Managing Safety-Related Compliance of Machines in Global Market

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ABSTRACT

In global trade a machine manufacturer must localize their products for different customers and market areas and they need to manage large variety of product safety requirements, conformity declarations and product liability issues. The aim of this study is to determine 1) which kind of problems there are involved in managing product safety-related requirements of machines intended for use at work internationally and 2) how globally operating companies designing and manufacturing machines have managed this issue in global market. The study is based on literature review and interviews of representatives of two large internationally operating European companies manufacturing machines intended for use at work. The companies' representatives experienced that the European integration has clarified the product safety requirements, but the actual practices may still vary between different member countries within the EU. The compliance with European product safety requirements were seen as a good basis for re-engineering the machines to the global market. The typical strategies to localize the products were 1) to meet the requirements locally in the front line, and 2) identify and take into account the local requirements and needs during the initial design and manufacturing of the machine.

Keywords: Product Safety, Requirements, Compliance Management, Global Market

INTRODUCTION

In order to succeed in global trade a machine manufacturer must be able to localize and modulate the products for different customers and market areas. The manufacturers must have tools to recognize the individual local needs and requirements but they need to be able to design the products for wider market as well. Within the European Union (EU), the Directive 2006/42/EC on machinery and the related harmonized standards define clear requirements and guidelines for product safety considerations in the design process of most machines. However, when the market area is wider than the EU the manufacturers may confront difficulties in gathering and managing all the existing local information. In addition, they may have difficulties in following forthcoming requirements. The globally operating machine manufacturer needs to be aware of the differing product safety requirements, conformity declarations and product liability issues within their market areas. They must be aware of and understand (as well as to comply with) the local or regional legislation and jurisdiction, the local operating conditions, duty types, the customers' fields of operation as well as to be able to apply the valid standards and specifications. In addition, the manufacturers must find suitable methods to take these issues into account in practice. These are e.g. the concepts of compliance management, mass customization and supply chain management.

The design of safe and ergonomic products can be an integrated part of engineering and design (e.g. Rausand and Utne; 2009; Hale, et al., 2007; Karwowski, 2005). Similarly, concepts of supply chain management as well as mass customization of products and services are quite widely publicized (e.g. Fogliatto et al., 2012; Marucheck et al.,

2011; Mentzer et al., 2001). However, despite the fact that safety design, compliance management and the supply chain management are well established disciplines, the product safety management of machines intended for use at work is not widely discussed from the compliance management and the supply chain management point of views. The aims of this study are to determine 1) which kind of problems there are involved in managing product safety-related requirements of machines intended for use at work internationally and 2) how globally operating companies designing and manufacturing machines have managed this issue in global market. In this study the management of safety-related requirements of machines is explored in two different market areas, the EU region and Australia. The study is based on literature review and interviews of representatives of two large internationally operating European companies manufacturing machines intended for use at work.

METHODOLOGY

Information on the present situation of the problems encountered in managing product safety-related requirements globally and the management practices was gathered by interviews. The interviews were conducted during 2012 and 2013 in two large companies manufacturing machines intended for use at work. Both of these companies are operating globally but they have notable business in Finland as well. The EU region and Australia are essential market areas for both of these companies. The interviewees represented product safety team, design and product line management. Representatives of the product safety teams were interviewed as individuals. Representatives of the design and product line management were interviewed in groups of 2 to 5 persons. Altogether 11 interview events with 25 interviewees were conducted; 4 representatives of the product safety teams, 16 representatives of design and 5 representatives of the product line management.

The interviews were semi-structured, including pre-prepared questions which were open-ended. The topics were covered in a nearly similar sequence in each interview. However, the group interviews were more like discussions including mutual discussion between the interviewees. The framework of the interviews was based on tentative discussions with the companies and literature review related to compliance management, differing requirements, regulatory strategies and the authorities' role. Questions for the interviews were divided into different categories including follow up of the requirements, determination/detection of the requirements, management of the requirements (compliance), liability issues and authorities' role in different market areas. The respondents also had the opportunity to discuss other issues that had not been covered in the interviews. The results of this study are qualitative.

