A qualitative examination of safety-related compliance challenges for global manufacturing

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Globally operating machine manufacturing companies need practices for recognising local safety requirements, as well as for designing the products for, and delivering them to, wider markets. This study aimed to determine (1) companies' product delivery strategies for managing product safety compliance and conformity in their supply chains, (2) the problems that arise in managing the product safety-related requirements and (3) how companies tackle these problems. The study comprised interviews with 25 representatives of 2 large internationally operating European companies manufacturing machines for use at work. The companies' strategies for decoupling the local safety requirements from their standard products covered make-to-stock, assemble-to-order, make-to-order and engineering-to-order. The problems were experienced mostly in systematic discovering and processing of the requirements, responsibility issues and unequal practices within global organisation. To tackle these problems a company must have tools and practices to manage the information needs and understand the concepts of product delivery strategies.

Keywords: product safety; requirements; compliance management; supply chain; global market

Introduction

Coordinating the various operations mandated by different foreign markets for safety requirements induces significant costs, and incorrect or insufficient knowledge of regulations may weaken the competitiveness of globally operating machine manufacturing companies. In addition, the lack of external help (such as from authorities) usually complicates the problem. Therefore, manufacturers need tools and practices for recognising local needs and safety requirements, while also designing and delivering products for wider markets.

As an example, in the European Union (EU), Directive 2006/42/EC on machinery, and the related harmonised standards, defines clear requirements and guidelines for product safety considerations in the design process of most machines. However, when the market area reaches beyond the EU, European manufacturers may confront difficulties in gathering and managing the local information and requirements. Manufacturers must be aware of differing product safety requirements, conformity declarations and product liability issues within all of their market areas. Furthermore, they must understand and comply with the local or regional legislation and jurisdiction, the local operating conditions, duty types and the customers' fields of operation. Manufacturers must also be capable of applying the valid standards and specifications. In addition, the manufacturers need suitable methods for taking these issues into account in practice, such as the concepts of compliance management, mass customisation and supply chain management. For instance, the manufacturers must decide how to plan their supply chains to ensure that they make products that meet uniform safety demands.

Several studies (e.g., Rausand and Utne 2009; Hale, Kirwan, and Kjellén 2007; Karwowski 2005) are available on how to integrate the design of safe and ergonomic products into engineering design process. Furthermore, the concepts of supply chain management and mass customisation of products and services are quite widely publicised (e.g. Fogliatto, da Silveira, and Borenstein 2012; Marucheck et al. 2011; Mentzer et al. 2001). However, from the compliance management and supply chain management perspectives, discussion of the safety design of machines intended for use at work remains scarce. These topics are not new per se, but they may create a novel combination in the safety research for the scientific community. The aims of this study were to determine (1) the kinds of product delivery strategies that globally operating

companies designing and manufacturing machines use to for manage product safety compliance and conformity in their supply chains, (2) the kinds of problems that companies have experienced in managing product safety–related requirements of machines intended for use at work internationally and (3) the kinds of practices that companies use to tackle these problems. The study explored the management of safety-related requirements of machines in two different markets: the EU and Australia. The data collection comprised interviews with representatives of two large internationally operating European companies manufacturing industrial machines. The two markets were chosen because of their importance to these companies and ongoing process of comparing the Australian way of regulating machinery safety to that of the EU.

The results of this study have both practical and scientific implications. Product safety engineers will be able to compare these results to the compliance management and product delivery processes in their own organisations. The authorities will understand the companies' perceptions and expectations of the authorities' role and enforcement strategies. Finally, the safety researchers will obtain novel information regarding safety-related challenges within global business as well as the applicability of adapted theories in safety research. This article begins with a theory discussion related to requirements, compliance management and supply chain management. After that the authors present the execution and results of the interviews conducted. The results are then discussed conjointly with the theory, and finally, in the conclusion section, we give recommendations to better tackle the issue of manufacturing compliant products cost effectively for differing customers and markets.

