RISK ASSESSMENT IN AUTOMATION AND DEFINITION OF REQUIREMENTS FOR THE LEVEL OF FUNCTIONAL SAFETY

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TIIVISTELMÄ

Tämän opinnäytetyön käytännön osuuden tavoitteena oli laatia työkalu ja ohjeistus Ferroplan Oy:n työntekijöiden avuksi automaation riskien arviointiin ja riskikartoitusten laatimiseen sekä turvalaitteiden toiminnallisen turvallisuuden tason määrittelemiseen.

Tässä opinnäytetyössä käytiin läpi riskin arvioinnin prosessi, riskin pienentämisen keinot sekä näitä ohjaavat tärkeimmät direktiivit ja standardit. Opinnäytetyön toimeksiantaja oli Ferroplan Oy:n sähkö- ja automaatio-osasto.

Opinnäytetyössä esitettiin erilaisia, standardiin perustuvia menetelmiä riskinarvioinnin laatimiseksi. Opinnäytetyön tuloksena toimeksiantajalle (Ferroplan Oy) valittiin käyttöön niin kutsuttu ”hybridityökalu”, jolla kerättiin yhteen samalla lomakkeella esitettäväksi havaitut vaaratekijät, riskin suuruuden ja riskin merkityksen arviointi. Ennen varsinaista käyttöönottoa riskin arvioinnin työkalu testattiin toimeksiantajan riskin arviointeja tekevän työryhmän toimesta kahdella eri asiakasprojektilla.

Avainsanat automaatio, koneturvallisuus, riskikartoitus, riskin arviointi, SIL

Sivut 24 sivua

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Abstract

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Subject Risk assessment in automation and definition of requirements for the level of functional safety of safety devices

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ABSTRACT

The goal of this project was to draw instructions and to design a tool for the employees of Ferroplan Oy for the risk analysis process and for doing risk assessments in automation.

This thesis reviews the risk assessment process itself, the measures for risk reduction and the relevant directives and standards that guide this process. The commissioner of this thesis was Ferroplan Oy, Electrical and Automation Department there.

In this study was shown various methods for compiling risk assessment. For the commissioner (Ferroplan Oy) was chosen so called Hybrid tool, which gatheres together the data from recognised risks, risk estimation and risk evaluation to be expressed at one single form. Before actual commissioning, the risk assessment tool was tested by risk assessment-team with two real customer projects.

Keywords Automation, machine safety, risk analysis, risk assessment, SIL

Pages 24 pages

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List of abbreviations

CCF	Common Cause Failure
HRNS	Hazard Rating Number System
SRECS	Safety-Related Electrical Control System
SRS	Safety Requirement Specification
SIL	Safety Integrity Level
PES	Programmable electronic system
PFH^d	Probability of dangerous Failure per Hour
TE	Test equipment
PL	Performance Level
PL_r	Performance Level required
Ti	The time between periodic tests on a safety system
TM	Mission time, period of time covering the intended use of an SRP/CS
MTTF	Mean Time To Dangerous Failure

1 INTRODUCTION

Risk assessment is based on demands rising from for example Machinery Directive, which requires manufacturing of safety machinery/equipment. A properly documented risk assessment is a prerequisite for the CE marking of a machine/equipment. The use of standards is not mandatory, but they are very helpful in going through and managing this multi-threaded and expertise demanding process.

In many companies, risk assessment is often done under pressure, in a hurry, with a lack of knowledge and enthusiasm towards the topic. It is an obligation in order to be able to use the CE-marking as a manufacturer, but in worst cases documents are created and handed over afterwards - on the customer`s demand.

At Ferroplan Oy risk assessments have belonged to the job description of one or two officers, but as the company is growing and the projects manufactured are getting wider, often including more electrification and automation than earlier, thus the number of staff members taking part in the risk assessment processes is increasing. This has raised the demand for a specific tool to be used and a form to be filled in. For this purpose, the aim of this thesis project was to develop the process inside the company, to make it more effective, consistent, time and money saving.

Standards are classified in three different levels. Class A standards are so called common standards, class B standards are more specific and targeted to a smaller group of items or a machinery. Class C standards are the most detailed ones. Class C standard is the most powerful, and if there is a conflict between standards, Class C standard must be complied.