The literature review was complemented with topics tangential to themes of the interviews. These topics consist of e.g. supply chain management, mass customization, modularization and postponement. Relevant publications were searched from the databases of electronic journals, other electronic publications and books.

THEORY

Globalization can be both challenging and an opportunity for a company. A company must decide e.g. which geographical markets they should offer their products, should they have similar product for customers throughout the world or do they need a variety of products with different specifications, and where they will develop and manufacture their products. Companies have to understand customer requirements and comply with regulations together with other requirements in many countries. (Stark, 2011; Sadiq and Governatori, 2010; Drahos and Braithwaite, 2001) The companies must also be aware of the regulatory agencies' (or authorities') strategies and styles to enforce the requirements in different market areas and what the atmosphere to comply is (Tallberg, 2002; Sutinen and Kuperan, 1999).

The basis of compliance can be either affirmative or negative (May, 2004). From the authorities perspective the implementation and enforcement can be distinguished by different approaches: cooperative/ accommodative approach and coercive/sanctioning approach. (Bluff, 2011; National Research Centre for Occupational Health and Safety Regulation, 2002; Ayres and Braithwaite, 1992; Braithwaite, 1985) The authorities may also apply different styles and approaches of interaction with the companies depending, for example on the field of business, size of the company, history of implementation and the actual legislation. (Bluff, 2011) All in all, the global market makes it more difficult to assure and enforce the product safety (Marucheck et al., 2011). Underlying issues with compliance

management are also the increasing of so called regulatory burden or overload and complex formulation/incoherence of the requirements. In general, there is a structural tendency for regulation to increase over time. (Hale et al., 2011)

Compliance management can be defined as ensuring that business processes, operations, and practices are in accordance with a set of prescribed and/or agreed requirements. It should not be a distinct activity but as a part of the business practice. (Sadiq and Governatori, 2010) Compliance with the requirements indicates e.g. that a company conforms the stated and applicable external requirements concerning it and its products and/or services (e.g. Carroll and McGregor-Lowndes, 2002). The basis of compliance is the comprehensive enough acquisition and management of the required information. However it may be asked what comprehensive enough is. The process of compliance (with the requirements) can be divided into e.g.: Identifying and discovering requirements, Interpreting requirements, Identifying changes (impact analysis), Decision of compliance, Specifying method of compliance, Communication, Implementation and applying, and Evaluation and monitoring (e.g. El Kharbili et al., 2008; Henson and Heasman, 1998). Compliance management should rather have a preventive focus, aiming to achieve compliance by design (Sadiq and Governatori, 2010; Lu et al., 2008). As a part of the compliance process the companies can try to influence the upcoming requirements (regulation, standards etc.) beforehand, try to effect on the requirements in force or their enforcement. In practice this can be carried out by the companies or the associations representing the companies. (Tala, 2001; Henson and Heasman, 1998) It can be presented that the companies have different strategic choices in responding to new or previously unknown regulations: opportunism, full compliance, partial compliance, noncompliance or influencing regulator/enforcer (Henson and Heasman, 1998). The choice may be based on e.g. the possible consequence of noncompliance (Bluff, 2011; Tala, 2001). Noncompliance can have both short-term and long-term consequences for a company, positive or negative (El Kharbili et al., 2008).

Regulation has both direct and indirect effects on product design. The companies must pay attention to existing and pending regulations that have direct and indirect effects on the designed products. (Baram, 2007) The principal instrument for regulating machinery safety in Europe is the Directive 2006/42/EC on machinery. Member nations may set additional requirements consistent with this Directive, but the freedom of movement of products must be assured (Baram, 2007). In Australia the Commonwealth government and each state and territory government regulates occupational safety and health in its own jurisdiction. There is variation in responsibilities and the duties to ensure that machine is designed and manufactured so that risks to safety or health do not exist. However, the harmonization has been initiated in the beginning of 2012. (“Occupational safety and health country profile: Australia”, 2014; National Research Centre for Occupational Health and Safety Regulation, 2002; “New work health and safety (WHS) laws”, 2014) There has also been an ongoing process of comparing the Australian way to regulate machinery safety to the EU and convergence to the EU’s regulations. The Australian regulations and codes of practice rely on general duty requirements, performance standards, process requirements and documentation requirements. The performance standards do not describe companies exactly how they should achieve compliance, instead they define the obligations of the companies by the goals they must achieve, or the problems they must solve. (Bluff and Johnstone, 2004) There are mutual features between the Australian Occupational Health and Safety (OHS) regulatory regime for plant and the regime created by the EU’s Machinery Directive. Both of these regimes have a risk management approach, require provision of information, utilize technical standards and require companies’ self-assessment of machinery. In addition, they provide a third party verification for specific types of machinery. However, there are some differences as well; e.g. different compound of performance-outcome, systematic process and specification provisions used in the regimes. The Australian regime is mainly process-based but the EU’s regime focuses more on achieving performance-outcomes. (National Research Centre for Occupational Health and Safety Regulation, 2002; Bluff, 2004)