Theory

Globalization can present challenges and opportunities for a company. Increasing globalization requires the ability to transfer and deploy knowledge across borders

(Subramaniam and Venkatraman 2001). This has become one of the central competitive concerns for many organisations (Subramaniam and Venkatraman 2001). However, the information that a company needs to solve a technical problem is often expensive to acquire, transfer and use in a new location (von Hippel 1994). A company must decide, for instance, in which geographical markets it should offer its products—should it offer similar products to customers throughout the world, or does it need to offer a variety of products with different specifications?—and where it will develop and manufacture its products. Companies must understand the customers' requirements and comply with regulations and other requirements in many countries (Stark 2011; Sadiq and Governatori 2010; Drahos and Braithwaite 2001). Companies must also be aware of the regulatory agencies' (or authorities') styles of enforcing the requirements in different markets and the compliance atmosphere (Tallberg 2002; Sutinen and Kuperan 1999).

International manufacturing strategies

A company may have different types of international strategies for manufacturing and products: (1) export, (2) multi-domestic, (3) global or (4) transnational. In an export strategy, as much of the value chain as possible is located in the company's home country. There may also be some overseas locations where the downstream activities occur, such as marketing (St. John, Young, and Miller 1999). However, a multinational company that has operations in more than one country, may view the following strategies as applicable (Ketchen and Short 2012). In a multi-domestic strategy, a company reproduces its operations in several countries around the world (St. John, Young, and Miller 1999). Hence, the approach emphasises responsiveness to the local requirements within each company's market (Ketchen and Short 2012). In a global strategy, each value activity is located in one or two countries that are best suited for that activity. Further, this strategy focuses on minimising duplication and costs (St.

John, Young, and Miller 1999). The company offers the same products or services in each market; however, it may make some minor modifications in the various locations (Ketchen and Short 2012). A transnational strategy aims to provide both local responsiveness and global efficiencies (St. John, Young, and Miller 1999). This strategy may also be defined as a middle ground between the multi-domestic and global strategies. Ultimately, a company will try to balance the desire for efficiency with the need to adjust to the local needs within various countries (Ketchen and Short 2012). Moreover, the company will develop its products to adapt to both the specific local requirements and those that are standardised across markets. In this case, the companies must be skilled at detecting the differences between countries in order to address any conflicting requirements (Subramaniam and Venkatraman 2001). They may employ either a "sprinkler" or "waterfall" strategy when deploying new products. A sprinkler strategy describes the simultaneous development of products for multiple markets, while a waterfall strategy means that a company first develops products for a single market and then develops variations for other locations (Subramaniam and Venkatraman 2001).

Compliance management

From the authorities' point of view, a company's international manufacturing strategy is less important than whether or not it complies with local regulations. Authorities may use different implementation and enforcement approaches, such as the cooperative/accommodative approach or coercive/sanctioning approach (Bluff 2011; National Research Centre for Occupational Health and Safety Regulation 2002; Ayres and Braithwaite 1992; Braithwaite 1985), and they may also use different styles for interacting 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 product safety (Marucheck et al. 2011). Underlying issues with compliance management also increase the so-called regulatory burden and add complexity to requirements. In general, there is a structural tendency for regulation to increase over time (Hale, Borys, and Adams 2011). This may also add incoherence to requirements.

Compliance management can be defined as ensuring that business processes, operations and practices are in accordance with a set of prescribed and/or agreed upon requirements. It should not be a distinct activity but a part of the business practice (Sadiq and Governatori 2010). Compliance with the requirements indicates, for example, that a company conforms to 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 sufficiently comprehensive acquisition and management of the required information. Here, 'sufficiently comprehensive' includes, for instance, identifying and discovering requirements, interpreting requirements, identifying changes (impact analysis), the compliance decision, specifying the method of compliance, communication, implementation and application, and evaluation and monitoring (e.g. El Kharbili et al. 2008; Henson and Heasman 1998). Compliance management should have a preventive focus aimed at achieving compliance by design (Sadiq and Governatori 2010; Lu, Sadiq, and Governatori 2008).

