manufacturer by utilizing, wherever possible, the documents that have already been developed by the importer to prove conformity to the authorized foreign standards and technical requirements. The discussion will be based on analyses of the EU (CE marking) and US systems for organizing documentation regarding the use of standards, conformity assessment and product certification.

## **B. The CE marking system**

The CE mark system for regulating product safety was developed by the EU to mitigate the potential impact of fifteen different national systems for regulating product safety in Community trade. Directorate General Enterprise (a department of the Commission) writes the governing new approach directives that establish the general parameters of product safety regulation. The details

are worked in cooperation with the European standards development agencies, notified bodies and national surveillance authorities.

The legal basis for the CE marking system is set forth in 22 “new approach” directives. Each directive defines the types of products and/or risks that are covered by the directive. The horizontal directives address attributes common to many products, such as electrical systems, machinery components, pressure vessels and electromagnetic compatibility issues. These directives are applicable to many different types of products. The vertical directives cover many attributes of specific types of products, such as medical devices, construction products and recreational craft. Both types of directives may be applicable to a specific product.

The directives list the “essential requirements” that the manufacturers must address in product development. The essential requirements include general statements about the types of risks that must be minimized in product development and the features must be incorporated into product design.

These essential requirements are too vague to be used in product development. Manufacturers generally use standards that address the topics listed in the essential requirements as a more practical basis for product development. Any standard can be used as the basis for implementing the essential requirements. However, manufacturers that use the harmonized standards developed by CEN, CENELEC and ETSI can benefit from a legal presumption that they have fulfilled the essential requirements. Manufacturers that do not use harmonized standards as the basis for product development are not covered by the presumption that the product conforms to the essential requirements set forth in the governing directives.

Most new approach directives also include a process for classifying the intrinsic risks presented by particular types of products. The Medical Device Directive, for example, sets forth seventeen rules for classifying medical devices into four risk categories. The Pressure Equipment Directive contains a series of tables that classify pressure systems into four risk categories according to the volume, pressure and nature of the working fluid.

The New Approach directives define the rules for product review that are based on the level of the intrinsic risk they present. The review rules cover both product design and the manufacturing processes. The options available for design review range from manufacturer's self-certification to a full design review by a notified body. The options available for certifying production quality range from the manufacturer's self-certification, the certification by a notified body of manufacturer's quality control system and the direct testing of either all products of a sample.

The conformity assessment options available to the manufacturer depend on the risk classification of their product. Companies manufacturing low risk products can self - certify their conformity with the CE mark requirements. Companies that manufacture higher risk products have to engage the services of a notified body to prove CE mark compliance.

The use of the CE mark logo does not necessarily prove that a product is in compliance with the CE mark requirements. A manufacturer does not have to register with any official organization or establish any proof of CE mark compliance before using the CE mark logo.

However, manufacturers must develop two other legally binding documents that prove that a product has met the requirements of the CE marking system. The first document is the "declaration of conformity". This is a legally binding declaration by the manufacturer that the CE mark requirements have been met for the product covered by the declaration. The declaration of conformity also contains information on how the manufacturer can be contacted if any safety issues arise regarding the product.

The manufacturer must also develop a "technical file" for each type of product that documents how the requirements have been met. The technical file usually includes a description and risk analysis of the product, a list of the applicable essential requirements, a description of the measures taken to address these requirements, copies of any reports from test houses and notified bodies, and a copy of the instructions for product storage, setup, maintenance, use and disposal.

In most cases, the CE mark system is enforced after a product is placed on the market or put into service. Customs clearance for imported products is usually limited to cursory review of the declaration of conformity and the technical file. However, if any safety issue concerning the product arises while it is in use, then the surveillance authorities are likely to contact the manufacturer to ask for a copy of the technical file to review in detail. If a review of the technical file suggests that the product, in fact, does not conform to the CE mark requirements, then the manufacturer may be subject to a wide range of civil or criminal penalties. Future exports may be banned. The manufacturer may be required to take all similar products off the market or out of use in Europe. Manufacturers may also be liable for civil and criminal penalties for fraud under national law.

