

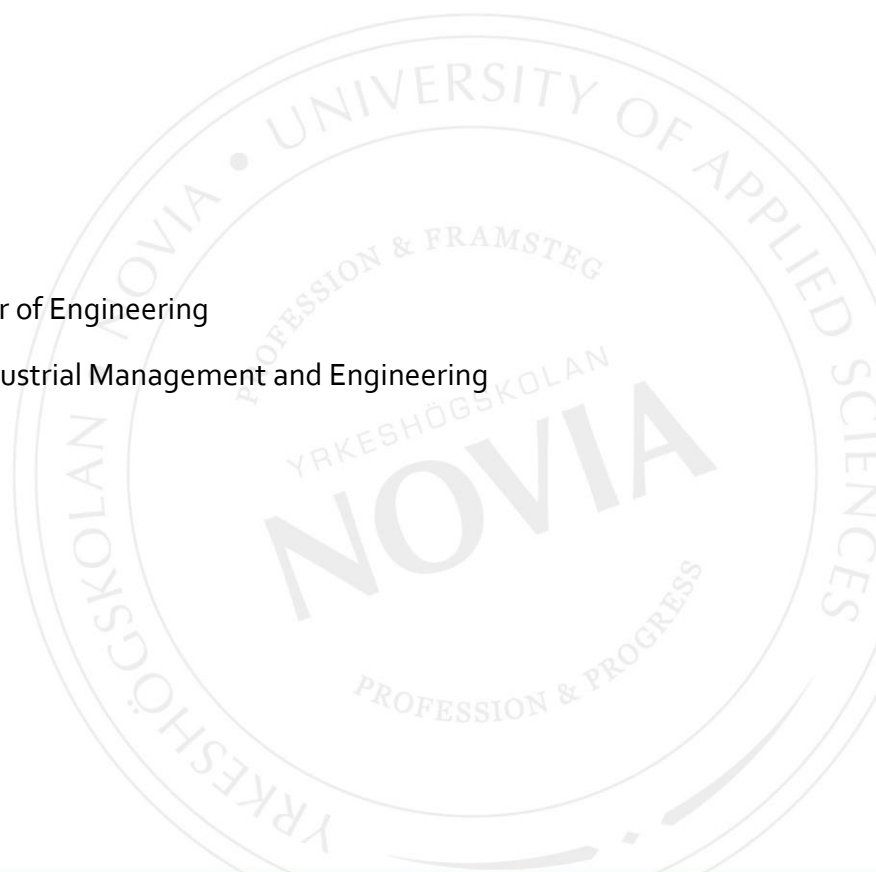
Auxiliary equipment portfolio introduction for Wärtsilä Marine Solutions

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EXAMENSARBETE

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Titel: Introduktion till validering av extrautrustning för Wärtsilä Marine Solutions

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Detta examensarbete behandlar validering av ny utrustning som Wärtsilä överväger att använda i sina fyrtakts motorer. Huvudsyftet med examensarbetet är att skapa en valideringsprocess som ska användas vid utvärdering av komponenter och underleverantörer.

Jag har använt mig av en kvalitativ metod i examensarbetet. Inom ramen för fältstudien har djupintervjuer utförts med utvalda experter inom ämnesområdet. Därtill bygger examensarbetet på grundläggande litteratur och journalinventering.

Resultatet är en valideringsprocess som är uppbyggd i programmet Microsoft Visio. Valideringsprocessen beskriver de olika steg som bör beaktas då utvärdering av nya komponenter och underleverantörer genomförs. Tillsammans med valideringsprocessen presenteras förklarande text och figurer.

Språk: Engelska

Nyckelord: Validering, Affärsutveckling, Flödesschema

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This thesis work is going to process validation of new auxiliary equipment that Wärtsilä is considering using in their four-stroke engines. The main purpose of the thesis is to create a validation process that will be used when evaluation of components and suppliers are done.

I have used a qualitative method in my thesis work. I have done deep interviews with selected experts in the subject as well as thorough literature and journal inventory.

The result of the thesis work is a validation process that is made in Microsoft Visio. The validation process describes the different steps that should be taken into consideration when evaluating new components and suppliers. Together with the validation process, I also present explanatory texts and figures.

Language: English

Key words: Validation, Business development, Flowchart

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1 Introduction

This thesis work is going to process the subject “Auxiliary equipment portfolio introduction”. The assignment was given to me on behalf of Sales tools in Wärtsilä Finland Oy Marine Solutions, Marine Engineering Department.

Wärtsilä is a world leading company in advanced technologies and complete lifecycle solutions for the marine market, and major part of auxiliaries used in Wärtsilä Marine Solutions are third party equipment.

It can be risky to introduce new equipment in connection with the engine and that is why it is important to focus on the quality of the product already at an early stage of the introduction. Introducing new suppliers and material compositions also carries a threat. The same applies to the change of manufacturing methods. Therefore, new products at the development stage should undergo tests such as calculations, analysis and review, before they are accepted. This should be done according to a certain system, a production qualification process that is considering all the factors, to guarantee the product's reliability and quality.

To ensure compliance with the complete engine portfolio, Wärtsilä is in need of developing a validation process for auxiliary equipment used together with four-stroke engines.

1.1 Purpose

The main purpose of this thesis work is to describe and solve the problem that was given to me and to provide the company a guidance for how they should use the solution. I strive to create a process proposal that evaluates new equipment Wärtsilä wants to use in connection with four-stroke engines. The process will also describe what product criteria Wärtsilä must be aware of when they are doing a contract with a new supplier or when the supplier changes the design of an equipment.

My intention is to produce a comprehensive product validation at a high-quality level. The goal is that the process corresponds to the criteria that is required for auxiliary equipment used for Wärtsilä four-stroke engines. The process shall be easy to use and easy to understand. The process shall also be well enough documented to be used as a pilot process together with a selected third - party equipment supplier.

The thesis requires background studies of current Wärtsilä validation processes used for third - party equipment suppliers. I will also discuss with other stakeholders such as the sourcing department and use available literature.

1.2 Problem area

The main problem in my study is that there is currently no official process for validation of auxiliary equipment for four stroke engines available in Wärtsilä. Today, components and suppliers are validated separately for one specific component whenever there is a specific need.

The assignment is to create a formal pilot process that defines the workflow of steps to approve and decline the use of certain equipment. The process will be used when Wärtsilä uses new equipment, new suppliers or if the design of a component changes. I will categorize the auxiliary equipment into different categories: *high critical/nonstandard, non-critical and Occupational Health and Safety critical*, according to their characteristics and it is the company's obligation to decide which product belongs to which category. In the result the flowchart will be explained step by step and the responsible parties for the steps will be decided.

When I have created the pilot process I will, if possible, test my release plan with a supplier and after that make a follow up process on performance of validated equipment or components. The release plan will be based on risk and we will check if the release plan implies sales potential.

1.3 Limitations

This thesis is focusing on and covering only four-stroke engine related components and equipment. I classify the auxiliary equipment into categories and I am not digging into details too much. Joint venture processes are also excluded. I will furthermore focus on covering both Wärtsilä and supplier Intellectual Property Rights.

My study is limited to short, relevant theory linked to the subject. However, the theory shall be large enough to cover the most important parts of this thesis and its content.

1.4 Central terminology

It this section central terminology is presented as follows:

B2B – Business to Business

B2C – Business to Customer

CFD - Computational fluid dynamics

CM – Category Manager

CQ – Component Qualification

DQ – Design Qualification

FAT - Factory Acceptance Test

IPR - Intellectual Property Rights

IQ – Installation Qualification

OQ – Operational Qualification

PQ – Performance Qualification

PQAP- Part quality assurance plan

PCPA – Process Control Plan Audit Procedure

QA – Quality assurance

QMS – Quality Management System

RFQ – Request for Quote

SDE – Supplier development engineer

VMS – Vendor Management System

WPAP – Wärtsilä Supplier and Part Approval Process

1.5 My thesis

It is important for Wärtsilä that their products correspond with their customer's needs, wants and expectations. The products have to satisfy the customers in all areas when it is up to quality, safety, function and design. This is why it is the right time Wärtsilä develops a validation process that is able to secure all of the agreements between the customers and the company, when Wärtsilä is choosing suppliers, new products or changes a product's design.

I want to create a validation process that corresponds with the criteria's that Wärtsilä has presented. In other words, the validation process should meet all the goals in the study.

In my opinion this is an important subject for Wärtsilä. A validation process would make the validation of products and suppliers easier. It would also make products less unsafe and fit the engines better.

1.6 Disposition

This thesis work is divided into six different chapters. In chapter two the organization is presented. I will first present basic facts about the company and the company's mission and vision. In section 2.2, 2.3 and 2.4 I will present Wärtsilä's three business areas.

Chapter three processes the theoretical points related to this thesis work and in the fourth chapter I will go through the method used in this study.

In the fifth chapter the results of the study are presented. In the in chapter six conclusions and proposals for further research are presented.

2 The organisation

Wärtsilä is an international company that provides advanced technologies and complete life cycle solutions for the Marine and Energy markets. Wärtsilä is based in 70 different countries and approximately 18 000 employees are working in the company today in over 200 locations. Wärtsilä consists of three different business areas and the areas are Marine solutions, Energy solutions and Services.

Wärtsilä desires to be a smart technology company. They strive to have a unique market position, deep customer understanding, predictive analytics and asset optimisation, global service network, extensive product range, engineering and technology expertise and significant investments in future technology. Their aim is to increase efficiency while enabling a zero-emission society.