If there is no C Class standard, but B Class standard for the items under risk assessment does exist, it is the one that must be complied. Still in a case of conflict between B Class and A Class standard, B Class standard is the one to be followed.

For the conveyors manufactured by Ferroplan Oy, there is no Class B or C standard on which to rely. Thus, only class A standards have been discussed in this thesis.

2 RISK ASSESSMENT IN AUTOMATION

When talking about risk assessment in automation, the fact that risk assessment in automation is strongly linked to the total safety of machinery, has to be ackknowledged. Thus there are several standards that give a strong frame of reference to this subject. On the other hand, by getting good, deep knowledge about the content of these standards, a high quality risk assessment is possible to be performed.

2.1 History of risk assessment

Risk assessment originally started from the idea,"how to avoid losing in the games where luck is decisive". Such issues as reducing the financial risk associated with chartering, large fires in various cities in the US in the 20th century, gave rise to risk assessment based on qualitative research. Together with the Industrial Revolution they generalized risk assessment. (Manninen, 2020)

2.2 Machine safety

At first, the definition for a machine must be given. A machine is a combination of parts and components connected to each other. At least one of these parts is moving. It works with no human or animal power. A machine is configured for a certain function. Accessories, which are incorporated in such a way to another machine that they cannot be classified as a tool or as spare parts, are called machines.

SFS 12100:2010, Safety of machinery – General principles for design – Risk assessment and risk reduction, can be regarded as the main standard in machine safety. Standard SFS-ISO/TR 14121-2 "Safety of machinery. Risk assessment. Part 2: Practical guidance", shows also how to perform risk assessment in practice. There is no difference between risk assessment in machine safety itself compared to the risk assessment in automation. The methods are the same.

What comes to the hazards of machinery in general, they can be categorized into two main classes a) mechanical and b) electrical. Mechanical hazards include crushing, shearing,

cutting, entanglement, impact, abrasion, and high-pressure fluid jets. Workers can also be exposed to electrical hazards, which include contact with live parts or parts becoming live under inappropriate conditions, contact with live parts carrying high voltage, and thermal radiation. Electrical hazards can lead to electric shocks (injuries), electrocution (death), heart attacks, and burns. (Gauthier, Lambert & Chinniah, 2012)

The main idea of the safety of machinery rises from the design. The best safety is achieved in a way naturally, if the risks are taken into account already at the beginning, as the machine is being designed. It is also seen that success of the risk assessment depends on the expertise of the team performing the risk assessment. Standard tells very clearly that the best result of the risk assessment is achieved if the procedure is performed by a group of experts - instead of a single person. Team members should have good knowledge and experience of different fields regarding the machine that is subject to the evaluation. There should be participants that are capable of taking stand to technical issues and construction of the machine. Also team members who can tell how the machine is actually used in practice and how it is maintained are needed. At least one team member should be familiar with the requirements given in laws and standards. (SFS 14121-2/2013, p. 10)

The Machinery Directive, like all the European Directives get a nature of law, at the moment they are translated to the national language. The Machinery Directive demands that risk assessment is done, so it is an obligatory process; but the use of standards is voluntary. Risk assessment is also a precondition for CE-marking (French Conformité Européenne) of machines. CE marking signals that manufacturer convinces that its machine or device is prepared in accordance with the requirements of EU-directives and that it has passed all the inspections required. (Machinery Directive 2006/42/EY)

The manufacturer or an authorized representative of the manufacturer shall provide a declaration of conformity. A product bearing the CE mark is allowed to move freely within EU-market. It should always be understood that no third part is controlling the CE-marking process, it is totally on the manufacturer`s or importer`s responsibility. (Tukes, n.d.)

2.3 Most significant directives, laws and regulations

Depending on the field of manufacturing or industry, several standards apply to risk assessment. In the next chapters the ones are introduced that are significant regarding risk assessment in automation and machinery of piece good conveyors; the field of manufacturing that the commissioner, (Ferroplan Oy), of this thesis represents.

2.3.1 Machinery directive 2006/42/EY

Machinery directive 2006/42/EY is one of the most significant regulation regarding standardizing the basic requirements of machine safety within European Union. This directive describes uniform safety and health requirements for human-machine interaction. The directive promotes the free movement of machinery inside EU-market and guarantees high level protection for EU workers and citizens. The Machinery Directive is tool that all EU member states have introduced. The Machinery Directive is in force among all Member States and ensures that machinery safety is uniform. (Pilz GmbH, n.d.)

