Development of a quality assurance framework for chemical coated sand used in Additive Manufacturing technologies

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ABSTRACT

The importance of South Africa's foundry industry cannot be overemphasized as it contributes towards the economic development of the country. It has been reported that the local foundry industry has been under severe pressure in previous years owing to very low economic growth, drought and continuing import leakage. The Vaal University of Technology positioned itself to provide cutting edge services to the foundry industry that are aimed to assist local foundries to become more competitive on a global scale. The services offered include casting simulation and printing of moulds and cores. The moulds and cores are printed with a Voxeljet VX1000 machine that uses a binder jetting process.

The local manufacturing of moulds and cores for the foundry industry, using binder jetting additive manufacturing technology, is still considered to be expensive. The high manufacturing cost can be directly linked to expensive printing material, supplied by the OEM. A possible solution to mitigate the printing cost could be to localise the chemical coated sand used in the Voxeljet 3D printing process. However, this poses a risk to the quality of the printed components, as no quality assurance measures, for chemical coated sand, are available. Due to this reason, a quality assurance framework for the chemical coating process had to be examined.

This study investigated the evolution and meaning of "quality" and defined quality assurance as processes, procedures and work instructions, which are used to ensure a repeatable product or service that adheres to a desired quality standard. The quality by design methodology was identified as a suitable methodology to aid with the development of the quality assurance framework that could be used to ensure the quality of the chemical coated sand. The methodology consisted of 8 sequential steps that were used to determine the quality target product profile, critical quality attributes, process flow diagram, critical process parameters and material attributes, quality risk assessment, design space, control strategy and continuous improvement strategy of the chemical coating process. These components serve as the QA framework that could be used as a basic structure or guideline for the development of processes, procedures or work instructions.

Key terms: Quality, Quality Assurance framework, chemical coated sand, Quality by design, South African foundry industry, Additive Manufacturing

ABBREVIATIONS

<u>3</u>	**<u>M</u>**
3D - Three Dimensional	MIT - Massachusetts Institute of Technology
<u>A</u>	**<u>O</u>**
ADV - Acid Demand Value	OEM - Original Equipment Manufacturer
AFS GFN - American Foundry Society Grain Fineness Number	**<u>P</u>**
AM – Additive Manufacturing	PDCA - Plan Do Check Act
AQL - Acceptable Quality Levels	PFD Process Flow Diagram
ASQ - American Society for Quality	**<u>Q</u>**
ASQC - American Society for Quality Control	QA - Quality Assurance
<u>B</u>	QbD - Quality by Design
BOB - Based on Binder Weight	QMS - Quality Management Systems
BOS - Based on Sand Weight	QRA Quality Risk Assessment
<u>C</u>	QTPP - Quality Target Product Profile
CIS Continuous Improvement Strategies	**<u>S</u>**
CMA - material attributes	SAIF - South African Institute of Foundrymen
CPP - Critical Process Parameters	SPC - Statistical Process Chart
CQA - Critical quality attributes	**<u>T</u>**
CS Control Strategy	TOC - Theory of Constraints
<u>D</u>	TQM - Total Quality Management
DS Design Space	**<u>V</u>**
<u>F</u>	VUT - Vaal University of Technology
FMEA - Failure Mode and Effect Analysis	
<u>I</u>	
ISO - International Organization for Standardization	
<u>J</u>	
JUSE Japanese Union of Scientists and Engineers	

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CHAPTER 1 - INTRODUCTION

1.1 Proposed title

Development of a quality assurance framework for chemical coated sand used in Additive Manufacturing technologies

1.2 Purpose of the study

To develop a quality assurance framework for the local production of chemical coated sand used in Additive Manufacturing applications. The quality assurance framework could contribute towards ensuring the quality of the printed moulds and cores. It should be noted that the author is currently employed at the Vaal University of Technology as a mechatronics specialist and has been involved with the Voxeljet printing technology since 2012.

1.3 Introduction

The importance of South Africa's foundry industry cannot be overemphasized as it contributes towards the economic development of the country. It has been reported that the local foundry industry has been under severe pressure in previous years owing to very low economic growth, drought and continuing import leakage. However, according to the South African Institute of Foundrymen (SAIF), there are signs of industry recovery. Although the signs are very minor, they can definitely be seen as positive (Liedtke, 2017). The following initiatives have been identified as possible catalysts to accelerate the recovery of the sector:

- Skills development - Focusing on closing the skills gap through training programmes and short courses (Liedtke, 2017).
- Industry engagements - Development of a new foundry trade, a smelter, as well as the trade testing of foundry artisans. Designation for local procurement and the associated localisation programme. Infrastructural development programme (Liedtke, 2017).
- Technological improvement – Utilising advanced technologies to make foundries competitive, enabling them to enter new markets, subsequently enabling them to offer cost, delivery and quality benefits to clients (Liedtke, 2017).

The Vaal University of Technology (VUT) positioned itself to provide cutting edge services to the foundry industry. These services are aimed to assist local foundries to become more competitive on a global scale. The services offered include casting simulation and printing of moulds and cores. The moulds and cores are printed with a Voxeljet VX1000 machine that uses a binder jetting process.

1.4 Binder jetting

Binder jetting can be defined as “an additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials” (ASTM, 2013). Binder jetting technology was originally developed at MIT and was initially called 3D printing, however the term was never registered and is currently defined as “the fabrication of objects through the deposition of a material using a print head, nozzle, or another printer technology” (ASTM, 2013). The operation of the binder jetting process is demonstrated in Figure 1.

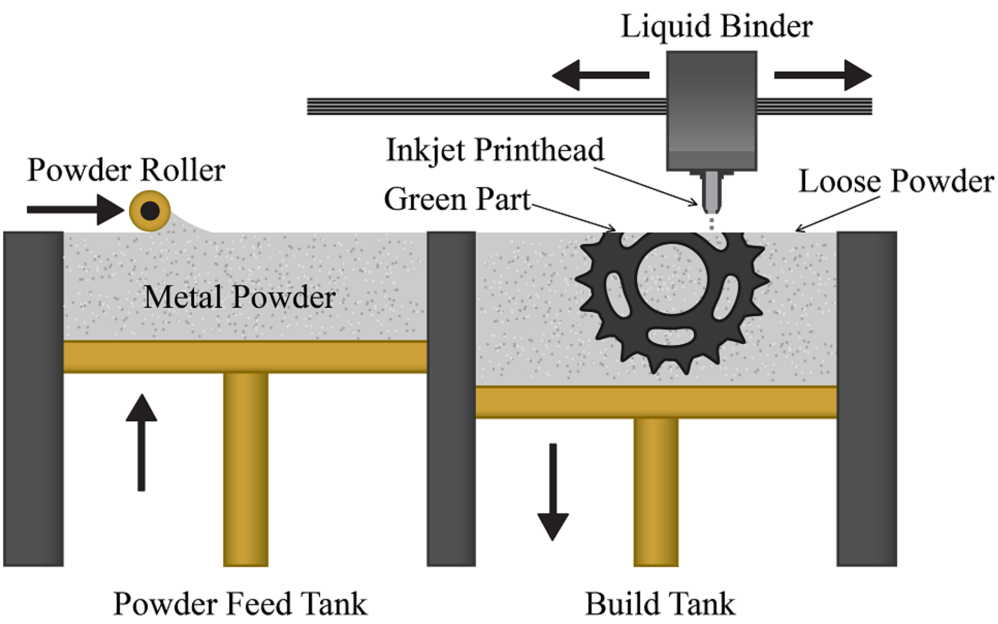

Figure 1. Binder jetting (Sand, 2017)

As highlighted in the description, binder jetting technology deposits a liquid binding agent onto a powder substrate to fuse the powder particles by means of a chemical bond. The binder is deposited onto the powder in the shape of spherical droplets typically with a diameter of 80 µm using a print head. Only the part geometry at the specific layer is printed onto the powder. After a layer is completed, the next layer is added, and the process repeated until sequential layers form the complete part. The individual printed geometries, of each layer, are in this way bonded together to form a single part. This process is repeated until the entire build is complete. The printed part normally needs to cure to increase the part strength. The post production activities of the process include: removing and cleaning of the printed part, recycling/discarding of the unused powder and infiltrating or baking of the part (Gibson, Rosen & Stucker, 2015). The Voxeljet 3D printing process can be summarised using the graphical representation in Figure 2.

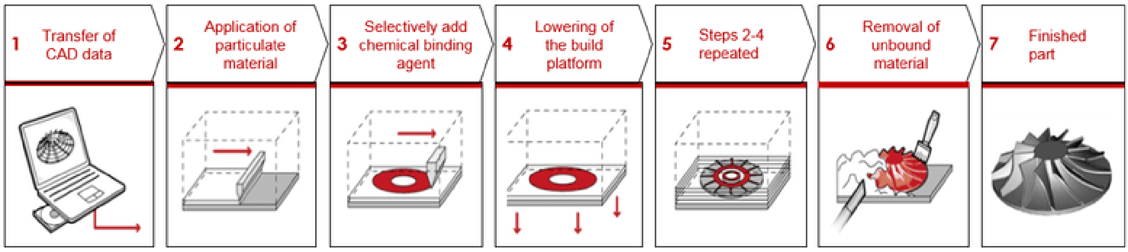

Figure 2. Voxeljet 3D printing process (CSIRO Research, n.d)

1.5 Voxeljet VX1000 process

The Voxeljet VX1000 is capable of printing sand moulds and cores used in the foundry industry. The printing process uses a no-bake Furan process to create a chemical bond between the sand particles. The no-bake Furan process is well-known and used in the traditional foundry industry, where both the Furan and Sulphonic acid are mixed with a refractory material by means of a continuous or batch mixer. After mixing, the Sulphonic acid acts as a catalyst for the Furan polycondensation process. Although the Voxeljet uses the same chemical process used in traditional foundries, the technique to mix the Furan and Sulphonic acid is different. The printing process selectively deposits the Furan binder on precoated Sulphonic acid sand layers, as explained in the Binder jetting section. The precoated sand needs to adhere to certain quality standards to ensure the reliability and repeatability of the printing process (Woods, 2018). Both the Furan and precoated sand are supplied by the Original Equipment Manufacturer (OEM) to ensure that the consumables meet the required quality standard.

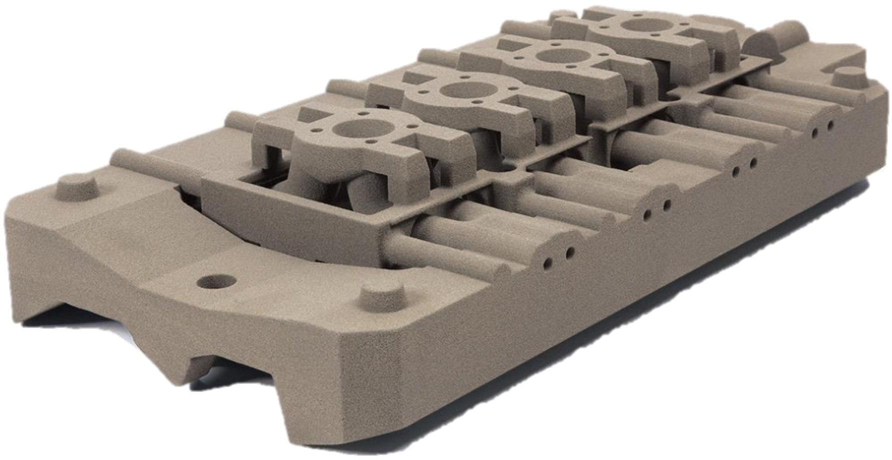

Figure 3. 3D printed sand mould (Metal resources, 2017)

Currently there are no local service bureaus to provide the chemical coated sand and as a result it needs to be imported from Voxeljet, which is based in Augsburg, Gemany. The major contributor towards high printing cost could be linked to high import costs and Euro/Rand exchange rates when buying the consumables.

1.6 Problem statement

The local manufacturing of moulds and cores for the foundry industry, using binder jetting additive manufacturing technology, is still considered to be expensive. The high manufacturing cost can be directly linked to expensive printing material, supplied by the OEM. A possible solution to mitigate the printing cost could be to localise the chemical coated sand used in the Voxeljet 3D printing process. However, this poses a risk to the quality of the printed components, as no quality assurance measures, for chemical coated sand, are available. Due to this reason, a quality assurance framework needs to be investigated.

1.7 Objectives

This study aims to establish a quality assurance framework to produce local chemical coated sand to ensure that the printing material adheres to the correct specifications for the Voxeljet VX1000 printing process.

The specific objectives are:

1. Identify and evaluate the critical characteristics of chemical coated sand that poses a risk to the quality management of the Voxeljet 3D printing process.
2. Determine the critical quality attributes required by the Voxeljet VX1000 process.
3. Define the quality assurance parameters for the chemical coated sand.
4. Develop a quality assurance framework.

1.8 Methodology

- Perform an in-depth literature study on quality to clearly define “quality assurance”. This activity will be sustained throughout the entire study.
- Identify a suitable methodology to aid with the development of a quality assurance framework. The methodology will determine how the framework is defined.

- Perform a critical evaluation on the critical quality sand parameters and their influence on the printed moulds and cores. The critical evaluation will focus on both additive manufacturing and conventional foundries.
- Compile the quality assurance framework, specifying the important parameters and required specifications of the chemical coated sand.

1.9 Delimitations of the study

This research did not include:

- Development of processes, procedures or work instructions.
- Cost accounting or supply chain management of the chemical coated sand process.
- Development of the actual coating process.
- Shipping and packaging processes.
- Material resource planning processes.
- The study excluded the validation of the QA framework. The option B Meng engineering management degree includes course work and a mini-dissertation. The mini-dissertation are limited to the verification of the research study, which excludes the validation process.

1.10 Summary

In this chapter, the background to the research and the statement of the research problem was provided. The objectives, delimitations and research methodology were also given. Chapter 2 will present a literature review on the quality, which will serve as the foundation of the study.

CHAPTER 2 - LITERATURE STUDY

2.1 Introduction

As discussed in Chapter 1, the lack of quality assurance measures for the chemical coated sand poses a risk towards the quality of Voxeljet VX1000 printed components. However, “quality” is a broad term and should be investigated to determine its importance in manufacturing systems. The following chapter demonstrates an in-depth literature study on quality and how it is defined.

2.2 Quality

In the global marketplace increased levels of competition have resulted in quality becoming of increasing importance to organisations (Martínez-Lorente, Dewhurst & Dale, 1998). According to the International Organization for Standardization (ISO) 8402-1986, quality can be defined as: “The totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs” (*Quality*, 2018). The evolution of quality is shown in Figure 4 and will be discussed below:

Figure 4. Quality evolution

2.2.1 Inspection Era

With the increase of specialisation and mass production in the 1800s, the necessity for more formal product inspections became evident. It was found that with an increase in production it became difficult to guarantee a flawless final product. In order to solve the following problem, inspectors were used to examine final products or components during the manufacturing line to detect flaws and variances. A measuring gauge is an example of the first tools used to detect deviant parts.

The 19th century marked the start of using quality control tools in the broader industry sector. This could have been linked to the increase in production volumes due to industrialisation and an ever-growing population. It was also during this time that business owners realised how the product quality affects sales (Sharma, 2010). In 1922, G.S Radford published a document linking inspection to quality control. The document, titled "The control of quality in manufacturing", recognised quality as a standalone function from the manufacturing process and that inspection is used as a means to control the set-up standards of quality control. Even though Radford's research was still in the early stages, he established some fundamentals known to modern quality management (Hoang, 2017).

2.2.2 Statistical Quality Control era

In the following era, industry became aware of the importance of quality control in the market space and can be broken down into three important milestones:

- The first statistical quality control method was introduced in 1931 by Walter A. Shewhart. The method theorised that "the same kind of product differs among themselves, or, in other words, the quality of a product is expected to vary" (Shewhart, 1930). Shewhart pointed out that there is a statistical distribution in almost all things, and by observing them it would be possible to identify the variable to stabilize the quality. Shewhart developed a statistical process chart (SPC), shown in Figure 5, that controls the variabilities of a product by creating criteria to determine whether the manufactured product meets the acceptable quality level. Although Shewhart's method was considered to be innovative, it took all the manufactured products into consideration which was time-consuming and inefficient (Hoang, 2017).

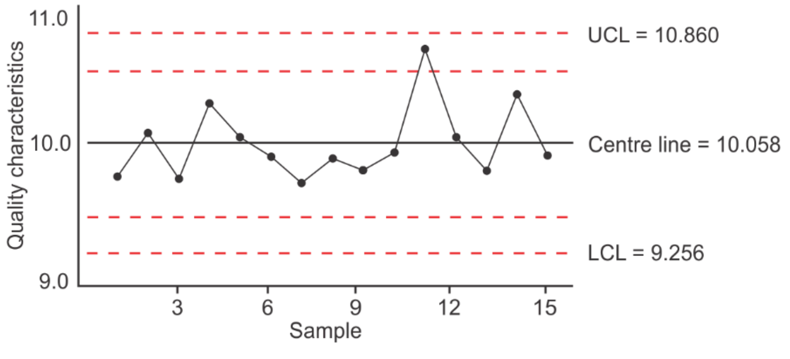

Figure 5. Statistical process chart

- In 1941, H. F. Dodge and H.G. Romi published a paper "Single Sampling and Double Table Inspection", which proposed to divide similar products into smaller groups and inspecting some of the products to determine whether the number of defects is acceptable by using a probability sampling table. This method was called the acceptance sampling method. The major advantage of using this method was that it decreased the number of inspectors necessary on a manufacturing plant. The method was extensively used during World War 2 with the mass production of weapons and ammunition. Acceptable Quality Levels (AQL) was used to measure the quality level, which could be defined as "quality level that is the worst tolerable". Although this method is no longer suitable for the world today it marked an important milestone in the development of quality systems (Hoang, 2017).

