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Safety Science

Practices and needs of machinery designers and manufacturers in safety of machinery:

An Exploratory Study in the Province of Quebec, Canada

Keywords: Safety of Machinery, Design, Manufacturer, Risk assessment

Abstract

This paper presents an exploratory study on the integration of safety during the design and manufacturing phases of machinery in the province of Quebec, Canada. The objective was to better understand the practices and needs of machinery manufacturers for safeguarding their products. Data was collected during interviews and observations with 17 machinery manufacturers. Given the purpose of this study, these companies specialize in the design and manufacturing of machinery used for production in other manufacturing companies. The machines designed and built by these manufacturers are intended for several sectors and are sold in Canada and in various parts of the word. These machines are mainly built and assembled in the workshops. The manufacturers who were interviewed rely on design teams generally made up of mechanical, electrical and mechatronic engineers; technicians in these same fields; designers; machinists and electricians to design their machinery. These teams use on average between five and six normative and regulatory documents depending on their clients' requirements. Most respondents are aware of the need to properly identify the risks related to the use of their machinery and to avoid improvising approaches that may prevent a comprehensive analysis. Their risk-analysis approaches are generally documented, depending on the scope of the project. All the manufacturers interviewed install guards and protective devices on their machines. They favour guards made up of rigid frames and polycarbonate panels and are less likely to use light curtains and laser scanners, because these devices are more expensive. Bypassing these safeguards remains a concern for most manufacturers. The causes cited for bypassing safeguards are summarized as problems related to the performance and adaptability of humanmachinery interfaces; the lack of integrated safety measures; safeguards that make machine set-up phase complex, reconfiguration or maintenance operations; and the acceptance of safeguards by machine users. Costs, productivity and operating time are some of the constraints that require very particular attention from design teams. For operational reasons and in order to respect their specific procedures, sometimes clients ask manufacturers for safeguarding solutions that are appropriate for them or, refuse the safeguarding solutions that are proposed. In addition to safeguards bypass and constraints imposed by the client, this study identifies other problems and needs, namely: 1) inherently safe design measures; 2) managing risks during the building phases of the machinery's life cycle besides production and maintenance; 3) ensuring the applicable standards are used and updated; 4) designing and validating safety-related control systems and; 5) making clients more conscious of the importance of safety of machinery.

1. INTRODUCTION

1.1 Context of the Research

Machinery-related accidents are frequent and numerous, causing from light injuries to fatalities. In the province of Quebec, Canada, the *Commission des normes, de l'équité, de la santé et de la sécurité du travail* (CNESST) (the organization responsible for applying the occupational health and safety laws and regulations in the province) reports that machinery caused 2465 occupational injuries in 2016 (CNESST, 2017b).

A recent study considered 106 serious and fatal machinery-related accident reports in the manufacturing and transformation sectors, covering the period from 1990 to 2011 in the province of Quebec (Chinniah, 2015). These 106 accidents caused 75 deaths (70.8%) and 31 serious injuries (29.2%), such as severe

lacerations and the loss of an upper or lower limb (jamming, crushing). The study showed that these accidents were caused by various factors, including several related to the design of the machinery itself:

- Easy access to the machinery's moving parts;
- The lack of fixed and interlocked mobile guards;
- The easy circumvention of safeguards (guards and protective devices);
- The failure of manufacturers to carry out risk analysis;
- The position of lubrication points, control panels and conveyor tensioning devices check points in dangerous areas;
- Safety-related changes to the machinery and its control system.

The integration of safety in the design phase is still the fundamental principle in safety of machinery. This study focuses on machinery manufacturers and more specifically on their practices for integrating safety in the design of their products. After a literature review, this paper presents the objectives and methodology. The results and their interpretation are then developed and discussed before listing some recommendations.

1.2 Literature Review

1.2.1 <u>Machine-related accidents</u>

According to International Standard ISO 12100 (Safety of machinery -- General principles for design -- Risk assessment and risk reduction), a machine is an *assembly, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application* (ISO, 2010). Machines present hazards that may cause serious and fatal injuries. As they are involved in most phases of machinery's life cycle, several groups of workers are exposed to these hazards, which results in numerous workplace accidents.

The US Bureau of Labor Statistics revealed that 1366 deaths were attributable to machinery or equipment in 2018 (US Bureau of Labor Statistics, 2019). Bulzacchelli et al. (2008) stated that in 2005, approximately 18% of workers were fatally wounded (i.e., a little more than 1,000) because of contact with an object or piece of equipment.

In the United Kingdom, the Health and Safety Executive (HSE) states that 50% of fatal accidents related to moving parts of machines occurred on printing presses and conveyors (Health and Safety Executive, 2006). In the Netherlands, Bellamy et al. (2007) report that 21% of workplace accidents are caused annually by moving parts of machines.

In Canada, 177 hospitalizations for injuries related to farm machinery are declared (on average) by segment of 100,000 inhabitants each year (Brison et al., 2003). A total of 159 machine-related injuries on 2,390 farm operations were declared in the province of Saskatchewan in 2006. These accidents involved farm machinery such as tractors (23%), transport (16%) and harvesting material (16%), drilling rigs (11%) and combine harvesters (11%) (Narasimhan et al., 2010). Accidents caused by agricultural machinery are also a concern in Austria (Robert et al. 2015). In the province of Quebec, 3,552 workers were injured in accidents related to machinery operation in 2010 and, between 2006 and 2010, 12 deaths per year (on average) were attributable to machinery (CNESST, 2010). Machinery hazards are even present in hospitals (Tremblay & Gauthier, 2018).

Most machinery has a control system that includes automated and safety-related components and parts. Accident statistics from all over the world indicate that a significant proportion (between 8% and 20% depending on the various studies) of accidents involving machinery are caused by a failure or unintentional operation of their control system (Karimi et al. 2019; Sangare et al., 2012; Svaldi and Charpentier, 2004;

Dźwiarek, M., 2004 Backström and Döös, 2000; Lüken, 2006). A significant number of accidents involving machinery is at least in part attributable to design gaps in the control system.

