Towards a Conceptual Framework for the Identification & Implementation of Additive Manufacturing Standards.

by

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Thesis presented in fulfilment of the requirements for the degree of Master in Industrial Engineering in the Faculty of Engineering at Stellenbosch University

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April 2019

Declaration

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the authorship owner thereof (unless to the extent explicitly otherwise stated), and that I have not previously, in its entirety or in part, submitted it for obtaining any qualification.

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Date:

Abstract

Although it is widely apparent that additive manufacturing (AM) is set to replace conventional, subtractive manufacturing methods in many applications, much of the industry agrees that standards are a key obstacle to widespread adoption of the technology. However, in recent times collaborations such as that between ISO and ASTM International have resulted in many AM specific standards being produced, yet the field remains largely unstandardized due to the industry's misperception that little AM standards exist. As such, this study seeks to determine how organisations can effectively and efficiently identify and implement AM standards. The main aim of this research is to use a systems engineering approach to develop a framework for the identification and implementation of standards that can be used by South African AM companies to increase their global competitiveness.

An in-depth literature review was done to determine the various key concepts of which the problem comprises. This review considered why standards are important and how they can be identified, as well as how they should be stored and implemented. The literature review also includes a look at the key players in the field of AM standards development, followed by an exhaustive analysis of the current state of AM standards, from which it was determined that there are currently 30 Standards Development Organisations (SDO) active in the field, as well as 537 standards applicable to AM with 144 of those being specifically developed for AM purposes.

To address the research problem, a framework is developed to aid organisations in the identification, storage and implementation of standards. The resulting framework is based on the Plan-Do-Check-Act model, ensuring an element of continuous improvement. As such, the framework consists of three phases, with five stages within each phase. In order to validate the framework, various industry experts evaluated the framework to determine its usability and effectiveness. The framework is also tested on two medical case studies to refine it to the final proposed solution. Upon completion of the validation activities, it was determined that the framework is ready for beta testing.

Not only does this research contain a rare analysis of the current state of AM standards, but the framework can be used to identify and implement standards to ensure the production of high quality products, thus increasing the global competitiveness of South African AM companies. The framework also facilitates newcomers in the field, thereby increasing adoption of the technology and simultaneously advancing the field.

Opsomming

Alhoewel dit duidelik is dat laagvervaardiging (AM) oppad is om konvensionele vervaardigingsmetodes in sekere toepassingsvelde te vervang, stem meeste van die industrie saam dat standaarde ‘n hindernis is tot die gebruik van dié tegnologie. Al het samewerkingsveldtogte tussen ISO en ASTM Internasionaal daartoe gelei dat talle AM toepaslike standaarde gepubliseer word, vind daar steeds min standarisering plaas danksy die mispersepsie dat daar min standaarde beskikbaar is in die veld. Dus poog dié studie om te bepaal hoe organisasies effektiewelik en doeltreffend AM standaarde kan identifiseer en implementeer. As sulks is die navorsing se doelwit om ‘n sisteemsingenieurswese benadering te gebruik om ‘n raamwerk te ontwikkel wat deur Suid-Afrikaanse AM maatskappye gebruik kan word om hul globale mededingendheid te verbeter deur die identifisering en implementering van AM standaarde.

‘n In-diepte literatuur studie is voltooi om die konsepte te bepaal waaruit die probleem bestaan. Dié studie het ondersoek hoekom standaarde belangrik is, hoe mens hul kan identifiseer, asook hoe hul gestoor en geïmplimenteer moet word. Die literatuur studie ondersoek ook wie die groot name is in die veld van AM standaard ontwikkelling, gevolg deur ‘n omvattende analise van die huidige stand van sake met betrekking tot AM standaarde. Hiervan is dit bepaal dat daar tans 30 Standaard Ontwikkelingsorganisasies (SDO) aktief is in die veld, asook 537 standaarde wat van toepassing is tot AM, waarvan 144 spesifiek vir AM toepassings ontwikkel is.
Om die navorsingsprobleem aan te spreek is ‘n raamwerk ontwikkel om organisasies by te staan met die identifisering, berging en implementering van standaarde. Dié raamwerk is gebaseer op die “Plan-Do-Check-Act” model om ‘n element van deurlopende verbetering te verseker. As sulks bestaan die raamwerk uit drie fases, met vyf stappe in elke fase. Om die raamwerk te valideer het talle kenners dit geëvalueer om die bruikbaarheid en effektiwiteit daarvan te bepaal. Die raamwerk is ook getoets op twee mediese gevallestudies om dit te verbeter tot die finale voorgestelde oplossing. Met voltooiing van die validasie aktiwiteite is dit bepaal dat die raamwerk reg is vir die beta toetsfase.

Dié navorsing bevat nie slegs ‘n skaarse analise van die huidige stand van sake met betrekking tot AM standaarde nie, maar ook ‘n raamwerk wat gebruik kan word om standaarde te identifiseer en implementeer om te verseker dat hoë kwaliteit produkte vervaardig word, sodat die globale mededingendheid van Suid-Afrikaanse AM maatskappye kan verbeter. Die raamwerk fasiliteer ook nuwelinge in die veld en verhoog daardeur die gebruik van AM tegnologieë.

Acknowledgements

The successful completion of this study would not have been possible without the valuable contributions of the following persons and I would therefore like to express my sincere gratitude:

- Prof. W. du Preez from the Central University of Technology, and the Collaborative Program in Additive Manufacturing (CPAM), for funding the research project.
- Gerrie Booysen, Johan Els and Andre' Heydenrych from the CRPM for providing aid during the evaluating case studies.
- Prof. A.F. van der Merwe for providing assistance and mentorship throughout the study.
- The experts mentioned in Appendix D for their valuable feedback and willingness to partake in the study.

Most of all, I would like to express my deepest gratitude towards my family, without whom these past two years would not have been possible.

"Families are the compass that guides us. They are the inspiration to reach great heights, and our comfort when we occasionally falter." – Brad Henry.

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Glossary

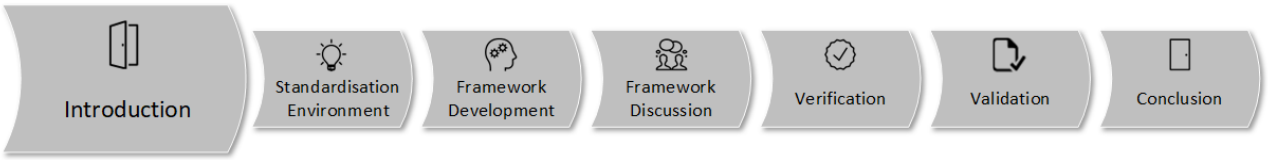
Additive Manufacturing (AM)	Also known as 3D printing, this term refers to *"the process of joining materials to make objects from 3D model data, usually layer upon layer"* (ASTM International, 2013).
Ti6Al4V	Titanium-6Aluminium-4Vanadium is a Titanium Alloy made of 6% Aluminium and 4% Vanadium. It is the most widely used powder in the metal AM industry due to its good machinability and mechanical properties. Furthermore, its reduced weight and added strength makes it perfect for many aerospace, automotive, marine and medical applications (Arcam, 2018).
Standardisation	In the context of this study, standardisation does not refer to the automation of a process, but rather the implementation of standards to a process. Please refer to Section 2.2 for more information.
ISO TC261	ISO has more than 250 technical committees, each focussing on a specific field of research. TC261 is focussed on standardisation within the field of AM concerning processes, terms, definitions, procedures, quality parameters and various fundamentals (ISO, 2017a).
ASTM F42	ASTM International also have various technical committees simultaneously developing standards in various fields. The committee F42 is focussed on *"the promotion of knowledge, stimulation of research and implementation of technology through the development of standards in AM technologies"* (ASTM International, 2015). For more information, refer to Section 3.4.3.
Practitioner	In the context of this study, the term *practitioner* refers to industry stakeholders such as AM company owners, AM product designers or those with relevant technical knowledge.

Acronyms & Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
AM	Additive Manufacturing
AMSC	Additive Manufacturing Standard Collaborative
AM-3DP	Standards, Specifications and Guidelines databases
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
BPP	Best Practice Procedure
BSI	British Standards Institute
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CPAM	Collaborative Program in Additive Manufacturing
CRI	Commercial Readiness Index
CRPM	Centre for Rapid Prototyping and Manufacturing
CSIR	Council for Scientific and Industrial Research
CUT	Central University of Technology
DBMS	Database Management System
DIN	Deutsches Institut für Normung
ERD	Entity Relationship Diagram
ETSI	European Telecommunications Standards Institute
FDA	U.S. Food and drug Administration
ICS	International Classification of Standards
IEEE	Institute of Electrical and Electronics Engineers
IP	Intellectual Property
IPC	Institute of Printed Circuits
ISO	International Organization for Standardization
LRQA	Lloyd's Register Quality Assurance
MPIF	Metal Powder Industries Federation
NIST	National Institute of Standards and Technology
OEM	Original Equipment Manufacturer
PDCA	Plan-Do-Check-Act Model
PKR	Partial Knee Replacement
RAPDASA	Rapid Product Development Association of South Africa
R&D	Research and Development
SABS	South African Bureau of Standards
SDO	Standards Development Organisation
SM	Subtractive Manufacturing
SME	Society of Manufacturing Engineers
SOP	Standard Operating Procedure
TWI	The Welding Institute
VUT	Vaal University of Technology

Chapter 1

Introduction



This chapter serves as an introduction to the study. The chapter instils a greater understanding of the research topic by providing background and an explanation of how the topic was decided on and what its general purpose will be. The problem is then described in detail, formulating the research question and aim, as well as three objectives. This is followed by the scope of the research, its limitations and the assumptions that were made during the study. The methodology followed during the study and the research design are also discussed. Finally, a roadmap to the document is provided.

1.1. Background

Additive manufacturing (AM) has the capability to disrupt the field of manufacturing, since it enables the production of parts on demand whilst potentially lowering energy consumption, cost and the carbon footprint of the operation. However, subtractive manufacturing is considered more cost effective due to the standardised nature. While it is widely accepted that additive manufacturing is set to replace conventional manufacturing methods in many applications, most experts agree that additive manufacturing standards are a key obstacle to adoption of the technology (Monzón *et al.*, 2014). Potential adopters have a need for repeatability and consistency of manufactured parts (Bourell *et al.*, 2009). The difficulty experienced whilst trying to find standards applicable to a specific process results in many major additive manufacturing companies creating their own set of materials- and processing guidelines (Stratasys Direct Manufacturing, 2015). Industry leaders have often discussed the problems and opportunities related to additive manufacturing during conferences and workshops, and repeatedly found a lack of standards to be a key issue (Bourell *et al.*, 2009) (Additive Manufacturing Platform, 2013). Owing to this, the International Organization for Standardization (ISO) and the American Society for Testing and Materials (ASTM International) crafted a standards development structure to ensure the joint development of standards in prioritized areas (ASTM International & ISO, 2016). Another such initiative is that of America Makes and the American National Standards Institute (ANSI) joining forces to establish the Additive Manufacturing Standardization Collaborative (AMSC), aimed at creating a roadmap-assessment of the state of standards in AM to address problem areas (America Makes & ANSI, 2017a).

1.2. Problem Description

1.2.1. Problem Statement

Previous research has extensively focussed on determining the gaps, problems and opportunities of AM. ISO and ASTM International are currently researching ways in which to address the standardisation issue, thereby also addressing many of the concerns within the industry. Much research has also been done regarding the state of AM, with only a few having a key focus on standardisation within the field. There has been little focus on the implementation of standards within AM, nor has there been much research outlining the various standards that are in existence and are being developed, as well as how these can be used to commercialise a product and gain international trust. Moreover, there is no tool to help manufacturers determine what standards they have to adhere to, and as such many standards aren't adopted.

When compared to subtractive manufacturing (SM), the field of AM has little standards regulating quality, since it is an emerging technology that is highly customisable. However, these technologies are steadily evolving into rapid manufacturing techniques for mass-production products (Dodabalapur *et al.*, 2004). Some countries are creating specific standards applicable to their field of expertise, such as NASA with the AM of parts in space. Although some ISO and ASTM standards do exist, they are all specifically tailored to certain fields of use, limiting the applicability to different applications. The current focus of AM companies in South Africa is that of commercialising the AM process in various fields, such as medical and industrial markets, in order to become globally competitive. However, although many AM standards have recently been developed by ASTM and ISO, it is increasingly difficult to find the standards specifically applicable to your process.

Owing to this, the problem being considered is that there is no tool to help in the identification of applicable standards. Standardisation is a key part of quality assurance and is required for the commercialisation of a process. Such a tool should be applicable to many forms of AM processes, as well as the various standards imposed on the end products. Use of the tool should ensure products of a constant quality that adhere to all the applicable quality standards and regulations, as well as the customer requirements, resulting in sense of assurance in the quality of products produced by South African AM companies on both national and international scale. It should work in conjunction with a database for storage of the standards, ensuring easy integration with ISO 9000 quality management systems.

1.2.2. Research Question & Aim

The research question is qualitative in nature and will be investigated by means of theory and practical knowledge. The main research question is:

How can organisations effectively and efficiently identify and implement AM standards?

Therefore, the main aim of this study is to use a systems engineering approach to develop a framework for the identification and implementation of standards that can be used by South African AM companies to standardise quality in both the AM processes and end products, to ensure customer satisfaction and compliance to regulation, in order to commercialise AM in South Africa as a whole and thereby increase global competitiveness. A database architecture will also be described for the storage of these applicable standards.

1.2.3. Research Objectives

The systems engineering approach used during this study corresponds with the Innovation Road Map W-model, which is based on the V-model but implements evaluation throughout (Converso, De Vito & Santillo, 2007). In accordance with the W-model, the following objectives had to be met:

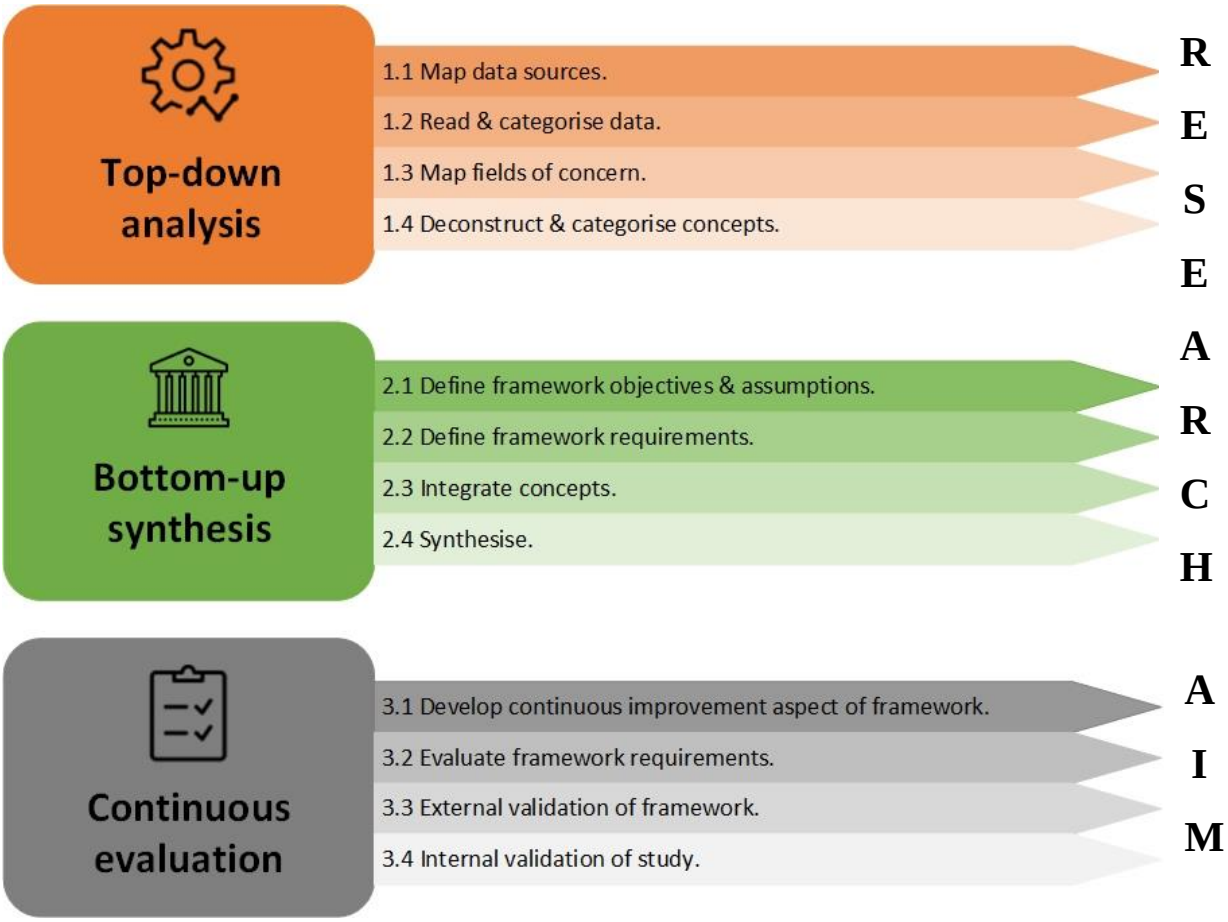


Figure 1.1 - Research objectives.

Objective 1: Top-down analysis of the research problem components.

The research problem must be broken down into its basic components for one to fully understand its extent. As such, a literature study should be done to determine and categorise the available data sources, followed by an investigation of the research problem's key components in order to map the fields of concern. From this information, the concepts must be deconstructed and categorised.

Objective 2: Bottom-up synthesis of components to build a framework that will address the research problem.

The deconstructed and categorised components from objective 1 should be used to develop a framework to aid users in the identification and implementation of standards applicable to AM processes. During the synthesis process, the framework objectives, assumptions and requirements must be defined, followed by the integration and synthesis of the various components.

Objective 3: Continuous evaluation

In accordance with the W-model, the framework requirements should be evaluated both before and after the synthesis process. The framework should also be validated to ensure that it is practical. Finally, an internal validation should also be done to ensure that this study achieved its stated aim.

1.2.4. Scope

This study is aimed at gaining a greater understanding of standards and standardisation in AM and investigate the difficulties to identifying AM standards. Due to the inherent difference between standards and regulations, the identification of regulations will not be covered in this study. Since adherence to regulation is governed by law, identification thereof is executed differently. However, the implementation activities will make provisions for regulations, since standards and regulations are normally implemented in unison.

Furthermore, while the framework will be largely applicable to many AM products or processes, it will only be tested on medical applications of Ti6Al4V. As such, the framework will require future expansion. Also, due to the competitive nature of the field and the case studies being based on an existing company, sensitive information will not be included. It should be noted that this study is mainly focused on South African AM companies and therefore application within the South African construct, but it can be expanded in the future.

1.2.5. Limitations and Assumptions

Since AM is an emerging technology, there are certain limitations to the extent that a study can be done. These include:

- Many standards are still in development, and may therefore be missed.
- AM technologies are constantly evolving and therefore the framework will only cover certain AM processes.
- Due to budget constraints, only one iteration of standards identification can be done.
- Due to the proprietary nature of the processes considered, the implementation phase of the framework cannot be fully completed during the case studies.

Furthermore, since the case studies are based on actual AM companies, certain information regarding Standards Operating Procedures (SOP's) and Best Practise Procedures (BPP) cannot form part of the framework due to confidentiality of the information.

1.3. Research Design

The research design used in this study is based on the work done by Henning (2017), and outlines how the research methodology is used to address the research questions and ultimately achieve the research aim.

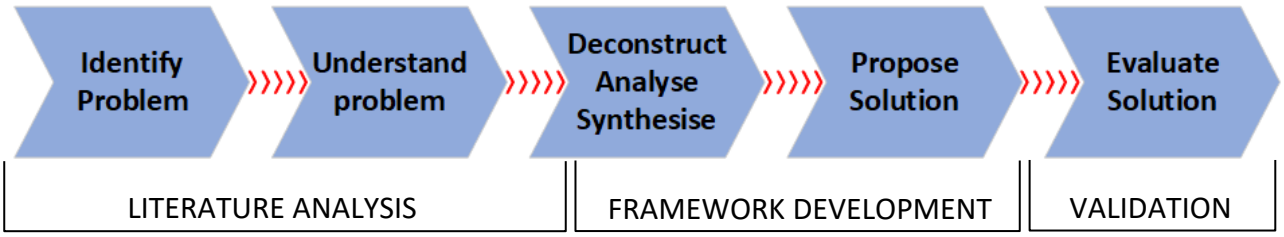


Figure 1.2 - Research design outline (adapted from (Henning, 2017)).

As shown in Figure 1.2, the research design is divided into five different steps, each dependent on information gathered during the previous step. The first step of the design is to identify and define the problem. This was done by completing a thorough literature review of the field, taking into account both the available theoretic and practical knowledge. The knowledge compiled during the initial literature review was used to gain an understanding of the problem, and subsequently another review of the literature and practical knowledge was done to determine the problem's key focus areas, or 'fields of concern'.

The third step entailed deconstructing the problem into key concepts, analysing those concepts and synthesising them into a problem solution in the form of a framework. The framework is then proposed as a solution to the research problem and finally evaluated to determine its effectiveness in addressing said problem.

1.4. Research Methodology

The research done is predominantly qualitative, based on expert interviews, and follows a systems engineering approach. The methodology steps are successive and as such, each step must first be completed before a following step commences. These steps are described in more detail within each of the corresponding chapters. As is apparent in Figure 1.2, the research design was realised using three main methodologies.

Literature Analysis

A systematic literature review should be conducted to develop a general picture of a specific area to direct future research (Petticrew & Roberts, 2009) or to identify gaps in research (Kitchenham & Charters, 2007). Therefore, this study consisted of an analysis of both theory and practical knowledge, owing to the limited availability of relevant information.

The first step was to gain a better understanding of standards and standardisation. This was followed by an investigation into the key players in AM standardisation, as well as the current state of standards in AM and South African AM initiatives. A continuation of the literature analysis can be found in Chapter 3. Here, the different types of frameworks were analysed to determine which would be preferable for the situation. This was followed by an investigation to determine if similar research has been done. Finally, the concepts of which the problem consists were reviewed and deconstructed.

The theoretic base of the study was gained from online databases such as Google Scholar, Science Direct, Research Gate, Scopus and Compendex. The practical knowledge was gained from local experts in the field, discussions and presentations at RAPDASA (see Section 2.5), and from various websites and forums discussing issues related to AM. As far as possible, peer reviewed journals and expert interviews were used preferentially. The online searches were conducted using a combination of the following keywords:

- Standards, Standardisation
- Standards Development Organisation
- Regulations
- Standards development initiatives
- Roadmap, Framework
- Additive manufacturing

Due to the inclusion of both theoretical and practical knowledge, the timeframe of the literature is vast. While the theoretical knowledge dates back to 1949, the practical knowledge dates up to 2018.

Framework Development

The second part of the research design is that of *Framework Development*. The methodology utilised for this was adapted from the methodologies proposed by Pretorius (2017) and van der Merwe (2017). The first step in this methodology is to map, read and categorise data, which was completed during the literature analysis.

In addition to the literature reviewed during Chapter 2, literature regarding the fundamentals of frameworks, problem definition, databases and implementation strategies were analysed to support the development process. Subsequently, the main fields of concern were investigated, from which the framework objectives, assumptions and requirements were derived. Finally, the various concepts were deconstructed, categorised and re-integrated into a framework aimed at addressing the research problem.

Validation

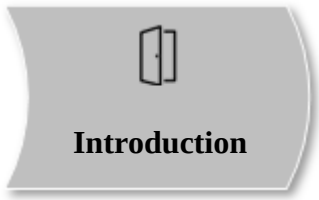
The final part of the research design aims to validate both the research done during this study and the problem solution that resulted from it i.e. internal and external validity. The internal validity was gauged by validating that each of the research objectives were achieved to a sufficient degree. The external validity was tested in two different ways. The framework itself was thoroughly tested through its application to two case studies. Expert interviews were also conducted to evaluate the framework, validate the need for it and highlight any remaining issues. The consulted experts comprised of various sectors in the AM industry, such as AM companies, academia and government initiatives.

1.5. Project Roadmap

The layout of this document is represented by the roadmap shown in Figure 1.3. This structure is aimed at enabling the reader to understand the problem and solution in the sequential order employed during the study.

Figure 1.3 - Document outline.

Chapter 1: Introduction



The first chapter introduces the study through providing background and stating the research purpose. The chapter also describes the problem being considered, followed by the research aim and subsequent objectives. The methodology and research design followed during this study, as well as the document outline is also discussed.

Chapter 2: The Standardisation Environment

Chapter 2 describes the first part of the literature review i.e. gaining an understanding of and investigating the field to determine gaps and opportunities. This is done by analysing standards and standardisation within the context of AM. The key players in the field of AM standards, the current state of AM standards and South African AM initiatives are also investigated to gain a better understanding of the field.

Chapter 3: Framework Development

This chapter describes the process that was followed to develop the framework. Firstly, an additional review of literature is done to determine the correct type of framework for the problem under consideration, as well as whether similar research has been done. This is followed by the deconstruction of the various concepts making up the problem to determine what is required from the framework. Finally, the methodology used to develop the framework is discussed in detail and substantiated by literature.

Chapter 4: Framework Discussion

The fourth chapter is meant to act as a manual to the framework. Thus, it gives an overview of the entire framework structure, followed by an in-depth description of each stage, methodology and tool.

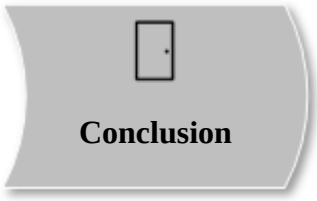
Chapter 5: Verification

This chapter is aimed at testing whether the developed framework adheres to the requirements specified in Chapter 3. It also tests whether the research done in this study aids in the adherence to these requirements.

Chapter 6: Validation

Chapter 6 describes the validation process followed to validate the study. First, a description is given of the external validation, aimed at validating the research findings by means of two case studies and expert interviews. Thereafter, the internal validation is discussed, which is aimed at determining whether the research objectives were achieved. Finally, the chapter is concluded with an analysis of the study and framework to determine its strengths and weaknesses.

Chapter 7: Conclusion



The final chapter concludes the study and gives a concise summary. It also describes how the study contributes to the field considered, recommendations made regarding the research and how the research can be expanded in the future.

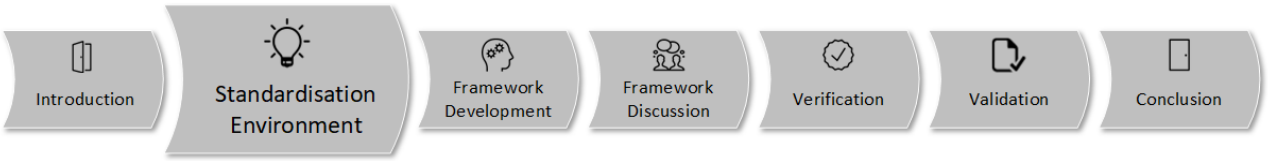
1.6. Summary

Owing to the small extent of standardisation in AM compared to SM and the resulting adverse effects, this study considers the question of how an organisation can effectively and efficiently identify and implement AM standards. Therefore, the aim of the study is to develop a framework for this purpose. In order to achieve this aim, three objectives were identified:

1. Do a top-down analysis of the research problem components to fully understand its extent.
2. Complete a bottom-up synthesis of these components to build a framework able to address the research problem.
3. Continually evaluate the research being done, as well as the proposed solution.

The research was completed using three main methodologies, each addressing parts of the five steps of the research design. The literature analysis is spread between Chapter 2 and a part of Chapter 3. The rest of Chapter 3 describes how the framework was developed, followed by Chapter 4 describing the proposed framework. Finally, the framework and the study is evaluated in Chapters 5 and 6, and concluded in Chapter 7.

Chapter 2
The Standardisation Environment



Chapter 2 describes the literature study that was completed to gain a greater understanding of the problem under consideration and the various aspects of which it consists. Firstly, the various types of standards are investigated, followed by the difference between standards and regulations. The concept of standardisation is also analysed to determine what its effects are and how it can be used advantageously. Thereafter, the key players in the standardisation efforts in the AM field are explored, followed by an investigation into the state of AM standards. Finally, a short summary is given of South African AM initiatives and how they contribute to research in the field.

2.1. Standards

The ISO define a standard as *"a document, established by consensus and approved by a recognised body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context"* (ISO/IEC, 2004). Technical standards are standards regarding technical systems and can be defined as *"documented consensus agreements containing technical specifications or criteria to be used as rules/guidelines, or definitions pertaining to the field"* (NPES, 2005). These specifications describe characteristics of a product such as quality levels, performance, safety or dimensions (BusinessDictionary, n.d). Standards Australia converts this concept into layman's terms by stating that standards are published documents setting out specifications and procedures designed to ensure that products, services and systems are safe, reliable and consistently perform the way they were intended to (Standards Australia, 2016). According to ASTM International a good engineering standard should stimulate a competitive market, encourage environmentally sustainable practices, be abreast with technological advancements and trends, whilst being concise, yet thorough and effective (Stiehler, 1949). Standards may take one of several forms, such as a definition of terms, specification of design, detailing of procedures or performance criteria for the product and/or process (International Trade Centre, 2017).

Standards can be implemented at various levels, as is depicted in Figure 2.1 on the following page. Although most literature agrees that there are only 3 levels, the categorisation as done by the British Standards Institution (BSI) was found to be more applicable to the field of AM. Since AM is an emerging technology, many of the standards in use by AM companies were developed inhouse and are thus classified in the bottom 3 categories and as such, the inclusion of those categories in the study was found to be warranted.

International Standards are the most complex, since it requires a high level of agreement between various participants, as well as adherence to various international requirements. Therefore, adherence to international standards also provide the highest level of confidence for clients and consumers. Regional standards, better described as continental standards, are developed and maintained by a regional Standards Development Organisation (SDO). In Africa, this role is played by the African Organization for Standardization (ARSO). However, the European Committee for Standardization (CEN) is widely considered to be preferable in the field of AM.

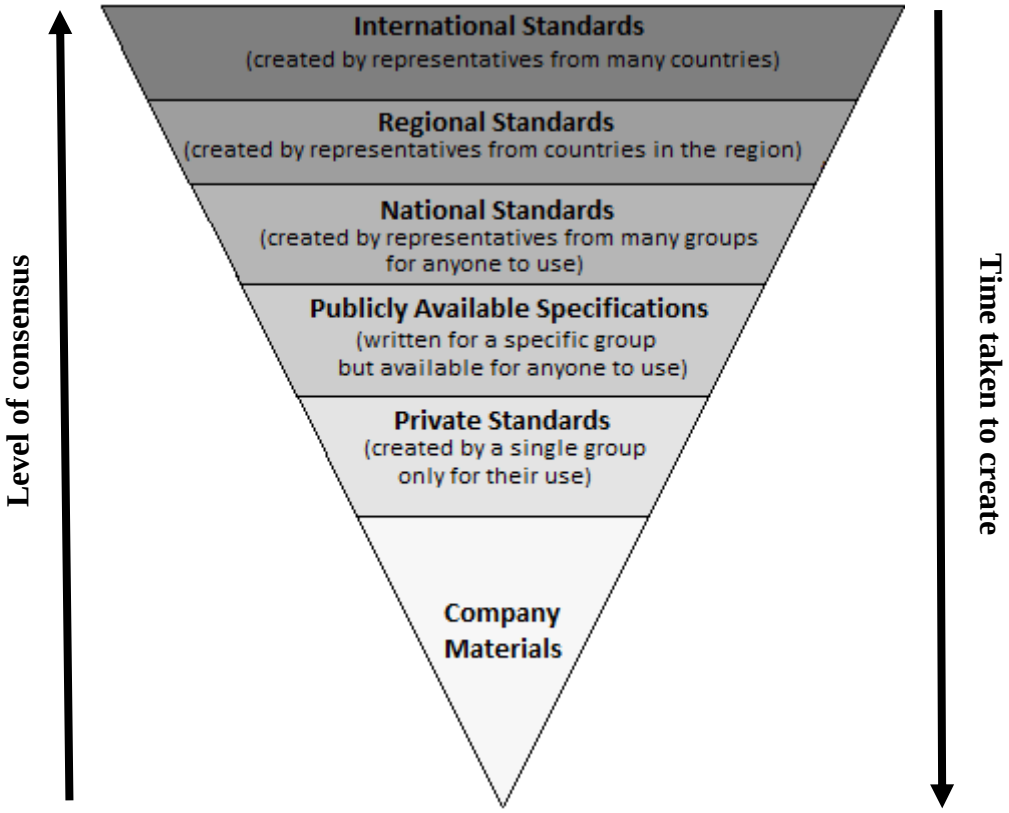


Figure 2.1 - Levels of standards (adapted from (BSI, 2016a)).

Country standards are regulated by national standards bodies such as the South African Bureau of Standards (SABS) and are most commonly used for products sold within the country. These standards are often based on international standards. Publicly available specifications are voluntary standards that are published by small groups or organisations other than SDO's and can be used upon consideration. These are commonly used in emerging fields where higher-level standards have not yet been developed. The final two levels refer to standards and materials developed inhouse, such as SOP's, which are specific to a company and handled in private to gain a commercial advantage.

2.1.1. Standards vs. Regulations

An important distinction to note is that between standards and regulations. A regulation is a document compiled by the government that specifies product characteristics or process/production methods, with which compliance is mandatory (International Trade Centre, 2017). This stands in contrast to the voluntary compliance of standards. The International Light Transportation Vehicle Association has defined regulations as *"a rule of order having the force of law, prescribed by a superior or competent authority, relating to the actions of those under the authority's control"* (Somers, n.d). Thus, another key difference is that regulations are written by a government authority, whilst standards are written by standardising bodies. Standards also rarely cite legislation, since this could change within the life cycle of the standard.

However, government often uses standards when compiling legislation, using them for the technical detail whilst the government focuses on long term policy objectives (BSI, 2018). Thus, it is evident that standardisation provides a basis for technical regulations and agreements (International Trade Centre, 2017).

2.2. Standardisation

According to Saltzman, Chatterjee & Raman (2008) standardisation is the process of developing and implementing standards based on consensus of the views of various participants. It should be noted that in this study, the word *"standardisation"* does not refer to the automation of a process, but rather the implementation of standards to a process, since AM is an emergent technology based on the premise of adaptability and responsiveness. However, many have argued that there is a big difference between standards and standardisation. Literary theorist Raymond Williams already noted the odd tension between these terms in 1985, stating that standards are normally deemed laudatory, whilst standardisation is disparaged due to its connotation with the suppression of individuality (Williams, 1985). This sentiment is still shared by many scholars who argue that the standardisation of a process has a detrimental effect to innovation (Grøtnes, 2009)(Wright, Sturdy & Wylie, 2012)(Dolfsma & Seo, 2013). So this begs the question, why standardise?

Cargill (2011) makes the statement that almost every industry is influenced and affected by standards. He also defines standardisation as follows:

> *"Standardisation is the product of a personally held belief that the market has the ability to understand and chart a valid future direction through the use of collective wisdom, to understand the impact of change on itself, and to adjust to that change."*

This type of market has been shown to exist, as in the case of large scale, conventional SM – a field not known for its innovation. It stands as a polar opposite to AM – an emergent technology, counting on innovation to pave the way forward. Yet, at the 2014 ISO-CERN 'Standardization and innovation' convention, it was shown by many researchers, business leaders and entrepreneurs that standardisation and innovation should not have to be at odds with one another (ISO, 2014). Through proper innovation management and policies, innovation could benefit from standards. According to the Director of Research and Education at ISO, this is possible in the following ways[1]:

[1] For more information and cases, refer to: www.iso.org/iso/home/about/training-technicalassistance/standards-in-education/education_innovation-list.htm.

- Timely application of critical design constraints to reduce redundant product development, freeing up resources for innovative work, thereby contributing to technical evolution.
- Allowing the exploitation of network effects and improving customer confidence to facilitate the development of new markets.
- Fostering innovation through collaboration, by sharing risks associated with R&D.
- Enabling the commercial exploitation of innovations by removing undue proprietary interests and barriers to trade.

Timmermans and Epstein (2010) claim that standards have a way of becoming part of the taken-for-granted technical infrastructure of modern life. Even though standards are an integral part of modern life, Lampland and Star (2009) observe that standards are often seen as boring and fail to evoke much attention. Standards are developed for various reasons, such as specifying safety, quality or performance objectives of a product or service, relaying regulatory requirements or purely for educational purposes. Standards look after the interests of both the business and the client. Standards protect consumers' rights to safety, promotes research and development (R&D) of the technical field and allows diverse contributions to be regarded (BSI, 2016a). Standardisation also ensures compatibility. This allows companies to design products that can use parts produced by other manufacturers who are knowledgeable in the specific field, whilst having full confidence in the quality and specifications of those sourced products. This improves competitivity, since production of such products would normally be more expensive than sourcing it. One such example is that of a Formula One racing car. Although racing teams go to great lengths to ensure the utmost quality in their cars, they aren't experts when it comes to racing tyres. Therefore, they outsource the task to tyre manufacturers, trusting that the product will be adequate, since it adheres to certain standards. This sentiment is reinforced by the Institute of Electrical and Electronics Engineers (IEEE), who believes that standards form the fundamental building blocks for product development through establishing universal protocols, thereby ensuring compatibility and interoperability which simplifies product development, shortens the time-to-market and facilitates international trade (IEEE Standards Association, 2011). Furthermore, Dr. David Anderson has found through practical cases that the standardisation of key parts in a process will result in a reduction of cost, improved constant product quality and flexibility in manufacturing (Anderson, 2017).

The German Institute for Standardization (DIN) substantiates these claims in a research project during which more than 4,000 companies were surveyed in Germany, Austria and Switzerland. The results also showed that a company can gain an important edge over the competition in terms of insider knowledge by being involved in the development of a standard.

Another advantage is the positive effect on the buying power of the company through avoiding dependence on a single supplier, since standards allow for a more competitive market (DIN, 2006). Standards and the implementation thereof also hold advantages to the commercialisation process, such as fostering commercial communication, diffusing/transferring technology, improving productive efficiency and process management, whilst also providing a basis for technical/trade agreements. It is important to note that standardisation has a simple definition, but can be implemented in countless different situations, each having its own pros and cons. Standardisation on a platform will foster innovation, whilst standardisation within an emerging technology may prohibit it. Similarly, standards allow technical progress and competitive markets to the benefit of consumers, whilst standardisation empowers the sellers through reduced competition. This study does not delve into the effects of standardisation within the context of the user, be it full-scale standardisation or only that of simple tasks whilst allowing innovation of the rest. This study is rather a reflection into the field of standardisation, producing a tool for the identification of standards to enable a standards-based approach for users who have decided to standardise some, or all, of their process.

2.3. Key Players in AM Standards

Although standards can be developed inhouse by companies with a dominant position in the market, they are mostly developed and governed by SDO's such as ASTM International or ISO (Utterback, 1996). These can also be referred to as standards organisations, standards bodies or standard setting organisations. Due to the increase in technological innovations, standardisation has become competitive. This is particularly evident in fast-emerging markets such as AM. Here SDO's develop standards to not only meet technical demands, but also real-world market requirements (Schneiderman, 2015). There are thousands of SDO's across the globe, but only a few have made significant contributions to the field of AM. It is evident that within this field, ISO and ASTM International are leaders in the standardisation effort, followed by ANSI, CEN and BSI. Although the SABS also has published standards regarding AM, they often refer to the aforementioned organisations, as is the case with most other SDO's. The Additive Manufacturing Platform produced the Strategic Research Agenda in 2013 that highlighted areas for future development, such as SDO's working together to develop standards in key categories (Additive Manufacturing Platform, 2013). This appeal was apparent once again in the road map produced by the Support Action for Standardization in Additive Manufacturing (SASAM), stating that there should be only one set of AM standards used across the world, common organisational structures should be used in AM standards and that ISO TC261 and ASTM F42 should work together (SASAM, 2015).

This call has been heeded, since ASTM International and ISO have jointly crafted the Additive Manufacturing Standards Development Structure, as can be seen in Figure 2.2.

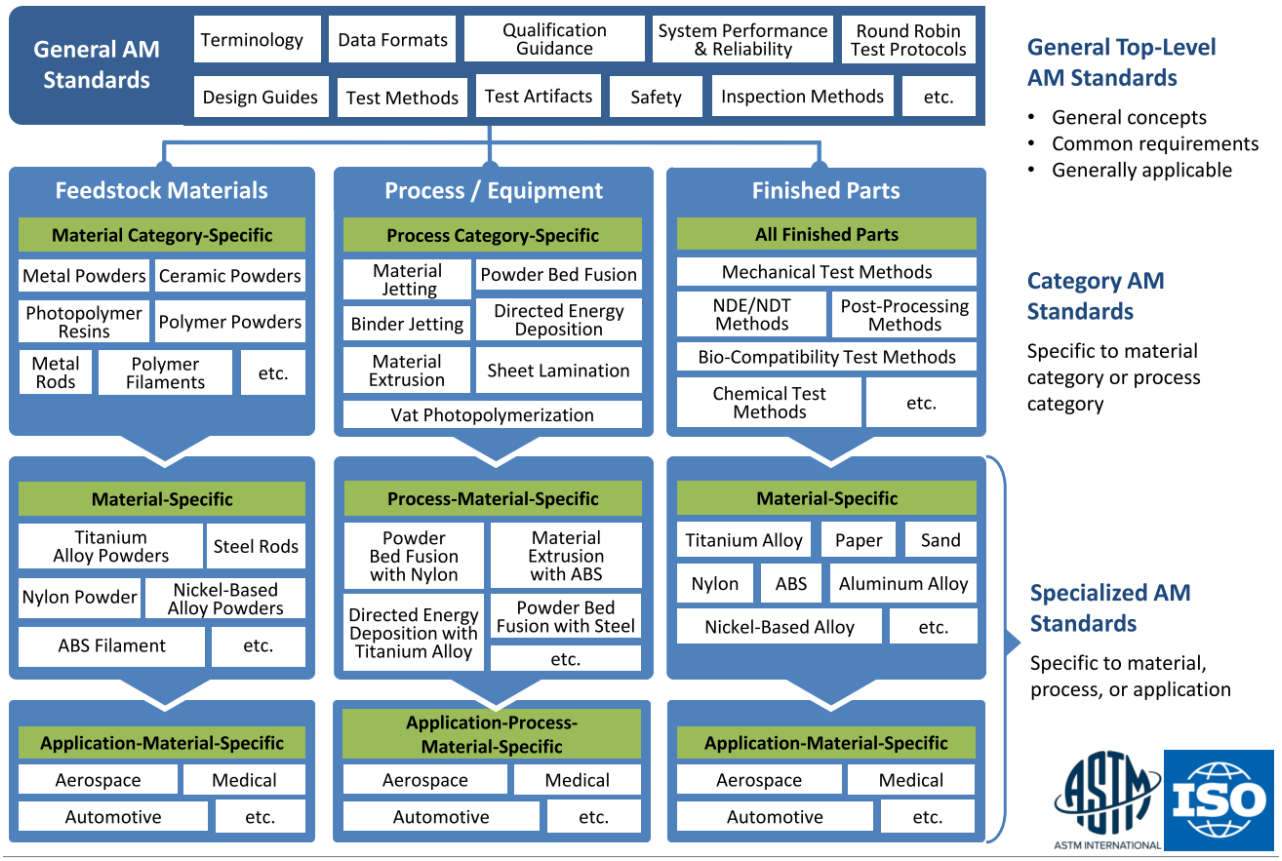


Figure 2.2 - Additive Manufacturing Standards Development Structure (ASTM International & ISO, 2016).

Based on this structure, standards can be developed at one of three levels. General standards will comprise of standards regarding common requirements, concepts, safety and guides. Category AM standards refer to those concerning materials and processes in general, whilst specialised AM standards refer to specific materials, processes or applications (Naden, 2016). The structure was developed with the aim of not confining the scope of an SDO's work, but guiding SDO's and industry experts in the development process. Use of this structure will also ensure cohesion in the standardising environment, prioritisation of areas in need of standards and encourage use of the technologies (Milsaps, 2016). The structures' goals also include preventing overlap and duplication of standards and improving usability and acceptance of standards in the AM community (Wright, 2016). According to the chair of ASTM's committee F42 future benefits would include uniform workforce training and a strengthened ability to focus on constant quality improvement (Dekker, 2016). This initiative forms part of ASTM International's Partner Standards Developing Organization agreement, aimed at eliminating duplication of efforts in the standardisation industry (Picariello & Gobbi, 2015).

