

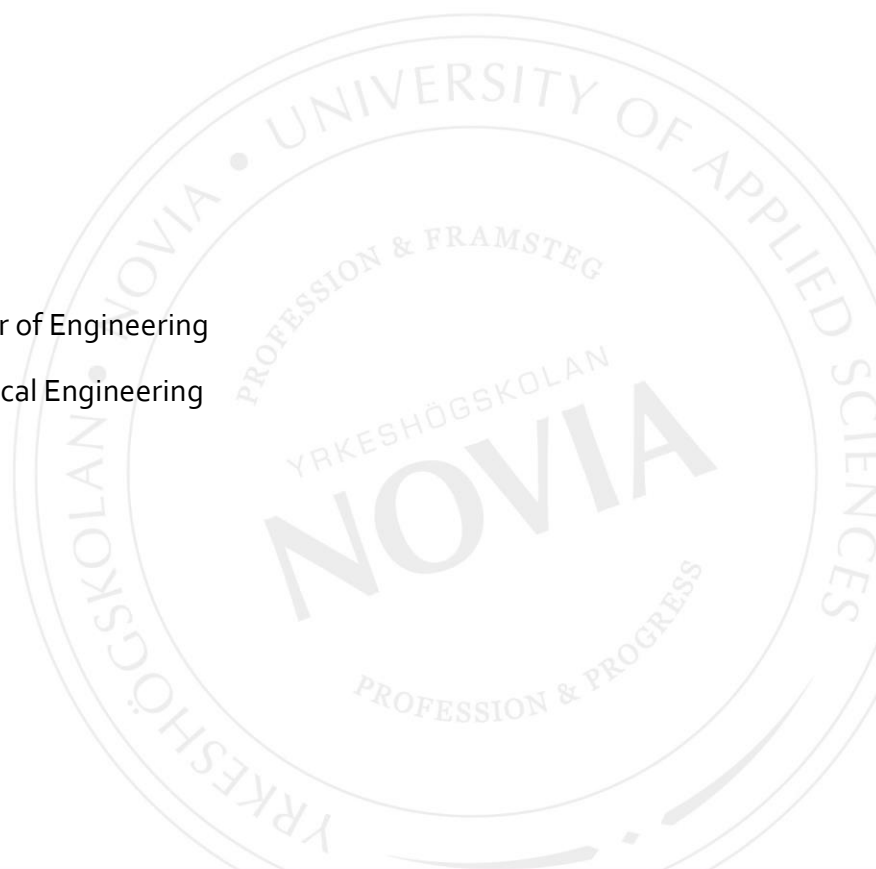
CE Marking Procedure for the Generating Set

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BACHELOR'S THESIS

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Abstract

The purpose with this thesis is to be able to have the full understanding about the application and affixing of the CE mark on the generating set for the Marine Industry. This Bachelor's thesis was produced for Wärtsilä, Marine Solution – Project management. The aim of the thesis is to ensure a smoother handling of CE marked products in the future.

The key method to arrive at a conclusion was regular meetings with the people of outstanding expertise in the field. These people had a very broad, yet detailed knowledge of the generating set which was essential for the completion of this thesis. The studying of necessary theoretical studies was the first action in order to be able to understand the fundamentals behind the CE mark and have meaningful meetings.

Following both the theoretical studies about the CE marking as well as regular meetings, the practical work began. The result of this practical work and the conclusion of this thesis is the following; templates, a risk analysis and a step by step guide. Together, these three types of documents all play an essential role in understanding and applying the CE mark. These documents will henceforth be adopted by the team in charge over CE marking the product.

Language: English Key words: Generating Set, CE marking, European Union

Please note! The appendices are excluded in the official version of this thesis due to confidentiality

EXAMENSARBETE

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Titel: Proceduren för att CE-märka ett generatorset

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Abstrakt

Syftet med detta examensarbete var att undersöka och få en full förståelse om hur och vad man måste inkludera för att ha rätten att CE-märka ett generatorset för den marina industrin. Examensarbetet är gjort på uppdrag av Wärtsilä, Marine Solution – Project Management. Målet är att CE-märkning av produkter ska löpa smidigare i framtiden.

Den viktigaste metoden för att uppnå ett resultat var återkommande möten med människor som har utmärkta kunskaper kring ämnet i fråga. Dessa personer har en bred och detaljerad kunskap om generatorsetet, vilket var nödvändigt för att genomföra examensarbetet. Nödvändiga teoretiska studier var det första skedet för att uppnå den fulla förståelsen kring märkningens innebörd, men det var även nödvändigt för att ge substans åt framtida meningsfulla möten.

Till följd av de teoretiska studierna om CE-märkningen samt återkommande möten, kunde det praktiska arbetet påbörjas. Resultatet av det praktiska arbetet och slutsatsen om detta examensarbete är följande: mallar, en riskanalys samt en steg för steg-guide. Tillsammans spelar dessa tre dokument en nödvändig roll för att förstå och applicera CE-märkningen. Dessa dokument kommer att användas av det ansvarande teamet för den CE-märkta produkten.

Språk: engelska Nyckelord: Generating set, CE-märkning, Europeiska Unionen

Observera! Bilagorna är uteslutna ur den officiella versionen av detta examensarbete på grund av konfidentiellt material

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Tiivistelmä

Tämän opinnäytetyön tarkoituksena oli tutkia ja saada ymmärrystä generaattoriyhdistelmän CE-merkinnästä meriteollisuudessa. Wärtsilä, Marine Solution – project management, on tämän opinnäytetyön toimeksiantaja. Tarkoitus on helpottaa CE-merkintää tulevaisuudessa.

Tärkein menetelmä tuloksen saavuttamiseksi oli toistuvia kokouksia heidän kanssa, joilla oli erinomaisia tietoja asiasta. Näillä henkilöillä on laaja tieto generaattoriyhdistelmistä ja tämä oli tärkeää opinnäytetyön teossa. Teoreettiset opinnot olivat ensimmäinen askel tavoittaakseen täydellistä ymmärrystä merkintöjen tarkoituksesta. Seuraava askel oli kokouksia asiantuntijoiden kanssa.

CE-merkinnän teoreettisten tutkintojen ja toistuvien kokouksien jälkeen oli hyvä aloittaa käytännön työt. Käytännön työn ja opinnäytetyön tuloksena ovat malleja, riskianalyysi sekä vaiheittainen opas. Yhdessä nämä kolme dokumenttia ovat tärkeitä CE-merkinnän ymmärtämisessä ja soveltamisessa. Jatkossa näitä asiakirjoja käyttävät CE-merkinnästä vastuussa olevat henkilöt.

Kieli: englanti Avainsanat: generaattorin yhdistelmä, CE-merkintä,
Euroopan Unioni

Huomautus! liitteet ovat jätetty pois virallisesta versiosta salaisen asian vuoksi

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Appendix 4	Risk assessment and risk reduction
Appendix 5	Essential health and safety requirements for the generating set

1 Introduction

This thesis work covers the application of CE marking for the generating set in the marine industry, as well as everything that is included in the affixing of the CE mark. The assessment was provided on behalf from Mr. Johan Wasberg, who works in a project management team within Marine Solution - Wärtsilä – Finland.

CE marking is more than just affixing the mark on a product, theoretical studies and patience are the key components to a deep understanding regarding what the mark covers and what needs to be applied in order to be able to affix the CE mark on a product. Declaration of incorporation and harmonised standards are just some parts to implement. Second opinions and the ability to criticise one's own, as well as others' opinions is helpful in order to think one step further in a certain process.

The generating set is covered by the machinery directive and is seen as a partly completed machinery. This implies, that it does not require the same requirements as a complete machinery in terms of safety- and health regulations. This thesis will help the employee in charge regarding CE marking on a project to faster understand what requirements such a project encompasses, as well as providing him or her with finished templates, which only require the filling of essential information, unique to the specific project.

The first parts of this thesis are theoretical chapters which all are essential to the conclusion of this thesis and therefore plays an important role. Afterwards, the description of the practical work is presented and lastly, in the Annex chapter, all finished templates can be found.

1.1 Background

CE markings are in most cases not applicable in the marine industry, which leads to the following problem: when a CE marked project is sold and applicable, the project engineer and project manager should have a full and comprehensive understanding of the regulations and legislation regarding CE markings.

To get the full picture regarding what is included in the CE mark, self-studies or a larger time frame for the project would be needed. Unfortunately, the time frame has already been determined when the project reaches the team in charge. During the last year there has been an on-going project where CE marking is applicable. With this project fresh in mind the person in charge over the CE marking wanted to get a second opinion as well as a finished step by step guide, templates and training material. Ideally, the project engineer in the future should know exactly how to implement the CE marking in the project without time loss or having to devote time when there are other time consuming matters.

1.2 Purpose of the study

The purpose of this thesis is to make templates for all documents which are needed for CE marking, as well as a step by step guide which is an information document with the essential ‘‘need to know’’ information. However, the document which take the most time and effort is to go through a risk analysis for the generating set and from the analysis make a risk assessment.

The templates are made for the project engineers and project managers. It will be easy for them to just fill in the information regarding their project in the highlighted parts of the template, and the step by step guide provides them with essential information all the way from the sale stage up until the execution stage.

1.3 Employer - Wärtsilä

Wärtsilä is a global company established in 1834 which provides smart technologies and complete lifecycle solutions for both energy and the marine market. According to Wärtsilä's own web site, they have approximately 18 000 employees with 200 locations in more than 80 countries. The biggest facilities are located in Vaasa, Finland and in Trieste, Italy.