1.2.2 Safe design of machinery

Most organizations involved in occupational health and safety prioritize the integration of safety from the design phase as the primary method of reducing risks associated with machinery. Moreover, this is consistent with the recommendations of International Standard ISO 12100:2010. The standard recommends implementing inherently safe design measures as a first step for the designer to eliminate the hazard or reduce the risks, followed by safeguards, complementary protective measures and information for use (Standard ISO 1200, 2010) (Figure 1).



Figure 1: Hierarchy of risk reduction measures from point of view of designer (Source: Adapted from Standard ISO 12100, 2010)

Design for safety theories and organisation of machinery design projects have been studied by numerous researchers (Sadeghi et al, 2015; Bluff, 2015; Fadier et al. 2014; Gauthier & Charron 2002). Many authors also looked at different specific aspects of safety of machinery: on safety of machinery control systems: (Bornemann et al., 2014a,b; Chinniah et al., 2019); on bypassing of safeguards: (Haghighia et al., 2019; Landi et al., 2017); on risk estimation: (Mödden, 2018; Jocelyn et al., 2018; Gauthier et al., 2018); on the use of standards: (Landi et al., 2019; Sangare at al., 2012).

However, few field studies have examined the actual process of safety integration at the design phase by machinery manufacturers. Studies in Quebec usually look at the safety of existing machinery in operation (Tremblay & Gauthier, 2018; Chinniah et al. 2017). Falconnet et al. (2013) argue that designing machinery requires numerous processes, including functional analysis and risk assessment to provide future users with machinery that meets both specific technical features and safety criteria. Designers must anticipate the operator's work in the future use context and therefore the potential risk scenarios.

De la Garza (2005) analyzed and compared safety integration terms and conditions in the engineering and design department at a printing press manufacturer. The author identified direct paths (explicit and formal) and indirect paths (implicit) during safety integration. Direct paths involve sharing a common operational reference related to a shared system of knowledge, for which a single safety expert is responsible. They rely on, among other things, standards, internal documents and the certification of machinery by outside organizations. Indirect paths involve knowledge on actual work, its requirements and constraints and/or field or accident reviews. They are related to an individual system of knowledge through which the safety integration is not systemic: safety objectives are integrated into design objectives.

Sangare et al. (2012) tried to establish a profile of machinery manufacturers in the province of Quebec, Canada, regarding their use of safety, quality and environmental normative and regulatory documents. Their study showed a relatively low level of knowledge and use of normative and regulatory documents. Thus, according to the results of this study, one quarter of machinery manufacturers do not use any normative or regulatory document, while almost half make moderate use of these documents in their design process. Although this study did not specifically focus on safety of machinery, it still shows that machinery manufacturers in Quebec have a positive perception of the use of normative and regulatory documents related to workplace health and safety, whatever their level of use. However, manufacturers report they are faced with documents that are often repetitive and difficult to interpret. They need better training for their staff, particularly for design and manufacturing engineers, for successful integration of standards and regulations in their companies. This study also concludes that further studies are necessary to better identify the needs of machinery manufacturers, particularly regarding safety of machinery.

1.3 Objectives of the study

Machinery manufacturers are the first line for safeguarding their products by integrating safety principles from the design phase. However, the literature clearly shows that the integration of safety from the design phase by machinery manufacturers is a complex process and therefore the level of proficiency can be highly variable. The practices and needs of machinery manufacturers for safeguarding their products are unknown.

In the specific context of machinery manufacturers in the province of Quebec in Canada, other factors also influence practices for integrating safety from the design phase. The responsibilities of the machinery manufacturers are not clearly defined in the province's *Act respecting occupational health and safety* (AOHS) and in the section « XXI – Machinery » of the *Regulation respecting occupational health and safety* (ROHS) (Government of Quebec, 2020a,b)

Section 63 of the AOHS states, without naming them directly, that machinery manufacturers must ensure that their equipment is safe and complies with current standards: "No one may manufacture, supply, sell, lease, distribute or install a product, process, equipment, equipment, contaminant or hazardous material unless they are safe and comply with regulations." However, the ROHS, which is the main regulation regarding occupational health and safety in Quebec, does not prescribe any standards for machine safety (CSST, 2015). Therefore, this legislative requirement remains vague.

Thus, even if many Canadian or international machinery safety standards are available to help machinery manufacturers, (like, for example Canadian Standard CSA Z432-2016 *Safeguarding of machinery*), the actual occupational health and safety regulations do not impose their use. Moreover, most machinery manufacturers in the province are SME's and find those standards to be numerous and complex to use (Sangare et al., 2012). Lastly, there is no certification process for safety of machinery in Canada as it is the case in Europe for example. Therefore, Canadian machinery manufacturers are not compelled to formally document their design for safety process.

This is the context in which this exploratory study aims to better understand the practices and needs of machinery manufacturers in Quebec for safeguarding their products. More specifically, the objectives of this study are to:

- Better understand actual practices and other procedures (internal processes, the use of specific tools, the use of external resources, etc.) of machinery manufacturers;
- Better understand the specific needs of designers related to the integration of safety in the design phase;
- Characterize the adequacy of standards to manufacturers' needs;
- Identify the different ways to meet the needs identified, the development of which could guide subsequent research.

2. METHODS

The methodology was based on the analysis of data collected during semi-structured interviews and observations conducted at a number of machinery manufacturers. It consisted of four steps:

- 1) Select companies to visit (machinery manufacturers):
- 2) Develop and validate data collection tools;
- 3) Collect data;
- 4) Process and analyze data.

2.1 Select and recruit participating companies

Companies had to meet the following criteria to participate in the study:

- Design and manufacture industrial machinery in Quebec;
- Design and manufacture machinery under their own name (i.e., they do not act as a manufacturing subcontractor of another company responsible for design) for which they hold their own trademark;
- Design and manufacture machinery for use by workers in a production setting;
- Design and manufacture machinery that includes a control system other than a single on/off switch.

The sample of companies selected should reflect to the extent possible the variety of machinery manufacturers in Quebec, in both their size (small, medium and large companies) and the type of product or production. A total of 17 companies agreed to participate in the study.

2.2 Develop and validate data collection tools

The on-site visit procedure included an interview with important actors in designing machinery in each company, followed by a period of observation of a manufactured machine. The purpose of the observation phase was to check the level of consistency between the answers obtained during interviews and the actual situation in terms of protective measures implemented by designers on their machinery mainly based on the principles of ISO 12100 standard.