The establishment of the American Society for Quality Control (ASQC) in 1946, also marked an important milestone in the evolution of quality. The ASQC is an aggregation of individuals and other smaller societies who are quality enthusiasts, sharing their studies and publications with each other and hosting quality-themed conferences. ASQC was renamed the American Society for Quality (ASQ) in 1997, keeping its original mandate of promoting the use of quality control in practice. America was the leader in quality control up until the end of World War 2, when Japan began to standardise certain quality elements. The rapid acceleration of the Japanese quality systems could be linked to W. Edwards Deming, a student of Shewhart, giving quality lectures to the Japanese Union of Scientists and Engineers (JUSE). The Japanese adopted Deming's Cycle, or PDCA Cycles, which focused on the fact that quality needs to be continuously controlled and improved. Deming's Cycle is a step by step approach with the goal to continuously enhance a product or service, as demonstrated in Figure 6. The Japanese also identified the need to solve quality problems, related to quality control, from the start to prevent the problem from occurring (Hoang, 2017).

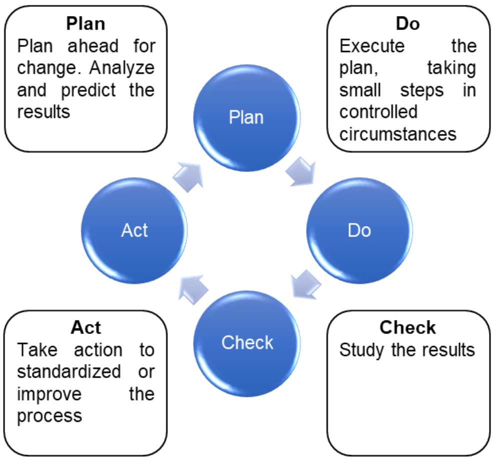

Figure 6. Deming or PDCA cycle (Tang, 2016)

2.2.3 Quality Assurance Era

The quality assurance era started in the 1950s, when the concept of "quality" shifted from being controlled to guaranteed. Up to the end of the previous era, quality was very much isolated to the production line or factory level. This was mainly due to no communication between departments. Quality at that point was a reactive process, which means remedies of addressing quality issues were made only when quality issues were found. The new quality era focused on analysing quality issues using a proactive approach, which included: cost of quality, total quality control, reliability engineering and zero defect (Hoang, 2017).

- Cost of Quality

  The cost of quality was not fully understood in the 1950s. At this stage, companies knew that implementing quality systems could be used to decrease defects, which at the end of the day were costly. However, no one had an idea of how costly defects were and how much quality should be improved. Joseph M Juran was known for his research on the cost of quality and theorised that the cost of quality could be divided into avoidable and unavoidable cost. Unavoidable cost was costs that still incurred even if quality activities are not performed, for example sampling, inspections, sorting, etc. Avoidable cost relates to the incurred cost due to defects and part failures such as labour, scrapped metal, compliant processing cost and the financial losses due to unhappy clients. It was also found that the avoidable and unavoidable costs were inverse proportional to each other, which meant that an increase in unavoidable cost will usually cause a decrease in the avoidable cost (Sharma, 2010).

- Total quality control

  The term "total quality control" was created by the New York Times and is defined as achieving and maintaining the highest quality throughout all levels of the organisation (Hoang, 2017). The total quality control approach is also called the company "wide quality control", which was developed by the Japanese. Juran studied the managerial dimensions of planning, organizing, and controlling quality. He also focused on the responsibility of management to achieve quality and the need for setting goals. With his managerial approach to improve quality he documented three basic processes, or also called Juran's Trilogy, shown in Table 1 (Neyestani, 2017). Armand Feigenbaum expanded on Juran's philosophy by highlighting the need for an inter-functional organisation, which can be defined as the collaboration between multiple departments working towards the same goal. He argued that if a product is controlled starting from the design process up to the point where the customer received it, the quality of the product would achieve the perfect status, thus "Quality is everybody's job".

Table 1. Juran's Trilogy

<table>
<tr><th>Quality planning</th><th>Quality Control</th><th>Quality improvement</th></tr>
<tr><td>Quality should be planned to ensure that the customer’s needs are met. Juran listed the following steps to plan quality:

❖ Establish quality goals.
❖ Identify who the customers are.
❖ Determine the needs of the customers.
❖ Develop product features that respond to customers' needs.
❖ Develop processes able to produce the product features.
❖ Establish process controls; transfer the plans to the process.</td><td>Create a system to compare the actual performance against planned performance and acting based on the difference. The steps listed to achieve quality control include:

❖ Evaluate actual performance.
❖ Compare actual performance with quality goals.
❖ Act on the difference.</td><td>Creating a cycle of constant improvement striving towards eliminating waste and defects to reduce the cost of poor quality. The steps listed in the quality improvement process are:

❖ Prove the need.
❖ Establish the infrastructure.
❖ Identify the improvement projects.
❖ Establish project teams.
❖ Provide the teams with resources, training, and motivation to diagnose the causes and stimulate remedies.
❖ Establish controls to hold the gains.</td></tr>
</table>

Feigenbaum suggested a system for different departments to collaborate on controlling the product design and manufacturing processes, with an end goal to satisfy the customer’s need (Hoang, 2017). A flow diagram of Feigenbaum’s quality system is shown in the Figure 7.

- <u>Reliability Engineering</u>

Although, Juran and Feigenhaum’s work focused more on the infrastructure of the company and the collaboration and cross-functional works, they thought applying statistical control into production is important. By adopting the military maintenance and logistics method, used during the Koria Civil Wars, US engineers developed a reliability engineering approach to determine a product or service’s reliability. The reliability engineering method used statistical methods to determine a product or service’s probability of failure across a defined time frame. It has also formed part of the Theory of Constraints (TOC) foundation. The techniques developed, which are still relevant in current practices, include (Hoang, 2017):

- ❖ Failure mode and effect analysis (FMEA), analysing the systematic failure of a product.
- ❖ Individual components analysis.
- ❖ Derating: require items to be used under their specifications level.
- ❖ Redundancy, identifying the important components.
- ❖ Monitoring of Field Failures.

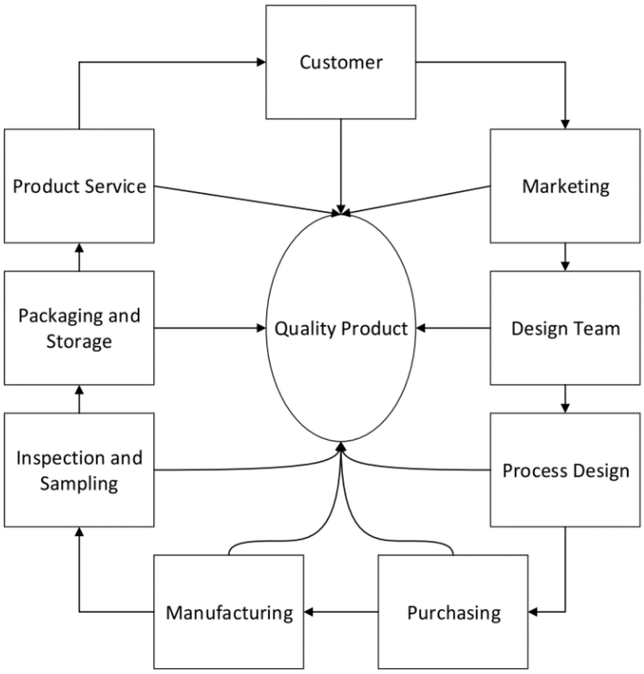

Figure 7. Quality responsibility flow diagram (Hoang, 2017)

- <u>Zero defect</u>

  During the development of quality management methods and procedures to reduce defects, it was noticed that the workers had no drive to achieve perfect results. In 1961, a missile company shifted the responsibility to manufacture perfect products to the workers instead of relying on inspection. It was found by raising worker's morale and awareness resulted in the manufacturing of better products with fewer defects. James F. Halpin, CEO of the missile company, published a book titled "Zero Defects: A New Dimension in Quality Assurance" explaining that if perfection is not expected and mistakes are treated as inevitable, defects will occur. He was of the opinion that if mindsets can be changed, it would be possible to achieve zero defects (Hoang, 2017).

Philip B. Crosby later added that Zero Defects should be used as a performance indicator. He dismissed the idea that “Zero defects” should be seen as a motivation-based programme but should rather be seen as a mindset of “doing the job right the first time”. Crosby was of the opinion that achieving the point of zero defects, will result in narrowing the gap between the cost of quality and the quality of the product itself (Hoang, 2017).

2.2.4 Strategic quality management era

From the late 1970s to early 1980s, quality was being looked at proactively and the general thought that achieving quality always comes with a cost disappeared. With the contributions coming from all preceding eras, the strategic quality management era marked the shift from product focus to customer focus, making quality a competitive advantage. During this era, the total quality management (TQM) philosophy was introduced which evolved from the Japanese “companywide quality control” philosophy, discussed in the total quality control section. Although TQM was traced back to the Japanese origin, strong ties could be made with the views of American quality gurus throughout the evolution of quality (Hoang, 2017). The philosophy could be summarized as: “A customer-focused organisation that involves all employees in continual improvement of all aspects of the organisation. It is an integrative system that uses strategy, data and effective communication to integrate the quality discipline into the culture and activities of the organisation”. The philosophy focuses mainly on 8 principles (Westscott, 2013):

- **Customer-focused**

  In the previous quality eras, the quality level was determined by the manager. The TQM philosophy is structured around customer satisfaction, thus ultimately the customer determines the level of quality.

- **Total employee involvement:**

  Total employee involvement refers to the participation of the entire workforce working towards common goals. This will only occur when management has created a suitable environment, which includes eliminating fear in the workspace and when employee empowerment has occurred. Deming expressed the importance of eliminating fear in the work environment as it destroys motivation. Employee empowerment refers to enabling or authorizing an individual to think, behave, act, and control work and decision-making in autonomous ways. Self-managed teams are an example of employee empowerment.

- **Process-centred**

  "Process" can be defined as a series of actions or steps taken in order to achieve a desired result. A process-centred approach helps to ensure that products or services rendered to clients, are correct and repeatable. The defined actions or steps are used to continuously monitor for unexpected variations.

- **Integrated system**

  Armand Feigenbaum expressed the need for internal departments to collaborate and to work towards a common goal, as quality is everyone's job. However, to achieve this it is important that everyone understands the vision, mission, guiding principles, policies, objectives and critical processes of the organisation. It is very important that the performance of a business is continuously monitored and communicated.

- **Strategic and systematic approach**

  The strategic planning of a company can be seen as providing an organisation with a vision, mission and measurable goals. Strategic planning is a tool that is useful for guiding day-to-day decisions and for evaluating progress and changing approaches when moving forward. However, the strategic and systematic approach in the TQM philosophy refers to the formulation of a strategic plan that integrates quality as a core component.

- **Continuous Improvement**

  Continuous improvement refers to the continuous drive to optimise processes and systems within an organisation with the goal to becoming more competitive and increasing the efficiency. It also refers to lifelong learning, that ensures employees perform their duties better and more efficiently.

- **Fact-based decision-making**

  Fact-based decision-making ensures a company makes decisions based on measurable results. Thus, TQM requires companies to continuously collect and analyse data to improve decision-making accuracy, achieve consensus, and allow prediction-based decisions based on past history.

- **Communications**

  Effective communication is the lifewire of any organization regardless of its size or nature. If properly used it is an instrument for effective job performance and serves as an index to employ motivation and the resultant high productivity. Communication can be defined as the exchange and understanding of information between two or more persons.

Keeping the above-mentioned principles in mind, the difference between traditional and TQM can be summarised in Table 2.

Table 2. Traditional vs TQM approach (Hoang, 2017)

Quality elements	Previous state	Total quality management
Definition	Project-orientated	Customer-orientated
Priorities	Second to service and cost	First among equals of service and cost
Decisions	Short-term	Long-term
Emphasis	Detection	Prevention
Errors	Operations	System
Responsibilities	Quality control	Everyone
Problem-solving	Managers	Teams
Procurement	Price	Life-cycle cost
Manager's role	Plan, assign, control and enforce	Delegate, coach, facilitate and mentor

2.3 Cost of quality

The following section defines the cost and importance of quality.

2.3.1 Quality cost

During the quality assurance era, the cost of quality was divided into avoidable and unavoidable costs. It also stated that unavoidable costs could not be managed using a quality approach. However, with the evolution of TQM it was discovered that the unavoidable cost could indeed be controlled using quality cost management tools. Juran developed a quality cost model to describe an optimal quality situation as shown in Figure 8. This model identified three cost drivers namely: prevention, appraisal and failure cost. Prevention costs refer to the cost incurred to prevent or avoid quality problems and the appraisal costs are associated with the cost of ensuring that a product or service adheres to the defined quality level. Thus, both the prevention and appraisal costs are associated with ensuring a product or service's quality is in place and is defined as unavoidable cost. The failure cost is cost associated with defects due to quality problems and is regarded as avoidable cost (Hoang, 2017).

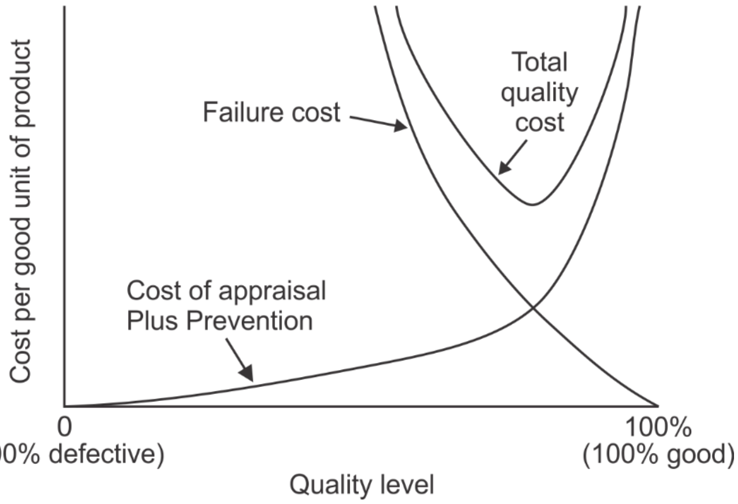

Figure 8. Juran's cost of quality model (Juran 1979)

It has been found that the cost associated with poor quality, an avoidable cost, can be difficult to measure. These costs can be divided into visible, easy to determine costs, and invisible costs that are difficult to find or measure (Vysochynska, 2016). Neglecting the invisible cost can have a huge impact on a business. The visible and invisible cost can be explained using the "iceberg" concept, as shown in Figure 9.

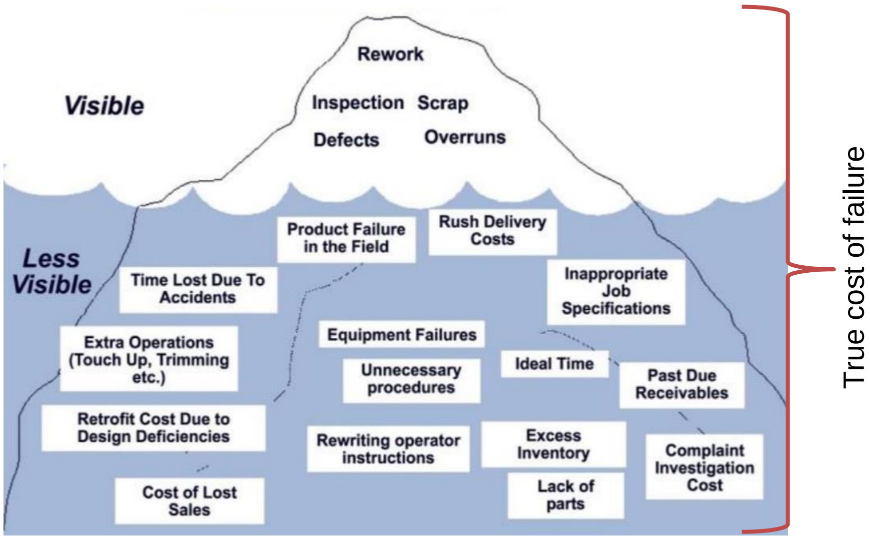

Figure 9. Iceberg concept (Krishnan, 2006)

Genichi developed a method used to identify invisible costs that is called the quality loss function. Genichi disagreed with the original quality definition of Crossby, stating that quality is aimed at conformance for requirement. He defined quality as "the loss impaired to society from the time the product is shipped" (Hoang, 2017). He believed that ideal quality refers to a reference point, which is expressed as a target value. The quality loss function is based on the assumption that any deviation from the target value will result in a loss to society (Vysochynska, 2016). The difference between the traditional and quadratic loss function is shown in Figure 10.