Wärtsilä consist of three main departments; energy solutions, marine solution and service. (Wärtsilä, 2018)

Wärtsilä offers one of the world's most complete marine solutions. For instance, Wärtsilä provides ship design, complete electrical and automation systems, environmental and emissions control systems etc. (Wärtsilä Corporation, 2017), 4-5

2. Generating sets

The generating set is a Wärtsilä engine with a generator mounted on a common base frame. The generating set can be used both for power generation purposes, as well as for diesel-electric propulsion. The generating set itself is installed on conical rubber mounts, which reduce the vibrations transmitted to the foundation.

In order to reduce the structure noise and vibration transmitted through the ship hull, resilient mounts are installed. To avoid resonance with excitations from the generating set engine the location and number of the mounts are calculated. (Wärtsilä Finland OY, 2015)

The engine and generator are sometimes separately mounted and separately delivered on the larger diesel engines, in most cases this happens when the whole generating set is too large to transport to the site, or if the customer wants to change the engine in an old project but have the same generator as used in the project before.

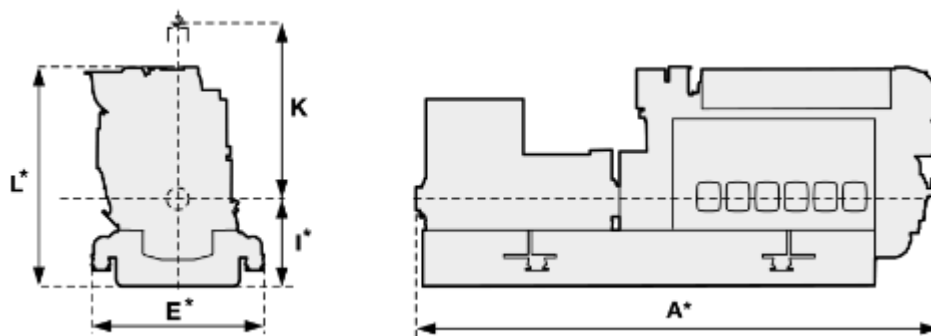


Figure 1 Generating set dimensions (Wärtsilä Corporation, 2017)

Generating set dimensions

- A** Total length of the generating set.
- E** Total width of the generating set.
- I** Distance from the bottom of the common baseframe to the crankshaft centreline.
- K** Minimum height from the crankshaft centreline when removing a piston.
- L** Total height of the generating set.

Figure 2 Explanation of letters in Figure 1 (Wärtsilä Corporation, 2017)

In Figure 1 the dimensions of the generating set is shown. When choosing which generator is suitable for a specific project there are certain dimensions and data needed to know. All generating sets have their own dimensions which are described in Wärtsilä's own manuals. The letters in Figure 1 is described in Figure 2.

Furthermore, it is possible to select generator voltage in all cases. (Wärtsilä Corporation, 2017), 44-69

2.1 Wärtsilä Engine

The engine which is used in the generating set is always a Wärtsilä engine.

The engine range includes both dual-fuel engines (Wärtsilä 20-, 34-, 31-, 46- and 50 DF) and diesel engines (Wärtsilä 20, 26, 32, 31 and 46F). The engines are 4-stroke engines/medium speed engines. Additionally, the configuration can be either In line- or V-engine. Further information regarding the engines can be seen below in Figure 3.

4-Stroke Diesel Engines

		
Wärtsilä 20 Robustness & reliability as the prime mover in smaller vessels or for generating set applications.	Wärtsilä 26 Compact & light unit with low operating costs, also used for generating set applications.	Wärtsilä 32 Designed for reliability & easy maintenance, also used for generating set applications.
		
Wärtsilä 38 Lightest and most compact heavy duty engine, also used for generating set applications.	Wärtsilä 46 The most popular engine for power generation onboard large cruise vessels.	Wärtsilä 46F Best-in-class fuel economy & outstanding power-to-weight as well as power-to-space ratios.

Figure 3 Wärtsilä Engines (Wärtsilä Corporation, 2015)

The engines have low emissions and operating cost as well as reliability and fuel flexibility. Furthermore, it is possible to choose between gas and liquid fuel without any interruption in power generation thanks to the multi-fuel technology. (Wärtsilä Corporation, 2017), 44-69

2.1.1 Engine function

The main components in the engines are the following: engine block, connecting rod, crankshaft, cylinder liner and head, piston and piston rings, camshaft and valve mechanism, fuel injection equipment, engine bearings and lastly turbocharger.

The diesel engine operates in accordance to the following four steps:

Energy (heat) releases because of the fuel reacts chemically → The gasses trapped in the cylinder head expands because of the heat confined by the cylinder and the expanded gases needs to move the piston for it to expand → The crankshaft converts the reciprocating motion of the piston into rotational motion. (Wärtsilä Corporation, 2015)

In Figure 4 below the 4 stroke process is described.

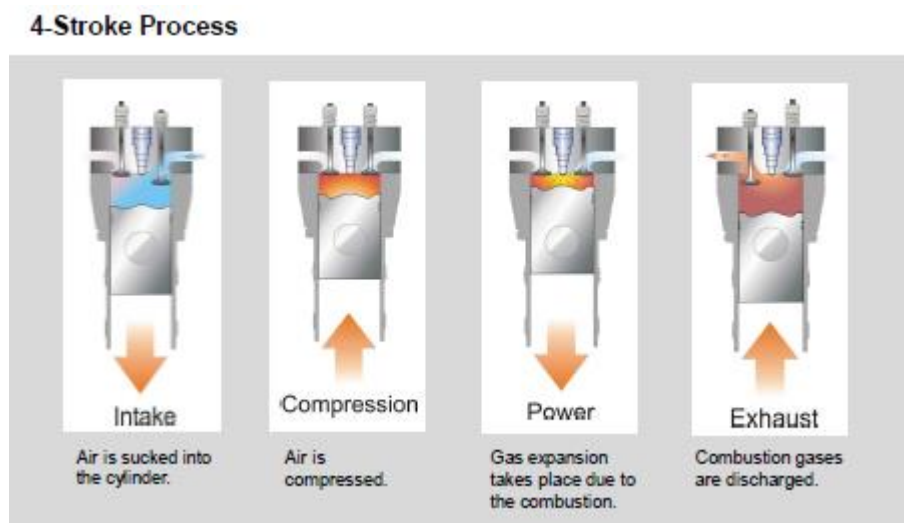


Figure 4, 4 Stroke Process (Wärtsilä Corporation, 2015)

2.2 Generator

A generator is needed when someone wants to convert mechanical energy into electrical energy. The generator uses the mechanical energy supplied by its own engine to charge electricity. In Figure 5 below, the main components of a generator are described. (Diesel Service and Supply, ei pvm)

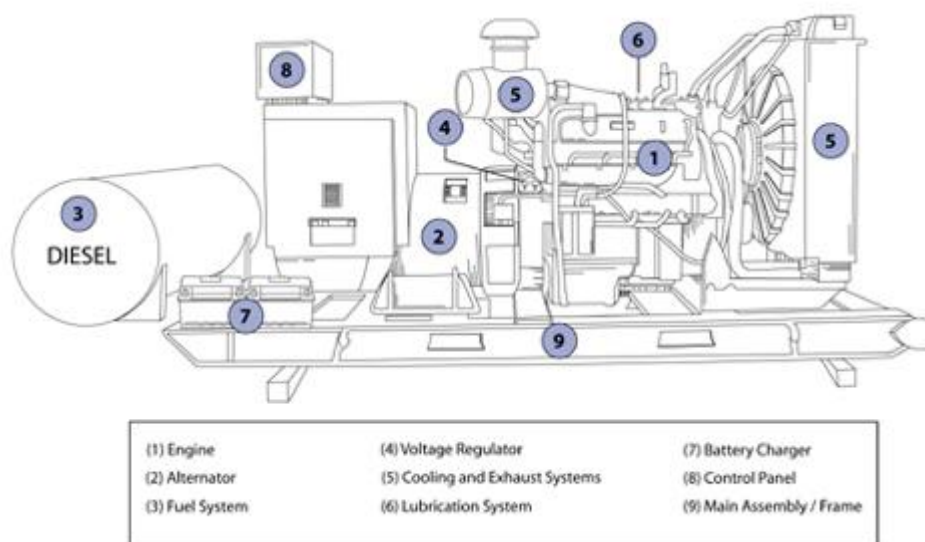


Figure 5 Main components in a generator (Diesel Service and Supply, ea.)

The generator which is implemented in the generating set is in turn purchased by Wärtsilä from other companies, for instance ABB and Siemens.

2.3 Flexible Coupling

General manager Mr. Holmberg, described the flexible coupling through a short interview.

“Flexible couplings are used in generating sets for transmitting torque from engine to generator. Misalignment couplings allows for the shafts to be slightly misaligned due to e.g. thermal expansion reasons. Torsionally flexible couplings control the torsional vibration characteristics of the shaft line and reduces vibratory stresses in the generator shaft. Typically the flexible coupling used in generating sets is a combination of misalignment and torsionally flexible coupling.” (Holmberg, 2018)

In the Figure 6 and 7 below, there are pictures of CENTA couplings, Wärtsilä are in some cases using CENTAs' couplings.