Another such initiative is that of America Makes and ANSI joining forces to establish the AMSC. This body is comprised of a wide variety of stakeholders, such as OEM's, government, academia and standards consortia. Their aim is to create a road-map assessment of the state of standards in AM in order to determine the resulting gaps (Tilton, Dobner & Holdowsky, 2017).

The main goal is to achieve consistent, harmonised and non-contradictory standards in AM (ANSI, 2017). In February 2017, the AMSC published the first version of a Standardisation Roadmap for Additive Manufacturing (America Makes & ANSI, 2017a), which addressed the aims as set out in Tilton, Dobner and Holdowsky (2017). However, this first version was largely developed by representatives from the aerospace, defence and medical sectors. Since the publication of Version 1, the AMSC have launched Phase 2 of the collaboration, which included promoting the road-map, meeting with other SDO's and gaining new perspectives from other sectors to help identify overlooked gaps (ANSI, 2017). Version 2.0 of the roadmap was published in June 2018, and identified the following SDO's in the AM space (America Makes & ANSI, 2018a):

- Association for the Advancement of Medical Instrumentation (AAMI).
- American Society of Mechanical Engineers (ASME).
- ASTM International.
- American Welding Society (AWS).
- Institute for Electrical and Electronics Engineers (IEEE).
- Institute of Printed Circuits / Association Connecting Electronics Industries (IPC).
- ISO
- Medical Imaging & Technology Alliance (MITA) / Digital Imaging & Communications in Medicine (DICOM) of the National Electrical Manufacturers Association (NEMA).
- Metal Powder Industries Federation (MPIF).
- MT Connect Institute (MTConnect).
- Society of Automotive Engineers (SAE International).

For more information regarding the activities of international organisations in the field of AM standardisation, refer to (Monzón *et al.*, 2014).

2.4. The State of AM Standards

The AMSC compiled a list of available standards in the AM field, referred to as the AMSC Standards Landscape, which consisted of 350 standards developed by 25 standards bodies (America Makes & ANSI, 2017b). The second version, published in June of 2018, updated this list to 537 standards from 30 different SDO's. Figure 2.3 below depicts the number of standards identified for each of the SDO's. It should be noted that while these standards are applicable to AM processes, not all of them were developed specifically for AM purposes. Thus, Figure 2.3 also depicts the number of standards identified for each of the SDO's that are AM specific.

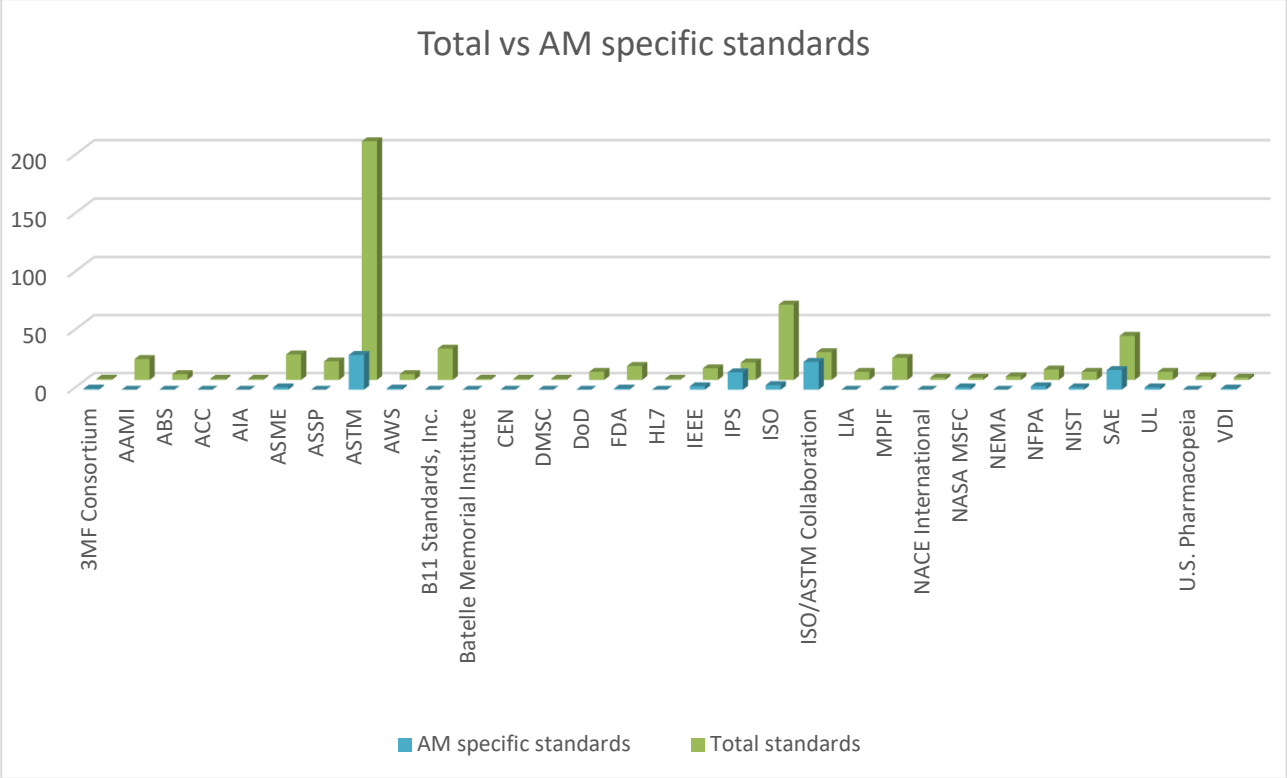


Figure 2.3 - AM standards per SDO.

From this it is evident that ASTM International has produced the most AM related standards, with ISO following. Other key SDO's are ASME, MPIF, SAE International and ANSI group B11.
While the AMSC list of standards has become more comprehensive and has gained knowledge from various stakeholders in the AM field, it is not yet an exhaustive list. As such, 36 additional AM specific standards were identified during case study 1 (see Section 6.1.2), raising the total of AM specific standards identified to 144. One such example is the National Fire Protection Association (NFPA) publishing standards regarding the handling of combustible dust and particulates e.g. NFPA 654: Standard for the prevention of fire and dust explosions from the manufacturing, processing and handling of combustible particulate solids.

To further investigate these standards, the information shown in Figure 2.4 was compiled from the standards identified during Case Study 1, the AMSC list, as well as ASTM group F42's and ISO TC261's lists of developed standards (America Makes & ANSI, 2018b)(ASTM International, 2018)(ISO, 2018).

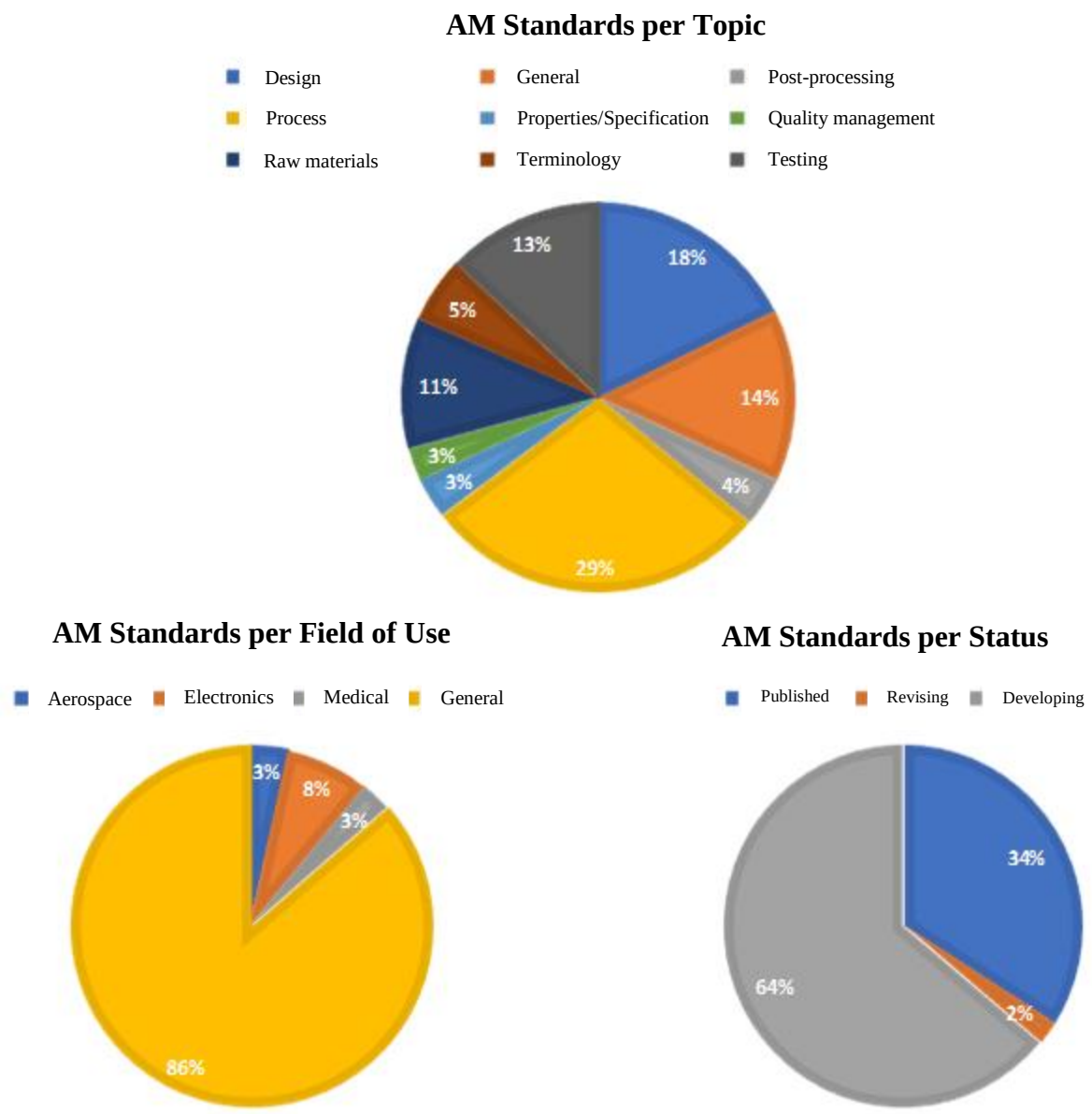


Figure 2.4 - AM standards landscape analysis.

From this, it is apparent that post-processing standards are still the biggest problem, since only few exist. However, 29% of the standards are focussed on AM processes, with another 3% aimed at providing specifications to be used during these processes. Furthermore, it is evident that AM specific standards are only being developed in three areas of application: aerospace, medical and electronics. The additional electronic AM specific standards can be attributed to the IPC, an association focused on creating standards for the printed electronics industry. The small number of industry specific standards are to be expected, since SDO's have only recently begun to develop such specific standards. This is also apparent in Figure 2.4, with 64% of these AM standards still in the development process.

According to Version 1 of the Standardisation Roadmap for Additive Manufacturing published by the AMSC, 89 gaps were identified where no published standard or specification exists, with 19 being classified as high priority. In Version 2, the identified gaps were re-evaluated. Each of the gaps were ranked according to the Criticality (urgency of issue), Achievability of the project, Scope (resources required) and Effect (impact on the field). A total of 95 gaps were identified, with 18 being considered to be high priority areas. These gaps were grouped according to the stages of the digital thread for AM (DTAM), shown in Figure 2.5, by Tilton, Dobner and Holdowsky (2018) to gain a better understanding of how they impact each stage of the AM process.

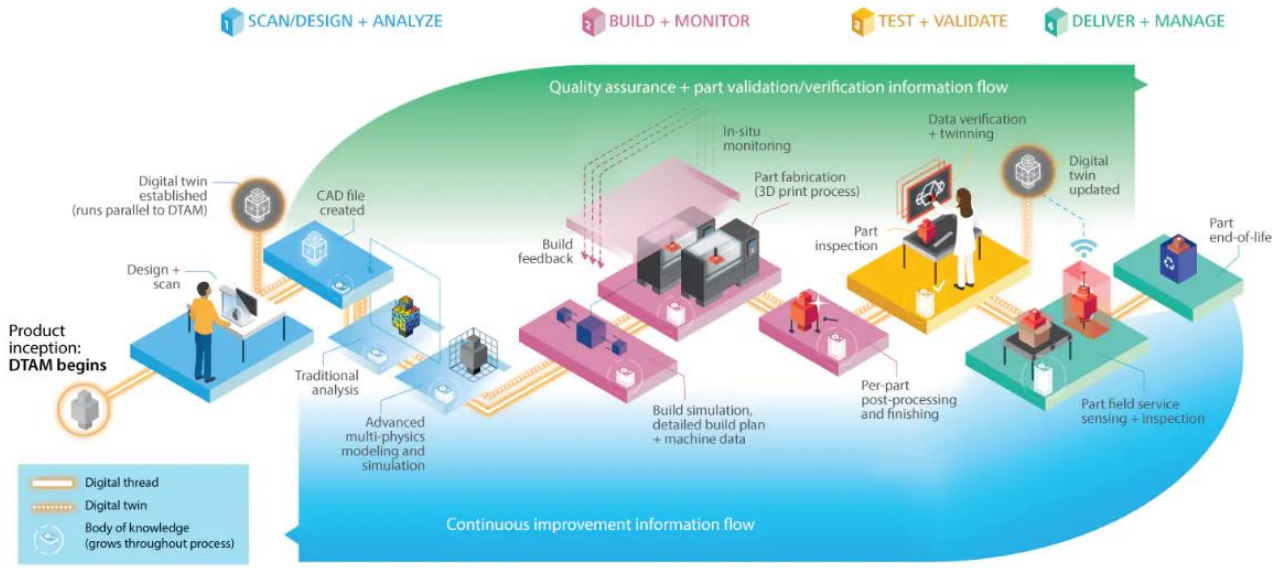


Figure 2.5 - Digital thread for additive manufacturing (Tilton, Dobner & Holdowsky, 2018).

The gaps identified for each stage are (Tilton, Dobner & Holdowsky, 2018):

- Scan/Design & Analyse - a number of key design-related gaps were identified for areas concerning design guides, tools, design considerations for specific applications, data formatting and interoperability.
- Build & Monitor – while many standards were identified for this stage, gaps were found regarding process control, AM machine calibration, as well as post-processing activities such as heat treatment and surface finishing. Gaps were also identified regarding certain material characteristics, such as flowability and morphology.
- Test & Validate – an important gap identified was that of qualification and certification requirements and how they pertain to each industry. Relatedly, the harmonisation of certification terms across industries was also deemed important, followed by the need for training certification criteria.
- Deliver & Manage – encapsulated in various gaps identified is the gap in standards focussed on closing the product life cycle loop.

However, in many of the remaining gaps, relevant standards or standards under development were available (America Makes & ANSI, 2017a). As such, the AMSC Standards Landscape list contains 429 standards that were not developed specifically for AM, but which are applicable to AM processes. One such example is *"ASTM B962-17: Standard test methods for density of compacted or sintered powder metallurgy (PM) products using Archimedes' Principle."*

According to a feasibility study done by the European Defence Agency the lack of design guidelines, standard equipment, standards for AM production and standard tests for AM products is identified as current non-technological limitations (Gonzalez & Alvarez, 2018). Although the number of standards in the field is progressing quickly, SDO's have to overcome various obstacles to produce these standards. One such obstacle is developing standards in a field that is always evolving. Therefore, SDO's have to balance how in-depth the standard is with the expected lifetime of the technology under consideration. Another obstacle is that of knowledge fragmentation (McMenamin, 2018). Due to the competitive nature of AM and standards development, knowledge is valuable and reluctantly shared. According to McMenamin, the Chairman of ASTM's group F42 states that there are still many misperceptions regarding the field. This is due to the fragmentation of knowledge into many small organisations with little background in the field, rather than having the information shared across the industry through one platform.

This is evident in a survey done on 52 Belgian companies by Sirris' Standards Cell focused on AM standardisation, where 78% of the companies admitted to not being aware of any AM standards that have already been published (Voets, 2018). This fragmentation also leads to overlapping and redundancy between standards, both of which inhibit standards adoption (Lu, Morris & Frechette, 2016). When presented with similar questions at the 2018 Rapid Product Development Association of South Africa (RAPDASA) conference, this misperception in the industry became more evident. As shown in Figure 2.6, the current industry belief is that there are much less standards available than what the AMSC determined. From this survey questionnaire, as shown in Appendix A, it was also determined that many believe more standards should be developed in areas such as process specifications, although this is the area where most AM specific standards have been published. Other areas believed to require more attention is that of design, aerospace and testing. Also important to note is that only 19% of the participants believe that it is not difficult to identify AM standards.

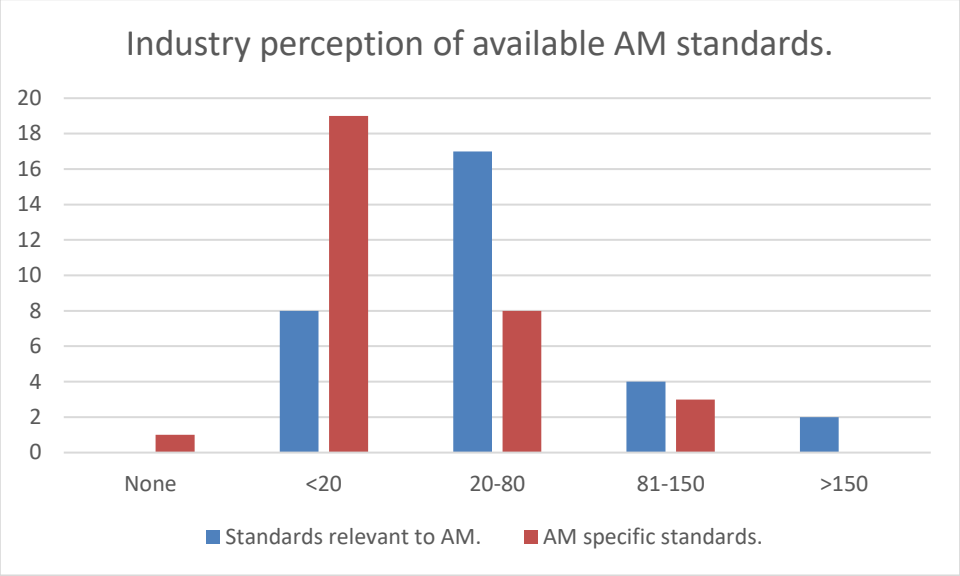


Figure 2.6 - RAPDASA survey results.

2.4.1. AM Standards in Practice

Standards are essentially a way to capture and communicate best practices that were compiled by various industry stakeholders. As such, they contain valuable information regarding the industry and play a large role in the diffusion of a technology.

The Gartner's Hype Cycle provides a graphic representation of the maturity and adoption of technological innovations. It provides a view of how an innovation will evolve over time, allowing one to discern the hype from commercially viable technologies. The cycle has five phases, namely the innovation trigger, peak of inflated expectations, trough of disillusionment, slope of enlightenment and plateau of productivity. An innovation will initially gather enthusiasm and expectations, until the industry determines what is and is not possible, at which time the expectations become more realistic and the innovation can then climb the slope towards sustainability. Standards provide and communicate this reality check. This is visible in the most recent version of the Hype Cycle for 3D printing, shown in Figure 2.7. Since aerospace and medical specific AM standards are currently being developed, with a few already published (see Figure 2.4), the knowledge is being communicated and expectations regarding these applications become more realistic, resulting in them dropping into the trough. However, in the case of electronics, the standards developed by the IPC have been in use for a few years. Thus, expectations have already been managed and this application is starting its way up the slope of enlightenment towards sustainable manufacturing practices.

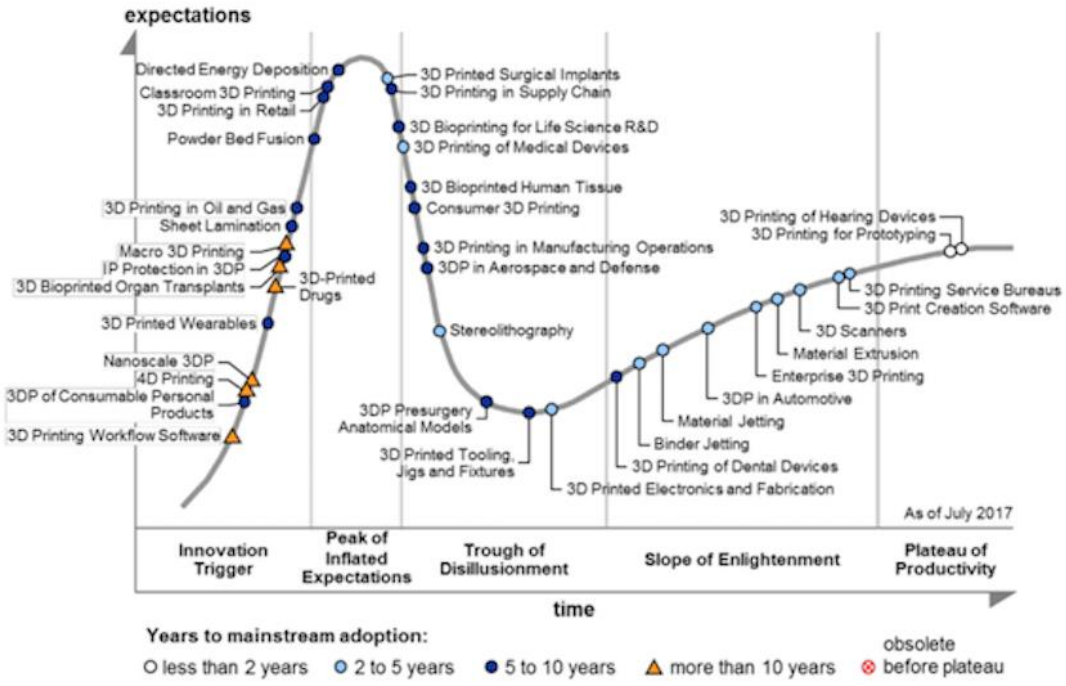


Figure 2.7 - Gartner's Hype Cycle for 3D printing (Gartner, 2018).

2.5. South African AM Initiatives

Although the SABS is not avidly active in the field of AM standardisation, South Africa is one of the leading countries in the field, with many initiatives already launched to further research and adoption in the field.

The Rapid Product Development Association of South Africa (RAPDASA) was launched in 2000 to create a strategic link between academia, science councils and industry. It is involved in a wide variety of activities aimed at furthering the development and usage of AM technologies. The most prominent of these is the annual conference, which offers a platform for academia and industry to share their knowledge and experience (RAPDASA, 2017). From the 2012 RAPDASA Annual General meeting, an Additive Manufacturing Roadmap for South Africa was developed in order to devise a national strategy. The Department of Science and Technology contracted the Council for Scientific and Industrial Research (CSIR) to coordinate the development of such a strategy, aimed at identifying future addressable markets and the associated resource requirements. From this, the South African Additive Manufacturing Strategy was developed (de Beer *et al.*, 2016). Four main areas of focus were identified, as can be seen in Figure 2.8.

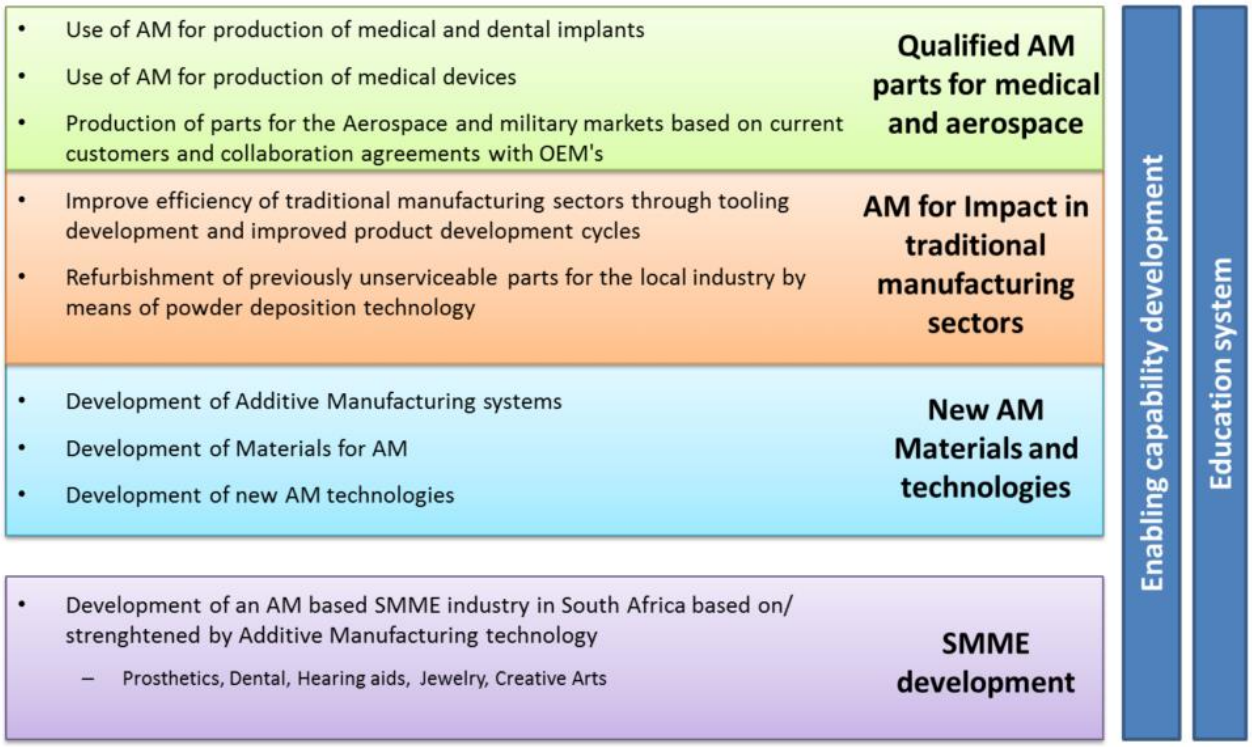


Figure 2.8 - A framework for the development of and investment in AM technology in South Africa (Greyling *et al.*, 2017).

In 2014, CSIR was tasked with the development of a business plan for AM technology development that would implement the South African Additive Manufacturing Strategy. The CSIR, along with leading universities and industry stakeholders, formulated the national Collaborative Program in Additive Manufacturing (CPAM). The aim of this programme is to increase the manufacturing readiness of AM, thereby increasing adoption of AM technologies in South Africa (CSIR, 2017). CPAM plans to accomplish this through focusing on four main programmes, namely:

- Qualification of AM of Ti6Al4V for medical implants and aerospace components.
- Design for AM.
- Polymer AM.
- Support program: Science communication and awareness.

Up until 2020, CPAM aims to produce 86 journal publications, 143 conference publications, 42 new processes, 7 patent filings, 25 PhD graduations, 70 M graduations and 100 B/Honours degree graduations (Greyling *et al.*, 2017).

2.6. Summary

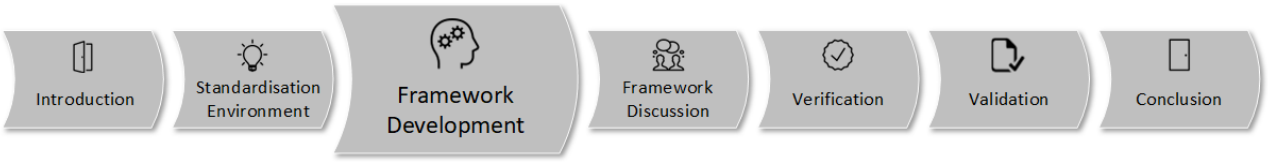
The aim of this chapter was to give the reader a general understanding of standards, regulations and standardisation within the field of AM, and to gain a better understanding of the problem under consideration. This was done by defining standards, standardisation and regulations. An overview of the key players driving the efforts to develop standards in AM was given, as well as an analysis of the current state of AM standards. Finally, a summary was given of South Africa's efforts towards researching the problem areas and developing problem solutions, of which this study forms part.

From the AMSC Standards Landscape list it is apparent that ASTM is currently leading the standardisation efforts when it comes to AM, with ISO following. However, it was found that many AM companies are only aware of large SDO's such as these. From the study done by the AMSC, it is evident that there are 537 standards applicable to AM developed by 30 SDO's, with 144 of those being AM specific. Therefore, a company may perceive a gap in the standards when there is actually a developed standard that they could use. Further analysis of the AMSC Standards Landscape list also revealed that most standards focus on the AM processes and accompanying specifications, with the least focusing on post-processing activities. Most standards are also still in the development phase, with only three industries being considered in industry specific standards. As such, 18 high priority gaps have been identified where no standards exist.

The rest of the report is aimed at further investigating how one can remedy the research problem, and the development and evaluation of a problem solution.

Chapter 3

Framework Development



This chapter serves as a description of the process followed to develop the framework, as well as the supporting literature that was referenced during this process. The chapter starts by investigating the different framework types to decide on the correct type to use in the study. Thereafter, a similar framework and database is described and discussed. The methodology used to develop the framework is developed from two existing methodologies and discussed in detail. This is followed by a description of the framework objectives, scope and assumptions. The various concepts affecting the research problem are investigated to determine what concepts should be included in the framework, from which the framework requirements are stated. Finally, the identified concepts are deconstructed to gain a better understanding and then integrated into the final proposed framework.

3.1. Frameworks

A framework is generally defined as "*an essential supporting structure of an object*" (Oxford University, 2010). Merriam-Webster further describes it as "*a set of facts or ideas that provide support for something*" (Merriam-Webster, 2018). However, in an academic setting, a framework can be summarised as "*concepts and the relations between them that are presumed to account for a phenomenon"* (Sabatier, 2007). These frameworks describe empirical phenomena through grouping into descriptive categories and not through explanations (Franfort-Nachmias & Nachmias, 1996). According to MohdZain et al. (2001:605) frameworks are a means of presenting concepts in a non-prescriptive manner, allowing the user to choose their own specific course of action and priorities, and to develop a system suitable to their institutional situation and available resources.

Due to the specific field and cases considered in this study, four types of frameworks were examined – strategic, theoretic, conceptual and practical. Strategic frameworks, also known as results frameworks, are aimed at increasing focus, selecting strategies and allocating resources accordingly. They generally have overarching strategic objectives that are met through key intermediate results (Adams-Matson, 2010)(Roberts & Khattri, 2012). These frameworks indicate how each intermediate result facilitates the attainment of the objectives, and how these objectives are related to one another and the ultimate goal (UN Women, 2012). A theoretical framework relies on existing formal theories and coherent explanations of phenomena or relationships (Eisenhart, 1991). Such a framework must indicate an understanding of relevant theories and concepts (University of Southern California, 2018). Closely related is the conceptual framework, defined as a network of interlinked concepts that provide an understanding of phenomena (Jabareen, 2009). It is an argument that the chosen concepts will be useful and appropriate to the given research problem (Eisenhart, 1991). This framework is also based on theory but includes that of practitioner's knowledge. Lastly, the practical framework focuses on the experience and knowledge of practitioners in the field rather than theoretical understanding (Scriven, 1986). As such, the research problem originates from practice, and preference is given to practical knowledge over theory.

Owing to the small amount of relevant literature available on the topic, much of the framework will be developed from practitioner's knowledge. Yet, some of the concepts making up the framework are dependent on literature and theories. As such, the framework will be a conceptual-practical hybrid framework i.e. a conceptual framework largely developed from practical knowledge, opinions and best practices.

3.2. Conceptual Frameworks

A concept has components and is defined by them. These components define the consistency of the concept and exhibit multiplicity i.e. no concept has only one component, nor is it true that every multiplicity is a component itself (Deleuze & Guattari 1991:15). Guba & Lincoln (1994:108) state that conceptual frameworks require assumptions to be made that are methodical, epistemological and ontological in nature. Methodical assumptions are made during the synthesis process and determining its applicability in the real world. An epistemological assumption is made when one assumes how things work in reality. Ontological assumptions refer to knowledge of the nature of reality. In other words, the researcher needs to make assumptions regarding how different concepts connect with each other. According to van der Merwe (2017) a conceptual framework should exhibit the following key features:

- The collection of concepts should be integrated to a certain degree.
- The approach should be interpretive rather than only causal or analytical (Jabareen, 2009).
- The aim is to strengthen the understanding of the user rather than provide a theoretical explanation (Jabareen, 2009).
- The framework should provide both the hard facts and "*soft interpretation of intentions"* (Levering, 2008).
- The framework does not enable the prediction of outcomes, but can improve the likelihood of certain outcomes (Levering, 2008).

3.3. Similar Work

3.3.1. Lloyd's Register

Lloyd's Register Group Limited is a technical and business services organisation owned by the Lloyd's Register Foundation, a charity dedicated to research and education in science and engineering. A sub-division of the group, Lloyd's Register Quality Assurance (LRQA), focuses on independent assessment services such as certification, validation and verification. Due to the rapidly growing interest in using AM techniques, LRQA has recently developed the Additive Manufacturing Product Certification service, aimed at providing a standardised way of proving that a printed product is safe. This service helps manufacturers prove the adherence of their product to the required standards and regulations by applying international standards to the processes used in order to prove equivalence with conventional manufacturing techniques (Lloyd's Register, 2017). This is done through the use of the framework, "Guidance Notes for the Certification of Metallic Parts Made by Additive Manufacturing", developed in conjunction with TWI.

This goal-based framework can be followed by manufacturers to achieve certification with Lloyd's Register. The framework is structured around the following key topics (Lloyd's Register Group Limited, 2017):

- The suitability of AM for the product
- Certification approach and activities
- Design aspects
- Materials
- Manufacturing aspects
- Post-processing aspects
- Inspection and testing
- Organisational requirements

Although there are some similarities between this study and the LRQA framework, the following key differences should be noted. While this study is aimed at including all AM techniques employed by the user, the LRQA framework is currently limited to three specific metal AM processes namely Laser Metal Deposition, Laser Powder Bed Fusion and Wire Arc AM. Another key difference is the categorisation approach. The LRQA framework uses six categories while this study found the need to add the field in which the product will be used. However, the biggest difference would be the framework's intended use. The LRQA framework is aimed at certification of the process to specific international standards, such as ISO 9001, in order to prove equivalence of the manufacturing method. This study is aimed at the identification, storage and implementation of all standards applicable to the process and is to be used at the user's discretion for the goals stated in Section 3.4.1. The LRQA framework can rather be used as a tool in Stage 2 and 5 of the framework produced in this study, and the study's framework can be used to aid in the certification/accreditation process. As such, this study draws from the LRQA framework to address an identified gap in the AM field.

3.3.2. SME Database

The Society of Manufacturing Engineers (SME) is aimed at generating solutions to challenges in the manufacturing industry by sharing knowledge and resources. With their main focus being on the state of manufacturing, advanced manufacturing technologies and the manufacturing workforce, they wish to advance the field and attract future generations in order to promote the associated technologies and develop a skilled workforce. As such, they have developed the "Standards, Specifications and Guidelines database" (AM-3DP) containing the available information relating to additive manufacturing.

As depicted in Figure 3.1, the AM-3DP database allows users to search by the area (design, materials etc.), employed technology (binder jetting, laser sintering etc.), material, material form (powder, liquid etc.) or SDO (SME, 2017). Thus, the user can search the database for standards, specifications and guidelines tailored to their specific process.

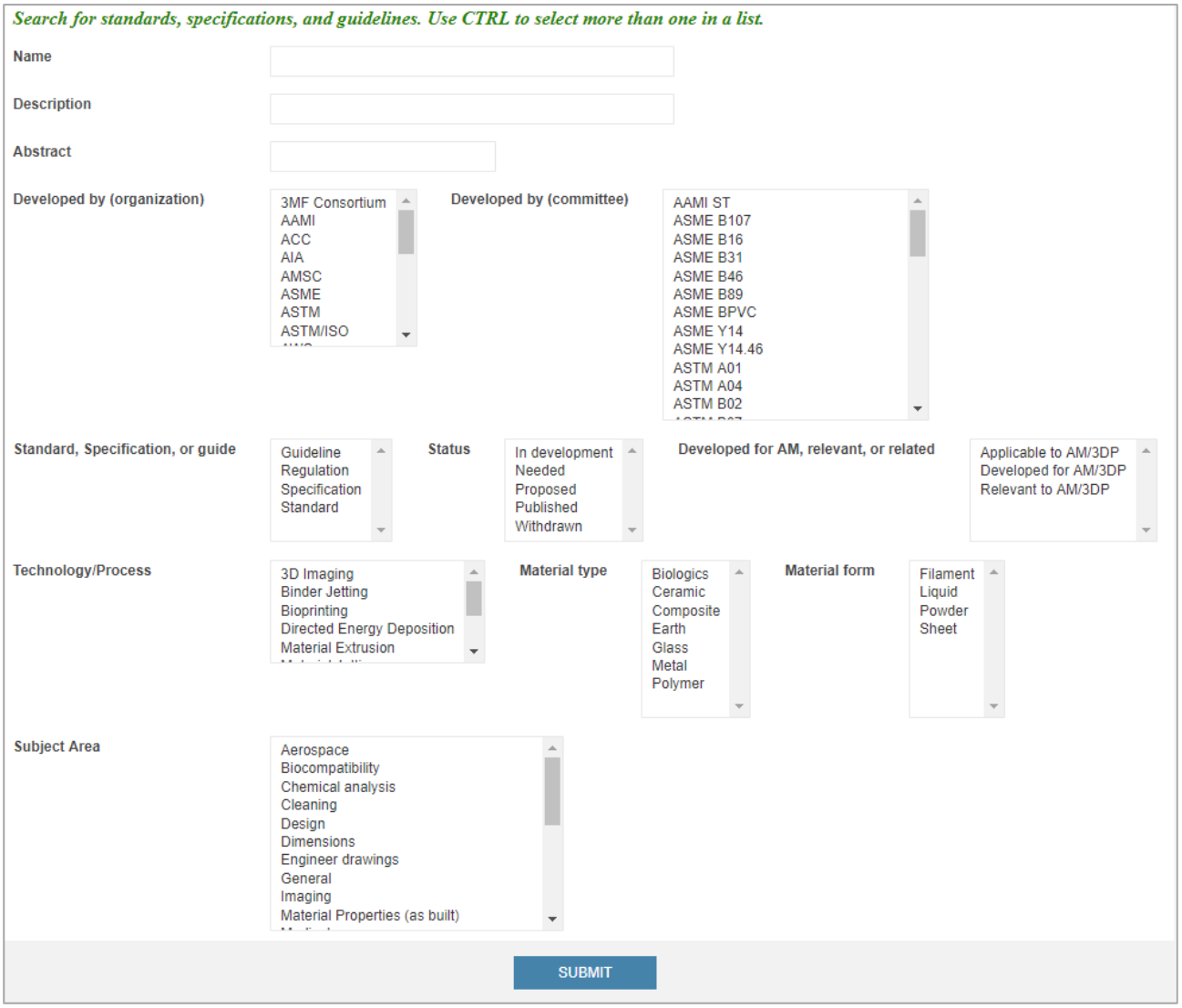


Figure 3.1 - AM-3DP search filters (SME, n.d.).

The framework being developed draws from the AM-3DP database's method of filtering standards. While the user may decide to include all of the filters that this database employs, the framework only proposes the "Subject Area" filter. Furthermore, although there are some similarities between the AM-3DP database and that proposed in this study, they are intended to be used in different ways. While the AM-3DP database aims to include all standards, specifications and guidelines relevant to AM, the proposed database only contains standards, regulations, SOP's and documents relevant to a specific company's processes. The proposed database can also be integrated into the company's systems, allowing easy reference. Another difference is the fact that the AM-3DP database is not a relational database.

Thus, whilst the AM-3DP database can be used during Stage 3 of the framework to identify standards, it will become more inefficient with each repetition of the framework. It should also be noted that the AM-3DP database is by no means an exhaustive collection of all standards pertaining to AM. It should therefore not be used as the only method of searching for standards, but rather be incorporated into the searching methods employed.

3.4. Framework Synthesis

This study employs a systems engineering approach, aimed at achieving the research objectives stated in Chapter 1. A conceptual framework can be developed in many ways, dependent on the case under consideration. Regoniel (2015) states that such a framework can generally be developed in four steps, namely choosing your topic, reviewing relevant literature, isolating important variables and synthesising these variables to form your framework.

Jabareen (2009) proposes a more elaborate procedure, as described in van der Merwe (2017), which comprises of the following eight steps:

1. Mapping the selected data sources – map multidisciplinary literature relating to the phenomenon in question.
2. Extensive reading and categorising of the data – review the selected data and group it according to discipline and importance.
3. Identifying and naming concepts – discover concepts from literature and practical knowledge to find interrelationships.
4. Deconstructing and categorising the concepts – deconstruct the concepts to identify their attributes, characteristics, features and epistemological, methodical and ontological roles in order to organise them into categories.
5. Integrating concepts - combine concepts into a whole that is easier to understand and manipulate.
6. Synthesis – iteratively synthesise the concepts into a conceptual framework and verify that it adheres to basic requirements.
7. Validate the framework – validate whether the framework is understandable and reasonable to scholars and practitioners.
8. Rethink – improve the framework based on the feedback received.

However, this procedure does not address some key steps in developing a framework, such as defining its objectives and assumptions. As such, the framework methodology that Pretorius (2017) adapted from Kennon (2010) was combined with that of van der Merwe (2017) to form a complete framework development process, as shown from step one to twelve in the following table.

Table 3.1 - Framework development methodology.

	VAN DER MERWE (2017)	PRETORIUS (2017)	CHAPTER
1	Mapping data sources		Literature Study
2	Reading & categorising data		
3		Define objectives & assumptions	Framework Development
4	Identify & name concepts	Map fields of concern	
5		Define structural requirements	
6		Define framework function	
7	Deconstruct & categorise concepts	Develop framework	
8	Integrate concepts		
9	Synthesise		Framework Discussion
10	Validate	Validate	Validation
11	Rethink		
12		Finalise	Conclusion

3.4.1. Framework Objectives

The main aim of the framework is as follows:

> *'To aid the user in identification, storage and implementation of standards applicable to the process being considered, resulting in the assurance of quality and customer satisfaction.'*

This will be achieved through meeting the framework objectives listed below. These objectives adhere to the key features of a conceptual framework mentioned in Section 3.2. Therefore, the developed framework should:

- Integrate the various concepts into a coherent whole that strengthens the user's understanding of the phenomena.
- Be interpretive in its approach, focusing on both theory and practitioner's interpretations.
- Improve the likelihood of identifying all relevant standards.
- Guide the user through the process rather than prescribe steps to follow, thereby strengthening the user's understanding of the phenomena.
- Allow and encourage continual improvement.

This framework can be used by starting AM companies to set up their process, for R&D of new products, in quotes to improve customer confidence, during certification/accreditation activities or to establish a standardised platform upon which to innovate.

3.4.2. Framework Scope & Assumptions

The framework was developed by focussing on South African AM companies specialising in titanium products in highly regulated fields, such as medical, aerospace or automotive. However, much of the framework is also applicable, but will not be tested, in more generic applications within the AM field. The framework guides the user through the processes required for proper identification, storage and implementation of standards, but it is required that the user develop their own tools, methodologies and SOP's from it. While it is conceded that standards and regulations are often implemented together, this framework is not aimed at the identification of regulations. However, it will make provision for the incorporation of the associated regulations identified by the company.

Furthermore, since AM is an emerging technology, little applicable theory is available for the development process. Although AM is similar in nature to other manufacturing processes, conventional theory cannot be applied without modification thereof, since various factors can affect the end product (Hopkinson & Sercombe, 2008)(Martinez-Garcia, Ibanez-Garcia, Sanchez-Reche & Leon-Cabezas, 2011). As such, much of the framework is developed from practitioners' knowledge and opinions. Therefore, it is assumed that the aggregate of these opinions provides a coherent theory to be used during the development process. It is also assumed that the theoretic application of the framework to case studies will be sufficient in evaluating the use thereof, owing to time limitations. However, it should be kept in mind that the framework is based on an emerging technology and as such there are many unknowns. Thus, until the framework is applied in reality, there are bound to be some unforeseen problems.

3.4.3. Fields of Concern

Before finding an effective solution, the problem being considered must first be thoroughly understood (Juech, 2014). However, due to the lack of available theory, an exploratory case study was done to determine the various concepts that play a role in the identification process. This case study considered the same product described in Case Study 1 of Chapter 6, but employed the methods most commonly utilised by AM companies, which comprises of scouring SDO databases using certain keywords[2]. From this case study, it was determined that the following four questions are of importance:

[2] See RAPDASA questionnaire results in Appendix A and transcripts in Appendix D for confirmation of the methodology.