### **C. The American system**

The American system: product regulation in the US is based in large part on a tort liability system that was inherited from the English. People who have been injured or killed as a result of a defective product are entitled to sue for compensatory damages. Manufacturers and distributors typically take out insurance policies to cover possible court judgments from unsafe products. Insurance companies will generally base their charges on their assessment of the risks of an adverse judgment.

Several of the largest standards development and conformity certification organizations, including Underwriters Laboratory and the National Fire Prevention Association, were organized to lower the risks of insurance loss by promoting product safety. Many of these agencies provide product certification services for manufacturers.

The terms of the certifications and the nature of the documentation vary from organization to organization. Underwriters Laboratory (UL), for example, retains the copyright to the UL logo. No manufacturer is allowed to use it without the explicit permission of Underwriters Laboratory. As a result, the use of the UL logo on a product is strong evidence that the product has been reviewed and

approved by Underwriters Laboratory. Other certification services may only issue a document of certifying product conformity to the required standards.

Because of this specialization by types of risk, product standards and certifications tend to address specific issues across a wide range of products rather than a wide range of issues for a specific product. Some certifications attest to efficiency or quality issues rather than safety. Even on safety issues, different certification agencies may focus on different aspects of safety. A certification of electrical safety on a heart lung machine, for example, may not imply that the machine can also be used to save lives.

Because a well developed tort liability and insurance system is available in the US to address most product liability issues, direct government regulation of product safety is largely reserved for specialized high risk areas. The Environmental Protection Agency regulates environmental issues, the Food and Drug Administration regulates health issues for pharmaceuticals, veterinary products and medical devices, and the Occupational Health and Safety Administration regulates industrial safety. In many cases, US regulatory bodies accept private certifications as proof of conformity to the relevant technical requirements.

#### **D. Suggestions for an Egyptian system**

The basic problem in liberalizing trade policies is how to harmonize the specific product review procedures and documentation requirements in the exporting and importing countries. Ideally, product safety review policies that a manufacturer must carry out in the exporting country would be equally as useful for product reviews in the importing country. There would be no need to run additional tests or to develop additional documents in order to enter a foreign market.

In effect, GOIEC could use European and American product conformity assessment procedures and compliance certification requirements to ensure that products imported into Egypt meet Egyptian product safety requirements. This would have several benefits in addition to trade liberalization. It would reduce

GOIEC's expenses for product review and lab maintenance and limit the risk of administrative irregularities. Notified bodies and test houses in the US and EU are kept honest through relentless pressure from governments, competitors and clients. The system proposed here would allow Egypt to also take advantage of this system.

However, this does not mean that both countries must adopt the same set of product safety standards. The system would work as long as both countries would base their product safety reviews on the same set of procedures, tests and documentary development requirements. The minimum acceptable levels of performance could be different. For example, both the exporting and importing countries could insist that a particular test be carried out on a product to check for flammability. The exporting country might accept goods that had a rating of "5" on the test. The importing country might only allow the importation of procedures, administrative classifications and documentary requirements that are consistent with EU and US regulatory practices. This administrative classification system would define product types, product risk areas and minimum performance requirements. To the extent that GOIEC documentation requirements are consistent with those in the US and EU, importers could use their European and American documentation to meet GOIEC requirements.

Setting product safety policy comes down to determining what categories of products should be reviewed, what types of risks should be considered, and what levels of safety assurances should be required. GOIEC could start by defining the relevant categories of products, risk areas and required safety assurances.

The GOIEC list of the general types of products and product systems that are subject to Government safety review should be consistent with, but possibly broader than, the categories used in the CE marking system in Europe and by US regulatory agencies. GOIEC should also develop a series of criteria for defining what constitutes "higher risk" categories of product types and risk areas. The minimum acceptable levels of safety assurances would be defined at a higher level higher for higher risk categories of risk areas/product types.

**Recommendation 1:** GOIEC should consider defining the specific areas of increased safety concern for goods that are included in the Annex Eight list. The definitions should be broadly consistent with the risk areas covered by the essential requirements under the CE marking system and the broad areas of safety concern covered by US certifications.