As a part of the compliance process, companies can try to influence forthcoming requirements (regulations, standards, etc.), the requirements in force or their enforcement. Companies can carry this out themselves or through associations representing them (Tala 2001; Henson and Heasman 1998). Companies have different strategic choices in terms of responding to new or previously unknown regulations: opportunism, full compliance, partial compliance, noncompliance or influencing

regulation/enforcement (Henson and Heasman 1998). Both compliance and noncompliance may have short- and long-term, positive or negative consequences for a company (Bluff 2011; Tala 2001; El Kharbili et al. 2008). Furthermore, regulation has both direct and indirect effects on the product design. Companies must pay attention to existing and pending regulations (Baram 2007).

EU versus Australian compliance example

The principal instrument for regulating machinery safety in Europe is Directive 2006/42/EC. The member nations may set additional requirements consistent with this Directive, but they must assure the freedom of movement of the products (Baram 2007). In Australia, each state and territory government regulates occupational safety and health in its own jurisdiction (together with the Commonwealth Government). There is variation in the responsibilities and duties to ensure that companies design and manufacture their machines so that they pose no risks to safety or health. However, as of 26 February 2014, the Australian Government and International Labour Organization stated on their websites that the harmonisation of the requirements was initiated at the beginning of 2012. There has also been an ongoing process of comparing the Australian way of regulating machinery safety to that of the EU and convergence with 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 exactly how companies should achieve compliance; instead, they define the obligations of the companies in accordance with the goals they must achieve or the problems they must solve (Bluff and Johnstone 2004). The Australian Occupational Health and Safety (OHS) regulatory regime for plants and the regime created by the EU's Machinery Directive have some common features; they adopt a risk management approach, require the provision of

information, utilise technical standards and require companies' self-assessment of machinery. In addition, they provide third party verification for specific types of machinery. However, there are some differences as well; for example, the regimes employ different sets of performance-outcome measures, systematic processes and specification provisions. The Australian regime is mainly process-based, while the EU's regime focuses more on achieving performance outcomes (National Research Centre for Occupational Health and Safety Regulation 2002; Bluff 2004).

Mass customisation and supply chain management

In addition to the compliance management, companies must be able to react to the varying regulatory and customer-specific safety requirements and implement the design, manufacturing and distribution of the products. There have been extensive discussions about the management of the variation in customer needs in the literature on mass customisation and supply chain management (Fogliatto, da Silveira, and Borenstein 2012; Marucheck et al. 2011; Mentzer et al. 2001). The key concepts of mass customisation and supply chain management are postponement, modularisation and the order penetration point. Postponement relates to a company's aim to halt supply chain activities until it receives a customer order. Modularisation, on the other hand, helps the company manage the varied customer needs by using a set of predefined modules and their combinations. Finally, the order penetration point is the point in the supply chain where the customer-specific and varying requirements are added to more general standard requirements (Brun and Zorzini 2009; Gosling and Naim 2009; Wikner and Rudberg 2005; Olhager 2003).

Depending on the order penetration point, a manufacturer may apply postponement and modularisation to devise different product delivery strategies (Table 1). Make-to-stock products are completely designed and made to stock on the basis of

forecasts and assumptions about customer demand. The assemble-to-order strategy is typically applied when varying customer needs can be fulfilled by configuring a set of standard modules, and the make-to-order strategy is applicable when customer orders include some new or special features that must be taken into account during the fabrication and procurement phase. The order may also require some new design work. Finally, the engineering-to-order strategy is an option when the standard or modified products do not fulfil customer needs and an extensive new design is required (Olhager 2003).

Table 1. The location of the order penetration point (OPP) in the product delivery strategies (adapted from Olhager 2003 with permission).

Product delivery strategy	Design	Fabrication and procurement	Final assembly	Shipment
Make-to-stock	----------	----------	----------	OPP +++
Assemble-to-order	----------	----------	OPP +++++++++	
Make-to-order	-------	OPP +++++++++++++++++++++		
Engineering-to-order	OPP +++++++++++++++++++++++++++			

----- Forecast-driven
+++ Customer-order driven

In the case of capital goods, such as manufacturing systems or heavy machinery, the goods are typically characterised as unique or customisable products. Unique products are designed and produced according to the specific customer needs, and customisable products are based on a basic product with standard options and some extent of a new design. Hence, the most typical delivery strategies for capital goods are the engineering-to-order and the make-to-stock strategies (Sanchis et al. 2012).