Figure 6 CENTA coupling: CENTAMAX-HTC (CENTA , 2018)

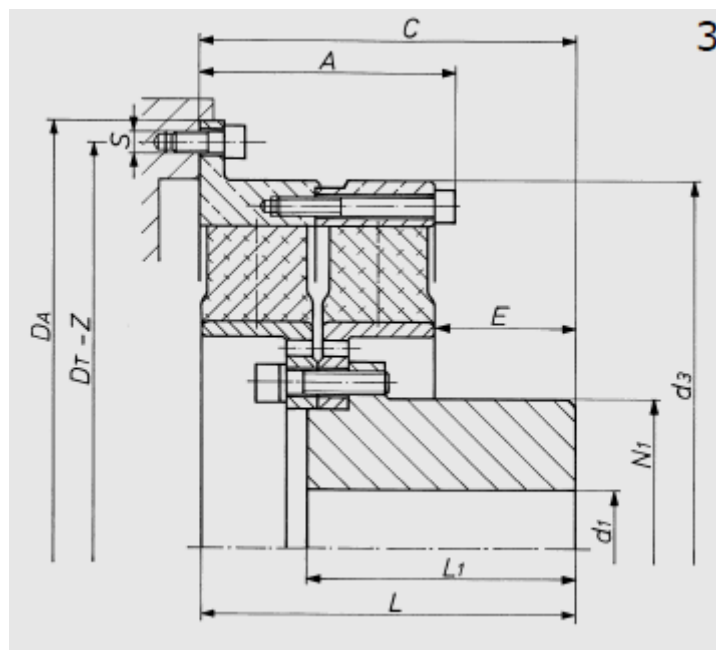


Figure 7 A CENTAMAX coupling variant (CENTA, 2018)

2.4 Common base frame and Flywheel cover

A common base frame is a frame which the generating set is built upon. A specific common base frame is thus needed for every generating set, meaning that the common base frame looks differently for every specific project. Various factors like engine model, generator dimensions, flywheel and coupling dimensions, oil sump dimensions as well as external components are needed to be taken into account in order to determine the dimension of the base frame.

Furthermore, the components to build a common base frame are the following: upper rail, partitions, support plates, bottom plates and side plates, side rail, support, partition wall as well as a lifting pin. Additionally, some projects require the base frame to be equipped with bow plates as well. (Slotte, F, 2016)

A sufficiently rigid common base frame is essential to carry the load from the generating set, otherwise structural failure can occur. (Wärtsilä Finland OY, 2015)

Previously, the common base frames were designed by an external company, but nowadays Wärtsilä designs them on their own.

To protect the flywheel itself, and to prevent people from possible accidents, the flywheel is covered by an arc-shaped cover. This flywheel cover is in turn mounted to the common base frame. (Slotte, F, 2016)

3. Machine directive

The machine directive (2006/42/EG) was taken into effect on the 29th of December 2009. This is a directive which encompasses essential health and safety requirements, covers machinery, safety components, chains, interchangeable equipment etc. As well as requirements for partly completed machinery.

The directive was carried out due to the large amount of people within the EU working with machines. As a direct effect of many people working within the machine industry, accidents were common and not decreasing in number. According to the factsheet by European Commission machine directive intended to ‘harmonise the rules governing the sales of machinery within the EU while guaranteeing the highest possible level for safety for consumer and worker’. For a manufacturer to be able to affix the CE mark on his machine, the machine directive thus needs to be followed. (European Commission, 2014), 1

3.1 Partly completed machinery

A generating set is designed as a partly completed machinery, this because Wärtsilä is selling just one product to the whole machine room. In other words, the generating set is a product that is similar to a complete machine; it has linked parts and with at least one moving component, but because it is missing some elements it therefore must undergo further construction to become a complete machinery. The custom at Wärtsilä is that the shipyard has the responsibility for the final product.

A partly completed machinery and a completed machine should be distinguished, since they are, according to the machine directive, not the same products as a whole. Due to this difference in legislation, the variation throughout the marking procedure before placing a partly completed machinery or a completed machinery on the market is described below in Figure 8.

As one can see in Figure 8, before a partly completed machinery is placed on the market the manufacturer must ensure that the assembly instructions and relevant technical documentation are prepared, as well as a declaration of incorporation has been signed.

Furthermore, the assembly instructions and the declaration of incorporation needs to be accompanied until the generating set is finished, afterwards it must be a part of the technical documentation.

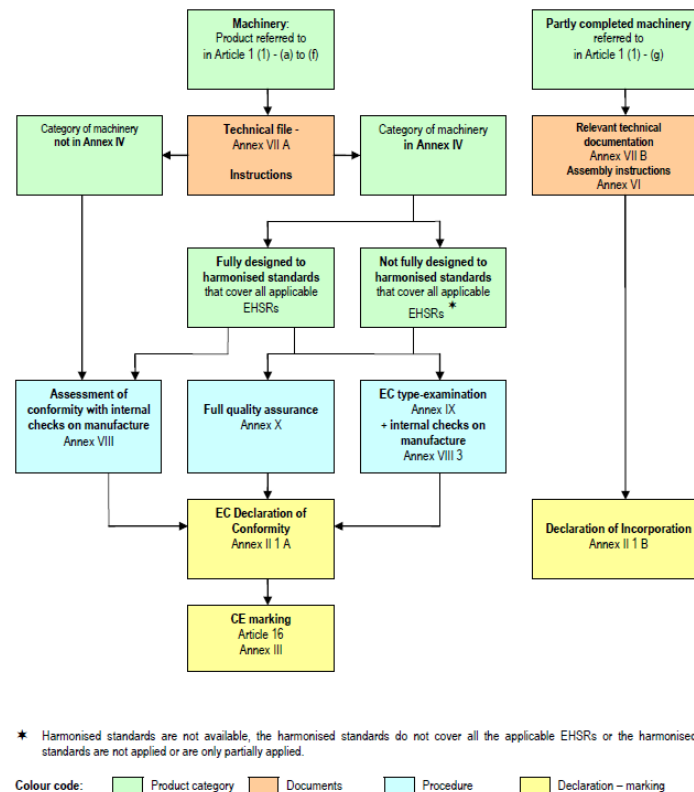


Figure 8 Placing a machinery on the market (Franser, 2010), 6

Because that certain risks are related to the fact that the machinery is not completed, a partly completed machinery cannot fulfil all the essential health and safety requirements. As a result, the manufacturer of partly completed machinery needs to post which essential health and safety requirements have been fulfilled through a declaration of incorporation.

An important thing to remember which is the main difference between completed and partly completed machinery is that the partly completed machinery shall not bear a CE mark! However, a declaration of incorporation and assembly instructions must accompany the generating set. (Franser, 2010)

4. Harmonised standards

Harmonised standards are recurrent in documents regarding CE marking, due to its importance in health and safety requirements. In the machinery directive page 68 they are described as ‘‘non-binding technical specifications’’ and are necessary tools when applying the Machine directive.

The European Committee for Standardisation (CEN), the European telecommunications Standard Institute (ETSI) and Committee for Electrotechnical standardisation (CENELEC) are the standardisation body behind these standards. Most harmonisation standards are founded completely or partially through international ISO- (International Standardisation organisation) or IEC- (International Electrotechnical commission) standards. The technical committee consist of representatives, which have mandates from the national member organisation CEN and CELEC.

The harmonisation standards are European standards and they are the only standards which provide presumption of conformity. By using harmonised standards, the manufacturer provides the customer with a good insight regarding the technical level required for the application of health and safety requirements at the time the product was put on the market. Note that these standards are not mandatory. (Franser, 2010)

When applying the standards to a product there might be several standards that can cover the same hazard, product or impact. Should this occur, the most relevant standard may be used to reduce overlapping. However, in most cases this requires a risk analysis or an analysis of the product’s intended purpose.

Even though the manufacturer has applied harmonised standards, he always has the sole responsibility to judge all risks his product might have. This to ensure relevant requirements are applicable. It is important to remember that harmonised standards will not replace legally binding essential requirements. When a manufacturer has gone through all risks his product may have, as well as provided a risk assessment, he can choose to implement risk reduction measures. In the case of a harmonisation legislation, harmonised standards mostly contain certain means to limit or reduce certain risks, but the manufacturer still remains having the full responsibility for the risk assessment.

In Figure 9 the procedure of choosing standards is described.