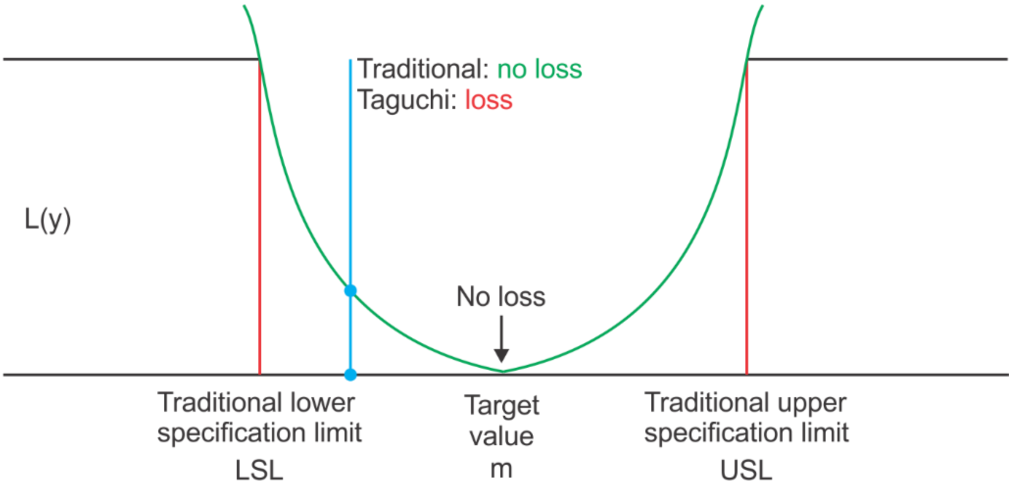

Figure 10. Traditional vs quadratic loss function (Vysochynska, 2016)

The target value is represented by 'm' and the lower and upper specification limit of the design parameter is represented by 'LSL' and 'USL'. Using the conventional loss function, products within the lower and upper specification values were deemed to have no loss impact. However, the quadratic loss function shows that the quality loss increases exponentially as the quality deviates from the target value. Genichi's approach shows that even if a product or service is not considered to be a defect, it still causes a loss. Thus, the quadratic loss function clearly demonstrates that any deviation from the target value represents a potential loss to society (Vysochynska, 2016). Genichi also highlighted that the deviation in quality could be reduced by decreasing the variation of operation in an organisation. This could be achieved by implementing a continuous improvement cycle for quality in the supply chain to maintain the stability of operations in an organisation (Hoang, 2017). Genichi's philosophy can be summarized in 4 statements, namely:

- A change in cost affects the quality.
- An increase in quality causes an increase in cost.
- The cost cannot be reduced by improving the quality
- The cost can be reduced by reducing the variation. The reduction in the variation increases the performance as well as the quality.

2.3.2 Quality cost matrix

As explained in the previous section, the quality applied to a product or service influences the final cost. If a product or service is not priced appropriately it could cause a loss in sales. However, a product with a lower quality can be more profitable simply because of its perceived quality. David Gravin used Genichi's philosophy to develop 9 core quality dimensions that are shown in Table 3. Each of these dimensions could be used in isolation but could create a bigger impact if they are used in conjunction with each other. Products or services do not necessarily have to adhere to all the nine dimensions to be classified as a quality product (Hoang, 2017).

Table 3. Core quality dimensions (Hoang, 2017)

Dimension	Meaning
Performance	Primary operating characteristics of a product of service
Features	Additional characteristics which improve the attractiveness of a product or service
Conformance	The tolerance level of a product or service compares to specifications and standards
Reliability	The consistence level of outputs that a product or service can operate without failure
Durability	Product or service lifespan, usually when it is not economical to operate
Service	Response time with a product or service break down
Response	The communication behaviour of the sale serviceperson and how competent they are
Aesthetics	The impression from the user to a product or service, using 5 common senses. Usually based on personal bias.
Perceived quality	Indirect measurements based on past performance of a product or service, or branding

It is important for a company to know their brand positioning in correlation to competitors. They must also know their customer target group to select the correct costing and marketing strategy. Philip Kotler developed a quality price matrix, demonstrated in Figure 11, to create a link between quality and price. The matrix could be used to support the decision-making process to determine the costing and quality of a product (Hoang, 2017).

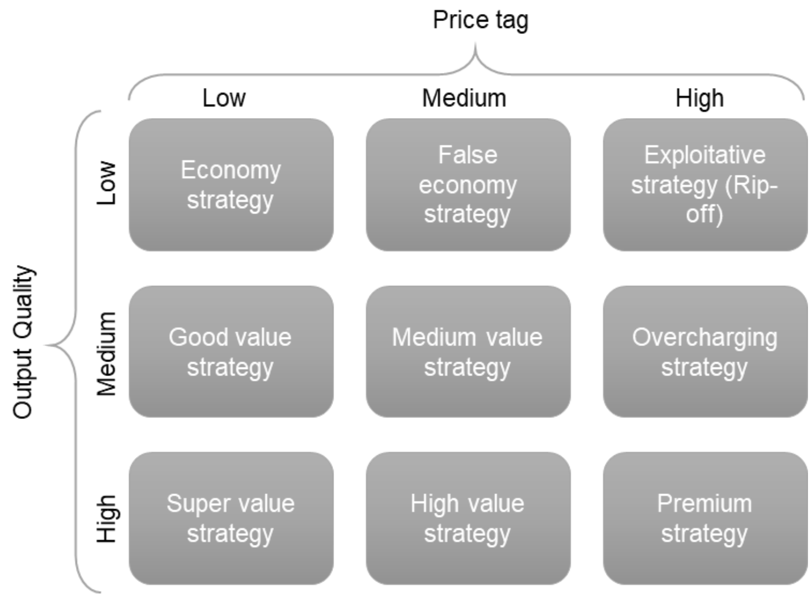

Figure 11. Nine quality price matrix (Hoang, 2017)

2.3.3 Cost of continuous improvement

Continuous improvement is listed as one of the key principles of the TQM philosophy. The continuous improvement method can be applied to all aspects of an organisation, with the end goal of increasing the satisfaction of the customers. As highlighted in the quality assurance era, Juran suggested that quality could be improved by optimising the planning, control and improvement process, also known as the Juran's Trilogy approach. Using the Trilogy approach, Juran showed the impact of quality improvement on the cost of quality as shown in Figure 12. During the planning process, the requirements of a product or service to satisfy customer's needs, are established. These requirements are then implemented during the control process. The control process includes the inspection and evaluation of products or services. The change in performance, measured by the control process, will cause a sporadic spike in the cost of quality. The variance in performance could be caused by system failures, unplanned maintenance, unmotivated staff, etc. Corrective actions, such as problem-solving, are then used to restore the performance and cost of quality back to their original setting. However, the corrective measures are considered to be "chronical waste" as it does not add value to the product of service. The improvement process is aimed to increase performance, which will ultimately decrease the cost of quality. According to Juran, this would only be possible when establishing a continuous improvement infrastructure. This requires top managers to identify the areas which need to be improved, and afterwards, back the project with time and personnel to diagnose the root of the problem. The improvements to the control process will result in a lower cost of quality (Hoang, 2017).

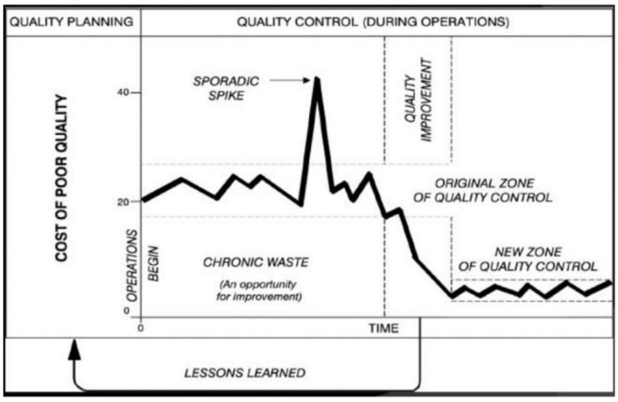

Figure 12. Impact of continuous improvement on the cost of quality (Hoang, 2017)

According to Maaski Imai, there are two types of improvement: breakthrough or incremental. Breakthrough improvements are innovative in nature and usually occur radically, whereas incremental breakthroughs are improvements implemented in a systematic manner and is also called Kaizen (Hoang, 2017). The differences between the two improvement types are shown in Table 4.

Table 4. Kaizen improvement vs. Innovative improvement (Hoang, 2017)

	Kaizen	Innovation
1. Effect	Long term and continuous but undramatic	Short term, but dramatic
2. Speed	Small steps	Big steps
3. Timeframe	Continuous and rising	Interrupted and limited
4. Chances of success	Always on a high level	Abrupt and unsettled
5. Protagonist	Every single employee	The chosen few
6. Approach	Collective spirit, teamwork, system	Individual ideas and efforts, ruthless
7. Motto	Preservation and improvement	Demolition and reconstruction
8. Recipe for success	Conventional know how and todays state of the art	Technological achievements, new inventions, new theories
9. Practical preconditions	Small investment, big effort to preserve the status quo	Big investment, small effort to preserve the status quo
10. Success orientation	Men	Technology
11. Criteria for evaluation	Performance and processes for better results	Profit
12. Advantages	Best sited for slow-growing economies	Best suited for fast-growing economies

To summarise the differences between Kaizen and innovative improvements: Kaizen is a long-term investment solution with a long turnaround time, whereas innovative improvements require technological breakthrough to work, which costs a significant amount of money when implemented. With both the Kaizen and Innovative approach pursuing the same goal, of increasing performance, the methods could be used in conjunction with each other to ensure maximum impact. The effect of using both Kaizen and innovative improvement methods in a continuous improvement system is demonstrated in Figure 13.

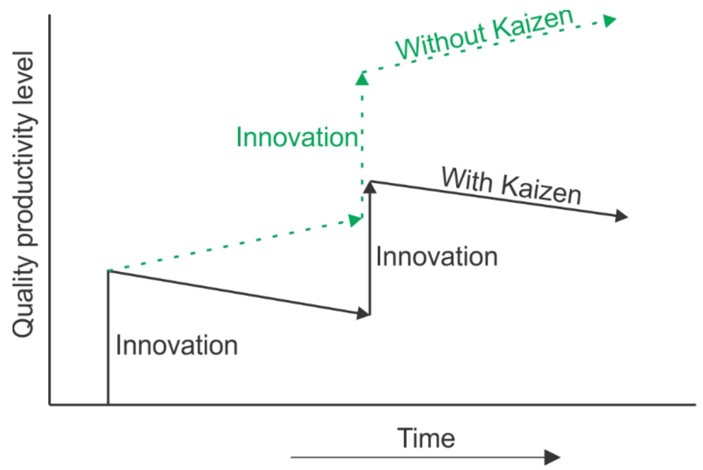

Figure 13. Continuous and Kaizen improvements (Hoang, 2017)

2.4 Summary

This chapter demonstrated the evolution of quality, which highlighted important quality aspects and how it is integrated into organisations. It also showed the affects that quality could have on the cost of a product or service. The literature study in Chapter 2 serves as the foundation to develop a quality assurance framework strategy, as shown in Chapter 3.

CHAPTER 3 – QUALITY ASSURANCE DEVELOPMENT STRATEGY

3.1 Introduction

Quality plays a crucial part of any business and can be defined as meeting the needs and expectations of customers. The scope of managing quality is very broad and requires a well-defined quality management approach. The following chapter focuses on the importance of quality assurance in a quality management system. It also identifies a method to develop a quality assurance framework.

3.2 Quality management system

The literature study in Chapter 2 demonstrated the evolution of quality, which also highlighted the importance and value of adopting a quality philosophy such as TQM. The TQM philosophy focusses on the entire company, with the objective to meet the requirements of customers with efficiency and effectiveness. A major problem with the TQM philosophy is that there are no standards or hard-line procedures for implementing such a system (Lakhe & Mohanty, 1993). Thus, TQM in its own capacity is not a standardised quality system and its implementation would differ between companies. The importance of standardisation of business management has increased significantly in the past four decades owing to globalisation and economic integration of markets (Heras-Saizarbitoria, 2017). There are several advantages of standardising quality management systems, which include: improved clarity, improved efficiency, better and consistent control of major business processes, improved market compatibility, reduced risk, improved customer satisfaction, consistency and regulation of successful working practices.

Companies that adopted a TQM philosophy often implement standardised quality management systems (QMS), such as ISO 9001 that is known as the most influential QMS to date. ISO 9001 is not a performance-based system but rather measures the quality conformance of companies' products or services. Thus, ISO 9001 standardises procedures, duties and roles rather than goals or outcomes (Heras-Saizarbitoria, 2017). The first ISO 9001 standard was introduced in 1987 and was reviewed every five years to determine whether it is still relevant to the market space or whether any amendments should be made.

ISO 9001 is not considered to be a TQM model, even though it incorporates some TQM principles. However, it has been reported that the gap between TQM and ISO becomes narrower with each revision after the 2000 release. A company will only be ISO 9001 certified, once they are successfully audited by an accredited certification body. ISO 9001:2015 is the latest standard, which replaced the previous ISO 9001:2008 standard, and is based on seven management principles (Fonseca, 2015). These management principles include: customer focus, leadership, employee engagement, process approach, improvement, evidence-based decision-making and relationship management (Jasiulewich-kaczmarek, 2016).

- **Customer focus**

  The first principle is focused on attracting and retaining the confidence of customers. Every aspect of customer interaction provides an opportunity to create more value to the customer and is important to fully understand the current and future customer requirements. An effective customer-focused management system understands both current and future customer requirements, aligning the company and objectives with the client expectation and needs and to continuously manage the customer-organisation relationship (Biswas, n.d).

- **Leadership**

  This principle states that leaders within an organisation need to establish unity of purpose and direction, to maintain a culture and system that promotes employee involvement to collectively achieve the organisation's objectives. Examples of good leadership include: establishing a mission, vision, strategy, policies and procedures throughout the organisation, establishing a culture of trust and integrity, encouraging and promoting of organisational wide quality and provide employees with the required training, resources and authority to act with accountability (Biswas, n.d).

- **Employee engagement**

  The employee engagement principle refers to ensuring that all staff members are competent, empowered and engaged in delivering value. Examples of employee engagement include: create a clear understanding of each employee's importance and contribution to the company, promote collaboration throughout the organisation, encourage and empower staff to identify performance constraints and developing solutions, perform regular staff satisfaction surveys to identify problem areas and to create open discussion forums to promote the sharing of expertise and knowledge (Biswas, n.d).

- **Process approach**

  Following a process management approach will deliver consistent and predictable results in a more efficient and effective way. A process or multiple interrelated processes are used to eliminate any uncertainty around activities and is structured to achieve clearly defined objectives in a systematic manner. It also creates a sense of responsibility and accountability of managing activities. Processes help to analyse and measure the capabilities of activities, while simultaneously evaluating the risks, consequences and impact (Biswas, n.d).

- **Improvement**
  Improvement refers to the well-known quality philosophy of continuous improvement and should be a permanent company-wide objective. Examples of continuous improvement activities include: establishing and promoting of companywide quality objectives, training staff on applying continuous improvement methodologies, implement improvement processes, recognising and acknowledging successful improvement activities (Biswas, n.d).

- **Evidence-based decision-making**
  Evidence-based decision-making management principles allude to making organisational decisions, based on the analysis and evaluation of data. Following this approach will reduce the risk of producing unwanted results. An example of evidence-based decision-making is to analyse evidence/data from existing processes to make decisions or suggest improvements (Biswas, n.d).

- **Relationship management**
  An organisation is dependent on its suppliers and a mutual beneficial relationship will enhance the ability for both parties to create value. Relationship management refers to the sharing of knowledge, vision, values, understanding and suppliers not treated as adversaries (Biswas, n.d).

According to ISO, there are four main benefits when implementing ISO 9001: the ability to consistently provide products or services that meet customer and applicable statutory and regulatory requirements, Creating the opportunities to enhance customer satisfaction, addressing risks and opportunities associated with its context and objectives and the ability to demonstrate the organisation’s adherence to an international quality management system. Due to the advantages mentioned above, ISO 9001 will serve as the foundation to address the aim of the research study.

3.3 ISO 9001 framework

The ISO 9001 standard promotes the use of a process-based approach when developing, implementing or improving the effectiveness of a quality management system. A process-based approach is the systematic definition and management of processes to achieve a result, which aligns with the quality policy and strategic direction of the organisation. Thus, a process can be summarised as an activity used to transform an input to a desired result or output. A quality management system could consist of a single or multiple interrelated processes, which enables:

- Understanding and consistency in meeting requirements
- The consideration of processes in terms of added value
- Increase both performance and efficiency
- Improvement of process based on evaluation of data and information

According to ISO, there are six main components in a single process namely: source of inputs, inputs, activities, outputs, receiver of outputs and monitoring and measuring checkpoints. The monitoring and measuring checkpoints are specific to each process and will vary depending on the related risks (ISO, 2015). A flow diagram of a single process, highlighting the interaction between the components, is shown in Figure 14.