2.2.1 Interview checklist

The interview checklist used during the visits made it possible to collect consistent and comparable data for each company. This checklist consisted mostly in open-ended questions to which respondents could answer freely. The main themes covered in the interview checklist were:

- The documentation used (regulations, standards, guides and other documents);
- The risk assessment performed (risk estimate tool used, method used, whether or not the process is documented, who conducts it, team participatory approach, etc.);
- The risk reduction strategies adopted (protective measures implemented, conformity with the hierarchy found in the standards, etc.);
- The design of control systems (use of basic safety principles, use of proven safety principles, architecture of control systems, control system validation processes, documentation of the procedure and technical file);
- The methods implemented to prevent the bypass or circumvention of guards and protective devices (visibility of work areas, use of positive activation, accessibility of safety switches, etc.);

- The maintainability of equipment (isolation devices for locking, use of reduced speed, accessibility to perform maintenance operations);
- Client requirements for protective measures (e.g., does the client impose certain conditions to facilitate production to the detriment of safety?).

2.2.2 Observation checklist

The observation checklist was used by researchers to structure their observations on machinery during manufacturing or in testing phase in the manufacturer's workshop. It had the same objective of consistent data collected on the following notions:

- The use of inherently safe design measures;
- The use of safeguards (guards, protective devices, protective measures aimed at reducing emissions such as dust and chemical contaminants);
- The adequacy of the implementation of safeguards (distance, height, positive actuated, safety components, design of safety-related control systems, etc.);
- The use of complementary protective measures (emergency stop devices, power source isolation devices which can accommodate padlocks, secure access devices, etc.);
- The use of information for use (signals and warning devices, written warnings and danger signals, user documentation, etc.).

2.2.3 Test and adjust checklist

The interview and observation checklists were tested in the first two companies visited to ensure they were comprehensive, properly understood by respondents and that they allow for the collection of all relevant information in the field. A few minor adjustments were made to the interview checklist after the first visit. These changes were on the format mostly than the content in order to take notes. A few redundant questions were removed. The second visit validated the changes made.

2.3 Collect data

Visits were usually conducted by one or two members of the research team. The research team was composed of one automation engineer, three industrial engineers and one mechanical engineer. All were safety of machinery specialists and one was also and ergonomist. The respondents, between one and five per visit, were always involved in machine designing although they had various titles and jobs.

The typical planned process, i.e., an interview followed by a period of observation, was overall followed even if the observation time was sometimes shortened due to the unavailability of respondents or due to time constraints when the interview lasted longer than planned. When the observation checklist was partially completed or even unused, research team members prioritized discussions with participants knowing that the photos taken would make it possible to answer many questions on the observation checklist. There were also cases where the machine was being assembled at the client's site and therefore actual observation of the machine was not feasible.

2.4 Process and analyze data

The data analysis strategy was based on two separate approaches: a descriptive approach and a comparative approach.

In the descriptive approach, the data collected were grouped by category in an Excel[®] worksheet making it possible to establish trends in the practices of machinery manufacturers. Documentation use, risk

assessment methods implemented and risk reduction strategies adopted were categorized for all companies. Data concerning the methods implemented to prevent the voluntary disabling of guards and protective devices and to ensure the maintainability of equipment were also grouped into categories. As the interview checklist provided sections to record participants' comments, this additional information was also taken into account when analyzing the data.

The comparative approach made it possible to more specifically check the adequacy of practices explained by various stakeholders during the interviews with the characteristics of the equipment they design. By observing the machinery on the shop floor, it was possible to better understand the challenges of implementing certain safety-related aspects. The triangulation of this information made it possible to establish a more accurate portrait of the situation and to contribute to the analysis of information obtained.

3. RESULTS

The results presented in this section are drawn from the interview and observation checklists completed at 17 machinery manufacturers. This limited sample was considered sufficient to meet the objectives of an exploratory study e.g. to get a better understanding of the situation, to identify trends and to provide relevant areas of consideration for future research.

MANUFACTURER	NUMBER OF EMPLOYEES	MACHINERY TYPE	MAIN ACTIVITY SECTOR OF CLIENTS	Market
A	1500	Packaging	Farming	International
В	20	Machine tools	General manufacturing	Local
С	95	Robot cells	Aerospace	International
D	45	General	General manufacturing	Canadian
E	750	Robot cells	Aerospace	International
F	150	Food processing	od processing Food industry	
G	500	Packaging	Pharmaceutical	International
Н	350	Test benches	Mobile equipment	Local
I	12	General	General manufacturing	Local
J	260	Packaging	General manufacturing	Local
K	100	Specialized	Automobile	Canadian / USA
L	70	Packaging	Food industry	International
М	15	AGV ¹	General Manufacturing	Canadian
N	350	Pumps	Farming	International
0	31	Packaging	Food industry	Canadian / USA
Р	300	Wood transformation	Wood transformation	Canadian / USA
Q	37	Specialized	Automobile	International

Table 1: Description of the 17 machinery manufacturers

Of theses 17 manufacturers, three are large companies (> 500 employees), six are medium companies (< 500 employees) and eight are small companies (< 100 employees) (Table 1). The machinery designed and built by these manufacturers is intended for different activity sectors (general manufacturing, food industry, pharmaceutical, farming, etc.) and are sold in Canada and in various export markets. This machinery is largely manufactured and assembled on the premises of these manufacturers. The manufacturing and installation of certain components may be transferred to sub-contracting companies. This is particularly the case for electrical and programming components.

¹ Automatic Guided Vehicule

3.1 Description of respondents

The semi-structured interviews (in groups) made it possible to question a total of 50 people who were part of teams charged with designing machines, researching, monitoring and integrating various machine-safety standards in the 17 participating companies. Respondents were engineers (mechanical, electrical and mechatronic), technicians (in these same fields), designers, machinists and electricians tasked with design. These 50 people occupied 28 different positions grouped into seven functional groups (Table 2).