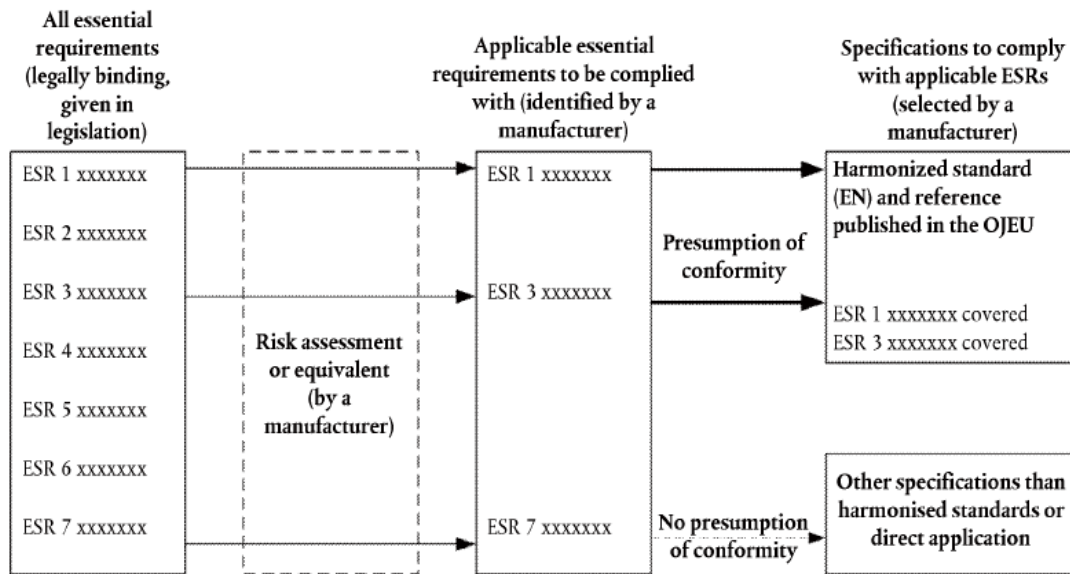


Figure 9 Implementing harmonised standards (European Union institutions, bodies, offices and agencies, 2016), 45

Note that the standards may contain errors, or they can be interpreted differently. Should a manufacturer find any errors or standards open for interpretation, he should contact his national standardisations body to get the error solved/interpretation. (European Union institutions, bodies, offices and agencies, 2016)

For the harmonised standards to be officially valid, they must be published in the Official Journal of the European Union (OJEU). The standard is published as a commission communication in the framework of the implemented directive, for example the machine directive. (Franser, 2010)

All the directives can be found on the European commission's webpage. There are 10 different headers such as chemicals, service, healthcare engineering etc. Each topic has in turn 32 different documents regarding harmonised standards. (European Union, 2018)

4.1 Understanding of different standards

As mentioned earlier, harmonised standards are based completely or partially on international ISO or IEC standards. Harmonisation standards can be developed together such as cooperation between CEN and ISO, these standards are known as Vienna Agreements. If CENLEC and IEC together develop a standard, it is known as a Dresden Agreement. Before the drafts are adopted as European harmonised standard, they go through an inquiry and adaption procedure at CEN or CENLEC, these procedures are carried out parallel with the procedures at ISO or IEC.

If a standard has the prefix ‘EN’ including a date and a reference number it means that the standard is approved by CEN or CELEC. If the standard gets upgraded later on it is easily found through the reference number and by the date changed in the old and new version.

If a CEN and ISO standard is identical it gets the same number and the prefix ‘EN ISO’. However, the numbers are different if a CENELEC standard is based on an IEC standard. (Franser, 2010)

4.2 Other possibilities to confirm essential requirements

Even though harmonisation standards are the only standards that provide automatic presumption of conformity against essential requirements after they been published in the OJEU, there are other ways to show conformity of a product.

Some national standards may give presumption of conformity according to some harmonisation acts. If a nation thinks they have a standard that meets the essential requirements, they may report the text in these standards to the European Commission. In order to decide whether the national standard should or should not enjoy presumption of conformity, the commission consults with the help of the other member states in the EU. If the member states are positive, the commission publishes the reference of these standards as well as the reference in the OJEU. (European Union institutions, bodies, offices and agencies, 2016)

Furthermore, the manufacturer may use technical specifications such as national standards, European or international standards which are not harmonised, or the manufacturers own specifications. This requires the manufacturer to be more accurate and specifically demonstrate how he provides conformity with the essential requirements in the technical documentation.

If a harmonised standard needs a status of national standard without any interchange from the national member state of CEN and CELEC, the prefix ‘EN’ and the prefix of the country concerned is placed next to each other. In Figure 10 the EU Member states prefixes are shown and Figure 11 the prefixes in the EFTA countries.

“ÖNORM EN” in Austria	“LVS EN” in Latvia
“NBN EN” in Belgium	“LST EN” in Lithuania
“БДC EN” in Bulgaria	“EN” in Luxembourg
“CYS EN” in Cyprus	“MSA EN” in Malta
“ČSN EN” in the Czech Republic	“NEN EN” in the Netherlands
“DS EN” in Denmark	“PN EN” in Poland
“EVS EN” in Estonia	“NP EN” in Portugal
“SFS EN” in Finland	“SR EN” in Romania
“NF EN” in France	“STN EN” in Slovakia
“DIN EN” in Germany	“SIST EN” in Slovenia
“EN” in Greece	“UNE EN” in Spain
“MSZ EN” in Hungary	“SS EN” in Sweden
“IS EN” in Ireland	“BS EN” in the UK
“UNI EN” in Italy	

Figure 10 EU member states prefixes (Franser, 2010), 99

"IST EN" in Iceland,	"SN EN" in Switzerland
"NS-EN" in Norway	

Figure 11 EFTA states prefixes (Franser, 2010), 99

Because standards on national level can be published the year after it has been published in the OJEU the dates can differ. The publication date in the national version of the harmonised standard can be later than the publication date in the OJEU. (Franser, 2010)

5. CE Marking

When a finished product is introduced to the EEA- (European Economic Area) as well as the Turkish market, they need to be CE marked, this whether they were manufactured in the EES, Turkey or in another country. The CE-marking is a key indicator of a product's compliance with EU legislation and enables the free movement of products within these previously mentioned countries.

Member states of the EEA are EU Member states and certain EFTA countries: Iceland, Lichtenstein, and Norway.

CE marking indicates conformity with the requirements laid down by the European Union. The CE marking itself is a harmonisation legislation, not a mark of origin. A CE marking thus does not indicate whether the product was made in the EU or not, only that it complies with the legislation of the European Union. CE marking also needs to be affixed on products which have been modified, even though they have been CE marked prior to the modification. Even though a product may have other marks, such as private markings, they are not to be seen as equal to a CE marking.

A frequently asked question is if the process of CE marking is somehow controlled by the authorities. This only occurs if the product is labelled as a high risk to the public interest, for example certain machine tools and lifts. These require conformity assessment, which is done by a third party. Normally the answer is simply no, it is the manufacturer who has the sole responsibility when he affixes the CE mark and drafts the EU declaration of conformity/incorporation.

CE marking is mostly done at the end of the production phase, because it may not, in principle be affixed before the conformity assessment procedure has been completed. This, in order to ensure that all the provisions of the relevant Union Harmonisation principles have been followed.

To prevent abuse and misuse of the CE marking, member states must provide in appropriate measures in their legislation. Measures may include withdrawal, recalling of products, penalties and criminal sanctions. The meaning for these measures is to be effective and proportionate to the seriousness of the offence and dissuasive of the CE marking.

If a product is affixed with the CE mark, but it is not covered by any of the Union harmonisation legislation, it is considered to be deceiving because consumers or users will

believe that the product satisfies certain Union harmonisation legislation provisions. Action will be taken against those responsible for a non-compliant product having the CE marking. (European Union institutions, bodies, offices and agencies, 2016)

5.1 Dimensions of the CE mark

The CE marking must have the form described below in Figure 12, if the CE marking is reduced or enlarged the proportions must be replaced.

For the CE marking to be readable its minimum height is 5mm. The minimum dimension of the CE marking may be waived for small devices or components. Even though it is possible for the CE marking to take different forms as long as it is visible, readable and its proportions is retained. For instance, the letters may have different colours, but they cannot differ in size in relation to each other.

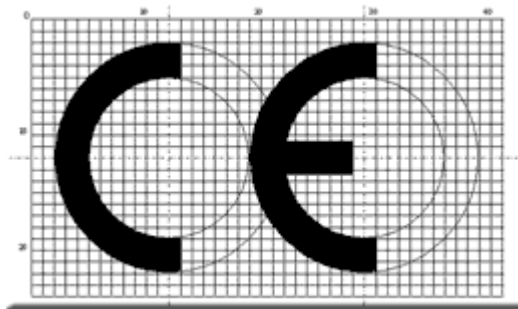


Figure 12 Official CE-mark (European Union, 2018)

CE marking should be affixed visibly on the product, or on its data plate so that it is legible and indelible. If this is not possible due to the nature of the product, the CE mark needs to be affixed on the packaging if any, and/or with a certain document. For instance, the marking can be affixed on the back or underneath the product for it to meet the requirements for visible means. However, this does not mean that the mark is needed to be visible before opening the packaging of the product. A must know is that it should under no ‘normal’ circumstances be possible to remove the mark without leaving noticeable traces.

There are cases when CE marking can be left out on certain products. (European Union institutions, bodies, offices and agencies, 2016)

5.2 CE marking for the manufacturer/importer/distributor

Manufacturers' responsibility is to make sure that the products follow the legislation regarding the affixing of the CE mark. Together with the importer they have a key role in making sure that only products which are in accordance with the legislation and bear the CE mark are placed on the market. This helps to strengthen the European Union's safety, health and environmental protection requirements, as well as to support fair competition where all stakeholders and competitors obey the same rules.

Manufactures may not be represented in the EEA, which implies that importers have a larger responsibility to make sure that the products introduced by them to the market fulfil the needed requirements and are not a risk to the EU. They also carry the responsibility of making sure that the documentation is available, if ever requested. National authorities may not understand the union harmonisation acts or have the necessary documentation such as the technical documentation. This in turn means that importers must have the knowledge and provide necessary support. Furthermore, importers should have a written assurance from the manufacturer that they will have access to the necessary documentation and are able to provide it if requested. Importers should also make sure that they always can have contact with the manufacturer.

Distributors need to have basic knowledge regarding legal requirements, including which products need to bear the CE mark, and what documentation is to accompany the product. Furthermore, they also need to demonstrate to national authorities that they have acted with due care and have confirmation from the manufacturer/importer that the necessary measures have been taken in regards to the CE mark.