Methodology

The researchers conducted interviews to gather information on the problems that arise in managing product safety-related requirements globally and the management practices. The researchers conducted the first interviews during 2012 and 2013 in two large companies manufacturing machines intended for use at work. Both case companies operate globally, and they conduct notable business in Finland as well. The EU and Australia are essential markets for both companies, and their global market shares within their field of business are around 20% and 15%, respectively.

The interviewees represented the product safety team, product line and design. The product safety team determines the requirements in general, follows the requirements, participates in drafting and supports the design with regard to safety issues. The product line owns the products, identifies the technical requirements, acts as a link to customers and the front line and approves the final products' compliance with the requirements (Declaration of Conformity). Moreover, the design applies the technical requirements that the product line has identified, and the product safety team supports the interpretation of the requirements.

The researchers interviewed representatives of the product safety teams individually, whereas they interviewed representatives of design and product line management in groups of two to five persons. Altogether, 11 interviews occurred with 25 interviewees, with 4 representatives of the product safety teams, 16 representatives of design and 5 representatives of product line management.

The interviews were semi-structured, including pre-prepared, open-ended questions. Each interview covered the topics in a fairly similar sequence. However, the group interviews resembled discussions including mutual discussion between the interviewees. The framework of the interviews was based on tentative discussions with

the companies and a literature review relating to compliance management, differing requirements, regulatory strategies and the authorities' role. The interview questions addressed the following topics:

- follow-up on the requirements
- determination/detection of the requirements
- management of the requirements (compliance)
- liability issues
- authorities' role in different markets

The respondents also had the opportunity to discuss other issues that the interview questions did not cover. Hence, the results of this study are qualitative.

The researchers conducted the next interviews during summer 2014 with the companies' product safety managers. The topics covered by these semi-structured interviews concerned the problems and practices relating to the following:

- managing product safety-related requirements
- decision making
- supply chain management
- mass customisation
- modularisation
- postponement

After the interviews, the researchers first determined the kinds of product delivery strategies that the companies apply and how the strategies appear in practice. During the next phase, the researchers analysed the companies' problems and practices in managing the product safety-related requirements. Then they analysed the central results and organised them into six theme groups: flow of information, competence, requirements, standards, interpretation of the requirements and standards, and actions of

the organisation. Subsequently, they tabulated the thematised results into two tables: problems and practices. The tables show the results from the perspectives of the two companies and three groups (product safety team, product line and design). In the tables, a group that mentioned a certain problem or practice is marked with a cross. The information that the crosses present is indicative of the fact that the interviews were sorts of discussions. During the last phase, the researchers compiled the general recommendations for tackling the problems in managing the product safety-related requirements of machines intended for use at work internationally.

Interviews and discussion

This section discusses the interviewees' understanding of the problems involved in managing the product safety requirements of machines and the practices which their globally operating companies (A and B) apply to manage these requirements. The interviewees' views are presented in general, but with particular emphasis on the EU and Australian perspectives.

The results of the interviews follow in three subsections: international product delivery strategies, problems experienced and practices in use, in accordance with the set aims. There are six theme groups representing the results concerning the problems experienced and practices in use subsections. Table 2 presents the essential problems that the representatives of the product safety team (PST), product line (PL) and design (D) highlighted, and Table 3 presents the essential practices.

Product delivery strategies

Both companies are multinational, and they have the features of several international strategies (see St. John, Young, and Miller 1999; Ketchen and Short 2012; Subramaniam and Venkatraman 2001). The companies apply mostly a transnational

strategy; that is, they typically develop their products to adapt to both the specific local requirements and those that are standardised across markets (see Subramaniam and Venkatraman 2001). The transnational strategy can be defined as a middle ground between a multi-domestic strategy and a global strategy. From the products point of view, companies' standard products may be seen as following a global strategy. Moreover, companies usually apply the multi-domestic strategy when designing and manufacturing customised products for a single or a few markets.