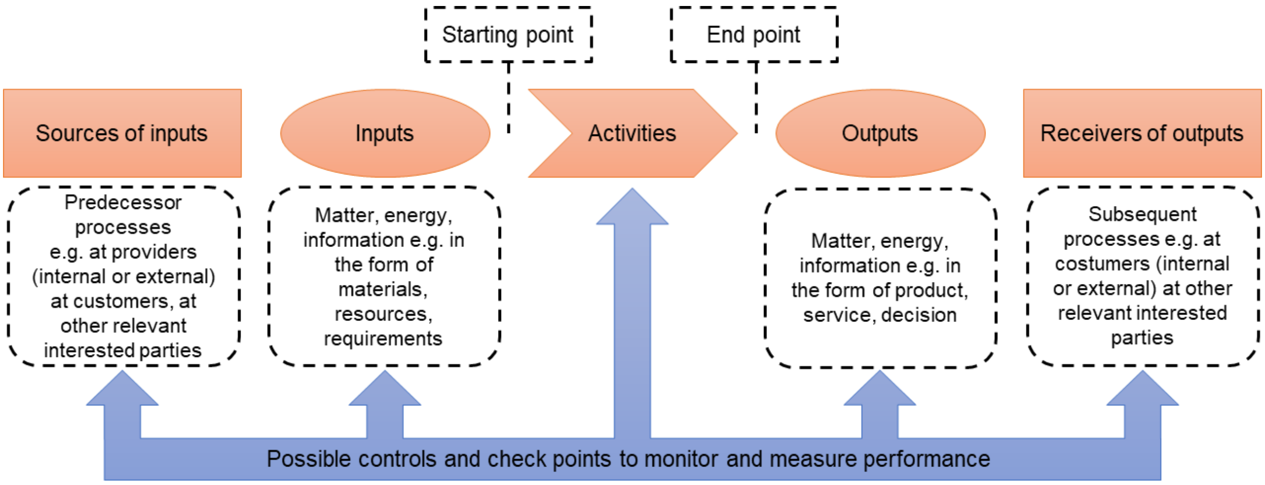

Figure 14.Process flow diagram (ISO, 2015)

ISO 9001 also highlights the importance of implementing a Plan Do Check Act (PDCA) cycle and is used as a process management tool. The PDCA cycle focuses on risk-based thinking, taking advantage of opportunities and eliminating or preventing undesired results and can be described as follows (ISO, 2015).

Plan – Establishing the objectives of the processes and resources necessary to deliver a product or service according to the customer's requirements and organizational policies, while simultaneously identifying risks and opportunities (ISO, 2015).

Do – Implementing the plan (ISO, 2015).

Check – Monitoring and measuring of the processes and products against the objectives, policies, requirements and planned activities and reporting of the results (ISO, 2015).

Act – Act on the results in the previous step, with the aim to improve the performance (ISO, 2015).

The seven ISO 9001 clauses can be incorporated in the PDCA cycle and is illustrated in Figure 15. The "do" activity is seen as a quality assurance (QA) function that ensures that the activities are done correctly. QA is based on the principle of "doing thing right the first (and every) time" and is seen as a proactive process-focused activity.

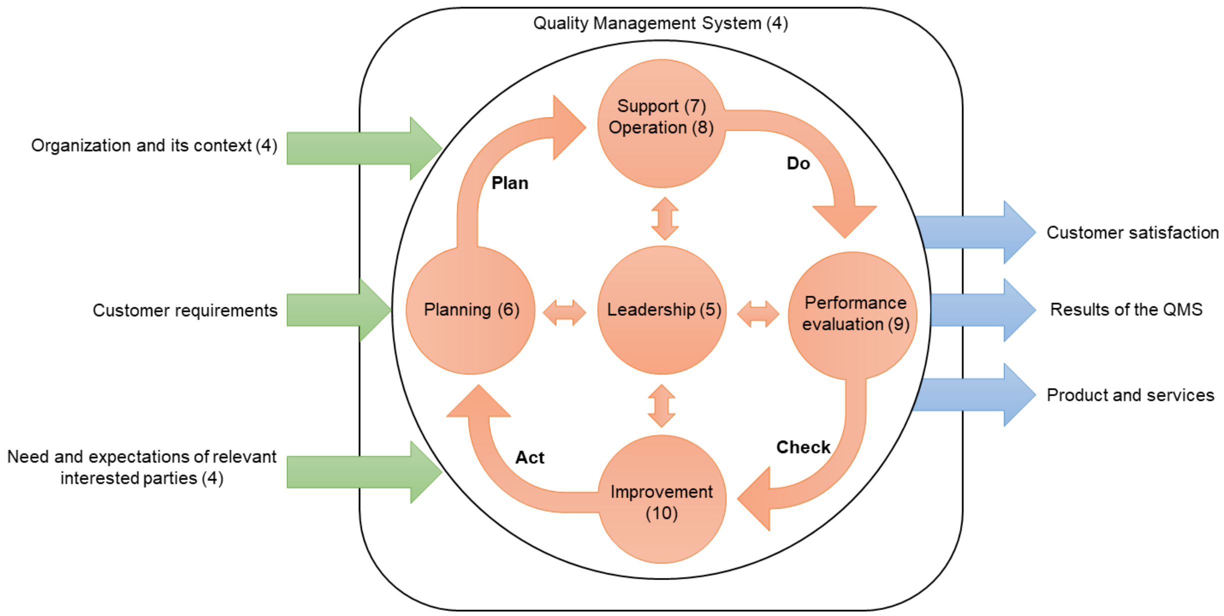

Figure 15. ISO 9001 PDCA cycle (ISO, 2015)

As highlighted in Figure 15, the "do" activity encapsulates both the support and operation clause of the ISO 9001 standard and is summarised in Table 5 (9001Council, 2017). Clause 7 focuses on ensuring that operational functions meet the quality requirements. These requirements could be determined internally or externally. The clause also highlights the use of processes, procedure and work instructions to ensure conformance.

Table 5. Summary of ISO 9001:2015 clauses 7 and 8

Clause 7 – Support	Clause 8 – Operation
Clause 7 is structure around support functions, which include: • Determine and provide the required resources to implement and improve a QMS system. These resources include human resources, infrastructure and work environment needed, maintenance, organisational knowledge and the competence of people. • Ensuring management and staff are aware of the quality policies and relevant objectives. • Implement a document control system.	Clause 8 specifies process requirements of operations and highlights the flowing crucial requirements: • Organisational planning and control processes, which emphasize how a company understands, communicates and meets customer requirements. • Design and development reviews requirements – verification and validation should be planned from the start. • Purchase and outsourcing processes. • Design and development processes. • Specify controls for actual production and service provision. • Delivery and signoff requirements. • Nonconformance processes.

3.4 Processes, Procedures and Work Instructions

Although ISO 9001:2015 has relaxed the strict requirement for quality management documentation, to satisfy the remaining documentation requirements, and (often more important), to properly implement the quality management system (QMS), Processes, Procedures and Work Instructions are typically still employed. (ISO 9000 store, n.d.). Processes, procedures and work instructions are considered to be QA measures as they ensure that the planned activities are done correctly. The relationship between processes, procedures and work instructions could be explained by organising them into three tiers, as shown in Figure 16.

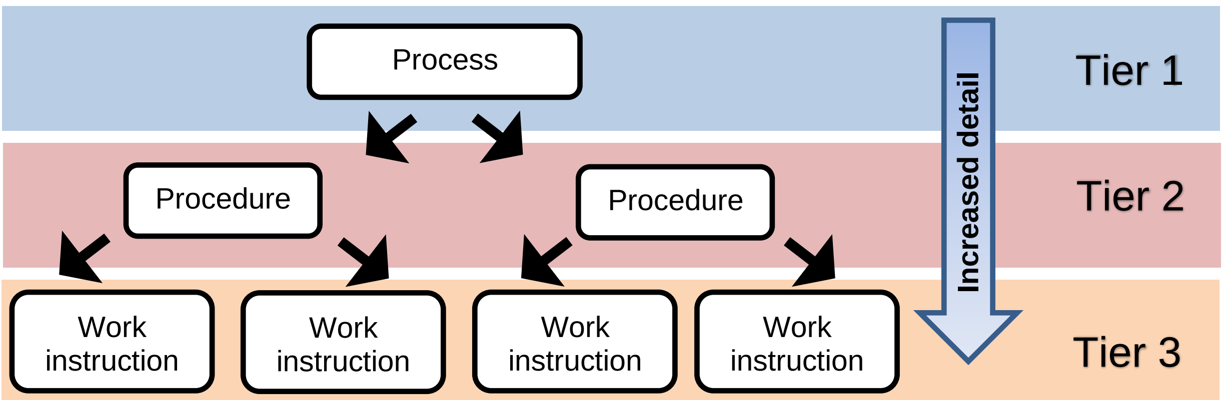

Figure 16. ISO 9001 Process, Procedure and Work Instruction

- **Tier 1 - Process**

As mentioned in the previous section, processes play an important role in the ISO 9001 standard. A process is an activity that transformS an input into an output, aligns with the quality policy and strategic direction of the organisation, and is seen as a high-level strategic method of control, which summarises the objectives, specifications and broad resources needed (ISO 9000 store, n.d.). A simplified representation of a process is shown in the figure below:

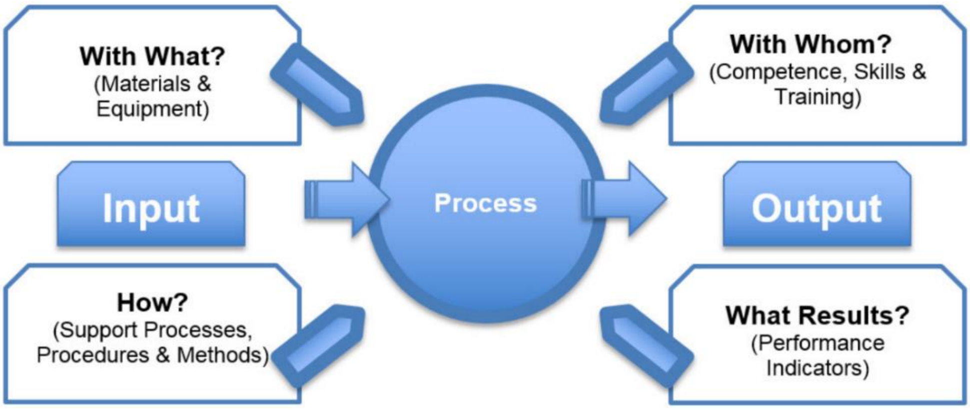

Figure 17. Process

- <u>**Tier 2 – Procedures**</u>

A procedure is a uniform method that specifies how to perform a process. Using procedures will ensure that the operation is repeatable and accords with to the required quality standards. There are no fixed document layout requirements, however the following elements are deemed to be important when compiling a procedure document (ISO 9000 store, n.d.):

- Purpose of the procedure – Why is the procedure important?
- Procedure objectives – What needs to be accomplished and how will it be executed?
- Responsibilities – Who needs to perform what action?
- Instructions on how to perform a process – how to convert the inputs into outputs
- Locational requirements – Where should the activity be performed?
- Important criteria that should be met.
- Tools, information or other resources required.
- Terminology, definitions, explanations, etc.

An example of a procedure is attached in Annexure A.

- **<u>Tier 3 – Work instructions</u>**

A work instruction specifies how to perform a certain task within a procedure and is usually a step by step instruction. Work instructions are only necessary when more detail is required for a task listed in the procedure and is not necessary for each task point (ISO 9000 store, n.d.). An example of a work instruction document is attached in Annexure B.

3.5 Procedure design methodology

As highlighted in the previous section, procedures are deemed as a QA measure that provides the necessary information on how to perform a process to achieve a repeatable and expected result. The quality by design (QbD) methodology has been identified as a suitable methodology to aid in the development of a QA framework for the chemical coated sand process. The QA framework could serve as a basic structure to develop process, procedure or work instruction documents. QbD was originally introduced in 1985 by Juran's book "Juran on Quality by Design" and is based on the Trilogy approach that describes the requirements to achieve breakthroughs in new product, service or process development. The methodology is widely used by both the automotive and pharmaceutical industries and is also known as concurrent, simultaneous or parallel engineering, since all the major development functions are required to be performed at the same time. The difference between traditional and QbD product development is shown in Figure 18 (Naidu, Babu & Rajendra, 2013).

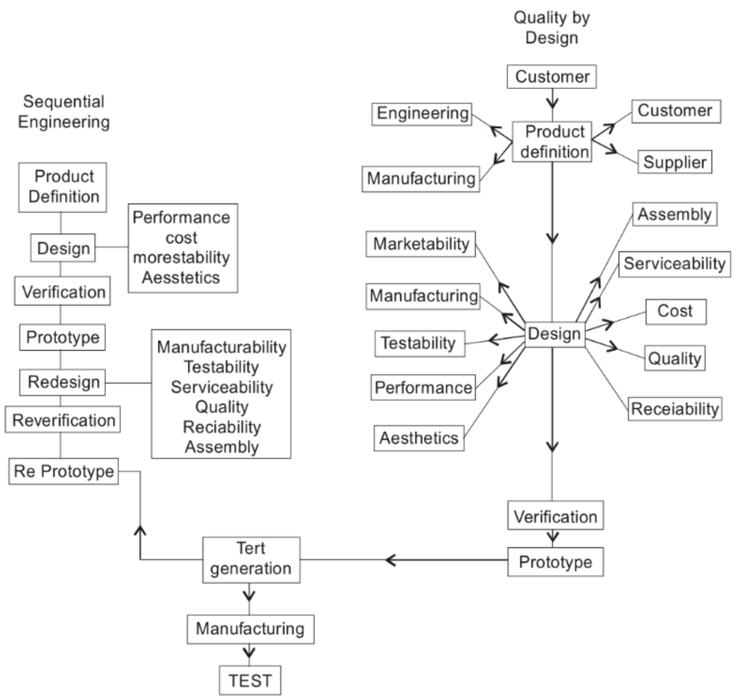

Figure 18. Product development flow diagram (Naidu et al., 2013)

Product development, using the traditional manufacturing principles, includes multiple changes and evaluations to the part, or service, to achieve the final product. In the pharmaceutical industry, early stage designs can consist of 70% of the total product lifecycle and influence between 70% to 85% of the total product cost. The major contributor towards the increase in the total product lifecycle and cost is due to the risks involved during the development stage. Thus, QbD is used as a tool to reduce risks and foster rational design thinking to avoid trial-and-error situations. This has proven to reduce both research lead times and development costs (Martinez, Carty, Mirnajafi & Stewart, 2018).The QbD methodology comprises of 8 sequential steps to create a better understanding of a product/service and its manufacturing process, which includes the identification and control of all the variables to ensure quality. The methodologies process flow is demonstrated in the figure below:

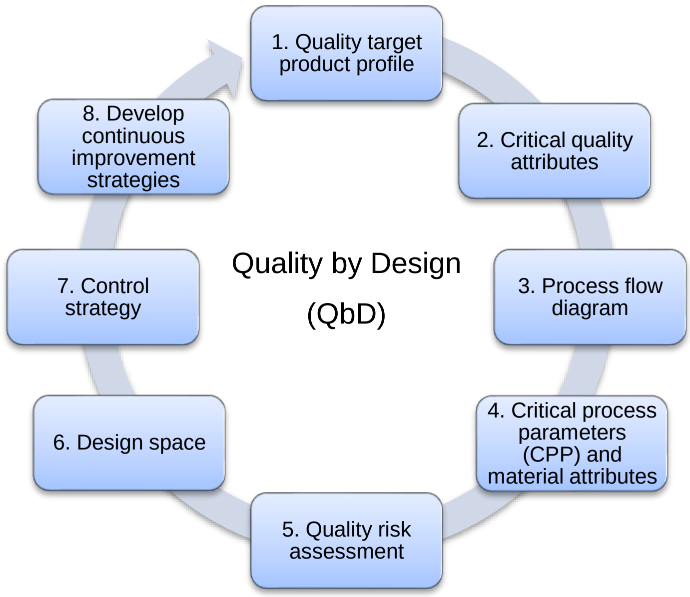

Figure 19. QbD framework

3.5.1 Step 1 - Quality target product profile (QTPP)

The QTPP describes how a product will be utilised by the end user, which include product information such as the ideal characteristics and features in relation to the safety and performance of a product. This will link the development process to a clear goal. The profile can be developed using the expertise from multiple professions, for example: marketing (defining the end user's needs), engineers, market specialists, etc. However, it should be noted that the QTPP is a dynamic process that incorporates the feedback of all the QbD steps. Garvin (1984) stated that quality can be divided into five approaches and is defined based on the end-user's perspective. These approaches are consider to be high level approaches and include: (Martinez *et al.*, 2018).