But if the importer / distributor places products on the market with his own name, trademarks or modifies them, he then takes the full responsibility for the affix of the CE marking and the conformity of the product. In this case, the manufacturer cannot be held responsible for any inconveniences that may occur afterwards.

For this to be achieved, all sufficient information on the design and product needs to be in the importer/distributor/other operator property, as he from now will be assuming the legal responsibility when affixing the CE marking. (European Union institutions, bodies, offices and agencies, 2016)

6. EC declaration of incorporation

As stated earlier, prior to the introduction of the machinery to the market, the manufacturer is obligated to draw up and sign a declaration of conformity. Since the generating set applies as a partly completed machinery, a declaration of incorporation is to be used instead. With this document, Wärtsilä shows that the generating set complies with all the relevant requirements of applicable legislation, and that Wärtsilä takes responsibility for this being true. This declaration needs to be kept for ten years after the machinery is introduced on the market, if nothing else is written in the legislation.

The declaration of incorporation may be a document, label or similar but needs to have the essential information regarding the product for it to be traceable.

The information needed in the Declaration of incorporation is as follows:

- The manufacturer's or the authorised representative's full business name and address
 - Name and address shall be the same as used on the machine
- The person in charge over the technical documentation's name and address
 - The person needs to be within the company, and cannot be a third party
- Description of the partly completed machinery for it to be identified, including generic demonstration, type, function, serial number, model and commercial name
 - If the machine is produced in large series, the manufacturer may produce a single EC declaration for multiple serial numbers and batches.
- A sentence which declares which essential requirements of the machine directive is fulfilled, and that the technical documentation provided match the standards of part B of Annex VII. Additionally, a sentence should also be produced, which declares the conformity of the partly completed machinery with other directives, granted that they are relevant.
 - Note that when creating these sentences, the directives which are referenced must be originating from texts published in the Official Journal of the European Union; OJEU.
- Date and place of the declaration
 - The place mentioned mostly is the place the manufacturer or his authorised are established.

- The person empowered to establish the declaration on behalf of the manufacturer or his authorized representative's identification and signature
 - The identification refers in this case to the person's name and position
 - Reproduction of the signature is approved on the copies of the declaration of conformity, which accompanies the machinery
- If applicable
 - A statement that declares that the partly completed machinery should not be put into use before the final machinery into which it is to be incorporated has been declared in conformity.

(Franser, 2010), 333-343

6.1 Partly completed machinery assembly instructions

The manufacturer or his authorized representative shall draw up assembly instructions for partly completed machinery which will be handed over to the manufacturer of the final machinery. The instructions will thereafter be a part of the final machinery's technical file.

The assembly instruction language must be one of the official EU languages which the manufacturer for the final machinery approves, however, the manufacturers may agree which language will be used for example in the contract of sale, but if there is no agreement the assembly instructions language shall be the official EU-language used in the specific country where the manufacturer of the final machinery is established.

All the safety related aspects regarding the partly completed machinery and of the interface between the partly and final machinery, which the assembler needs to take into consideration when incorporating the partly completed machinery into the final machinery, shall be indicated in the assembly instructions.

If some safety requirements have not or only partly been fulfilled by the manufacturer of the partly completed machinery the manufacturer of the final machinery needs to take actions for these requirements. (Franser, 2010), 357-358

6.2 Technical file for a partly completed machinery

To ensure the product's conformity with the applicable requirements the manufacturer is obligated to draw up a technical file which must be available when the machine is placed on the market. (European Union institutions, bodies, offices and agencies, 2016), 58

The technical file's aim is that the manufacturer can strengthen the machine conformity of the essential health and safety requirements, and furthermore to help the market surveillance to check the machine conformity.

The technical documentation for partly and completed machinery have some differences. Partly completed machinery requires a construction file which include: overall drawing of the machinery and control circuits, detailed drawings which includes any calculation notes, certificates, test results etc. to be able to check that the essential health and safety requirements have been applied.

Furthermore, documentations over risk assessments includes:

- A list of applied and fulfilled essential health- and safety requirements
- A description of the safety measures introduced to remove identified risks or minimise risk and in certain cases information regarding the residual risks
- Used standards and other technical specifications covering the essential health and safety requirements
- Manufacturer's test reports including the results of different tests. These tests may also be carried out by a third party, chosen by the manufacturer.
- A copy of the partly completed machinery's assembly instructions

In cases of serial manufacturing, documents showing which internal actions implemented to make sure that the partly completed machinery remain equal with the essential health and safety requirements must accompany the machinery.

To make sure that the partly completed machinery is constructed and manufactured for it to be assembled and used safely, the manufacturer shall carry out necessary research and tests on the different components, these reports and tests shall be included in the technical file.

Furthermore, this technical documentation needs to be saved for ten years from the date the machinery was placed on the market. The saved technical documentation does not need to be in material form permanently, nor available on the internal territory of the community. (Franser, 2010), 359-366

6.3 Risk assessment

The risk assessment is an annex in the machine directive. By identifying hazards, some accident which are related with the machinery may be prevented. When the potential hazards are identified it is possible to eliminate these risks and apply the health and safety requirements. The manufacturer of the machinery, his authorised or a person acting on their behalf is responsible to carry out a risk assessment. In the procedure of carrying out the risk assessment they shall:

Determine the machine's limit which includes identifying its intended use and predict possible incorrect use of the machine → identify possible hazards and how possible risk situations may intend → judging these hazards and how serious the situation may be → evaluate if the risk have to be reduced → eliminate or by using protective measures reduce these risks.

If the risk assessment is carried out by a person acting on the manufacturer's behalf, the manufacturer still possesses the full responsibility for the risk assessment as well as reducing possible hazards and implement protective measures. It is thus not possible to abolish the responsibility of the risk assessment by simply appointing a third party to perform it, the responsibility still lies with the manufacturer.

After the evaluating of the risks, the machine has to be designed and constructed in accordance to the risk assessment. The final risk assessment shall be a part of the technical documentation.

The essential health and safety requirements shall be distinguished from the harmonised standards - the health and safety requirements in the machine directive are mandatory while the harmonised standards are voluntary. However, it may be impossible to meet all aims in the machine directive. In such circumstances where they are not implemented, the machinery has to be designed and manufacturer to approach them as far as possible. The technical solution used in the design and manufacturing of the machine needs to be the most effective solution at the time for a reasonable cost to be able to apply the essential health and safety requirements. Even though a manufacturer can only apply the technical evaluation possible at the time when the machine is manufactured, should a more effective technical evaluation to a relative cost become available which would help achieve the requirements more closely than the manufacturer's design has to be upgraded accordingly.

The risk assessment annex consists of several parts. First there is a general part which is applicable to all kinds of machinery while the other parts refer to more specific hazards which are shown in the Figure 13 below. Additionally, there are three sections which are mandatory to apply, they are: Principle of safety integration (1.1.2), marking of machinery (1.7.3) and Instructions (1.7.4). (Franser, 2010), 141-145

Parts 2 to 6 of Annex I deal with the following specific hazards:

- | | |
|--------|---|
| Part 2 | hazards specific to certain categories of machinery: |
| | – foodstuffs machinery, |
| | – machinery for cosmetics or pharmaceutical products, |
| | – hand-held and hand-guided machinery, |
| | – portable fixing machinery and other portable impact machinery, |
| | – machinery for working wood and material with similar characteristics; |
| Part 3 | hazards due to the mobility of machinery; |
| Part 4 | hazards due to lifting operations; |
| Part 5 | hazards specific to machinery intended for underground work; |
| Part 6 | hazards due to the lifting of persons. |

Figure 13 Annex according to risk assessment (Franser, 2010), 145

7. Other standards applicable to this thesis

There are other standards and directives which also may be relevant to CE-marking. For instance, ISO standards which are implemented in the risk analysis, ATEX directive which are implemented if the project is used in potentially explosive atmospheres and finally the PED directive which is implemented on pressure hazards.

7.1 ISO standard

ISO stands for ‘International Organization for Standardization’ and is an independent international organization. Almost every industry such as, food safety and technology are covered by international standards published by ISO which means these standards has an impact for almost everyone.

162 nations have a membership in the organization, represented by one member per country. Individuals and companies are excluded from ISO membership since this could pose a conflict of interest. Figure 14, located below, illustrates different nations status regarding ISO membership. As of today, more than 22009 international standards have been published. (International Organization for Standardization, u.d.)