2.3.2 Operation regulation and occupational safety law

All machines in use, also those that have been put to service before the Machine Directive, applies Operation regulation 403/2008 and occupational safety law 738/2002. According to the Occupational safety law all machines, tools and other equipment that are used in work, have to apply all regulations concerning them, and they have to be appropriate to the work and working conditions in question.

According to the occupational safety law machinery tools and equipment must be used, cared for, cleaned and maintained properly. Also access to the danger area of the machinery or implement must be restricted by their construction, position, guards or safety devices or by any other appropriate means. The law also requires that preparation must be made for maintenance, adjustment, repair, malfunction and emergency situations so that neither health or safety of workers is to endanger or impair. (Occupational safety law 738/2002)

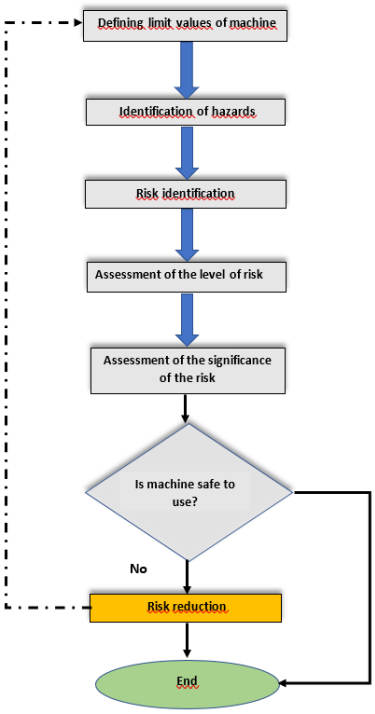
2.3.3 Low voltage directive

Low voltage directive 2014/35/EU applies to all electric devices, that are planned or modified to be used in professional or domestic use at 50 V – 1000 V AC and 75 V – 1500 V DC voltage ranges. The purpose of this directive is to guarantee the safety of electrical devices. (Low voltage directive 2014/35/EU)

2.4 Risk assessment process

The purpose of risk assessment is to identify all hazards. It is physical assessment and inspection that has to be documented and follow all the international standards. The goal is, not only to identify the risks related to the use of machine but assess both magnitude and significance of the risks as well as define how to mitigate the risks to accepted level. This level is defined in legislation, standards and by the industry as good installation practice level. Risk assessment needs to be continuous as shown in Figure 1. (Manninen, 2020)

Figure 1. Risk assessment process



If for example the machine itself, or the work done with it changes, risk assessment should be updated. (SFS-ISO/TR 14121-2, p. 7)

By executing proper risk assessment, many advantages can be achieved in form of better quality, better ergonomics, better safety and saves in costs. The manufacturer shows with risk assessment that responsibilities determined in the machinery directive have been met.

2.4.1 Definition of machine limit values

It is very essential to get a good picture about the whole system that the machine under assessment is a part of. By defining accurate limit values also risk assessment will be more precise. These limit values also define the responsibilities between different equipment suppliers when the machine is a part of a larger lay-out or installation.

Standard “SFS-ISO/TR 14121-2 Safety of machinery. Risk assessment.” instincts to describe clearly mechanical and physical properties as well as functional capabilities of the machinery, its intended use and reasonably foreseeable misuse, and the type of environment in which it is likely to be used and maintained. (SFS-ISO/TR 14121-2, p. 13)

Machine-based functions are based on their construction and operations such as:

- power supply
- control
- modes of operation
- feeding
- movement/traveling
- lifting
- machine frame or chassis which provides stability/mobility and
- attachments

(SFS-ISO/TR 14121-2, p. 13)

Task based uses of the machinery should give wide information about all the persons who are affected, with the intended use and the reasonably foreseeable misuse of the machinery.

Definition of machine limit values should cover the whole life cycle of the machine, including:

a) transport

b) assembly, installation and commissioning

c) setting

d) operation

e) cleaning, maintenance

f) fault finding/trouble shooting

g) decommissioning, dismantling

(SFS EN-ISO 12100:2010, p. 35)

2.4.2 Risk estimation

The goal for assessment of magnitude of risk; in other words for risk estimation is to score the observed hazards by their magnitude.