- **Transcendental perspective -** a metaphysical aspect of quality, which makes it very hard to define. For example, when a client uses a certain brand of cosmetics and feels pretty but cannot provide any physical proof (Ross, 2009).
- **User-based view -** when a product satisfies a specific target group's preference. This approach is based on quality as defined by the end user (Ross, 2009).
- **Manufacturing-based -** relates to the production and engineering requirements. The following approach defines quality from a manufacturer's point of view, which includes aspects such as product specifications, requirements, available technology, reducing scrap rates, etc. (Ross, 2009)
- **Value-based -** can be defined as the quality level perspective from the price and other attributes. In other words, the value a client associates with a certain product cost. (Ross, 2009)
- **Product-based** - When the quality can be assessed by quantifiable and measurable characteristics or attributes. This approach does not necessarily satisfy a specific customer's need but rather answers a specific question. An example might include the time it takes for a computer to start? (Ross, 2009)

The actual quality of a product, in each of the above-mentioned perspectives, could be measured using the quality dimensions developed by David Gravin. These dimensions can be seen as quality indicators and are listed in Table 3. The relevance of each of the indicators are based on the target market and customer needs. An example of a QTPP developed by Martinez et al. (2018) for 3D printed bone prostheses and scaffolds are shown below:

Table 6. QTPP for 3D printed bone prostheses and scaffolds (Martinez et al., 2018)

Quality approach	Dimension	Description
Product-based approach	Performance	Each 3D printed bone prosthesis and scaffold is custom designed to restore the functional characteristics of patient's bone, provide long term osseointegration, operate properly in normal conditions, and to last the required number of years for its purpose.
	Features	3D printed bone prostheses have special features such as bioactive surfaces that promote bone ingrowth, a modulus of elasticity similar to the host bone, are specifically designed according to each customer's geometry and functional characteristics, and possess a hierarchical macro, micro, and nano architecture that resembles bone structure.
	Reliability	Due to the fact that each prosthesis is custom made and fabricated with the latest technologies and materials, its life expectancy should match or exceed traditional bone prosthesis reliability and functional characteristics. In the case of bone scaffolds they are tuned to resorb based on each patient's biological conditions to restore bone tissue. Moreover, The fabrication process of such products should be robust with minimum quality variations.
Manufacturing-based approach	Conformance	Each 3D printed bone prosthesis meets or exceeds medical device regulations. The design and fabrication processes are subjected to strict quality tests (control) to provide a product with zero defects (according to tolerances needed).
	Durability	Products are made with the best materials and technologies available, using a direct interaction with the customer to design custom bone implants that exceed the life expectancy of traditional bone prosthesis.
User-based approach	Serviceability	Each client is unique. Therefore, the company is responsible for providing a personalized service where each client is involved in the prosthesis design process. Moreover, the company must meet all customer specifications on time and be responsible for any irregularity. Additionally, it is important to provide an easy and accessible service to any potential customer.
	Aesthetics	The product has the correct materials and appearance for the target market. The technologies used for the product design and fabrication allow a precise reconstruction of defects from trauma or surgery, providing a correct custom shape and superficial finish to achieve better cosmetic enhancement and functional rehabilitation.
	Perceived quality	In this case the client has a clear understanding about the product's attributes, which can be found in medical performance reports and statistical data.

3.5.2 Step 2 - Critical quality attributes (CQA)

This step identifies the product characteristics which should be contained within certain limits to ensure that they conform to the desired quality level, defined in the QTPP. Examples of CQA attributes include, but are not limited to mechanical, electrical, biochemical, etc. functions. A scientific or risk management rationale are usually being used to effectively identify the product characteristics. However, the CQA are only identified but not defined within limits, for early product development phases. An example of CQA identified for 3D printed bone prostheses and scaffolds is shown in Table 7.

Table 7. CQA for 3D printed bone implant (Martinez *et al.*, 2018)

Dimensional	Mechanical	Biological	Physicochemical	Functional
Match patient specific geometry	Low modulus of elasticity (resemble bone Young's modulus)	Material purity	Biocompatibility	Patient's bone characteristics
Macro surface geometrical accuracy	Shear/Compressive/tensile strength	Protein adhesion	Tuned resorption rate (biodegradable implants)	Muscle moment arms
Micro geometrical accuracy	Fatigue strength	Cell adhesion	Corrosion resistance (permanent implants)	Real life implant's loading conditions
Nano geometrical accuracy	Hardness	Cell migration	Surface micro and nano topography	Implant's bone interface contact forces
3 dimensional structure	Toughness	Cell proliferation	High surface area	Implant's soft tissue interface contact forces (metallic implants)
Pore size	Poisson's ratio	Mineralization	Bioactives	Customised rehabilitation program
Pore shape	Wear resistance	Control of inflammation	Resistance to sterilization process	
High pore interconnection		Antibacterial properties	Surface energy (wettability)	
High percentage of porosity		Transport of nutrients and waste removal		

3.5.3 Step 3 - Process flow diagram (PFD)

The PFD helps to represent processes visually through the identification of the necessary steps, participants and decisions in a process. The PFD improves the understanding of the current process and helps to identify problem areas that might affect the product performance and CQA. It also helps to achieve a more accurate identification of the most critical processes. An example of a PFD, for a 3D printed bone implant, is shown in Figure 20.

3.5.4 Step 4 - Critical process parameters (CPP) and material attributes (CMA)

This step is aimed at determining the process parameters and material attributes whose variability could potentially affect CQA. Usually the CPP and CMA should be monitored and controlled throughout the process to ensure process consistency, repeatability and accuracy. The attributes could be determined using a scientific or quality risk approach by linking the QCA groups (Step 2) to each of the processes mapped in the workflow map (Step 3).

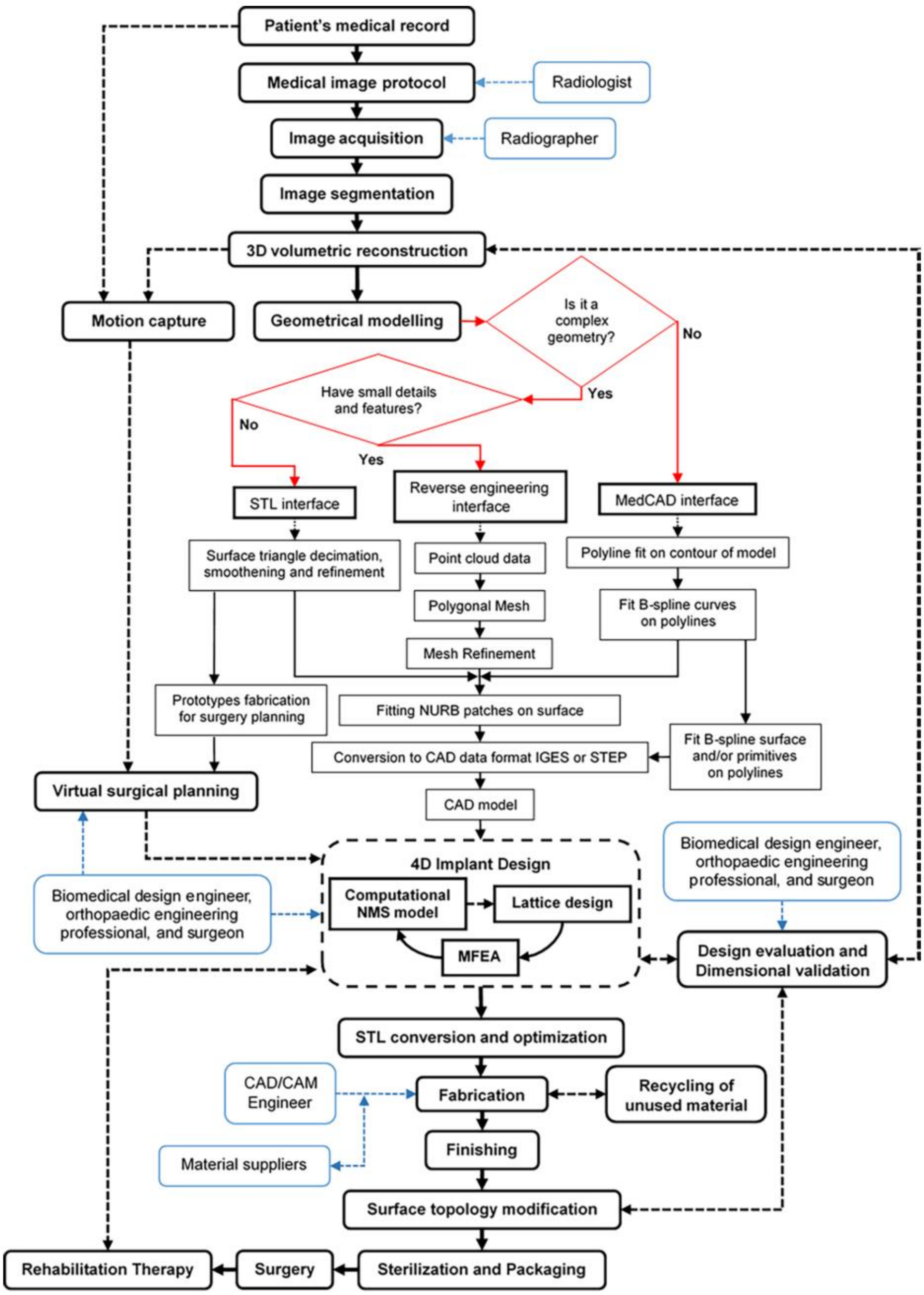

Figure 20. PFD for 3D printed bone prostheses and scaffolds (Martinez *et al.*, 2018)

3.5.5 Step 5 - Quality risk assessment (QRA)

The QRA identifies and controls potential quality risks during the development and manufacturing process to ensure a high-quality product. An Ishikawa diagram could be used to identify and group the major influencing factors for a given problem, whereafter a FMEA could be used to identify potential failure modes, determine their effect on the operation of the product and identify actions to mitigate the failures. Any factor with an uncertain probability of occurring can influence the outcome of a project and is considered to be a risk or hazard. An example of the Ishikawa diagram analysis for 3D printed bone prostheses and scaffolds is shown in Figure 21.

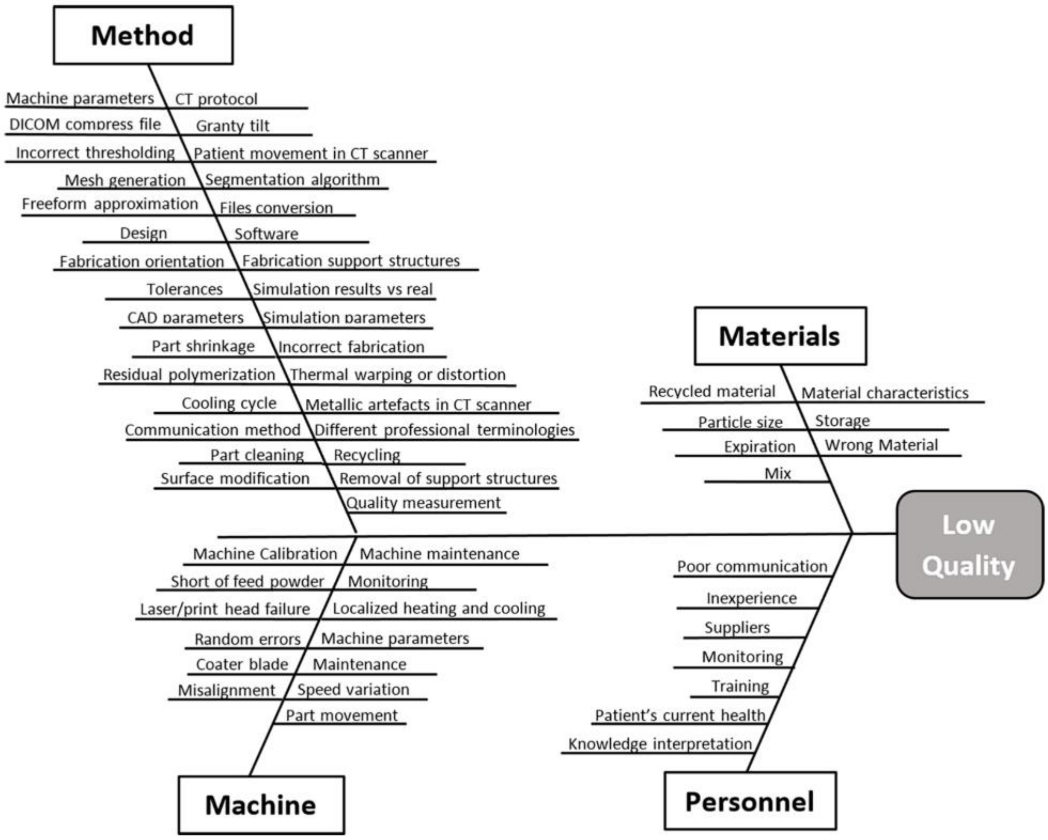

Figure 21. Ishikawa diagram analysis for the 3D printing (Martinez *et al.*, 2018)

3.5.6 Step 6 - Design space (DS)

The design space describes the link between process inputs and critical quality attributes. Thus, it is used to determine the multidimensional combination and interaction of input variables (e.g. material attributes and process parameters) that have been demonstrated to provide the assurance of quality. The DS defines the critical parameters and limits, identified in Steps 1-5, to ensure an acceptable quality product. A well-defined DS results in repeatable product performance across different manufacturing batches. (Peltonen, 2018)

3.5.7 Step 7 - Control strategy (CS)

The control strategy will list the required monitor or control actions to ensure that the processes will remain within the predefined critical process parameter and material attribute range. There are several control strategies available, which include but are not limited to: procedural control, in-process controls, batch release testing, process monitoring, characterization testing, comparability testing and consistency testing (Chavan, Pimpodkar, Kadam & Gaikwad, 2015).

3.5.8 Step 8 - Continuous improvement strategies (CIS)

CIS will list a plan with activities designed to bring gradual and ongoing improvement to products, services or processes through constant review, measurement, and action. Deming Cycle or Kaizen are well-known strategies used to support continuous improvement actions.

3.6 Summary

This chapter demonstrated the advantages of implementing a standardised quality management system and highlighted the importance of quality assurance. It also discussed how the quality by design methodology could be used to develop a quality assurance framework.

CHAPTER 4 – QUALITY ASSURANCE FRAMEWORK

4.1 Introduction

The QbD methodology has been identified as a suitable methodology to assist with the development of a QA framework. The methodology uses a concurrent engineering approach for the development of a product or service, with quality as the main focus. The QA framework developed in this chapter could serve as a basic structure or guideline for the development of chemical coating processes, procedures and work instructions.

4.2 Quality assurance framework

The ObD methodology, discussed in Chapter 3, is based on 8 sequential steps to systematically develop a new product, service or process, while simultaneously reducing risk and fostering rational design approaches to avoiding the trial-and-error approach. The methodology is used to determine the critical QA aspects that could be used to ensure the quality of the chemical coated sand.

4.2.1 Quality target product profile

The QTPP is a product description that summarises the desired quality characteristics of a specific product of service. The profile highlights how the end user defines quality and is used as the point of focus throughout the methodology. The end user in this case was the Vaal University of Technology's Additive Manufacturing department, as they will use the chemical coated sand to produce sand moulds and cores for the foundry industry. The QTPP was developed using the researcher's experience with the Voxeljet printing technology and the casting industry. The QTPP that was identified is shown in Table 8. Please note that the manufacturing and value-based quality QTPP fall outside the scope of this research study and will not be discussed. The manufacturing-based QTPP will be addressed upon the integration of the QA framework into the QMS. The Value-based QTPP will be addressed by performing a cost accounting or supply chain management study.

Table 8. Chemical coated sand QTPP

Quality approaches (high-level)	Quality indicators	Description
Manufacturing-based	Features	Chemical coated sand that offers a traceable manufacturing process. The following aspect is necessary in the QMS system.
Value-based	Performance	The performance of the local coated sand should be comparable to the OEM coated sand but at a lower cost.
Product-based	Reliability	The chemical coated sand should consistently perform within specification. There are no existing specifications for chemical coated sand used in additive manufacturing technologies. Thus, the OEM sand will serve as a reference. If the sand performs out of specification it would affect the 3D printing process.
User-based	Conformance	Adheres to the requirements of the target group. The target group in this case would be sand foundries.

4.2.2 Critical quality attributes

The following step will identify the critical characteristics that should be controlled within an appropriate limit, range, or distribution to ensure that the QTPP is met. It is important to note that the CQA refers to final product, which consists of a refractory material that is coated with a specific chemical. The CQA were identified through performing an in-depth literature study on the effect of refractory materials and chemical coatings on foundry and AM processes.

4.2.2.1 Refractory material

The performance of the refractory material, used in moulds and cores, plays a crucial role in producing high quality castings. Schleg (2003), compiled a refractory material quality checklist that demonstrates the important aspects to consider when selecting an appropriate refractory material. The checklist, shown in Table 9, can be divided into refractory requirements and supply chain management aspects, only the refractory requirements are discussed in this research study.

Table 9. Sand selection checklist (Schleg, 2003)

Refractory material selection checklist	
Refractory requirements	Supply chain management
☑ Casting material	☑ Transportation cost
☑ Melting temperature	☑ Sand cost
☑ Metal/sand ratio	☑ Supplier technical support
☑ AFS GFN	☑ Dependable delivery
☑ Particle size distribution	☑ Adequate reserves
☑ Grain shape	☑ Consistency of product
☑ Sand type	
☑ Chemical composition	
☑ Cleanliness	

4.2.2.1.1 Casting material and metal/sand ratio

The composition of the casting material and the physical size of the casting are listed as key aspects to consider when selecting a refractory material. Different casting materials are poured at various temperatures and may react with the chemicals used during the moulding process. Thus, it is important to determine whether the material being cast is compatible with the binder system used to produce the moulds and cores (Schleg, 2003). The metal/sand ratio is used to indicate the mechanical and thermal strain during casting process. A high ratio will indicate that the refractory material is exposed to high stain during the casting process, which could result in mould failures (Schleg, 2003). The casting material and metal/sand ratio were not considered as a CQA as they are dependent on the mould design process, which falls outside the scope of this research study.