GROUP	JOB TITLE	NUMBER
	Engineering Manager	5
	Vice-President and Project Manager	2
	Drafting Room Manager	2
Managamont	R&D Manager	2
wanayement	Technical Manager	1
	International Standards and Security Manager	1
	Engineering and Assembly Manager	1
	CEO	1
	Electrical Design Engineer	5
Engineer and	Mechanical Design Engineer	5
Programmer	Project Engineer	3
riogrammer	Automation and Occupational Health and Safety (OHS) Engineer	1
	Programmer	1
	Project Manager Supervisor	1
	Electrical Supervisor	1
Supervisor	Engineering Supervisor	1
	Mechanical Supervisor	1
	Engineering Method Supervisor	1
	Electrical Design Technician	1
Technician	Product Validation Technician	1
and Designer	Designer	1
	Draftsperson	1
	Safety Standards Advisor	1
OHS Specialist	OHS Officer	1
	Product Certification Specialist	1
Technical	Project Manager, Mechanical	4
Project	Electrical Design Coordinator	1
Manager	Project and Documentation Manager	1
Documentation	Provisions and Drawing Manager	2
	TOTAL:	50

Table 2: Group and positions held by respondents

3.2 Project specifications development practices

3.2.1 Machine functionalities

In general, all the interviewed manufacturers offer a range of basic machinery that can be adapted to the specific client needs. The usual approach begins with initial contact with the client who submits a general requirements document for a machine that meets its production needs. Once the initial contact has been established with the manufacturer, a list of specifications laying out the various technical, dimensional and production capacity specifications is prepared by the manufacturer in cooperation with the client. Sometimes clients have only an approximate idea of what they need. Manufacturers then examine the

client's manufacturing processes in greater details so they can propose a machine that best meets their needs.

3.2.2 Machine safety

Clients in the province of Quebec generally request machinery that complies with the minimal requirements of the applicable standards, and with the requirements of the *Commission des normes, de l'équité, de la santé et de la sécurité du travail* (CNESST), the organization responsible for applying the occupational health and safety laws and regulations in the province. The data obtained suggest that clients from other provinces of Canada are less demanding regarding protective measures on machinery. Nevertheless, for all clients, considerations of competitiveness weigh heavily on purchasing decisions and the safety aspect is often viewed as a barrier to productivity. Therefore, clients sometimes ask to remove certain protective measures, requiring manufacturers to assess the legal impact of these requests. Canadian clients are more interested in machinery price and performance than in safety.

According to respondents, the requirements of clients in Europe and the United States are often greater than those of Canadian clients. Proposals for these clients often include more specific references regarding safety of machinery such as the application of specific standards of the International Organization for Standardization (ISO) or the Occupational Safety and Health Administration (OSHA).

3.3 Use practices for normative and regulatory documents

The manufacturers interviewed rely on more than 30 standards and regulations when designing their machines. Although these standards and regulations cover various subjects, most concern safety of machinery. These documents are generally available to all employees via an intranet. Updates are generally monitored, but it is not a generalized practice and manufacturers do not all have a formal standards and regulations monitoring process.

Table 3 presents the list of normative and regulatory documents used by the manufacturers interviewed. All manufacturers consult on average between five and six normative and regulatory documents to design their machinery according to the requirements of their clients and the health and safety rules in the countries where they will be delivered.

General safety of machinery standards CSA Z432 (Safeguarding of machinery) and ISO 12100 (Safety of machinery -- General principles for design -- Risk assessment and risk reduction), are used by a majority of manufacturers. One note that ISO 12100 standard is used by 12 of the 17 manufacturers, even if only 8 are exporting their products on the international market (ref. Table 1).

Surprisingly, Quebec's Regulation respecting occupational health and safety (ROHS) is referred to by only 10 of the manufacturers. This could be explained by the general nature of this document on the topic of safety of machinery compared with the more detailed and specific national and international standards.

International standard ISO 13849 (Safety of machinery -- Safety-related parts of control systems) is used by 8 manufacturers and IEC 62061 standard (Safety of Machinery - Functional Safety of Safety-Related Electrical, Electronic and Programmable Electronic Control Systems) is used by 2 manufacturers. Canadian standard CSA Z434 (Industrial robots and robot systems) is used by 6 manufacturers.

Table 3 also shows that many manufacturers also use documents more specific to their needs. These documents may be ISO type C standards (e.g. ISO 14120 standard on the design of guards), specific to the machinery they design (e.g. ANSI B155.1 standard on safety of packaging machinery), internal design guidelines or requirements specific to certain clients. Examples of such internal design guidelines or client's specific requirements used by the 17 manufacturers are rules with requirements beyond electricity codes, adaptation rules regarding the geometry of components and rules concerning the dimensions of guards to give operators better visibility.

While the sample size was not sufficient to establish a clear correlation, one noted a preoccupation among manufacturers to use more specific standards and to have a more structured design for safety process when exporting on the international market (8 manufacturers ref. Table 1).

Document	Торіс	Number of	Frequency of use (by number of manufacturers)							
	•	manufacturers	Daily	Weekly	Monthly	Yearly	N/D			
Internal	Internal design guidelines	14	1	4	Б	3	1			
documents		14	I	4	5	5	I			
CSA Z432	General safety of machinery	13	1	4	4	4	-			
ISO 12100	General safety of machinery	12	-	2	4	6	-			
ROHS	OHS Regulation	10	2	-	3	4	1			
ISO 13849	Safety of control system	9	2	1	3	1	2			
CSA Z434	Robot safety	6	2	-	1	3	-			
CSA C22.2	Safety of electrical equipment	3	1	-	1	1	-			
CSA Z460	Lockout/tagout	2	-	-	-	2	-			
CSA W47.1	General welding	2	1	1	-	-	-			
ISO 10218	Robot Safety	2	1	-	1	-	-			
ISO 13857	Welding of pipelines	2	1	-	1	-	-			
IEC 62061	Safety of control system	2	-	-	1	1	-			
AFNOR NF-C ²	Safety of electrical equipment	1	-	-	-	-	1			
ANSI B11	General safety of machinery	1	-	-	-	1	-			
ANSI B56.5	Safety of AGV	1	1	-	-	-	-			
ANSI B65.1	Safety of printing machinery	1	-	-	-	1	-			
ANSI B155.1	Safety of packaging machinery	1	1	-	-	-	-			
CSA Z142	Safety of power presses	1	-	-	-	1	-			
CSA Z462	Workplace electrical safety	1	-	-	-	1	-			
ISO 13850	Emergency stop functions	1	-	-	1	-	-			
ISO 13855	Design of safeguards	1	-	-	1	-	-			
ISO 14119	Interlocking devices	1	-	-	-	-	1			
ISO 14120	Design of guards	1	-	-	-	-	1			
ISO 14121	Risk Assessment	1	-	1	-	-	-			
ISO 14122	Means of access to machinery	1	1	-	-	-	-			
ISO 23125	Safety of turning machines	1	-	-	-	-	1			
NFPA 484	Combustible metals	1	-	-	1	-	-			
OSHA 18001	OHS management system	1	-	-	1	-	-			
ANSI/RIA 15.06	Robot safety	1	-	-	1	-	-			

Table 3: Use of normative and regulatory documents by manufacturers

Note: References for the standards cited can be found in the reference list.