For one specific hazard - in accordance to the SFS-ISO/TR 14121-2 standard -two main factors can be determined; a) severity of harm and b) probability of occurrence of this severity of harm. Expression of risk estimation can be given as a level, index, score or verbal description. (SFS-ISO/TR 14121-2, p. 19)

2.4.3 Risk evaluation

The assessment of the significance of a risk; in other words risk evaluation is performed in order to make decisions which risks or hazards need to be reduced. On the other hand it is needed to define, whether the risk reduction done is achieved without getting other risks occurring or the level of other risks rising. (SFS-ISO/TR 14121-2, p. 42)

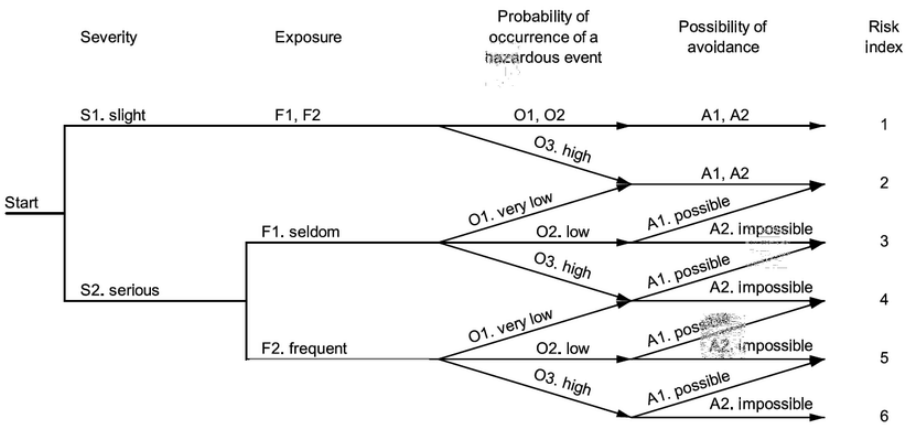
2.5 Different methods for risk assessment

After recognition of dangers, risk caused by them should be assessed in relation to their magnitude and to their significance. There are several different methods for assessment of risks. Hereunder are described three common methods, that are 1) Risk graph, 2) Risk matrix and 3) Hazard Rating Number system. Different methods can also be combined – one sample of so called “Hybrid-tool” as given in the standard SFS-ISO/TR 14121-2 Safety of machinery. Risk assessment. Part 2: Practical guidance and examples of methods. (SFS-ISO/TR 14121-2, p. 34)

2.5.1 Risk graph

A risk graph reminds of a fault tree design. Every parameter of risk is described with a node and every branch growing from a node represents class of the parameter (for example slight or serious severity) as can be seen in Figure 2.

Figure 2. Risk graph for each parameter (EN ISO/TR 14121-2)



As a result of making decisions, that guide through this tree, the index for risk is given. Risk graph takes a stand to severity, exposure, probability of occurrence of a hazardous event, and possibility of avoidance.

Severity of occurrence can be either slight or serious. Exposure can be either seldom or frequent. Probability of occurrene of a hazardous event is low, medium or high. Possibility of avoidance is judged either possible or impossible.

For each hazardous situation, a class should be allocated to each parameter. The path on the risk graph is then followed from the starting point. At each joint the path proceeds on the appropriate branch in accordance with the selected class. The final branch points at the level or index of risk associated with the combination of classes (branches) that have been chosen. The end result is an estimation of risk qualified with terms such as “high”, “medium”, “low”, a number, for example 1 to 6, or a letter, for example A to F. (SFS-ISO/TR - 14121-2, p 27).

If using numbers from 1 to 6 for scoring, explanations for each level of risk are following: 1 – No need for risk reduction, 2 – Education and personal protective equipment for risk reduction, 3 – Risk reduction measures should be considered, 4 - Protective measures are required. To be done as soon as possible, 5 – Safety measures must be done urgently, 6 – Stop the machine. Safety measures must be done immediately.

2.5.2 Risk matrix

There are several variations of risk matrices at the market. Before starting risk assessment using risk matrix, the goal level should be decided. There should also be made decision about what level requires reducing of risk.