4.2.2.1.2 AFS GFN, particle size distribution and grain shape

The American Foundry Society (AFS) grain fineness number (GFN), particle size and grain shape are dependent on the physical properties of a sand sample. The AFS GFN value is expressed as a dimensional number and represents the overall average grain diameter for a given sand volume. Higher AFS values indicate that the refractory material consists of a finer sand, which generally provides a smoother mould and casting surface finish. However, different sand samples with similar AFS GFN values are not necessarily identical as the grain distribution and shape between the samples may differ. The AFS GFN specification is determined by foundries and depends on the casting application, but usually ranges between 25 to 170 (Schleg, 2003).

The particle size distribution, also referred to as the screen distribution, illustrates the distribution profile of a given sand sample. In traditional mould-making methodologies, the particle distribution has an effect on the mould packing density that influences the mould strength and permeability (Woods, 2018). Both the particle size distribution and AFS GFN are determined using the AFS GFN 1106-12-S standard, which involves sieving a known quantity of sand through a series of sieve mesh sizes. The percentage of sand collected in each sieve is multiplied by its own multiplying number/factor to determine a single product number. The AFS GFN is calculated by dividing the summed products by the summed retained percentages (Woods, 2018). An example of both an AFS GFN and particle size distribution analysis are shown in Table 10 and Figure 22. In addition to the particle distribution, foundries also determine the AFS clay content that measures the percentage of fine particles (less than 20 microns) in the refractory sand. These particles consist of clay particles, silt or organic materials, which influence the refractoriness and chemical binder requirement of the refractory material.

Table 10. AFS GFN

Raw Sand				
Sieve #	Mesh	% Retained	Factor	Product
1	1700	0	5	0
2	850	0.34	10	3.4
3	600	1.58	20	31.6
4	425	4.93	30	147.9
5	300	19.3	40	772
6	212	26.94	50	1347
7	150	28.1	70	1967
8	106	15.26	100	1526
9	75	3.17	140	443.8
10	53	0.3	200	60
11	Pan	0	300	0
	Total	99.92		6298.7
	AFS	63.04		
	Fines %	3.47		
	Screens	4		

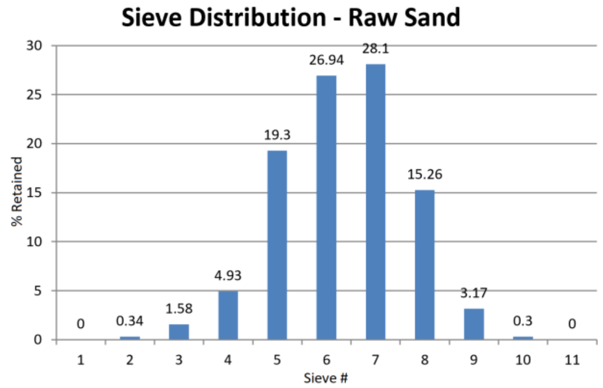

Figure 22. Sieve distribution

The sand analysed in Table 10 was classified as a "four-screen" sand, as indicated in the bottom row of the table. A four-screen sand will indicate that 10% or greater of the sand sample were retained on 4 individual sieve/screens (Woods, 2018). Usually foundries will request a three or four screen sand due to mould compaction advantages (Schleg, 2003). The grain shape also plays an important role in conventional mould and core making. The grain shape is determined by viewing a sand sample under a microscope and comparing the results against a published chart. As demonstrated in the chart (Figure 23), the grains shape may vary from rounded to angular.

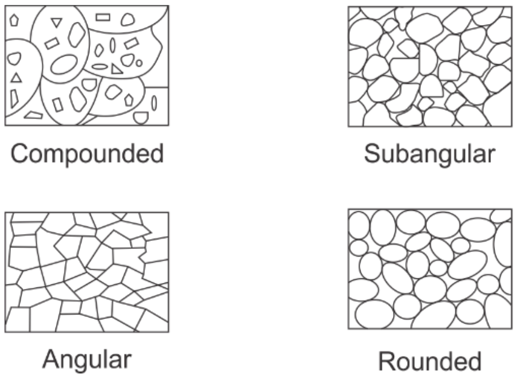

Figure 23. Grain shapes (Jain, 2008)

The shape influences the packing density, flowability and binder requirement of sand used for mould and core production. The features of the different grain shapes are shown below (Jain, 2008):

- Rounded – Rounded grains offer excellent flowability but have the least contact with each other in a rammed structure, thereby making the sand highly permeable to gasses. The sand also produces weaker moulds due to the reduced contact points between the sand grains. The binder requirements are minimum.
- Subangular – Subangular grains offer lower permeability and flowability when compared to rounded grains. It will also require more binder but will produce stronger moulds due to the increase in contact points between the grains.
- Angular – The Angular grains are defined by sharp edges and flat surfaces that results in higher strength and lower premeable moulds, when compared against subangular grains. These grains will have the highest binder requirement and offer the lowest flowability.
- Compound – Compound grains are grains that are cemented to each other. For example, these grains can consist of rounded, subangular and angular grains that are joined together. These grains are the least desirable due to their tendency to break down during high temperatures.

Foundries usually prefer a subangular grain distribution due to the acceptable binder requirement, flowability, permeability and mould strength. The effect of the grain shape on the binder requirement can be explained by the change in the grain surface area between round and angular grain shapes. Angular sands yield a larger surface area that will result in a higher binder requirement to provide a specific strength to the mould. (Schleg, 2003). The theoretical surface area of a given sand sample can be calculated using the AFS 1109-12-S standard, which incorporates the AFS GFN, grain shape, and grain type (Woods, 2018). The AFS GFN, particle distribution, grain shape and AFS clay content were identified as CQA. These attributes could influence five main factors in traditional foundry practices and is summarised in the table below:

Table 11. AFS GFN, particle distribution and grain shape impact

Factor	Description
Binder requirements	The binder requirement for a given volume of sand is dependent on the surface area of the sand. The surface area is calculated using the AFS GFN, grain shape and grain type values.
Mould and core strength	The particle distribution, shape and size will affect the mould strength. Weak moulds and cores could result in casting defects.
Sand bulk density & compaction properties	The particle size distribution and grain shape affect the bulk density and compaction properties of the sand, which influences the mould permeability. A low mould permeability may result in casting defects.
Sand flowability	Rounded grains yield the best flowability, whereas more angular grains cause a reduction in flowability. The flowability assists with adequately filling the voids of the mould and core pattern.
Surface roughness of the casting	Generally, a lower AFS GFN value results in a rough surface finish, due to the presence of coarser refractory media.

4.2.2.1.3 Chemical composition

The chemical composition, listed in the sand selection checklist, refers to the chemical composition of the sand and not the chemical binder system used in the moulding process. The chemical composition of a sand sample affects the fusion point, pH and Acid Demand Value (ADV). The fusion point, or also referred to as the sintering temperature, provides an indication of the sand's refractoriness. The sintering temperature specifies the melting temperature of the sand and if reached during casting may result in burn-on defects, as demonstrated in Figure 24. The sintering temperature is affected by the chemical composition and purity of the refractory material. The most used and well-known refractory materials, with their chemical composition and sintering point, are shown in Table 12. The sintering temperature requirement of a refractory material is dependent on the material being cast. The average pouring temperatures for commonly used foundry alloys range between 345 – 1900°C, as demonstrated in Table 13.

Burn-on casting defect | No casting defects

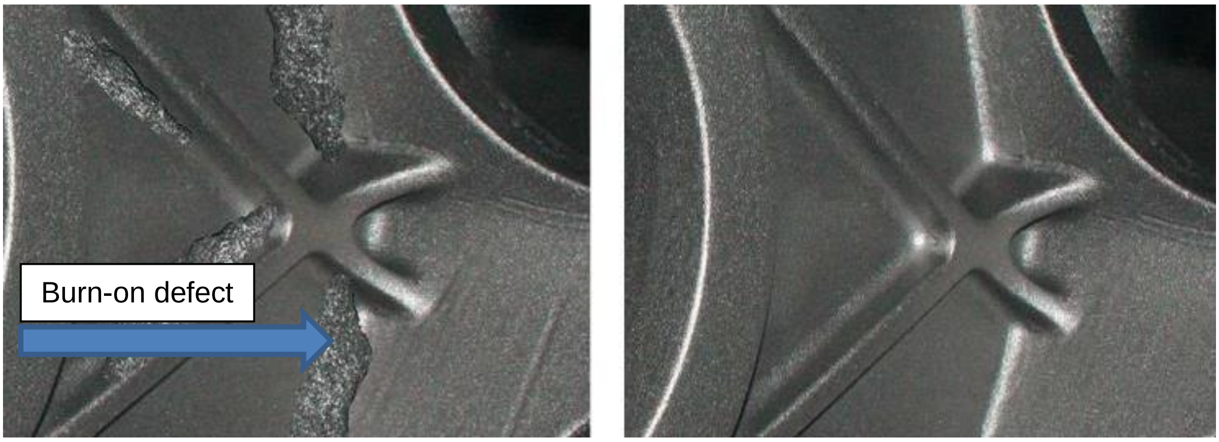

Figure 24. Burn-on defect (ASK, 2018)

The pH and acid demand value (ADV) are used to indicate the acidity or basicity of the sand and is used to select an appropriate resin binder system for the moulding process. Impurities in the sand will change both the pH and ADV, depending on whether they are water-soluble or soluble in dilute acid. The difference between the pH and ADV can be explained through the individual testing methodologies. The pH is determined by mixing 25 g of sand with 100 ml of distilled water and stirred for 5 minutes, whereafter the pH of the water is measured. The water dissolves the water-soluble impurities, which causes the pH of the water to change.

Table 12. Chemical composition vs. melting point (Schleg, 2003)

Chemical	Silica	Olivine	Chromite	Zircon
SiO_2	98.82	41.2	1.32	33.5
MgO	0.031	49.4	8.75	--
Cr_2O_3	--	--	45.8	--
ZrO_2	--	--	--	65.00
Al_2O_3	0.049	1.8	21.34	1.0
Fe_2O_3	0.019	7.1	19.5	0.03
CaO	0.0016	0.2	0.94	--
TiO_2	0.012	--	0.03	0.19
Melt point (C^o)	1710	1875	2093	2538

Table 13. Alloy vs. pouring temperature (Schleg, 2003)

Alloy	°C
Zinc Alloy	345 - 455
Aluminium Alloys	620 – 735
Magnesium Alloys	620 – 735
Copper-base Alloys	908 – 1180
Cast irons	1340 – 1480
High-Mn Steel	1400 – 1455
Monel (70N,30Cu)	1370 – 1540
Ni-based superalloys	1430 – 1540
High-alloy steels	1480 – 1600
High-Alloy irons	1540 – 1650
Carbon & low alloy steels	1565 – 1700
Titanium Alloys	1700 – 1820
Zirconium Alloys	1845 – 1900

The ADV is determined by mixing 50 g of sand with 50 ml of distilled water and 50ml of dilute hydrochloric acid. The sand/water/acid mixture is stirred for five minutes and allowed to stand for 1 hour, the mixture is then analysed to determine how much of the diluted acid has reacted with the impurities in the sand. The Voxeljet VX1000 uses a Furan cold setting process, which is known as an acid catalysed binder system. Impurities such as carbonates will neutralise acid catalysts that is necessary to initiate the polycondensation process and could result in weak or inferior moulds. The ADV is used to determine whether a specific sand is compatible with an acid catalysed binder system and is demonstrated in Table 14.

Table 14. Acid demand value

Acid demand value (ADV)		
ADV ≤ 6 ml	6 ml > ADV ≤ 10 ml	ADV > 10 ml
Suitable for acid catalysed binder systems (require low amount of acid)	Suitable for acid catalysed binder systems. However, would require high amount of acid	Not suitable for catalysed binder systems

4.2.2.1.4 Cleanliness

Natural silica sand usually contains numerous impurities, which are dependent on the location where the sand was mined. These impurities could include clay, heavy iron metals, salts, rootile (tree root) and calcium carbonite, all of which affect the chemical composition of the sand. As discussed in section 4.2.2.1.3, the chemical composition has a direct impact on the performance of refractory material and needs to be monitored and controlled. Thus, sand supplied to foundries undergoes a washing process to reduce and control the impurities present in the sand. The washed sand is also dried to get rid of the excess water, which may still be attached to the sand grains. It was found that a high sand moisture level could result in casting defects due to the formation of large volumes of steam during casting and the reduced mould strength in resin-bonded systems (Jain, 2008).

4.2.2.2 Chemical coating

The Voxeljet VX1000 system requires the sand, which is used during the printing process, to be pre-coated with an acid catalyst. The chemical coating CQA that has been identified includes:

4.2.2.2.1 Chemical bonding

As mentioned in section 4.2.2.1.3, the Voxeljet VX1000 uses a Furan cold-setting process to create a chemical bond between the sand particles. Furan bonding systems are widely used in traditional foundries and are known to offer good flexibility, strength, rapid curing time and high reclamation yields. The process consists of a liquid acid catalyst that is used to cure a Furan liquid binder at ambient temperature. During curing, the binder will experience an exothermic polycondensation process due to the cross linking of the chemical chains (Holtzer, Górny & Dańko, 2015). The chemical reaction, demonstrated in Figure 25, produces water as a by-product, which tends to slow the cure rate.

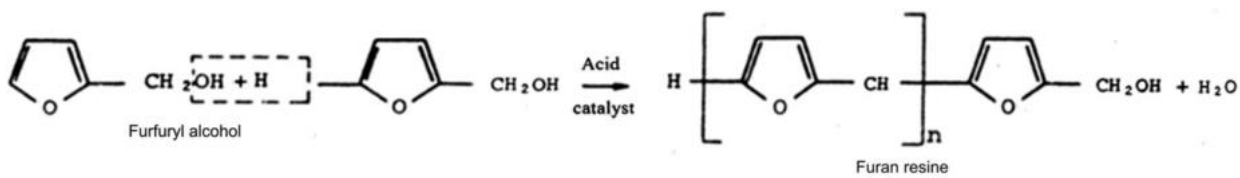

Figure 25. Furan - acid catalysed reaction (Holtzer et al, 2015)

The curing rate is directly proportional to the moisture, ambient temperature and the type of the acid catalyst used. Although an increase in the acid will accelerate the curing rate, too much acid will cause the Furan resin to become brittle and cause a decrease in the cohesiveness of the mould or core. Too little acid will result in a long curing time, which will affect the cohesiveness of the mould or core. Thus, the mixing ratio between the Furan resin and acid catalyst plays a crucial role in the performance of the cured resin (Frohn, Koch & Gieniec, 2014). The effect of the acid content on the curing time and mechanical properties of Furan-resin-bonded mould are demonstrated in Figure 26.

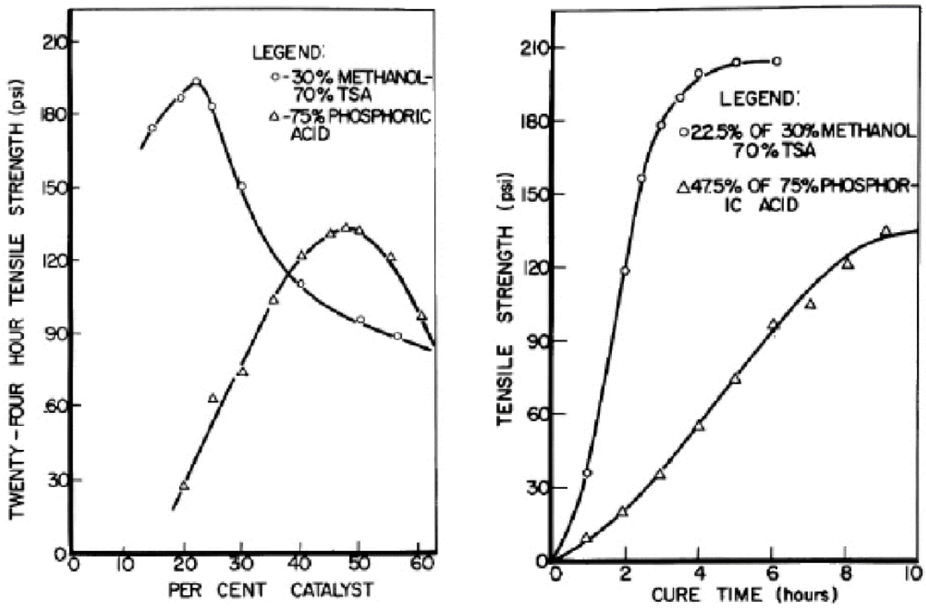

Figure 26. Effect of the acid catalyst on the mechanical properties and cure rate of Furan-resin-bonded sand (Nelson, 1973)

The mixing ratio between the binder and catalyst are usually specified by the chemical suppliers, but generally vary between 0.8 – 1.2% resin content, based on sand weight (BOS), and 20 – 50% catalyst content, based on binder weight (BOB) (Mancusi Chemicals Ltd, 2005).

4.2.2.2.2 Flowability

In conventional sand castings, a mould or core is formed by ramming resin coated sand onto a pattern. The pattern is removed after the sand has cured, which results in a cavity in the shape of the desired casting (Davis, 1993). An example of the conventional moulding process is shown in Figure 27. The fundamental difference between the conventional moulding and 3D printing process is that the printing process adds individual layers of sand to create the desired mould geometry, as explained in section 1.4. The layers of sand are applied using a recoater, as shown in Figure 28.