Wärtsilä's mission is to shape the marine and energy markets with advanced technologies and focus on lifecycle performance, to enhance our customers' business and benefit for the environment. The company's vision is: we will be our customers' most valued business partner and the value is: Energy – Capture opportunities and make things happen. (Wärtsilä, 2018)

2.1 Marine Solutions

Marine solutions represent approximately 35 % of Wärtsilä and they are focusing on the marine business market. Marine solutions are the leading provider of innovative products and integrated solutions in the marine and oil & gas industries. They are providing ship machinery, propulsion and manoeuvring solutions. Thanks to the experienced employees in Marine solutions Wärtsilä can provide customers customized solutions so that the customers benefits from buying from them. (Wärtsilä, 2018)

2.2 Energy solutions

Energy solutions, the second area at Wärtsilä that represents 20 % of the company, is focusing on the Energy market. They are designing and building power plants operating on gaseous and liquid fuels. The business area is offering a wide variety of environmentally sound solutions and they are providing ultra-flexible internal combustion engines, LNG terminals and distribution systems. Energy solutions have delivered power plants to over

170 countries in the world and the power plants can have the capacity up to 600 MW. (Wärtsilä, 2018)

2.3 Services

The third business area in Wärtsilä is Services and they are representing 45 % of the company. They are working on supporting all Wärtsilä's customers through the whole installation lifecycle. Services are available in 160 different countries and about 11000 professionals working at services are serving more than 12 000 customers every year. The service portfolio consists of spare parts, maintenance, and optimization services etc. (Wärtsilä, 2018)

In chapter three the theory building in this thesis is presented.

3 Theory

In this chapter I will describe the theoretical aspects of this thesis. Since I am writing a thesis work about how Wärtsilä shall develop their business I will start the theoretical chapter, in section 3.1, explaining what business development is. I describe why business development is important, how to be a successful salesperson and what business to business means.

Section 3.2 will include facts that define what validation and verification are. I will explain what instrument validation is, when validation is needed and which validation methods, techniques and tools Wärtsilä are using.

In section 3.3 Wärtsilä's requirements for new suppliers and components will be presented. First, I will focus on requirements that are important overall: quality and communication and after that I will list additional Wärtsilä requirements.

In section 3.4 I will present earlier validation processes that have been used in the company. The processes are WPAP and PCPA.

3.1 Business development

Business development is the ideas, initiatives and activities aimed towards making a business better. It can be described as the tasks and processes concerning analytical preparation of potential growth opportunities and the support and monitoring of the implementation of growth opportunities. The concept is a subset of the fields of sales, marketing, project management, product management and vendor management. Other factors involved are networking, negotiations, partnerships and cost-savings efforts. All of these sections and activities are driven by and aligned to the business development goals. (Shobhit, 2018)

3.1.1 Definition

According to Pollack, 2012 business development can be defined as:

“Business development is the creation of long-term value for an organization from customers, markets and relationships”.

According to Pollack, 2012 business development is all about figuring out how the interactions of those forces combined together to create opportunities for growth. He also says that business development is not about get-rich-quick schemes and I-win you lose

tactics that create value that is gone tomorrow as easily as it came tomorrow. Instead it is about creating opportunities for that value to persist over the long-term, to keep the floodgates open so that value can flow indefinitely. To succeed in consistently growing an organization the only true way of thinking about business development is as a means to creating long-term value. (Pollack, 2012)

3.1.2 Activities

There are several tasks, processes and human resources issues related to business development. Business development investigates three activities as follows:

- 1) Identify new business opportunities through analyzing market information and undertaking networking activities
- 2) Evaluate the most profitable opportunities by analyzing potential partner profiles, market and financial evaluation and strategic fit with the company
- 3) Negotiate terms and conditions and adapt internal resources to enable implementation. The tasks that the business development managers must handle are often to vary according to the different phases of the business development process. (Shobhit, 2018)

3.1.3 Success factors for professional salespeople

An understanding of the key success factors in selling is a key issue for aspiring for current salespeople and sales managers. To be successful in selling, salespeople and managers have to be aware of the ten success factors affecting selling. Understanding these factors can improve the overall effectiveness of the salesperson-customer interaction in several ways. Factors that affect the selling are as follows:

1. Listening skills
2. Follow up skills
3. Ability to adapt sales style from situation to situation
4. Tenacity – sticking to the task
5. Organizational skills

6. Verbal communication skills
7. Proficiency in interacting with people at all levels within an organization
8. Demonstrated ability to overcome objections
9. Closing skills
10. Personal planning and time management skills (Jobber & Lancaster, 2017)

3.1.4 Business to business in marketing and selling

Based upon the category of customers being targeted, marketers and salespersons often distinguish between two major categories of types of marketing and selling. The two distinct categories are: *business to business marketing (B2B)* and *business to consumer marketing (B2C)*. Since Wärtsilä is mainly on the B2B field I am focusing on that field.

Business to business markets are often characterized by large and powerful buyers, purchasing predominantly for the furtherance of organizational objectives and in an organizational context using skilled/professional buyers.

B2B is very different from B2C. Buyers are for example more likely to negotiate on price. Delivery and service are very important in B2B. The salesperson probably has to deal with skilled negotiators and the process of buying, and hence selling, can extend over months or even years for certain types of capital equipment. The main sub-markets within B2B markets are the following:

1. Markets for supplies and consumables
2. Markets for capital equipment
3. Markets for business services (Jobber & Lancaster, 2017)

3.2 Validation

Verification and validation, in engineering are methods that are settling that a product or service meets the needs of its users. Equipment validation is a term used to describe a set of independent procedures that are used to check if a product meets the specifications and requirements of its intended purposes. Regulatory agencies around the world have strict

requirements for quality, procedures, performance testing, safety checks and the like, for a wide range of products. (B.H.Thacker, et.al., 2004)

Verification is defined as a quality control process used to evaluate if a product, service or system submits with regulations, specification, or conditions that are imposed at the start of a development phase. On the other hand, validation is defined as a quality assurance process that establishes evidence that provide a high degree of assurance that a product, service or system accomplishes its intended use requirements. (B.H.Thacker, et.al., 2004)

3.2.1 Instrument validation

Validation of an instrument is traditionally categorised in five separate qualification categories: DQ, IQ, OQ, PQ, and CQ.

The first step, design qualification, is to investigate and demonstrate whether the suggested design of the instrument can cope with the functional requirements of the end user. Before starting with construction and procurement of parts the design must be satisfying.

The second step in the validation plan is installation qualification. During the installation qualification step the instrument together with all its components and documentation, is placed properly and checked for performance according to the requirements.

In the third step, operational qualification, all the instruments major parts are tested to ensure they all perform correctly and are in sync with the entire system.

In the fourth step, performance qualification, the instrument is monitored to check if it consistently delivers results within the required parameters, over a period.

The last step is component qualification. Third-party manufactured auxiliary components and parts are periodically subjected to random tests for quality and performance, to ensure they are manufactured to the right specifications and will not hamper the performance of the instrument. (RS Calibration, 2015)

I will concentrate my thesis work on the last step, the component qualification.

3.2.2 For which components is validation needed?

Components can be categorized according to their criticality, based on either qualitative or quantitative methods. There are three categories describing how critical a component is: *high critical, non-critical and standard critical*.

High critical components are parts associated with multiple critical features, complex design or new technologies. Standard critical components are parts that have at least one critical feature. Not critical components are remaining parts, with other words, the supplier's quality system and quality performance meet expectations. (Wärtsilä, 2018)

3.2.3 Validation methods, tools and techniques in Wärtsilä

In this section validation methods, tools and techniques that Wärtsilä currently are using when they are validating equipment are presented as follows:

- Design assurance – A validation technique that is based on pre-defined or standard calculation methods. Examples of methods used in design assurance are international standards, requirements from classification societies and good engineering practice.
- Virtual validation – Methods that are used to predict how a product behaves under various conditions. Examples of virtual validation methods are CFD and other hydrodynamic performance methods, FEA and other load simulation methods and tolerance stack-up analysis.
- Technical reviews – Reviews done by a team of experts who evaluate product performance, suitability for its intended use, identify discrepancies from specifications and standards. Examples of this kind of validation are design reviews, FMEA's and criticality assessments.
- Read-across validation – Validation grounded on historical data. The validation involves the evaluation of past experiences with similar applications.
- Quality assurance & quality control – Techniques focusing on product verification and needs to ensure:
 - Drawing requirements
 - Quality instruction requirements

- Documents, measurements and any other quality control requirements
- Classification requirements
- Assessment of supplier's capability to meet these requirements.
- PQAP
- Manufacturing process validation – Evidence which is documented and provides a high degree of assurance that a specific manufacturing process will consistently result in a product that meets its predetermined specifications and quality characteristics.
- FAT – validation of the system or product during factory acceptance test. Examples of FAT are tooth contact pattern gears and seal leakage tests.
- Prototyping/test order – Wärtsilä uses prototypes for product development purposes. The purpose with a prototype is to confirm product performance or ensure the suitability of a specific design choice. Prototypes are not build for customers.
- Laboratory testing – Tests to control the products conditions to ensure endurance and overall performance. An example of a testing method used is field measurements.
- Field measurements – Field measurements used in Wärtsilä are:
 - Commissioning: validation based on field measurements, obtained during the builder's trials and/or sea-trials.
 - Field follow-up- validation based on field measurements, obtained during operational conditions of the application (in first year). (Wärtsilä, 2018)

3.3 Requirements

Since Wärtsilä is purchasing a huge amount of materials and services globally, clear supplier guidelines are required. Wärtsilä is aiming for the external suppliers to provide products with the right quality, deliveries that are on time with the lowest total cost and that they are fulfilling their lead time requirements.

It is important that the communication between the organization and the company is clear in order to achieve the correct requirements for products and services. It is especially important

for a manager since the organization's livelihood is affected by the quality of the communication. It is also important that the processes used for customer communication is reliable. (Wärtsilä, 2018)

3.3.1 Quality

Quality is an important factor affecting both products and services and it has become an increasingly important means of competition on the world market. Therefore, a strategy based on management commitment to continuous quality improvement has become more usual today in organizations. Organizations not aware of the importance of quality will lose large shares of the market to those competitors who are.