Manufacturers implement various approaches to ensure they integrate the requirements of these standards and regulations in the design of their machines. Most respondents indicated that design teams have one member who ensures knowing and documenting these references, compiling the various updates and informing other team members. Respondents also indicated that it was sometimes difficult to comply with standards because the measures they recommend may be impossible or too expensive to implement. It also seems that the complexity of certain standards makes them difficult to understand and requires manufacturers to increase the expertise of their staff. With 14 of the 17 manufacturers being SME's (ref. Table 1), this is reported as a difficult task for most.

² A compilation of electricity standards from France that cover both building electrical, material and performing electrical installation.

3.4 Risk assessment practices

Most (82%) of the design teams interviewed had a formal, documented risk assessment approach adapted to their machine design process (Table 4). This approach includes the four usual steps recommended in standard ISO 12100 at nine of the 17 manufacturers (the last four lines of Table 4). The entire process is documented at 14 manufacturers, depending on the project scope. A worksheet similar to what is proposed in standard (technical report) ISO/TR 14121-2 (2012) is often used as a basic risk assessment tool.

Although clients are not usually involved in analyzing the risk, they are sometimes consulted to make sure that the design does not contravene their safety or production specifications.

Because most manufacturers offer basic machinery that can be adapted to the specific needs of clients, subsequent analyses constitute the point of departure for most risk analyses. These analyses are updated to take into account each specific case and the evolution of applicable safety standards.

		Manufacturers																
	Α	В	С	D	Ε	F	G	Н	Ι	J	Κ	L	М	Ν	0	Ρ	Q	
Formal process documented	~		~	~	~	~	~	~	~	~	~	~	~	~			~	82%
Determination of the limits of the machine	~	~	~	~	~	~	~	~	~	~		~	~	~			~	82%
Identification of hazards	~	~	~	~	~	~	~	~	~	~		~	~	~			~	82%
Risk estimation	~	~	~	~	~	~	~	~	~	~		~	~	~			~	82%
Risk assessment	~		~	~	~	~	~	~		~				~			~	59%

Table 4: Risk assessment process

Most respondents confirm that they are aware of the need to properly identify the hazards present on their machinery. They tend avoid, to the extent possible, informal approaches which may impede comprehensive analysis. However, a comprehensive risk assessment process is not systematically conducted for each machine when the company manufactures quasi-identical machinery that is adapted only based on client needs. In this case, a simple design review is performed to ensure that all OHS aspects are covered.

Manufacturers who conduct risk assessment report that this step can be lengthy and that it requires thorough discussions to determine the level of acceptability or tolerability of each risk. Respondents also indicate that standards do not give specific benchmarks to guide designers in this step. Ultimately, a corporate-level decision is often necessary to set a clear benchmark based on costs, timeframes and technical feasibility.

Three manufacturers do not have a formal documented risk assessment process or do not follow the usual steps recommended in standard ISO 12100 (Table 4). One mentioned that they rely on their design reviews to complete the risk assessment. The other two indicated that the newly designed machines are not sufficiently different from the original basic machine to justify a new risk assessment.

3.5 Risk reduction practices

In this part of the study, the incidence of use of different types of protective measures and the incidence of specific client requests regarding risk reduction are analyzed.

3.5.1 Protective measures implemented by designers

Table 5 presents the frequency of implementation of the different types of protective measures by the machinery manufacturers interviewed. Most manufacturers regularly implement inherently safe design measures. Ten of the 17 manufacturers confirm that they always try to eliminate hazards using inherently safe design measures on the machinery they manufacture. However, respondents indicated that even if these approaches could sometimes be economically advantageous, they are often more difficult to implement. This confirms the results of other studies suggesting that many machine designers find those measures to be constraining and time consuming, compared with guards and protecting devices (Marso et al., 2017).

We also note that all manufacturers use guards, closely followed by protective devices. They particularly favour guards made up of rigid frames and polycarbonate panels. Several respondents expressed significant concern that guards should not hinder the operation of the machine. However, respondents consider protective devices expensive. They use them only when none of the previous solutions is feasible. For example, the respondents interviewed rarely use safety light curtains and safety laser scanners, because this equipment makes machinery significantly more expensive. Also, in general, respondents confirmed that the higher the risks, the more stringent the requirements for the safety-related part of the control system should be. Standard ISO 13849-1 is actually often cited by respondents.

		Frequency								
Type of protective measures	Number of manufacturers	Always	Very often	Often	Rarely	Never	Do not know	No information		
Inherently safe design measures (avoiding hazards)	16	10	1	4	1	1	-	-		
Inherently safe design measures (<i>reducing risk</i>)	16	7	2	5	2	1	-	-		
Guards	17	17	-	-	-	-	-	-		
Protective devices	17	16	-	-	1	-	-	-		
Complementary protective measures	17	13	1	1	2	-	-	-		
Information for use	17	14	1	1	1	-	-	-		
Individual protective equipment	11	9	-	1	1	4	-	2		

Table 5: Frequency with which protective measures are taken into consideration in the manufacturer's deliberations

Information on the use of machinery is also one of the practices generally used by manufacturers. In almost every case, pictographs of hazards and safety notices are present on the machines. Training is sometimes offered either on site or at the client's premises. They also often integrate complementary protective measures, such as those that make it possible to facilitate lockout/tagout of the machinery. Of the 17 manufacturers, nine recommend the use of personal protective equipment in the user manual. However, several of the design teams interviewed insist on the fact that clients are responsible for this aspect.