3.4.3.1. Why do you require the use of standards?

While many may believe that the use of standards will have detrimental effects, standards are proven to have a positive effect when implemented properly. However, since the use of standards is voluntary for the most part, companies must decide for themselves whether they need standards. Standards can be used for the following purposes:

To gain knowledge

Being an emerging technology, few experts exist in the field. Therefore, newcomers must go to great lengths to ascertain the relevant knowledge, often having to make costly mistakes to learn from them. However, through use of standards these companies can gain vast amounts of knowledge regarding different aspects of the AM process without having to waste money on these costly mistakes. Thus, the technical detail provided in standards allow for a steep learning curve leading to effective policies being implemented and ultimately saving money in the process (ISO, 2017b). This knowledge can also be used to avoid duplication of work and ensure that your product is marketable (CENELEC, 2013).

Legal security

In most cases the use of standards is voluntary. However, the implementation of standards is sometimes mandated by regulation (ISO, 2012). These regulations are devised for various reasons, such as ensuring the safety of the customer and personnel, or for environmental care efforts (ETSI, 2018). No matter the reasoning behind the regulation, the use of standards allows the mitigation of liability in highly regulated fields such as medical or aerospace, providing legal security to the company and peace of mind to the consumer.

To gain a competitive edge

The ultimate goal of any company is sustainability. As such, standards can give a company an advantage over the competition. The standardisation of your process can lower production costs by optimising the production efficiency and reliability, facilitating the maximisation of profits (DIN, 2007)(ETSI, 2018). The use of standards also help in providing the customer with confidence that the products adhere to quality norms, which will enhance customers' perspectives and satisfaction regarding the product (BSI, 2012)(ISO, 2012). International standards also promote international confidence in the product, allowing access to international markets and ensuring the product complies with market conditions (CENELEC, 2013). Furthermore, standards ensure that systems are compatible and interoperable, allowing outsourcing to reduce production costs or the manufacturing of products that are compatible with various existing platforms (Karachalios, 2017)(SFS, 2015).

To stimulate the market

While some may view more competitors as a disadvantage, it has a positive effect in emerging markets such as AM since it promotes fair competition. Standards allow more companies to enter the field. This in turn promotes innovation in the field, be it technologically or managerially, and helps to prove the credibility of new products and markets (ETSI, 2018). Standards also affect 80 percent of all world trade (Karachalios, 2017). It can therefore help to break down trade barriers, allowing the market to grow (ISO, 2017b).

To encourage innovation

While many believe standards inhibit innovation, as discussed in Chapter 2, it may in fact improve innovation in the field and a company. Not only does competition in the field stimulate innovation in order to remain competitive, but standards allow compatibility between companies, which in turn stimulates solutions to national and international issues through working together (ISO, 2017b). The use of standards also increase confidence in innovations, which could help win funding for research. Furthermore, being involved with the development of future standards can help to translate your innovations into marketable solutions (CENELEC, 2013).

3.4.3.2. How do you identify relevant standards?

The framework is predicated on the idea that if you know which standards exist, you can decide which can be implemented to your advantage. Most SDO's have a database filled with their standards and related documents. However, the sophistication of each varies significantly. Many are of the opinion one can just search for "additive manufacturing standards", but this only captures standards with these keywords in them, which has been proven to be too few. As such, further investigation into methods of standards identification is required.

The International Classification of Standards (ICS) code is a hierarchical classification convention managed by the ISO, which is used to classify standards (ANSI, 2009)(NIST, 2016). The ICS ranges in topics and has three levels. The first level describes the various ICS fields. The second and third levels describe sub-categories of a specific ICS field. For the exploratory case study being considered, ICS field 11 would be of interest i.e. Health care technology. ICS code 11.040 distinguishes medical equipment standards from other health care technology standards. In this case, the relevant standards would be found under the ICS code 11.040.40 group, which contains standards regarding implants for surgery, prosthetics or orthotics (ISO, 2015a). However, it should be noted that the 11.040.40 group only represents a small aspect of the product being considered.

As such, many ICS fields must be scoured to find relevant groups, after which a search must still be done to find the relevant standards within each group, which can be a difficult task if not approached correctly. Due to the tedious and complicated nature of the ICS codes, this method is not commonly used. Another method used to classify standards is through the use of standards identifiers. These are a series of numbers and letters that SDO's use to identify different standards and are unique to each SDO. An example of ASTM's designations is shown in the figure below. However, while this is an effective method of naming standards for referencing, it is an ineffective way to search for standards, since you need to know each designation beforehand.

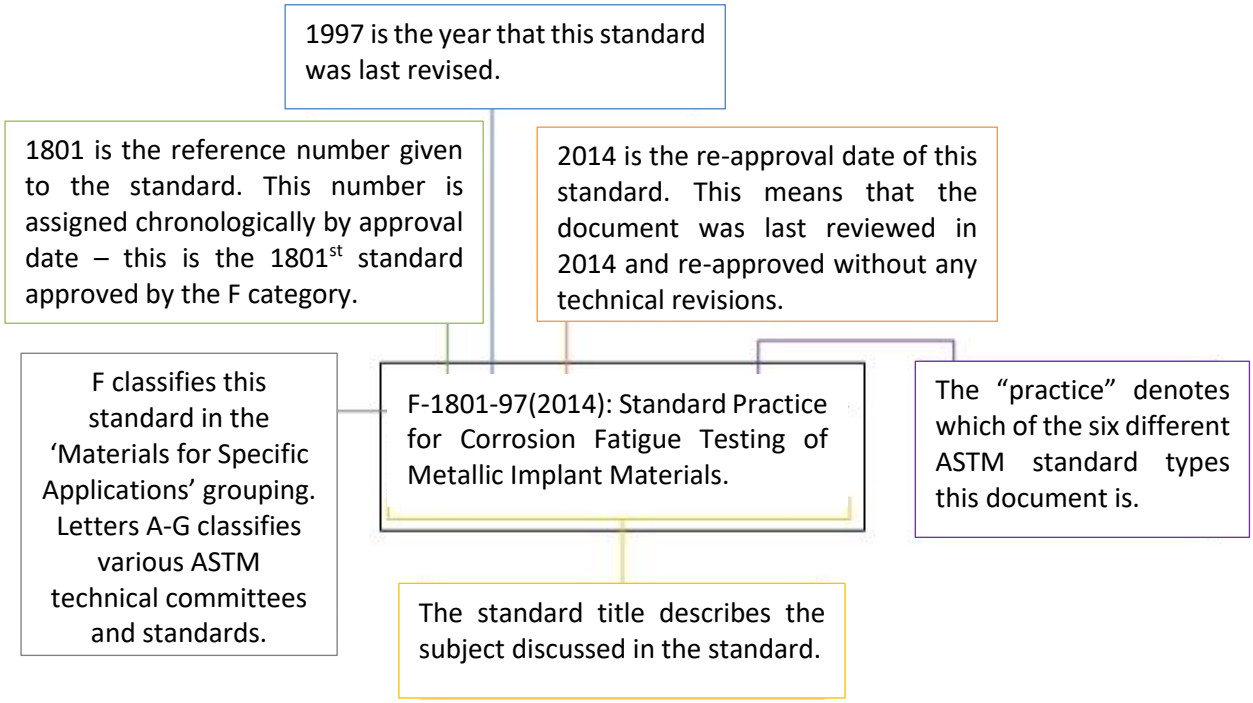


Figure 3.2 - Explanation of ASTM's designations (adapted from (ASTM International, 2005)).

Another method of searching for standards is to search according to specific technical committees (ASTM International, 2011). These committees develop and maintain standards for the SDO and a SDO will have many such committees, applicable to various specific fields. A technical committee is made up of members from the specific field or industry being considered and the level of participation varies (SABS, 2015). In the case of ASTM, as shown in Figure 3.2, the letters A-G classifies the different technical committees and their standards. Since group F represents materials for special applications, it would follow that the additive manufacturing committee (F42) would form part of group F. One would therefore search the ASTM database according to the list of standards that ASTM technical committee F42 have published. In the case of ISO, one would search the list of technical committee TC261. However, while this is a more comprehensive way to search for relevant standards, one would still have to search through the standards of various technical committees from various SDO's, each with its own naming conventions.

The most popular and widely used method of searching for relevant standards is by using certain keywords and the website's search function. While this is a simple way of finding standards, it should be noted that the search algorithm employed for these databases may vary significantly in its sophistication. Many of these databases also don't take into account a subject, but rather search for the specific keywords in a standard's title. From this exploratory case study, the following problems were identified with this method of searching:

- The search results only contain standards with the specific keywords in the title, resulting in a fraction of the relevant standards being identified.
- A SDO's search result only contains standards developed by that specific SDO, or perhaps a partner institution. As such, one may perceive a gap in the standards, while such a standard was developed by another SDO.
- It is often difficult to devise the correct keywords to accurately describe the process. As such it may become a time-consuming task.
- Expansion of the keywords may result in too many irrelevant or unnecessary standards being identified.
- The process must be re-iterated for each SDO database.
- The keywords are often not recorded for future reference.
- Effectiveness of the search is dependent on the searcher's knowledge regarding terminology within the field and SDO.

3.4.3.3. How should you store these standards?

Companies most often store their standards collection electronically (DIN, 2007). There are two main ways of storing electronic standards: a file-oriented system or a database. A file system entails a systematic and organised method of saving standards and related files in folders. These files and their locations can be linked to an Excel spreadsheet. This method is still commonly utilised by many AM companies and has many advantages to its use, such as its simplicity, low cost, ease in migrating information to other files or cloud storage and in some cases, increased performance since the storage of large files could inhibit the performance of a database (Sulaiman, 2017). However, there are also many disadvantages to such a system. One such disadvantage is the unavoidability of data redundancy i.e. some files will have to be stored in more than one location, leading to numerous duplications and the associated increase in storage space required. This may also lead to data inconsistency, since varying data may have been entered into a duplicate, resulting in two varying versions of the same document (Islam, 2011). Another disadvantage is the limited user access, since file-oriented systems often do not support multiple users (Jackson, 2015).

It should also be noted that companies often do not have specific instructions in place regarding the storage of files, which could lead to difficulty accessing data, as well as data integrity and concurrency problems. A database is a collection of tables and allows relationships to be defined between such tables (Pearson, 2013). A database, on the other hand, is self-describing, since it contains the database itself as well as the metadata that describes the database and the relationships between tables, thus allowing the user to use this information if required (Watt, 2014). Perhaps the biggest advantage to the use of databases is its ACID consistency (Sulaiman, 2017). In computer science, ACID refers to Atomicity, Consistency, Isolation and Durability. The advantages of data consistency and database durability are obvious. Atomicity refers to a database system dictating that information must either be complete or not be entered at all (Saracevic & Masovic, 2013), which ensures that there are no data integrity problems. Isolation refers to the database's ability to concurrently process multiple actions without them affecting one another (Chapple, 2018). Another benefit is the ease with which changes can be made, since it only has to be changed in one place, whereas a file system would require the change to be made in numerous locations (Watt, 2014). Databases also use little space if used correctly, simplify searching for information, facilitate the addition of information, allow information to be used in other applications, allows access by multiple users, has increased security, facilitates the use of queries to evaluate and analyse complex data, compiles reports and facilitates the navigation between different documents (Brown, 2016)(Kapur, 2014). However, there are some disadvantages to employing a database as well. These include its complexity, the associated development and maintenance costs, and the risk of security breaches if the users aren't trained regarding database security (Masters, 2018).

Therefore, the chosen storage method depends on its compatibility with the company and use being considered.

3.4.3.4. How do you use these standards?

While the identification of applicable standards is the first step to improving a process, implementation thereof is required before it will affect the company. Implementation is defined as "the process of putting a decision or plan into effect" (Oxford University, 2015). It is the process that transforms plans from a document on the shelf into actions that drive business growth, and is required to accomplish strategic objectives and goals (Olsen, 2014). As such, all standards require some form of implementation for them to become effective. These standards must be incorporated into your business by adapting the principles to your existing structures (BSI, 2016b). This can be done by compiling SOP's, thus clearly conveying the concepts to all. Such a document learns from the BPP captured by the standard and clearly demonstrates how to undertake specific tasks accordingly (Advice Manufacturing, 2013).

The following benefits are obtainable by implementing standards through SOP's:

- Capturing the knowledge of industry experts, and implementation thereof through the experience of skilled employees.
- Assistance in the training and guidance of employees.
- Ensuring resource efficiency, regardless of the employee.
- Ensuring compliance, regardless of the employee.
- Minimising the likelihood of defects or process variations.

According to Kosutic (2011) SOP's can be developed in seven easy steps:

1. Study the standard's requirements.
2. Use your risk assessment to determine which issues must be addressed first.
3. Plan the SOP development to optimise and align them to what is required.
4. Plan the integration of the standard's requirements into your processes i.e. the document's structure.
5. Write your SOP.
6. Have the document approved by the management team.
7. Train the employees in use of the new SOP.

3.4.4. Requirements and Function Analysis

According to the work of Brockmöller (2008, p.89), Weber et al. (2011, p.170) and Van Aken (2004), design requirements can be divided into five categories, namely:

1. Functional requirements = F.
2. User requirements = U.
3. Boundary conditions = B.
4. Attention points = A.
5. Design restrictions = R.

The requirement analysis is done using these categories and draws on the implementation thereof as discussed by Krause & Schutte (2015) and Stelzner (2017) due to the similar nature of the work done in these studies. The design requirements are listed according to their respective categories, accompanied by a motivation. Each requirement's reference indicator consists of the corresponding letter and number.

3.4.4.1. Functional requirements

Functional requirements denote the framework specifications regarding performance and results thereof (what is the framework supposed to do). These requirements are listed in the following table.

Table 3.2 - Functional requirements.

F1	Requirement: The framework should guide the user through the process, rather than be prescribing.
	Motivation: One of the key features of a conceptual framework, as discussed in Section 3.2, is to strengthen the user's understanding rather than only provide an explanation of the phenomenon (Jabareen, 2009). Correspondingly, a key objective of the framework is not to be prescriptive.
F2	Requirement: Proper use of the framework should lead to traceability and accountability.
	Motivation: Since the framework will be used in highly regulated areas such as the manufacturing of medical devices, it must ensure high levels of traceability as is required in the ISO 9001 quality management standard (ISO, 2015b).
F3	Requirement: Use of the framework should assist the user in identification of relevant standards.
	Motivation: The main goal of the framework is to aid users in identifying relevant standards, as mentioned in Section 3.4.1.
F4	Requirement: The framework should include or recommend tools to assist with application thereof.
	Motivation: Although the framework is not aimed at prescribing the use of specific methods or tools, some should be provided to guide the user and facilitate application of the framework.
F5	Requirement: All activities mentioned should be integral to successful application of the framework i.e. no unnecessary activities.
	Motivation: To avoid institutional inertia (discussed in Section 3.4.5.3), the activities included in the framework should be kept to a minimum, which also drives down the associated costs.
F6	Requirement: The framework should be applicable to various products within the specified scope.
	Motivation: The value of AM lies in its inherent customisability (Wu, Connor & Weider, 2017). As such, the framework must be usable in various settings.
F7	Requirement: The framework should enable learning through experience by means of continual improvement.
	Motivation: Due to the competitive nature of the AM field and small amount of readily available knowledge regarding the management of AM companies, the framework should enable the user to learn by doing, whilst allowing a feedback loop to apply the lessons in practice. This also increases the user's understanding of the field over time.

F8	Requirement: The framework should facilitate the implementation of standards and regulations.
	Motivation: “Creativity is useless without a structured implementation process” (Levitt, 2002). As discussed in Section 3.4.3 and 3.4.5.3, the implementation process is of critical importance.
F9	Requirement: The framework should facilitate creation and/or evaluation of the process to be considered.
	Motivation: The framework should be applicable to both existing processes and those still being developed, and should integrate seamlessly with the case being considered.
F10	Requirement: The framework should aid users in designing and implementing a storage mechanism.
	Motivation: As discussed in Section 3.4.3 and 3.4.5.2, the framework should include a database for effective storage of the documentation.

3.4.4.2. User requirements

User requirements are specifically focused on the user’s viewpoint to determine what the user would require from the framework and what requirements there are in terms of usability, such as maintenance or operational specifications. These requirements are listed in Table 3.3.

Table 3.3 - User requirements.

U1	Requirement: The framework should be user-friendly i.e. easy to understand, adopt and implement.
	Motivation: As mentioned in Chapter 1, many companies prefer to develop their own standards over the struggle of identifying existing standards (Stratasys Direct Manufacturing, 2015). The framework must therefore be an easier alternative and take resource constraints into account.
U2	Requirement: The framework should allow repeated and continuous use.
	Motivation: The intention of this framework is to put in place a management practice that allows repeated use, with the process becoming easier with each repetition.
U3	Requirement: The framework should be clear in its requirements and explanations.
	Motivation: The framework is meant to be easy to use, and the user should be able to implement it from the descriptions provided. As such, these descriptions must be clear and concise to avoid becoming a barrier to use, as mentioned in Section 3.4.5.3.
U4	Requirement: The framework should not only provide new information, but also use existing information.
	Motivation: Since the framework is developed from practitioner's knowledge it should facilitate the incorporation of the companies' knowledge to allow improvement of the framework.

U5	Requirement: The framework should allow changes to be made and facilitate those through specific procedures.
	Motivation: Due to U4, provisions should be made to allow the user to make changes through use of specific mechanisms, thus avoiding the changes affecting the framework's performance.
U6	Requirement: The framework should allow customer input and define actions for the processing thereof.
	Motivation: Since this study is based on practitioner's knowledge, it is encouraged that the users incorporate their own companies' knowledge into the framework. However, this should be done using the mechanisms mentioned in U5.
U7	Requirement: The framework should require minimal resources.
	Motivation: As described in Section 3.4.5.3, large resource requirements often result in institutional inertia.
U8	Requirement: The framework should be applicable to many products.
	Motivation: As discussed in F6, AM companies often produce more than one product. The framework should therefore be versatile.

3.4.4.3. Boundary conditions

Boundary conditions are arguably the most important requirements. These specifications or rules must be met unconditionally and may not be altered. Examples include legislation or ethical habits. The applicable boundary conditions can be found in the following table.

Table 3.4 - Boundary conditions.

B1	Requirement: The framework must protect the user's IP.
	Motivation: AM is a highly competitive field based on each companies' innovation. As such, the framework must not allow company IP to be divulged to any other parties.
B2	Requirement: The framework must ensure a high regard of customer requirements.
	Motivation: Because the framework is focused on highly regulated areas, the customer requirements should be held in high regard since failure herein could lead to loss of life. This is also stipulated in standards such as ISO 13485 (ISO, 2016).
B3	Requirement: Use of the framework must adhere to legal and ethical requirements.
	Motivation: It is important to define reasonably assumed boundaries of application to avoid exploitation of others when using the framework (Weber, Weggeman & Van Aken, 2011). It is therefore assumed that the framework will be applied in a legal and ethical way.
B4	Requirement: Use of the framework must provide value to all parties involved.
	Motivation: As mentioned in B3, exploitation of other parties should be avoided. Therefore, use of the framework must be beneficial to all of the parties involved, be it the researcher, manufacturer or customer.

3.4.4.4. Attention points

These are specifications that are relevant to the framework and should be noted, but do not have to be met, nor do they limit the design like restrictions do. For this framework, only two have been identified, as discussed in Table 3.5.

Table 3.5 - Attention points.

A1	Requirement: The framework can be used to the extent a company requires.
	Motivation: As mentioned in U4, U5 and U6, the framework should allow user input. Different cases may require the framework to be applied to different extents and in different manners. Therefore, the framework should allow the flexibility to adapt the application depth to the specific case.
A2	Requirement: Since AM is an emerging technology and limited theory is available, this framework should be seen only as a reflection of early best practice within an evolving field of knowledge.
	Motivation: Since little research has been done regarding standards in AM, the development of this framework draws on a small pool of experts' experience and the application of this framework in small companies.

3.4.4.5. Design restrictions

These requirements are limitations and exclusions to the design and function of the framework. The restrictions applicable to this framework can be found in the following table.

Table 3.6 - Design restrictions.

R1	Requirement: The framework must only focus on standards and regulations applicable to AM.
	Motivation: The problem being considered is specific to AM, due to its relative new nature. Therefore, the framework development should be focused on the problem area.
R2	Requirement: The framework must be developed for medical applications, but should be adaptable for other applications.
	Motivation: To avoid scope creep and conflicting requirements hampering development efforts, the framework should be developed for medical applications and expanded to include other applications at a later stage as required by F6.
R3	Requirement: Use of the framework will not result in accreditation, but it can be used as a tool during the accreditation process.
	Motivation: Process accreditation is a field of study in itself and is not the aim of this framework. The user should consult an expert in accreditation activities if this is the desired outcome, and can use this framework as a tool if applicable. For more information on the accreditation activities, refer to Section 3.3.

R4	Requirement: Use of the framework should not guarantee an improvement in quality, but it should help the user in attaining quality products.
	Motivation: Owing to the objectives discussed in Section 3.2, this framework will not guarantee the production of quality products, since this is dependent on many contributing factors. The framework should only provide a guide based on practitioner's knowledge for identifying, storing and implementing standards in an AM process.
R5	Requirement: The number of tools and methods included should be limited to that which is imperative.
	Motivation: "*No single method can be all things for all situations*" (Krause & Schutte, 2015). The framework should be comprehensive, but it is expected that the users develop their own tools where required as to avoid the framework becoming clustered and decreasing adoptions.

3.4.5. Deconstruction of Concepts

In accordance with the framework development methodology described in Table 3.1 the various concepts that play a role must first be identified and investigated. The main problem under consideration is the difficulty in identifying standards relevant to the field of AM. As such, this constituted the departure point for the deconstruction of the various concepts.

This problem was comprehensively reviewed in Section 3.4.3, and from that exploratory case study emerged the remaining concepts to be considered: understanding the problem, storing the standards, implementation of the standards and continual improvement. As such, the concepts were believed to be structured as depicted below, and theory pertaining to each further investigated in the following sections.

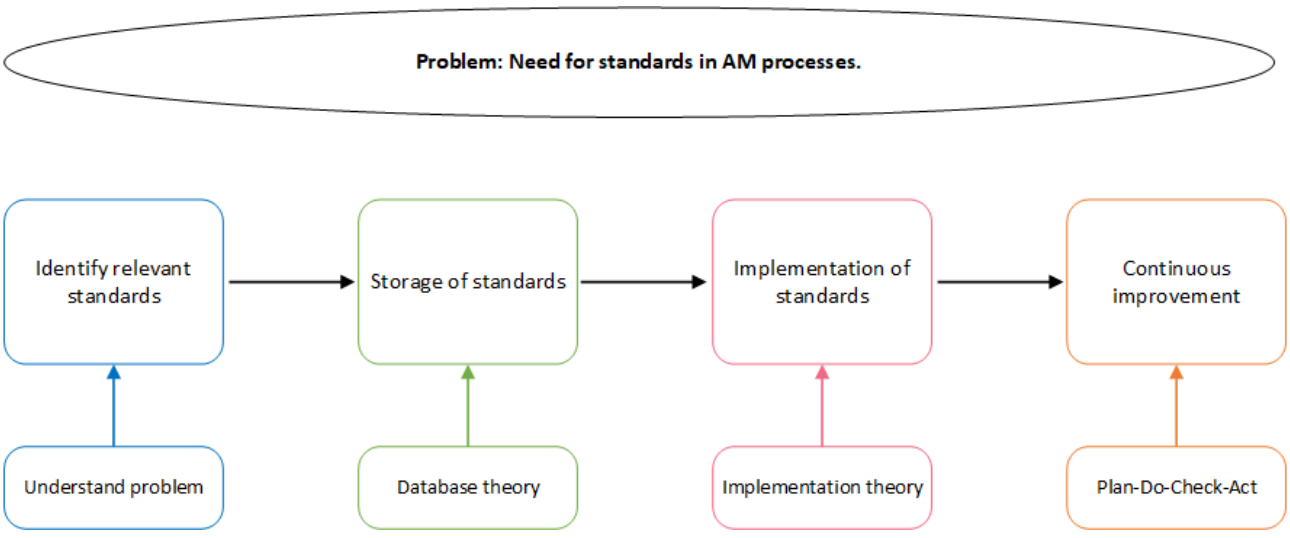


Figure 3.3 - Deconstruction of concepts of which problem consists.

3.4.5.1. Understanding the problem

"Given one hour to save the world, I would spend 55 minutes defining the problem and 5 minutes finding the solution." – Albert Einstein.

As mentioned in Section 3.4.3, understanding the full extent of the problem is of vital importance for an effective solution. This sentiment is shared by Voola, Johnston & Hughes (2016) who argue that one must first recognise the importance of the problem and then ascertain the full extent thereof, which can be done by starting with what you know. Analysing the current state gives one a good indication of where your business is and allows stakeholders to make informed decisions. It helps one obtain a clear definition of the problem and its needs, provides a thorough understanding of the domain and identifies key parts of the issue. This allows the stakeholders to make well supported recommendations about the future vision, or 'to-be' state (Korban, 2015). As such, the problem is understood in its entirety – where the company is now and where the company wishes to be – allowing the stakeholders to devise a thorough plan for reaching this vision.

Another key part of understanding the problem is visualisation thereof (Voola, Johnston & Hughes, 2016). A standard tool that can be used to understand your current state is a process map (Rath & Strong, 2017). There are many variations of process maps, such as value-added or process-interaction maps. The first defines activities in a process according to whether they add value to the product or incur costs. The second depicts the process steps, the interactions and how each relates to another (Savory & Olson, 2001). According to Bell (2012) one should start with a high-level map of your process, only describing the general flow thereof. The detail of each process step should then be expanded incrementally to avoid being overwhelmed before fully understanding the process(Bell, 2012). This allows a company to see the process as a whole, thereby facilitating the identification of high-risk and unnecessary activities, whilst also ensuring that the process and product adheres to customer requirements, and constitutes the first step towards benchmarking (Fraser *et al.*, 2012).

3.4.5.2. Databases

A database management system (DBMS) is a system software used to make and run databases. It must manage the data, the database schema (the structure according to which the data is organised) and the database engine that allows data to be opened and altered (Alabdulaly, 2016). There are four main DBMS types, based on their respective data models: Hierarchical, Object-oriented, Network or Relational (Panwar, 2011). However, during this study only hierarchical and relational databases were considered.

A hierarchical database consists of a collection of records linked through parent-child relationships, meaning that only two records may be directly linked and those must be stored consecutively. In such a relationship, one record will be the "parent" record, with the other being a sub-ordinate record (child) (Elmasri & Navathe, 2016). The child-record is therefore only attainable through its link with the parent-record, and as such a hierarchical database is represented by a tree-like data structure, as is depicted in Figure 3.4. This data structure is similar to the file-oriented system mentioned in Section 3.4.3 and therefore also requires documents to be stored multiple times. This replication will inevitably lead to data inconsistency and wasted space (Silberschatz, Korth & Sudarshan, 2010), which will also cause a decrease in the database's performance. Furthermore, this method makes navigation between the records arduous (Parthasarathy, 2014).

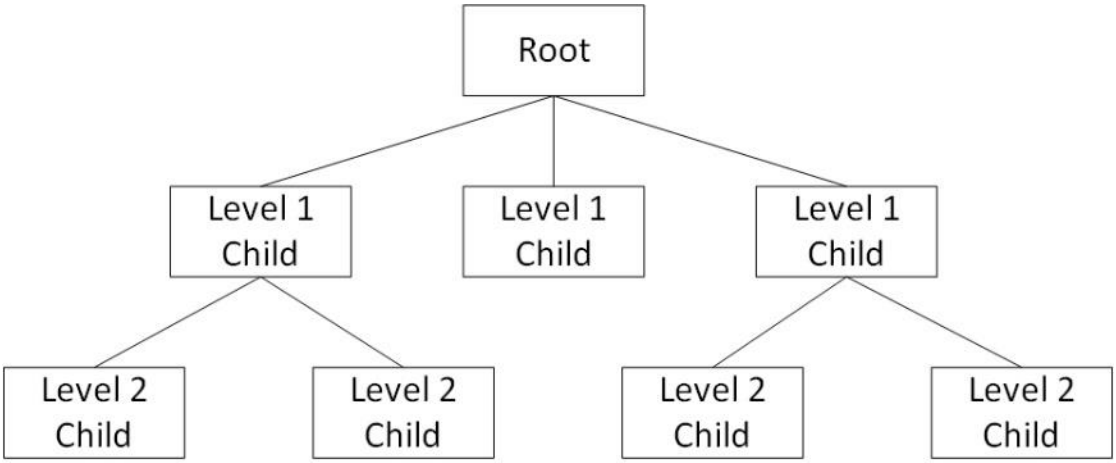


Figure 3.4 - Hierarchical database data structure (adapted from (Panwar, 2011)).

A relational database comprises of data tables that group elements into relations. Each table will include a primary key or identifier, which is used by the other tables to provide relational data links. This allows any files to be related to one another by means of a common field (Elmasri & Navathe, 2016). In such a database, the table will be the relational variable, as shown in the data structure depicted in Figure 3.5. Advantages of this database type includes reduced maintenance cost, flexibility, reliability, easy management of large amounts of data and overall good performance (Rao, ul Haq & Khan, 2018). Thus, due to the numerous advantages and the ability to link any document with another, a relational database would provide a better alternative to the file-oriented systems, as well as hierarchical databases which closely relate to such file-oriented systems.

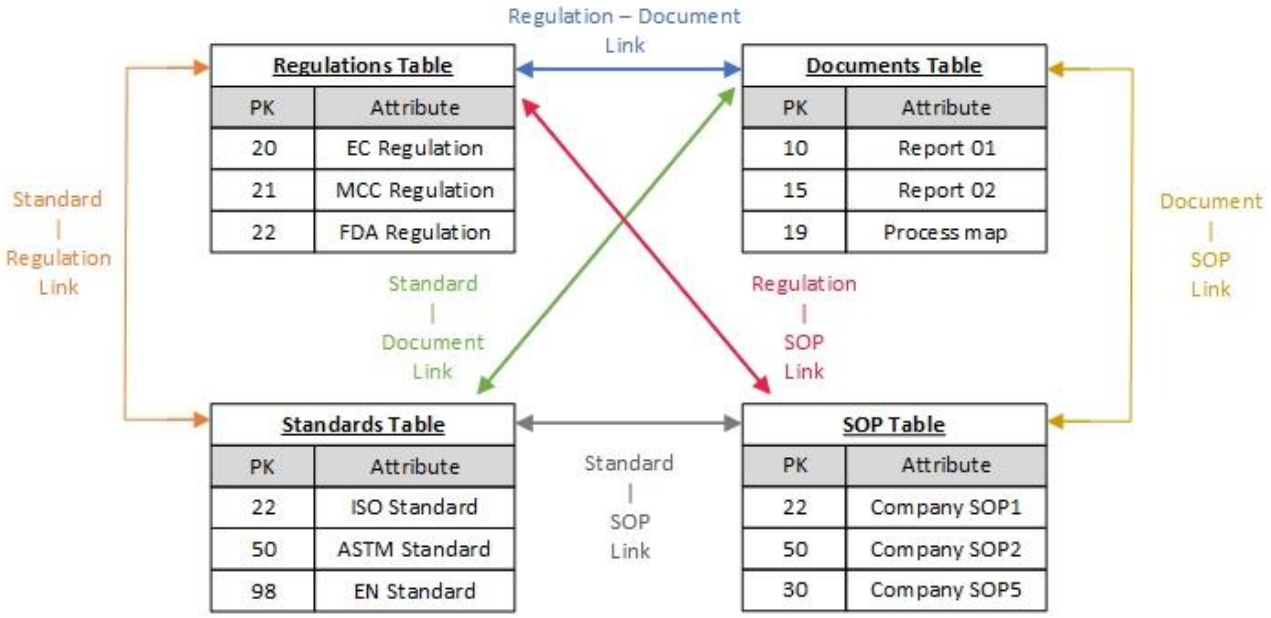


Figure 3.5 - Relational database data structure (adapted from (U.S. Department of Transportation, 2001)).

The goal of any DBMS is to *"provide a convenient and effective method of defining , storing and retrieving information"* (Gunjal & Koganurmath, 2003). Consequently, Gunjal & Koganurmath (2003) propose that a database should be designed in two phases. The purpose of the first phase is to do an initial study during which the organisation is analysed to determine the problem under consideration and its associated constraints, as well as the database objectives, scope and boundaries. The second phase entails the designing of the database model, which can be completed in the following six steps:

1. Collection and analysis of requirements.
2. Conceptual database design.
3. Choice of DBMS.
4. Mapping of data model.
5. Physical database design.
6. Implementation of database system.

Watt (2014) substantiates these claims, stating that the database life cycle encompassing the second design phase can be represented by a version of the *Waterfall Cycle*, first described by Royce (1970) as sequential phases (requirement analysis, design, implementation, verification and maintenance) to be used during software development[3]. Figure 3.6 depicts the waterfall model proposed by Watt (2014).

[3] It should be noted that while Royce (1970) did view the model as flawed, the perceived problems have been addressed in more recent adaptions e.g. (McConnell, 1996) (Matkovic & Tumbas, 2010).

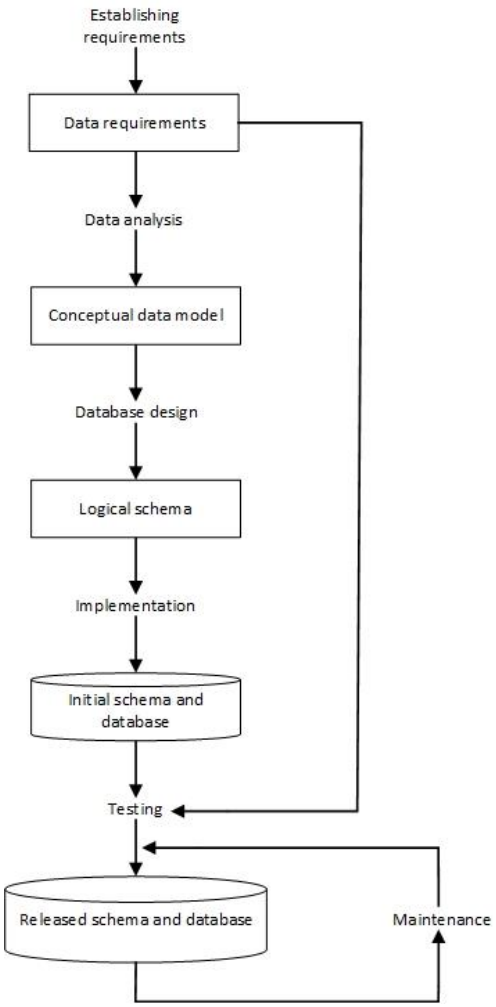


Figure 3.6 - Waterfall model of the activities and their outputs for database development (Watt, 2014).

The first phase of the method proposed by Gunjal & Koganurmath (2003) was done during the exploratory case study discussed in Section 3.4.3. From this, it was determined that there is an opportunity to optimise the storage methods employed through use of a database. The developed framework should therefore describe the requirements to develop such a relational database. Therefore, the following database design method should be integrated into the framework and its outcomes to allow the development of a personalised database:

1. Requirement collection and analysis.
2. Conceptual/Logical design.
3. Physical database development.
4. Database system implementation.
5. Population.
6. Maintenance.

It should be noted that this study is not aimed at developing such a relational database, since most companies will rather outsource such an undertaking to an expert. However, the framework should state the requirements for the proposed database and guide users in its seamless integration.

3.4.5.3. Implementation

The PIE analytical framework was developed to investigate the impact of adopting international standards on the competitiveness of manufacturing firms in China (Yeung & Mok, 2005). It proposes that the three processes shown in Figure 3.7 are inter-related in determining the successful implementation of international standards.

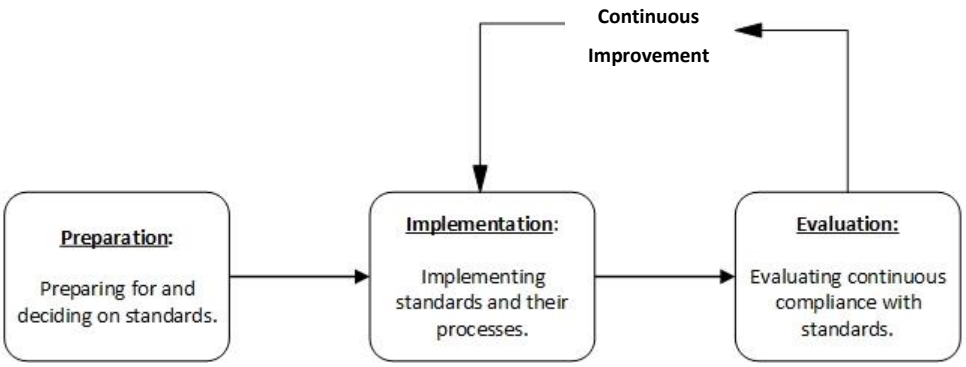


Figure 3.7 - PIE analytical framework (adapted from (Yeung & Mok, 2005)).

Preparation

A strategic plan addresses the 'what' and 'why' aspects of activities beforehand and is critical to success. The 'P' of the PIE framework regards the question of whether a standard is necessary. As mentioned in Section 3.4.3, there are many reasons for using standards, both market-driven and producer-driven. The first step would therefore be to decide whether standards are in fact necessary and why (Yeung & Mok, 2005).

However, Oliver (2007) argues that you must first know and understand your organisation thoroughly to be able to make such a decision, since implementation strategies should take into account the broader cultural environment. As such, commitment is required from the top management and other stakeholders. Once the decision has been made, an implementation team should be compiled and a gap analysis done to determine where the implementation of standards would be beneficial (QualiCertus, 2009). From this information, the implementation team can devise an implementation plan that is tailored to the organisation's situation and environment.

Implementation

According to FitzGibbon (1996), the successful implementation of standards is dependent on the following four underlying principles of international standards:

1) Say what you do - document every step of the company's process.

Documentation is of critical importance during both the preparation and implementation of standards (Yeung & Mok, 2005). However, FitzGibbon (1996) discovered that consultants would often over-generalise system documents in an effort to simplify them due to the workforce's resistance to change, or over-complicate such documents and scare the workforce through production of heavy-duty documents. The documentation process also tends to have financial implications during the initial phases. Yeung & Mok (2005) show that while there is a loss in productivity due to the employees spending an estimated one-third of working hours on documentation activities, this transitional period can be limited to one or two years if sufficient preparation was done. It is also of critical importance that effective communication channels are established during this process – if the plan is not communicated to the employees, they will not know how to contribute (Olsen, 2014). As such, the division of labour (who does what and when) must be clearly communicated. In order to avoid institutional inertia – the reluctance of a workforce to adopt changes – these communication channels should also allow feedback from the workforce.

2) Do what you say - ensure that the implementation takes place and that the company's processes adhere to the standard's requirements.

While there are many pitfalls to the implementation process, it is widely recognised that a lack of stakeholder involvement is detrimental to any such effort. Top management must be closely involved in the implementation process and take responsibility thereof (CEBOS, 2012). This sentiment is shared by Pustkowski, Scott & Tesvic (2014) who state that effective implementation is dependent on commitment and ownership from the management. Management can ease the workload and ensure effective implementation by establishing an implementation team (BSI, 2016b). Such a team should avoid pitfalls by ensuring that there is effective communication, that the implementation efforts remain aligned to the vision and mission, and that the implementation efforts do not end with the planning phase (Olsen, 2014). The implementation team and the management should also work towards avoiding institutional inertia by engaging the workforce (Yeung & Mok, 2005). This can be done through proper preparation, including influential employees during the planning phase, communication, considering the staff's feedback, training the workforce regarding the changes and providing incentives to promote participation (Berg, 2012).

3) *Show what you have done - document evidence that the company's processes meet the standard's requirements and that they are being implemented effectively.*

While the importance of documentation is evident, it is also important to show what has been done to ensure that it is effective and aligned with the vision and mission. Implementation plans may be well thought out, but practical implementation thereof could prove more difficult. Often such plans are overwhelming when implemented, with too many goals and actions resulting in confusion of the workforce. As such, non-critical actions should be excluded from the final implementation plan. Such a plan may also prove to be meaningless, with the vision and goals not being aligned with practicality or employees not being invested in the implementation process (Olsen, 2014). It is therefore important to document what has been done so that its effectiveness can be measured.

4) *Verify - conduct internal audits periodically to ensure continued compliance.*

The implementation strategy must be a living document, allowing it to be adapted when necessary. The pitfalls mentioned may all take place, and the strategy should be adaptable to address these problems if they occur. As such, the progress should be tracked and the effectiveness of the strategy in meeting its objectives should be measured (Berg, 2012). This allows changes to be made as soon as problems are discovered, thereby minimising the transitional period and ensuring continued compliance.

Evaluation

The 'E' of the PIE framework entails continually evaluating the company's processes to ensure continued compliance. While 4) proved the importance of continually evaluating the implementation process throughout and adapting it as required, it is also important to evaluate the systems put in place once the implementation has finished, to determine if the end product is aligned with the initial vision (QualiCertus, 2009). It therefore provides an opportunity to reconsider the objectives (May, 2005). This sentiment is shared by the SDO's themselves, since ISO standards require the implementation of a continually improving process approach that takes into account measurement and review (CEBOS, 2012).

3.4.5.4. Continuous improvement

From the theory mentioned in Section 3.4.3, as well as the PIE framework, it is apparent that continuous improvement is an important aspect that should be included in the framework. One tool to aid in the process of continuous improvement is the Plan-Do-Check-Act (PDCA) model. As depicted in Figure 3.8, the PDCA model is iterated until the solution has been implemented without resulting issues.

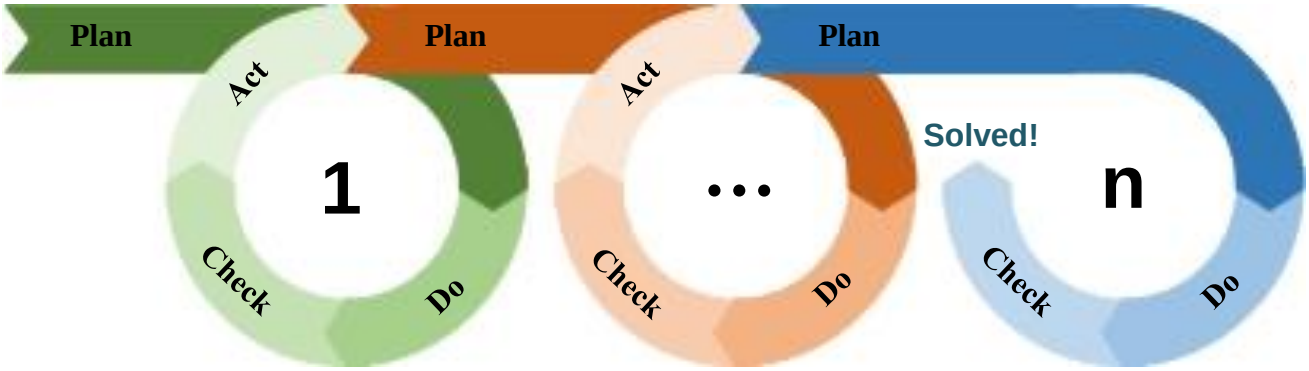


Figure 3.8 - Multiple iterative loops of a PDCA (adapted from (Rouh, 2017)).

The four steps of the PDCA entail the following (Weinstein & Vasovski, 2004):

- Plan – identify and analyse the problem.
- Do – develop and implement solutions.
- Check – evaluate the results and determine if the desired goal has been achieved.
- Act – document the results and make recommendations regarding the next problems to be addressed.

Use of the PDCA model ensures a continuous strive for better methods of improvement. As such it is also widely used by the ISO in their standards, such as ISO 27001. Each iteration of the PDCA model should result in an increase in knowledge being considered, converging on the ultimate goal with each cycle (Chandrakanth, 2016). In order to ensure that the PDCA cycle is applied thoroughly, it is important to assemble a team to participate and communicate the outcomes thereof with all stakeholders (Gorenflo & Moran, 2010).

3.4.6. Integration of Concepts

The procedure followed during this study corresponds with the Innovation Road Map W-model depicted in Figure 3.9 (Converso, Santillo & Federico, 2007). This model is based on the V-model, but implements evaluation throughout the process. As such, this approach is still based upon three key steps: top-down analysis, bottom-up synthesis and evaluation (Nicholas & Steyn, 2012). The W-model is also consistent with the development process described in Table 3.1, consisting of the deconstructing, categorising and integrating of the various concepts.