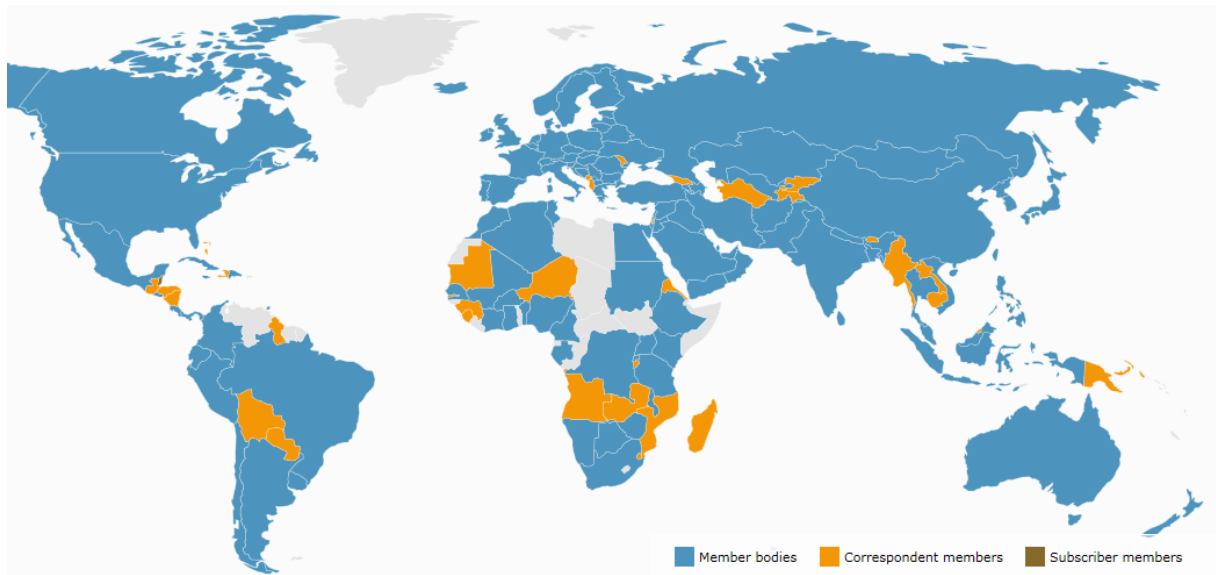


Figure 14 ISO members states (International Organization for Standardization, u.d.)

The machine directive in turn refers to certain ISO standards which is why they are highly relevant in this case. The ISO 12100:2010 is the standard which is mentioned the most within the machine directive.

This standard covers a risk assessment as well as risk redirection and is referred to in most companies’ declarations of conformity/incorporation. The primary purpose is to achieve safety in the design of the machine and for the machine to be safely used. The standards are put into three categories: A-, B-, and C-standards. Together, they cover basic safety-, generic safety- and machine safety standards. Furthermore, the standard specifies principles in risk redirection and risk assessment. (European Committee for Standardization, 2010)

7.2 ATEX – Directive

The ATEX directive 2014/34/EU, previously named 94/9/EG, must be applied on equipment and protective systems which are going to be used in potentially explosive atmospheres.

Accompanied with the equipment and protective systems the following instructions are needed:

- A summary where equipment or protective systems are marked, together with the summary of adaptable additional information to support maintenance.
- Safety instruction for use, assembly, dismantling, putting into service, maintenance, adjustment and installation.
- Information which will collateral that the equipment for a certain category or protective system may be safely used in the intended area under expected operating conditions
- Critical limits of certain values, for example electrical and pressure parameters
- If necessary:
 - Training introductions
 - Information regarding possible danger zones.
 - Condition of use, and possible misuse which by experience have previously occurred
 - The most important characteristics of the tools which can be fitted to the equipment or protective system

Furthermore, the instruction must include drawings and diagrams necessary for maintenance, service and inspections etc. (European Parliament, Council of the European Union, 2014)

The instruction language must be the language used by the manufacturer or his authorized representative.

When the product is put onto service a translation of the instructions must be made for all equipment and protective systems. The translation language shall be the language / languages used in the country where the equipment or protective system will be used. The manufacturer, his authorized representative or the supplier is the person in charge for the translation of said instructions.

The maintenance instructions on the other hand, which will be used by the specialist personnel employed, shall be translated to the language used and understood by the employed specialist.

Just as with the CE-marking the ATEX mark must be visible, readable as well as durable. The mark must be put on a place which is visible from the outside and the letters must be large enough to be readable. If the mark is affixed on a sign it shall be permanently fastened, preferably through welding, bonding or reverting. (Franser, 2010)

The specific mark of explosion protection shall be used:



Figure 15 ATEX logo (Wikipedia, 2018)

Followed by the mark we can see above, an additional symbol of the category of the equipment shall be used. The equipment group II, explosive atmospheres caused by gases, vapours or mists uses the mark 'G'. The letter 'D' is meant for equipment concerning explosive atmospheres caused by dust. (European Union institutions, bodies, offices and agencies, 2016)

7.3 PED – Directive

The PED directive is a directive which covers pressure hazards. The directive, 2014/68/EU, previously 97/23/EG, is enough to make an appropriate assessment regarding the hazards related to high pressure. The purpose of this standard is to ensure that pressure equipment is safe within the European Economic Area.

The directive covers equipment with pressure over 0.5bar. Equipment with less than 0.5bar is deemed to not have a significant impact on hazards due to the low pressure.

Pressure equipment must be designed, manufactured, controlled and, if applicable, installed in a way that their safety is guaranteed when the whole product is put into use.

Just as with EC-declaration and ATEX, the PED directive needs a technical file. However, depending on different classifications of the machinery, the technical file includes different documentation. This means that it is important to have a good conversation with the customer in order to be able to provide the right documentation.

The manufacturer is responsible to make sure that the CE marking is affixed on all individual pressure equipment as well as drawing up a EU declaration of conformity for pressure equipment and saving it together with the technical documentation for 10 years. (European Parliament, Council of the European Union, 2014)

8. Theoretical studies in the practical work

To be able to handle this task, theoretical studies have played a key-role in gathering information in order to be able to understand CE marking itself and furthermore, what the CE mark actually covers. The documents are extensive in terms of content, meaning they can take a long time to read through. The essential documents of this study were:

- “Blue guide”, which is an introduction guide for the EU-member countries regarding free movement of products and high level of protection throughout the EU market.
- “Machinery directive”, which is an essential and important document that covers all essential health and safety requirements.
- Essential ISO standards such as, ISO 12100 Safety of machinery and ISO 14121. The standards are referred to in the declaration of incorporation.
- Harmonised standards, standards for everything covering health and safety
- Essential documents from the EU and Tukes official websites
- Information covering ATEX, mainly 2014/34/EU
- Information covering PAD, mainly 2014/68/EU

However, it was important to be able to have an understanding regarding the actual machinery which this thesis work has covered, namely the generating set. Previous work as a trainee at Wärtsilä during two summers has helped to acquire the basic information about Wärtsilä products, but unfortunately not enough to be able to have the full understanding. Expert Mr. Johan Wasberg has acted as supervisor from the Wärtsilä side, he has also gone through the same material as this thesis require regarding CE marking. Initially a meeting on the 2nd of October 2017 was conducted at the Wärtsilä factory in Vaasa city. Throughout the day all necessary information regarding the generating set as well as Wärtsilä’s engines was thought out, providing a good start for more theoretical studies. Through the factory tour together with product guides, Wärtsilä’s homepage and an information document put together by Mr. Wasberg the necessary information in order to be able to include the theoretical information into the practical work was finally bundled together.

To mark and organise all information was necessary, otherwise it would have been difficult for other employees involved to share constructive criticism on the practical work. Furthermore, all of the documents containing information were read in both Swedish and English. Reading in Swedish was useful in order to go through the documents more quickly and to screen out the essential information, which all had to be relevantly applicable to the generating set.

After the relevant info was marked in the Swedish version, the English version was read through in order to get the best understanding. This is possible due to the fact that the EU must provide all information and documents in most languages used within the EU.

In order for a manufacturer to be able to apply the CE mark on a product, different directives need to be followed. The CE mark itself was helpful to understand, but everything it encompasses took a while to comprehend. The EC directive was the first problematic directive to figure out and understand. The question remained, how would the best way to clarify it in a project be. By printing out essential pages and putting the machinery directive into three different sections helped in order to comprehend this 800-page long document. The result was the following three sections: Annex I: information covering the risk assessment and Annex II: everything covering EC declarations. The remaining pages left were either removed or saved as one section. Afterwards, everything essential was highlighted and notes were marked out, which eased the locating of finding the right information quickly.

The major thing which made it helpful to sort out necessary information is that the generating set is covered as a partly completed machinery which basically means not all information in the machinery directive covers this particular kind of machine.

Further on, there was an ongoing project where the CE mark had already been issued, which then presented the next task. The task was to investigate how the CE marking process was conducted in that particular project and from there, criticise both the process and the approach. The investigation also shed light on the practical approach, which provided factual evidence that this thesis work was not only relevant but also correct. Parallel with the Wärtsilä project, other companies' solutions and understandings regarding EC declarations became important. With the help of their declarations, several ideas of what information needed to be implemented in the template as well as the graphical design came into mind. Tukes (Finnish Safety and Chemicals Agency) in turn, had examples of templates and further information about how to affix the CE mark.

The machinery directive as well as the project which was previously done at Wärtsilä both referred to ISO 12100. This was understandable since this particular ISO standard covers machinery safety. All machinery should thus be able to apply this ISO standard for basic health and safety. This ISO document was necessary to read through parallel with the risk assessment needed to be done for the EC declaration.

Through Wärtsilä access was granted to register to the website Saiglobal, from where Wärtsilä has bought certain ISO documents such as the previously mentioned standard. This was very fortunate, otherwise the struggle with buying the document myself or completely leave it out from the theory would have come up.

The CE mark demands theoretical studies in order to achieve a complete understanding on how to implement it in projects which, naturally, was the case for this thesis as well.

8.1 Methods with arguments

A method which was used in order to get all documents that this thesis required was through conducting regular meetings with Mr. Wasberg. The key point of these meetings was to determine, from a critical point of view, how the application process of the CE mark should be conducted.

It was very beneficial to discuss some of the thoughts with another professional colleague to get two or more point of views, especially since some of the information in the official standards' documents can be interpreted differently.