3.5.2 Specific client requests

Even if clients expect machinery to meet generally recognized normative health and safety prescriptions, they sometimes make specific requests related to the protective measures implemented by the manufacturer. Sometimes clients steer manufacturers toward protective measures that meet their needs or, conversely, they refuse those proposed by the design team. These requests are not always accepted and are often the subject of negotiation between the client and the manufacturer. This exercise requires taking into account the costs resulting from these requests, the technical feasibility and their impact on the use and safety of the machinery. Table 6 presents the frequency of the different categories of these requests.

Of all the manufacturers interviewed, only one reports not having received specific requests from its clients because the machinery is used within its own company. Users contribute to the design by participating in discussions, deliberations and the different steps leading to the design of the machine. The other manufacturers all receive modification requests from their clients. Some clients request the addition of specific protective measures to standardize their machinery pool. This type of request is, however, rather rare or non-existent at 14 of 17 manufacturers.

Sometimes the client asks not to install some protective measures. As the perception of risk is sometimes subjective, it can be difficult to judge whether or not a risk is acceptable with the client. In these specific cases, manufacturers make sure to officially inform clients of the risks associated with the use and maintenance of the machinery without these measures and request a waiver of liability.

				Frequ	iency		
Type of requests	Number of manufacturers	Always	Very often	Often	Rarely	Never	Do not know
Addition of protective measures	12	-	1	2	9	5	-
Withdrawal of protective measures	10	-	1	3	6	7	-
Modification of protective measures	15	-	-	6	9	2	-
Compliance with some standards or rules (OSHA, colour, dimensions or other)	13	2	2	4	5	1	3

 Table 6: Frequency of specific client requests

Modification requests generally consist in standardizing equipment to make either changes of colour, layout, and access to various elements or to include other types of guards. Protective measures are sometimes modified during design when discussions with the client are frequent. The reason given by respondents is that clients' thinking changes and health and safety requirements can also evolve throughout the design process. These modification requests are often made by the clients of six of the manufacturers interviewed.

Lastly, requests to comply with certain specific standards are sometimes made for machinery intended for outside Canada. Two manufacturers believe they always receive these types of requests from their clients and these requests are "often" or "frequently" expressed to six manufacturers. Six other design teams say they are rarely, if not never, asked for these types of compliance requests and three say they are not able to answer the question

3.5.3 <u>Constraints in implementing protective measures</u>

Respondents report that design teams must deal with several constraints when implementing protective measures:

- Costs, productivity and operating time are some of the constraints that require the most attention from design teams;
- Clearance around and in machinery is often limited and presents a challenge regarding ergonomics, visibility, access to machine parts and components and respect for safety clearances;
- In the case of machinery subject to pharmaceutical and food safety standards, the design must take into account hygiene requirements for frequent cleaning with machinery that is easy to clean while being safe;
- Noise can be used to detect a problem of wear on machinery or to diagnose problems. Totally insulating machinery can therefore be an obstacle to certain tasks;
- Design teams try to consider workers' behaviour on machinery. Feedback is nonetheless difficult to obtain, particularly in the case of new machinery.

There are other constraints such as reducing training duration, simplifying and making intuitive production and maintenance operations and workstation ergonomics. These various constraints are an even more significant issue for manufacturer: prices and timeframes initially set for building machinery are generally fixed and manufacturers must often assume any overages as required.

3.6 Circumvention of protective measures

Lüken et al. (2006) found that protective measures are frequently circumvented or disabled (tampering). The main causes of this phenomenon are related to the performance and adaptability of human-machinery interfaces; the lack of integrated safety measures; the absence of devices making it possible to safely perform assembly, reconfiguration and maintenance operations; and lastly the acceptance of safeguards by employees and managers. Standard ISO 12100 recommends taking these causes into account in the risk-assessment phase.

The solutions implemented or planned by the manufacturers interviewed to avoid the circumvention or disabling of protective measures by users can be classified into five types, by decreasing order of popularity:

- Dissuasion: using techniques and materials intended to make circumvention or disabling difficult (solution referenced by 15 of 17 manufacturers). The main technical solutions identified are described as follows:
 - Tamper-proof screws that required an unconventional special tool to disassemble a guard or protective device;
 - Component redundancy (e.g. sensors);
 - Coded-magnet or RFID-chip magnetic switches;
 - Mechanical switches that follow the positive mechanical principle (ISO 12100);
 - Password to access the control program or a bypass mode (allowing users to temporarily operate the equipment with the protective measures deactivated).

- Entrance tunnel with safety light curtains (to prevent the physical circumvention of a guard).
- 2) Adequacy of protective measures: protective measures properly adapted to production and maintenance tasks are less likely to be an obstacle, thereby reducing workers' temptation to remove them (5 of 17 manufacturers). Respondents referred to the importance of properly developing protective measures to limit the incentives to circumvent them. This includes, for example, making sure guards allow for good visibility at all times. One manufacturer raised the possibility of facilitating access rather than installing fixed guards difficult to disassemble and reassemble and that will not be put back into place. One tool machinery manufacturer even made the guard an essential part of the machine by integrating controls as well as lighting on the guard: the operators need it and cannot circumvent it.
- 3) Training: making workers aware of the risks of such practices (2 out of 17). One manufacturer reports that "workers are aware of the importance of safeguards so the circumvention of guards and protective devices is not a big challenge." A second manufacturer believes that "more comprehensive training for dealers (responsible for equipment maintenance) would allow for greater awareness of the need to put safety guards back in place."
- 4) Suppression of need: work from the design phase to remove the need for access for a specific task (1 of 17). For this purpose, for example, the manufacturer integrated a self-lubricating system. The manufacturer is also considering instrumenting the machinery so that measures that must be taken regularly during the course of the process are performed remotely. This solution also presents production advantages (no interruption and more accurate measures).
- 5) Disclaimer: one manufacturer discussed a disclosure clause warning users against possible improper uses of the equipment (1 of 17).