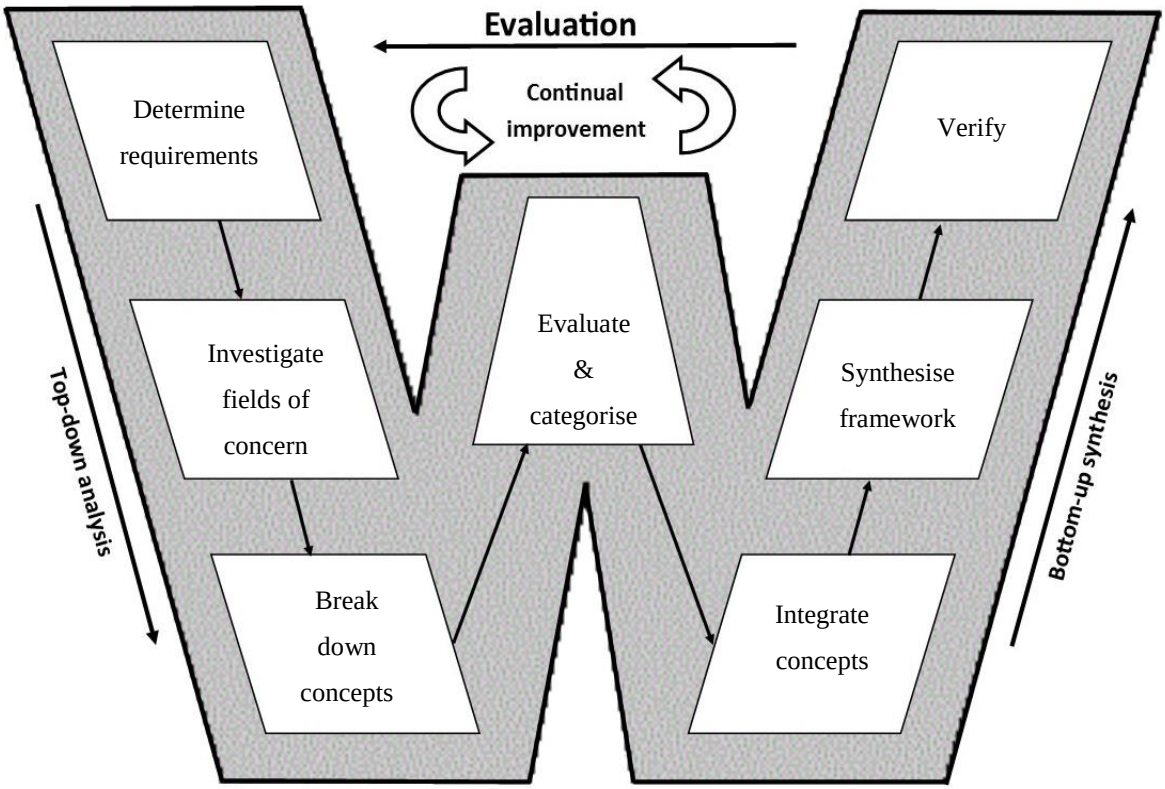


Figure 3.9 - W-model (adapted from (Converso, Santillo & Federico, 2007)).

The previous sections described the top-down analysis stage of the model. From this, it was determined that the identification of standards alone will not have a sufficient outcome. As such, the framework should include the storage and implementation thereof as well. Figure 3.10 depicts how each of these concepts can be categorised and integrated into a coherent and logical framework, followed by a description of the reasoning behind each stage. It should be noted that Figure 3.10 depicts the initial framework planning, and as such, the names of some of the stages have changed.

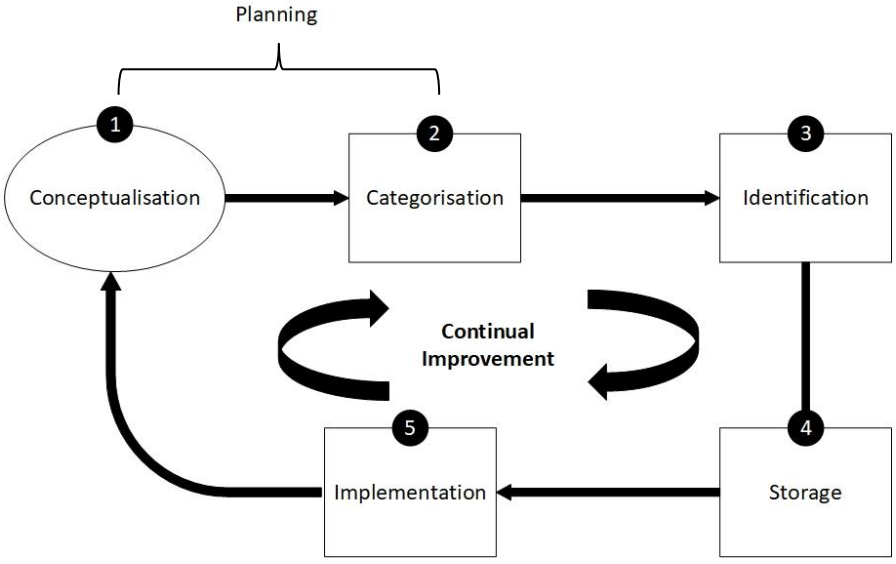


Figure 3.10 - Initial framework structure.

As mentioned in Section 3.4.5.1 the first step in any process should be to investigate the problem to gain a thorough understanding of what is required. Therefore, sufficient planning is of vital importance. This sentiment is substantiated by the theory of Sections 3.4.5.2 & 3.4.5.3, since planning is also required for an effective database and implementation strategy. Consequently, the first stage in the framework is that of *Conceptualisation*, the idea of which is to devise a detailed plan for application of the framework. This is done by first determining the current state – understand what you have, to determine what you need. As mentioned in Section 3.4.5.1, this can be done by mapping the process, which also provides a visual aid for the identification of high-risk activities. Correspondingly, the next step would be to determine your "to-be" state. This encourages the involvement of management and provides a constant goal to avoid scope creep. The first stage can therefore be described as the planning required for effective application of the framework.

The *Categorisation* stage stems from the exploratory case study mentioned in Section 3.4.3. This stage entails planning for the following stages. It is meant to categorise the process under consideration into generic categories of which all AM processes comprise. This is done for various reasons. One is division of the workload between the different taskforce members, which also allows each member to focus on their field of expertise. Another is for the identification of the keywords required during the search for relevant standards. This form of grouping also allows for an improved method of storage in a database. As such, the second stage is important for successful application of each of the remaining stages.

The identification of standards can be approached in many different ways, as exhaustively discussed in Section 3.4.3. While the framework aims to guide the user rather than be prescriptive (see F1), this study also provides a methodology to aid the user in effectively searching for standards[4]. The methodology makes use of the technical committees of the SDO's to identify standards, thus proposing a structured approach to maximise the number of relevant standards captured. This method is also adapted to the three scenarios in which the framework can be applied, providing an example of how the identification of standards becomes easier through repeated application of the framework. The *Identification & Processing* stage also includes a review of the list of standards and keywords, thus ensuring an aspect of continuous improvement. Another such activity is the vision coherence check, confirming that the framework is being applied in adherence to the ultimate goal.

[4] It should be noted that any tool or methodology mentioned in this study is a description of a best practice, and as such, the user may choose to use it or a different method, as long as the outcomes are adhered to.

Finally, responsibility is allocated to taskforce members, thus mitigating the effects of institutional inertia mentioned in Section 3.4.5.3 by involving the workforce.

As mentioned in Section 3.4.5.2 the storage of standards, regulations and related documentation will be most effective if using a relational database, since such a database will allow any document to be linked with another. This allows ease when navigating between the various documents. In accordance with the theory mentioned in Section 3.4.5.2, the database should first be thoroughly planned. Phase one of the database development method proposed by Gunjal & Koganurmath (2003) was completed during the exploratory case study. In adherence with this method, an exhaustive description of the proposed database can be found in the following chapter. Corresponding to the second phase's methodology, the framework requires the user to compare the company's requirements with the proposed database and amend it accordingly. From this, the database should be thoroughly planned, developed and implemented into the company's systems[5]. To ensure continued effectiveness thereof, it is also required that a maintenance policy is put in place and that the database is rigorously tested. Finally, feedback mechanisms should be accommodated and considered to mitigate institutional inertia.

From the theory described in Section 3.4.5.3 it is evident that implementation of the standards is of critical importance for it to have an effect. As discussed in Section 3.4.3, this can be done through the development of SOP's. In accordance with the PIE framework, the first step is to meticulously plan the implementation strategy. While a tool is provided for this action, the planning can be done in any manner deemed fit. However, upon completion of the planning it must be evident which activities, standards or regulations require the development of SOP's and in what order. The development and integration of SOP's and standards must be overseen by those with the allocated responsibility, thereby avoiding institutional inertia. Another action aimed at mitigating the effects of institutional inertia is to train the workforce according to the new SOP's and standards, thus adhering to the PIE framework requirements.

Continuous improvement

From the theory mentioned in Section 3.4.5.4 the importance of continuous improvement is evident. The framework therefore incorporates an adaption of the PDCA model mentioned in Section 3.4.5.4 as depicted in Figure 3.11. As such, the framework constitutes three phases. The first is focussed on an initial system being put in place, encompassing the 'plan' and 'do' aspects.

[5] It is advised that the user outsource the development process to those with the relevant expertise. This study is not aimed at developing such a database, but rather describes the requirements thereof.

The second phase allows the user to learn from the knowledge accumulated during the first phase and revise the system accordingly i.e. check the work that has been done and act where required. Whilst both the first and second phases are to be repeated until each outcome specified for that phase is completed, the second phase should be iterated until the user deems the system to be sufficient. To ensure continued effectiveness, the framework includes a third phase. This phase entails maintaining the current system and updating it as is required, and as such is a continuous loop of the PDCA. This phase also functions as a check to determine if it is required that the framework be re-applied.

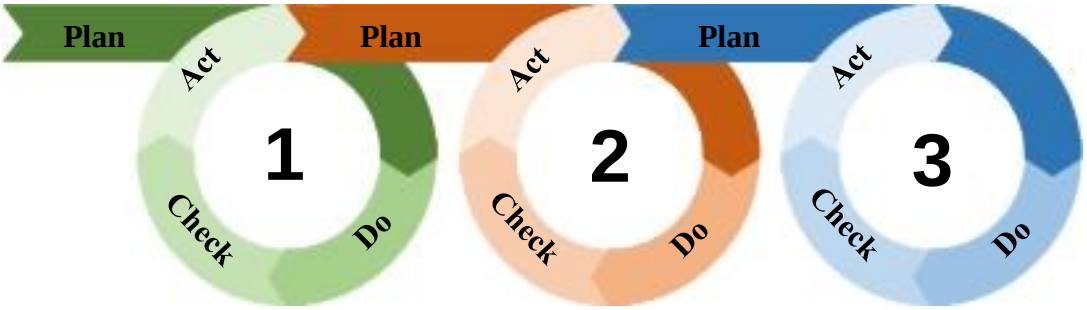


Figure 3.11 - Adapted PDCA model.

3.5. Summary

The aim of this chapter was to describe the methodology followed to develop the proposed framework, as well as the supporting literature. This was done by first defining a framework, to determine which type of framework would be best suited to this study. Subsequently, it was decided that the framework will be a conceptual-practical hybrid framework i.e. a conceptual framework largely developed from practitioner's knowledge. This was followed by an analysis of similar work that has been done to determine applicable gaps or usable tools.

The methodology implemented to develop the framework was assembled from the studies of van der Merwe (2017) and Pretorius (2017). The first step was to define the framework objectives, scope and assumptions. This was followed by the fields of concern, investigating why standards are important, as well as how one can identify, store and implement them. From this it was determined that standards can be used to gain knowledge or a competitive edge, for legal security, to stimulate the market or to encourage innovation. It was also found that the process of identifying standards is still largely unoptimized, unstandardized and therefore difficult to execute thoroughly. As such, the framework's requirements were specified to address this problem.

The problem was further deconstructed to reveal three additional concepts, of which the theory was investigated to determine how each concept can be re-organised and integrated into a problem solution, as discussed in Section 3.4.6. The following chapter describes this solution in detail.

Chapter 4

Framework Discussion

This chapter serves as a manual to the framework, explaining how each of the stages and phases work and how the user should apply the framework to gain the most from its use. Firstly, an overview of the framework phases and stages is given. This is followed by a mechanism to facilitate the process of making changes to the framework. Finally, the methodologies to aid in the identification and review of standards are described, followed by the tools developed to aid in the application process.

4.1. Framework Overview

The framework consists of five stages, as depicted in Figure 4.1 below. The framework can be used during implementation of a new product, or to update the standards regarding an already in-use product. However, the stages should always be implemented in successive steps, with the exception of continual improvement.

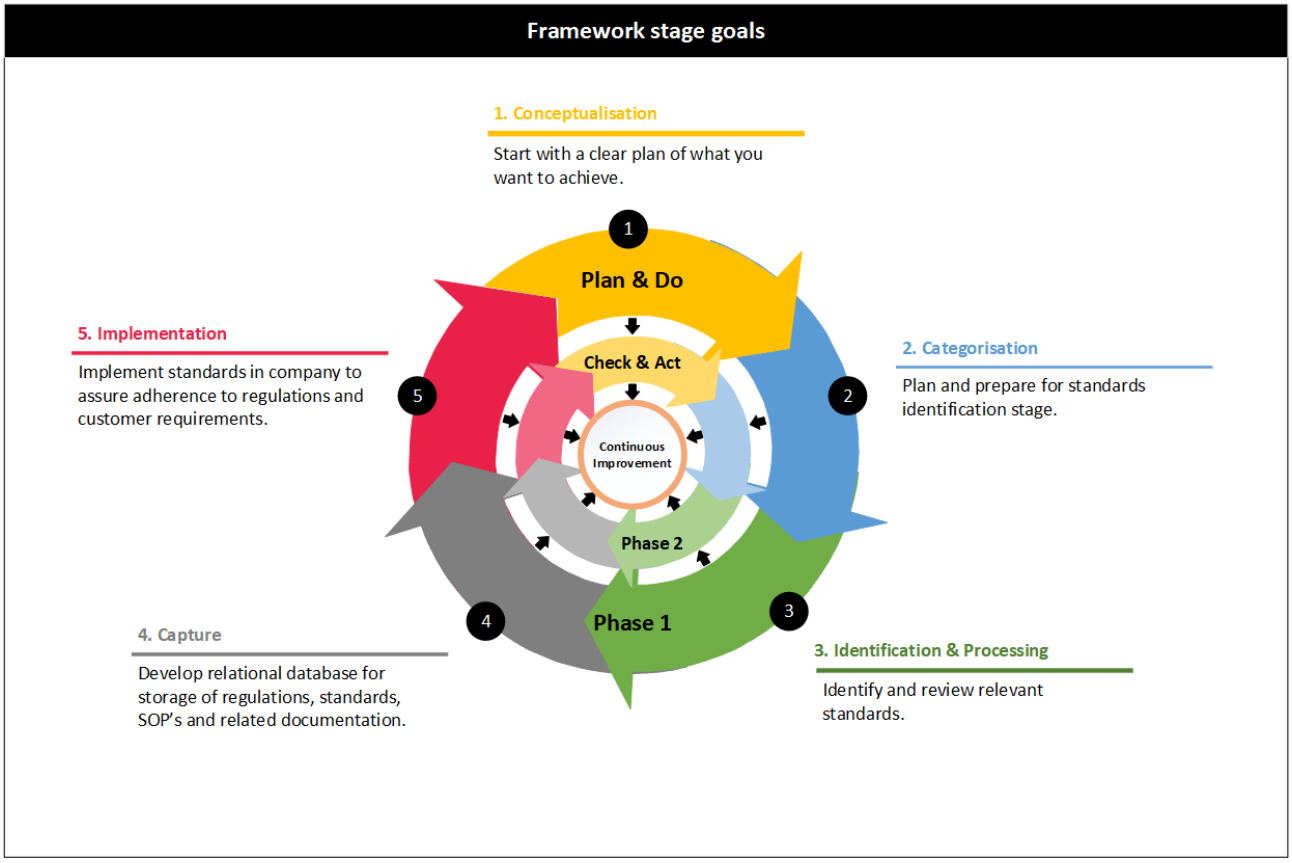


Figure 4.1 - Standards framework overview.

The framework is further divided into three phases, as described on the following page. These three phases were developed based on the PDCA model described in Chapter 3. In order to pass from one phase to the next, the outcomes stated in each stage must be addressed. For each phase, the stages must be completed in sequence, since a change in one will influence another. The exception to this rule is described in Stage 4. However, all stages end in continuous improvement. If during a stage it is determined that a previous stage requires change, the user should return to that stage and redo all succeeding stages in that phase.

It should be noted that the framework is not meant to automatically identify the standards for the user, but rather guide the user through the process to do so efficiently. Nor does the framework decide on each standard's applicability, since this is specific to each process and each organisation.

Phase 1

The outer ring constitutes Phase 1 of the framework. This is the planning phase. During this phase, the plan and do aspects of the PDCA are handled as to develop a 'light' version of the system. This phase is focused on the initial identification and implementation of all important aspects. Although this phase takes the most time to complete, it requires less iterations than the following phases.

Phase 2

The middle ring of the framework is referred to as Phase 2. This is when the check and act aspects of the PDCA are used to develop and implement a final version of the system. As such, the phase focuses on revision and improvement of the work done during Phase 1. During this phase the user should strive to be as specific as possible to avoid future misunderstanding. This phase can be iterated as many times as is deemed necessary to develop a system deemed sufficient by the user and that is implementable in the company.

Phase 3

The inside ring of the framework is that of continuous improvement, which is Phase 3. This phase can only be entered once a final version of the system is decided on and implemented. Phase 3 is focussed on maintenance of the system, to ensure continued effectiveness and improvement. During this phase, stages do not have to be handled in sequence. Each stage can be improved as and when deemed necessary by the maintenance plan. However, if during this phase a substantial problem is discovered which constitutes returning to Phase 2 for any stage, all stages must be relegated to Phase 2 and revised.

4.2. Admin Agent

Since it is rare that one person is knowledgeable in all of the categories related to an AM process, many people will have to work in conjunction for each step. Therefore, to avoid confusion and duplication of efforts, one person should be tasked with all admin related duties. These duties are further described in each of the stages. This person, referred to as the admin agent, is tasked with the minimum of this role, but is not limited to only performing these duties. The admin agent must also be present or included in all actions related to the framework.

4.3. Framework Taskforce

In order to ensure a coherent vision for the use of this framework, a taskforce should be compiled to handle the application thereof. The taskforce has two sections – one dealing with the technical details of the framework, the other tasked with managing application of the framework. Although it is not required that these be two different groups of people, the members should approach each task with the mindset required. These tasks will be discussed further in the stage descriptions.

The members of the taskforce should be documented by the admin agent. These members can change throughout use of the framework, but if that change results in a change of vision for the stated product or use of the framework, all previous steps should be reiterated. The managerial section of the taskforce should be compiled as the first task of this framework to ensure management's commitment in its application, with the technical section being added during Stage 2.

4.4. Stage 1: Conceptualisation

The first stage in the framework is that of conceptualisation. This is a key step in the use of the framework, since it will act as a guide for the following stages. Upon completion of this stage, the goal and objectives of the process should be defined. The user should also have defined the goal and objectives to be reached through use of the framework, which will guide the efforts during the following stages. In order to visualise the current state, the process being considered should be mapped. The level of detail or completeness of the process-map can be decided at the discretion of the user. However, it should be noted that a more detailed process-map will result in a wider range of standards being captured by the framework i.e. a higher level of accuracy. When considering the process activities, factors such as the following should be examined:

- What product will be developed, and in which market is it to be sold?
- Which processes, machines and other technologies will be used to manufacture the product?
- What raw material/s will be used for the manufacturing of this product?
- What customer requirements were stated and how will these be satisfied?
- To what level of quality should the product adhere to?
- Is the framework being employed to identify standards for an actual process or as research in preparation for future processes? Thus, how thorough should the search be?

The aim of this stage is to define all of the activities to be completed during the manufacturing process, thereby ensuring the identification of as many applicable standards as possible. When considering each activity, the associated personnel, machinery, materials, and all other resources should be included. Based on the process-mapping and customer requirements, the user should compile a list of requirements for the end product. Examples of such requirements include the customer requiring that the product is non-toxic, the manufacturer preferring the use of specific methods, or regulations stipulating certain tests be done. It is also during this stage that one person will be appointed as the admin agent. The admin agent should ensure that the process map is stored with an appropriate title and that the list of requirements is documented and stored for reference during the standards identification stage.

If an existing product or process is being reconsidered, all tasks in this stage should be revisited to ensure that the process vision and map is still relevant and accurate. Upon completion of this stage, the following outcomes should have been addressed.

Table 4.1 - Stage 1 outcomes.

Phase 1	
Admin agent	One person should be appointed to handle all admin related functions of the framework.
Current state analysis	Determine the company's current state to ascertain the full extent of the problem and what the required outcome is.
Process vision	The goals and objectives of the process should be stated to ensure a coherent and defined vision for use of the framework.
Framework vision	Based on the process vision, the goals and objectives to be achieved through use of the framework should also be stated to ensure that the framework is applied in accordance.
Process-chain mapping	The actions of the process-chain should be mapped to portray their specific interactions.
Requirement analysis	All relevant requirements to be met by the end product should be documented and stored.
Identification of high-risk activities	High-risk or important activities should be identified for use during the following stages.
Phase 2	
Update list of high-risk activities	Review the list of important activities and adapt if necessary.
Review	Review all other activities completed during Phase 1 of this stage to ensure they are still relevant.

4.5. Stage 2: Categorisation

The aim of this stage is to divide the process-actions into categories, thus compartmentalising the actions into knowledge fields/element families, thereby facilitating the identification and reviewing of standards by those with the related knowledge. These categories should be identified from the process-map. This study proposes that in all AM processes, seven generic categories exist, as described in Table 4.2.

However, these categories may be omitted or adapted at the discretion of the user. It should be noted that such actions will influence the effectiveness of Stage 3 and should be documented thoroughly to ensure traceability.

Table 4.2 - Description of AM process categories.

Category	Description
Field of use	In which technical field will the product be used, since some fields of use may require adherence to regulations for safe manufacture? e.g. Medical, Aerospace etc.
Design	Any technical aspect specifically related to the design of the product e.g. tolerances, STL format etc.
Process	Any aspects related to the manufacturing process, technologies used, and those related to raw materials whilst being used during the process.
Raw materials	All aspects related to the specific raw material before and after the process, including storage, characterisation, handling and disposal thereof.
Post-processing	Any action that must be done after manufacturing of the product to ensure adherence to requirements e.g. polishing, treatments, stress relief etc.
Testing	This category specifically refers to tests conducted on the part to ensure adherence to requirements. Examples include CT scans to test for defects, biological tests or density tests. Any tests done regarding the raw materials or calibration testing of the machines should form sub-categories of those respective categories.
Quality management	Any aspects related to admin or quality management systems, principles or actions.

The user/s should review the seven categories and omit those not necessary for the specific application of the framework. In this case, however, the changes should be documented thoroughly by the admin agent and stored with a succeeding title. It would be prudent to identify persons with knowledge in each of the categories to form part of the framework taskforce as head of a specific category/categories, thus enabling them to aid in the identification of key words or phrases that can be used during the standards identification stage. This is meant to guide the person searching for standards to focus on the specific aspects within each category that are important and should also refer to the product requirements identified in the previous stage. It should be noted that keywords relating to safety should be added to each of the categories, thus ensuring that safety standards are identified for each aspect of the process.

This does not refer to end-user safety, since that is covered in the “field of use” category, but rather safety of the personnel. The admin agent should document these keywords/phrases, as well as categories and save them appropriately for future reference or improvement.

If an existing system is being reconsidered, all tasks in this stage should be revisited to ensure that all aspects are still relevant and accurate. The following outcomes should be attended to during the stage.

Table 4.3 - Stage 2 outcomes.

Phase 1	
Categorisation	Dependant on the process map, the seven generic categories should be reviewed and adapted to aid in the standards identification and storage stages.
Technical taskforce	Technical members should be added to the taskforce to handle the identification of key words and phrases for each category.
Reviewers	The taskforce should identify at least one person with relevant knowledge for each category, to aid in revision during stage 3. These persons do not have to be part of the taskforce.
Keywords	Keywords or phrases should be identified for each category to aid in the identification of standards. It should be noted that these keywords must be used in combination and not apart, as to avoid the identification of irrelevant standards. Keywords regarding safety should be included wherever possible.
Phase 2	
Review	Review all activities completed during Phase 1 of this stage and adapt if necessary.

4.6. Stage 3: Identification & Processing

This stage is aimed at identifying as many standards relevant to the specified keywords/phrases within each category as is required or deemed satisfactory. Although the identification does not have to be completed by only one person, it is advised that only one person handles a category or sub-category, as to avoid duplication of efforts and unnecessary admin. The person/s handling the search should compile a list of all identified standards and send it to the admin agent for further processing. The ultimate aim of this stage is to populate a database with all standards relevant to your processes for personnel to use as reference, for R&D of new processes and for addition to quotes to boost customer confidence. This stage, or a variation thereof, should be completed with each iteration of the framework. The actions required in this stage can be done by using the tools provided in Section 4.10.

It should be noted that some international standards are reprinted by national SDO's, sometimes with a different code, but are inherently the same. Since duplication of standards will result in wasted space, it is advised that the user choose one of these standards to store and only reference the other standards as related. Thus, the knowledge is preserved without cluttering the database. The identified standards should be reviewed by the identified technical taskforce members according to the process vision and customer requirements, as well as the technical requirements of the category, and the list of standards should be modified accordingly. Factors to keep in mind include the following:

- Is the standard relevant to your category?
- Is the standard relevant to another category?
- Can this standard be implemented to improve the process?
- Were standards identified for all actions related to the category?
- Are there enough standards identified for each action?
- Are the standards identified better than developed SOP's in use by the company?
- Will the standard aid in accreditation?
- Will the standard boost international confidence?

The aim of this activity is to ensure that the standards identified are indeed relevant, and to determine in which areas standards are lacking. Upon completion of their duties, the reviewers are to provide the admin agent with the altered lists for compilation of the final list. At this time the following outcomes must have been considered.

Table 4.4 - Stage 3 outcomes.

Phase 1	
Regulation identification	The entire taskforce should compile a list of relevant regulations that must be adhered to. This can also be done in conjunction with an expert in the field. The regulatory requirements should be considered when reviewing standards and developing SOP's.
Identification: Categories	Standards should be identified for each of the categories.
Identification: Keywords	Standards should be identified for each of the keywords or phrases stated.
Categorisation	Standards should be divided into a list for each category by the admin agent. Each standard should only be grouped into the most relevant category.
Standards revision	All standards should be revised, and the list adapted accordingly.
Categorisation feedback	The reviewers should give feedback regarding the categories: are they too inclusive, should they include sub-categories, is one or more of the categories irrelevant?
Keywords feedback	The reviewers should give feedback regarding the effectiveness of the keywords: are they too concise, do they ensure sufficient capturing of standards etc?
Phase 2	
Review	Review all activities completed during Phase 1 of this stage and adapt if necessary.
Key standards identification	Standards that are deemed important to the success of the product, or is linked to key activities, should be identified.
Final list	The final list of standards should be compiled and stored appropriately by the admin agent.
Vision coherence check	Determine if the stated visions can be achieved through use of the identified standards.
Responsibility allocation	Responsibility and accountability over each standard and regulation should be assigned to a member of the taskforce.

4.7. Stage 4: Capturing

To ensure that the identified standards and regulations are readily available for use, a database should be used for the organised storage of these and related documents. Therefore, the aim of this stage is to develop a database architecture for the storage of identified standards and regulations, as well as developed SOP's and related documents, in a manner that ensures traceability and easy reference. As discussed in Section 3.4.5.2, it is proposed that a relational database be developed for this purpose. Such a database allows links between various tables containing different information, as shown in Figure 3.5, i.e. a regulation can be linked to a standard, SOP, document or all of these, and each is directly accessible. This allows the user to store all of the related documentation together, facilitating the navigation process. The idea is that the user can click on the link to a related document and see that document's interface, as shown in Figure 4.2 below. An Entity Relationship Diagram (ERD) depicting an example of the proposed database architecture, as well as an example of an interface can be viewed in Appendix C. Each standard should also be given a ranking according to the risk assessment, in order to differentiate key documents.

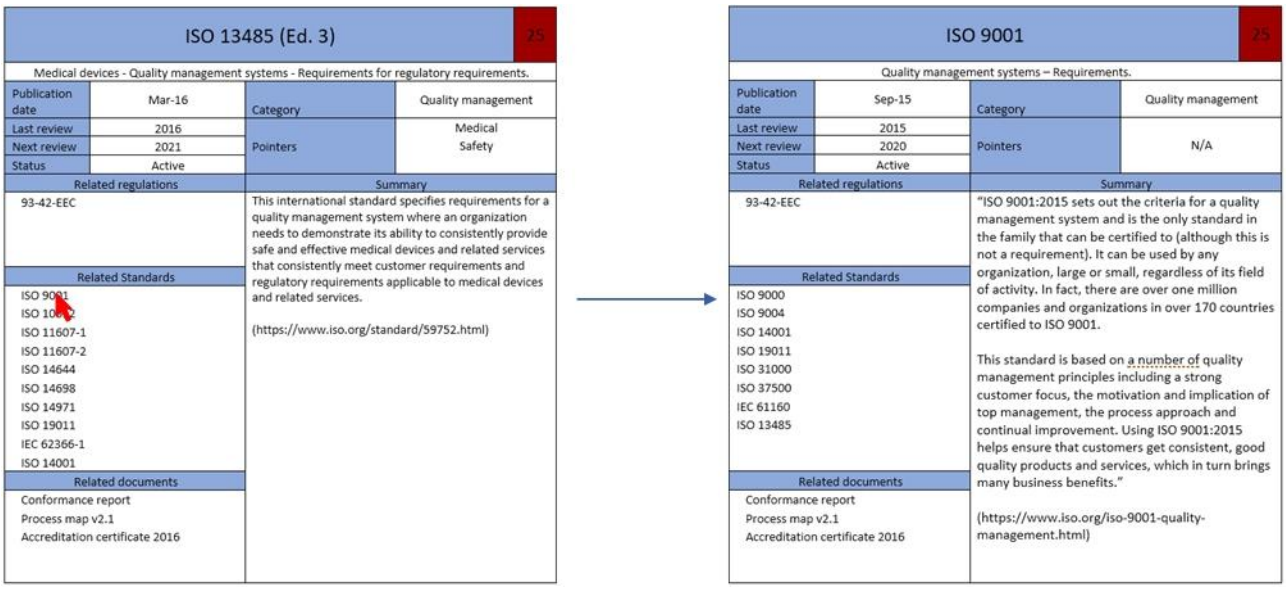


Figure 4.2 - Example of navigation between documents.

In order to facilitate the searching for standards during future uses of the database, it is proposed that the standards are categorised according to the categories described in Stage 2. As shown in Figure 4.2, each document should be assigned a relevant main category, as well as pointers to any other relevant categories. This allows the user to search through the database of standards according to various filters relating to the process under consideration, such as what material is being used or which technology will be employed. Dependent on the filters that are activated, a list of relevant standards, regulations and SOP's can then be compiled.

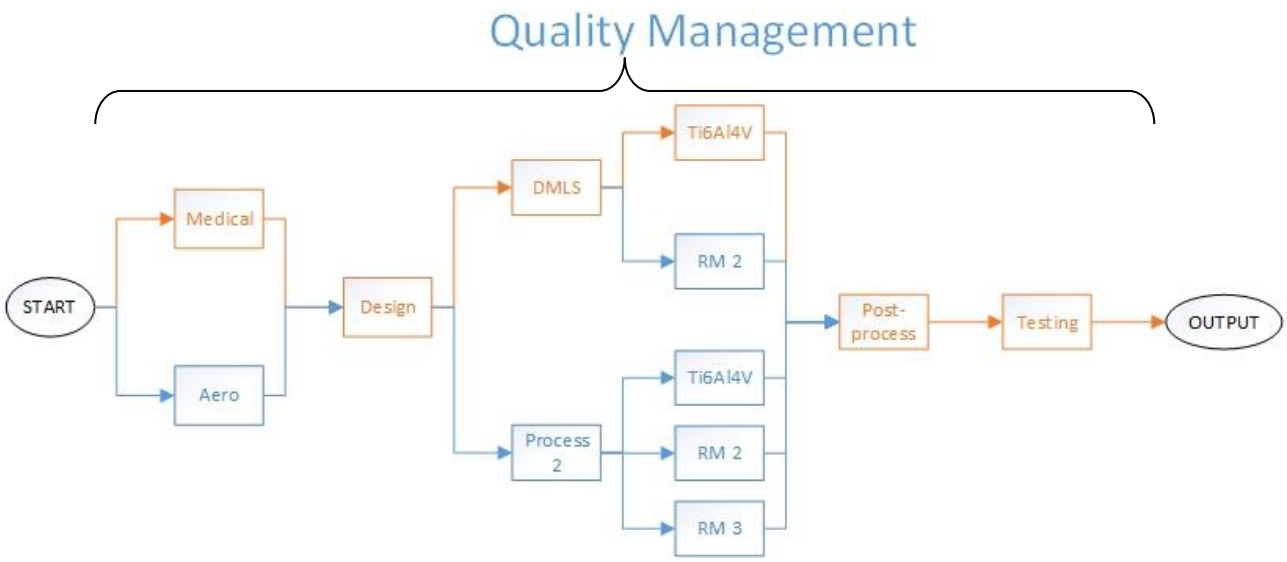


Figure 4.3 - Process of filtering standards according to categories.

The orange path in Figure 4.3 depicts how the documents in such a database would be filtered in accordance with the process considered during Case Study 1 (see Chapter 6). Since the management of quality is a constant in any process, any documents in the quality management category should be filtered according to the process being considered and included in the final list. This is also the case for documents in the design, post-processing and testing categories. An example of this filtering technique can be found in the SME database mentioned in Chapter 3. The database can also employ additional filters, such as only presenting documents above a certain ranking. The documents should also be linked to activities to which they are relevant, thus allowing easy reference.

Once the alpha version of the database has been developed, trial runs should be done to identify problem areas and bugs, after which the database should be improved. A maintenance policy should be developed for the database to ensure that it remains efficient, effective and up to date. Its usability should also be tested to ensure that it is an asset rather than a hurdle.

Stage 4 is the exception to the rule that all stages in a phase should be applied in succession, since the database will only be developed once and then remain in the continuous improvement phase for all further applications of the framework. As such, this stage should be used normally during the first application of the framework within a company, after which the stage can be applied only within Phase 3 for all additional applications. During this stage, the following outcomes should have been addressed:

Table 4.5 - Stage 4 outcomes.

Phase 1	
Plan database	The database should be planned thoroughly to ensure development of an effective database.
Interface development	An interface should be developed to aid personnel in navigating the database to the relevant documentation.
Standards-database-process mapping integration	The standards in the database should be linked to their respective process activities, assuring ease when searching for the relevant standards or documents.
Phase 2	
Review	Review all activities completed during Phase 1 of this stage and adapt if necessary.
Develop database	Development of a database fit for storage of all required standards and relevant documentation.
Maintenance policy	A maintenance policy should be developed to ensure that the database remains current and is improved according to staff and management recommendations. This should be done in conjunction with the database developer.
Trial runs	Trial runs should be completed to vet the database thoroughly, and changes should be made accordingly.
Usability testing	The database should be tested to ensure that it is effective in reality.
Information input	Information relating to the standards and regulations should be added to the database.

4.8. Stage 5: Implementation

In order for the identified standards and regulations to have an effect, they must be integrated into the business and process at all levels. The aim of this stage is to implement standards where necessary, and document which documents are relevant to which actions, in order to ultimately achieve the stated visions and adhere to all applicable regulation and customer requirements. As is the case with any widespread implementation into an existing business, this stage will require a lot of time and effort. In accordance with the PIE framework discussed in Chapter 3, it is proposed that the taskforce first plan the implementation phase, mapping where each standard will be implemented. Once the planning is done, the standards can be implemented to the key activities first, which are decided upon at the discretion of the user/s, followed by others when deemed prudent.

A person or persons with knowledge relevant to the applicable category must be appointed the responsibility of overseeing the implementation of a standard or group of standards. This entails ensuring implementation of its methods, maintaining the relevant documentation in the database and managing the development/integration of SOP's. During this implementation process, the following should be considered:

- Does the activity require guidance?
- Is this a key activity?
- What other documentation is required for this activity?
- How can this standard or SOP be used to improve the activity?
- What resources are required for the implementation of this standard or SOP?
- Will the use of this standard ensure alignment with the stated process vision?
- Will the use of these standards and SOP's ensure compliance with regulations and customer requirements?

Table 4.6 - Stage 5 outcomes.

Phase 1	
Implementation planning	Link standards and regulations to activities in process map, starting with key activities and advancing as required.
SOP development	Where standards are missing or deemed sub-par, SOP's should be developed and added to the database. These SOP's should be developed from the standards to ensure integration of standards to the process.
Standards implementation	All identified standards should be incorporated into the process to a degree specified by the user, starting with key standards and activities.
Identify training	Identify necessary training of employees required for the standards to be implemented.
Phase 2	
Review	Review all activities completed during Phase 1 of this stage and adapt if necessary.
Workforce training	Relevant personnel should be trained regarding use of the database and implementation of the standards and SOP's.
Revise SOP's	Revise developed SOP's to ensure that they adhere to standard and regulation requirements. Also ensure that they are being implemented.
Database implementation	The database should be made available to all relevant personnel for reference.

4.9. Continuous Improvement

The final phase of the framework is that of continual improvement. This is to ensure that the standards, regulations, process maps, SOP's and database stays updated and relevant. This phase is only reached once a working system is in place and all required outcomes have been met. Phase 3 is focused on maintaining the effectiveness of that system.

As is the case with any maintenance, improvements are preferred in small and regular increments. As such, a framework improvement/maintenance plan can be developed, planning the various stages of continual improvement and frequency of these actions. This phase is, in essence, a continual loop of the check and act actions of the PDCA. Whilst this phase is primarily intended as continual maintenance of the existing and set system, if the user encounters a problem deemed important enough to require it, Phase 2 should be reiterated since the reiteration of one stage will influence all succeeding stages. Such problems or changes include the hiring of new technical staff tasked with integral technologies, implementation of new technologies or changing of the process vision. Examples of possible maintenance activities include, but are not limited to, the following:

Table 4.7 - Examples of maintenance activities.

Stage 1	
Update process-chain	The process chain should be revised periodically and updated if required.
Update product vision	The product vision should be revised to ensure that the stated vision is still valid.
Update list of requirements	The list of customer, manufacturer and regulation requirements should be revised to ensure that it is up to date.
Appoint admin agent	Someone must be appointed admin agent at all times.
Stage 2	
Update key words/phrases	The key words/phrases should be revised to ensure that they are still sufficient for achieving the stated visions.
Appoint head of category	At least one task force member must always be appointed as head of one or more categories. Each category must have a head appointed to it at all times.

Stage 3	
Update standards	Standards are revised every five years. As such, each standard being used must be revised by the user once the new version is released to determine if the old standard is still sufficient or if the new standard contains changes relevant to improving the process.
Update regulations	Regulations are updated less frequently than standards. However, periodical checks should be done to determine if regulations were amended or if new regulations were published. If this is the case, the user should ensure that all SOP's are aligned with adherence to said regulation.
Revise process-map i.t.o. standards	Revise process-map to ensure that all key activities have standards identified and linked to them.
Revise SOP's	Revise SOP's whenever a new standard or regulation has been identified. Ensure that changed SOP's still adhere to applicable standards and regulations.
Stage 4	
Database maintenance	Regular maintenance will ensure that the database runs smoothly. These actions should be discussed with the database developer.
Update information	Information regarding standards, regulations, SOP's and related documents should be updated with each application of the framework, or when deemed necessary.
Database improvement	The comments made regarding the database should be revised periodically, and the database should be improved in the required areas.
Stage 5	
Database commenting	Comment on required changes to the database when encountered.
Assign responsibility	Ensure that each standard and regulation is assigned a person who is accountable for the implementation and maintenance thereof.
Update documentation	Update standard, regulation and SOP documents and information regularly.

4.10. Making changes to the framework

This framework was developed as a guide for manufacturers using an emergent technology to identify and implement standards and regulations relevant to their process. As such, it is aimed at guiding the user through the process, and not meant to be a rule. The user may alter the framework to fit their process and intended use. However, while the users may decide to what extent the framework is applied, they must still adhere to each of the specified outcomes. The application depth should be documented thoroughly by the admin agent and stored with an appropriate title. Any changes or deviations should also be accompanied by an explanation of why the change was made, and why it would have a better effect. It should be noted that changes made to the framework will influence successive stages, and as such it is not recommended.

4.11. Methodologies

4.11.1. Identification of Standards

During the identification of standards activity of Stage 3, three cases are considered:

- Updating the list of standards related to a product to which the framework has already been applied (Methodology A).
- Identifying standards for a product similar to another to which the framework has already been applied (Methodology B).
- Identifying the standards for a product unlike any other manufactured by the company to which the framework has been applied (Methodology C).

For each case, a different methodology is applicable. Before using any of these tools, the user should define the goal to be reached through its use. For example, should only national standards be considered? Or only ISO and ASTM standards are of importance. This is an important step, since it dictates to what scale standards will be identified. If the user starts off with a large base, the exponential effect of the successive steps will ensure a larger end result. This part of the framework can be executed by any person with knowledge of the process.

Methodology A: Updating method

1. Revise the process-map and determine important activities for which sufficient standards have not been identified and document these.
2. Revise the standards as divided into their categories and determine which categories are lacking a sufficient amount of standards. Document these categories.

3. Revise the list of requirements and identify requirements for which sufficient standards have not been identified. Document these requirements.
4. Focusing on these activities, categories and requirements, follow the steps of methodology C to identify additional technical committees and their standards.

Methodology B: Analogy method

1. Consider the final list of standards of the analogous product and determine applicable standards.
2. Divide standards according to categories.
3. Consider key standards of analogous product and determine if they are applicable. If so, add to list as such.
4. If the number of standards is found to be sufficient, review the completeness of the list by using methodology A. Otherwise, determine problem areas and continue using methodology C whilst focusing on the problem areas.

Methodology C: New product identification method

1. Search for any applicable international, national and/or regional standardising bodies or authorities.
2. For each of the identified bodies/authorities, search through the various affiliated committees (normally referred to as technical committees) and identify those relevant to your process.
3. For each of these committees that has been identified, search through their list of standards and identify relevant standards from the standard's title using the combined keywords and process vision.
4. Compile a list of standards deemed relevant thus far.
    a. The list must at least include the standard's designation (including standardising body and number, version date and the title).
5. Scan through the abstract of these standards on the SDO's website to determine if they are indeed relevant. Remove irrelevant standards from the list.
6. Have the category heads review the provisional list of standards and adapt it as is required.
7. Acquire those standards remaining on the list from the relevant authorities.
8. Work through the standard to ensure relevance to the process. If deemed irrelevant, save in the database for future reference.
9. For every standard still deemed relevant, scan through the bibliography for more relevant standards, dependant only on their title.
10. Repeat steps 5 through 9 iteratively until no new standards are identified or enough have been identified for thorough standardisation of the process.

4.11.2. Revision of Standards

The list of standards applicable to each category of the process-chain must be sent to the taskforce members identified for each category for revision. The stated framework, product and methodology visions should also be communicated to the reviewers. These persons can then use the following steps to eliminate irrelevant standards:

1. Scan through the list of standards and divide it into the following sections, dependent only on the title and abstract:
    a. Relevant – containing all standards relevant to the process.
    b. Uncertain – containing standards which may be relevant, but require further inspection.
    c. Irrelevant – containing standards that are blatantly irrelevant to the process.
    d. Future reference – containing standards that are irrelevant to the current process being considered, but may be relevant to another process or future endeavours.
    e. Switch – containing any standards that may be more relevant to another category.
2. Work through any standards in the 'Uncertain' section and sort those into any of the four remaining sections.
3. Return the list to the admin agent, who will exchange standards added to the "Switch" section.
4. If another reviewer has added standards to your list through the "Switch" section, the revised list will be sent to you. Read through the "Switch" section and sort those into the relevant sections on your list.
5. Repeat steps 3 and 4 iteratively until no more "Switch" lists are received.
6. Return the final list to the admin agent for final processing.