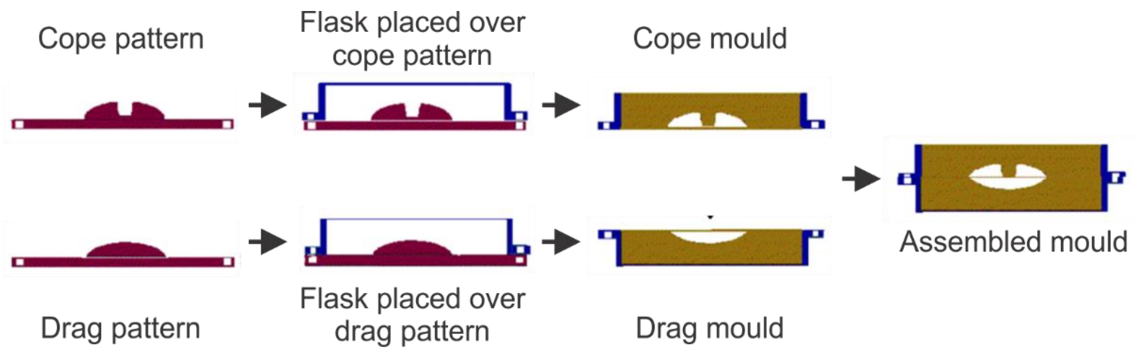

Figure 27. Traditional moulding process

The recoater consists of a sand storage hopper with a narrow opening at the bottom. The sand in the hopper will not flow through the bottom gap due to the inter-particle forces, such as frictional and capillary forces between the sand particles (Schleg, 2003). However, by introducing a vibrational force to the recoater will result in a reduction of the frictional forces between the particles and enable the sand to flow through the opening at the bottom.

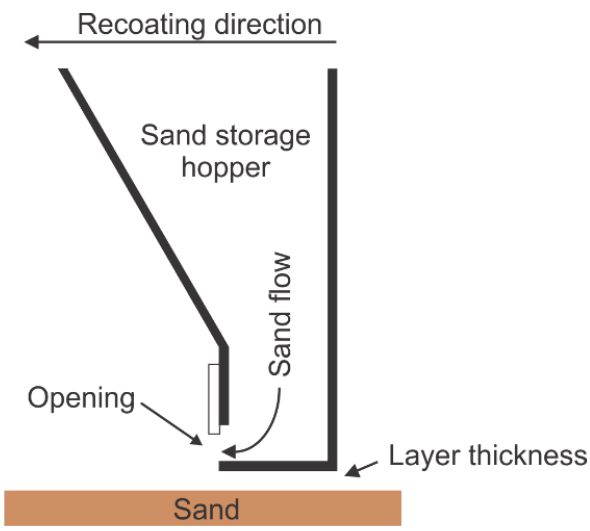

Figure 28. Recoater

It should be taken into consideration that the sand will only flow if the gravitational force exceeds the sum of the frictional and capillary forces (Chakrabarti & Acharyya, 1992). The frictional forces occur between the sand particles and are dependent on the particle composition, density, shape and size (Ghazavi, Hosseini et al, 2008). If particles are in contact with each other, and a liquid is present, capillary bridges are formed in the gaps between the particles, which results in a capillary force that affects the flowability of granular assemblies. An example of this phenomenon is demonstrated in Figure 29. However, these capillary bridges can only occur under low level saturation situations. The capillary force is dependent on the geometry of the bridge between two particles. The bridge geometry is affected by the interparticle separation distance, liquid bridge curvature and particle radii ratio, which are dependent on the particle diameter, distance between the connected particles, wetting angle and the bridge volume (Harireche, Alani & Faramarzi, 2013).

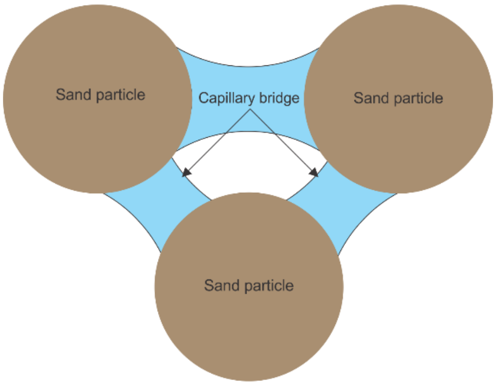

Figure 29. Capillary bridges

The flowability of the sand is listed as a critical attribute, as it has a direct impact on the recoating process of the Voxeljet VX1000. Sand with a low flowability could result in recoating errors causing mould defects or printing failures. A good and homogeneous flow will result in a uniform recoater wave (Figure 30) whereas sand with a low flowability will result in an uneven recoater wave (Figure 31) (Woods, 2018).

Figure 30. Uniform recoater wave (Woods, 2018)

Figure 31. Uneven recoater wave (Woods, 2018)

The flowability of granular material can be determined using the angle of repose. The angle of repose is the angle which is relative to the horizontal base of the conical pile produced when a granular material is poured onto a horizontal surface, as demonstrated in Figure 32 (Haque, n.d).

Figure 32. Angle of repose (Haque, n.d).

The angle of repose of a bulk material can vary from 0° to 90°, where lower angles represent a better flowability. The flowability of granular material can be characterized using the angle of repose as an index, as displayed in Table 15.

Table 15. Relationship between the angle of repose and flowability (Haque, n.d)

Flowability	Angle of repose (°)
Excellent	25 – 30
Good	31 – 35
Fair	36 – 40
Passable	41 – 45
Poor	46 – 55
Very poor	56 – 65
Extremely poor	> 66

According to ASK, the chemical supplier of the catalyst product, freshly coated sand should be allowed to rest a minimum of 2 days to improve the flowability of the sand. The resting period allows the water, used as the acid carrier, to evaporate and results in the reduction of the capillary forces and improved sand flowability (Polsakiewicz, 2018).

4.2.3 Process flow diagram

This step graphically maps the sand coating process to improve the understanding of the relationships between the critical procedures that are necessary to control the quality of the coated sand. The procedures and activities were identified using the CQA, outlined in the previous section. The CQA, listed in Table 16, are grouped according to the procedures and activities necessary to achieve the QTPP.

Table 16. Summarised critical attributes

Critical attributes	Procedure or activity name
AFS GFN	Physical classification
Particle distribution	
Grain shape	
AFS clay content	
Water content	Cleanliness
ADV	Chemical composition
Sintering temperature	
Resting	Resting period
% acid/sand weight	Catalyst verification
Flowability index	Flowability verification

The chemical coating process consists of several sequential procedures and activities and is demonstrated in Figure 33. The "coating" and "packing and shipping" procedure falls outside the scope of this research study and will not be addressed.

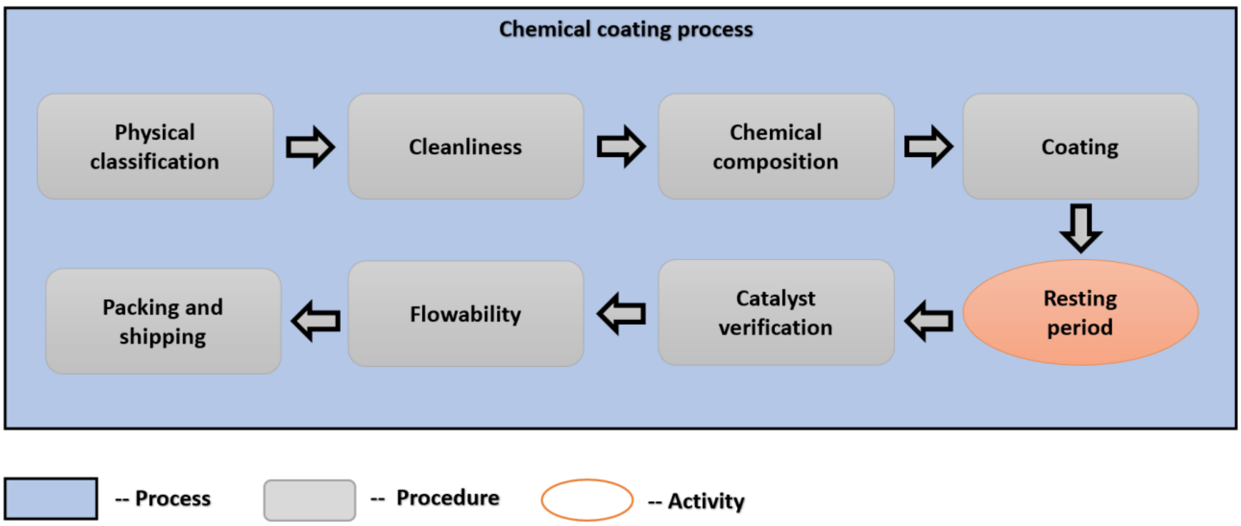

Figure 33. PFD for the chemical coating process

4.2.4 Critical process parameters and critical material attributes

Both the CPP and CMA are sets of parameters used to control and monitor processes to ensure consistency, repeatability and accuracy. The CPP and CMA for each of the procedures and activities listed in the PFD were determined using literature in both the foundry and additive manufacturing field.

4.2.4.1 Physical classification procedure

The key critical attributes of the physical classification process include the AFS GFN, sand distribution, grain shape and AFS clay content. These attributes are affected by the sand's origin, mining method and screening processes. The CMA that were identified for this procedure are demonstrated in Table 17.

Table 17. Physical classification CMA

Critical attributes	Recommended range	CMA
AFS GFN	According to Brown (2010), an AFS GFN range of between 50 and 60 is the most commonly used and accepted silica sand. This range offers a good surface finish and requires low binder levels. However, it should be taken into consideration that foundries could specify the AFS GFN range to achieve a specific surface finish.	If not specified, the AFS should range between 50 and 60.
Sand distribution	According to Brown, sand with a 95% spread over 4 - 5 screens offers good packing and minimises expansion defects (Brown, 2010). Schleg mentioned that foundries usually prefer a three or four screen sand, due to mould compaction advantages (Schleg, 2003)	3 – 5 screen sand.
Grain shape	Rounded and sub-rounded offer good flowability and permeability with high strength at low binder additions (Brown, 2010), (Schleg, 2003).	Rounded to sub-rounded
AFS Clay content	No bake processes require the lowest possible clay content. However, a maximum allowable clay content of 0.3% is specified. An increase in the clay content will influence the sand refractoriness and chemical binder requirement (Jain, 2008).	≤ 0.3%

4.2.4.2 Cleanliness procedure

The cleanliness procedure determines the amount of sand moisture. The CMA that were identified for the following procedure are demonstrated in Table 18.

Table 18. Cleanliness CMA

Critical attributes	Recommended range	CMA
Moisture	Moisture in the sand dilutes the acid catalyst and slows the condensation curing reaction. Sand with a moisture level above 0.2% will significantly affect the cure rate, cured strength and sand flowability (Mancusi Chemicals ltd, 2005).	< 0.2%

4.2.4.3 Chemical composition procedure

The chemical composition procedure will determine whether the sand is compatible with acid catalysed binder systems and the metal being casted. The key critical attributes of this procedure include the ADV and sintering temperature of the sand. The CMA that were identified are demonstrated in Table 19.

Table 19. catalyst verification process CMA

Critical attributes	Recommended range	CMA
ADV	The chemical composition has a direct effect on the ADV and is used to determine whether a sand could be used in acid catalysed binder systems (Brown, 2010). As demonstrated in Table 15, sands with an ADV of 6 ml and lower are deemed compatible with acid catalysed binder systems (Brown, 2010). High ADV sands offer low mould strengths and require high amounts of acid catalyst that influences the flow behaviour of the coated sand, due to the increase in capillary forces.	ADV ≤ 6 ml
Sintering temperature	The sintering temperature specifies the melting temperature of the sand and if reached during casting may cause burn-on defects. According to Brown (2010), a high purity silica sand has a sintering point of 1450°C and above. However, the sintering temperature requirement depends on the pouring temperature which is specified by the foundry.	Sintering point ≥ 1450°C

4.2.4.4 Resting period

The resting period is an activity within the chemical coating process that is necessary to improve the flowability of the coated sand. The CPP that was identified for this action is demonstrated in Table 20.

Table 20. Resting period CPP

Activity	Recommended range	CPP
Resting period	A study conducted by Dady, Nyembwe & van Tonder (2018) proved that the flowability of Sulphonic acid coated sand increases over a period of 48 hours. It is therefore recommended to allow a minimum resting period of 2 days, as suggested by the chemical supplier (Polsakiewicz, 2018).	Min of 2 days

4.2.4.5 Catalyst verification procedure

The catalyst verification procedure is used to verify that the sand adheres to the acid coating requirements. The mixing ratio between the Furan resin and acid catalyst has a direct effect on the performance of the cured resin. The CMA that was identified for this procedure is demonstrated in Table 21.

Table 21. Catalyst verification process

Critical attributes	Recommended range	CMA
% acid/sand weight	Too much acid causes the Furan resin to become brittle resulting in a decrease in the cohesiveness of the mould or core. Too little acid will result in a prolonged curing time and also influences the final strength of the mould or core (Frohn et al., 2014). The OEM sand is coated with an acid supplied by ASK chemicals that was specially developed for AM technologies. ASK advised to keep the acid content between 0.4% and 0.2% BOS. However, according to an ASK research and development engineer a 0.3% BOS coating was found to be the optimal coating ratio (Polsakiewicz, 2018).	0.3% BOS. With an allowable variance of ±0.1%.

4.2.4.6 Flowability procedure

The flowability procedure is used to verify whether the coated sand is suitable to be used in the Voxeljet VX1000 recoater system. A sand with a low flowability could cause recoating error, which reduces the reliability of the printing system. The CMA which was identified for the flowability procedure is demonstrated in Table 22.

Table 22. 4.2.4.5 Flowability verification process CMA

Critical attributes	Recommended range	CMA
Angle of repose	A study conducted by Dady et al. (2018) showed that an increase in the Sulphonic acid coating affected the flowability of the sand. During the study three silica samples were coated with a 0.3%, 0.6% and 0.9% BOS Sulphonic acid coating. The results show that the 0.3% BOS coating offered a uniform recoating wave, which indicated that the sand adhered to the recoater specifications. The 0.6% BOS coating resulted in an uneven recoating wave with signs of clotting, which increased the possibility of a recoating error. Although this sand was printable it was not recommended due to its unpredictable flow properties. The 0.9% BOS coating proved to be incompatible with the printing process due to recoater blockages and weak flowability. The flowability of the three sand coatings were 0.3% BOS → Good (31° – 35°); 0.6% BOS → Poor (46° – 55°); 0.9% BOS → Very poor (56° – 65°).	Angle ≤ 45°

4.2.5 Quality risk assessment

The QRA identifies potential quality risks parameter during the chemical coating process. All the risks that could influence the quality of the chemical coating process, were identified and demonstrated using the Ishikawa diagram methodology in Figure 34.

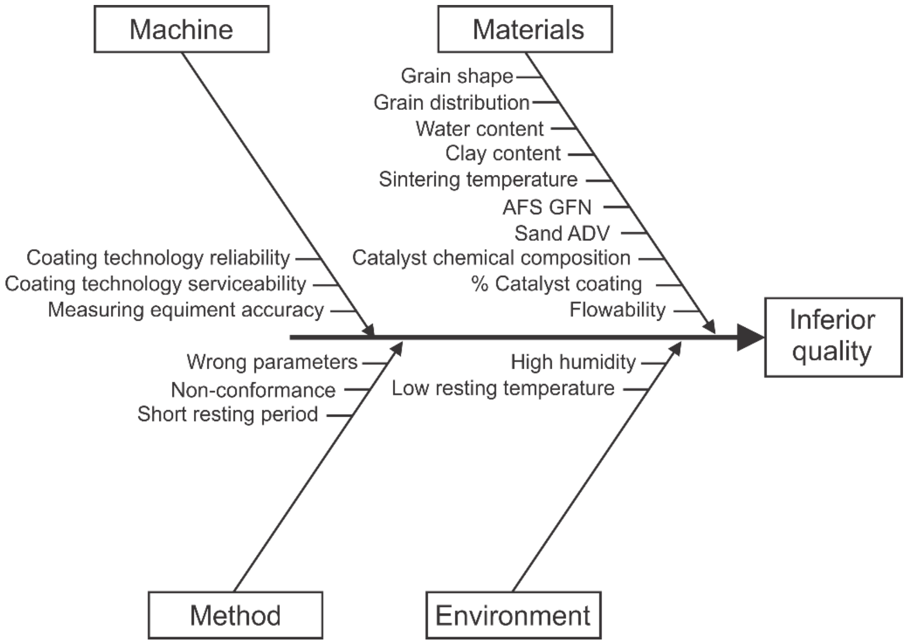

Figure 34. Chemical coating process risks

4.2.6 Design space

The DS is defined as a multidimensional combination and interaction of input variables and process parameters to provide the assurance of quality. The DS could be used as a framework for the development of the chemical coating process and is shown in Table 23.

Table 23. Chemical coating process design space

Process	Consideration	Specification
Chemical coating	AFS GFN	50 – 60 (if not differently specified)
	Sand distribution	3 – 5 sieve
	Grain shape	Rounded to sub-rounded
	AFS clay content	< 0.3 %
	ADV	≤ 6 ml
	Moisture	< 0.2 %
	Sintering temperature	≥ 1450°C
	Resting period	Min 2 days
	Coating ratio	0.3 % BOS ±0.1%.
	Angle of repose	≤ 45°

4.2.7 Control strategy

The control strategy is defined as the methods necessary to monitor/control the important aspects of the manufacturing process to ensure the process is repeatable and adheres to the correct quality requirements. The in-process monitoring methods that were identified to indicate whether the coated sand adheres to process specification, are shown in Table 24.