Quality can be defined in many ways. One definition is:

“The quality of a product (article or service) is its ability to satisfy the needs and expectations of the customers”. (Bergman & Klefsjö, 1994)

According to ISO 8402 – 1986 quality is defined as:

“The totality of features and characteristics of product or service that bears its ability to satisfy stated or implied needs”. (Bergman & Klefsjö, 1994)

3.3.1.1 Quality dimensions of a product

The term product quality has many dimensions. Some of the dimensions are:

- *Reliability* – is a measure of how often an error appears and how serious these problems are.
- *Performance* – suited to the customers on the intended market segment, for example speed, efficiency, length of life and size.
- *Serviceability/maintainability* – summarize how easy or hard it is to detect, locate and correct errors.
- *Environmental kindness* - tells which impact the product has on the environment for example how environmental aspects are considered during production and how easy it is to recycle the product.
- *Aesthetics*– an aesthetic parameter.
- *Faultless* – the product has no errors or flaws.

- *Safety* – describes how safe the product is, for example how easy the product cause damage to a person or property.
- *Durability* – how easy a product can be used, stored and transported without deterioration or getting damaged. (Bergman & Klefsjö, 1994)

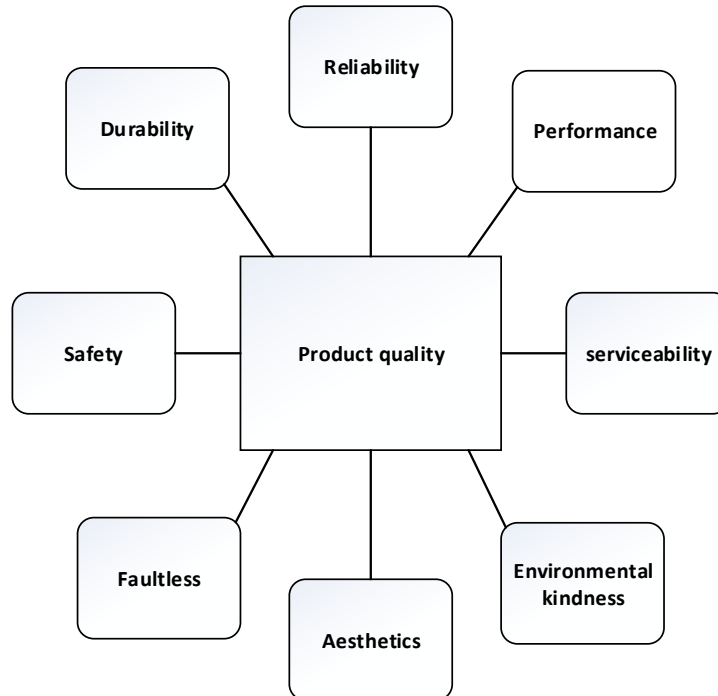


Figure 1: Factors affecting the quality of products (Bergman & Klefsjö, 1994).

3.3.1.2 Quality dimensions of services

The quality of service has many dimensions and some of them are:

- *Reliability* – the consistency of performance and dependability, for example punctuality and precision.
- *Assurance* – how trustworthy the supplier is.
- *Access* – how easy it is to contact the supplier.
- *Communication* – the ability of talking in a way which is understandable to the customer.
- *Responsiveness* – the supplier's willingness to help the customer.
- *Courtesy* – supplier behavior, for example politeness and kindness.
- *Empathy* – the ability to understand the customer's situation.
- *Tangibles* – the physical environment in which the service is presented. (Bergman & Klefsjö, 1994)

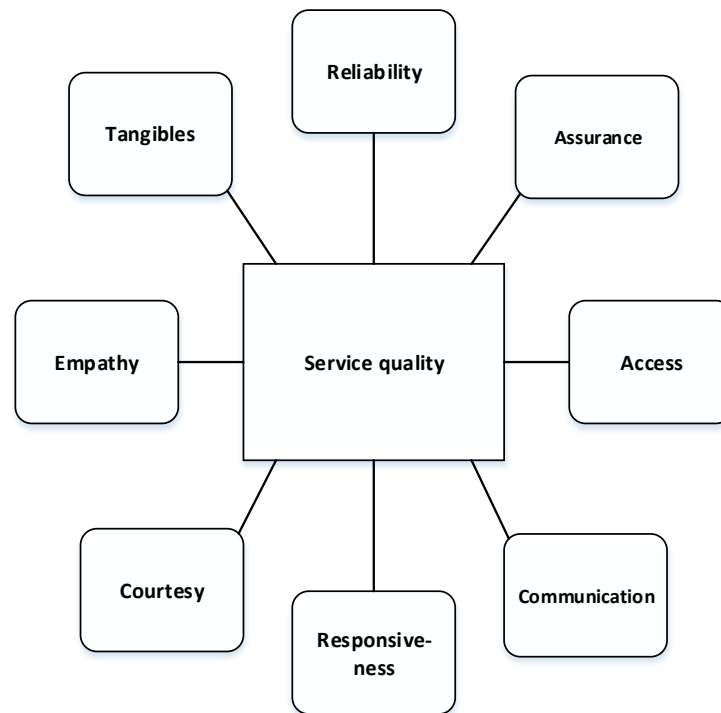


Figure 2: Factors affecting the quality of services (Bergman & Klefsjö, 1994).

3.3.1.3 Design quality and production quality

The term design quality designates that the product or service is planned to satisfy the demands of the customers. The external customer's experience of quality is affected when it comes down to usage, reliability in operation and user friendliness. In other words, good design is necessary, but not sufficient, to be able to produce a good product. The meaning of production quality is that the product or service fulfils the specifications that were set during design or planning. (Bergman & Klefsjö, 1994)

3.3.2 Communication

According to ISO 9001:2015 an organization is required to communicate with its customer for discussions relevant to products and services, initial customer contact by potential buyers, contract and changes, purchase orders and changes, fulfilment of purchase orders, customer feedback-satisfaction, customer feedback – complaints, customer arrangements when necessary and contingent arrangements for product or service provision if needed.

In order to optimize customer satisfaction, the first step is to determine the customer's requirements. According to ISO 9001:2015 an effort to capture the requirements for

completion of products and/or services, including those required by law and those necessary for internal reasons, is obligatory.

When the organization is aware of what needs to be done, it must determine that it can be completed. The organization needs to be sure that it has the capability to meet the determined requirements and fulfil any promise made to potential customers about products or services being offered.

The management's role in the determination depends on the size of the company and the importance of the potential contract. Regarding the employee's role, it is important that those of the employees working directly with the customers, extract as much information as possible and the preference is to obtain documented detailed product or services requirements from each customer.

Customers usually send a RFQ with the customer requirements, and the review of the RFQ is typically the company's first opportunity to evaluate the customer requirements. The company's respond to a RFQ is a quote and if all goes well the quote matures into a contract. A contract is an agreement between the company and another entity to sell or buy product or service. The contract can be very formal containing many clauses or it could simply be the buyer's purchase order. (E.P.Link, 2015)

3.3.3 Additional Wärtsilä supplier requirements

The supplier specific requirements are based on legal, ethical, environmental and employee related standards. The requirements are also connected to Wärtsilä's own expectations. The requirements shall be determined in the contract that has been made between Wärtsilä and the suppliers. In order to achieve the preferred outcomes, the supplier needs to have the necessary design and/or manufacturing capabilities as required by Wärtsilä. The quality of the products and services delivered by the supplier shall fulfil Wärtsilä's performance and compliance requirements.

The definition of a new supplier is suppliers that are not yet introduced in Wärtsilä Supply chain and/or a supplier that has never produced this specific component for the specific product type before. PME is the unit responsible for the validation and they also approve the follow up of tests for new suppliers on existing products. (Wärtsilä, 2018)

3.3.3.1 Requirements

- *Compliance* - Wärtsilä requires that the supplier have to comply with all applicable laws and regulations, and conform with the requirements of good citizenship in each jurisdiction where the supplier does its activities. The requirements include, but is not restricted to, compliance with laws and regulations on competition, corporate governance, taxation, financial disclosure, employee rights, environmental protection, occupational health and safety and export control.
- *Occupational health and safety* - When Wärtsilä chooses suppliers they are following the third-party certified occupational health and safety management system according to relevant OHS standards. According to the system the supplier has to be fully responsible for its liabilities as an employer, the supplier shall have a valid and implemented safety plan and the supplier shall ensure that accidents and near misses are reported and that appropriate actions are taken as a result of these reports.
- *Social issues* – Wärtsilä requires that the supplier shall support and respect the protection of human rights. The protection of human rights is defined in the United Nation's Universal Declaration on human rights. Any act that violates these human rights principles are forbidden, both directly and indirectly. This comprises freedom from discrimination, freedom of association and collective bargaining, compensation, child labour and forced labour.
- *Innovation and protection of proprietary information* – Wärtsilä requires that the supplier shall support and encourage innovation in its activities. One of Wärtsilä's most valuable assets is their intellectual property and it has to be protected, but at the same time, the supplier shall respect the intellectual property rights of others.
- *Quality* – When Wärtsilä chooses a supplier they promote application by the supplier of a quality management system certified by an accredited certification body. Wärtsilä requires that the supplier has a quality management system that complies, as a minimum, with the international standard IS 9001 latest valid editions, and which shall be utilized for continual improvement of its operations.
- *Environment* – Wärtsilä values application by the supplier of the third-party certified environmental management system. The supplier has to have an environmental

management system that complies with the international standard ISO 14001 or Eco-management and Audit scheme latest edition, as a minimum.

- *Security* – Wärtsilä requires that the supplier shall have a security management system that has identified, evaluated and treated the security risks, ensures and documents the supply chain security processes and prevents unauthorized access to, and tampering with, the supply chain's premises, cargo units, goods in transit, and/or the storage facilities. The system shall also comply with special security instructions issued by Wärtsilä and it has to have information security management with document classification, access rights, data protection and identify management. The system must have a background screening policy for personnel in security critical positions and continues improvement as a management value.
- *Business continuity planning* – It is important to Wärtsilä, the client and the supplier that the production of components and/ or services is uninterrupted. All suppliers shall have a written Wärtsilä specific Business Continuity Plan (BCP) based on a production related business impact analysis on components/services relevant for Wärtsilä, to ensure this.
- *Submitting the necessary information* – The supplier is obligated to provide all necessary information to Wärtsilä upon request in order to allow an assessment of the supplier's compliance with these requirements. Furthermore, the supplier must inform Wärtsilä of any deficiencies in its performance. (Wärtsilä, 2018)

3.3.3.2 Additional Wärtsilä requirements for new designs

Validation and verification of engineering designs are of primary importance as they directly influence production performance, and ultimately define product functionality and customer perception. The most important part of designs is that the design meets the needs and expectations of customers. Good design starts and ends with the customer.