4.12. Tools

4.12.1. Implementation Planning Tool

From the first case study (see Chapter 6) it was determined that a tool should be developed to aid with planning the implementation activities of Stage 5. Consequently, the tool shown in Table 4.8 was developed to plan the implementation of standards and regulations according to the outcomes specified in the framework. As such, the tool allows the user to link the standards and regulations to the process activities and subsequently the process map. It also allows the user to specify whether the activity requires regulations and/or standards, whether it is a high risk activity, which specific standards and regulations are applicable to each of the processes, whether SOP's have to be developed and in which order the standards should be implemented. It should be noted that the implementation planning of standards through SOP's is shown to consist of three rounds, but can be implemented in more or less rounds as well.

Table 4.8 - Implementation planning tool.

A	B	C	D	E	F	G	H	I
Act #	Activity	Requires regulations	Requires standard	High risk act.	Related regulations	Related standards	Existing SOP	Implementation order
1	Design baby bottle and nozzle.		YES			ASTM WK54856: Principles of design rules.	Y	Round 2
2	Handle raw materials.		MAYBE				Y	Round 3
3	Preparation of AM machine.		NO	X		SOP	Y	Round 2
4	Manufacture baby bottle and nozzle.	X	YES	X	FDA Reg01: Safety of toys.		Y	Round 1
5	Destructive and non-destructive testing.		YES				N	Round 1
6	Quality checks.	X	YES	X			N	Round 1
7	Package and ship parts to customer.		NO			SOP	N	Round 3
	Customer and company requirements							
1	Product must be non-toxic.	X	YES	X	FDA Reg01: Safety of toys.	ISO TR 8124: Safety of toys.	N	Round 1
2	Product must be free of internal and external defects.		YES	X		ISO 9001: Quality management	Y	Round 2
3	Product must conform to relevant quality standard.	X	YES	X		ISO 9001: Quality management	N	Round 1
4	Product must adhere to relevant regulations.	X	YES	X	FDA Reg01: Safety of toys.	ISO TR 8124: Safety of toys; ISO 7001: Nursry or baby care.	N	Round 1
5	Product must have no choking hazards.	X	YES	X	FDA Reg01: Saftety of toys.	ISO TR 8124: Safety of toys.	N	Round 1

4.12.2. Checklist Tool

Based on difficulties experienced during the first case study and expert feedback during the validation phase of this study, a checklist was developed to aid users in determining criteria to gauge whether they have adhered to the specified outcomes, as shown below. The complete set of checklists can be found in Appendix B. These should be used together with the rest of Chapter 4, and as such, each stage is colour coded to its corresponding framework section, as is depicted in Figure 4.4 and 4.5.

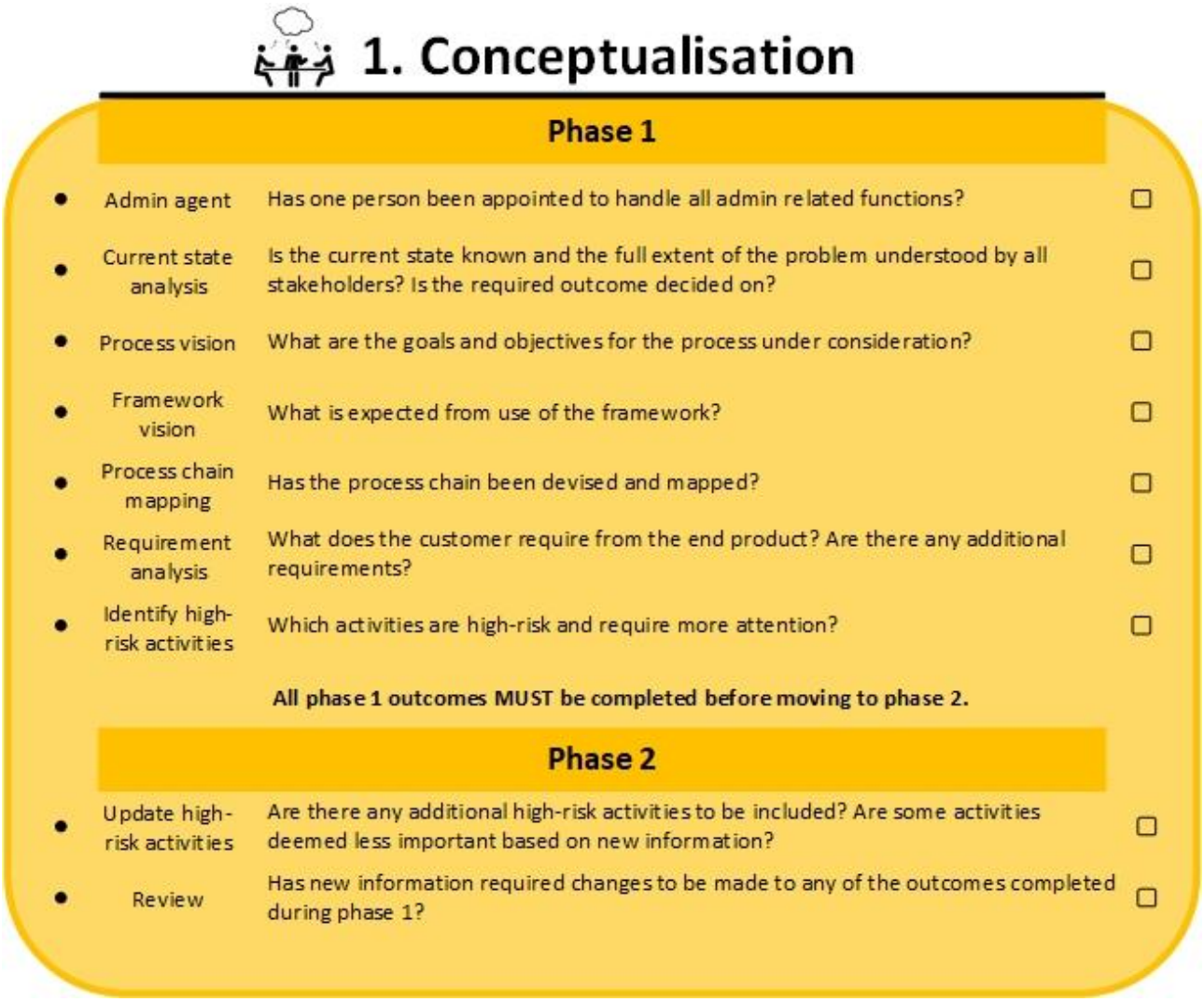


Figure 4.4 - Stage 1 checklist.

The user should ensure that the specified criteria are achieved, after which the activity can be checked off. It should be noted that Phase 1 of each stage should be completed before the criteria of Phase 2 are considered.

4.13. Summary

This chapter served as a description of the framework and how it should be used. The framework can be used by organisations during the inception of a new product, or to update the standards regarding products which are already in use. The framework consists of three phases based on the PDCA model discussed in Chapter 3. Phase 1 constitutes the planning phase during which an initial version of the system is put in place. Phase 2 is when the work done during Phase 1 is audited and changed accordingly. Phase 3 is the final phase and implements the continuous improvement process.

The framework consists of five stages, executed sequentially during each phase. Stage 1 is the *Conceptualisation* stage during which essential planning is done to ensure a coherent vision for application of the framework. Stage 2 is the *Categorisation* stage, used to compartmentalise the information to ensure that it is referred to the correct taskforce member, and to prepare for the following stages. Stage 3 is the *Identification & Processing* stage aimed at identifying relevant and helpful standards. Stage 4 is the *Capturing* stage during which a relational database is developed for the interactive storing of the standards and all related documentation. Stage 5 is the *Implementation* stage, aimed at implementing the standards and related regulations by means of SOP development. While the user is free to implement any method they prefer, methodologies for the identification and revision of standards are provided, as well as tools to aid in the application process. However, each of the stage outcomes must be adhered to before moving to the following stage.

The complete framework depicting each of the stages and their outcomes can be found on the following page.

The remaining chapters describe the methods employed to verify that the developed framework adheres to the requirements stated in Chapter 3, as well as the validation of the framework and study.

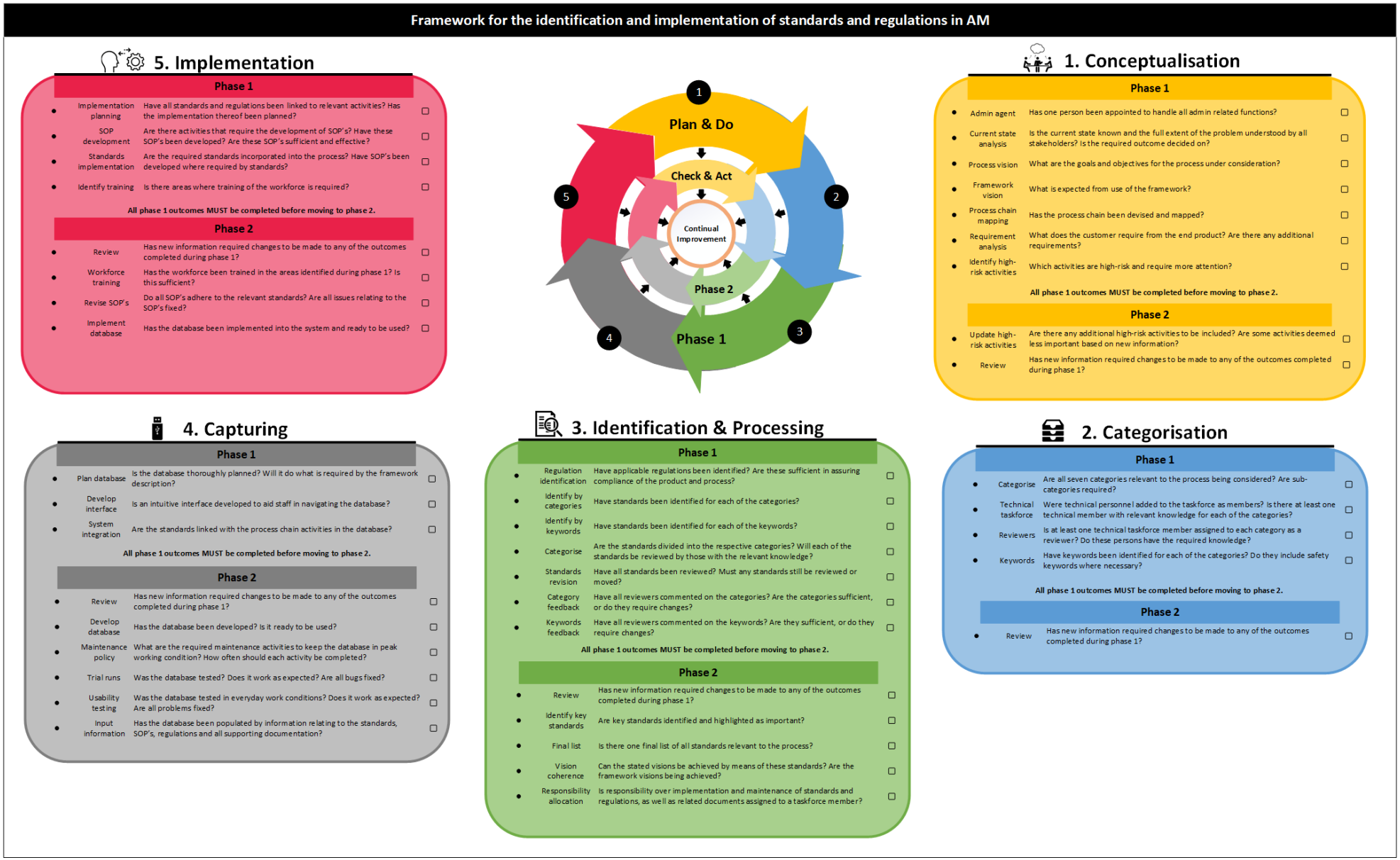


Figure 4.5 - Complete standards framework.

Chapter 5

Research Verification

Both verification and validation are closely related solution evaluation methods, with each addressing a different aspect of the evaluation process (Henning, 2017). Verification refers to whether the solution has been developed correctly according to the specified requirements. As such, verification of the framework will ascertain whether the solution is of sufficient quality, but not ensure that it addresses the problem being considered (Srai, Alinaghian & Kirkwood, 2013). This is investigated in Chapter 6.

Therefore, the framework will be verified according to the requirements specified in Chapter 3 to determine if the resulting framework adheres to said requirements. This can be seen in the following tables, where each design requirement is linked with a section of the study, followed by a description regarding how the requirement is fulfilled.

Table 5.1 - Verification of functional requirements.

Ref	Requirement	Related section/s	Description	
F1	The framework should guide the user through the process, rather than be prescribing.	3. Framework development 4. Framework discussion 4.13 Summary	The framework only specifies the outcomes to be achieved, thus guiding the user to the objective without specifying how to complete the activities.	✓
F2	Proper use of the framework should lead to traceability and accountability.	3.4.5.3 Implementation 4.2 Admin agent	The framework requires thorough documentation of all activities to be done and responsibility to be allocated.	✓
F3	Use of the framework should assist the user in identification of relevant standards.	4.6 Identification & Processing 6.1.2 Case Study 1	The framework aids the user in the identification of relevant standards.	✓
F4	The framework should include or recommend tools to assist with the application thereof.	4.11 Methodologies 4.12 Tools	Tools and methodologies are provided with the framework to aid in the application thereof.	✓
F5	All activities mentioned should be integral to successful application of the framework i.e. no unnecessary activities.	4. Framework discussion 6.1.2.9 Case Study 1 results 6.1.3 Expert interviews	The framework was developed to be as concise as possible. Any remaining unnecessary outcomes were removed after Case Study 1 and the expert interviews.	✓
F6	The framework should be applicable to various products within the specified scope.	3.4.2 Framework scope 6.1.2 Case Study 1 6.1.4 Case Study 2	The framework is currently confined to medical applications of Ti6Al4V, since it has not been tested in other applications. However, it can be used for various products in this field.	✓
F7	The framework should enable learning through experience by means of continual improvement.	4. Framework discussion 4.9 Continuous improvement 6.1.4 Case Study 2	The framework uses continuous improvement to improve its efficiency, since each application thereof can be based on the previous application's outcomes.	✓
F8	The framework should facilitate the implementation of standards and regulations.	4.8 Implementation 4.12.1 Implementation tool	The last stage facilitates the implementation of standards and regulations through the development of SOP's.	✓
F9	The framework should facilitate creation and/or evaluation of the processes to be considered.	4.4 Conceptualisation	The first stage of the framework requires activities that facilitate process creation, such as process chain mapping. These activities are also aimed at evaluating the process.	✓
F10	The framework should aid users in designing and implementing a storage mechanism.	3.4.5.2 Database theory 4.7 Capturing	The framework sufficiently aids users in designing and implementing such a mechanism in the form of a database.	✓

Table 5.2 - Verification of user requirements.

Ref	Requirement	Related section	Description	
U1	The framework should be user-friendly i.e. easy to understand, adopt and implement.	6.1.3 Expert interviews Appendix D	From the expert reviews, it is apparent that the framework is extremely user-friendly and effective.	✓
U2	The framework should allow repeated and continuous use.	3.4.5.4 & 4.9 Continuous improvement 6.1 External validation	The continuous improvement aspect allows the framework to be used many times, and become more efficient with each iteration.	✓
U3	The framework should be clear in its requirements and explanations.	4. Framework discussion	Each outcome is concise, yet descriptive. The outcomes are also explained thoroughly.	✓
U4	The framework should not only provide new information, but also use existing information.	3. Framework development 3.4.5.4 Continual improvement 6.1 External validation	The PDCA model is incorporated into the framework to ensure continual improvement. As is evident in the case studies, existing information is used and improved upon.	✓
U5	The framework should allow changes to be made and facilitate those through specific procedures.	3.4.5.3 Implementation theory 4.10 Making changes	The user may use their experience to make changes, as described in Section 4.10.	✓
U6	The framework should allow customer input and define actions for the processing thereof.	3.4.5.3 Implementation theory 3.4.5.2 Database theory 4.10 Making changes	The user may execute the actions in the manner they prefer, as long as all outcomes are adhered to.	✓
U7	The framework should require minimal resources.	4. Framework discussion	The framework can be applied by one person if required, as long as that person is knowledgeable in all of the categories.	✓
U8	The framework should be applicable to many products.	3.4.2 Framework scope 6.1.2 Case Study 1 6.1.4 Case Study 2	Refer to F6.	✓

Table 5.3 - Verification of boundary conditions.

Ref	Requirement	Related section	Description	
B1	The framework must protect the user's IP.	4. Framework discussion 4.6 Capturing	The framework does not require any IP to be shared without consent. The database also requires safety features to avoid security issues.	✓
B2	The framework must ensure a high regard of customer requirements.	4.4 Conceptualisation 4.5 Categorisation 4.8 Implementation	The framework includes an analysis of the customer requirements, which is also utilised to determine keywords. The requirements are also highlighted during the implementation activities.	✓
B3	Use of the framework must adhere to legal and ethical requirements.	4. Framework discussion	No parts of the framework cross legal or ethical boundaries.	✓
B4	Use of the framework must provide value to all parties involved.	3. Framework development 4. Framework discussion	The framework is developed such that it benefits the user, the customer and employees.	✓

Table 5.4 - Verification of attention points.

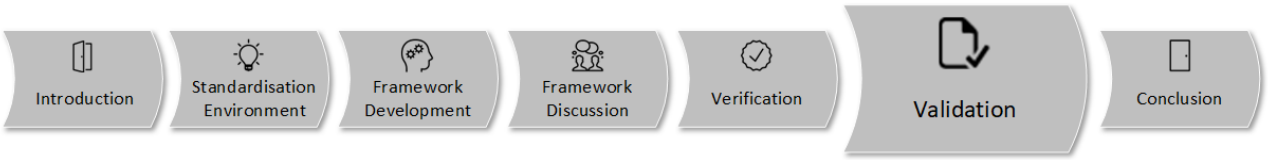
Ref	Requirement	Related section	Description	
A1	The framework can be used to the extent a company requires.	3. Framework development 4. Framework discussion	The framework is developed such that the user can decide to what extent the framework is applied.	✓
A2	Since AM is an emerging technology and limited theory is available, this framework should be seen only as a reflection of early best practice within an evolving field of knowledge.	3. Framework development 3.4.3 Fields of concern	The framework, its tools and methodologies were developed from practitioner's knowledge and practical applications to case studies. As such, it is a reflection of early best practices within the field.	✓

Table 5.5 - Verification of restrictions.

Ref	Requirement	Related section	Description	
R1	The framework must only focus on standards and regulations applicable to AM.	2.4 The state of AM standards 3.4.2 Framework scope 4.1 Framework overview	The framework is focused on application within the field of AM.	✓
R2	The framework must be developed for medical applications, but should be adaptable for other applications.	3.4.2 Framework scope 7.3 Future work	The framework is developed in conjunction with CRPM and only tested on medical products. However, it can easily be adapted to other products in the future.	✓
R3	Use of the framework will not result in accreditation, but it can be used as a tool during the accreditation process.	3.3.1 Lloyd's register	The framework is not aimed at ensuring accreditation, as is the case with Lloyd's register, but can be used as a tool during such activities.	✓
R4	Use of the framework should not guarantee an improvement in quality, but it should help the user in attaining quality products.	4.1 Framework overview	Use of the framework does not guarantee an improvement to the user's process, but rather provides the tools to enable it.	✓
R5	The number of tools and methods included should be limited to that which is imperative.	4.11 Methodologies 4.12 Tools 6.1.2.9 Case Study 1 results	Only the tools and methodologies deemed necessary were added.	✓

Chapter 6

Research Validation



Validity considers the integrity of conclusions made from research and ensures that the results thereof are truly addressing the investigated concept and yields the correct answers (Kriege, 2015). As such, validation is the process of assessing whether the developed framework addresses the identified problem. The two main forms of validity is internal and external validity (Kothari, 2004). External validity is focused on the extent to which the research project is relevant to a larger population i.e. to what extent can it be generalised. Internal validity in this context refers to whether the research objectives were achieved, and serves as a form of internal auditing of the study.

Since it is important to test both forms of validity, each aspect of the validation process is described in detail. Firstly, the external validation methodology is discussed, followed by a description of two case studies and expert interviews. Thereafter, the internal validation is done to ensure that the research objectives were adhered to. Finally, conclusions are drawn from these validation efforts and interpreted.

6.1. External Validation

The purpose of this section is to investigate the following research questions:

- Is there a recognised business need for the developed framework?
- Does the framework address this need?
- Is the framework effective in attaining its goal?

According to van der Merwe (2017), there are four methods of external validation commonly utilised by researchers. The first is to validate the framework through implementation. The advantages are obvious, and this would irrefutably confirm or deny the work done. However, whilst this does allow a real-world test of the framework's applicability and effectiveness, implementation of the framework requires time, resources and repetition across different factors and environments. Full-scale implementation of the framework is expected to take months of working with company stakeholders, which is an unrealistic expectation. Time constraints related to this study also makes this an infeasible task. Furthermore, due to the proprietary nature of the work being done in the AM field, and the high levels of competition, companies are reluctant to provide access to the confidential information required. As such, this method is not feasible at this time, but should be conducted in the future by those with the relevant means.

The second method is that of conducting a case study. The application of the framework to an appropriate case study allows insight into the real-world applicability and the effectiveness thereof in obtaining its goal. However, case studies can easily be manipulated due to hindsight bias (van der Merwe, 2017) and are specific to the environment or field being considered. In the context of this study the risks associated with case studies are acceptable, since the framework was developed in conjunction with one specific industry of AM. Therefore, the real-world applicability of the framework must first be proved within the medical field before it can be expanded into related regulatory fields.

Another method of validation also deemed suitable to this study is the use of interviews with industry experts, during which they refute or confirm the claims made during this study. According to Mouton (2008) there are four main interviewing types:

1. Structured, self-administered questionnaires
2. Structured telephone interviewing
3. Semi-structured focus-group interviewing
4. Free attitude interviewing

In order to determine the feasibility and usability of this framework, semi-structured interviews were required to gather expert opinions on a few open-ended questions, whilst allowing the experts to raise any problems they foresee, thus drawing from their expertise. However, since AM is an emerging technology, few experts exist to the point that they can provide valuable feedback regarding the management of an AM manufacturing facility producing products for a regulated purpose. As such, the sample size will be small, but contain our country's leaders in the field of AM.

The fourth and final validation method is that of survey analyses. This is a quantitative validation approach that allows the framework's components to be deemed feasible, useful and effective in achieving its goals. However, such a survey would ideally be predicated on a framework whose validity has been determined, as to avoid wasting time with irrelevant components being considered. The field being considered also has a limited number of experts to consult. Therefore, the population could be too little to make justified conclusions from. As such, while survey analyses may not be the best method of validation at the time, it is suggested as a future step.

6.1.1. External Validation Design

The aim of this study is to solve an identified problem through use of the framework. As such, the framework is a solution concept. According to Brockmöller (2008) heuristic solution concepts cannot be justified conclusively. Therefore, it must be justified by means of *pragmatic validity*, which means that the framework is tested in its intended context to produce sufficient supporting evidence (van Aken, 2004). Furthermore, within the testing of design knowledge, there is a distinct difference between alpha and beta testing. While they may serve the same purpose, they are employed at different stages of the research. Alpha testing takes place during the development phase and entails testing of the concept by the researchers themselves. Alternatively, beta testing is when the concept is tested by third parties, thereby obtaining objective evidence. While both alpha and beta testing offers insight into the consequences and possible scope of its application (van Aken, 2004)(Stam, 2007), beta testing rules out investigator bias (Yin, 2003) and knowledge transfer from the researcher to the users i.e. is it the framework itself or the combination of knowledge and experience that allows the framework to succeed (Stam, 2007)? Since the framework is still in the development phase, alpha testing was employed in the form of case studies and semi-structured interviews. To prove pragmatic validity, the case studies focused on application of the framework within the medical AM field. While the interviews were conducted with many AM industry experts, some of them were also active in the medical AM field. As such, the pragmatic validity of the framework was thoroughly tested. Once the development phase has been concluded, beta testing should be conducted in the form of full-scale implementation and survey analyses to ensure continuous improvement of the framework.

6.1.2. Case Study 1

The first case study considers the scenario where a company is manufacturing medical implants by means of AM technologies. Since this process is already established and the implants are readily being manufactured, the case study is a retrospective case study aimed at demonstrating how use of the developed framework will improve the process through identifying additional applicable and usable standards. It also serves as an example of how to implement the framework in an existing process. While the implants are currently being manufactured for South-African patients, the ultimate aim is to become internationally commercially viable. As such, the framework is used to identify standards that will lead to large scale standardisation of many aspects of the process and accreditation to internationally recognised quality standards. Therefore, the case study will investigate the following questions regarding the framework:

- Is the framework usable in reality?
- What are the short-comings?
- Is the order of the stages logical and realistic?
- Does use of the framework result in the identification of more standards that are relevant?
- Is use of the framework beneficial to manufacturing companies?
- Does the framework achieve its objectives?
- Is the framework applicable to products that are already being manufactured?

6.1.2.1. Background

The Centre for Rapid Prototyping and Manufacturing (CRPM) forms part of The Central University of Technology (CUT) in Bloemfontein, South Africa. Established in 1997 as a centre for commercial work and research, they specialise in the development of new products using AM and Medical Product Development technologies (Booysen, 2017).

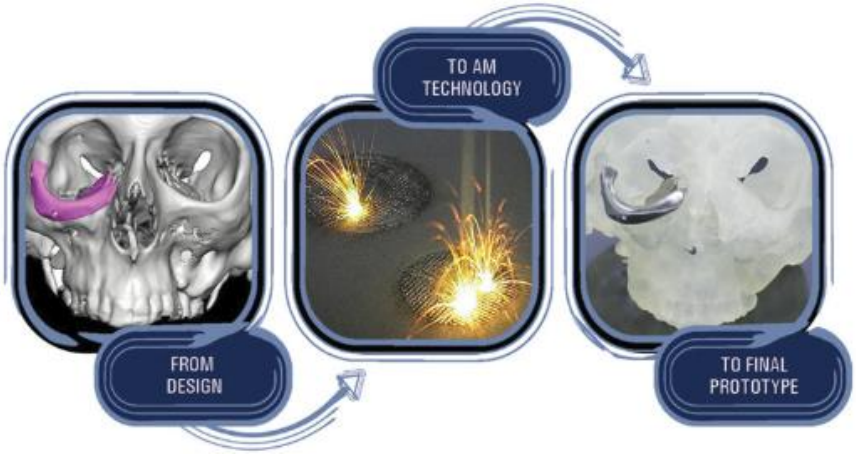


Figure 6.1 - Medical implant manufacturing process (Booysen, 2017).

The technologies employed allow the CRPM to use Computer-Aided Designs (CAD) to accurately manufacture complex implants, as illustrated in Figure 6.1. One such implant is the maxillofacial implant, which is a customised implant specially designed for patients who have lost a significant part of their facial bone structure due to diseases such as cancer. The implant is manufactured from titanium powder (Ti6Al4V) using the Direct Metal Laser Sintering (DMLS) process. Since each implant is customised according to a specific patient's bone structure, a polymer pre-operative model is printed from the Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scans to allow collaboration between the surgeon and the CRPM during the design process. Once the part has been printed, it can also be fitted to the pre-operative model to ensure that it fits correctly, as is apparent in Figure 6.2.

Figure 6.2 - Maxillofacial implant fitted to pre-operative model (Bezuidenhout, 2017).

Since the maxillofacial implants are centred around the patient, it must comply to all customer requirements. Risk factors that the CRPM had to consider includes the biocompatibility of the raw material, failure of the implant and wear of the implant and the remaining bone. Furthermore, any medical implant manufactured for surgeons or hospitals must adhere to certain regulations, be it FDA, CEN or SAHPRA. A medical implant is any structure that replaces a missing part of the body, and can be made from a large variety of raw materials. In most cases, such as the maxillofacial implant, this involves surgery which may lead to infection or death (U.S. Food & Drug Administration (FDA), 2018). As such, numerous regulatory bodies exist to protect and regulate public health at every level (Grimm, 2014). While patient care is the responsibility of the surgeon and the hospital, it is expected that the manufacturer (CRPM) adhere to all relevant medical regulations and requirements. As such, this case study applies the successive steps of the framework, as described in Chapter 4, to investigate the real-world impact of its use and can be used as an example of how to implement the framework to a process. However, it should be noted that Stage 4 and 5 of the framework could not be completely implemented. This is due to time and resource limitations, as well as limited access to company IP.

Therefore, only the planning activities were completed and the management consulted regarding its effectiveness.

6.1.2.2. Framework Preparation

In preparation for application of the framework to CRPM's process, a taskforce was compiled from the key stakeholders. Tables 6.1 and 6.2 describe the taskforce members involved during this case study, as well as their respective roles and duties in the application process:

Table 6.1 - Management division taskforce.

Stakeholder	Role	Duties
Gerrie Booysen	Director	• Ensuring that all stakeholders are invested in application of the framework. • Facilitating framework steps. • Enabling access to company knowledge. • Providing managerial insight.
Prof. W. du Preez	Advisor	• Providing insight w.r.t. real-world application of the framework. • Contact person. • Facilitating framework steps. • Providing managerial insight.
Prof. A.F. van der Merwe	Advisor	• Providing insight w.r.t. real-world application of the framework. • Providing insight w.r.t. case study validation process. • Facilitating framework application.
Barend Duvenage	Admin Agent	• Documenting framework application. • Facilitating framework application. • Contact person. • Processing of information. • Standards identification. • Facilitating database design. • Consultant.

Table 6.2 - Technical division taskforce.

Stakeholder	Role	Duties
André Heydenrych	Quality management	• Quality management category head and reviewer. • Ensuring quality management interests are represented throughout.
Gerrie Booysen	Quality management, Process, Raw materials, Post-processing, Testing	• Process and field of use category head and reviewer. • Post-processing category head and reviewer. • Providing technical insight w.r.t. process, post-processing, raw materials, testing and quality management.
Johan Els	Design, Process, Post-processing, Testing	• Design and testing category head and reviewer. • Providing technical insight w.r.t. design, process, post-processing and testing.
Prof. W. du Preez	Raw materials	• Raw materials category head and reviewer. • Providing technical insight regarding raw materials.

6.1.2.3. Stage 1

Table 6.3 - Stage 1 implementation.

Outcomes	Phase 1	Phase 2 Round 1	Phase 2 Round 2
Process vision	To produce a titanium implant that adheres to all customer requirements and related regulations.	Unchanged.	Implant should also adhere to international regulations and quality standards.
Framework vision	To identify all applicable standards related to the maxillo-facial implant manufacturing process.	To identify both national and international standards.	To identify at least one standard for each high-risk or key activity.
Requirement analysis	• Product must be biocompatible. • Product must have a long life-cycle. • Product must be free of internal and external defects. • Joints must be polished. • Implant body must be the same roughness as bone.	• Product life cycle should be 10 years. • Product must be non-toxic. • Product must not cause wear on surrounding bone structures.	CRPM requirements: • Process must be in conformance with ISO 13485. • Product must adhere to all relevant SAHPRA, CEN or FDA regulations.
Process-chain mapping	See Appendix C.2 for current version of process chain. More information on the compilation of this process chain can be found in (Bezuidenhout, 2016).	Unchanged.	Unchanged.

Identification of high-risk activities	N.A	• Do planning and risk assessment. • AM pre-operative skull replica model in Nylon. • Complete design of prothesis. • AM prosthesis and recycle used powder. • Perform stress relief/annealing. • Do heat treatment. • Perform final quality verification. • Complete non-conformance report and do preventative action. • Quality checks.	• Receive CT/MRI scan files. • Receive signed purchase order confirmation and indemnity form. • Reverse engineer wax mock-up into CAD model. • Prepare machines according to set-up protocol. Added red dots on process-chain to visually represent high-risk activities.

6.1.2.4. Stage 2

Table 6.4 - Stage 2 implementation.

Outcomes	Phase 1	Phase 2 Round 1	Phase 2 Round 2
Categorisation	It was decided that the categories should remain as they are, since they represent all aspects of the manufacturing process.	Sub-categories were considered, but ultimately decided against. Standards within categories can be discerned by means of keywords.	Unchanged.
Technical taskforce	Members remain as per Table 6.2.	Unchanged.	Unchanged.
Reviewers	Reviewers remain as per Table 6.2.	Unchanged.	Unchanged.

Keywords	• Quality management
	  ○ Risk management/Safety
	  ○ Terminology
	• Design
	  ○ File format
	  ○ Usability
	• Process
	  ○ DMLS
	  ○ Facility/Safety
	  ○ Specifications
	• Raw materials
	  ○ Ti6Al4V/Titanium alloys
	  ○ Storage
	  ○ Safety
	  ○ Cleaning/Disposal
	  ○ Characterisation
	• Post-processing
	  ○ Heat treatment
	  ○ Sterilisation/Cleaning
	  ○ Surface texture
	  ~~○ Engraving~~
	  ○ Stress relief
	• Testing
	  ○ Density
	  ○ Non-destructive
	  ○ Tension
	  ~~○ Fatigue~~
	  ○ Testing equipment
	• Field of use
	  ○ Titanium implants
	  ○ Sterilisation
	  ○ Biocompatibility
	  ○ Surgery
		• Quality management
		  ○ Compliance management
		  ○ Customer satisfaction
		  ○ Environmental management
		  ○ Financial management
		• Design
		  ~~○ Symbols~~
		  ~~○ Texture~~
		• Process
		  ○ Training
		  ○ Specifications
		  ▪ Materials
		  ▪ Product
		  ▪ Machine settings
		• Raw materials
		  ○ Re-use
		  ○ Handling
		  ○ Sampling methods
		  ○ Characterisation
		  ▪ Gases
		  ▪ Particle size distrubution
		  ▪ Density
		  ▪ ~~Flow rate~~
		• Post-processing (remains the same)
		• Testing
		  ○ Mechanical testing
		  ○ Porosity
		  ~~○ Test artefacts~~
		  ~~○ Ductility~~
		• Field of use
		  ○ Usability
		  ~~○ Degradation~~
		  ~~○ Wear~~
			Unchanged.

6.1.2.5. Stage 3

Table 6.5 - Stage 3 implementation.

Outcomes	Phase 1	Phase 2 Round 1	Phase 2 Round 2
Regulation identification	Completed by expert.	Unchanged.	Unchanged.
Identification: Categories	Standards were identified for each of the categories.	Unchanged.	Unchanged.
Identification: Keywords	Standards were identified for each of the keywords.	Standards were identified for new keywords.	Unchanged.
Categorisation	Standards were grouped according to the respective categories. Each standard is grouped into only one category to avoid duplication.	New standards were divided into relevant categories.	Unchanged.
Standards Revision	Standards were revised by admin agent according to stakeholder feedback.	Standards were revised according to new keywords.	Standards were revised by CRPM taskforce members to produce final list.
Categorisation feedback	Categories contain many standards and it is difficult to find the different subsets.	Division of standards within categories by means of keywords makes revision easier.	Unchanged.
Keywords feedback	Quality management keywords only focus on superficial concepts and should be expanded.	Design standards regarding texture and symbols were found to be irrelevant, thus exclude them from further searches.	Unchanged.

	Require standards regarding process training and more specific keywords regarding process specifications are required. Standards regarding recycling, handling and sampling of raw materials were seen and may be important. Characterisation of which elements of raw materials? Post-processing standards regarding engraving found to be unnecessary. Is mechanical testing important? Found standards regarding usability engineering, degradation and wear that may be relevant.	Flow rate standards were found to be irrelevant, thus scrapped. Ductility testing standards are included in mechanical testing standards, thus exclude term from future searches. Test artefact standards were found to be irrelevant, thus scrapped. Degradation and wear standards rather applicable to future endeavours, thus leave in the database but stop searching for these standards.	
Key standards identification	N.A	See Appendix C.1 for initial key standards planning.	Unchanged.
Final list	N.A	See Appendix C.1 for final list of standards as revised by CRPM.	Unchanged.
Vision coherence check	N.A	Stated vision will be attainable through use of standards and regulations.	Unchanged.
Responsibility allocation	N.A	Taskforce category heads allocated responsibility over respective categories.	Unchanged.

6.1.2.6. Stage 4

Table 6.6 - Stage 4 implementation.

Outcomes	Phase 1	Phase 2 Round 1	Phase 2 Round 2
Plan database	See Appendix C.3 for initial ERD planning.	See Appendix C.3 for final ERD.	Unchanged.
Interface development	See Appendix C.4 for initial interface development planning.	See Appendix C.4 for final interface planning.	Interface will be re-evaluated after trial runs and usability testing.
Standards-database-process mapping integration	Standards-process map integration done during implementation planning activity in Stage 5.	Final database planning allows for standards to be linked to process activities in database.	Activity will be completed once database is developed.
Database development	N.A	After consulting literature (Microsoft, 2008) and experts (Treurnicht, 2018), it was decided that the database prototype will be developed in MS Access due to the relatively small amount of information.	Database to be developed as part of beta testing.
Maintenance policy	N.A	See Appendix C.5 for performance parameters to be included in the service level agreement with database developers.	Policy to be discussed with database developers and revisited upon completion of trial runs and usability testing.

Trial runs	N.A	Trial runs to commence once the database has been developed, thus as part of beta testing.	Unchanged.
Usability testing	N.A	Usability testing to commence once the database has been developed, thus as part of beta testing.	Unchanged.
Information input	N.A	Final information input will commence once database has been developed and thoroughly tested.	Unchanged.

6.1.2.7. Stage 5

Table 6.7 - Stage 5 implementation.

Outcomes	Phase 1	Phase 2 Round 1	Phase 2 Round 2
Implementation planning	See Appendix C.6 for initial implementation planning.	Added standards related to the list of requirements.	Unchanged.
SOP development	See Appendix C.6 for SOP development planning, showing which activities only require company developed SOP's rather than standards.	Due to the proprietary nature of the knowledge, it is still unclear which company SOP's exist. This should be added during the beta testing phase.	Unchanged.

Standards implementation	See Appendix C.6 for standards implementation planning.[6]	Standards to be implemented as part of beta testing.	Unchanged.
Identify training	• All personnel that will use the database must be trained in its functions. • Safety training with regards to new safety standards and SOP's. • Quality management systems training for a company representative.	Unchanged.	Training will be re-evaluated once the framework is fully implemented during beta testing.
Workforce training	N.A	• Database training to be outsourced to database developers. • Safety training to be outsourced to experts in the field. Additional training regarding SOP's will be done by management. • Quality management systems training to be identified.	Workforce training to be done during beta testing stage.
Revise SOP's	N.A	SOP's to be revised by CRPM during beta testing stage.	Unchanged.
Database implementation	N.A	Database to implemented once it has been developed.	Unchanged.

[6] Implementation will be done in various rounds. The first round will constitute the implementation of standards for all high-risk activities. Round 2 & 3 are for the remaining activities requiring standards.

6.1.2.8. Continuous Improvement

In this case study, all of the framework stages are still in Phase 2. As such, a framework maintenance plan is not yet required. However, the following table suggests maintenance activities and their frequency, and is to be discussed once the framework has been fully implemented during the beta testing stage.

Table 6.8 - Continuous improvement planning.

Activity	**Frequency**	**Responsibility**
Stage 1		
Update process-chain	Once a year, or whenever the manufacturing process has been adapted in any way.	Gerrie Booysen
Update product vision	Once a year.	Management taskforce
Update list of requirements	Once a year.	Management taskforce
Appoint admin agent	Whenever the post is vacant.	Management taskforce
Stage 2		
Update keywords	Whenever Stage 3 is done.	Category heads
Appoint category head	Whenever the post is vacant.	Management taskforce
Stage 3		
Update standards	An annual check must be done to determine if a newer version of a standard has been developed.	Admin agent
Update regulations	An annual check must be done to determine if a newer version of a regulation has been published.	Admin agent
Revise process-chain i.t.o standards	Whenever new standards or regulations have been identified.	Admin agent
Revise SOP's	Whenever new standards or regulations have been identified.	Category heads

Stage 4		
Database maintenance	Maintenance to be done according to maintenance policy.	Outsourced Gerrie Booysen
Update information	Whenever new standards or regulations have been identified, new documentation is compiled, new SOP's are developed or with each framework application.	Category heads Admin agent
Database improvement	Annually.	Outsourced Gerrie Booysen
Stage 5		
Database commenting	Daily.	All users
Assign responsibility	Annually, or whenever a new category head is appointed.	Management taskforce Category heads
Update documentation	Whenever required by specific standard, regulation or SOP.	Responsibility holder

6.1.2.9. Results

Although the outcomes of the framework were ordered logically, the order of a few outcomes were not practical. One such example is the identification of high-risk activities taking place before the process mapping. As described in Chapter 3, practically, it is more efficient to first map the process to understand the role each activity plays, from which it is easier to determine its importance. Some shortcomings in the framework were also discovered. During the application of Stage 1 it was discovered that some aspects of the product's requirements were not addressed by only considering the process map. Thus, an outcome was added to determine the customer's and company's requirements, allowing the search and implementation of standards to include these important facets.

Opportunities to implement continuous improvement within application of the first two phases were also discovered, such as the addition of feedback regarding the categories. Not only does this ensure traceability through documentation, but it also ensures that the categories are representative of the process and that the correct technical personnel provide input when and where required. The addition of a review outcome to all stages was also made to realise the continually improving nature of the PDCA model.

While the framework is easily applicable to the case that was considered, it was also discovered that the standards identification methodology would not be effective when using the framework to update a process' standards or when a similar product is being considered. Thus, methodologies A and B shown in Chapter 4 were developed. A need for a tool to be used during the implementation activities of Stage 5 was also discovered and subsequently developed, as discussed in Section 4.12.1.

Apart from these shortcomings, the framework was found to be effective in achieving its objectives, realistic, easy to use and efficient. These sentiments were shared by the CRPM during their evaluation of the application process (Booysen, Els & Heydenrych, 2018). As depicted in Figure 6.3, use of the framework resulted in the identification of many more standards than had been in use by CRPM or were identified through a blind search. Furthermore, only 50 of the standards initially identified were deemed to be irrelevant.

Figure 6.3 - Respective amounts of standards identified.

6.1.3. Interviews

The first case study was aimed at ascertaining whether the developed framework is practical, applicable to real-world situations, effective and logical. The application of this case study allowed it to be vetted thoroughly and all errors were corrected.

To further investigate the framework's validity, experts in the field were interviewed regarding the framework and their feedback used to make the required improvements. This also facilitates the development process of a practical framework, since it uses knowledge from practitioners to improve the framework. A semi-structured interviewing method was chosen, since it allows certain questions to be addressed without constraining the conversation. As such, each expert could elaborate regarding the framework's strengths and weaknesses in his/her field of expertise and ensure that it is thoroughly evaluated in a practical context, whereas a structured interview may have inhibited the possibility of the conversation's evolution past superficial topics.
The objective of the interviews was to determine whether these experts agreed or disagreed with the developed framework, and to what extent, as well as determine if the framework is practical, logical and realistic.

The interviews were structured as follows:

i. Background of the research was presented, including the problem statement, research objectives and research methodology.
ii. The framework was presented and explained according to Chapter 3.
iii. The research and framework were discussed at the hand of the predetermined questions, allowing the experts to air their questions and concerns.
iv. The interview transcriptions were processed to gather the required data.

6.1.3.1. Interviewees

The persons interviewed are experts in various aspects of AM. Some are practitioners, others academics, but all are avidly involved in the effort to promote South Africa's stance in the international AM field. A description of the experts and their background can be found in the following table[7].

[7] For more information on the various institutions mentioned and their roles in AM, please refer to the Nomenclature on page xiii.

Table 6.9 - Experts interviewed during validation.