Later on in the work there were more frequent meetings in order to get the template for essential health and safety requirement. This template will be discussed in detail later. The other templates required meetings as well, in order to make sure that the templates would meet the standards required.

9. Smoother projects through the usage of finished templates

The practical work includes all documents which are needed for CE marking the generating set. Note that the generating set is a partly completed machinery, which means that the documents for the CE mark is not the same as it would be for a complete machinery.

Templates for these documents will in turn lead to more efficient and simpler CE marking processes, which hopefully will enable the employees involved in projects to devote more time into other important matters. Thanks to the previously done project at Wärtsilä as well as looking at other company's documents, it was easier to have a clear picture on what shape was preferred on template. This together with the newly learned theoretical knowledge, a good picture regarding the content of these templates came into mind.

In all the templates, there are information boxes which describes the template itself. Furthermore, there are yellow highlighted parts and/or blue parentheses in the document which are meant for the project engineer(s) to fill in information which is essential to the specific project. This could for instance be the name of the project, the project manager in charge, dates and other important information. Upon viewing the template, one can see certain highlighted areas, which in turn have a more thorough description in the comment section, located to the right of the template itself. Bear in mind that both these highlighted parts and the comments should be deleted before saving the final document as a PDF file.

9.1 Step by step guide

One of the first documents a project engineer or project manager will need is the 'step by step' guide. This document is made for project engineers and project managers, allowing them to get familiar with the actions they need to execute if a project demands CE marking. The main goal of this guide is to give the reader a simple, yet comprehensive guidance in order to make the process more efficient in terms of time usage. The guide is also helpful in rapidly giving the reader a clear picture of what is expected from Wärtsilä in these projects. The completed guide can be found in the annex chapter, denoted as annex I.

The steps are written, starting from the sale stage and ending with the execution stage. In the sales stage, information regarding the identification of requirements such as CE marking, ATEX or PED is found. Furthermore, it also informs offers preparation- and resource planning, which includes, the importance of making sure the essential documents are sent from our customers to Wärtsilä in time.

The execution phase is dealing with the practical execution of purchase orders, signing documents etc. Links to templates for the different documents are also found in this section.

The last chapter covers the case if an employee wants further information regarding CE marking, ATEX and PED directives. Links to all essential documents and webpages is found in this section, as well as a short guide on how to get access to downloading and reading ISO standards as a Wärtsilä employee.

This step-by-step guide is different from the others in the sense that it is not made to be changed in any way, this due to the fact that it is simply a guide and not a template. Naturally, should any regulations be altered, this in turn will force changes in the step by step document.

Together with Mr Wasberg and document coordinator Ms. Stam additional meeting was conducted on the 19th of February 2018 regarding the ATEX and PED directives. Both colleagues have handled projects where these directives have been applied and thus a meeting with both of them was crucial in order to ensure that the step by step guide contains the necessary and correct information. The finished step by step guide is found in the appendices chapter as appendix 1.

9.2 Templates for EC declaration for incorporation and technical file

The EC declaration of conformity and in this case, incorporation of a partly completed machinery is a document, which is the first document a project engineer may need from other companies where Wärtsilä buys items / parts from. Such a part could, for instance, be the generator. The information in this document covers information regarding what standards are applicable, and that Wärtsilä ensures that their product is safe to use.

An EC declaration of incorporation is needed for the generating set. In order to simplify this process, a template for this has been made for the Marine Solution department to use. The information which is essential to be presented in the declaration is described well in the machinery directive and in the previous projects where this declaration has been made.

It helped greatly to see some specified information, for instance who had been responsible for signing the document from project management side.

The technical file is a template with all drawings and information documents which are essential to the product. The template was made for the project engineer to know exactly what document has to be found in the file without having to read the machinery directive.

The template is made to allow copy-pasting of links to the drawings/information.

The finished templates is appendix 2 and 3 in the appendices chapter. Please note, comments which can be found in the official version were deleted for the PDF versions to make the graphic look better as a whole.

9.3 Information guide

The theoretical part in this thesis which concerns information regarding CE marking, harmonised standards, EC declarations, ISO standards ATEX and PED was made as an information guide. This in order to make it easier for the employee concerned to read the most essential information and get a broader picture regarding what a CE marked project involves.

To have all employees who are concerned in the project to read through all guides and document regarding CE marking and EC declaration would be strenuous and inefficient. The information guide will therefore be a good training material without having to devote too much time, but still allowing the reader to grasp the subject's entire picture.

9.4 Risk analysis for the generating set, Marine Solution

The Risk assessment and risk analysis was this thesis' practical work, which took the most time and effort. This, because the documents are not meant to be changed in a near time, it is generally made for all generating sets and therefore it was made with a lot of concern. However, product specific assessment must be carried out for each declaration. Together with Mr. Wasberg, several meetings were conducted where the machinery directive Annex I was gone through. To showcase the large amount of effort this stage required; there are in Annex I alone some 151 hazards to consider for all machineries put on the EU market.

An excel sheet where all hazards were written was followed including the following sections:

- Applicable, yes/no
- Requirements fulfilled, yes/no
- Applied EN standard(s) or other guidance
- Applied clauses of the standards
- Generator fulfilled requirements
- Engine fulfilled requirements

The hazards were investigated one at a time and taken into consideration whether each and every one was applicable for the generating set or not. An example of a hazard which was declared in the declaration of incorporation is shown below in Figure 16, in Figure 17 is the followed answers.

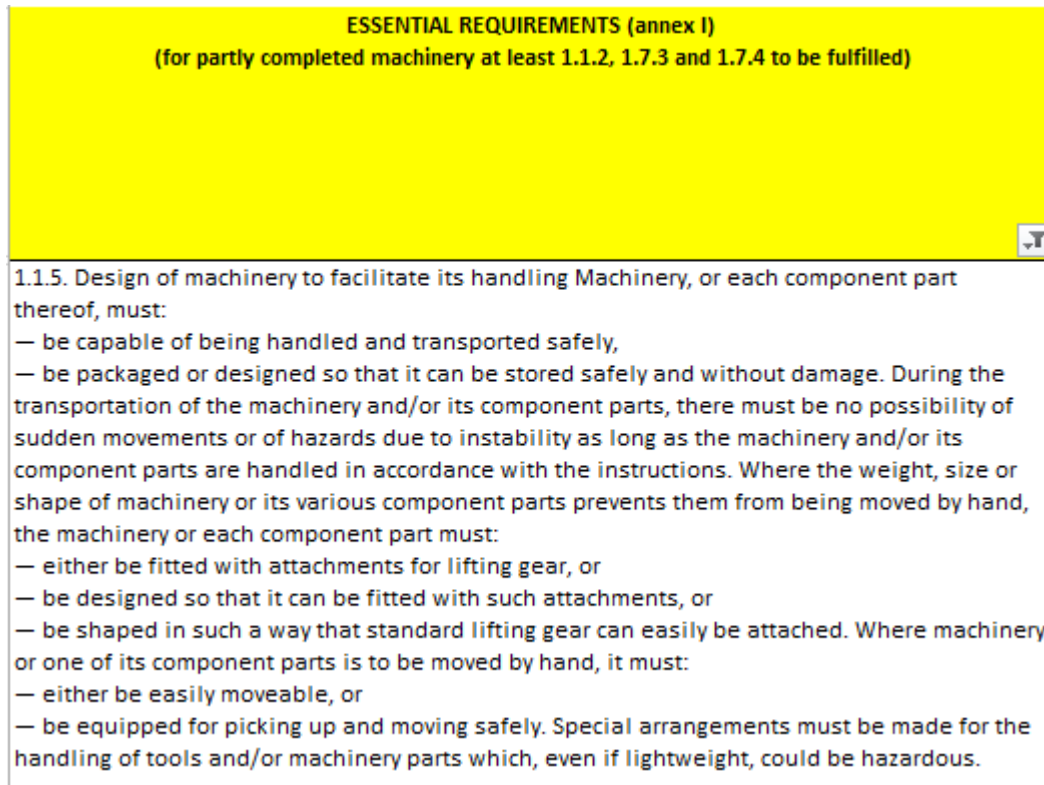


Figure 16 An example of a hazard

If the answer to that question was *yes*, the question whether the generating set fulfils the required safety actions needed or not needed to be answered. Additionally, it was also compulsory to investigate whether Wärtsilä had prevented the hazard in the right way to be able to declare the hazard as fulfilled. If both answers were *yes*, then continued thinking followed regarding if it was going to declare it or not. If there was any doubt regarding this the decision was to not state that the hazard prevention was fulfilled in the declaration. This, in order to prevent Wärtsilä from facing legal reprimands in the future. On the other hand, the mandatory points were of course declared as well as some others which the generating set was deemed to confidently fulfil. Afterwards, a note regarding why and how we had arrived at this conclusion was written.

Applicable — yes/no	Require- ments fulfilled yes/no	Applied EN standard s/ other guidance	Applied clauses of the standard s	Notes	Generator fulfilled requirements	Engine fulfilled requirements	Shipyard responsibil- ity for there applicable but not fulfilled items	Items declared as fulfilled in the DoI of the gener
Yes	Yes			The generating set weight is depending on the specific design for the delivery project and therefore provided with lifting lugs in the common base frame according to the specific configuration of the product. The design calculations are part of the technical file and shows accurate safety levels. During transport and storage is the generating set protected by tarpauline.	x	x		x

Figure 17 Answers applicable to Figure 16

If the hazard was applicable but the generating set cannot meet the requirements it was made clear why Wärtsilä cannot meet the requirements in the note section.