The instructions below describe the requirements for the approval of new designs. The requirements are taken from existing validation samples used in Wärtsilä.

The requirements for new designs are the following:

- Component design assurance
- Testing and Performance guidelines

- Product validation map
- Quality assurance and Quality control. (Wärtsilä, 2018)

3.4 Validation processes used in Wärtsilä today

I will refer my field study in to two existing validation processes used in Wärtsilä. The processes are Wärtsilä supplier and Part Approval Process (WPAP) and Process Control Plan audit procedure (PCPA).

3.4.1 Wärtsilä supplier and part approval process (WPAP)

The validation process “Wärtsilä Supplier and Part Approval Process” is used when new suppliers are introduced to the supply chain and in supplier development activities for components with new design. The process involves three main phases:

- Supplier compliance assurance – In the first phase of WPAP the supplier assessments are updated. The supplier assessment is used to evaluate suppliers to ensure that they are capable of supplying to Wärtsilä. The evaluation verifies that that the supplier corresponds with Wärtsilä requirements, company’s structure, relevant technical capability and quality management system.

Supplier assurance consists of four work processes: Pre-assessment, VMS rating, QMS audit and Technical assessment. (Wärtsilä, 2018)

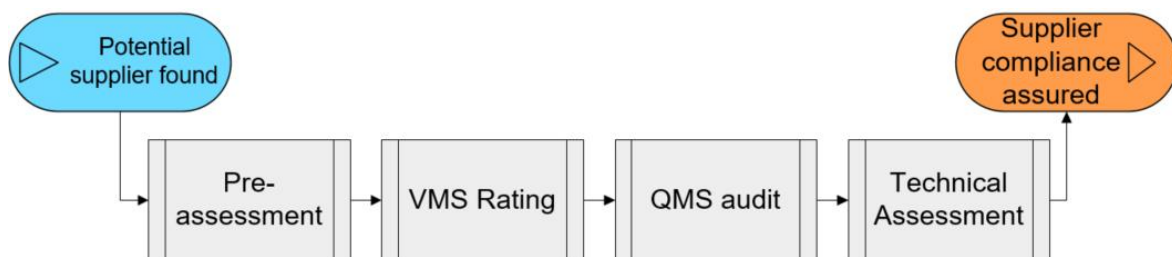


Figure 3: Work processes in supplier compliance assurance (Wärtsilä, 2018).

- Part quality assurance - An essential phase in the part quality assurance phase of WPAP is the part quality assurance plan (PQAP). Every component produced by a supplier shall be quality assured in order to provide Wärtsilä with satisfactory units.

PQAP secures that the units correspond to the specifications and quality requirements, and delivered at the right time. Important to note is that once the PQAP is finalized, the supplier cannot make any modifications or changes into the unit or manufacturing processes without written approval from Wärtsilä. (Wärtsilä, 2018)

- Part functionality assurance – In the third phase the component is tested and validated to make sure that it corresponds with Wärtsilä requirements. (Wärtsilä, 2018)

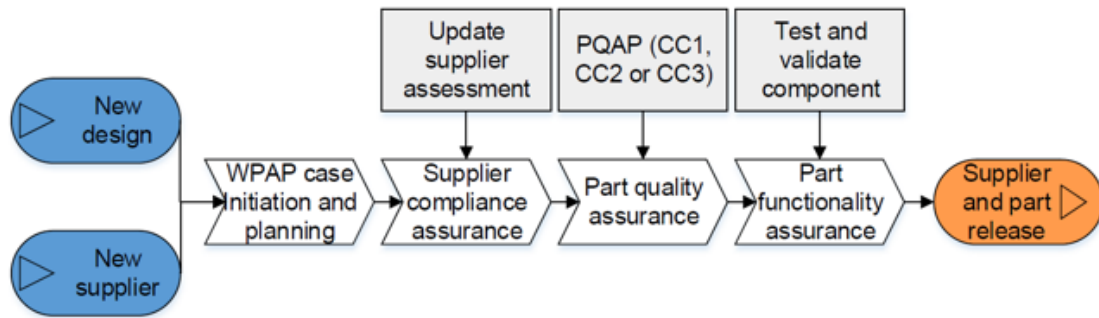


Figure 4: WPAP phases (Wärtsilä, 2018).

3.4.1.1 The fulfillment of WPAP

In the beginning of a case work a WPAP case team is nominated. The team usually consists of stakeholders within product design, supply management and other relevant organisations. A team leader is also selected, and the appointed team leader is commonly the supplier development engineer.

A WPAP case can be initiated by a design manager, a component expert, a designer depending on if a new component is introduced or if a component's design is revised. In case a new supplier is introduced the case is initiated by the category manager or the strategic purchaser. Regardless of who the initiator is, it is important that all concerned roles above get the information about the initiation.

A case is introduced in the planning phase in case of new design or when the need for a new supplier arises. Cases that are typically new design cases are new material number or updated material, for example new revision of existing material number. Cases that typically is called "new supplier" cases, are when a completely new supplier is introduced to Wärtsilä.

During the work case a validation project request-file has to be filled in. The file captures requirements and information for the business case. The file acts as a formal communication document between the design manager and category manager during the initiation. Furthermore, the file provides the SDE with formal information on the business case. (Wärtsilä, 2018)

3.4.1.2 Pre - assessment

Pre – assessment is a preceding step to the VMS rating. The procedure is used for potential suppliers, new suppliers for specific product or service, and when there are significant changes in supplier’s operations. The purpose of the procedure is to collect information about the supplier and get an understanding of the supplier’s organization, technical capabilities, their customer base, their key customers and general business and management system information. The procedure also gives inputs for VMS rating and technical assessment.

Roles and responsibilities: Any member of the category team or from supply management is responsible for sending out requirements to the supplier. SDE is responsible for its analysis after the template has been filled in by the potential supplier. (Wärtsilä, 2018)

3.4.1.3 VMS rating

VMS rating is a supplier assessment tool. It is used to make sure that the supplier can comply with “Wärtsilä supplier requirements” and to fulfil Wärtsilä’s performance and compliance requirements. It is also used to evaluate Wärtsilä external suppliers by identifying strengths and weaknesses in order to develop the supplier performance.

The person who does the VMS rating should be a member of the category team who has the best understanding of the supplier’s operations, and the rating needs to be performed for all new suppliers. VMS rating should be renewed at least every third year in case of existing supplier. A more frequent review based on the status of the supplier performance or on the changes in the supplier operations is however recommended for the critical suppliers.

Possible statuses in VMS rating are the following:

- Approved
- Approved with remarks
- Banned

When a supplier is approved the supplier can be utilized by Wärtsilä without any limitation. A supplier that is approved with remarks needs to define an action plan in the areas of concern and implement corrective actions by the defined deadlines. During the action plan the supplier will be monitored and will not be prioritized in case of development activities and ramp-up. A banned supplier cannot be utilized by Wärtsilä for development activities or ramp-up, in case of an existing supplier a ramp-down will be planned. (Wärtsilä, 2018)

3.4.1.4 Quality Management system

Quality Management System (QMS) audit is used to confirm the existence of relevant quality management processes, documents and practices. It is also used to identify areas of improvements to meet project specific or Wärtsilä Supplier requirements.

The process shall be used, if the supplier does not have a certified quality management system or project specific requirements compliance evaluation is requested. The person responsible for QMS is a qualified lead auditor, together with the category team and or other relevant stakeholders. (Wärtsilä, 2018)

3.4.1.5 Technical Assessment

To identify the supplier's technical capability, the supplier's capacity to deliver products/services according to the needs of Wärtsilä, areas of improvement in order to develop the supplier's performance to meet the requirements Technical Assessment.

The process is applied for when technical capability has to be confirmed in detail, with other words for new suppliers, and, for existing suppliers, when there are important readjustments in the supplier's production process. Unit responsible for Technical assessment is SDE together with category team/ and or relevant stakeholders such as manufacturing experts and technology. (Wärtsilä, 2018)

3.4.2 PCAP – Process Control Plan audit procedure

PCPA is used to evaluate supplier's production management system against Wärtsilä's requirements. The purpose with the procedure is to evaluate how a supplier controls its manufacturing process and if those compliant to Wärtsilä's requirements. With the procedures help you get a good understanding about supplier's process control level and which areas are seen to improve. PCPA is usually limited to certain component/product/equipment/ portfolio. (Wärtsilä, 2018)

3.4.3 PCPA evaluation

Areas included in the PCPA evaluation are the following:

- Product related documentation.
- Tooling/equipment.
- Process control.
- Production related human resources and organisation.
- Production capacity management.
- Quality implementation.
- Logistics and internal material handling.
- Corrective actions and continuous improvement. (Wärtsilä, 2018)

3.5 Conclusion

Based on theory building from books, journals and websites I take with me the following central findings when I am step wise move in my study:

1. What business development is and why it is so important.
2. The definition of validation and verification.
3. Which validation methods, tools and techniques Wärtsilä are using
4. Important requirements that should be considered during validation.
5. Existing validation processes used in Wärtsilä.

The next chapter is about the study's methodology.

4 Method

In this chapter the gathering of information and material regarding validation processes and the practical work methods for making a flow map are presented. The method is meant to help me reach a good result, my purposes and my goal with this thesis.

4.1 My choice of method

I have chosen a qualitative method because it is the most suitable way to gather information for my research. I have used the method to gain an understanding of underlying reasons, opinions and motivations. I have gathered data for the validation process mainly from meetings and interviews with Wärtsilä internal stakeholders and employees affected by the processes and users of possible results. Furthermore, I have used training videos to gather additional knowledge I need for this thesis.