According to respondents, sometimes client perceive these difficult-to-circumvent protective measures as potentially preventing the smooth operation of machinery and reducing productivity. Discussions follow to inform these clients of the need to put these protective measures in place. The exercise can be laborious with the constant worry that the integration of too many proposed protective measures could cause clients to seek out other manufacturers.

Many of the manufacturers interviewed remain concerned about the circumvention of protective measures. However, there was agreement from several respondents that it was difficult to get feedback from clients. But it is specifically by knowing the needs and behavioural trends of workers that they could better anticipate and prevent the circumvention of risk-reduction methods.

ISO 12100 and CSA Z432 standards are used by a majority of manufacturers and provide some guidance on how to prevent the circumvention or disabling of protective devices. However, only one manufacturer reported using ISO 14119 and ISO 14120 standards (ref. Table 3), event if these two documents regarding the design of guards and their associated protecting devices are very relevant in this matter.

3.7 Design of the safety-related part of the control system

Regarding the design of the safety-related part of the control system of the machine, the concepts addressed are the documentation used by manufacturers, the design principles, the difficulties encountered, the determination of the level of reliability and the process for validating safety-related control circuits.

3.7.1 Documentation used

The results are summarized in Table 7. One manufacturer reported not knowing which documentation is used because it subcontracts its control-system design. Just one manufacturer uses, for one specific case,

standard ANSI/ISA-62443 (American National Standards Institute, 2007), which contains basic cybersecurity-related concepts and models.

Documents used	Yes	Νο	Do not know
ISO 13849	9	7	1
IEC 62061	2	14	1
Safety device installation manual provided by the vendor	12	4	1
Drawings provided by the vendor	11	4	2
CSA Z432	11	5	1
CSA Z434	8	8	1

Table 7: Use of documentation by manufacturers for the design of a safety-related control system

The most frequently used documents are those related to a specific component, with assembly instructions and wiring diagrams. Next is Canadian standard CSA Z432, which provides some guidance on the design of simple control systems. Eight manufacturers interviewed deal with robots and use standard CSA Z434 on the topic.

International standards ISO 13849 and IEC 62061 are the primary current standards regarding the reliability of safety-related control circuits, regardless of the machine. Manufacturers seem to mostly favour the first because only two of them use the second. This could be explained by the use of hydraulic and pneumatic sub-systems in many of their designs: IEC 62061 is only applicable to electrical and electronic control systems. Of the four manufacturers who say they do not use either of these two standards, two say they use standard EN 954. This standard, withdrawn in 2012, defines the safety-related parts of control systems and preceded standard ISO 13849. Furthermore, the manufacturer that sub-contracts the design of control systems stated that some of its sub-contractors also used standard EN 954. We can therefore say that a majority of the manufacturers interviewed use at least partially the recommendations of one of the control system reliability standards.

3.7.2 Design principles for safety-related control systems

Four basic principles for the design of safety-related control systems were submitted to the manufacturers. Table 8. Summarizes the results by combining the answers "always", "very frequently" and "often" in the "yes" column, and the answers "rarely" and "never" in the "no" column. When a manufacturer believes it rarely uses a design principle, this means that it is a procedure too infrequently used to be considered a principle followed by the company. The results show that these principles are followed by most of the manufacturers interviewed.

Design principles	Yes	No	Do not know
Separate safety functions from standard control functions	14	1	1
Use of certified components to ensure safety functions	15	0	1
Use of over-dimensioning	8	7	2
Use of redundant components	13	1	2

Table 8: Design principles followed by manufacturers for control systems

Note: We were not able to raise these questions with one of 17 manufacturers interviewed because there was no one qualified to answer them on the day of the visit.

3.7.3 Determination of the level of reliability and validation of the safety-related control circuit

Ten of the 17 manufacturers indicated that they determined the required performance level (PL according to standard ISO 13849-1) or the Safety Integrity Level required (SIL according to standard IEC 62061) for each safety function of their machinery. However, several manufacturers do not do so for each safety function, but only for those related to the highest risks and then apply the same reliability requirements for the whole machine. Others indicated knowing from experience the required reliability level because they have manufactured the same machinery for years.

Using the same components for all of a machine's safety functions results in a higher level of reliability than required for several safety functions. Although these components are more expensive, manufacturers report that purchasing them in large numbers achieves an economy of scale that compensates for the difference in price. Furthermore, less time is spent on reliability calculations.

Two manufacturers report not having a process to validate the control circuit. The other manufacturers describe using two types of processes to validate the safety-related control circuit:

- Functional tests (10 of 17): it consists in simply validating that each protective device produces the desired effect. Two manufacturers also verify the behaviour of the circuit in the event of failure;
- Theoretical validation of the circuit (9 of 17): control circuit plans are double-checked, for example by an internal or external third person (an engineer), to make sure the principles enumerated in the standard used as a reference are respected. Two manufacturers use the SISTEMA software from the *Institute for Occupational Safety and Health of the German Social Accident Insurance* to compare the actual reliability level (PL) to the one required.

Five of the 17 manufacturers combine the two verifications.

3.8 Consideration of maintenance during the design phase

Respondents reported considering maintenance activities on six points from the design phase, so as to reduce the risks associated with these activities. Table 9 summarizes the results by combining the answers "always", "very frequently" and "often" in the "yes" column and the answers "rarely" and "never" in the "no" column.

Points considered	Yes	No	Do not know
Positioning of isolation points for power sources (location, access)	16	1	0
Implementation of an isolation device for each power source	17	0	0
All isolation devices can be locked	17	0	0
Positioning of maintenance points	12	5	0
Specific control mode for maintenance	13	4	0
Alternative methods to lockout/tagout	3	14	0

Table 9: Points taken into account by manufacturers for the safe maintenance of machines

Solutions to allow and facilitate lockout/tagout are largely implemented by manufacturers. Alternative methods to lockout/tagout (other power control methods) are addressed by only three of the 17 manufacturers. To a lesser degree, the two points aimed at facilitating maintenance are also well represented: respectively 12 and 13 of 17 for the positioning of maintenance points and a control mode for maintenance.

3.9 Ergonomics and industrial hygiene

The large majority of hazards reported by the manufacturers were of mechanical and electrical nature. However, the answers of manufacturers also reveal their concerns and their practices to prevent risks related to ergonomics, noise and hazardous substances. With regard to ergonomics (Table 10), most manufacturers are concerned about several aspects of the ergonomics of their machines. For example, they reported significant concern for the work posture of both maintenance technicians and operators. Heatrelated problems are not an issue for most manufacturers interviewed because their respective machines do not or hardly emit heat.