Typical to risk matrices, they can have various amount of risk levels for each risk factor. Table 1. presents an example of standard EN ISO/TR 14121-2, on page 24.

Table 1. Estimation of severity (EN ISO/TR 14121-2, p. 24)

Probability of occurrence of harm	**Severity of harm**			
	Catastrophic	Serious	Moderate	Minor
Very likely	**High**	**High**	**High**	**Medium**
Likely	**High**	**High**	**Medium**	**Low**
Unlikely	**Medium**	**Medium**	**Low**	Negligible
Remote	**Low**	**Low**	Negligible	Negligible

Table 1 estimates the severity of harm or its consequences for each possible hazard.

The severity levels in Table1 are:

- **catastrophic** – death or permanent disabling injury or illness (unable to return to work)
- **serious** – severe debilitating injury or illness (able to return to work at some point)
- **moderate** – significant injury or illness requiring more than first aid (able to return to same job)
- **minor** – no injury or slight injury requiring no more than first aid (little or no lost work time) (EN ISO/TR 14121-2, p. 24)

The left column of this table – “estimation of probability of occurrence of harm” is more or less subjective and thus brainstorming of knowledgeable people is considered advantageous.

Similar to severity, there are many scales used to estimate the probability of occurrence of harm. Some methods do not provide descriptions other than the terms used. Other matrices provide additional descriptions as in Table 1:

- **very likely** – near to certain to occur
- **likely** – can occur
- **unlikely** – not likely to occur
- **remote** – so unlikely as to be near zero (EN ISO/TR 14121-2, p. 24)

Standard EN ISO/TR 14121.2 tells that the probability should be compounded to one kind of interval, like lifetime of the machine.

By using this kind of a risk matrix for judging all the possible risks that can occur, the severity and occurrence together give us an understanding about the risk level.

2.5.3 Hazard Rating Number system

There are in the market several methods for scoring risks numerically. One numeric method; Hazard Rating Number System is presented hereunder.

Hazard Rating Number system – often abbreviated as HRN, gives numeric rating for different dangers. If performed in a chart and using different colours for scoring , HRN can be very visual, easy to read way to assess different risks. In HRN method there are eight different risk levels that are used: acceptable, very low, low, significant, high, very high, extreme, unacceptable. HRN takes into account, how many people and for how long time they are in a specific danger. HRN is got by calculating LO: Likelihood of Occurrence, FE: Frequency of Exposure, DPH: Degree of Possible Harm and NP: Number of Person at risk. Thus the formula is relatively simple as shown in Figure 3. (Manninen, 2020)

Figure 3. Formula of Hazard Rating Number (HRN)

Likelihood of Occurrence (LO) is scored in accordance with the following Table 2.

Table 2. LO (Likelihood of Occurrence)

0.033	Impossible	Cannot happen under any circumstances
1	Almost impossible	Still possible
1.5	Unlikely	But may occur
2	Possible	But unlikely
5	50 - 50	Can happen
8	Likely	Not surprising, if it happens
10	Very likely	In prospect
15	Certain	Will surely happen

Frequency of Exposure is scored in accordance with the following Table 3.

Table 3. FE (Frequency of Exposure)

0.5	Yearly
1	Monthly
1.5	Weekly
2.5	Daily
4	Hourly
5	Continuously

Degree of possible harm (DPH) is scored in accordance with the following Table 4.

Table 4. DPH (Degree of possible harm)

0,1	Scratch/contusion
0,5	Rupture/Incision/Mild effect to health

1	Fracture of the smaller bone (temporary)
2	Fracture of the bigger bone (permanent)
4	Partial loss of one limb or vision/Serious injury (permanent)
8	Loss of two limbs/Total loss of vision/Very serious injury (permanent)
15	Death

Number of persons that are exposed to danger (NP) is scored in accordance with the following Table 5.