The meetings have provided me insights into the problem and helped me develop ideas for my result. Through the meetings I have achieved a more personal result and I have been able to take into account the employees wish. The meetings also have helped me avoid misunderstandings since the communication has been straightforward.

4.2 Meetings and training videos

I have, together with my supervisor, chosen the respondents according to their suitability for the thesis work. I have held meetings with internal Wärtsilä stakeholders that are experts in the area, and employees that will use the process in their daily work.

The time of the meetings have varied, ranging from short 15 minutes meetings to two-hour meetings. The interviews have mostly been individual but in a few of the meetings I have interviewed several employees at the same time. I have used an unstructured technique when I have collected the data.

Besides the interviews and meetings, I have been educated in the different validation processes used in Wärtsilä through training videos. The videos have been used to educate Wärtsilä employees and through the videos I have been able to get a lot of information about the existing processes.

4.2.1 Meetings in detail

The first meeting was held with my supervisor, and the goal and purpose of the thesis were explained. During the first meeting we also selected the respondents for the study and I got the necessary information for this thesis work.

In the second meeting I collected the essential documents and data needed for the work and an expert educated me in different validation processes used in Wärtsilä. We agreed on how I should structure my work and how I would continue with my project.

In the other meetings and interviews I mostly got feedback on my work. I have also been able to ask questions and get ideas for my result.

I held the last meeting together with my supervisor and the most important stakeholders for the study.

4.3 Template creation

The validation process flowchart is created in Microsoft Visio Standard. A flowchart is a diagram that shows the steps in a process. Visio is especially useful for showing basic business processes.

In Visio I was able to create a flowchart easily. The program had many options and I could use many shapes to show many kinds of processes. It was easy to understand the program and I think it was a good way to make the flow chart.

4.3.1 Meaning of the shapes

According to the program different shapes on the stencil represent a different kind of step in a process. I have used four shapes in my flow chart, and below the meaning of the shapes are explained as follows:



Figure 5: Start/End. (Microsoft, 2018)



Figure 6: Process. (Microsoft, 2018)

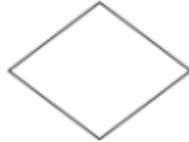


Figure 7: Decision. (Microsoft, 2018)

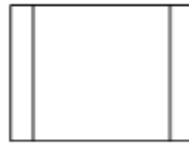


Figure 8: Subprocess. (Microsoft, 2018)

4.4 Validity and reliability

Validity is referring to the credibility or believability of the research. I have done my best to achieve my purpose and goals of this thesis and in my opinion the validity of my study is in order. My study is based on both theory and a real case in thorough. I mean the data input is the right one and the validity for this case is in order. The flowchart corresponds with the assignment and thanks to the meetings, where I have been able to take into account the stakeholder's wishes, the result has become more correct.

Reliability means the repeatability of findings. Should the result be the same if the study were done a second time? In my opinion the reliability of this study is good. As mentioned earlier I have listened to the stakeholder's wishes and balanced my result between theory, information given and a component supervision.

All in all, I am aware that my study and the study's result cannot be generalized. This study has to be seen as a study for Wärtsilä.

5 Results

In this chapter the results of my thesis are presented. In the result chapter I explain what I achieved, how I built my process and explain the parts of the process step by step. The result is based on both the theoretical chapter and the findings from the field study at Wärtsilä.

5.1 Auxiliary equipment portfolio

There has been created a process proposal, that evaluates new auxiliary equipment and new suppliers Wärtsilä is considering using in connection with four stroke engines. The process is defining the workflow of steps to approve and decline the use of certain equipment, and it is used when new suppliers, new components and new designs of components are introduced to the supply chain. The validation process consists of *six steps* and it is based on the existing process WPAP. The process is not the same as WPAP, but it incorporates parts and applications of it. The process is applicable to only auxiliary components at a general level. The process is defined in appendix 7.

Auxiliary equipment are components that connect the engine interface with the ship systems interfaces, in other words, auxiliary equipment are engine or regulation related equipment loosely delivered for shop system installation.

5.2 Categories

In the Auxiliary portfolio flow chart components were categorised according to their criticality. The categories are *high critical/non-standard critical*, *non-critical* and *personnel critical*. The department in charge of the risk mapping is the product owner.

- High critical and non-standard: High critical components are parts that can damage the engine if the part is not working as it is supposed to. If a high critical component stops working the engine does not work. High critical components have several critical features, complex designs or new technologies. Non-standard components are components that are special for the case and have not been used before.
- Personnel critical (Occupational Health and Safety Critical): Personnel critical components are components that can be a safety risk for people. The personnel critical components can also be a protection for humans and if a personnel critical component stops working it does not protect the personnel anymore.

- Non-critical: Non-critical components are remaining parts and have been used by Wäertsilä before. The components quality system and quality performance meets the requirements.

5.2.1 Step 1 – Business evaluation need

In the first step the need of a new supplier and new designs are validated. Is there a need for additional suppliers and new designs? Responsible persons for the evaluation of new suppliers are category managers and/or strategic purchasers supported by engine experts and SDE.



Figure 9: The first step of the process. (Hanses, 2018)

5.2.2 Step 2 – Component risk mapping

If there is a need for a new supplier or component, the next step is to categorise the specific component according to their criticality. The categorisation is based on the component's functionality and operating conditions (chapter 5.2 page 27), in other words, the risk assessment is based on what happens if the component does not work as specified. The product owner should take part in doing the risk mapping. The components can be divided into three categories: *high critical/non-standard*, *non-critical* and *Occupational Health and Safety critical*.

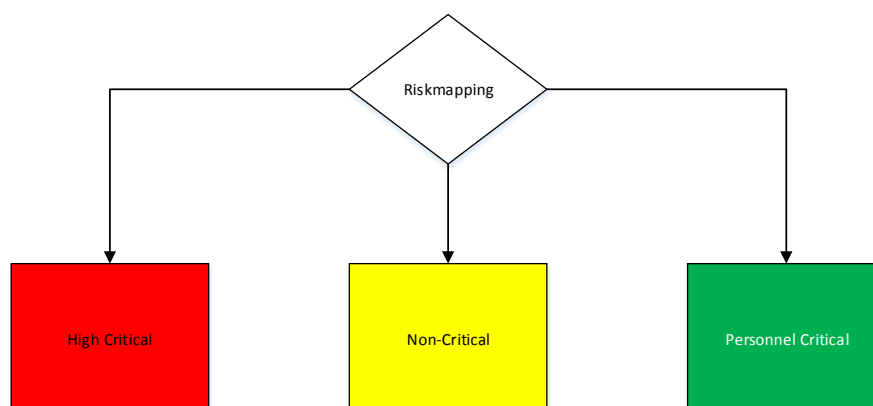


Figure 10: Components can be divided into three categories according to their criticality. The color red represents high critical components, the color yellow represents non-critical and the color green represents personnel critical components. (Hanses, 2018)

5.2.3 Step 3 – Part approval start

When the criticality of the component has been notified the validation of the component and supplier starts. Before the main phases of the part approval process start all necessary information and requirements must be gathered. This is called kick off & budget release. The Kick-off process is done to ensure that all relevant information and stakeholders are identified before engaging in the process tasks. It is mandatory to have a meeting concluding the kick-off activities for validating projects. The kick-off activities are for example: agreement on requirements and scope of supply, confirmation of case owner, case leader and team setup, agreement on tasks and responsible persons, and reviewing of supplier documentation.

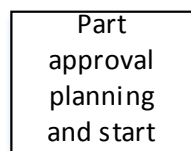


Figure 11: The next step is to plan and start the part and supplier approval. (Hanses, 2018)

5.2.4 Step 4 – Supplier validation

In step 4 the supplier’s capability and capacity is validated. The validation of suppliers may contain as suitable six steps: Pre – assessment (appendix 1), VMS rating (appendix 2), QMS, Technical assessment, PCPA and supplier validation approval. Applicable steps are agreed in project kick off. Supply management is responsible for doing the validation.

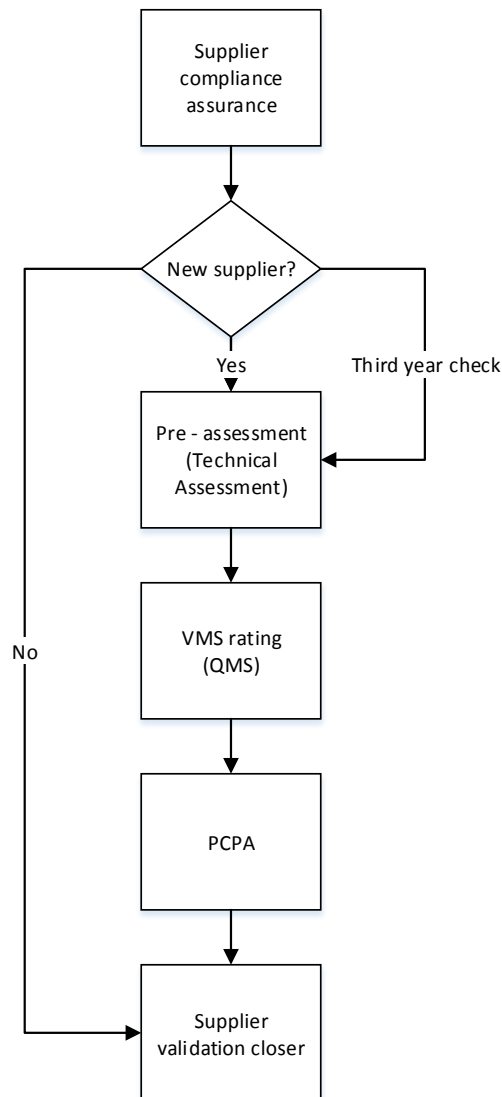


Figure 12: The steps in supplier validation. (Hanses, 2018)

The process starts with establishing if it is a new supplier, or if Wärtsilä has used the supplier earlier. Depending on the answer the validation continues with either step “pre-assessment” or “supplier validation approval”. Also, every third year an existing supplier has to be evaluated so that the supplier still meets Wärtsilä’s requirements. In this case the evaluation starts with step “vendor management system”.