The interviews showed that the case companies manufacture products in accordance with each of the aforementioned product delivery strategies: make-to-stock, assemble-to-order, make-to-order and engineering-to-order (see Olhager 2003). The companies primarily strive to postpone supply chain activities until they have a certain customer order and until the related legal and customer-specific safety requirements are clearly sought, defined and understood. Postponement helps the companies avoid the risk of tying equity to products that may fail to fulfil all the essential safety requirements and that might require expensive redesign, partial disassembly and reassembly. In the worst case scenario, the failure to find and apply the right requirements could cause severe accident losses and product liability costs. Therefore, the companies avoid the true make-to-stock strategy. On the other hand, postponement may adversely extend product delivery time, and thus the companies may occasionally manufacture some standard products mainly to dealers' stocks on the basis of forecasts about customer demand and defined information about the local safety requirements. In some cases, the local dealers or the company's front line personnel may also order a standard product and then modify the product to fulfil the local requirements and preferences. The case companies generally require the front line personnel to seek permission for the modifications from the design and manufacturing unit in order to

ensure the conformity of the modification. However, this is not always realised in practice. Similarly, even if the dealer is legally responsible for the conformity of the modifications that it has made to the standard machine, the reputation risk may fall upon the original manufacturing company in the case of an accident. One may also argue that from the viewpoint of the dealer or the front line personnel, such projects are more like engineering-to-order or make-to-order projects than make-to-stock projects.

The assemble-to-order strategy applies once a customer can build the product by selecting the desired combination of pre-designed standard modules. The strategy is applicable especially in the cases of broad customer demand, limited variability of product features together with a well-defined and uniform set of safety requirements. A company can either base the standard product platform on the safety requirements of a single (e.g. European) market, or it may take into account all the main markets simultaneously (see Stark 2011). The primary challenge for manufacturing companies is to decouple the specific local safety requirements from the standard product platform and then design the corresponding standardised safety modules and add them into the supply chain.

The make-to-order strategy covers projects wherein the standardised safety modules cannot fulfil the customer needs or local safety requirements and small changes are executed by redesigning a standard product platform or standard modules. Furthermore, companies apply the engineering-to-order strategy once they design a product, for example, for a new application, new environment or a new market, and therefore there is a requirement for entirely new studies about possible safety requirements as well as extensive new engineering designs. However, in this case, the products are still partially based on standard modules and products.

Although both case companies have extensive international supply chains, and they apply all the four product delivery strategies, it seems that the product safety engineers, the designers and the product line managers do not fully share the common conception of the company's delivery strategies. Therefore, a more conscious application of the product delivery strategies (make-to-stock, assemble-to-order, make-to-order and engineering-to-order) would benefit the companies by allowing them to structure the safety information and their information analysis practices (see Olhager 2003).

Problems experienced

Flow of information

The interviewees recognised the flow of information as a problem in several situations. Almost all of the interviewees remarked that their discovery of information about the requirements is coincidental; in other words, the studied groups do not systematically search and discover the requirements. The information may flow inadequately both inside the different units of the company as well as between the units. For example, the representatives of product lines and personnel working on specific projects may not adequately exchange information. Hence, individuals search similar information concurrently and repeatedly. One reason for this may be a lack of systematic documentation and data management. It is also possible that the personnel in the company's local unit in another market area, the front line, modify the product to meet the local requirements (see Brun and Zorzini 2009). However, in one of the case companies, the centralised manufacturing unit is not always informed of the content of these modifications. In this case, the responsibility issues and the validity of the risk assessment may be unclear as well. Altogether the inadequate flow of information

induces abundant work and increases the companies' expenses.

Competence

Several interviewees representing designers in both of the case companies perceived that the personnel in sales and marketing, as well as the front line, had insufficient understanding and competence regarding product safety. They wished that sales and marketing would consult with more designers and those on the product line before negotiating and informing potential customers; they should receive all the requisite information relating to the requirements and not promise in excess to the customer. On the other hand, some of the interviewees highlighted the essential role and expertise of the front line personnel with regard to managing the local requirements. However, the front line personnel usually represent more sales and marketing expertise without particular competence in relation to safety issues.