Code	Interviewee	Background / Reason for inclusion	Interview date
AH	André Heydenrych	As a design and quality engineer at the CRPM, he is knowledgeable regarding AM quality management systems and quality standards. He is also trusted with the risk management of CRPM's processes, design of the parts and is involved in the identification of standards and regulations.	03/07/18
DM	David Mauchline	Being a Mechanical Engineer and AM Specialist at VUT with 12 years' experience in the AM industry, David aims to push the limits of AM through education, research and industrial collaborations. As such he provides valuable feedback regarding the AM process from an industry and designer's perspective.	04/07/18
DHH	Devon Hagedorn-Hansen	As a Lecturer in Manufacturing Systems and Processes, General Manager of the Stellenbosch Technology Centre and Project Coordinator at the Stellenbosch Learning Factory, he is extremely knowledgeable in the field of AM and the difficulties associated with AM processes. He is also a member of the RAPDASA Management Committee and involved with COMA.	08/05/17
LT	Dr. Lerato Tshabalala	Dr. Tshabalala is a Senior Researcher at the CSIR and the research group leader for the CSIR's National Laser Centre metal AM program. She therefore has experience in the development of such frameworks, developing and identifying standards, and realising AM concepts. She is also involved in the CSIR Aeroswift project.	06/07/18
GB	Gerrie Booysen	As Director of the CRPM, he has unparalleled experience and is well known as a pioneer in the field of AM. He is intimately involved with the cutting-edge research being done at CRPM and has valuable experience in the realisation of AM concepts, negotiation of AM standards and regulations, and requirements of a framework such as this.	03/07/18

HvM	Hendrik van der Merwe	Being the Operations Manager at VUT's Science and Technology Park, he is involved in many research projects regarding AM applications. As such, he understands what is required for a product to progress from researching to commercial viability and can provide valuable insight to the applicability of the framework.	04/07/18
JE	Johan Els	As operations manager at the CRPM, he is keenly involved with ensuring that the products manufactured are of top quality and adhere to all requirements. He is knowledgeable in the details of the manufacturing process and the requirements a framework like this has to negotiate. He is also involved in CRPM's standards and regulations identification process, and is trusted with quality management systems.	03/07/18
JPS	Jean-Pierre Serfontein	As a Senior Engineer at Aerosud handling product development and quality management systems, Mr. Serfontein is intimately involved with the difficulties of identifying and implementing standards and regulations. Being involved with the Aeroswift project, he now has to apply his knowledge to AM processes for aerospace applications and can provide first-hand knowledge regarding the needs and requirements such a framework would have to fulfil.	06/07/18
MvT	Dr. Malan van Tonder	Dr. van Tonder is the head of the Idea-2-Product Lab at VUT and a systems integration specialist for new technology. As such he is keenly involved with the development of new concepts for AM application to commercially viable products, which requires the negotiation of standards and regulations. He therefore provides valuable insight from both a management and technical perspective.	04/07/18

MV	Marius Vermeulen	Mr. Vermeulen is the Program Manager of AM at Aerosud, a RAPDASA Management Committee member, a member-at-large of ASTM's Committee F42 on AM Technologies and involved with the Aeroswift project at CSIR. As such, he is one of the foremost authorities in the field, with experience in both the research and business aspects of AM.	06/07/18
WdP	Prof. Willie du Preez	As an Associate Professor at CUT, he has vast experience in the researching of AM processes. Due to his time spent with the CSIR, he also has valuable knowledge regarding the development and identification of standards in AM. He is also actively involved in RAPDASA and CPAM activities and will therefore provide valuable feedback regarding the applicability of the framework to the field.	02/07/18

6.1.3.2. Interview Process

Each of the experts received a summary of the research beforehand, outlining the research background, problem statement, objectives and providing a shortened version of the framework. This document provided the experts with a basic understanding of the topic, and what the framework is designed to achieve. They were then given a chance to decline if they felt they would not contribute to the project. Subsequently, the experts were interviewed face-to-face, during which the project background and methodologies were discussed, followed by an in-depth presentation on the framework and its various aspects.

Once all of the expert's questions, misunderstandings or uncertainties were addressed, the prepared research questions were brought up. Care was taken to allow a natural evolution of the discussion, as to gain the maximum amount of knowledge, whilst steering the conversation to address all of the research questions. The following questions were directly or indirectly addressed during each interview, investigating the various key aspects of the research depicted in Figure 6.4:

- Is there a need for such a framework in the AM industry?
- Is the framework effective in attaining its goals?
- Is the framework easy to use?
- Is there an opportunity to apply this framework in your institution?
- Would you be willing to apply this framework in your institution?
- Would you advise any changes to the framework?

Figure 6.4 - Key aspects of the research investigated during interviews (adapted from (Van Zyl, 2017)).

All of the interviews were transcribed and processed to gather the required feedback, as discussed in the following section. For transcriptions of the interviews, please refer to Appendix D. All interviewed experts consented to the use of these transcriptions.

6.1.3.3. Framework Feedback

The review of the feedback received during these interviews is structured according to each stage of the framework, as well as general feedback regarding the framework. This section contains general feedback and highlights some shortcomings.

i. Stage 1: Conceptualisation

Consensus was reached that the first stage is very important to successfully employ the framework to a process. **DHH** stated that the admin agent is an important part of this framework, since nobody wants to do this type of work. Also, the customer requirements are important, to ensure that the process remains focused. However, he mentioned that this stage should also look at the companies' current state: *"You want to know what you have before you know what you can make…and the process-mapping plays into that."* This sentiment is shared to some extent by **WdP** who stated that your 'field of use' should be the first thing you know in order to determine if standards are actually relevant. As such, he also believes the list of customer requirements is of utmost importance and should be thorough.

ii. Stage 2: Categorisation

While **DHH** understood the relevance of the stage, he believed that it could rather be a subset of stage 1. This comment was largely disputed by the other interviewees. However, **MV** advised including safety as a category, since it is a key focus in the field at the moment and not prominently visible in my existing categories. **GB** raised concern that the use of keywords may result in the identification of an incredible amount of standards, and was unsure whether the keywords are governed sufficiently to prevent this phenomenon (a concern that was shared by other experts as well). He mentioned comparing the keywords I identified during Case Study 1 to those found in ISO 13485 to measure the accuracy of my filtering technique.

iii. Stage 3: Identification & Processing

The concerns regarding governance of the keywords were raised again during evaluation of the identification methodologies, one such concern being raised by **LT.** However, **GB** started to understand the need for these keywords to limit a search**. MvT** felt the methodologies are useful, since they will ensure that the same activities can be done in the same way by different people. While **JPS** may have agreed with the methodologies, he disagreed that the identification will be done by admin personnel. **MV** stated that he believes companies will struggle with this stage, since it is a difficult process to identify relevant standards: *"Not only are there conflicting standards, but there are also gaps in the standards"*. As such he proposed the addition of an identification tool not only showing companies how to identify the standards, but also how to determine if they are relevant. Similarly, **WdP** mentioned that the identification tool should have you determine standards relating to the 'field of use' first and expand from there. **DHH** stated that he believes the two problems with standards are that they are hard to find and expensive to buy. He also drew attention to the fact that standards are normally applicable to more than one category, which would cause confusion in the categorisation of the standards. Finally, he also mentioned that the stage required a better name to encompass the fact that the standards and regulations are both identified and processed.

iv. Stage 4: Capturing

Widespread consensus was reached that this is an important aspect of the project, apparent from **DHH** calling it the "oomph" to the project. **WdP** agreed that this will make life much easier for the users. However, both **DHH** and **WdP** mentioned that the stage should be renamed to something like "capturing", implying that the standards are captured in some intelligent manner that allows access to them, since the stage names still resembled that shown in Figure 3.10. **JE** stated that such a database will be governed by the need for it, since it will incur maintenance costs, whilst **GB** voiced the concern that a standard's information is protected and only the buyer may access it. As such, the information added to the database and access thereto must be managed carefully.

v. Stage 5: Implementation

Although **JPS** stated that this stage is very similar to the change management employed by Aerosud, **DHH** called it unrealistic, since employees are resistant to change, and suggested incorporating some existing theories into the stage. **AH** also made the important observation that there aren't necessarily standards for everything, and as such you may not be able to identify standards for some activities. This should be noted to avoid a concurrent loop of searching for standards relating to some activities if there aren't any.

vi. Continuous improvement

It was unanimous that this phase of the framework is incredibly important to its effectiveness. **DHH** stated that sustaining the system is very important and mentioned that the visual representation should have feedback loops to emphasise the continual improvement aspect. **WdP** also said that it should be apparent from the start that the framework is based on continuous involvement from all stakeholders. He further commented that *"the constant reflection on the ultimate requirements is an important interaction"* and that it is important for users to recognise that all stages *"work together, feed into each other and reflects on one another"*.

vii. General

Overall, the general feedback regarding the framework was mostly positive. **DHH** agreed that the second phase should be done more often than the first, since it basically constitutes auditing the work done in Phase 1, which would especially benefit the medical and aerospace fields that require 100% traceability. However, he also mentioned that he struggled to follow the flow of the initial visual representation and that a checkbox tool would be useful to ensure that all of the outcomes are met (a view shared by **HvM**). **WdP** later stated that he liked the revised diagram, since it is effective in explaining use of the framework and its flow. **JPS** felt that the research didn't have enough exposure to the highly regulated aerospace field during its development, in which case the original equipment manufacturers (OEM's) specify what standards and regulations one must adhere to. He therefore stated that existing aerospace platforms should be incorporated into the framework before it would be applicable in the aerospace industry, and that he sees a correlation between the AS 91000 standard and this framework. He goes on to mention that the framework would be very applicable to a start-up company. **GB** shared in this opinion regarding aerospace and mentioned that the scope be limited to medical applications at this time. While **LT** stated that this framework is known to work, she agreed that the initial focus should be limited to one industry and emphasised that they always find it difficult to close the continual improvement loop.

JE disputed these opinions by stating that he believes the framework would work just as well for aerospace applications, since the framework would work the same and function the same with only the application being more difficult due to the associated regulating authorities and their rules.

6.1.3.4. Research Questions Feedback

This section provides a summary of the general feedback received with respect to the remaining three key aspects of the research shown in Figure 6.4 i.e. Need, Opportunity and Functional.

a) Is there a recognised need for such a framework in the AM industry?

All of the interviewed experts unanimously agreed that there is a widespread need for such a framework in the AM community. **HvM** mentioned being in Germany for an AM symposium where he noticed companies that were created for the same purpose as this framework. He therefore stated that the framework will definitely contribute towards the field. This need is also apparent locally, since **GB** stated that commercialisation of the technology will only be possible once they can outsource the production of parts within the country and across the world and still see production of the same quality parts repeatedly, which requires standardisation. According to **DHH**, one of the biggest issues with standards is finding them. Subsequently, **JPS** stated that this framework would be most applicable to companies without configuration management, such as start-ups.

b) Is the framework effective in attaining its goals?

This question also received largely positive answers. Most experts agreed that the framework follows the correct recipe to be successful. **WdP** stated that the framework will assist in the process of qualification of Ti6Al4V parts. **LT** mentioned that the framework is very similar to the quality management principles they apply at CSIR and **JPS** stated that it is essentially what they do at Aerosud. However, **DHH** and **MV** maintain that although it is very logical and correct in principle, it will only be effective once the adjustments mentioned in the previous section are made.

c) Is the framework easy to use?

While **WdP** is of the opinion that it clearly sets in place a good process regarding how to apply it practically, other experts weren't convinced without testing its implementation. **GB** and **LT** were concerned that the keywords will expand the search too much and make the framework less user-friendly. However, **GB** did mention that there are a few places in the CRPM system where the framework can easily be integrated.

DHH, HvM and **MV** agreed that more tools were needed to facilitate the application process. **DHH** specified a checkbox tool to be necessary for tracking the various outcomes of the framework, while **MV** requested a more in-depth tool for the identification stage.

d) Is there an opportunity to apply this framework in your institution, and would you?

As is apparent from question a), there is consensus that there are widespread opportunities to apply the framework. Only **JPS** stated that they had no reason to implement the framework at Aerosud, since they already have established processes addressing these aspects and they would be reluctant to change. While **HvM** did concede that, with the advancements being made, standards are becoming more necessary and therefore there is an opportunity to apply the framework, he was cautious to apply it before determining the true effect of implementing the framework in their processes. **MV** was willing to pursue application of the framework to a project done in conjunction with AHRLAC aircraft maufacturers. **GB** and **WdP** stated that they would apply the framework since it is relevant and timely, and can be used by all AM businesses and universities.

6.1.3.5. Results

Owing to the feedback received, some changes were made to the framework where deemed prudent. However, it should be noted that not all additions proposed by the experts were considered necessary or beneficial, and therefore the changes were focused on areas where consensus was reached.

According to **MV**, SDO's are increasingly focussing on safety aspects within AM. Although the identification of safety standards is important for all AM processes, it was not added as a separate category, but rather incorporated into existing categories by stating that each category where it would be applicable should add keywords relating to safety. In this way, a company can still customise the categories according to their process, with the additional benefit of only identifying relevant safety standards. The risk of identifying a large number of irrelevant standards, as mentioned by **GB**, was further mitigated by the addition of a feedback outcome regarding the keywords that were used. Thus, the keywords can be adapted after each round of identification according to the results. The theory discussed in Section 3.4.5.3 was also incorporated into Stage 5 to avoid the effects of resistance to change. Finally, the implementation tool was altered to include planning related to the development of SOP's for activities where standards do not exist, as discussed in Section 4.12.1.

Some changes were also made to the structure of the framework. The name of stage 3 was changed from "Identification" to "Identification and Processing" and stage 4 from "Storage" to "Capturing", thus making them more descriptive. Furthermore, arrows were added to the framework diagram to impress the continuous improvement aspect and depict the interaction between the stages.

6.1.4. Case Study 2

The second case study considers a product that is still in the development phase. As such, it is a prospective case study, aimed at testing the framework's effectiveness in aiding companies with the R&D of new products or processes. Since the product being considered is also a medical implant to be manufactured by CRPM, this case study will double as a test of the framework's improved efficiency when applied to a similar product. It should be noted that this case study was done after both the first case study and interviews had been completed, thus testing the effect of the changes that were made. Therefore, the following questions were evaluated during this case study:

- Is the framework usable in prospective cases?
- Will the framework aid its users in the development process?
- Are there any shortcomings in such an application?
- Are the changes made upon completion of Case Study 1 improvements?
- Are the changes made upon completion of the interview's improvements?
- Does the framework achieve its objectives in such an application?
- Does repeated use of the framework increase efficiency?

While each step of Case Study 1 was shown extensively, this case study is not meant to double as an example. Therefore, the application thereof and differences to Case Study 1 will be discussed, with only the important information shown in Appendix E for reference. It should also be noted that since this case study is prospective in nature, the regulations are still being identified and will not be included at this time.

6.1.4.1. Background

Following the success of the maxillofacial implant, the CRPM was approached by the Knee Clinic in Stellenbosch to research the possibility of using AM to manufacture a titanium implant and plastic cutting guide that will be used in a Partial Knee Replacement (PKR) surgery, or more specifically a Patellofemoral Arthroplasty.

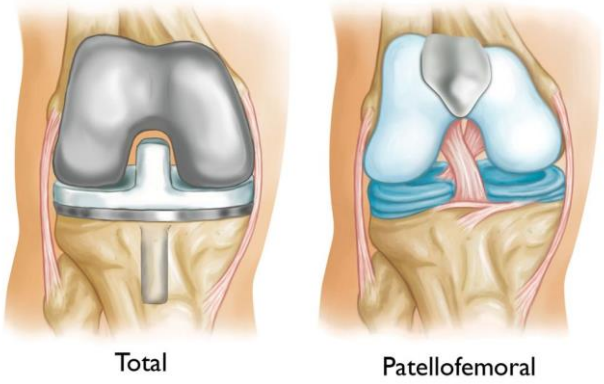


Figure 6.5 - Total Knee Replacement vs. Patellofemoral Replacement (Melnic, 2017).

As shown in Figure 6.5, patellofemoral implants aim to reproduce the kinetics of the joint between the patella and femur, called the Patellofemoral joint (Lustig, 2014). The proposed PKR implant is based on the work done by Dr. Pieter Erasmus and KJ Cho, as presented at the 2017 RAPDASA conference (Cho, 2017). Due to the customisable nature of AM, each implant can be patient specific and pre-operative models can be manufactured to test the product beforehand. This stands in contrast to the current method employed, which consists of assessing the patient's MRI/CT scans to determine the general shape and size of the implant required and making the necessary adjustments during surgery.

Since this implant is still in the planning phase and not an established process, the current focus is only on application in South Africa. Thus, the application of the framework is aimed at identifying standards that can help with the process and its setup. The factors discussed in Section 6.1.2.1 are also important during this case study, and as such, Case Study 1 will be used as the base for the application of the framework. Therefore, each stage of the framework will be applied to the case study being considered, starting with the final results of the first case study and making the required changes. It should be noted that Stage 4 does not have to be re-applied for this case study, since the database stage only has to be done once per company and then remains in the continuous improvement phase.

6.1.4.2. Framework application

Since this case study was done at the same organisation, the admin agent and taskforce members remained the same. While much of the final results obtained during Case Study 1 can be used in this instance, certain adaptions were required. During the application of Stage 1, the process vision was still to develop an implant adhering to customer requirements and relevant regulations. However, in this case the following requirements were added to those specified in Case Study 1:

- The implant and cutting guide should fit together perfectly.
- The cutting guide should be non-toxic and not cause adverse reactions during surgery.

Although the process chain describing this product is largely similar to that considered in the first case study, there are significant differences. As such, the new process was mapped to include the additional activities, as can be seen in Appendix E.3. The addition of a new process map inevitably led to additional high-risk activities being identified, and therefore the high-risk activities were depicted as blocks shaded in red on the process map. The categorisation remained as per Chapter 4, since standards were required for each of these categories. Additional keywords were devised to adapt the search for standards according to the product being considered.

These keywords considered two distinct differences from Case Study 1: the addition of a plastic cutting guide and the requirement of the implant to resist wear due to the additional kinetic forces imposed compared to a static maxillofacial implant. Taking into account these additional keywords, relevant standards were identified according to methodology B as described in Section 4.11.1. During this process it was discovered that no AM specific standards could be found regarding linings, nor could any surgery specific standards be found for plastics. As such, the keywords were adapted accordingly. As a result, 75 standards were identified in addition to those of Case Study 1. Since Appendix C.1 already describes the key standards identification done during Case Study 1, Appendix E.1 only shows the key standards identification within these 75 additional standards. This list was revised by CRPM and it was determined that the stated visions would be attainable through the application of these standards.

Stage 4 of the framework was not applied again since it only has to be completed once for each organisation, and it was decided that the planning done during Case Study 1 remained sufficient and up to date. Thus, the next step was to plan the implementation phase. This planning can be seen in Appendix E.2. It was also decided that training is only required with regards to the new safety standards and the associated SOP's.

6.1.4.3. Results

Owing to the improvements made upon completion of Case Study 1 and the interviews, no shortcomings were discovered during this case study, and the framework is therefore deemed ready for the beta testing stage. These improvements were also deemed satisfactory and beneficial. The addition of methodology B is one such example, since it was required during this case study and resulted in the identification of 75 additional relevant standards. Another example is the addition of the keywords feedback loop, which allows the search parameters to change according to the feedback received from the reviewers.

This second application of the framework within an organisation was also found to be much more efficient than the first. This is due to various factors. The first is the fact that much of the framework outcomes can draw on the work done during previous iterations, only altering it where required. Another is that the search for standards starts with a much larger knowledge pool. Therefore, the standards identification process is not only more efficient, but also more effective. Furthermore, since many of the activities of Case Study 1 and Case Study 2 are similar, the implementation planning from Case Study 1 only required modification rather than restarting the entire outcome. Thus, it is evident that the framework will become more efficient with each application. This efficiency will increase further once the database is implemented.

The framework achieved its objectives, since 75 additional relevant standards were identified. As depicted in Figure 6.6, this brings the total number of identified standards to 218, with only 13 standards deemed irrelevant. This follows the expected trend i.e. with each iteration more standards will come from previous iterations, less new standards will be identified and less standards will be eliminated as irrelevant. It should be noted that the implementation planning of Case Study 1's key standards has already been completed. As such, only the implementation planning of these additional 75 standards has to be completed during this iteration. As a result of this planning, only 41 standards are required to be implemented at this time. In addition, many of the SOP's developed during the first case study may already adhere to these requirements and only require a slight re-alignment. Thus, the time spent on identification, SOP development and implementation planning also reduces with each iteration.

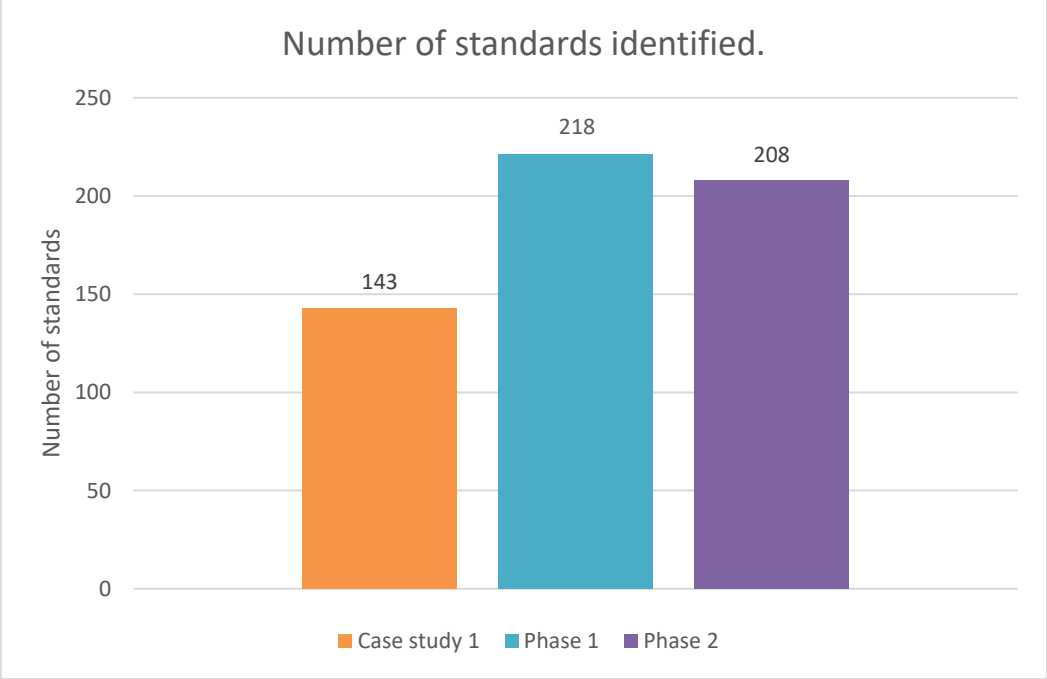


Figure 6.6 - Case Study 2 results.

During this case study, the framework also proved its worth in aiding the user to develop a new process. Stage 1 allows the users to determine their vision for the process and product, as well as the requirements they and the customer have. The process mapping outcome also allows them to visualise the process and identify problem areas. Through the identification of standards much knowledge can be gained and used to develop new techniques and processes. The implementation outcome also allows for the structured development of SOP's to implement standards and ensure adherence to regulations. Therefore, the framework is an asset during both prospective and retrospective cases.

6.2. Internal Validation

As mentioned in Section 3.4.5.3, it is important to audit the work which has been done to ensure that it adheres to the original requirements, thus avoiding scope creep. As such, this section functions as an audit of the research and framework to ensure that the research objectives have been achieved. The research objectives stated in Section 1.3.3 and the corresponding sections of this study during which each objective has been addressed can be seen in the Table 6.10.

Table 6.10 - Internal validation of research objectives.

Objectives	Sub-objectives	Related Section
1. Top-down analysis of the research problem components.	1.1 Map data sources	2
	1.2 Read & categorise data	2
	1.3 Map fields of concern.	3.4.3
	1.4 Deconstruct & categorise concepts	3.4.5
2. Bottom-up synthesis of components to build a framework that will address the research problem.	2.1 Define framework objectives & assumptions.	3.4.1 3.4.2
	2.2 Define framework requirements.	3.4.4
	2.3 Integrate concepts.	3.4.6
	2.4 Synthesise	3.4.6 4
3. Continuous evaluation.	3.1 Develop continuous improvement aspect of framework.	3.4.5 3.4.6 4.9
	3.2 Evaluate framework requirements.	5
	3.3 External validation of framework.	6.1
	3.4 Internal validation of study.	6.2

As such, it is evident that each of the objectives and sub-objectives mentioned in Section 1.3.3 have been addressed and achieved. Thus, the study has not diverged from the original objectives and the research aim has been achieved.

6.3. Summary

The aim of this chapter was to validate both the research done and the resulting framework. The internal validity was tested to determine if the research objectives were adhered to, from which it was determined that all research objectives had been achieved and as such no scope creep had occurred. The external validity tested whether the framework is practical and logical by means of two case studies and interviews with various industry experts, from which improvements were made to the framework to rectify any issues. During Case Study 2 it was determined that the improvements made to the framework worked well, and no further issues presented. Case Study 2 also proved that the framework becomes more effective and efficient with repeated use, since its application took much less resources and time to complete. While 193 standards were identified during Case Study 1, of which 143 were deemed relevant, Case Study 2 identified 75 additional standards with only 13 irrelevant standards.

From the interviews it was evident that although the framework required minor improvements, it was largely accurate in capturing best practices from the industry and theory. Consensus was reached that Stages 1, 3 and 4 are very important, as well as the continuous improvement aspect. However, some concern was raised that the framework may result in the identification of too many standards, or that the search may evolve to include too large a pool of topics. This risk was mitigated by including the outcome to provide feedback regarding the keywords after each iteration, with the keywords being altered accordingly. From the results of Case Study 2, it is evident that the addition of this feedback eliminated the issue. The experts also stated that while some believe the framework would work just as well in related highly regulated areas, the study should first confine its scope to the medical field to prove pragmatic validity.

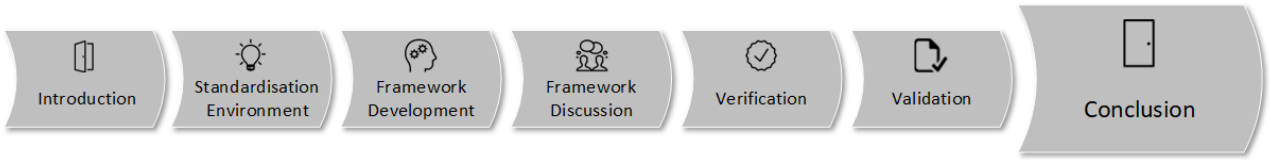
As such, it is apparent that the framework is effective in achieving the objectives stated in Section 3.4.1 i.e. the various concepts were integrated into a coherent whole in a way that strengthens the user's understanding by focusing on both the theory and practitioner's interpretations, it improves the likelihood of identifying all standards relevant to the case being considered, it guides the user rather than prescribe the course of action and it allows and encourages continual improvement. Through reaching these objectives, the framework successfully reaches its aim of aiding the user in identifying, storing and implementing applicable standards, resulting in the assurance of quality and customer satisfaction.

However, from the evaluation process it was determined that the use of keywords to search for standards in various SDO databases is not an optimal search method. Alas, due to the storage methods employed by the SDO's, this is currently the best way to go about the task. Therefore, it is obvious that this process can be further improved through better storage methods, such as the proposed database.

Therefore, the pragmatic validity of the framework has been tested to produce supporting evidence, during which the framework was proven effective in both retrospective and prospective cases. From the interviews it was also proven that the concepts were logically sound and practical. As such, the alpha testing phase is completed, and the framework is ready for beta testing.

Chapter 7

Conclusion and Recommendations



Chapter 7 is the final chapter of this research document. It contains a conclusion to the study and discusses the findings of the research. A description is also given regarding how the research contributed towards knowledge in the field and why it is relevant. Finally, recommendations regarding the research is made, as well as how it can be improved in the future.

7.1. Conclusion

The research aim stated in Chapter 1 can be divided into three distinct parts, each equally important in ensuring that the research question is successfully addressed. These three parts are:

- To use a systems engineering approach.
- To develop a framework for the identification and implementation of standards.
- To be used by South African AM companies to standardise quality in both the AM processes and end products, to ensure customer satisfaction and compliance to regulation.

The systems engineering approach implemented during the study was that of the Innovation Roadmap W-model, which entails a top-down analysis of the problem, a bottom-up synthesis of the solution and continuous evaluation throughout the process. As such, the problem under consideration was thoroughly investigated to determine the key aspects thereof. In terms of the identification of standards it was found that while there are better methods to employ, most organisations use the limiting and inefficient method of searching the internet or SDO database for "additive manufacturing standards". It should be noted that while relational databases, such as the AM-3DP database, aren't complete yet, this inefficient method remains the most effective. Therefore, the framework aimed to improve the efficiency and accuracy thereof through the use of various keywords and databases. It was also determined that standards and regulations can be implemented through the development and use of SOP's.

In order to develop a proposed solution that adhered to the research aim and practically contributed to the practice, it was determined that additional steps were required. Therefore, the framework is made up of five different stages, each aimed at addressing certain aspects of the research problem. While the *Conceptualisation* stage is aimed at understanding the extent of the problem before applying the rest of the framework, it also requires that the customer requirements are documented to ensure that they are considered throughout. Similarly, the *Categorisation* stage may ensure that the information is grouped such that those with relevant knowledge contribute to the keywords, but it is also aimed at developing a filter process to aid in the development of a relational database. The development of this database is described in the *Capturing* stage and is aimed at improving the way in which standards are identified. Finally, the third and fifth stages are used to identify and implement standards.

The framework therefore proposes a structured approach to identifying standards that is more effective and become more efficient with each iteration. This aids in ensuring legal security and improving competitiveness. It also describes an improved method of storing the standards, regulations and related documents that is more efficient. This allows the user to capture a large body of knowledge to reference when searching for standards, during accreditation activities or when researching new technologies. It also allows employees to work independently, since they can easily reference relevant material.

As discussed in Chapter 6, improvements were made to the framework after concluding the first case study and the expert interviews. However, during the second case study it was found that the framework is ready for the beta testing stage. From these case studies, it was determined that the framework is effective in achieving its objectives and easy to use. Although there were some concerns that the framework will identify too many standards, it was determined from the expert interviews that there is a recognised business need for such a framework, that the framework addresses those needs and that the framework is easy to use.

Therefore, it is evident that all three parts of the main research aim have been achieved, resulting in a proposed solution for the research question.

7.2. Contributions to Practice

The framework aided the industrial partner (CRPM) in identifying standards that can be used to improve their process by improving quality management principles, as well as providing reference materials and benchmarks. Use of the framework also improves the commercial viability of such a product, since it improves the Commercial Readiness Index (CRI) thereof. As described by Bezuidenhout (2017), the CRI is an indicator of the commercial readiness of a business. Although there are many factors contributing to the commercial readiness of a business, one is the regulatory environment. A high level of readiness in this CRI indicator requires that there is an ongoing process of review and refinement and that the regulatory and planning processes are thoroughly documented. It also takes into account accreditation to certain international standards, such as ISO 9001, and regulatory compliance.

As such, the framework can be used by an organisation to identify standards to be used to ensure regulatory compliance or accreditation to specified international standards. It will also ensure a high level of traceability and a continuous process of review and refinement, thus improving the commercial viability. The identification and use of standards can also lead to new and improved market opportunities, as discussed in Section 3.4.3, which is another CRI indicator.

Through use of the framework, any AM company can identify and implement AM standards, thus improving customer confidence in the manufactured products, leading to an increase in the global competitiveness of South African AM companies. The framework also facilitates newcomers in the field, thus increasing adoption of the technology and simultaneously advancing the field.

Another contribution is the analysis and report of the current state of AM standards described in Section 2.4. As mentioned in Chapter 1, little literature exists on standards within the field of AM. As such, this study provides a much-needed overview of the current state of AM standards i.e. how many there are, what the key focusses are, what the industry perceptions are and where gaps still exist.

7.3. Recommendations and Future Work

7.3.1. Recommendations

Whilst conducting this research some areas requiring improvement were identified, and therefore the following recommendations are made:

1. The method of searching for standards by using keywords is largely inefficient. While the framework improves this to a large extent, the process should be improved even further, since it still requires too much time and resources.
2. The framework should include a tool with criteria for determining the importance of a standard to aid the user when planning the implementation process.
3. Research should be done to determine how the framework can be expanded to be applicable to various fields.
4. The proposed relational database should be developed and the effectiveness thereof tested.
5. While the implementation tool described in Section 4.12.1 aids the user in the implementation planning activities, the efficiency thereof can be improved. As such, improvements should be made to this tool during future applications, such as finding an improved method of linking the standards to their associated process activities.

7.3.2. Future Work

- Research should be conducted to determine the costs associated with implementation of the framework, as well as its associated market effects.
- A national initiative should conduct research into how the AM-3DP database developed by SME (see Section 3.3) can be improved to include all standards relevant to AM and how the filters can be used to develop an improved method of searching for applicable standards.
- Beta testing of the framework should be done by companies to determine any remaining problems, according to which the framework should be improved.
- More research should be conducted to determine how the use of standards affect the CRI of a company, and how they can be used to lead to commercial viability.

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Appendix A

RAPDASA survey

Table A. 1 - RAPDASA survey questionnaire and results.

Name:	**Institution:**				
Country:	**Position:**				
Validation questions					
	Strongly agree	**Agree**	**Neutral**	**Disagree**	**Strongly disagree**
1. To what extent do you agree that					
1.1 it is important to use standards in the additive manufacturing (AM) field?	25	6	1	0	0
1.2 there are enough standards available that were developed specifically for AM purposes?	1	3	9	17	2
1.3 there are areas in the AM process for which standards have not been developed?	13	14	5	0	0
Please elaborate: (eg. Design, process, post-processing, aerospace etc.) Parameter optimisation, CAD variance, porosity, process, post-process, aerospace, tooling, materials specifications, design, use of raw materials, testing.					
1.4 it is difficult to identify relevant AM standards?	3	13	10	6	0
1.5 a lack of standards in the field is preventing adoption of the technology?	3	15	6	8	0
1.6 the use of standards prevent innovation in the field?	1	7	12	10	2
1.7 a lack of standards in the field is preventing further development of the technology?	1	12	10	9	0
	None	**<20**	**20-80**	**81-150**	**>150**
2.1 How many standards do you think there are that are relevant to AM?	0	8	17	4	2

2.2 How many standards do you think there are that were specifically developed for AM?	1	19	8	3	0
2.3 How many AM standards do you make use of?	9	19	2	0	0
If none, please elaborate: Four participants did not answer, since they don't actually work in the field, but are busy with research.					
3. Which Standards Development Organizations are you aware of that develop AM standards? (eg. ISO, ASTM, ANSI, SABS etc.) ISO, ASTM, SABS, FAA, EC					
4. How would you go about identifying standards? While there were many different answers to this question, the consensus was to do a search on the internet or SDO databases.					

Appendix B

Checklist Tool Forms

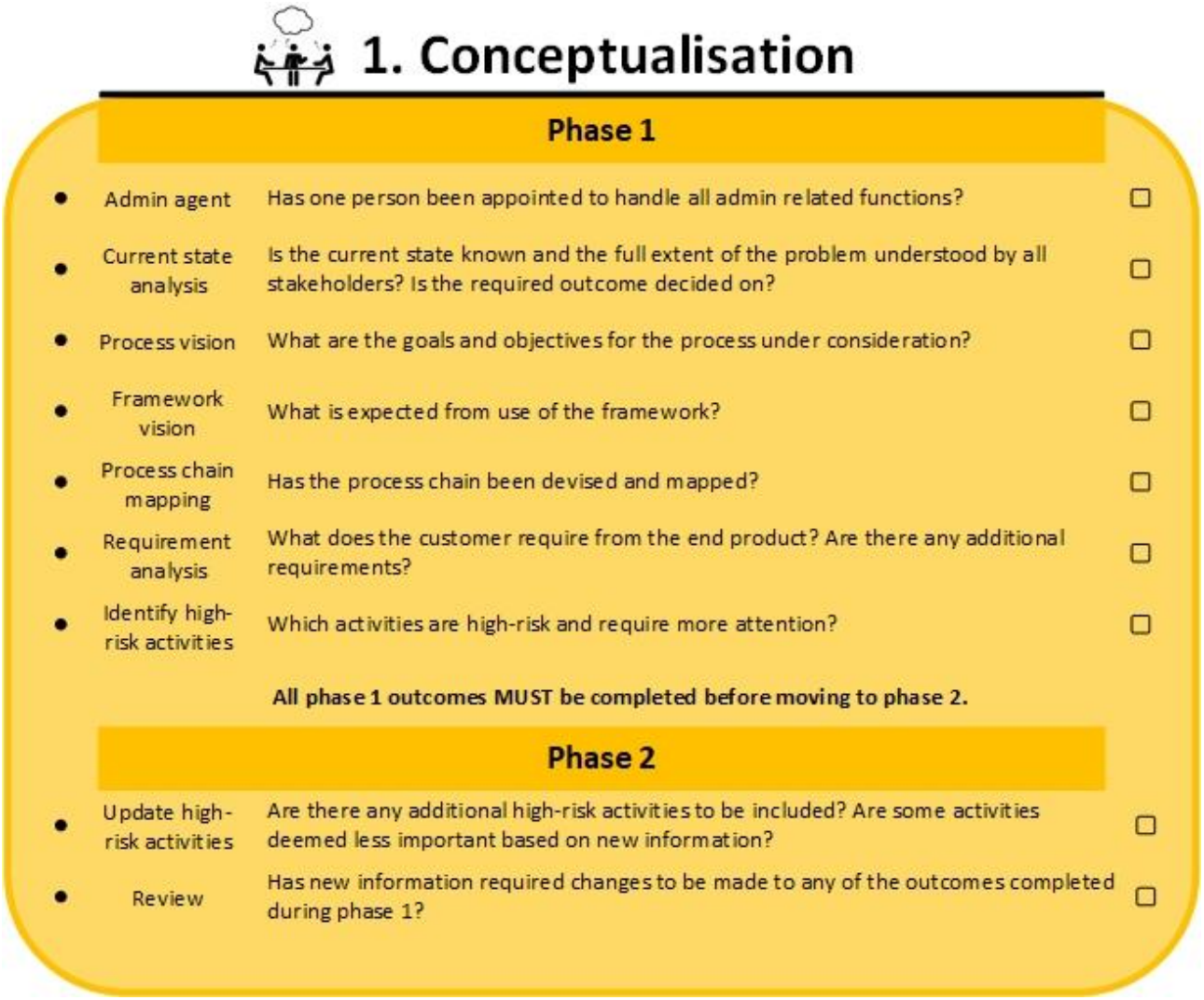


Figure B. 1 - Stage 1 checklist form.

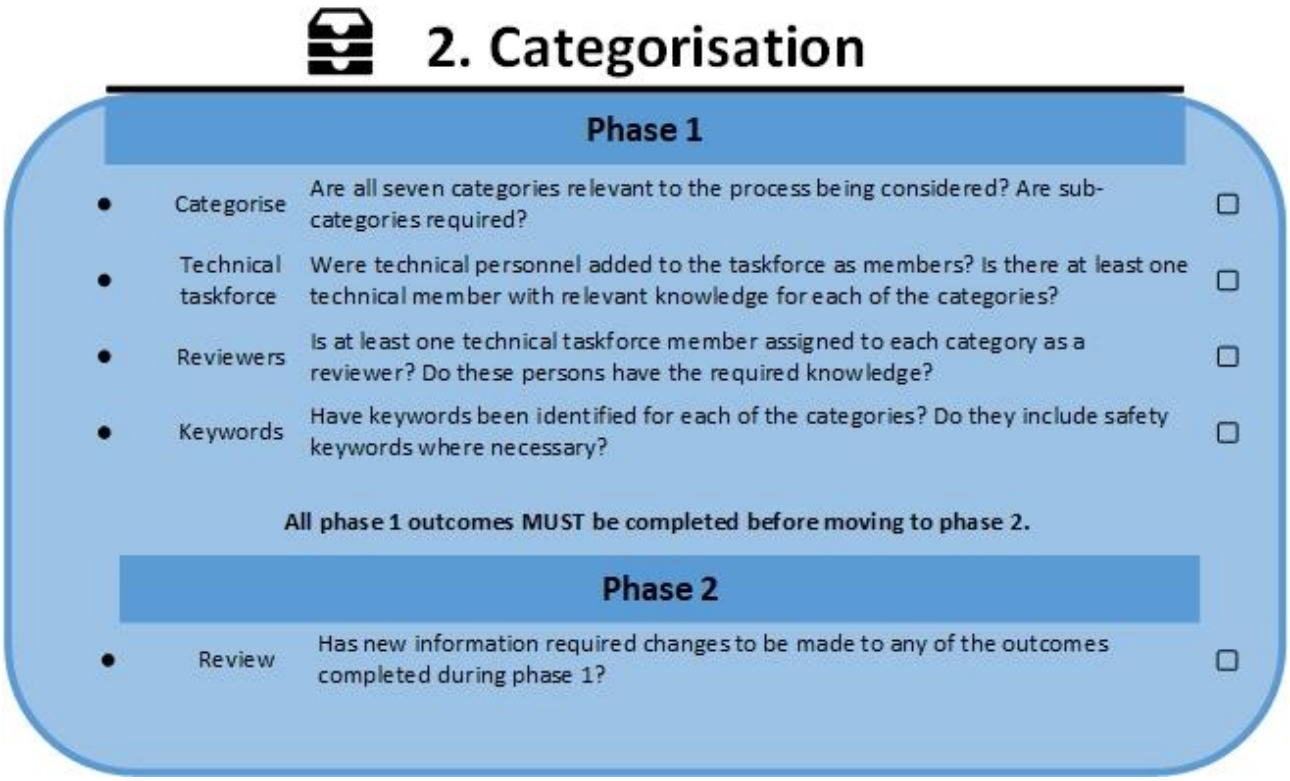


Figure B. 2 - Stage 2 checklist form.

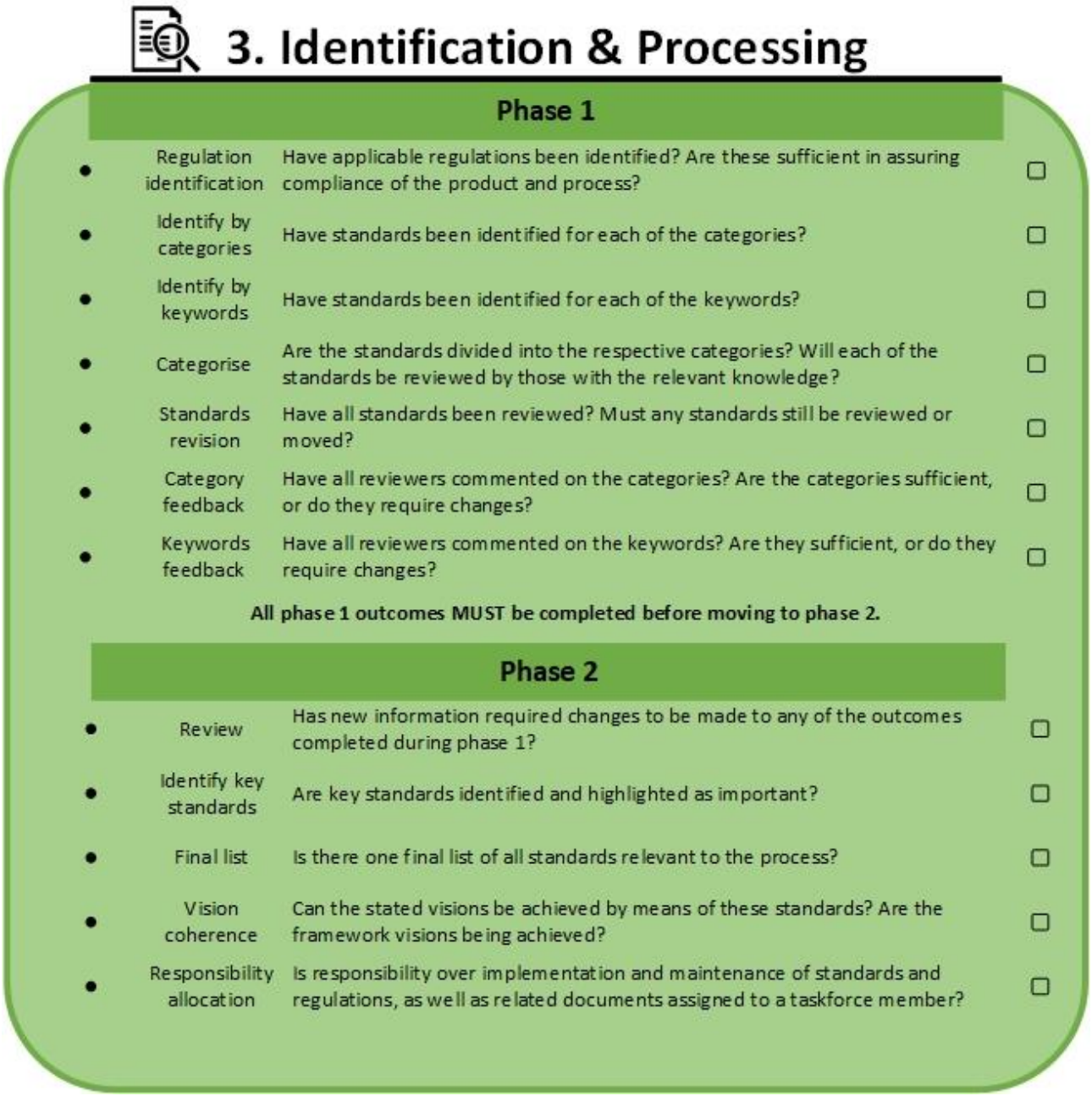


Figure B. 3 - Stage 3 checklist form.