When the need of a new supplier is defined the purchasing department shall create a list of potential suppliers. The next steps are to decide the need for supplier pre-scanning, send out pre-assessment questionnaire and Wärtsilä supplier requirements, and pre-assessment analysis and supplier visits. After this it is the category team's assignment to decide if the pre-assessment is approved or if the supplier has to correct anything.

In combination with pre-assessment the category questionnaire is done. CQ is used for the evaluation of new potential or existing suppliers for Wärtsilä supply management, and the purpose of the CQ is to identify supplier's technical capability and capacity to deliver products/services according to the needs of Wärtsilä.

When the pre-assessment is approved the VMS process starts. If the supplier is new the next step is VMS rating, and if it is an existing supplier the next step is VMS Check. The difference between VMS rating and VMS check is that the first two steps in VMS rating are to gather information about the supplier and then provide the information in pre-assessment form. After that VMS rating and VMS check continues the same way.

The first step is to control if on site audit/visit is needed. If it is needed the following step is to conduct on site audit/visit and provide information. After that all information about the supplier shall be collected and then, complete the VMS rating report and give in data to SAP.

After the VMS rating is completed the decision about the supplier approval shall be made. If the supplier meets all requirements checked during VMS rating, the supplier is ready for scope specific assessment. If the supplier does not meet all requirements the first step is to inform the supplier about the status. After that a plan and for corrective actions shall be provided to the supplier and then provide a status report on corrective actions.

The possible statuses the supplier can get is "*banned*" or "*approved with remarks*". If the supplier becomes banned Wärtsilä has to decide if they should keep working with the supplier in the future. The two options are "supplier to be phased out" and "escalation to management". If the supplier does not get banned Wärtsilä shall do a follow up on the corrective actions and then perform a new VMS rating.

VMS rating should be completed by category team supported by QA and R&D as required. Rating is mandatory for all new suppliers.

In combination with VMS rating QMS-audit shall be done. It is SDE in co-operation with the category team and relevant stakeholders, that is in charge of the process. The process is

used to evaluate conformity of new, potential or existing suppliers against project specific and/or Wärtsilä supplier requirements.

After VMS rating PCPA starts. PCPA evaluates how a supplier controls its manufacturing processes and whether those are compliant to Wärtsilä requirements. PCPA shall be done for only critical components, non-standard components and personnel critical components. SDE or member of Wärtsilä pool of auditors may have a role of lead auditor to complete PCPA together with selected audit team selected. After PCPA the supplier validation is done.

5.2.5 Step 5 – Part approval process

After the supplier has been validated the component and design validation starts. The first step is to control if it is a new component or design. If it is a new component or design the part approval rating starts. After that the design should be reviewed with the supplier. The supplier development engineer is responsible for this. Then a test sample (prototype) should be ordered and inspected. The quality should also be checked in this step. Responsible for the testing and inspection is the component expert, or designer. Then the component expert, or designer, verifies the prototype inspection and testing results. The prototype is approved if the results meet the requirements and the decision is communicated to stakeholders. If the prototype is not approved the component expert, or designer, shall inform the supplier about remarks and a plan for corrective actions. The component is tested based on its criticality and functionality. The component's criticality (and then test plan) must be made in conjunction with the technical expert of the component in question. The critical components require tests in the lab while non-critical components only require filed tests.

After that the component expert shall release a detailed development and design specification to the strategic purchaser and supplier development engineer. The strategic purchaser shall then issue prototype order in SAP, and after that an initial sample inspection shall be done. Component Expert, or Designer, shall review the inspection and test results, both from quality assurance and supplier against validation requirements in the Part Validation Plan, and assess the residual technical risk. The initial sample is approved if the results meet the requirements. The decision is communicated to stakeholders (Strategic Purchaser, Supplier Development Engineer, Quality Assurance, etc.).

Testing Manager supervises the laboratory testing, and field testing and Category Manager decides on approval of the supplier, based on recommendation by the Component Expert, or Designer.

Figure 13 describes the first steps in the part approval process.

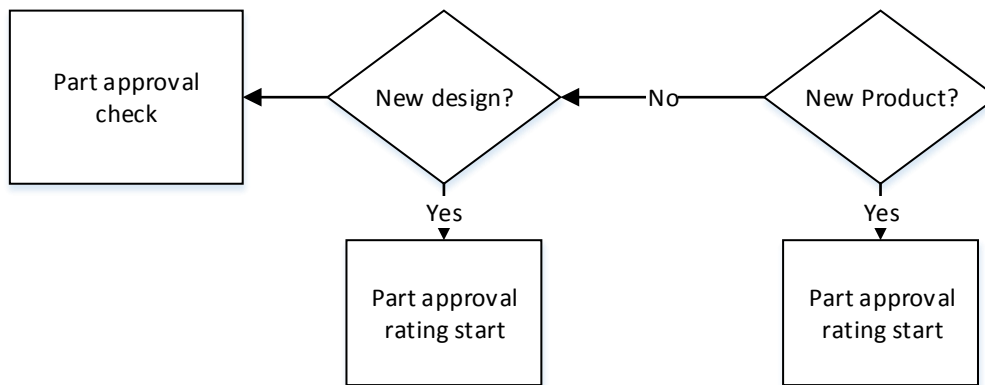


Figure 13: The first steps in the part approval process are to define if the component is new or if it is a new design of the component. The whole part approval process is found in appendix 4-6.

5.2.6 Step 6 – Component and supplier release

Product Owner decides on approval of scope of supply, based on recommendation by the Component Expert, or Designer, and ensures that all pre-conditions are met. Step 6 is visualized in figure 14:

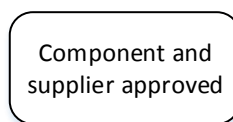


Figure 14: The last step in the validation process.

In the next chapter the conclusion of the study will be presented.

6 Conclusion

In this chapter I will present the conclusions of my study. In section 6.1 I do a reflection of how well I was able to achieve the goals of my thesis and in section 6.1.1 I present my contribution in this study. In section 6.2 I mention all the issues I have dealt with during the journey and in the last section, 6.3 proposals for further research are presented.

6.1 How well could I reach my purpose?

The assignment given to me has been challenging but at the same time very educative. The thesis has been outside my area of knowledge and when I selected this subject for my thesis, I did not know where to start. Theory studies and the meetings with the respondents have mainly helped me understand the important parts of validation processes, but my ongoing education and earlier knowledge have also been useful and most supporting.

This assignment has been interesting and given me a lot of new knowledge within different business areas and strategies that I have brought up in this study. I am glad I chose this particular subject and I think I will benefit from it in the future.

6.1.1 My contribution

My contributions based on this study are as follows:

1. I have gathered related theory for this study and explained all processes I am referring to in my result.
2. In the theory I am presenting the most relevant requirements that should be taken into account when validating suppliers and equipment.
3. I have created a flow chart showing how to validate new suppliers, components and designs.
4. I have explained the steps in the flow chart and mentioned the unit responsible for the steps.
5. I have categorised the components in three different categories according to the component's criticality.

Overall, I think I have reached my purpose quite well. I have created the process so that it will fit auxiliary equipment and explained all the steps in the process thoroughly. I have also categorised the components according to the assignment and the process is easy to use.

I have not yet tried the process as a pilot process together with a selected third – party equipment supplier, because there has not been a suitable case, but the process should be well enough documented to be used as a pilot process. I am looking forward to putting my study in use.

6.2 Challenges

The biggest challenges in this thesis work has been to gather all the information and data needed for the study's purpose. It has also been hard to find theory related to the subject and I have spent several hours on trying to find relevant data.

Since the subject was new for me, the work has taken a lot longer than I expected. It has been difficult to find time to really acquaint myself with the issue, since I have had a lot of other school work too.

Another issue has been to understand all the processes that I have referred to in my result. One process contains many different steps and since I am not working in this particular area, it is understandable that it takes time to learn.

Information has also not always been available when needed, and sometimes the communication with the respondents have been difficult. The respondents have often had full schedules since they are working at the company, which has resulted in long waiting lines when I have needed help.

Although these challenges, I am looking forward to seeing my result partly or more put in use.

6.3 Proposals for further research

Since this thesis is not component specific and the flow chart is general and meant for all components, further researches could be to design a more specific flow chart for often used components.

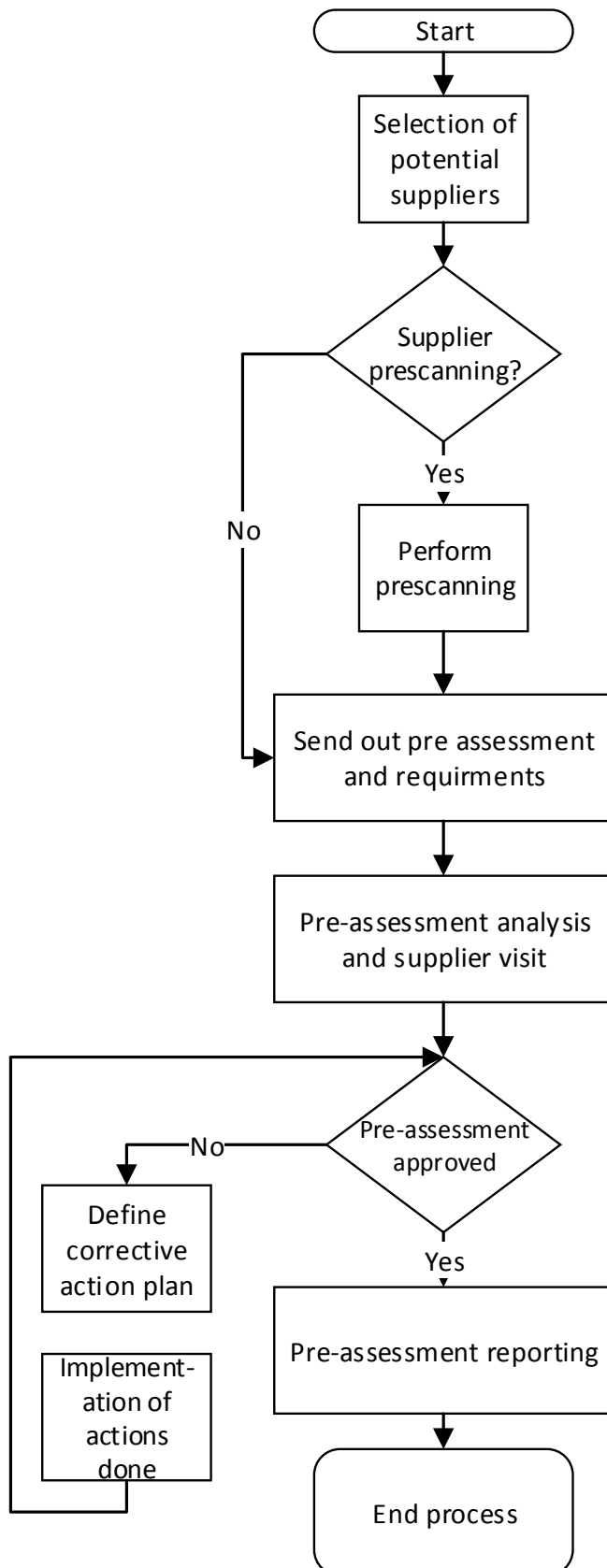
Another proposal would be to test my flow chart when a suitable case appears with a component third-party supplier and corrected based on how well it works in the practice.