Requirements

As the case companies are multinational and predominantly applying a transnational strategy, they must be aware of the specific local requirements as well as the requirements that are standardised across markets. In addition, the companies must identify the differences between countries (see Subramaniam and Venkatraman 2001). The interviewees stated that the requirements and attaining compliance relate to both problems in terms of information management and the technological difficulties relating to fulfilling the requirements in some countries. The issue may be the lack of an adequate and available system for processing the requirements. The interviewees in one of the case companies, especially the representatives of the product safety team, called for a more specific and feasible requirements management system, a comprehensive list of safety-related requirements, and a proper comparison between the similar

requirements of the different markets for which they manufacture products. However, the country-specific packages of the requirements may be difficult to compile, for instance, due to language and the difficulty of tracing all the information. Thus, the companies are continuously applying less cost-effective engineering-to-order and make-to-order strategies, although modularisation and the related assemble-to-order strategy would be applicable and more cost effective.

Even though the EU seems to have harmonious legislative requirements concerning the safety of machinery, the practices and requirements and their enforcement may vary between the member countries (see Tallberg 2002; Sutinen and Kuperan 1999). According to the interviewees, especially the designers, the United Kingdom and Sweden pose distinct difficulties. It may also be reasonable to ask whether there is truly effective market surveillance within the EU.

In Australia, the other focal market, the requirements are occasionally stricter than in other markets. The country is not uniform, as the requirements differ from one territory to the next. The requirements listed in sales contracts are also extensive, and thus, it is crucial to master contract techniques. In addition, personal liability in relation to safety falls upon the designers.

Standards

This study differentiated standards as a separate part of the requirements because they are instructions for fulfilling the requirements. Almost all of the interviewees stated that it is difficult to comprehend the standards and their interpretation. In addition, the information pertaining to the standards is not necessarily up to date. It is especially costly for a company if it notices non-validity only after initiating a project. Further, the interviewees from both case companies stated that the lack of more detailed European type C standards (safety standards for specific machines) is either negative or positive.

Type C standards clarify the design, but they may also complicate yielding added value from safety solutions. Even though a standard exists, it is not mandatory, but advisable, to design the product in accordance with it. However, when a standard is not applied the manufacturer must be able to indicate that their solution is as safe as the solution recommended in the standard.

Interpretation of the requirements and standards

The interviewees described the problems relating to interpretation around lacking guidance and alignments. Usually, there is no external body from which to seek support. According to the interviewees representing product safety and design in one of the case companies, they would appreciate clear and generally available written guidelines for interpreting the requirements, as similar requirements can be interpreted repeatedly and/or differently. In proportion, a documented code of practice for design and consistent global alignments for safety could unify the operations according to the other company's representatives.

Actions of the organisation

As regards the organisation's actions, the perceived problems in one of the companies relate to non-uniform practices in projects and unclear responsibilities, and in the other company, the operations on the front line. A global requirements management system and code of practice for design could facilitate controlling these problems. In addition, it is essential to define the personified responsibilities of complying with the requirements at different stages of the project life cycle. The parent company must be aware of the actions on the front line as well. If the parent company is not aware of these actions, it may induce more work and obscure the responsibility issues.

Table 2. The essential problems in managing product safety requirements of machines

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

Practices in use

Flow of information

Information management facilitates the flow of information. The information must be stored, and it must be available and understandable for all the necessary groups and persons. The requirements management system, product data management system and the documentation of the design stages are examples of applied practices. For example, in one of the case companies, the product line managers compile country-specific packages of the requirements. However, it must be noted that these packages are not necessarily true assemble-to-order modules. Instead, they are information packages that are applied in make-to-order and engineering-to-order product delivery strategies.

A company may also have a system for reaching all of its customers, as the other case company does. Such a system is needed, for instance, to gather feedback or to inform customers of detected hazards or deficiencies. Another important element is the ability to trace all parties in the company's supply chain and the manufacturing dates of all the components.

Competence

According to the interviewees, the practices for ensuring or improving competence are mostly indirect. The practices around competence relate to the multi-professional members of the product safety team, international networking meetings between different units, the product safety engineers participating in the drafting of the requirements, benchmarking from other companies' products and learning from accidents. Representatives of maintenance have a significant role in adding competence as well. They act as a direct contact point to customers.