**Recommendation 2:** GOIEC should consider defining the minimum acceptable level of conformity assessment review with regard to the areas of increased safety concern for the products on the on the Annex Eight list.

**Recommendation 3:** GOIEC should consider accepting declarations of conformity and technical files for CE marked products imported from the EU as evidence of conformity to relevant Egyptian product safety requirements. To implement the second recommendation, GOIEC should consider defining which conformity assessment modules must be used to meet the levels of proof discussed in Recommendation 2.

**Recommendation 4:** GOIEC should consider accepting product certifications developed by American organizations if the certifying organization was accredited, it assumed responsibility for the adequacy of the underlying standards and the certifications were recognized by US regulatory authorities as proof of conformity to US safety requirements. See the second memo for an extended discussion of these issues.

The next issue is to define the format for the documentation that should be produced by the importer and how these data could be used by GOIEC to ensure product safety. This documentation should be consistent with the materials that would have to be developed by Egyptian domestic manufacturers to show that they have met Egyptian product safety requirements. Since the CE marking

system is based on a reasonably well integrated system of product requirements and one set of documentation requirements, it provides a better model for a proposed Egyptian system than the more fragmented American system.

**Recommendation 5a:** GOIEC should consider adopting the basic documentary requirements of the CE marking system. Manufacturers would have to develop a declaration of conformity, a legal attestation by the manufacturer that the Egyptian requirements have been met. The declaration of conformity could include: a designation of the product, contact information for the company, a list of the major standards and/or directives used in product, contact information for any conformity assessment agencies or notified bodies used in product development and a legal attestation that the Egyptian requirements had been met.

**Recommendation 5b:** the manufacturer would also have to develop a "technical file" that would include a detailed description of the product and its performance characteristics, a description of the measures taken to address the GOIEC requirements and copies of all test house reports and conformity assessment certifications

Companies that have already CE marked their product could simply submit their CE marking technical file to document compliance with the GOIEC requirements. The product and risk classification systems would be congruent, we assume that the minimum performance requirements would be identical and the types of documentation required would be consistent.

Manufacturers could also use the documentation developed for US regulatory purposes for their GOIEC technical files. However, the manufacturer might have to also submit some documentation on the certifying agency or that specified the types of products, risk categories and minimum performance levels that were certified by the document. For example, an approval letter from the FDA might be accompanied by passages from the Code of Federal Regulations

defining the FDA approval criteria. A document from Underwriter's Laboratory describing in detail the scope and terms of their certifications could accompany a UL certificate of conformity.

Including a requirement in the GOIEC regulations that manufacturers document the scope of any third party certifications would make it far less likely that manufacturers would use irrelevant, even if valid, certifications for their technical files. Manufacturers could not use, for example, a UL certification of electrical safety to prove that GOIEC flammability requirements had been met without including a fraudulent statement on the scope of the certification in their technical file.

The unique element in enforcement of the EU system is their reliance on reviewing product safety issues after a product has been placed on the market or put into service. Customs review of CE documentation usually consists of a request for a copy of the declaration of conformity. The review process may also include a check to make sure that the manufacturer has developed a technical file for the product. In general, the surveillance authorities only become involved in product review when a question has been raised about product safety after it has been put into service. When a safety question is raised about a product, the surveillance authorities can use the declaration of conformity to identify the manufacturer. They can then ask the manufacturer to review the technical file in detail. If the safety and CE mark compliance claims made by the manufacturer cannot be supported by the technical file, then the appropriate enforcement measures may be taken.

This approach has several advantages. Enforcement efforts can be based on more information about product performance. It may be very difficult to determine whether or not a product is safe until it has been used for a while. Information about the safety performance of products that are in use can be gained from buyers, users, consumers' organizations and competitors. It is entirely consistent with Law 67 of 2006 on Consumer Protection. Review costs for safe products are also limited through this approach. GOIEC would not have to spend

much time reviewing products that are safe, since they are not likely to generate questions about product safety.

**Recommendation 6:** GOIEC could consider a policy of limiting enforcement proceedings and rigorous product reviews to situations in which there is other evidence that a product does not meet GOIEC safety requirements. In most cases, this would be after a product has been placed on the market or put into service.