In addition to the compliance management and the related information flows, companies must be able to react to changes in customer requirements and implement the design, manufacturing and distribution of the products and services. In their literature review Kara et al. (2002) introduce three basic forms of flexibility that companies need: External flexibility, Inter flexibility and Intra flexibility, which are then further divided into more detailed subgroups. The development flexibility is seen as a part of the companies’ technology and inter flexibility and it describes the economic costs of product modification caused by the response to external or internal changes. Similarly, the design change and modularity flexibility is a part of the technology flexibility, but it refers more on the time rather than the costs that a company needs to implement the changes to a specific part. (Kara et al., 2002)

A commonly used framework for modelling and managing the flows of products, services, information and the financing is the supply chain management (Mentzer et al., 2001). One of the key concepts of the supply chain management is the decoupling point, the point of supply chain where the customer specific and varying requirements are added to more general standard requirements and decoupled to product structures or to a specific

customer order (Brun and Zorzini, 2009; Gosling and Naim, 2009). The management of the variation in customer needs is also extensively discussed in the mass customization literature (Fogliatto et al., 2012). The typical strategies of mass customization to tackle the problems caused by the variation are postponement and modularization (Brun and Zorzini, 2009). In the case of the postponement, the decoupling point of the customer needs and the final product customization are typically located and implemented at the later parts of the supply chain as an addition to a more pre-designed or even pre-manufactured standard product. In the case of modularization, on the other hand, the variation of the customer needs is managed by the pre-defined modules and their combinations on the basis of the customer preferences and selections.

RESULTS AND DISCUSSION

The interviewees' understanding of the problems involved in managing product safety requirements of machines and of practices the globally operating companies apply when managing these requirements are presented in this chapter. The views are discussed in general but paying particular attention to perspective of the EU region and Australia.

The problems and practices can be divided into six categories: Flow of information, Competence, Requirements, Standards, Interpretation of the Requirements and Standards, and Actions of the Organization. The essential problems remarked are presented in Table 1 and the essential practices correspondingly in Table 2. These are presented from two companies' (A and B) perspective, the results are quite consistent in both of these companies.

Problems experienced

Flow of information

Flow of information was conceived as a problem in several situations. In many cases the information of the requisite requirements is coincidental, i.e. the requirements are not systematically searched and discovered. The information may also flow inadequately both inside the different units of the company as well as between the units. For example, the information may not be exchanged between product lines and projects and therefore; similar information is searched concurrently and repeatedly. One reason may be the lack of systematic documentation. It is also possible that the company's local unit, front line, in other market area, e.g. Australia, modifies the product to meet the local requirements (see Brun and Zorzini, 2009). However, the content of these modifications are not always informed to the manufacturing unit.

Competence

Several interviewees perceived that sales and marketing, as well as the so called front line had insufficient understanding and competence in product safety. They wished that sales and marketing should consult more designers and product line when negotiating and informing potential customers. They should both receive all the requisite information related to the requirements and not promise in excess to the customer. On the other hand, the interviewees highlighted the essential role and expertise of the front line when ensuring that the local requirements are managed. However, the front line usually represents more sales and marketing without competence related to safety issues.

Requirements

Requirements and attaining compliance were related to both the problems in information management and the technological difficulties to fulfill requirements in some countries. The problem may be the lack of an adequate and available system to process the requirements. The interviewees called feasible requirements' management system, comprehensive list of safety-related requirements and the proper comparison of the similar requirements between different market areas which the products are intended.