Requirements

The practices relating to the requirements and compliance concern how to detect the requirements, which requirements are incorporated into global products (see Sadiq and Governatori 2010) and the possibility of having an effect during the drafting stage (see Tala 2001; Henson and Heasman 1998). The requirements cover regulation, standards and customer requirements. The European CE-marking ordinarily assures the wide exportation of products to different markets. However, when applying the transnational strategy, the personnel participating in the product development must be aware of both the local and universal requirements (see St. John, Young, and Miller 1999; Subramaniam and Venkatraman 2001). It is insufficient to meet only the EU's requirements.

In both case companies, the members of the product safety team follow the requirements in general and make specific determinations for a project or product as well as share information between product lines. In one of the companies, the product line managers also identify the requirements (compile the country-specific packages) for the project or product by way of the front line personnel and customers.

Standards

The interviewees specified several practices relating to standards, such as the product safety engineers' participation in the drafting process for standards, applying standards as part of the design, comparing similar standards in different markets and performing a compliance check of the standards as part of a project (see Baram 2007). Participation covers both national and international drafting committees. Besides offering the possibility of influencing the committees, this offers an area for inter-company benchmarking.

Interpretation of the requirements and standards

The interviewees hardly mentioned specific practices for the interpretation requirements and standards. The product safety engineers and designers utilise research institutes, consultants and inspection bodies. In Australia, the interviewees referred to the authority as proactive. It is possible to ask their representatives for advice, and they educate the companies' representatives. In addition, a versatile product safety team comprising members with differing backgrounds and educational qualifications, as well as international networking between the company's different units, promote the interpretation in one of the case companies.

Actions of the organisation

The interviewees from both case companies mentioned practices around the actions of the organisation. The clear distribution of responsibilities among the designers, product line managers, members of the product safety teams, front line personnel and subcontractors are the most important actions. Generally, the product safety teams support designers and product line managers to fulfil safety requirements, but their roles may vary on different projects and product lines.

The localisation of the products is typically carried out by 1) identifying and taking the local requirements and needs into account during the initial design and manufacturing of the machine or 2) meeting the requirements locally in the front line. In the first option the parent company seeks the help of the local front line personnel and customers to prepare the design and manufacturing at once. In the other option it is essential that the front line personnel communicate and understand boundaries of local modifications and seek permissions from the parent company in order to modify the products to meet the local requirements (see Brun and Zorzini 2009).

The parent company must also note the role of subcontractors when considering safety-related responsibilities in supply chain. The compliance of subcontractors is typically managed, for instance, according to uniform requirements, auditions, classifications and quality control. Hence, the quality of the products must be equal, regardless of where and by whom they are manufactured within the supply chain.

Table 3. The applied practices in managing the requirements

	Company A			Company B		
PRACTICES	PST	PL	D	PST	PL	D
Flow of information						
Requirements' management system under construction	x	x	x			
Product data management system					x	x
Documentation of the stages in design			x			
Risk assessment	x			x	x	x
System to reach all their customers					x	
Competence						
International networking meetings	x					
Multiprofessional product safety team	x		x			
Participation to the drafting	x			x		
Requirements						
The product safety team follows the requirements	x		x	x		x
The standard product platform based on European markets requirements	x	x				x
The main markets simultaneously taken into account in standard products					x	
Products are based on standards					x	
Common minimum requirements and the specific local regulatory requirements defined	x	x				
Divergent requirements in contracts or orders			x		x	x
Local information from the front line	x			x	x	
Sales companies' and dealers' assistance		x		x		x
Standards						
Participation to the drafting	x			x		
Comparison between different markets		x				
Compliance checks in projects	x			x		

Interpretation of the requirements and standards						
Utilisation of external bodies	x		x	x		
Benchmarking	x			x	x	x
Actions of the organisation						
Multiprofessional product safety team	x		x			
The product safety team follows the requirements	x		x	x		x
The product safety team determines requirements in general	x		x	x		
Project-based determination			x			x
The product safety team compiles a safety plan for a project	x					
The product lines identifies the requirements	x	x	x			
Global product council					x	
The product safety team as a link for the design	x	x	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	x	

Conclusions and recommendations

This study was based on two case companies' views on the problems that they encounter in managing product safety-related requirements globally and their management practices. Even though the number of companies was limited, the researchers conducted the interviews widely within the companies. The study paid particular attention to two markets: the EU and Australia. The case companies seem to fully satisfy the EU's general requirements, and the European integration has even clarified the requirements regarding product safety. 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 requirements diverge in different territories of Australia, though the harmonisation process is ongoing.