Table 24. Control strategies

Critical attributes	Monitoring methods (Standardised Testing Method)	Description
AFS GFN & Sand Distribution	AFS GFN 1106-12-S	Determine the particle size distribution and AFS GFN of loose, dry sand using the standard test sieves standard (AFS GFN).
Grain shape	AFS 1107-00-S	Standard test for determining the grains shape.
ADV	AFS 1114-00-S	Standard test for acid demand value (ADV).
AFS Clay content	AFS 2110-04-S	Standard test for determining the percentage of clay.
Moisture	AFS 2216-00-S	Standard test for determining the percentage of moisture in a sand sample.
Sintering temperature	VGD-Merkblatt p26	Method used to determine the sintering temperature of refractory material
Coating ratio	AFS 5100-12-S	Loss of emission (LOI). Determining the weight change of a sample when fired. The weight loss is due to volatilization of organics substances.
Angle of repose	ASTM C1444-00	Standard test method for measuring the angle of repose of free-flowing mould powders.

It is important to note that a sand sampling standard should be used when taking samples for the control strategies listed in Table 24. There are two main standards available for sampling from a pile as well as bagged sand and is demonstrated in Table 25.

Table 25. Sand sampling procedures

Procedure	Standard	Description
Sand sampling	AFS 1101-13-S	Sampling of a sand pile
	AFS 1104-13-S	Sampling of bagged sand

4.2.8 Continuous improvement strategy

Continuous improvement is a recurring activity to increase the ability to achieve the quality requirements. As demonstrated in the previous chapter, ISO 9001 highlights the importance of implementing the "Plan-Do-Check-Act" methodology as a process management tool. This concept is a cycle for implementing change which, when followed and repeated, leads to repeated improvements in the process it was applied to. The "Act" cycle refers to making physical changes / decisions based on evidence or data captured during the process. The ISO 9001 standard highlights 6 methods to ensure continuous improvement within a process, which include:

- Design and development review
- Control of design and development changes
- Monitoring and measurement of processes
- Control of non-conforming products
- Corrective actions
- Preventive actions

4.3 Summary

Chapter 4 shows the development of the quality assurance framework for chemical coated sand, used in the Voxeljet VX1000 printing process. The framework was developed by using the quality by design methodology that focused on the following important aspects: Quality target product profile, Critical quality attributes, Process flow diagram, Critical process parameters and material attributes, Quality risk assessment, Design space, Control strategy and Continuous improvement strategy.

CHAPTER 5 - CONCLUSION

5.1 Introduction

In this chapter, an overview of the study is provided, final conclusions are drawn, and recommendations are made.

5.2 Overview

The study was structured in 5 chapters, which included an introduction, literature study, QA strategy, QA framework and a conclusion. A summary of chapters one to four are shown below:

<u>Chapter 1</u> – This chapter provided the background and problem statement of the study. The problem statement highlighted the perception that the printing of moulds and cores are still considered to be expensive by the local foundry industry, which could be linked to high OEM material costs. A possible solution to mitigate the printing cost was to localise the chemical coated sand used in the Voxeljet 3D printing process. However, this posed a risk to the quality of the printed components, as no quality assurance measures, for chemical coated sand, are currently available. The aim and objectives of the study was identified in such a manner as to develop a solution for the identified problem.

<u>Chapter 2</u> – In this chapter a literature review was done to investigate the evolution and meaning of “quality”. This chapter was seen as the foundation of the research study and explored the inspection, statistical quality control, quality assurance and strategic quality management era. The literature study showed that quality is ultimately defined by the customer and quality management philosophies are used to ensure the integration of all functions of a business to achieve high quality products through continuous improvement efforts of all employees.

<u>Chapter 3</u> – This chapter pointed out that the quality management philosophies, addressed in Chapter 2, are not standardised and their implementation may differ between organisations. The advantages of using standardised QMS were highlighted and the ISO 9001 was identified as a suitable system for this study. ISO 9001 highlights processes, procedures and work instructions as QA measures to ensure a repeatable product or service that adheres to a desired quality standard. There are several risks when developing new processes or procedures and identified the QbD mythology to guide the development process. The methodology is based on the Trilogy

approach that describes the requirements to achieve breakthroughs in new product, service or process development. The methodology is often used by pharmaceutical and automotive companies as a tool to reduce risks during new development, while simultaneously fostering rational design thinking to avoid trial-and-error situations.

Chapter 4 – In this chapter, the QbD mythology was applied to the research focus. The methodology consisted of 8 sequential steps that were used to determine the quality target product profile, critical quality attributes, process flow diagram, critical process paraments and material attributes, quality risk assessment, design space, control strategy and continuous improvement strategy of the chemical coating process. These components serve as the QA framework that could be used as a basic structure or guideline for the development of processes, procedures or work instructions.

5.3 Conclusion

The purpose of the study was to develop a quality assurance framework for the local production of chemical coated sand used in Additive Manufacturing applications. The framework is aimed to ensure that chemical coated sand adheres to the AM and foundry quality requirements. These requirements had to be developed as no existing literature was available. By using the QbD methodology, it was established that the desired quality characteristics of the chemical coated sand included:

- Reliability - The coated sand consistently performs within specification of the AM technology.
- Conformance - Adheres to the requirements of the target group, which was identified as sand foundries.

Using these characteristics as focus, numerous critical quality attributes were identified. These attributes were defined as critical characteristics that should be controlled within an appropriate limit, range, or distribution to ensure the quality characteristics are met, which included the AFS GFN, Grain shape, AFS clay content, sand moisture, sintering temperature, acid demand value, coating ratio and the sand flowability. The critical quality attributes were used to develop a chemical coating process, which identified the required procedures and activities necessary to ensure the quality of the coated sand. The process, procedures and activities that were identified, are demonstrated in Figure 35, which also incorporated the PDCA cycle as a continuous improvement strategy. The critical material attributes and process parameters for each of the procedures and activities were also identified and served as the quality requirements of the coated sand.

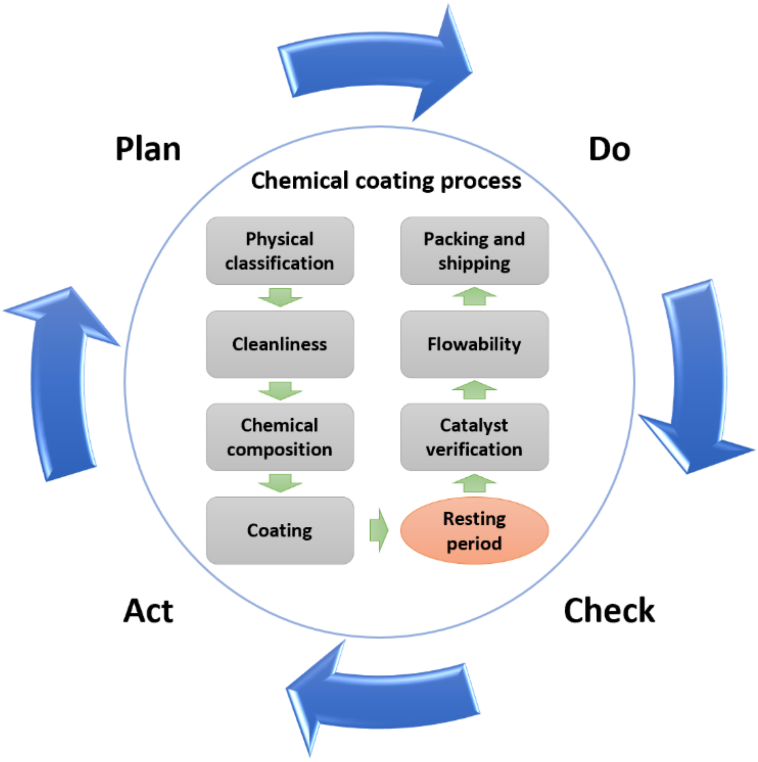

Figure 35. Chemical coating process

The quality assurance framework developed during Chapter 4, is summarised in Table 26. The framework could be used as a basic structure or guideline for the development of chemical coating processes, procedures or work instructions.

5.4 Recommendations

This study can be expanded to include non-conformance, sand coating and packing and shipping procedures.

Further research can be structured around production optimisation topics. These topics could include philosophies such as lean and theory of constraints.

The QA framework should be validated and investigated into the Vaal University of Technology's quality management system.

Table 26. QA framework summary

Process	Procedure	CPP	CMA	CS	CIS	QTPP
		Design space				
Chemical coating	Physical classification		50 ≥ AFS GFN ≤ 60 *	AFS GFN 1106-12-S	Implement ISO 9001 (PDCA cycle)	❖ Reliability - The coated sand consistently performs within specification. ❖ Conformance - Adheres to the requirements of the target group.
			3 – 5 Sieve sand			
			Rounded to sub-rounded grains	AFS 1107-00-S		
			AFS clay content < 0.3%	AFS 2110-04-S		
	Cleanliness		Sand moisture < 0.2%	AFS 2216-00-S		
	Chemical composition		Sintering temperature ≥ 1450°C	VGD-Merkblatt p26		
			ADV ≤ 6 ml	AFS 1114-00-S		
	Resting period	Min 2 days				
	Catalyst verification		0.3 % BOS ±0.1%.	AFS 5100-12-S		
	Flowability		Angle of repose ≤ 45°	ASTM C1444-00		

CCP Critical Process Parameter
CMA Critical Material Attribute
CS Control Strategy
CIS Continuous Improvement Strategy
QTPP Quality Target Product Profile

* If not specified

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ANNEXURE A

The following procedure document was attained from the ISO 9000 store (ISO 9000 store, n.d.).

Procedure Excerpt

Customize with your information

Insert Your Company Name/Logo Here

P-720-A

Customer Related Processes

Documents are all numbered to comply with document control requirements

1.0 Purpose

1.1 This procedure describes the process used for communicating with customers and reviewing information from the customer, including customer feedback.

2.0 Responsibilities

2.1 *Customer Service or Sales and Marketing Representatives* are responsible for taking orders from clients, determining customer requirements, and reviewing the orders for acceptance.

2.2 *Prcject Managers* are responsible for communicating with the client, keeping them informed as the project progresses, and getting feedback from the client.

3.0 Definitions

3.1 None

Requirements of the standard are all addressed

4.0 Equipment/Software

4.1 No additional equipment or software required.

5.0 Instructions

5.1 Request for *product or service:*

5.1.1 Orders are accepted *electronically or by phone, fax or mail.*

5.1.2 When a *customer service or sales and marketing* representative receives a request for *product or services* from a client or a potential client, *the representative* identifies and documents customer requirements.

5.1.3 *Identify how you determine all customer requirements for each type of order.*

1. For example, for orders received electronically, by fax or by mail, the order is reviewed using a checklist *(Create a checklist for your organization, and enter your form number here)* to make sure all required information has been provided.

1. Required information includes: *(list your required information here. Include information important to your product such as:*

- *Catalogue number or other ID*
- *Quantity*
- *Statutory and regulatory requirements*
- *Additional requirements that Your Organization identifies*

Recommendations for customization are included in blue type

5.1.4 *Customer service* reviews the requirements to make sure:

1. The client requirements are adequately defined,

1. If *Your Company* is unable to meet the requirements *customer service* will contact the client to resolve the differences between what you can provide and customer requirements, or tell the customer you cannot provide the *product or service.*

Customer Related Processes Page 1 of 2

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During the early review stages and while assessing the customer requirements, you can document their needs on a Client assessment memo, F-720-001.

5.1.5 If *Your Company* is able to meet the requirements, accept the *order, contract or prcject.*

5.1.6 *If a confirmation will be sent to the customer describe the steps here.*

1. necessary. If it is, he or she initiates a corrective action request.

1. Customer feedback is requested from clients by using scheduled customer surveys and routine calls to the customer.

- *Prcject managers make routine calls to the customer as the prcject requires, and at the end of the prcject to ask the customer if requirements were met or exceeded.*

1. Customer feedback, including complaints is measured and analyzed according to the Monitoring, Measuring and Analysis of Customer Feedback procedure (P-821).

6.0 Forms and Records

6.1 *Customer feedback spreadsheet*

6.2 *Order forms*

6.3 *Customer Inquiry Form*

6.4 *Client assessment memo, F-720-001*

7.0 Attachments

7.1 None

8.0 Related Documents

8.1 P-821 Monitoring, Measuring and Analysis of Customer Feedback

8.2 P-852 Corrective Action

8.3 P-853 Preventive Action

Related forms, records and documents are referenced to comply with document control requirements.

9.0 References

9.1 None

10.0 Revisions

Revision	Date	Section	Paragraph	Summary of change	Authorized by
A				Initial issue	

ANNEXURE B

The following work instruction document was attained from the ISO 9000 store (ISO 9000 store, n.d.).

TITLE of ELEMENT Fabrication Procedure

WORK INSTRUCTION WI-750-001	Revision: 121510 Initial Trial	Page 1 of 3

Blue text is used as an example.

1.0 PURPOSE

1.1 (What is the reason for writing this work instruction) Start with the following statement: "The purpose of this document is to provide instructions for - - - - - - - - - ."

This work instruction describes the basic flow of an unpainted product through a milling machine.

1.2 Be as specific as you need to be to define the purpose of the document.

The Purpose of this procedure is to control the fabrication processes. This procedure provides for the communication of customer requirements to the shop, and inspection of product to the customer requirements.

2.0 SCOPE

2.1 (Define the area or process that this instruction applies to)

Cutting, drilling, fitting, and welding operations before sending to painting.

3.0 RECORDS

3.1 (Indicate specific type of records to be maintained and where they will be maintained)

Record machine hours on the traveler (F-750-001) to track usage until calibration.

4.0 ASSOCIATED DOCUMENTS

4.1 (Reference upward to the procedures that the work instruction is controlled by and reference forms by control number used to create records. Also, reference other documents, standards or information that are relevant.)

F-750-001 Traveler, MP-750 Control of Production and Service Provision, "Rejected" Tag, Customer Drawing, etc.

5.0 DEFINITIONS

5.1 (Define any terms and phrases that might be unique to this instruction or to this particular industry)

Appropriate drill components to match requirements.

6.0 RESPONSIBILITY

6.1 (List department(s) or functions responsible for maintaining these instructions)

It is the responsibility of the shop supervisor to maintain this procedure. The Shop supervisor is responsible to assign and train inspectors. It is the responsibility of the welder to fabricate the part to the customer drawing and to follow this procedure and not move on to another step without inspection. The inspector must inspect the parts to the customer drawing.

7.0 TOOLS, GAGES, FIXTURES

7.1 (List all unique tools required to perform tasks as indicated in this work instruction)

Appropriate drill components to match requirements.

8.0 SAFETY REQUIREMENTS

8.1 (List all necessary safety precautions that employees must comply with and all safety equipment that must be used while following the operations specified in this work instruction)

Safety glasses, welding shields, etc.

9.0 INSTRUCTIONS

9.1 (List all steps to be taken to complete the scope of this work instruction, in the exact sequence necessary. Work instructions may be in the form of flow charts, bullet instructions, text, photos, digitized images, numbered instructions or any combination of all, as long as the instructions are clear, crisp and do the job as intended)

F-750-001 Traveler

9.2 The fabrication shop is given a Job Pack to fabricate a product.

9.3 The Shop Lead man looks at the drawings, bills of material, and cut sheets to verify that there is adequate information to fabricate the part.

9.4 The shop lead man gets the materials from the storage area and verifies that they are correct to the BOM and Cut sheet requirements and signs the fabrication traveler (F-750-001).

9.5 The shop lead man gives the materials and job pack to a welder to fabricate the parts to the drawings. The welder completes the layout.

9.6 The shop supervisor or lead man inspects the layout of the part to the drawing and signs the fabrication traveler (F-750-001).

9.7 The welder cuts the material to match the drawing. The welder or cuts or drills holes in the material to match the drawing.

9.8 The welder fits up the parts as described on the drawing. If the welder does not understand the drawing, the welder is to ask the supervisor. If the drawing is still unclear, the QA Manager or Plant Manager is contacted to resolve the question with the customer in accordance with MP-750.

9.9 The shop supervisor or lead man inspects the fit-up of the part to the drawing and

9.10 signs the fabrication traveler (F-750-001).

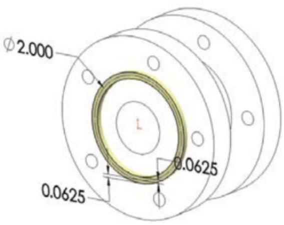
9.11 The weld is completed by the welder.

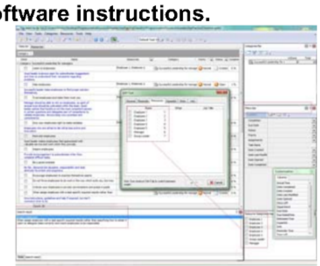
9.12 The shop supervisor or lead man inspects the weld of the part to the drawing and signs the fabrication traveler (F-750-001).

9.13 If necessary steps 4.7 to 4.10 are repeated until the part is completed.

9.14 When completed the part and job pack are moved to paint or to Final Inspection.

You may choose to add images– including software instructions.





You may choose to add a flowchart. (for more info see: Flowchart Basics)