Table 1: The essential problems in managing product safety requirements of machines

	Company A	Company B
Problems		
Flow of information		
Lack of documentation	x	x
Flow of information, inside of a unit	x	x
Flow of information, between the units	x	
Coincidental information	x	x
Local modifications not informed	x	
Competence		
Lacking competence of the sales and marketing	x	x
Lacking competence in the front line	x	
Requirements		
No requirements' management system	x	
No lists list of the safety-related requirements	x	
Lacking comparison of the requirements between different market areas	x	
Requirements of Australia	x	x
Requirements of the UK		x
Requirements of Sweden	x	x
Standards		
The apprehension and interpretation	x	x
Lack of type C standards	x	x
Interpretation of the requirements and standards		
No guidelines for interpretation	x	
No code of practice for design		x
Lacking global alignments for safety		x
Actions of the organization		
Non-uniform practices in projects	x	
Unclear responsibilities	x	
Operations in the front line		x

Table 2: The applied practices in managing the requirements

	Company A	Company B
Practices		
Flow of information		
Requirements' management system under construction	x	
Product data management system		x
Documentation of the stages in design	x	
Risk assessment	x	x
System to reach all their customers		x
Competence		
International networking meetings	x	
Participation to the drafting	x	x
Requirements		
The standard product platform based on European markets requirements	x	x
All the main market areas simultaneously taken into account in standard products		x
Products are based on standards		x
Certain common and minimum requirements and the specific local regulatory requirements defined	x	
Divergent requirements in contracts or orders	x	x
Local information from the front line	x	x
Sales companies' and dealers' assistance	x	x
Standards		
Participation to the drafting	x	x
Comparison between different market areas	x	
Interpretation of the requirements and standards		
Utilization of external bodies	x	x
Benchmarking	x	x
Actions of the organization		
Multiprofessional product safety team	x	
The product safety team follows the requirements	x	x
The product safety team determines requirements in general	x	x
Project-based determination	x	
The product safety team compiles a safety plan for a project	x	
The product lines gather the requirements	x	
Global product council		x
The product safety team as a link for the design	x	
Customers help in tracing and verifying the local requirements		x
Products are modified to meet the local requirements by the front line	x	x
The front line asks permission for modification from designing and manufacturing unit		x

Even though the EU region seems to have harmonious legislative requirements related to safety of machinery the country-specific practices, requirements and their enforcement, may vary (see Tallberg, 2002; Sutinen and Kuperan, 1999). Especially the United Kingdom and Sweden were stated to be difficult. In Australia, the other market area studied, the requirements are occasionally stricter than in other market areas. The area is not uniform, the requirements diverge territorially. Lists of requirements mentioned in sales contracts are also extensive and contract techniques must be well mastered. In addition, a personal liability related to safety falls upon the designers.

Standards

Standards are differentiated as a separate part of the requirements, due to their nature of being instructions to fulfill the requirements. The apprehension of standards and their interpretation were perceived to be difficult for the companies. In addition, the information is not necessarily up-to-date. The lack of more detailed type C standards (machine safety standards) was seen either negative or positive. Type C standards clarify the design but they may also be experienced to complicate yielding added value of safety solutions.

Interpretation of the requirements and standards

The problems related to interpretation were related to the lack of guidance and alignments. According to many interviewees clear and generally available guidelines for interpreting requirements would be appreciated. Due to this similar requirements can be interpreted repeatedly and in a different way. Code of practice for design and global alignments for safety could also unify the operations.

Actions of the organization

From actions of the organization point of view the perceived problems were around non-uniform practices in projects, unclear responsibilities and the operations in the front line. The global requirements' management system and code of practice for design could facilitate controlling these problems. The responsibilities of complying the requisite requirements during different stages of projects life cycle must be defined as well as the parent company must be aware of the actions in the front line.

Practices in use

Flow of information

The flow of information is facilitated with information management systems and documentation. The information must be stored, available and understandable for several parties. The requirements' management system, product data management system and the documentation of stages in design are examples of applied practices. A company may also have a system to reach all their customers. The system of this nature is needed e.g. to gather feedback or inform customers for detected hazards or deficiencies.