Ergonomic concerns	Yes	No	Not applicable or do not know
Operator work position	11	3	3
Maintenance technician work position	12	4	1
Number of tools required for maintenance	7	7	3
Adaptation of the machinery to operators	14	3	0
Lifting aid (lifting hooks)	11	3	3
Ease of changing production tools	13	2	2
Cognitive ergonomics (signage, error prevention)	16	0	1
Ease of access to the different parts of the machine (e.g., mounting on the mould of a press)	12	1	4
Visibility	14	1	2
Heat	5	3	9
Work area lighting	13	2	2
Clearance, workspace	13	1	3

Table 10: Ergonomic concerns of manufacturers

The methods or procedures for considering ergonomics during the design phase reported by manufacturers can be summarized in five points. Some manufacturers combine several of these methods, while others use just one:

- 1. Follow recommendations as laid out in different guidelines;
- 2. Provide designers with training on or initiate them to basic ergonomic principles;
- 3. Rely occasionally on an outside ergonomist;
- 4. Use virtual mannequins in computer-assisted design software (CAO) to check dimensions, reach zones or identify potential obstacles to worker movements;
- 5. Address ergonomics concerns in the risk analysis checklist.

Table 11 shows that most manufacturers say they are not concerned by the level of noise generated by the operation of their machines. Some of them reported being concerned about the choice of materials, changes to procedures, using acoustic panels and suggesting personal protective equipment (PPE).

Concerns regarding noise	Yes	No	Not applicable or do not know
Choice of materials	5	12	0
Modification of the manufacturing procedures	2	15	0
Covering machinery with acoustic panels	4	13	0
The preceding solutions are impossible or insufficient, so the use of Personal Protective Equipment (PPE) is recommended	6	11	0

Table 11: Respondents' concerns regarding noise

Ten of the 17 manufacturers propose solutions to reduce the emission or use of hazardous substances. These solutions range from confinement to local exhaust, including measures aimed at reducing the use of hazardous substances, such as a design that makes cleaning easier, without special cleaning agent.

4.DISCUSSION AND CONCLUSION

The 17 manufacturers interviewed integrate safety in the design of their machinery. Professionals from various backgrounds operate around design teams for this machinery and, in general, at least one engineer is involved in the design team. They fairly understand the hierarchy of risk reduction measures recommended by general standard ISO 12100:2010 (Figure 1). This observation, and the fact that 14 of the 17 manufacturers carry out a formal documented risk assessment process including the four steps recommended by ISO 12100 (ref. section 3.4), suggests that machinery manufacturers are well aware of the basic principles of safety of machinery. It should be noted that these manufacturers were not selected based on their performance in safety of machinery. However, some selection criteria may have influenced the type of participating companies. For example, they had to design and manufacture machinery that includes a control system other than a single on/off switch. It is possible that these criteria favoured the participation of companies with a relatively robust product development structure and that are therefore more aware of best practices in safety of machinery. Consequently, it is conceivable that the profile could have been different if companies manufacturing more simple equipment had been interviewed.

If the manufacturers interviewed generally applied the hierarchical risk reduction process, most of their clients are limited to wanting to respect the minimal regulatory requirement, sometimes even less than the minimum. The delicate balance between safety, functionality and the cost of machinery was also raised by several of the stakeholders interviewed. However, some manufacturers make safety integral to their brand

that distinguishes them from their competition. Indeed, these manufacturers succeeded in integrating effective risk reduction measures so that their equipment becomes even easier to use than that of the competition.

The manufacturers also adopt protective measures for the maintenance activities, for example by facilitating lockout/tagout or by integrating a specific control mode. However, unlike production and maintenance, assembly, installation and dismantling phases are generally not considered in the design. For 12 of the 17 manufacturers, the procedures or work methods are the primary risk reduction methods for these phases, as opposed to technical methods. Thus, safety during the other phases of the machinery life cycle is given very little consideration in machine design.

Preventing the circumvention of safeguards is a concern for manufacturers who have to strike a balance between establishing stable, long-standing protective measures and allowing the user to handle certain specific situations. For the time being, the dissuasion technique remains the most widespread. But the literature contains information on other possible solutions to circumvention of safeguards (Haghighi, Chinniah and Jocelyn, 2018). Several manufacturers noted the difficulty in obtaining feedback from users to better limit circumvention.

With regard to standardization, monitoring and updating applicable standards remains a concern for manufacturers who struggle to keep pace with the amount of documentation to which they have to refer to for the design of machinery. The difficulty lies not in obtaining these standards, but in knowing which are actually useful for designing their machinery. For the standards applicable to designing safety-related control systems, manufacturers have developed procedures to simplify their work. For example, they use the same components for all of a machine's safety functions and adopt a level of reliability higher than the level required for several safety functions. However, the very complex nature of the two current standards (ISO 13849 and IEC 62061) remains a major challenge for these companies. The uncertainty of designers regarding full compliance with these standards in the equipment they manufacture was noted during interviews and they are more likely to use simplified documents based on these standards rather than the standards themselves.

While the limited number of data collected was not sufficient to lead to conclusive results (only 17 manufacturers interviewed), this study offers a better understanding of the situation of Quebec's machinery manufacturers. Unlike "field" studies that generally cover the safeguarding of machinery in operation, this exploratory study concentrated on the integration of safety of machinery by manufacturers from the design phase.

The results shine a light on actual practices that are a result of internally developed processes, the use of specific tools, the use of outside resources and other considerations among machinery manufacturers. In addition to circumvention of safeguards and constraints imposed by the client, this study also identifies other problems that affect machinery manufacturers, namely 1) how to integrate more inherently safe design measures, 2) how to take into account risks during the phases of machinery life cycle other than production and maintenance such as the machine building phase, 3) how to ensure applicable standards are monitored and updated, 4) how to design and validate safety-related control systems in a more reliable way, and 5) how to improve their clients' awareness of the importance of safety of machinery. These problems should be the starting point for future, more thoroughgoing, research.

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