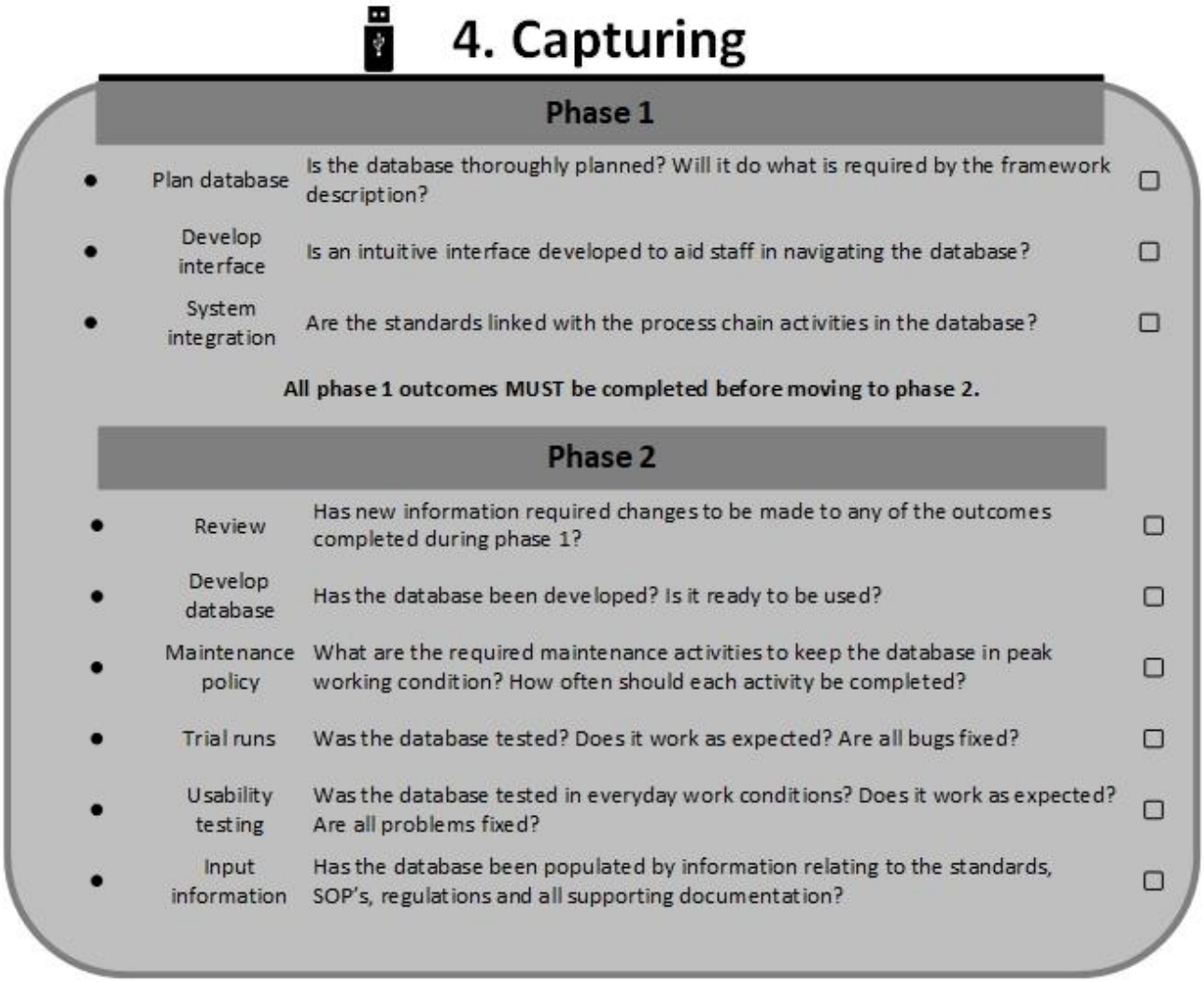


Figure B. 4 - Stage 4 checklist form.

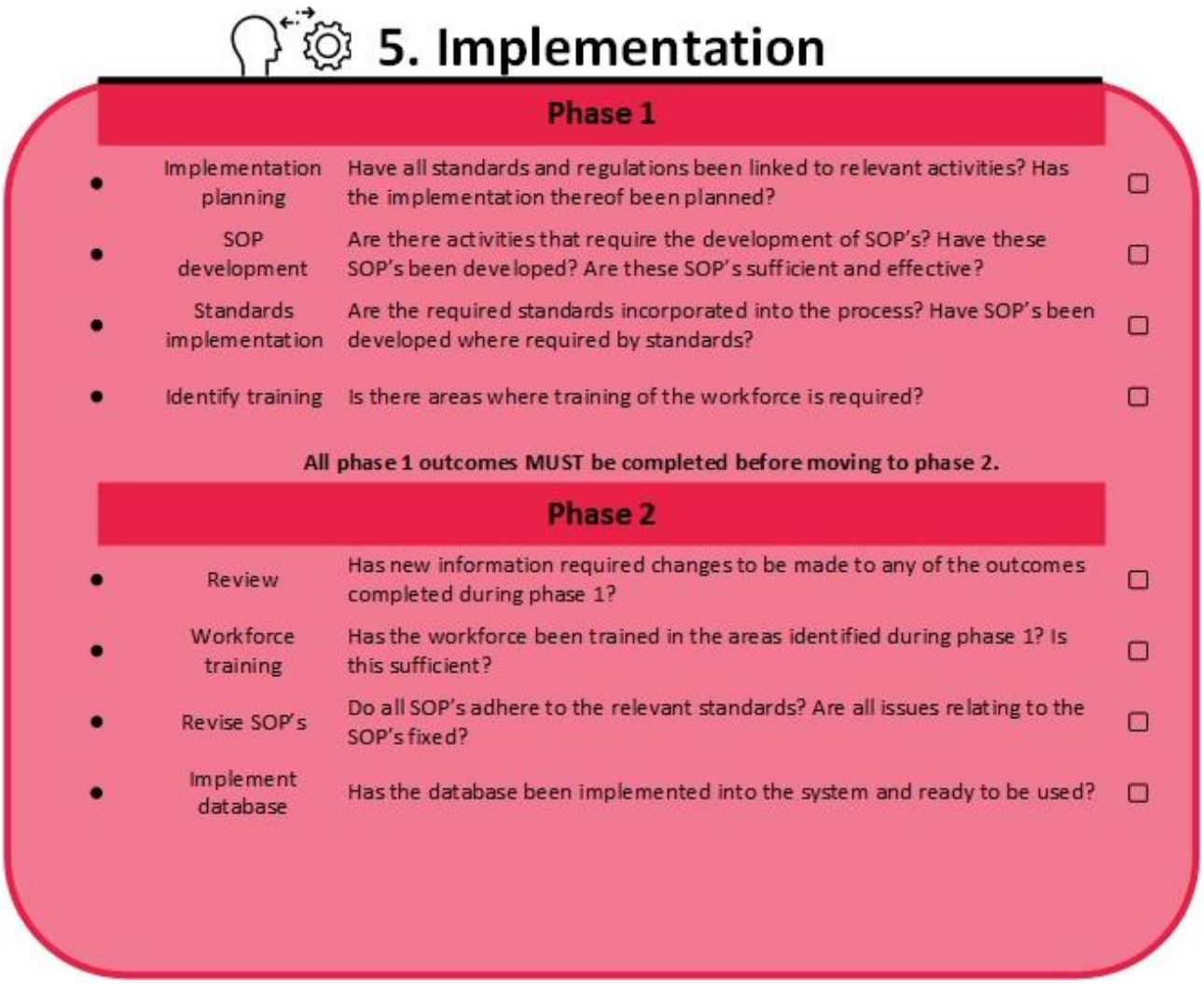


Figure B. 5 - Stage 5 checklist form.

Appendix C

Case Study 1 Appendices

C.1 Final Standards List.

Table C. 1 - Final list of standards.

Key	
R1	Standard contains information that is imperative for the success of the process i.e. key standards.
R2	Standard contains information that will actively improve process.
R3	Standard contains information that may prove of some help, but is not considered urgent.
F	Standard contains information that is relevant to future endeavours.
I	Standard contains relevant information regarding the overall process which may be of value at a later stage.

Medical		
R1	ASTM F2847	Standard Practice for Reporting and Assessment of Residues on Single Use Implants
R2	ASTM F748	Standard practice for selecting generic biological test methods for materials and devices
R1	FDA Doc1	Use of International Standard ISO 10933-1, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
R1	ISO 10993-01	Biological evaluation of medical devices Part 1: Evaluation and testing
R1	ISO 10993-03	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
R1	ISO 10993-04	Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
R1	ISO 10993-06	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
R1	ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity
R2	ISO 10993-12	Sample preparation and reference materials
R1	ISO 11737-01	Sterilization of medical devices - Microbiological methods Part 1: Determination of a population of microorganisms on products
R1	ISO 11737-03	Sterilization of medical devices — Microbiological methods Part 3: Guidance on evaluation and interpretation of bioburden data
R1	ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice

R1	ISO/TR 15499	Biological evaluation of medical devices - Guidance on the conduct of biological evaluation within a risk management process
R1	ISO 11607-1	Packaging for terminally sterilised medical devices - Requirements for materials, sterile barrier systems and packaging systems.
R1	ISO 11607-2	Packaging for terminally sterilised medical devices - Validation requirements for forming, sealing and assembly processes
R3	ISO 8828	Guidance on care and handling of orthopaedic implants
R3	ISO 10993-9	Framework for the ID and quanitification of potential degradation products
F	ISO 10993-15	ID and quantification of degradation products from metals and alloys
R2	FDA Doc2	FDA Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
R1	ISO 10993-02	Biological evaluation of medical devices Part 2: Animal welfare requirements
R2	ISO/TR 16142	Medical devices – Guidance on the selection of standards in support of recognised essential principles of safety and performance of medical devices
F	ISO 17853	Wear of polymer and metal implants
I	ISO/TR 14283	Fundamental principles of implants for surgery
R3	AAMI TIR17	Compatibility of materials subject to sterilization
R2	ANSI/AAMI ST67	Sterilization of health care products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled 'sterile'
Design		
R1	ASTM E2807	Specs for 3D imaging data exchange
R1	ASTM F2915	Standard specification for additive manufacturing file format (AMF)
R1	ISO/ASTM 52915	Specs for AM file format
R3	3MF Consortium	3D Manufacturing Format (3MF)
R1	EN 62366	Medical devices - Application of usability engineering to medical devices
I	ASME Y14.46	Product Definition for Additive Manufacturing (DEVELOPMENT)
R1	ASTM WK54856	Principle of design rules in additive manufacturing
R1	ASTM WK59131	AM, Technical design guideline for powder bed fusion Partv 1: Laser-based powder bed fusion of metals
R3	IEC 61160	Design review

R3	ISO/ASTM 52910	Guidelines for design
R1	ISO/ASTM CD 52911-01	Technical design guideline for laser-based powder bed fusion of metals
R2	VDI 3405 Blatt-3	Additive manufacturing processes, rapid manufacturing - Design rules for part production using laser sintering and laser beam melting
Process		
R3	ASTM B348	Specification for titanium and titanium alloy bars and billets
R1	ASTM F1108	Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants
R1	ASTM F136	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
R1	ASTM F1472	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications
R1	ASTM F2924	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
R1	ASTM F3001	Specs for Ti6Al4V ELI with powder bed fusion
R1	ASTM WK60552	AM, Finished part properties - Standard specification for AM titanium alloys via powder bed fusion
R1	ISO 5832-03	Implants for surgery
R1	SAE AMS7003	Laser Powder Bed Fusion Process
R1	ASTM F3127-16	Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices
R1	ASTM WK58226	Initial, operational and part qualification of metal powder bed fusion machines
R1	ASTM WK58227	Digital workflow control for metal powder bed fusion process
R1	ASTM WK58231	Creating maintanance schedules and mantaining metal powder bed fusion machines
R1	ASTM WK58232	Calibrating of metal powder bed fusion machines and subsystems
R1	ASTM WK58234	Storage of technical build cycle
R1	ISO 17296-02	Overview of process categories and feedstock
R1	ISO 17296-04	Overview of data processing
R1	ASTM WK58225	Facility requirements for metal powder bed fusion
R1	ISO 17296-03	Main characteristics and corresponding test methods
R1	NFPA 91	Standard for Exhaust Systems for Air Conveying of Vapors, Gases, Mists, and Particulate Solids, 2015 edition

R1	NFPA 652	Standard on the Fundamentals of Combustible Dust, 2016 edition
R1	NFPA 654	Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, 2017 edition
Raw materials		
R2	AMS 2249	Chemical check analysis limits, Titanium and titanium alloys
R2	ASTM B215	Practices for sampling metal powders
R2	ASTM E120	Test methods for chemical analysis of titanium and titanium alloys
R2	ASTM E1409	Test method for determination of oxygen and nitrogen in titanium and titanium alloys by inert gas fusion
R2	ASTM E2371	Test method for analysis of titanium and titanium alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (performance based methodology)
R1	ASTM F3049	Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes
R3	MPIF 01	Sampling metal powders
R1	ASTM F3122	Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes
R2	ASTM B214	Test method for sieve analysis of metal powders
R2	ASTM B822	Test method for particle size distribution of metal powders and related compounds by light scattering
R2	ASTM F1877	Practice for characterisation of particles
R2	ISO 4497	Metallic powders - Determination of particle size by dry sieving
R2	MPIF 05	Sieve analysis of metal powders
R2	ASTM B331	Test method for density of powder metalurgy materials containing less than two percent porosity
R2	ASTM B527	Test method for determination of tap density of metallic powders and compounds
R1	ASTM B923	Test method for metal powder skeletal density by helium or nitrogen pycnometry
R3	MPIF 46	Tap density of metal powders
R2	ASTM F763	Short-term screening of implant materials
R1	ASTM F981	Standard practice for assessment of compatibility of biomaterials for surgical implants with respect to effect of materials on muscle and bone
R1	ISO 10993-18	Biological evaluation of medical devices Part 18: Chemical characterization of materials
R3	ASTM B213	Test methods for flow rate of metal powders using the hall flowmeter funnel

R3	ASTM B964	Test method for flow rate of metal powders using the carney funnel
R3	MPIF 03	Flow rate of free-flowing metal powders using the hall apparatus
I	ASTM B243	Terminology of powder metallurgy
R1	ASTM WK58219	Creating feedstock specs for metal powder bed fusion
R1	ASTM WK58221	Receiving and storing of metal powders used in powder bed fusion
R1	ASTM WK58222	Metal powder reuse in powder bed fusion process
R1	ASTM WK58223	Cleaning metal powders used for powder bed fusion
R1	ASTM WK58224	Disposal of metal powders used in powder bed fusion
Post-processing		
R1	AMS 2801	Heat Treatment of Titanium Alloy Parts
R1	ASTM WK58233	Post thermal processing of metal powder bed fusion parts
I	ASTM G131	Practice for cleaning of materials and components by ultrasonic techniques
R1	EN 556-1	Sterilisation of medical devices – Requirements for medical devices to be designated STERILE – Part 1: Requirements for terminally sterilised medical devices
R2	ISO 11137	Sterilisation of health care products – Requirements for validation and routine control – Radiation sterilisation
F	ISO 14644	Cleanrooms and associated controlled environments
F	ISO 14698	Cleanrooms and associated controlled environments - Biocontamination control
F	ISO 14937	Sterilisation of health care products - General requirements for characterisation of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices
R2	ISO/DIS 19227	Cleanliness of orthopedic implants
R3	ASTM D3951	Practice for commercial packaging
R3	ISO 15378	Packaging materials for medicinal products
R2	MPIF 58	Standard 58 (ASTM B946-11(2016), Standard Test Method for Surface Finish of Powder Metallurgy (PM) Products)
Testing		
R2	ASTM A370	Test methods and definitions for mechanical testing
R2	ASTM E111	Test methods for young's modulus, tangent modulus and chord moduluss

R3	ASTM E132	Test method for Poisson's ratio at room temperature
R3	ASTM E143	Test method for shear modulus at room temperature
I	ASTM E6	Terminology relating to methods of mechanical testing
R2	ISO 3369	Impermeable sintered metal materials and hardmetals – Determination of density
R2	ISO 5579	Non-destructive testing – Radiographic testing of metallic materials using film and X- or gamma rays – Basic rules
R2	ISO/ASTM NP 52905	Non-destructive testing of AM products
R1	ASTM E8M	Standard Test Methods for Tension Testing of Metallic Materials
F	ASTM E606	Test method for strain-controlled fatigue testing
F	ASTM F1801	Corrosion fatigue testing of metallic implants
F	ISO 16429	Implants for surgery - Measurement of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods
F	ASTM E1012	Practice for verification of testing frame and specimen alignment under tensile and compressive axial force application
F	ASTM E4	Practices for force verification of testing machines
F	ASTM E691	Practice for conducting an interlaboratory study to determine the precision of a test method
R2	AMS 2631	Ultrasonic inspection titanium and titanium alloy bar, billet and plate
R1	ASTM E1570-11	Standard Practice for Computed Tomographic (CT) Examination
R1	ASTM F2971	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing
R3	ASTM B962-15	Standard Test Methods for Density of Compacted or Sintered Powder Metallurgy (PM) Products Using Archimedes' Principle
Quality management		
I	ASTM F1251	Terminology relating to polymetric biomaterials in medical and surgical devices
R1	ASTM F2792	Standard Terminology for Additive Manufacturing Technologies
I	ASTM F2809	Terminology relating to medical and surgical materials and devices
R1	ASTM F2921	Standard terminology for additive manufacturing -- Coordinate systems and test methodologies
R1	ISO 15223-01	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
I	ISO 17296-1	Additive manufacturing - General principles - Part 1: Terminology

R1	ISO/ASTM 52921	Terminology for coordinate systems & test methodologies
R2	EN 1041	Information supplied by the manufacturer of medical devices
R2	ISO 37500	Guidance on outsourcing
R1	ISO/ASTM 20194	PWI requirements for purchased AM parts
R2	ISO/IEC 17007	Guidance for drafting normative documents suitable for use in conformity assessment
R1	ISO/IEC Guide 51	Safety aspects - Guidelines for the inclusion in standards
R1	OHSAS 18001	Occupational health and safety management systems - Requirements
R2	OHSAS 18002	Guidelines for the implementation of OHSAS 18001
R1	FDA Doc3	Technical Considerations for Additive Manufactured Devices
R3	IEC 60812	Analysis techniques for system reliability - procedures for failure mode and effects analysis (FMEA)
R3	ISO 90003	Application of 9001:2008 to software
R2	ISO 19600	Compliance management systems
R3	ISO 50001	Energy management systems - Requirements with guidance for use
R3	ISO 14001	Environmental management systems – Requirements with guidance for use
R1	ASTM WK58230	Establishing a personnel training program for metal powder bed fusion part production
R1	ASTM WK58228	Establishing manufacturing plan and sequence of operation work flow for metal powder bed fusion
R2	ISO/DIS 41001	Facility management
R2	ISO 19011	Guidelines for auditing management systems
R2	ISO/TR 10013	Guidelines for quality management system documentation
R2	ISO/FDIS 45001	Occupational health and safety management systems - Requirements with guidelines for use
R3	ISO/CD 50501	Innovation management - Innovation management systems - Guidance
R3	ISO/Np TR 50502	Innovation management - Assessment - Guidance
R2	ISO/AWI 50505	Innovation management - Intellectual property management
R2	ISO 9000-3	Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintance of computer software.

R2	ISO/TS 9002	Guidelines for the application of ISO 9001:2015
R3	ISO 10019	Guidelines for the selection of quality management system consultants and use of their services
R1	ISO 9004	Managing for the sustained success of an organization - A quality management approach
R1	ISO TR 24971	Medical devices - Guidance on the application of ISO 14971
R1	ISO 14969	Medical devices - Quality management systems - Guidance on the application of ISO 13485:2003
R1	ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
R1	AS 9100	Quality systems – Aerospace – Model for quality assurance in design, development, production, installation and servicing
R3	ISO 10002	Quality management – Customer satisfaction – Guidelines for complaints handling in organisations
R3	ISO 10003	Quality management – Customer satisfaction – Guidelines for dispute resolution external to organisations.
R2	ISO 10004	Quality management – Customer satisfaction – Guidelines for monitoring and measuring
R3	ISO 10015	Quality management – Guidelines for training
R2	ISO 10007	Quality management systems - Guidance for configuaration management
R2	ISO 9001	Quality management systems - Requirements
R2	EN 29001	Quality systems - Model for quality assurance in design/development, production, installation and servicing
R1	EN 14971	Medical devices - Application of risk management to medical devices
R1	ISO 14971	Medical devices - Application of risk management to medical devices
I	ASTM E2910	Standard guide for preferred methods for acceptance of product

C.2 Maxillo-facial Implant Process Chain

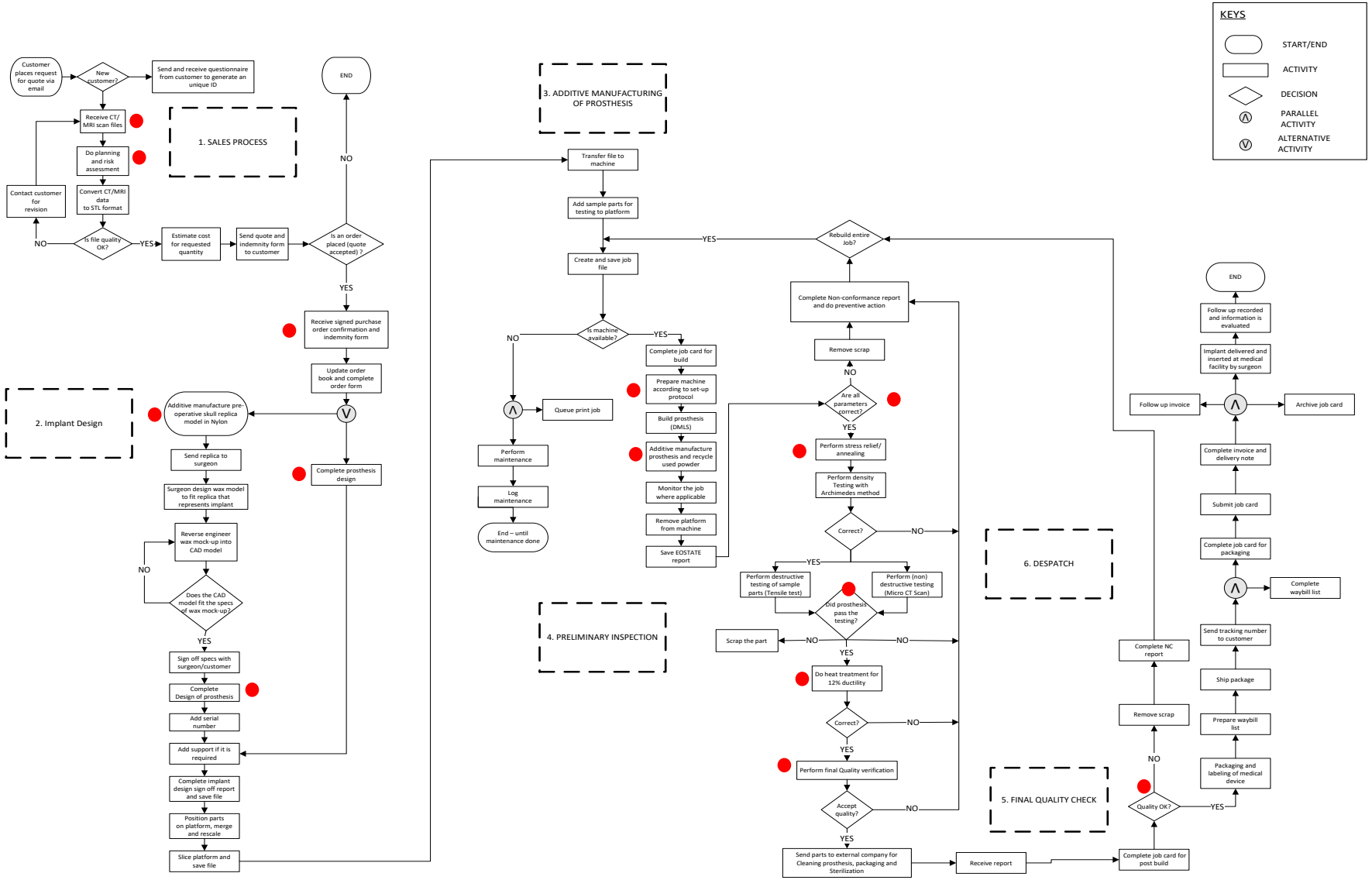


Figure C. 1 - Maxillofacial process chain (Bezuidenhout, 2016).

C.3 Entity Relationship Diagram (ERD)

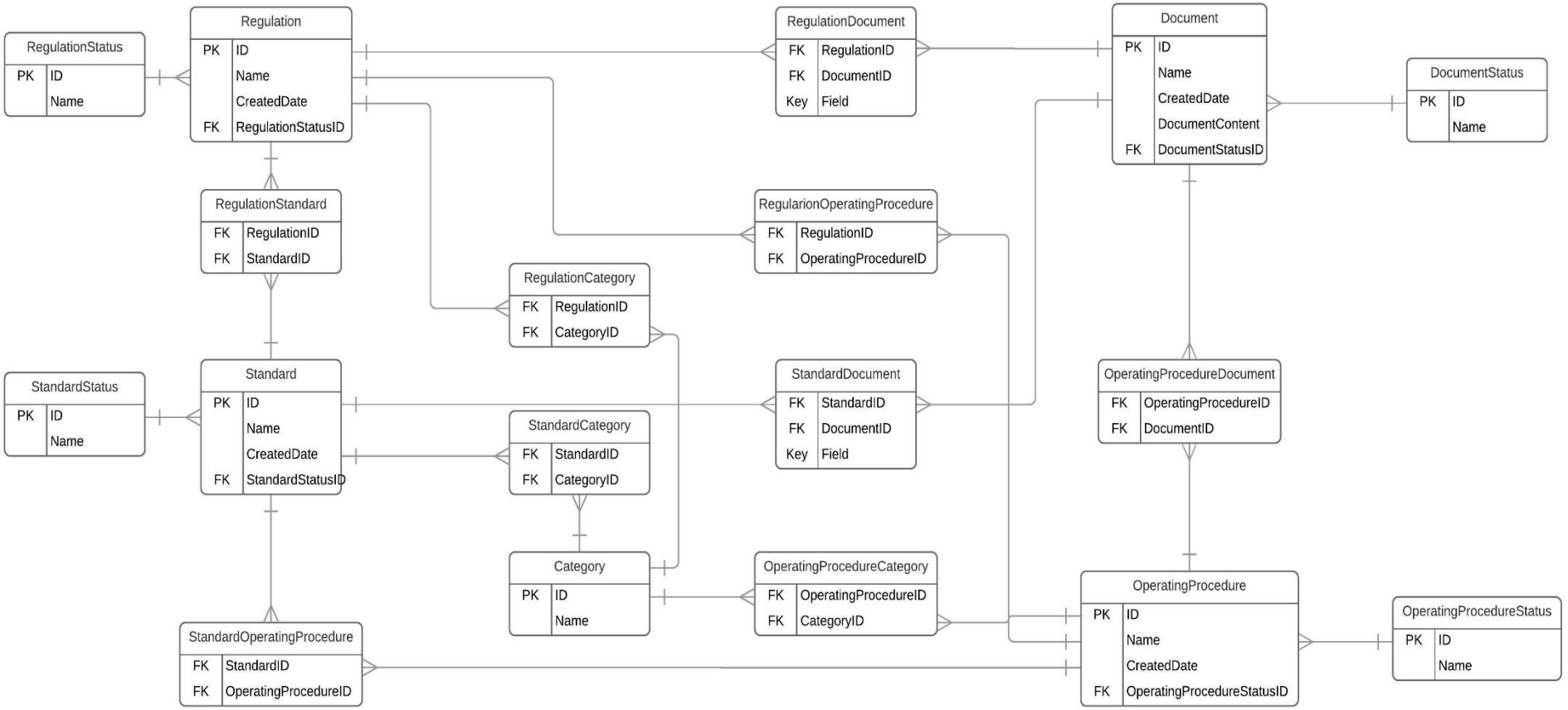
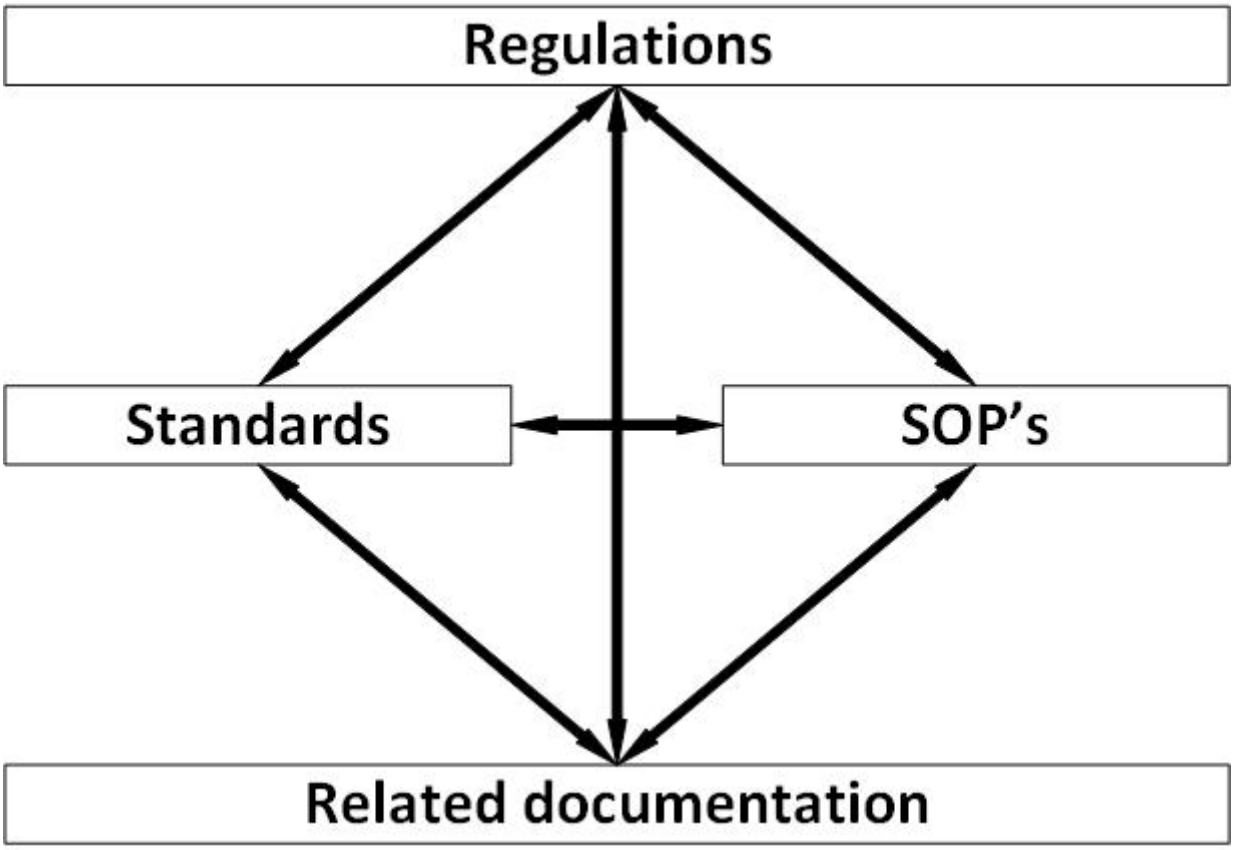


Figure C. 2 - Final ERD.



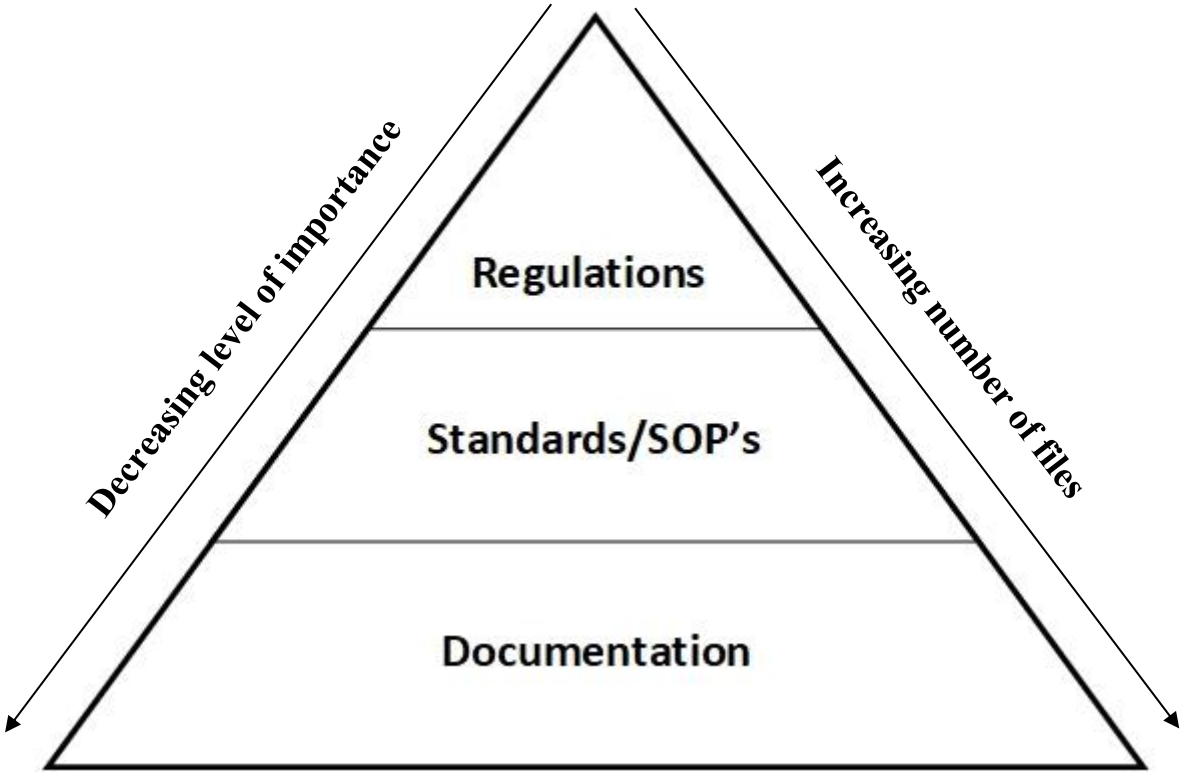


Figure C. 3 - Initial ERD planning.

C.4 Database Interface Planning

Table C. 2 - Initial interface planning.

ISO 13485 (Ed. 3)	25
Medical devices--Quality management systems--Requirements for regulatory purposes.	
Summary	
This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. Devices must be safe and effective.	

Date published	2016-03	**Category**	Quality management
Last review	2016	**Pointers**	Medical
Next review	2021		
Terms & Definitions			
		Related Standards	

Table C. 3 - Final interface planning.

ISO 13485 (Ed. 3)			25
Medical devices--Quality management systems--Requirements for regulatory requirements.			
Publication date	2016-03	**Category**	Quality management
Last review	2016	**Pointers**	Medical
Next review	2021		
Status	Active		
Terms & Definitions		**Summary**	
Medical device Sterile medical device Advisory notice			
Related standards			

C.5 Maintenance Policy Planning

Table C. 4 - Maintenance policy performance parameters.

Maintenance plan	
Activity	**Description**
Check database integrity	Check the accuracy and consistency of the data stored in the database.
Database backup	Backup the database regularly to ensure that no data is lost.
Validate database backups	Ensure that the database backups aren't corrupted and can be used to restore the data.
Validate recovery strategy	Ensure that the recovery strategy is practical and will ensure the recovery of data from the backups.
Validate backup strategy	Ensure that the database backups are done correctly and are stored correctly.
Check database performance and health	Check whether the database performs as it is intended to.
Update statistics	Update database statistics to optimise queries and improve the usability of the database.
Restore defaults	Restore all database defaults that may have been changed.
Reorganise and rebuild index pages	Ensure database indexes are reset to their defaults to improve the speed of data retrieval.
Shrink data	Shrink data contained in the database to minimise the amount of space used and maximise performance.
Clean-up tasks	Clean unnecessary data from the database to decrease use of space.
Report on maintenance	Compile a report of all maintenance activities completed for management taskforce members.

C.6 Implementation Planning

Table C. 5 - Implementation planning.

Act #	Activity	Requires regulations	Requires standard	High risk act.	Related regulations	Related standards	Existing SOP	Implementation order
1	Customer places request for quote via email		No			SOP	Y	
2	Send and receive questionnaire from customer to generate an unique ID		Maybe			ISO 13485; ASTM F2792; ASTM F2809; EN 1041	N	Round 3
3	Receive CT/MRI scan files		Yes	X		ASTM E2807		Round 1
4	Do planning and risk assessment	X	Yes	X		ISO/ASTM 20194; ISO/IEC Guide 51; ISO 13485; EN 14971; FDA Doc1; ISO TR15499; ISO TR16142		Round 1
5	Convert CT/MRI data to STL format		Yes			ASTM F2915; ISO/ASTM 52915		Round 2
6	Contact customer for revision		No			SOP		
7	Estimate cost for required quantity		No			SOP		Round 3
8	Send quote and indemnity form to customer		No			SOP		
9	Receive signed purchase order confirmation and indemnity form	X	Yes	X		ISO 13485; ISO/ASTM 20194		Round 1
10	Update order book and complete order form		Maybe			SOP		Round 3
11	AM pre-operative skull replica model in Nylon		Maybe	X		See activity 27 & 28 for relevant standards.		Round 1
12	Send replica to surgeon		No			SOP		

13	Surgeon design wax model to fit replica that represents implant		No			SOP		
14	Reverse engineer wax mock-up into CAD model		Yes	X		No standards found. Develop own SOP.		Round 1
15	Sign off specs with surgeon/customer		Yes			ISO 13485		Round 2
16	Complete design of prosthesis	X	Yes	X		ASME Y14.46; ASTM WK54856; ASTM WK59131; IEC 61160; ISO/ASTM 52910; ISO/ASTM CD 52911; VDI 3405 Blatt-3; EN 62366; FDA Doc3		Round 1
17	Add serial number		Yes			EN 1041; ISO 13485; ISO/ASTM 20194		Round 2
18	Add support if it is required		No			SOP		Round 3
19	Complete implant design, sign off report and save file		No			SOP		
20	Position parts on platform, merge and rescale		No			SOP		
21	Slice platform and save file		No			SOP		
22	Transfer file to machine		Maybe			ASTM WK58234		Round 3
23	Add sample parts for testing to platform		Yes			ASTM E8M		Round 2
24	Create and save job file		No			SOP		
25	Complete job card for build		Maybe			ISO 13485		Round 3
26	Prepare machine according to set-up protocol		Maybe	X		ASTM WK58226; ASTM WK58232; ASTM WK58225; ASTM WK 58228; ASTM WK58230; ISO DIS 41001; ASTM B214; ASTM B822; ISO 4497; MPIF 05; ASTM B527; ASTM B923; MPIF 46; ASTM B213; ASTM B964; MPIF 03		Round 1
27	Build prothesis (DMLS)	X	Yes			ASTM B348; ASTM F1108; ASTM F136; ASTM F1472; ASTM F2924; ASTM F3001; ASTM WK60552; ISO 5832-03; SAE AMS7003; NFPA 652; NFPA 654		Round 2

28	AM prothesis and recycle used powder		Yes	X		ASTM F3127; ASTM WK58221; ASTM WK58222; ASTM WK58223; ASTM WK58224		Round 1
29	Monitor job where applicable		Yes			ISO 17296-02; ISO 17296-04; ASTM WK58227		Round 2
30	Remove platform from machine		No			SOP		
31	Save EOSTATE report		No			SOP		
32	Perform maintenance		Yes			ASTM WK58231; ASTM F3127		Round 2
33	Log maintenance		No			SOP		
34	Check parameters	X	Yes	X		ASTM A370; ASTM E111; ASTM E6; ASTM F136; ASTM F1472; ASTM F2924; ASTM F3001; ASTM WK60552; ISO 17296-03; ASTM B331		Round 1
35	Perform stress relief/annealing		Yes	X		No standards found. Develop own SOP.		Round 1
36	Perform density testing with archimedes method		Yes	X		ASTM B962; ISO 3369		Round 1
37	Perform destructive testing of sample parts (tensile test)		Yes	X		ASTM E8M; ASTM F2971		Round 1
38	Perform non-destructive testing (micro ct scan)		Yes	X		ASTM F2847; AMS 2631; ASTM E1570; ISO 5579; ISO/ASTM NP52905		Round 1
39	Do heat treatment for 12% ductility		Yes	X		AMS 2801; ASTM WK58233		Round 1
40	Perform final quality verification	X	Yes	X		ISO 13485; ISO 9004; AS 9100; ISO 9001; EN 29001; ASTM E2910		Round 1
41	Send parts to external company for cleaning, packaging and sterilisation		Yes			MPIF 58; ASTM G131; EN556-1; ISO 11137; ISO 14937; ISO DIS 19227;ASTM F2847; ASTM F748; FDA Doc1; ISO 10993; ISO 11737; ISO TR 15499; ISO 11607; ISO 8828; ANSI/AAMI ST67; ANSI/AAMI TIR17		Round 2
42	Receive report		No			SOP		

43	Complete job card for post build		Maybe			ASTM WK58227		Round 3
44	Quality check	X	Yes	X		See activity 40		Round 1
45	Non conformance report and preventative action		Maybe			IEC 60812; ISO 13485		Round 3
46	Packaging and labelling of medical device	X	Maybe			ISO 11607; ISO 8828		Round 2
47	Prepare waybill list		No			SOP		Round 3
48	Ship package		No			SOP		Round 3
49	Send tracking number to customer		No			SOP		
50	Complete waybill list		No			SOP		
51	Complete job card for packaging		Maybe			ISO 13485		Round 3
52	Submit job card		No			SOP		
53	Complete invoice and delivery note		No			SOP		
54	Archive job card		No			SOP		
55	Follow up invoice		No			SOP		
56	Delivery of implant and insertion by surgeon	X	No			SOP		
57	Follow up interview and evaluation of information	X	Yes			ISO 10002; ISO 10003; ISO 10004		Round 2
Customer and company requirements								
1	Products must be biocompatible	X	Yes	X		ASTM F748; FDA Doc1; ISO 10993; ISO TR15499; AMS 2249; ASTM B215; ASTM E120; ASTM E1409; ASTM E2371; ASTM F3049; MPIF 01; ASTM F3122; ASTM F981;ASTM F1877		Round 1
2	Product life cycle should be 10 years		Maybe			EN 62366; IEC 61160		Round 2
3	Product must be non-toxic	X	Yes	X		ASTM F748; FDA Doc1; ISO 10993; ISO TR15499; ASTM F763; ISO 10993-18		Round 1

4	Product must not cause wear on surrounding bone structures	X	Yes	X		ISO 17853; ISO 10993-09		Round 1
5	Product must be free of internal and external defects	X	Yes	X		See activity 40		Round 1
6	Joints must be polished		Maybe			MPIF 58		Round 2
7	Implant body must be the same roughness as bone		No			SOP		Round 2
8	Process must conform with relevant quality standards.		Yes			ISO 90003; ISO 9001; ISO 13485; ISO 9004; ISO 19600; ISO 19011; ISO TR 10013; ISO 14969; ISO 10007; ISO TR 16142; ISO 14155		Round 1
9	Product must adhere to all relevant regulations	X	Yes	X		See activity 4, 9, 16, 27, 34, 40, 43, 46, 56 & 57; OHSAS 18001; OHSAS 18002; ISO FDIS45001; FDA Doc2; NFPA 91		Round 1

Appendix D

Expert Interview Transcriptions

D.1 Devon Hagendorn-Hansen Interview Transcription

Date: 08/05/18

Venue: Stellenbosch University, Stellenbosch

The framework was explained according to Chapter 4 using a fictional application of the framework to a small titanium bracket additively manufactured for aerospace applications.