Competence

The practices brought out for ensuring or improving competence were mostly indirect. The practices around competence were internal international networking meetings, participating the drafting of the requirements, benchmarking from other companies' products and learning from accidents. Maintenance has a significant role in adding competence. They are a direct contact to customers, as well as customers working with competitors machines.

Requirements

The practices related to the requirements and attaining compliance was around how to detect the requirements, which requirements are incorporated into global products (see Sadiq and Governatori, 2010) and possibility to effect on drafting stage (see Tala, 2001; Henson and Heasman, 1998). The product safety team is following the requirements in a general level and determining specifically for a project or product. The product line may also gather the requirements for the project or product, by way of the front line, at first. A company may have differing strategies for decoupling the additional local requirements to their standard products. The standard product platform can be based on single (for example European) market requirements or the company may take all the main market areas simultaneously into account (see Stark, 2011). The requirements for customized products are partially

following the basis of standard products. All the products must meet certain common and minimum requirements and the specific local regulatory requirements as well as the customer specific requirements are decoupled to these (see Fogliatto et al., 2012). Both mass customization strategies, modularization and postponing, are applicable (see Brun and Zorzini, 2009; Gosling and Naim, 2009). If the customization strategy is based on the postponing, the front line may modify the product to meet the local requirements and they may be required to ask permission from designing and manufacturing unit.

Standards

The direct practices related to standards were mentioned to be participating the drafting process of standards, their application as a part of the design and comparison between similar standards in different market areas (see Baram, 2007). The participation covers both national and international drafting committees. Besides offering possibility for proactive influencing the committees offer an area for inter-company benchmarking as well.

Interpretation of the requirements and standards

The companies hardly expressed specific practices for interpretation. They may utilize research institutes, consultants and inspection bodies. In Australia the authority was described to be also proactively interested. They can be asked for advice as well as they are educating companies' representatives. The versatile product safety team and international networking are promoting the interpretation as well.

Actions of the organization

The actions of the organization were the mostly mentioned practices for managing the requirements. The importance of clear distribution of responsibilities between the design, product line, local front line and product safety team is the most important of the actions. Product safety team is a support but their role may be varying in different projects and with different product lines. The determination can be carried out under a different body. The boundaries of local modifications, informing and permission of these are required to deal with the front line as well. The products may be modified to meet the local requirements by the front line (see Brun and Zorzini, 2009). However, it should not be executed uninformed. Another strategy to meet the local requirements is to by the help of the local front line and customers design and manufacture ready at once.

CONCLUSIONS

The companies' problems in managing product safety requirements of machines globally and the practices when managing these requirements can be divided into six categories: Flow of information, Competence, Requirements, Standards, Interpretation of the Requirements and Standards, and Actions of the Organization. According to the interviewed companies' representatives most of the perceived problems were related to the flow of information and requirements. The essential problems were not distinctly reflected to the current management practices. Most of the practices in use were instead around the actions of the organization.

In this study a particular attention was paid to two market areas: the EU region and Australia. The EU region's general requirements seem to be well under control and the European integration has clarified the product safety requirements as well. However, the varying country-specific practices, requirements and their enforcement may pose difficulties. In the Australian market the requirements are occasionally stricter than in other market areas. In addition, the area is not uniform. The requirements diverge territorially, though the harmonization process is ongoing.

The required information from another market area is typically gathered with the help of the company's local unit, the front line, and the customers. It is also possible that the designing and manufacturing unit does not determine all the local requirements, i.e. the front line may modify the product to meet the local requirements. A company may have differing strategies for decoupling the additional local requirements to their standard products. The standard product platform can be based on a single market's requirements or a company may take all the main market areas into account simultaneously. If the customization strategy is based on postponing, the problem may be that the front line does not always inform the content of these modifications to the designing and manufacturing unit. Related to the flow of information a notable problem is also that information may not be exchanged between product lines and projects and therefore; similar information of the requirements is searched concurrently and repeatedly. More

specific, a generally available and accessible documentation is required.

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