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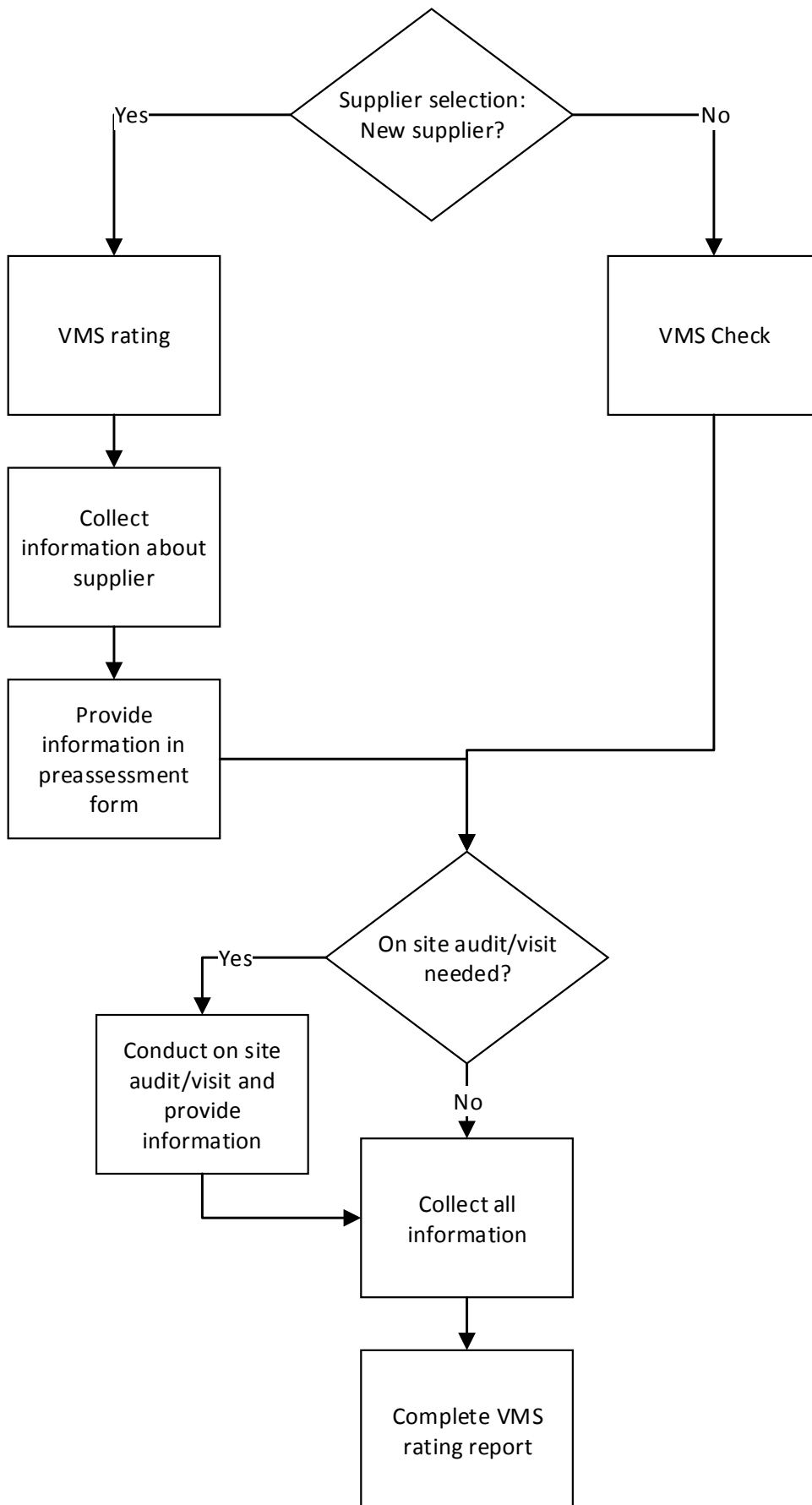
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Appendices

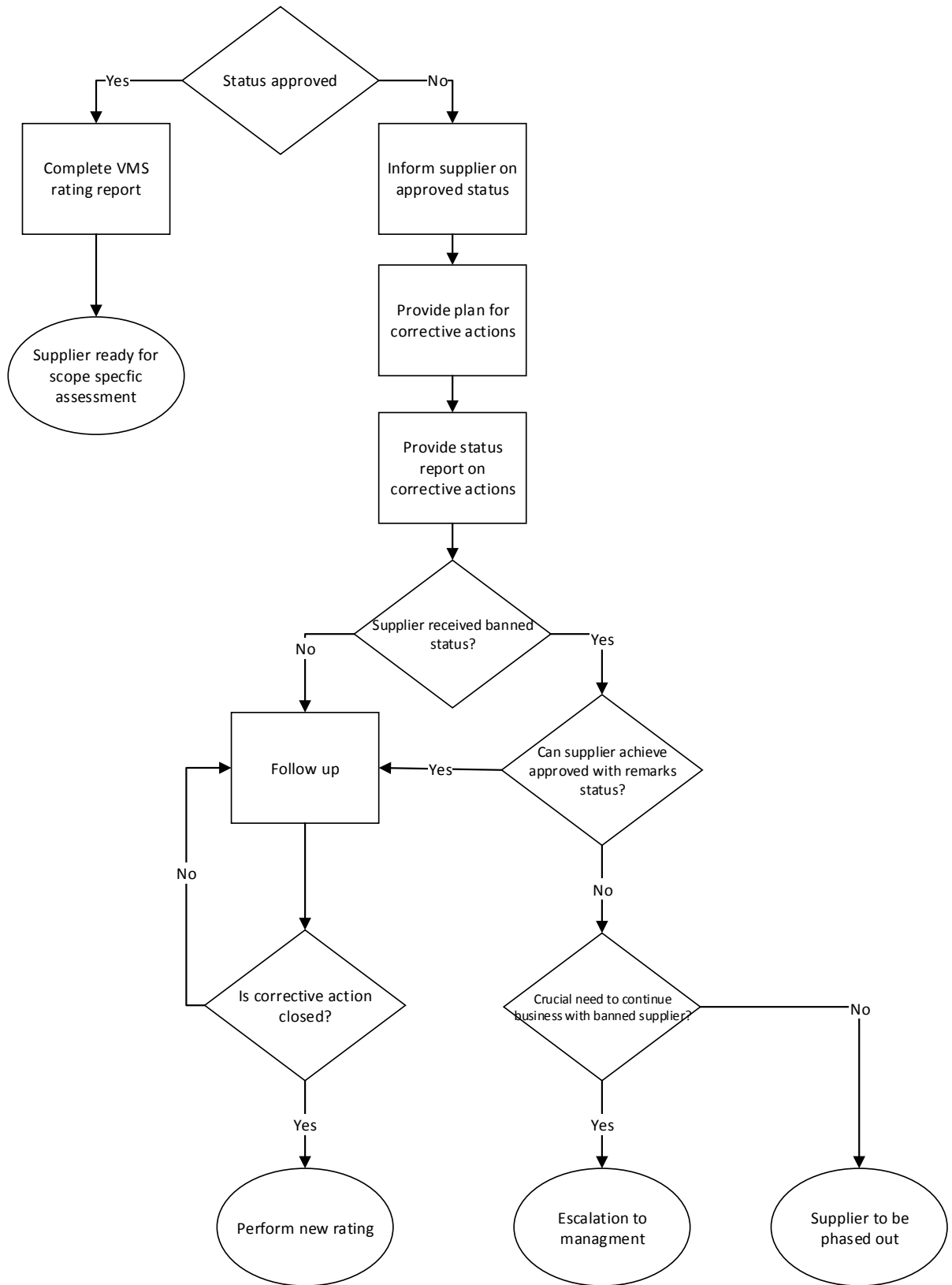
Appendix 1: Pre – assessment method.