The results revealed that the two case companies' problems and practices in regard to managing the product safety requirements of machines globally could be organised into six theme groups: flow of information, competence, requirements, standards, the interpretation of the requirements and standards, and the actions of the organisation. According to the interviewees, most of the perceived problems relate to the flow of information and requirements. However, the current management practices do not distinctly reflect the essential problems. Moreover, most of the practices in use concern the actions of the organisation.

The companies' strategies for decoupling the local safety requirements from their standard products covered all four product delivery strategies (make-to-stock, assemble-to-order, make-to-order and engineering-to-order). Typically, the standard product platform is based on a single market's requirements, or a company may take all the main markets into account simultaneously. The required information from another market is gathered with the help of the company's local unit, the front line and the customers. In some cases, the front line modifies the product to meet the local requirements. The problem may be that the front line does not always communicate the content of these modifications to the design and manufacturing unit. In this case, it may be unclear who is responsible of, are the risk assessments carried out and who should sign the declarations of conformity. Regarding the flow of information, a notable problem is also that information may not be exchanged between product lines and projects; therefore, the personnel search similar information about the requirements concurrently and repeatedly. More specifically, generally available and accessible documentation is required. In addition, the process of compliance with the requirements should be more systematic, from identifying and discovering to evaluating and monitoring the valid requirements. Especially when a company is multinational and

applying a transnational strategy for manufacturing, it must have functional practices to determine all the valid requirements. In addition, a company must be able to detect the differences between countries if the product is proposed to be global. However, a multinational company has better possibilities for identifying and discovering local requirements than a company located in only one country. In Table 4 is summarised the essential problems that the case companies' representatives have experienced, and after each problem follows the recommendation for improving safety design and compliance management.

Table 4. The essential problems experienced and recommendations related to the problems

Problem	Recommendations
The requirements are not systematically searched, discovered, documented, processed, interpreted and/or compared	The requirements and product data management systems Company's representatives participation in the drafting All tangible and intangible information about the different global and local safety requirements, interpretations and safety engineering solutions within the organisation gathered and documented Compiled country-specific requirements packages Help from local units, customers, maintenance and other companies
Unclear responsibilities	Requirements management system, where the responsibilities are personified and presented for each phase of a project
Equal understanding and practices of the safety issues	International networking meetings between company's different units Similar level of safety in every market and place of manufacture Regard safety as a company's primary value

Suitable strategies for tackling differing requirements in several markets	Help from local units, customers, maintenance and other companies More application of assemble-to-order strategy
Local modifications of the products and the awareness of these modifications	The design and manufacturing is prepared at once The local unit seeks permission from the parent company for modifications

The observations suggest that the companies' safety design and the management of safety-related compliance are not entirely consistent with the product delivery strategies. Each product delivery strategy presents different challenges and possibilities for safety design and compliance management. The make-to-stock and the assemble-to-order strategies provide superb logistic efficiency but require thorough knowledge and the implementation of all the relevant and general safety requirements long before the order penetration point. The product features are fixed on the basis of the forecasted customer demand and the compliance requirements. Therefore, possible changes in the products may be difficult and expensive to implement afterwards. In the cases of the manufacturing-to-order and the engineering-to-order strategies, the order penetration point is closer to the design, and it is possible to identify and analyse the customer-specific requirements together with the customer requirements, thus enabling the company to benefit from the customers' expertise. To better tackle the issue of manufacturing compliant products cost effectively for differing customers and markets, the manufacturing companies would benefit from carrying out systematic development activities aiming to move safety-related design practices from engineer-to-order and make-to-order strategies to assemble-to-order strategy.

In the future, more conscious application of the concept of product delivery strategies might help the product safety specialists to adopt a specific safety information management process for each delivery strategy. The application of the concept of a

product delivery strategy would also accelerate the communication between the safety specialists, the designers and those on the product lines.

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