Table 5. NP (Number of Persons exposed to danger)

1	1 to 2 persons
2	3 to 7 persons
4	8 to 15 persons
8	16 to 50 persons
12	more than 50 persons

If by making the calculation in accordance with formula: LO x FE x DPH x NP zero (0) or 1 is given as a result, the risk has no significance. Numbers from 2 to 5 stand for a very low risk. Numbers from 6 to 10 signify that the risk is low. Scoring numbers from 11 to 50 show a significant risk. Numbers from 51 to 100 show a high risk, from 101 to 500 signify a very high risk, numbers from 501 to 1000 an extreme risk. Numbers over one thousand show that the risk is impossible, i.e. not acceptable. (Manninen, 2020)

3 RISK REDUCTION

If there are any risks noted that are at the level that is not acceptable, there should always be done measures in order to reduce this particular risk. Best result is achieved if these measures can be taken into account already in the design phasis of machinery.

So called naturally safety designing of machinery means that hazards are eliminated or reduced by designing and building machine safe by following the principle of safe technology; choosing naturally safe technology and processes, taking into account

ergonomic principles, by applying safety principles when designing control systems and by mechanising or automating manual work steps. (SFS-ISO/TR 14121-2, p. 42)

3.1 Three step method

Three step method for risk reduction starts with issues, that are to be avoided through designing of the machine (step one). Step two shows that together with use of suitable safety devices major amount of risks can be reduced to a tolerable level.

Third step of the method is highly depending on human behaviour and needs a lot of attention to work methods, using of warning signs, warning tapes and signals.

This third step is thus secondary and tells that there has not been done enough in steps one and two. (Occupational Safety and Health Administration in Finland, n.d.)

3.2 Residual risks

After having assessed the magnitude and the significance of the risk, answer to the question whether the risk is acceptable or not, can be given. If the risk is seen to be acceptable, there can still remain some residual risks, about which the users or workers should be informed.

Information for employees and other users may be provided by instructions, warnings or various markings. As such safety measurements are regarded for example warning signs, light- and sound signals, access control, special training and familiarization and personal protective equipment. (SFS-ISO/TR 14121-2, p. 42)

3.3 Safety measures

Always the best way of reducing risks is to take them into account as designing stage of the machine. Despite high quality designing and manufacturing of machinery, often many kinds of safety systems and devices are needed, in order to ensure the safety use. Guards and safety equipment have to be used to protect persons against hazards, that have not been able to be removed or adequately limited through designing. (SFS-ISO/TR 14121-2, p. 42)

The risk assessment performed for the designed machinery, gives the PL_r - Performance Level required – for the machinery.

Performance Level required is the minimum level that should be obtained with the use of functional safety devices. In practice safety components are defined on higher level than required, in order to still apply, in case the requirements of the safety control system should change. (Manninen, 2020)

3.4 Safety control systems

This chapter is based on the standard SFS-EN ISO 13849-1 Safety of machinery. Safety-related parts of control systems. Part 1: General principles for design, and to the practical applications of it.

Before choosing of the safety device, should be examined all measures, with which the risks could be totally eliminated, or through which the risk could be adequately reduced with use of naturally safety principles. The possibility of using mechanical guard should also be surveyed. (SFS-EN ISO 13849-1, p. 34)

In the choice of safety device following issues should be regarded: features of the machine, features of production and product, environmental features, human-machine interaction, different ways of using the machine, need of entering to the area of danger, the possibilities and possible need to bypass the safety devices. (Rantanen, 2019)

Figure 4. SICK light curtain safety devices

There are different types of safety devices. Person-detecting safety devices can be divided in three groups. Access guarding devices, for example safety light barriers and safety light cells detect person entering to a guarded area. Point of operation guarding includes such safety devices as security light curtains, security cameras, security scanners. Area guarding devices are mainly security scanners but also light curtains shown in the Figure 4. are used for this purpose.

List of other useful safety devices is long, containing for example safety mats, safety edges, safety limit switches, permitting devices, two-hand controls, sensors, safety relays, security logic, emergency stop devices, contactors, logic, frequency converters, valves etc. (Rantanen, 2019)

3.4.1 Performance levels

Functional safety forms part of the overall safety of machinery and it is dependent on the functionality of the safety equipment, and the control systems.