There is also a possibility that the hazard is not deemed to be applicable to the generating set at all, this is common when the hazard covers all kind of machineries. However, if the conclusion was that the hazard was not applicable at all it was given the value *no* and, in some cases, a note was written as to why and how the way to the conclusion had been carried out.

Regarding the section Applied EN standard(s) or other guidance means, if the generating set cannot meet the requirements it is possible it can meet other standards which have the same effect. Considering there are many standards, it was not possible to go through all of them and even though there are standards which should have been good to cover there was unfortunately not enough time to investigate them.

Wärtsilä does not manufacture any generators themselves. Instead, these are purchased from a third party, and from this company we acquire the declaration of conformity/incorporation of the generator.

Through this declaration it is possible to see whether the manufacturer for the generator thinks the generator fulfils the requirements or not. The same thing goes for the engines, the declaration for the engine itself is not made by Project management but the engine designer. In the sections generator fulfilled requirements / engine fulfilled requirements an “X” was made, this was the main point for making the decisions for some hazards, if it was fulfilled from both sides the generating set could in most cases also fulfil the requirements.

This risk assessment had previously been made for a specific project which made it go somewhat smoother, but since we wanted to make it generally applicable there was a lot that needed to be changed from the previously done one.

By applying multiple sheets to the excel workbook it became more polished and easier to read. Constructing this excel sheet called for good technical knowledge, as well as design knowledge and good insight into how the generating set is manufactured. The assistance that Mr. Wasberg provided at this stage cannot be highlighted enough.

On the 19th of February 2018, a meeting was conducted by me, Mr. Wasberg and Manager Mr. Klockars. The meeting's agenda revolved some of the hazards that were still undetermined. These were all hazards which were related to the electrical parts of the generating set. A person with more expertise to share thoughts with was needed. Thankfully, Mr. Klockars' knowledge on the matter ensured that the conclusions were indeed factually correct. In Figure 18 the hazard regarding failure of power is found. This was one of the hazards Mr. Klockars' help and expertise was needed in order to settle its status. Thanks to the meeting with Mr. Klockars, the best possible analysis and answers was ensured. A pdf version of the risk analysis is located in the appendices chapter as appendix 5.

ESSENTIAL REQUIREMENTS (annex I) (for partly completed machinery at least 1.1.2, 1.7.3 and 1.7.4 to be fulfilled)	Applicable — yes/no	Requirements fulfilled yes/no	Applied EN standard s/ other guidance	Applied clauses of the standards	Notes
1.2.6. Failure of the power supply The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations. Particular attention must be given to the following points: — the machinery must not start unexpectedly, — the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations, — the machinery must not be prevented from stopping if the command has already been given — no moving part of the machinery or piece held by the machinery must fall or be ejected, — automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded, — the protective devices must remain fully effective or give a stop command.	Yes	No			The system is prepared for redundant power supply. Requirement that one of the two supplies is with battery backup. If total power supply is lost protective devices does not remain fully effective but the generating set will stop due to forward acting fuel rack actuator. If the engine is a DF in gas mode it will stop due to lost electronic fuel injection control

Figure 18 Hazard regarding failure of power supply

9.5 Risk estimation according to ISO 12100

In the technical file a risk assessment is implemented, which is based on ISO 12100 Safety of machinery. Hazards had previously been identified through the risk analysis which needs to be conducted before the risk redirection. From the identified hazards the task was now to think one step further and analyse how the scenario could look like, namely how likely is the scenario to occur, and if so how severe is the harm that the hazard produces?

The template for the risk assessment was drafted from ISO 14121, which covers practical guidance and examples for the risk assessment. Thanks to the examples in the ISO standard and the previously done risk assessments the template and final document was made.

The risk assessment is made in four different sections: Hazard identification, Risk estimation, Risk evaluation and finally Risk reduction as can be seen in Figure 19.

Risk assessment and risk reduction																						
Project		Project name										Document number				Revision						
Partly completed machinery		Workfile engine and serial number										Page				Author						
Information sources used		Technical file										Checked by				Approved by						
Method(s)		Checklists ISO 12100:2010, Annex B										Risk graph ISO/TR 14121-2:2012, Section 6.3.2										
Hazard identification			Risk analysis					Risk estimation					Risk evaluation					Risk reduction (when applicable)				

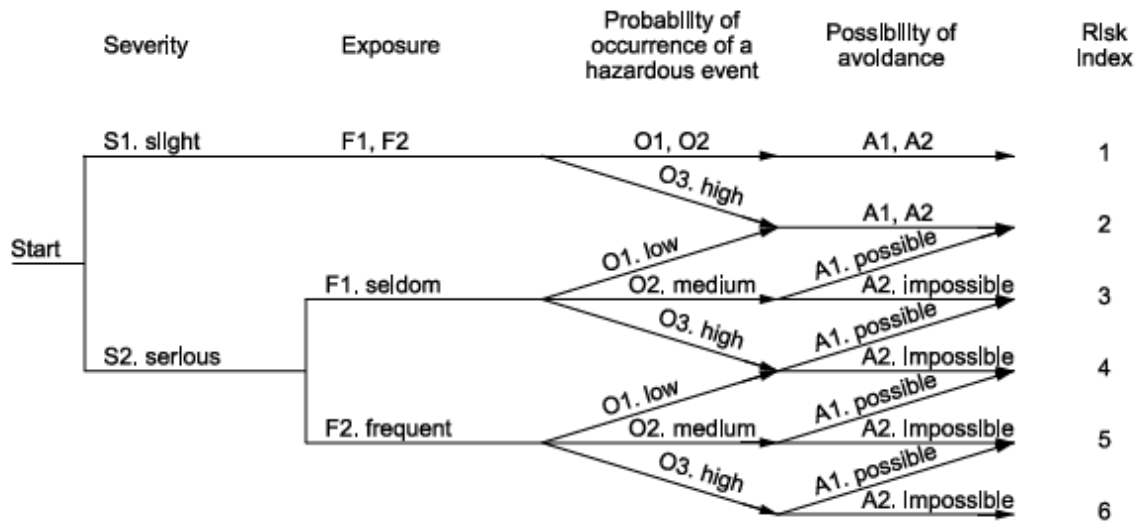


Figure 21 Risk graph (ISO/TC, 2013), 14

However, in order to arrive at a conclusion, the hazards which had been identified in the risk analysis was analysed with the following steps:

→ If an employee would get an injury from the discovered hazard, how serious would the injury be? We choose S1 for slight injury and S2 for serious

→ How often is an employee exposed to the hazard? F1 for rarely to quite often and exposed a short period. F2 for frequent and long explosion.

→ How high is the probability for the injuries to inflict due to the identified hazard? O1 for low, O2 medium and O3 for high

→ And lastly, how possible is it to avoid the harm? A1 for sometimes possible and A2 for impossible.

From the following answers the hazard would fall under a certain category. Should the hazard fall under the categories medium or high risk, then Wärtsilä has to prevent this hazard with a risk redirection and furthermore, estimate the hazard once more in the same way as previously done. If the hazard is estimated as 1 or 2 it was clear to proceed.

The identified hazards were mostly related to the flywheel and to extreme temperature, but thanks to the flywheel cover and the identification of these hazards in the instruction book, the risk index indicator landed on 1 and 2. The risk estimation is found in appendices chapter as appendix 4.

10. Conclusion and reflections

After all of the templates were verified and approved, they were in turn uploaded on Wärtsilä's documentation network IDM. From there, the people concerned can access them and use them. Together with the step by step guide, these templates serve as a useful toolkit ensuring a good start with the CE marking of products in the future.

As they were uploaded the goal was reached for this thesis. From here, I wish the templates will get frequently used as soon as Marine solution receives a project which involves CE marking. Furthermore, I hope that this thesis will make a great fit as training material for anyone wanting to get a quick training with just the essential information regarding CE marking of the generating set. Considering that there was the previously done project to look back at and criticise, it magnified the sense of impact that this work had.

Thanks to having a supervisor who had good knowledge and a solid background within this topic, the thesis as a whole went smoother than expected. It was immediately clear which theoretical documents were essential to start with, and from there the next step and what other information that would be useful to take into account. Through weekly meetings I knew how to proceed with my work and what needed to be looked through a second time. It was grateful to be stationed at the same location as during my trainee period, and therefore I had the opportunity to spend most of my writing time at the office. This enabled not only the achieving of a high level of efficiency, but also making enquiries in person which resulted in rapid communication with my supervisors.

The most difficult part was to be confident that every piece of information correctly was understood correctly, which was a requirement for knowing what the templates should look like and what they should contain. I initially was not aware of how much the CE mark covers and how much is needed to be implemented in a project for it to be eligible for CE marking. Most of the information was read multiple times and the reading took much more time than I expected from the beginning. I should have tried to come up with a more efficient way to remember from where I had read what specific information sooner than I actually did. Additionally, I would also have started with the templates much sooner to get the risk analysis started earlier. But in the end through effective meeting I do not think I had any time loss in the end and the result was done in the timeframe expected.

I know this thesis have given me knowledge which I can make use of at multiple companies and positions further on throughout my working career. I am grateful for the opportunity to have gotten a deeper understanding of such an important standard, as well as to get a basic understanding of the PED and ATEX directive.

I wish to extend my *deepest gratitude* to my supervisor Johan Wasberg at Wärtsilä for handing me this thesis work from the beginning, and continuously being supportive in countless ways to make this thesis as good as possible.

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