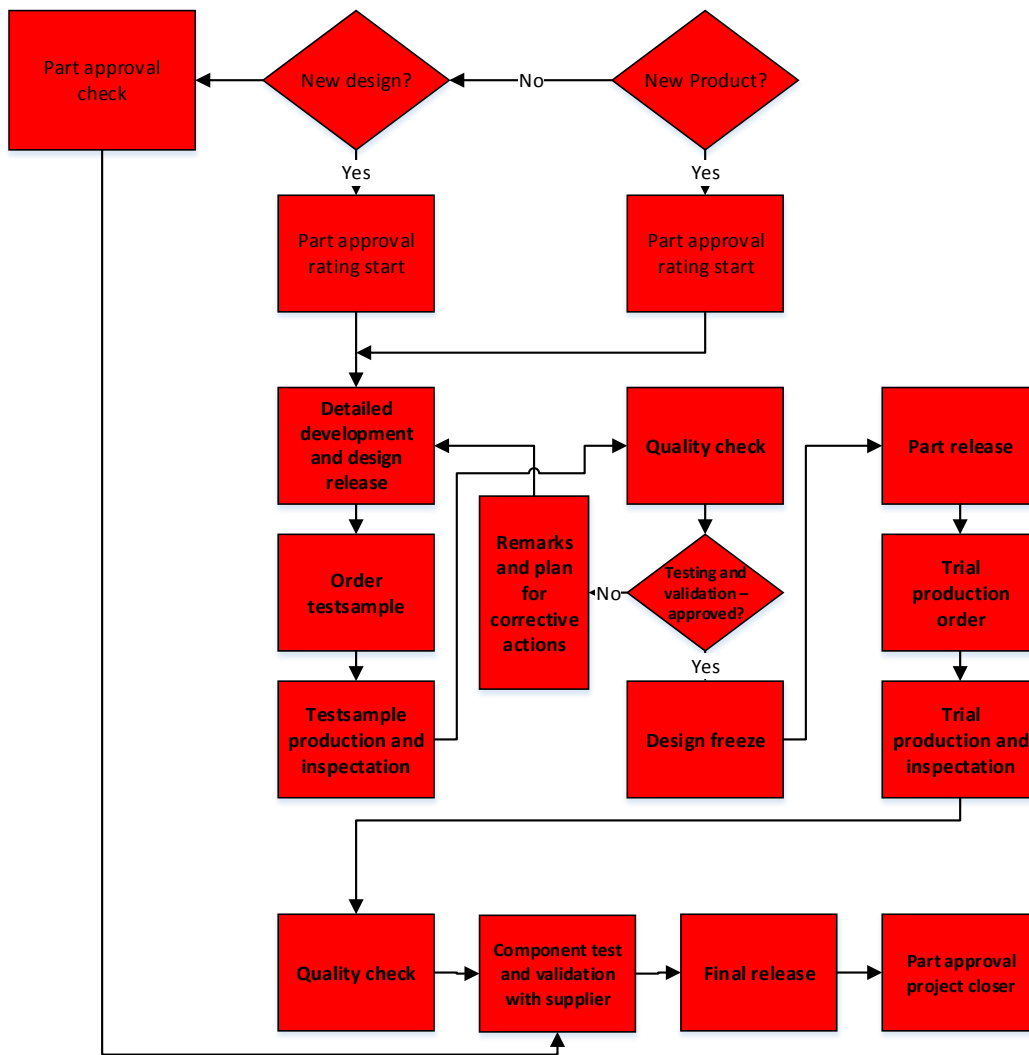
Appendix 2: VMS rating document (1/2).



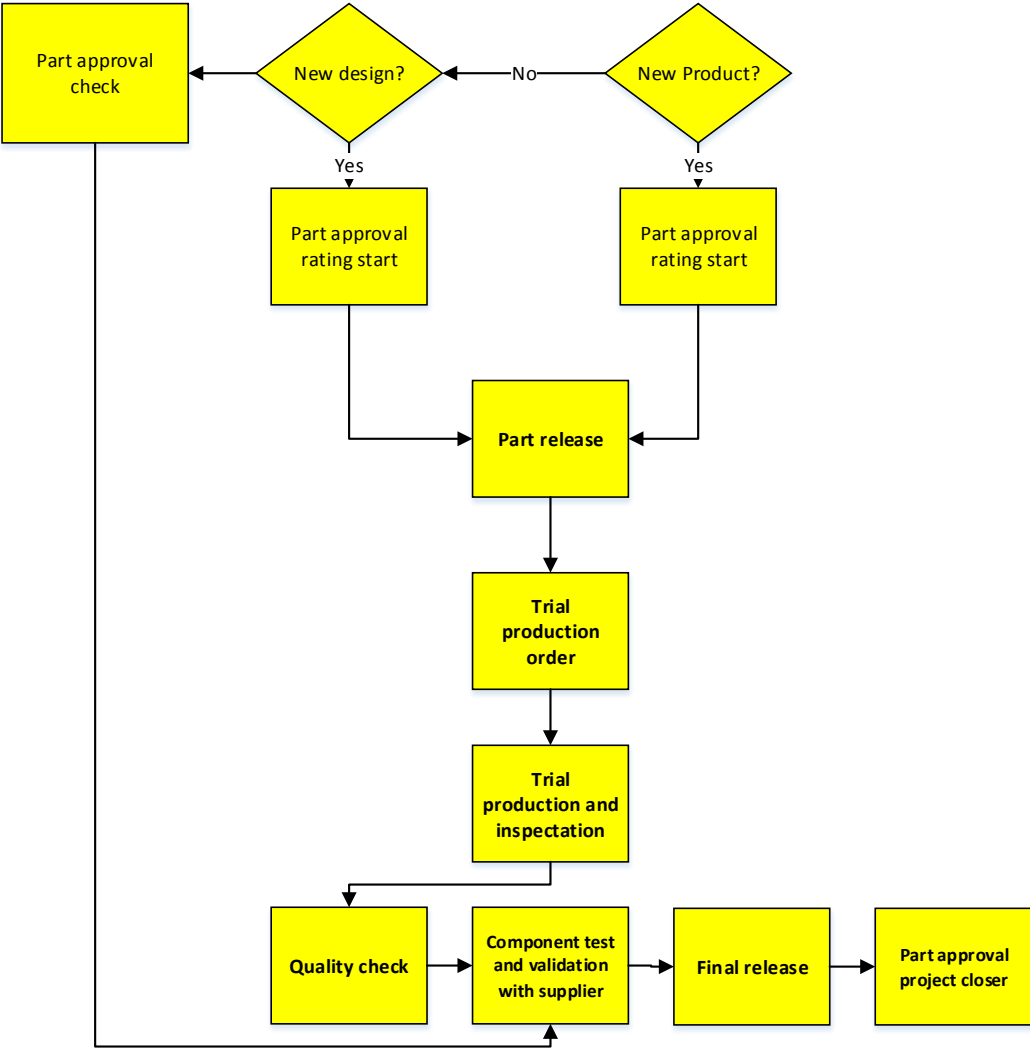
Appendix 3: VMS rating (2/2).



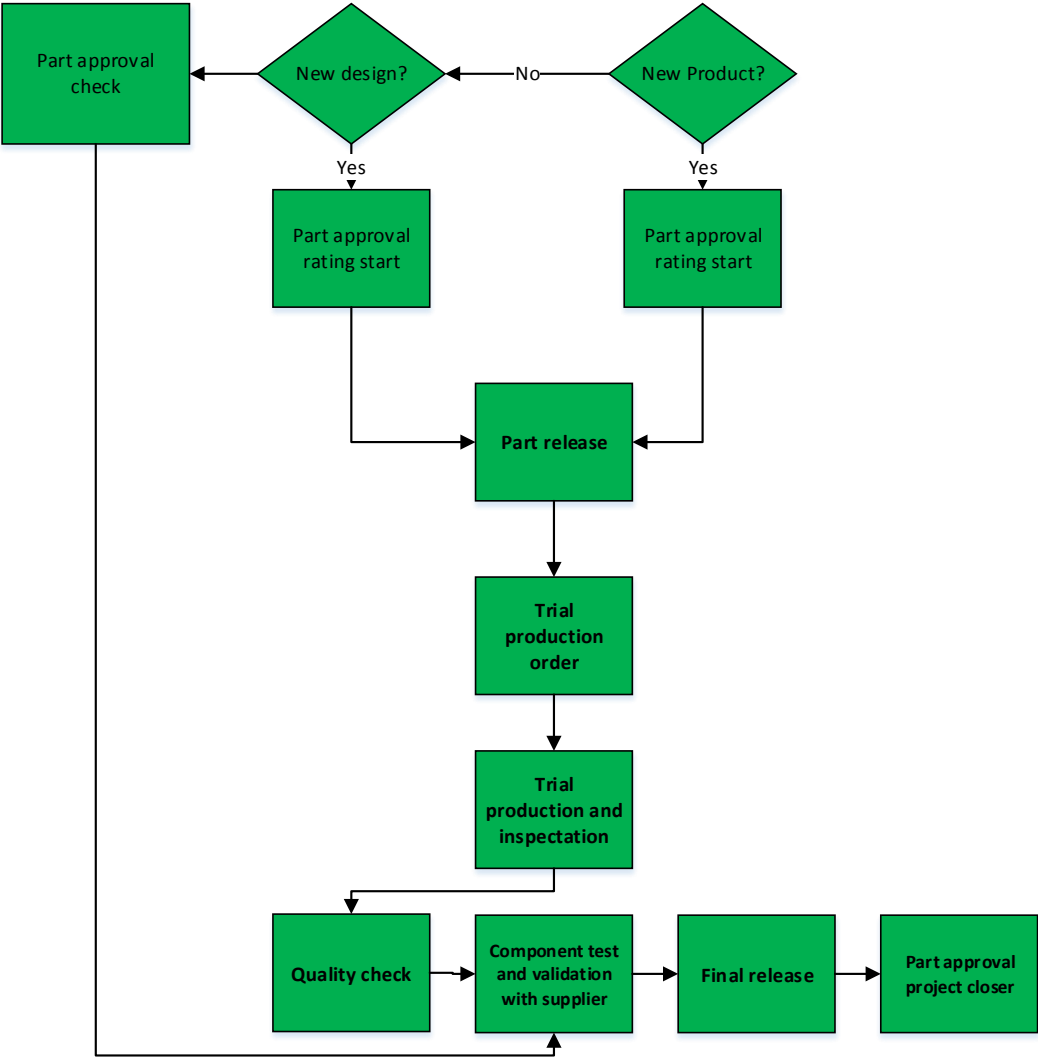
Appendix 4: Part approval process for critical components.



Appendix 5: Part approval for non-critical components.



Appendix 6: Part approval for personnel critical components.



Appendix 7: The complete validation process for auxiliary equipment.