Standard SFS-EN ISO 13849-1 gives performance levels (PL) as probability of dangerous failure per hour of safety devices. There are five different performance levels defined from a) to e), as seen in Table 6. (SFS-ISO/TR 13849-1, p. 42)

Table 6. Performance levels (PL)

PL	**Average probability of dangerous failure per hour**	**$MTTF_d$ (approximately) in years**
a	$\geq 10^{-5} \ldots < 10^{-4}$	1…10
b	$\geq 3 \times 10^{-6} \ldots < 10^{-5}$	10…30
c	$\geq 10^{-6} \ldots < 3 \times 10^{-6}$	30…100
d	$\geq 10^{-7} \ldots < 10^{-6}$	100…1000
e	$\geq 10^{-8} \ldots < 10^{-7}$	1000…10000

The performance level should be defined separately for every single safety device, that is part of safety-related control system.

In this definition should be considered: Mean Time To Failure ($MTTF_{d}$), Diagnostic Coverage (DC), Common Cause Failure(CCF), structure, behaviour of safety function under fault condition(s), safety-related sofware, systematic failure, ability to perform safety function under expected environmental conditions. (SFS-ISO/TR 13849-1, p. 43)

3.4.2 Defining SIL for safety devices

In accordance with the standard IEC 62061 Safety Integrity Levels (SIL) can be derived from the Risk matrix, as shown in the Table 7.

Table 7. Risk matrix and defining SIL

Consequences	**Severity**	**Class Cl**				
	Se	**3-4**	**5-7**	**8-10**	**11-13**	**14-15**
Death, loss of vision or hand	4	SIL2	SIL2	SIL2	SIL3	SIL3

Irreversible, loss of a finger	3			SIL1	SIL2	SIL3
Reversible, requiring medical attention	2				SIL1	SIL2
Reversible, requiring first aid	1					SIL1

Class is calculated as an addition Fr (Frequency and Duration), Pr (Probability of dangerous event) and Av (Avoidability) in accordance with Table 8 on the next page. The formula is simply**: Cl = Fr + Pr + Av.** (IEC 62061)

Table 8. Factors of SIL-Class

Frequency and duration, Fr		**Probability of dangerous event, Pr**		**Avoidability, Av**	
<= 1 hour	5	Very likely	5		
> 1 h - <= day	5	Likely	4		
> 1 day - <= 2 weeks	4	Possible	3	Impossible	5
> 2 weeks - <= 1 year	3	Rarely	2	Possible	3
> 1 year	2	Not taken int account	1	Probable	1

Performance level (PL); introduced in standard 13849-1, and safety integrity level (SIL); introduced in IEC 62061 standard, are parallel methods for determining the level of functional safety of safety devices.

There is no correspondence for Performance level a. in the table of Safety Integrity Level (SIL). Performance levels b. and c. correspond to SIL 1, performance level d. corresponds to SIL 2 and performance level e. corresponds to SIL 3.

3.5 Qualifications for the CE-marking

By CE marking the manufacturer declares that the product complies with the requirements of the relevant EU directives. CE marking is physical sign giving detailed information about product and its technical features. CE marking also guarantees for the product entry to European market – in this case for machine/equipment.

The manufacturer is responsible for the conformity of the product. In order to meet all the requirements of CE marking, the company or the manufacturer who imports the machine or equipment to the European market, should follow a 6-step process describe here.

1) At first the applicable legislation should be determined. There can be several directives relating to machinery.

2) Secondly all the legal requirements should also be clarified. Which specific standards should be followed during manufacturing? Also question about risk reduction measures through risk assessment should be defined. Customer can also set own contractual and safety requirements.

3) At step number three appropriate conformity assessment procedure should be selected. Conformity assessment can be based on internal audit or it can be done in co-operation with notified body. Type approval and different quality aspects should be observed fundamentally.

4) The fourth step includes defining the qualification process. Which essential health and safety requirements given at the step two should be met and what qualifications

are required for this specific product? There might be for example qualification of electrical equipment, functional safety qualification, qualification of guards, noise and vibration measurements and other tests needed to be conducted.

5) At the fifth phase it should be indicated, what to include in to the technical file. A demand for these documents may rise from directives, standards, from customer. Also administrative requirements should be regarded. These may apply questions about language of the documents, form of files (in paper or electric version), storage time etc.

6) After successful completion of these steps finally the step six includes declaration of conformity and the CE marking itself. (Manninen, 2020)

From the website of Tukes can be found ready to fill in template forms of declaration of conformity in Finnish, Swedish and English. There is given the minimum, what should be included in this declaration.

A declaration of conformity should include at least the following information: product model, name and address of the manufacturer or his authorised representative, an assurance “this declaration of conformity is issued under the sole responsibility of the manufacturer”, the object of the declaration, a list of relevant European Union harmonization legislation, references to the relevant harmonised standards, or references to the other technical specifications, and a signature (signed for and on behalf of). (Tukes, n.d.)

4 EMPIRICAL PART OF PROJECT

Ferroplan Oy is a manufacturer of high quality piece goods- and bulk conveyors as seen in Figure 5. Company delivers conveyors and conveyor solutions for several fields of industry. The company was established in 1983 and is today the market leader in the Finnish conveyor market.

Figure 5. Ferroplan roll conveyor for package handling

4.1 Introduction of the company

Ferroplan Oy is a privately owned company, with around 50 employees in Finland and 20 employees working at SIA Ferroplan, a subsidiary which is located in Jelgava, Latvia. The turnover of the parent company was 9 Million euros in 2019. (Asiakastieto, n.d.)

The operations of the company stretch from being a machine supplier to providing projects offering total deliveries including all the phases from mechanic design, project management, manufacturing, electrification and automation, security as well as assembling and testing of conveyor systems. (Ferroplan, n.d.)

According to Minna Patosalmi, CEO of Ferroplan Oy, the product range of Ferroplan Oy has grown with several new innovations during the last few years. The company aims towards a significant increase in the turnover and is also approaching new fields of industry. (Patosalmi M., personal communication 11.1.2021)

4.2 Development projects

Ferroplan Oy has continuously sharpened its processes throughout the whole company in order to improve their competitiveness inside a very competitive market. The company has lately invested in their first Enterprise Resource Planning-system and a 5S-project was recently launched in the production department, confirms Minna Patosalmi. (Patosalmi M., personal communication 11.1.2021)

4.3 Tool for risk assessment

CE-marking is an internal company process as well as all the measures done to improve the safety of machinery. The goal of the practical part of this thesis was to perform a ready to fill in form for risk assessment conducted at Ferroplan Oy.

4.3.1 Background survey

At first several officers working with tasks of performing and documenting risk assessment were interviewed asking for their visions and opinions regarding a good formula for risk assessments. These pre-interviews gave the impression that an easy to read Excel-based model, that could give basis for a consistent, more effective and time saving process would be the most desired tool. Also previously conducted risk assessments were examined, in order to support the development for establishing easily accepted template form.

A customer oriented implementation of the project, that in practice would entail taking into account user preferences, introduction and utilization of fill in a form would have been be significantly smoother and faster selection than by ignoring the future users.

4.3.2 Choice of base for the form

A so called hybrid tool, which could perform 2 in 1 formula, was preferred as the best option for the realization of the risk assessment tool that was customized for Ferroplan Oy.

Herein 2 in 1 meant that both risk assessment (magnitude of the risk and significance of the risk) and risk reduction measures were presented by using one single form.

There was also guidance and examples given as enclosures of the standard SFS 13849-1. They made it a lot easier to start the design in this project.

4.3.3 Designing phase

It was challenging to get all the explanations of several abbreviations of classifications to fit the restricted size of the form and yet to keep the visuality at high level and the form clearly divided.

There was plenty of input data to start the risk assessment with. Together with the lay-out and other visual material, figures, 3 d-drawings etc., the first page was a kind of a technical sheet, so it was chosen to be provided in the Word-format.

The functionality of the customized fill in form was tested with two real customer cases before introducing it to the personnel/becoming users of the form. Instructions for the use of the form were handed over as enclosure together with the form itself.

5 CONCLUSION

Risk assessment in automation – and also in machinery – requires specialising into manufacturing and automation in this specific field of industry, a good knowledge about risk assessment methods, directives, standards and applicable laws and other restrictions. It is certainly the field where one can endlessly develop his/her skills.

Studying for this thesis gave gave the author a basic knowledge about risk assessment and defining the Safety Integrity Level for safety devices.

Taking part in a real working life development project is always not only challenging but also rewarding. As the subject of this thesis arose from an actual need, also the result of the empirical part, the risk assessment tool was taken into use at the company.

After a longer period of time, this tool can be evaluated by the users and it can be used as a basis for continual developing progress.

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