Table D. 1 - DHH interview transcription.

DHH :	In SA in general, the safety standards are shocking. There aren't any OHSA standards related to AM powders. Even the international standards have holes in them. My theory is that AM is following suit with the asbestos phenomenon of old – we used them in our houses until someone proved it is bad. In AM people don't wear PPE, believing the machines are safe, effectively waiting for the day where someone says the powders are actually unsafe. The nano-particles fly around and is being breathed in by the operators. I was shocked to hear how some companies remove their machine filters – removing the filter and spraying it with a fire extinguisher! This should not be SOP. Companies are now developing methods such as flooding the chamber before removing the filter. So they are improving their methods.
Interviewer:	Exactly. This is the problem we saw. We are trying to determine if there aren't enough standards, or if they're just not well known.
DHH :	The problem is that ISO and ASTM don't necessarily reach all of the experts when developing a standard. As such, the standards have many holes in them. Many companies developing new machines or methods don't know what they are doing and are experimenting to find ways that work, and in such a case you're going to have to burn your fingers and learn from it. You have to learn with baby steps. Companies focus on developing their own standards for their process through these steps…and whether it is the right thing to do is difficult to say. Some companies' SOP's are safer than others. I wouldn't say there are many AM experts out there.

Interviewer:	This is exactly what my framework is aimed at. Why would someone just stepping into the field spend time and resources developing basic AM concepts when the standards are already there to explain these things.
DHH :	The problems with standards are 1) finding them and 2) buying them. Those are your 2 biggest problems. We don't want to spend the vast amounts of money on standards if we can get along without them. Is it justifiable until something happens? But people don't want to take the time and spend those resources to learn what not to do. A company would not spend money on that piece of paper rather than new equipment whilst it is running fine. Something else I just want to mention is that I am struggling with your visual representation. I struggle to follow the flow.
Interviewer:	Okay, I will go look at improving that.[8]
DHH :	So as I understand it, your second phase is like auditing your work? So I agree it should be done more often. If we look at stage 1, the admin agent is important, because the fact is that no one has time for those activities and you can't expect them to do this on top of their work, so someone will have to be given these responsibilities and time to handle these activities. I do think, however, that your first stage is missing the current state. You need to know what you have in terms of technology, standards etc. before you can move on.
Interviewer:	That is very true. I haven't considered that but think I will add it to the stage.
DHH :	Mapping the process also plays into that, and is a very important aspect of that stage. Another outcome I agree with is the identification of high risk activities, since we work with highly combustible titanium powders. The problem is though that you can review something without knowing any better, in which case it won't make a difference.
Interviewer:	That is why the framework has different phases, so that you can learn in the process and continually improve.
DHH :	You should just make sure to show this feedback in your diagram. But this is a very important stage, to know where you are and where you're going. Furthermore, I think stage 2 can become a subset of stage 1. I don't know if it should be a stage on its own.
Interviewer:	I will keep that in mind during the following interviews.

[8] It should be noted that the framework visual representation has been changed following this interview. Following interviews were done with the new visual representation.

DHH :	I want to know how you propose to ID standards, because it is quite difficult. It is like a bottomless pit…you can go how deep you want to go. I only focused on fire safety, and it was like a rabbit hole. It just kept pointing me elsewhere and each country has different standards for the same thing. It's also a question of affordability.
Interviewer:	You would just follow the methodology that I propose. Not only will that, in conjunction with the keywords, limit your search, but you would only spend money on the standards that you know you would use.
DHH :	I understand. And there I agree that the keywords should keep the process chain in mind. Something else to consider is that it is not always possible to categorise a standard into just one category. Some overlap. I would include them into both. When I save files, I save many of them in 2 places because they overlap.
Interviewer:	Yes, that is true. With the identification stage you would use the category descriptions to save the standards in only one category, as to avoid duplications. But you would add pointers to other categories, and in the database that standard would be saved as relevant to more than one category, without having to be saved more than once.
DHH :	The database structure you propose can be quite daunting. Why would they develop this database?
Interviewer:	First of all, they should outsource that to a developer if they do not possess the required expertise. I give an example of how the planning was done for a case study, so they can use that to help them. But this allows traceability and for the standards, SOP's, regulations and documentation to be available in an organised and useable manner.
DHH :	I agree that in medical and aerospace you need 100% traceability, and that will help during auditing and quotes etc. I would look at database management standards though.
Interviewer:	I will see if that is possible, but those standards are expensive to ascertain, and mostly work as guides as well.
DHH :	During stage 5, I think that before you develop SOP's for gaps where there aren't standards, you should loop through to search again and make sure that is the case.
Interviewer:	That is true, and this is the way it is handled. The first phase would be to plan the SOP's and where they should be developed, but then you do another iteration or two until you are sure of your list.

DHH :	I also have a problem with the training. Who is going to train them? And employees normally don't want to do the training before they know it is going to benefit them.
Interviewer:	That is true. But that is a problem for management to handle. They can decide whether they have the resources to outsource the training, or if one of the management team will be sent for training and relay that information, or if management want to handle the training themselves. As long as a regulation does not require it to be done a certain way, they can choose.
DHH :	Okay, so that is outside of your scope? You just propose the outcomes, they handle how it is done. I understand. And sustaining this system is very important, so I agree with the continual improvement part. However, the implementation part isn't realistic. People are resistant to change, unless they are personally involved. I think you should look at more literature regarding implementation, since that part won't work in my opinion.
Interviewer:	Okay, I understand. I will go look at the existing theories and literature and see how I can improve the implementation activities
DHH :	Overall, I think a checkbox tool for all the outcomes would be a good addition. Stage 3 should also be given a different name, since you don't only identify standards but also process them. Look for a better word to encompass all of that. Same with storage. That being said, I think the storage part is the oomph to your project. It would definitely help me to implement this, because I have all of my documents stored in one folder, and I should organise that.
Interviewer:	Those are great ideas. I will have a look at that.
DHH :	I'm not a fan of standards, because every case is different. But you also need to start somewhere. You need to learn from someone. It is also too expensive for small companies to buy all of these standards. They would rather figure it out for themselves.
Interviewer:	Most people in AM don't like using standards, and it is a lot of extra effort. But for the industry to grow and become commercially viable, standards and regulations will have to play a part. And smaller companies will have to decide between the cost of standards versus the cost of learning through mistakes. But they can also start by buying only those standards they deem most useful and build on it at a later stage.
DHH :	Okay, well that is everything I can think of right now.
Interviewer:	Great, thank you for your help.

D.2 Prof. W. du Preez Interview Transcription

Date: 02/07/18

Venue: CUT campus, Bloemfontein

The framework was explained according to Chapter 4, using the maxilla-facial application as an example (Case Study 1).

Table D. 2 - WdP interview transcription.

WdP :	During your categorisation phase, you mention 'Field of Use' as one of your categories. I would say that your field of use should be the first thing that you should know. Because if you want to interpret the other standards and determine if they are actually relevant, you have to understand the field of use, or the customer specifications. I don't know if you've looked at that, but I think in terms of the order in which these activities are done, you should start with field of use. First determine your standards relating to that field and then go from there.
Interviewer:	Yes, I agree that is the order in which things should be done, and they are done in that order, to some extent. The user requirements or specifications are identified in the conceptualisation stage so that all the stakeholders understand the greater context of the product being manufactured. From there, these requirements are kept in mind when reviewing the categories, and then when devising the keywords. That then assures that the person searching for standards is keeping those requirements relating the product's use in mind. Finally, the reviewers will also keep those requirements in mind when reviewing the standards, ensuring that only the standards that are truly relevant remain.
WdP :	Okay, so when you do stage 1, you make sure the list of requirements are complete? And all of the reviewers and stakeholders should be involved from the start…to avoid that you have to backtrack at a later stage?
Interviewer:	Yes, that is also why the taskforce is compiled before you start going through the stages, to ensure that these requirements are captured beforehand and everyone involved in the process understands them.
WdP :	You also mentioned the database of standards. Did you develop this database yet?

Interviewer:	No. Since this is such a company specific factor and I don't have the necessary expertise, I decided to rather give guidance regarding what the database should be able to do and the company can then get a professional to do it for them at the hand of this description.
WdP :	Okay, so you don't prescribe a specific software? You just give guidance regarding the ultimate outcome?
Interviewer:	Yes. And this is also something I was adamant about. I don't want to prescribe what a company must do. I want companies to be able to adapt this framework to their company. So by guiding them through the process and only describing the ultimate outcomes, they have the freedom to adapt the framework to their company, whilst also achieving the goals that the framework aspires to. This is meant to be the 'alpha' version of the framework, and the idea is to allow companies to use it and use the feedback to make the necessary changes.
WdP :	Okay, I understand that. So at this stage you have only categorised and stored these standards in a file system?
Interviewer:	Yes. And this proves the problem with this method of storage for someone like CRPM. If you have document that is linked to 5 standards, you will have to save it in 5 different places, or have a great memory to find it in the one place that you have saved it. But once this is scaled up to hundreds of standards, and thousands of documents, that becomes a real problem.
WdP :	Yes, you will have to save that in many places. So if you have this database, you just have to save it once but can reference or access it from many standards?
Interviewer:	Exactly
WdP :	That is definitely very important. It will make your life much easier.
Interviewer:	And help with accreditation processes.
WdP :	That is true. I also think that it is great that the framework focuses on guidance rather than being more like a methodology. It looks very good. If you look at your diagram as well. A while back we looked at some concurrent engineering processes and we also worked with circular structures like this, which implies that there is constant interaction between the various stages and activities. I think that is something you should mention clearly from the start, is that the framework is based on continual involvement of all of the stakeholders. Practically I think it is good that you reflect on the ultimate requirements during all decisions that are made. That interaction, also with each other, is very important.

	I think it is also important that the users recognise that you don't do each stage apart, but that they all work together, feed into each other and reflect on one another. It is a categorisation of concepts for the purpose of managing each aspect, but ultimately they should work in harmony with each other and be connected at all times.
Interviewer:	Yes, I agree with all of this. There should always be that aspect of continual improvement. If you change one thing, you should take into account how that affects the other stages and activities as well.
WdP :	Yes. I like the diagram, and I assume you also explain the use thereof in your thesis. And all of the arrows imply that there is a concurrent interaction between the stages and phases. I also feel the diagram is effective in explaining the use of the framework. I cannot think of a way to change it for the better. I also think it helps a lot to show the PDCA diagram before this framework diagram so that the users first understand the iterative nature of the continual improvement.
Interviewer:	I agree that would be beneficial.
WdP :	Stage 4 could perhaps also be described better by something like 'capturing' rather than storage, implying that they are captured in some intelligent manner that allows access to them. But other than that it looks really good. It is clear and sets in place a good process regarding how one will practically apply this.
Interviewer:	Do you agree that the framework will ensure identification of most relevant standards and regulations?
WdP :	Yes I do.
Interviewer:	My final question is this: Is there, in your opinion, an opportunity to apply the framework in your institution, and would you be willing to do so?
WdP :	Yes, I believe there is a need for such a framework and I would be willing to try the framework. It is relevant and timely and will assist in the process of full qualification of Ti6Al4V AM parts.
Interviewer:	Great! Thank you very much.

D.3 CRPM Interview Transcription

Interviewees: Andre' Heydenrych, Gerrie Booysen, Johan Els

Date: 03/07/18

Venue: CRPM, Bloemfontein

The framework was explained according to Chapter 4, using the maxilla-facial application as an example (Case Study 1).

Table D. 3 - CRPM interview transcription.

GB :	In terms of case studies, I think you could speak to Dr. Johan van der Merwe at SU regarding his work with Dr. Erasmus on knee replacements. You could even speak to George about a case study on manufacturing a scapula.
JE :	I think the biggest differences will be regarding the test methods, since there will be movement in these joints whereas the maxilla-facial implants are static.
Interviewer:	I also think that will be the case, and it will be interesting to see what differences the framework picks up, and how that differs from what we initially thought.
GB :	Furthermore, in terms of the keywords you identified, it would perhaps be prudent to look at ISO 13485 to see what keywords they have identified as important and see if that can add to your list. There are many keywords about governance and quality. The problem that I foresee, however, is that with some of these keywords that you have identified you are going to find an incredible amount of standards. How will you govern that and filter this?
Interviewer:	That is exactly one of the problems that this framework addresses. Because if you type in AM standards, you will only identify a few. However, by using the methodology I propose, you start to identify standards regarding safety and risk management, which is linked to AM standards, and expand your list as you go. But then you will limit the knowledge gained through the keywords and the admin agent will ensure that only the relevant knowledge is captured.
GB :	So you will actually look at the list of standards each standard refers to? Because I just think your search can become incredibly wide if you don't govern it in some way. I know that AM is too small a pool, but you need some way to ensure the keywords don't get too generic and inclusive.

Interviewer:	I agree, and that was a problem that I experienced initially. But that is why the framework is designed like it is, and the methodology takes this into account. By using the framework and methodology together, you can control this through the keywords and framework vision, as well as govern this during the reviewing stage. By making this a manual task, there is also the aspect of opinion that eliminates irrelevant standards, which isn't present if you do a blind search on the standard organisation's websites.
GB :	Another thing I'm thinking of now in terms of keywords is software validation at either medical or quality management. It is becoming quite a problem for us, ISO 80002. All of our machine's software must now be validated.
Interviewer:	I have not captured that standard yet, and it shows you the importance of this continual loop of improvement. I have now been told that this is an important standard, and another iteration of standards identification will ensure you identify other standards which may help you during this process. I will also add this to the list of medical keywords.
AH :	And the problem is that this standard does not fall under AM, but it is very important to our process.
Interviewer:	That is exactly what I am trying to help companies with, is bridging that gap between AM and other relevant standards which also exist.
GB :	Another document you should perhaps look at is the Medical Device Directive. It's not a standard, but it would also be beneficial.
Interviewer:	Thanks, I will also have a look at that. And now you can see that just by adding two pieces of knowledge to out knowledge pool, I can potentially identify many more standards which will ultimately benefit you.
GB :	I'm not sure if you address this in your framework, but the Medical Control Council (MCC) which is now becoming the South Africa Health Product Regulations Authority (SAHPRA) are perhaps going to implement new regulations for South African products. We currently work according to the European standards, but this may have to change. If you want to sell in America, you have to look at the FDA. So you should just keep in mind that we aren't going to look at everything.

Interviewer:	Yes, that is a good point. And that is another area where the framework can help you achieve your goals. You need to specify your vision and goals for using this framework, whether it is only for South African production or to sell in the European market, and from that identify your stakeholders – is it SAHPRA or the EN? And all of that is then built in and taken into account when searching for the standards. But this is knowledge that I don't have, which is why this knowledge must first be captured, so that I can do my job thoroughly.
GB :	With relation to the database idea – when you buy a standard from lets say ASTM, only one person is allowed to use that standard. You won't be able to load it onto a server and share it with anyone in the company. So will it basically only give you an overview of the standard?
Interviewer:	Well, with such a database it is possible to restrict the access of certain people to certain documents. But that is why you will have to implement the standards by means of SOP's, which are then linked to those standards. Then the knowledge that is contained in that standard, which only management may access, is captured and available to the relevant technical personnel in SOP's which they understand and can reference whenever they require.
GB :	How does ASTM's website compare to this? Can you also do a search for certain keywords and then find the relevant standards?
AH :	I haven't tried before. You can search for specific standards though.
Interviewer:	You can search for such keywords and find relevant standards. And if you prefer this method, you can use this instead of the proposed methodology. The framework guides you to the end result, but doesn't prescribe how you must get there. You should just take note that ASTM's website won't necessarily refer to ASQ standards. Due to the competitive nature of standardisation in the field, ASTM would ather refer to their own standards, or ISO's. So you are already losing some information. Therefore it would be great to have a national database which comprises of all of these standards, which isn't linked to a specific SDO and gives you all of the information to use.
GB :	I agree.
JE :	But such a database will be governed by the need for it, because it will cost money to maintain it.

Interviewer:	That is true. That is why I propose this. I think a following project or some committee should look at the possibility and need, and decide for themselves. But in the meantime, you can develop this database for yourself. Then it is easy to reference any standard you have, as well as its related documentation.
GB :	Well, we have to go through our standards once a year to see what new standards have been developed as part of our management review.
JE :	And this is currently a manual process. You know, search for one specific standard, see if it is the newest version etc.
GB :	Yes, and our safety representative which we hired lets us know if there are new international developments. We actually started with his initial list.
Interviewer:	This framework will help make this task much easier. We know that standards are only reviewed every 5 years. So you can do a search for the standards in the database that have reached 5 years since their last review, and only look at those. Ultimately, this can later be an automated process. This is also something that the admin agent can handle.
GB :	We actually have a few places where this framework is easily integratable. We can already review our list of high risk areas with what you have identified, and look at which of those activities actually have standards linked to them. And our list of essential requirements will also play into that. This framework is mostly focused on medical?
Interviewer:	Yes, this case study is a medical application, but we are also looking to apply it to an aerospace case study.
GB :	I think you should rather leave that for now, because that is a whole other can of worms. They have many other regulations and organisations etc.
JE :	I think the framework will work the same. It is just the application within the field that is more difficult, since it is completely different regulating authorities and rules. But I think the framework is great. I think it will work well and easily.
GB :	I am just worried that a person will end up with an unending amount of standards that will be very difficult to filter.
Interviewer:	As I mentioned, this will be limited through various actions, but I will go through that again and make sure there are enough measures taken to avoid that happening.
AH :	It is also worth noting that there aren't standards for everything.

Interviewer:	Yes, that is true. That is why the implementation phase is so important. So that you develop SOP's or work instructions where standards don't exist. That being said, do you believe that there is a need for such a framework and database?
GB :	Yes, we do. To commercialise this technology we will need to produce the same quality parts repeatedly over time.
AH :	And it must be possible to outsource the production to other companies worldwide, so definitely.
Interviewer:	Do you think the framework sufficiently aids the user in the process of standards identification, storage and implementation in a manner that is easy to use?
AH/GB/JE :	Yes, it does.
GB :	However, I am still slightly unsure about how easy it is to use, especially with the keywords and filtering part.
Interviewer:	Would you be willing to apply the framework in your institution and test how well it works?
GB :	Yes, I would be open to that.
Interviewer:	Great! Perhaps that can be part of the beta testing phase. The final question I have is if you could just provide your overall impression of the study and its results.
GB :	It is a very relevant study that can be used by AM businesses, universities etc.
JE :	Like I said earlier, I think it is a great idea that will work well.
Interviewer:	Well, thank you very much for your time.

D.4 VUT Interview Transcription

Interviewees: Hendrik van der Merwe, Dr. Malan van Tonder, David Mauchline

Date: 04/07/18

Venue: VUT Science and Technology Park, Van Der Bijl Park

The framework was explained according to Chapter 4 using a fictional application of the framework to the planning process of a baby bottle teat additively manufactured from a mixture of polymer materials.

Table D. 4 - VUT interview transcription.

HvM :	If we were to consider a product such as this, we would have many risks associated. If the teat comes off from the bottle and the child asphyxiates, we have to be able to show how we developed the product. So we would have to use a process like this one you are proposing to ensure that the product is safe and we can answer all of these questions.
Interviewer:	That is exactly the type of case where this framework comes in handy. Through its use, you use all of the resources available to make sure that the product is safe, works well and is produced to your required quality measures.
HvM :	This framework also doubles as a test to make sure you are on the right path, because the AM process happens rapidly and some aspects may go unnoticed and you could make mistakes and end up with a product that is dangerous.
Interviewer:	Exactly. So now you can do these type of checks, that may have been skipped, to make sure that production of the product is actually feasible and commercially viable, whilst also mitigating the risks by adhering to regulations and standards. Furthermore, if you want to R&D such a product, where does one start searching for the applicable standards?
HvM :	Well we would just phone current suppliers of such bottles and use what they mention.
Interviewer:	I'm not saying that is the wrong way to do this, but they might not want to divulge company information to a competitor, and they also don't make these products by means of AM. So you won't capture any AM standards that may make the product much easier, or contain information that is very important. This framework uses their knowledge and builds on that.
DM :	What about SABS? Isn't it easy enough to get that information from them?

Interviewer:	It's not as easy as you think. The keywords you use for the search must be very specific and well thought out, something you don't do when doing such a blind search. Also, many of these SDO's don't refer to other SDO's standards, since it is a very competitive market. And if you only search for AM standards, you will only capture a fraction of the standards applicable to AM, since they don't actually contain the word in it.
DM :	I've tried before to get a hold of the SABS, but it's not a body of knowledge as one would expect. For AM you have ASTM F42. But I agree that there are other standards that they don't cover, which are still applicable to AM.
HvM :	This framework isn't meant for prototyping, is it?
Interviewer:	No, it is definitely for manufacturing processes of a product that will be manufactured on a regular basis.
HvM :	That makes sense. I think it is also great that the framework has accompanying tools, since that is something I would want to use. I think you should just make sure that there are enough tools to facilitate each stage.
Interviewer:	I will have a look at that and test it against a case study.
MvT :	These methodologies will also make sure that if we have two people identifying standards for different products, that it is done in the same way, which means that you can always ensure the same outcome regardless of who does it.
Interviewer:	Yes, which is the whole idea of standardising the basics and innovating on top of that platform. So you know the basic activities which are the same for any product will be done in the same way every time.
HvM :	This framework, with the database idea, encompasses a bit of product life cycle management into it as well. Documenting what the decision-making process was etc.
Interviewer:	Yes, that part came from the whole traceability aspect of ISO 9001.
HvM :	This framework can even be expanded to include a market related aspect to it. You know, start asking the market related questions as well and how the standards will play into that.
Interviewer:	That is a very interesting suggestion. I think that is a valid point, since things like ISO quality standards accreditation play a large role in the market, and this can be added or linked to this framework. I think it would be a good topic to investigate in the future.

HvM :	I have one problem with your framework though. There are some risks that the framework addresses very well, but one part I don't see in it is the viability of the product in the end. One can make a great product, but maybe no one wants to buy it. I think you should include a validity element, to show that this product doesn't just adhere to the standards, but is also in demand. Also, does the product do what it is intended to do? This is something many engineers forget about in the product development phase.
DM :	I don't think that should be part of this framework though. I think it's outside this project's research scope.
Interviewer:	Viability of the product in the market is not part of my scope, but I do think that could be added to some extent in the future, looking at the effect of standards and regulations on the market. But validation of the product and how it functions is part of the framework. That is covered by the customer requirements. With each iteration, you revisit the requirements, identify standards and regulations relating to those requirements and during the implementation phase you make sure those requirements are taken care of. And then the loops make sure that this is thoroughly checked.
HvM :	Okay I understand. The customer requirements part is then very important in my view. I just want to make sure that you don't do all of this for five rounds and then remember about some customer requirement you forgot.
Interviewer:	That is completely understandable, and why you should use this framework. Because that is one of the first steps you do, and you revisit it many times throughout. Even if you think you handled them all, you must re-evaluate them with every iteration.
MvT :	Just something to keep in mind, is the way I see it the first phase is basically verification and the second phase validation. Verification meaning you make sure it is possible to produce a product that adheres to these standards and requirements, and validation meaning you actually produce the product to determine if it really does what it is supposed to do.
Interviewer:	That is a very interesting observation, and true. Perhaps I will use that explanation.
HvM :	I think you should go look at CEDA's growth wheel, which is completely different, but I think it would be worth looking at how it works and maybe using some of their philosophies.

Interviewer:	I am unfamiliar with them, but will go have a look. Maybe I can use that to better the framework.
MvT :	TIA is pressuring all technology stations to ISO 9001 accreditation. If that continues to happen, this framework would be very useful. TIA would most likely want all technology stations to use the same standards, to make it easier for them to audit. So perhaps you should speak to them about beta testing the framework.
HvM :	Another idea would be to look at existing products that are in production, run it through your framework and see what you some up with in comparison.
Interviewer:	Yes, that is what I did with the first case study, and I got promising data from it, But I will also look at TIA, or leave it for future researchers to do during beta testing.
HvM :	I was in Germany recently for an AM symposium, and there are companies that are being created to do exactly what your framework is focussing on. To help companies with this exact decision process. So I think you have a good idea here, that will contribute value to the field. This type of decision making process is definitely a hot topic in the area.
MvT :	I think your framework even has an element of process development to it. Even if we look at a process, we would also look at the customer requirements, but it is not necessarily a specific product that you are manufacturing. But this framework will still be applicable and useful.
Interviewer:	That is very true, and I should perhaps look into explaining it in that sense. Because the framework would remain the same even if you consider a process rather than a product. But I thank you for your feedback, it will definitely help a lot.

D.5 Jean-Pierre Serfontein Interview Transcription

Date: 06/07/14

Venue: Aerosud, Johannesburg

The framework was explained according to Chapter 4 using a fictional application of the framework to a small titanium bracket additively manufactured for aerospace applications.

Table D. 5 - JPS interview transcription.

JPS :	I disagree that admin personnel will do the identification step. My view is that admin personnel will do the categorisation, as in they will search for all the standards and create a big pool. And in identification, you want your technical personnel to determine what is applicable or not, because the admin personnel don't know the technical details and the relevance of standards.
Interviewer:	I understand and agree. The framework is set up in the same manner. During the first phase of the identification stage, the admin personnel identify all standards they deem relevant from the keywords and create a big pool of standards. Thereafter, the technical personnel review the standards according to each category and determine which are indeed relevant and useful. They then have the final say in which standards will be retained and used. However, the admin agent doesn't necessarily have to be admin personnel, but can be a junior engineer, or a technical head that has taken the task upon himself. The name just refers to the task of handling all the associated admin.
JPS :	Another question is, considering different industries that are stable and have been around for many years, what are they doing there versus AM?
Interviewer:	Do you mean the differences between conventional and additive manufacturing?
JPS :	No, just a completely different industry. AM is a very specific process. Lets look at billet manufacturing. There is a specific number of standards that exist to create these billets, to ensure that they comply to the correct AMS standard for example. What storage mechanism exists for those streams? Because you are now proposing a stream for AM. How is your stream different from those that already exist?
Interviewer:	I understand what you are saying. I will definitely have to look into that. So far I haven't seen anything like this database. The companies I have spoken to all just go onto ASTM's website and search for AM standards
JPS :	That's the way we do it now.

Interviewer:	The problem I found in AM specifically, is that there is this concept of redesigning the wheel, where companies develop their own SOP's, when there are actually standards out there regarding the same thing. In the case of billets, the standards are already there and they have been tried and tested, and everyone knows about them and where to find them. With AM, this isn't the case. They have only started developing standards which are process or product specific. So what I am saying is that you need some place to group this knowledge, making it easier to find standards, and they can then be tried and tested, allowing more feedback and ultimately better standards in the AM field.
JPS :	Maybe I can elaborate more. If you look at aerospace grade materials, we have a particular database, which is just a publication from a committee that establishes what the material properties are for a given material manufactured to this specific standard. So it's not a pooling of standards, but it is a pooling of materials manufactured to a specific standards and which is a characterised material property set for that material. It can be used with confidence. So if you speak about RAPDASA running something like this, I think these kind of committees already exist.
Interviewer:	Yes, that is true. In this case that is only the background of where this idea started. I am aware that these committees exist and want them to take this idea to the next level. However, what I am proposing in the framework is for each company to develop such a database for themselves. I am sure your company already has such a database, but that is because you are a big and established company in a highly regulated field. Many other companies don't have such a sophisticated database, but still rely on a folder system.
JPS :	I would also say that these companies don't have the configuration management which we have in place because it's a mandatory requirement from NADCAP to have in place.
Interviewer:	Exactly. Although this framework can be used by all companies, a less established company would develop the database as well. You wouldn't need to do Stage 4 to the same extent, but you would just integrate your database with the other stages. But that is only the database stage. Is this database I propose similar to what you have at Aerosud?
JPS :	With this database, are you proposing a system for a company, or more a procedure they can follow?

Interviewer:	Definitely it is a procedure they can follow to develop a database such as the one I am proposing
JPS :	How does this differ to existing system that people use?
Interviewer:	The novelty of the framework does not lie in the database, but rather the system that is developed through use of the whole framework. A database alone will not help you identify, store and implement standards and regulations. So the database I would imagine is very similar to many that are already in use, with the differences being its customisation to standards, regulations, SOP's and supporting documents. However, the systems that companies already use are all confidential. So the feedback I have received is that this is a good way to get to where they are, which is the ultimate goal of the framework.
JPS :	My concern is this: what other industry companies are you looking at?
Interviewer:	At this stage it is only medical and aerospace.
JPS :	Ourselves and Denel are probably the most regulated companies, since we are NADCAP approved. If you look at someone like Aeroservices and Epsilon, they are low key aerospace manufacturers. They probably don't focus too much on these requirements, but are governed by the CAA ensuring that their configuration management exists. What I am getting to is that we have inhouse process flows that are specifically designed this way, that give you the relative link to the process or specification that you are drawing into. So I am seeing the perspective that you don't have enough exposure from the more regulated guys versus the 'cowboys'. The nature of what we understand within the aerospace manufacturing environment is that there is a specific way in which we are regulated to show conformity to the specification that the OEM's require. So you may have to expand on existing platforms and how they can be incorporated into your framework, as opposed to developing the wheel again.
Interviewer:	I understand and agree. Just to clarify, I know there are quite a few accreditation frameworks out there, and the other day I did look at the NADCAP checklist. But this framework is designed to work in conjunction with such a checklist, rather than doing the same thing. And this is why I didn't want to make the framework too specific, because I wanted a company to be able to integrate it into their systems that already exist.

JPS :	That is what I am seeing. But the thing is, we won't want to adapt our system. But your process may be more applicable to a start-up, or a company that may require this sort of implementation.
Interviewer:	I understand. The idea is definitely for you to decide whether you require help from this framework or not. In your case it may not be necessary, but it will help other companies develop their systems to the level you are now. For AM to grow, you need more adoption of the technology and use it in more fields. So through use of this framework, it is easier to start an AM company and get to where you are now. But I understand what you are saying, and I will definitely have a look at the other companies you mentioned as well. That is another problem I have, identifying aerospace companies in SA.
JPS :	You can speak to Denel Dynamics, who focus on UAV's and missiles, so I don't have too much understanding in terms of what they are doing. I can maybe give you a contact.
Interviewer:	That would be great.
JPS :	Another point is that ISO 91000/AS 91000 have particular ways of defining many of the points you look at in your framework. So I think it would be prudent to look at what they do in terms of your outcomes. I see a close cross-over. For example, it requires us to have flow charts regarding how we do particular actions. It also handles risk mitigation through redundancies.
Interviewer:	I would definitely like to have a look at that, if I am able to buy it. Because the framework is set up in such a way that I believe they will work together. You can implement the methods mentioned there to achieve the outcomes stated in the framework. But first you will have to identify the standard, which requires this framework.
JPS :	Also, if you focus on aerospace, it may be a good idea to look at the CAA requirements as well. We conform to NADCAP. They do an audit and from their findings you have to change your processes to adhere. With the CAA, if there are irregularities, the CAA would note the finding during their audit and they will have to fix it. So perhaps it would be good to look at what the CAA require, specifically in terms of the manufacture of parts. I think you would be able to benefit from these frameworks and adapt them to AM. From our experience in terms of international conferences and what people are saying about AM, specifically powder bed and SLS processes, is that it doesn't work, you don't get good part quality etc.

	That's not linked too greatly to ISO, since it still does require a lot of development. So I am not saying that your process is wrong, I just think if you want to go the aerospace route, it would be beneficial to look at these existing frameworks.
Interviewer:	That is a good idea, I will definitely have a look at that. It is great insight, something that I obviously can't understand from my limited knowledge in the field of aerospace.
JPS :	I think this would be more applicable to companies battling with their configuration management, and their quality standards.
Interviewer:	Yes, I agree. In terms of the framework, do you think it is the right way going about things?
JPS :	Yes, it is what we do. We plan, we implement and we check. We just call it change management. Because that's what is required from our OEM's. However, I think there is definitely a difference between where medical is and where aerospace is. I don't know if there is a cross over or what sort of regulations they adhere to. But there is a definitive relation between what we do and what you propose.
Interviewer:	That is great to hear. I will still have to determine whether it is worth it to apply this to aerospace at this time, since it is very regulated.
JPS :	Yes, that is very true. I think your best bet would be to look at the AS91000, NADCAP since Boeing, Airbus and Bombardier all utilise that specific framework. And again, NADCAP is the committee regarding the storage method you are talking about. From what I have heard, they are also developing such a committee for AM. Internationally they are setting up different consortiums to handle that pool of AM standards and development of them. We just conform to what the OEM's ask from us. Every major OEM has their own standards, which often incorporate ASTM or ISO standards, but they don't necessarily overlap much. NADCAP may not propose this philosophy in terms of what you must do, but it can give you a more concise perspective of the different functions that you are proposing.
Interviewer:	Yes, well thank you very much. I will go have a look at those.
JPS :	I think perhaps you should come again and talk to our quality management personnel, and our configuration management lady. They might help you more than we were able to.
Interviewer:	I will definitely keep that in mind, thank you very much.

D.6 CSIR Interview Transcription

Interviewees: Dr. Lerato Tshabalala, Marius Vermeulen

Date: 06/07/18

Venue: CSIR National Laser Centre, Johannesburg

The framework was explained according to Chapter 4 using a fictional application of the framework to a small titanium bracket additively manufactured for aerospace applications.

Table D. 6 - CSIR interview transcription.

LT :	For me, the critical part is 'What is the need?'. Do SMME's actually need this? This is a type of continual framework that is known to, or is supposed to, work. But it may have loop holes in many areas. If it is not driven by a specific need, this may be a problem. Are you proposing that this is something that CSIR should have, ending up with a repository of standards for a list of parts?
Interviewer:	Yes, that is one use, but that is focusing only on the database stage of the framework. If you R&D a new project, it is quite expensive. The idea of this framework is to help you find standards and regulations to aid you in developing a new product without having to develop SOP's in areas where standards already exist.
LT :	Our work is mostly guided by the ASTM standards, and that is mostly the repository where we search. I think in AM, a lot of institutions are now advancing into the development of standards, keeping in mind the ASTM/ISO standards development framework. So I am wondering how these to frameworks work together? Since AM is so new, there are links to the existing standards. If you look at standards regarding the surface texture of a product, the standards would be completely different, and therefore we want to benchmark them for a specific application. So, that is how we are working. We are trying to understand and then develop a standard. It's not that there are standards already existing.
Interviewer:	I understand that in many cases you work in areas where standards aren't developed yet. The idea of this framework is to help a company find the standards that are already developed. In many cases, the underlying technology has been standardised. As such, there are some standards which could be used. The idea isn't for the development of those standards.

	The problem is that on ASTM's website, you will find only some of the standards relevant to AM, such as those developed by F42. But there are many others. It is a very competitive and profitable field to develop AM standards, so they will not want to refer you to other SDO's. Therefore, someone stepping into the AM field only know of these big SDO's, but are unaware of the other SDO's who have standards that they can use. This is also the case with established AM companies, since everyone is technically still 'new' to the field. ASTM and ISO don't want to focus on areas where the standards already exist to avoid duplication of efforts. Therefore, a gap in their standards could mean that it already exists. This framework helps to identify those standards. If you research a field at CSIR, this will help you do that research into standards thoroughly, also ensuring that you don't duplicate efforts. Although this helps integrate the standards as well, you can implement those standards into the standards you develop
LT :	It feels a bit too wide. There is always a need within an industry. But what you are saying, is that this is a framework you would like SA to adopt. Who would have access to this? Should CSIR have their own repository that a SMME could use?
Interviewer:	There are two parts to the project. On the one side, I believe such a database should be made national for companies to use and to advance the field of AM in our country. But the framework itself is something you will use in your company. Any company can use that to develop their own database filled with relevant standards and regulations, which they can use for accreditation purposes, for R&D etc. That is why I didn't make it prescriptive in nature so that it can be moulded to your company. This is also still the alpha version, therefore I want to give companies a chance to use it and amend it from their feedback. Do you think I should rather focus on a specific industry first, and prove the need in that industry?
LT :	That would make sense to me. If you have done a case study and proved a specific need. Because if your scope is too wide, you might lose traction of what should fit in.
Interviewer:	I understand that. The framework is set up that you don't go too wide with capturing standards, through the use and revision of key words.
LT :	How you control that is my concern.

Interviewer:	I understand. But that is where you use and adapt the keywords.
LT :	But the keywords will be guided by the need? Because if you only focus on AM, you yourself have seen how wide your scope could go.
Interviewer:	I understand what you are saying. I did do a case study on a medical application.
LT :	You see, it's not a company. It's a specific product, a specific need. That's why I am saying, this should be focused to a specific part. For a structural part, the standards could go into the thousands, but for something like a part of a landing gear, it would be more focused.
Interviewer:	Yes, this is true. The framework is focused on a product within a company. Thus, it will have a specific need and be guided by it. Even with a structural part, the framework, and the keywords, will help you to limit which of those thousands of standards are identified. Then that list will be shortened through revision, until you are left with only those that are actually relevant.
MV :	At stage 2, I would comment that you should include safety into your seven categories, since it is not explicitly stated.
Interviewer:	That is very true. I will have to rethink the categories to include that.
MV :	What is the topic to your thesis?
Interviewer:	It's still a work in progress, but basically a framework for the identification, storage and implementation of standards.
MV :	For a company?
Interviewer:	Yes, for a company. But you would apply it to a specific product within the company. Lerato, do you still have any concerns from earlier?
LT :	I think I understand it a bit better. What level are you at now? Are you ready to hand in yet?
Interviewer:	This is the evaluation phase. I will use this input to better the framework, after which I will do another medical case study. So it is still in the development phase. However, since this is a alpha version, it will have to be applied to a few companies after the completion of my project to work out any resulting kinks. Unfortunately, I can only test its applicability in certain cases since the AM companies are very secretive regarding their products.
LT :	So is this more of a literature review on standards to determine what standards are applicable to a specific part?

Interviewer:	Well, yes, that is a part of it. The case study will be to test the framework and determine whether I can capture the relevant standards and regulations using this framework. From my first case study, I have seen that the framework does help certain companies in determining relevant standards.
MV :	So what standards libraries are you taking into account? Is it part of your study to determine the different libraries?
Interviewer:	Yes. I also propose three methodologies for identifying standards. Most people, like yourselves as Lerato has told me, refer to the SDO's they know. In your case, you go to ASTM and search for a few keywords you can think of. From that they follow the related standards and go from there. But the framework helps you to build on the knowledge you have and broaden it. I have looked at 25 different SDO's. Some libraries are easy to use, other quite difficult to understand. But this framework helps anyone be able to do this process efficiently. Once you have your database in place, you have so much more knowledge to build on.
LT :	How long does it take you to do a case study?
Interviewer:	The first one took me about a month. The next time around I believe it will take about two weeks, but this time around it will be me using the analogy method.
LT :	How easy will it be for someone else to use this framework on their own case study
Interviewer:	Actually it will be pretty easy. Like I said, I try to make the framework not too prescriptive. So it should be easy to apply to most products. The limiting factor would be the company. A large, established company could possibly already have developed SOP's regarding these stages and would be pretty set in their ways.
MV :	So what is your question to us?
Interviewer:	Whether this framework is something you believe could work. I know CSIR does a lot of R&D for various products to which this framework would be applicable.
LT :	I think that when you focus the framework on a specific product, this would be very similar to the quality management principles we apply. But we find that it is always a challenge to close the loop.

Interviewer:	The framework is similar to some quality management frameworks, but the key focus is not directly that of managing the quality, but rather of identifying standards and regulations. So this can be used as part of your quality management systems.
MV :	My opinion is that the process is very logical. The thing that I believe most companies will struggle with is stage 3. The rest makes sense, and I believe it would make sense to most. But the third stage is potentially very difficult. It is a fairly clear path. But I have two issues there. The first is that identifying the correct standard is not easy. There are many standards that conflict with one another. So understanding which is relevant will be difficult. From what I see here, it is not addressed. The other problem is the gaps in the standards. ASTM, which is the biggest of those AM libraries, maybe have 10 standards. VDI maybe have 2 or 3. ISO has 3. So there are huge gaps. So, to a large extent, you need to find standards outside of the AM sphere that apply to some extent. Those are the things we struggle with at CSIR. I think there is a lot of value if you could extend the framework to add an identification tool to guide you through these problems.
Interviewer:	I understand. The methodology I have added to stage 3 helps with the identification part. But you were correct, I don't look at which standards are actually relevant, but that is something which should be left up to the company. It is very product and company specific. From my case study, I have learnt that it depends on what resources they have available, not which standards is the best. As such, the factors dictating the decision will differ between companies. The idea is to rather identify all standards, and they can decide which to use and which to eliminate. This is definitely a difficult and tedious process, but it is something they will have to do regardless. However, the gaps part is addressed in the thesis. After your first loop, you will identify the areas where gaps exist. You can then focus on those areas, and if you still cannot find standards, you can use this knowledge to comment on standards and help SDO's determine where they should focus their efforts. I also looked at AMSC's list of standards, but most of them aren't AM specific. But there are many existing standards that can be used in the AM field. So the idea is to show companies what is out there, and they can decide on their own what they want to use and how.

MV :	Okay, I understand. Another problem I foresee is that companies don't WANT to use standards. They use standards because they have to, for whatever reason. Standards generally rather make life more difficult than making life easier. For someone stepping into the field, it is difficult to know what is important. We still don't know which standards are really important or the best, and it will only matter once something happens to someone and legal matters ensue. So maybe you should look into a tool to say that if you are in this industry, you should look at these and these organisations and regulations and standards, and develop a tool for this. Because most people don't know what they need. This is also why I mentioned safety. ASTM have recently identified this as a key focus area, because companies don't know what they have to do to comply to safety standards. So how do they find those sources saying what is important in your field? In stage one you mention all of the involved parties, and these people are very critically involved parties.
Interviewer:	That is very true, and I will definitely look at those concerns. But to a large extent, the conceptualisation phase will help them determine where they need standards.
MV :	Maybe you should also focus a section of your dissertation on the reasons why people use standards, because that will help you investigate these concerns[9]. One reason is because they have to, another is to get contracts. If you are in court, you have to be able to show that, within reason, you have done your part to ensure that the product is safe and does what it's supposed to. In aviation, we look at mass production of parts for someone like Airbus. They provide you with the standards and regulations your parts should adhere to. Essentially, standards don't necessarily help you produce a better product.
Interviewer:	This is very true. In my case study, many of the standards I identified were in areas the company were struggling with. So these people can then use these standards to develop SOP's.
MV :	Well, one of the reasons for looking at standards would be to gain knowledge, and this would trigger a different type of search.
Interviewer:	That is very true, and I agree it would be beneficial to look into why people use standards.

[9] As suggested, literature was investigated to determine the various reasons for using standards. For more information, refer to Section 3.4.3.

MV :	In principle, I think that this is correct. But I would just add a few things. In the yellow part, that is where you decide WHY do I want to find standards, and the green part is HOW do I find standards. Just add some tools to help with this. Are you looking at specific AM processes?
Interviewer:	I am trying to focus on as many as possible, but I know currently standards are only focussing on things like laser sintering and titanium products.
MV :	The reason for this is because people want to sell parts that are of high value and critical parts, and typically polymer products don't fall into that category. So you find some standards in those materials, but the need isn't there. These parts aren't being used in such regulated fields.
Interviewer:	Do you perhaps have products where this framework can be tested? Like a case study?
MV :	If you would like to do a case study, we can speak to my colleagues at ARLAC in Wonderboom. We have some aerospace parts we are converting into printed parts, and the parts aren't for Boeing. It is our aircraft, so we decide everything. Thus, it is much easier than producing a part for someone like Boeing, who tells you what standards to use.
Interviewer:	That would be great. I will definitely keep that in mind.

Appendix E

Case Study 2 Appendices

E.1 List of Additional Standards

Table E. 1 - List of additional identified standards.

Key	
R1	Standard contains information that is imperative for the success of the process i.e. key standards.
R2	Standard contains information that will actively improve process.
R3	Standard contains information that may prove of some help, but is not considered urgent.
F	Standard contains information that is relevant to future endeavours.
I	Standard contains relevant information regarding the overall process which may be of value at a later stage.

Medical		
R3	ASME B89.4.23-201x	X-ray Computed Tomography (CT) Performance Evaluation Standard
R2	ASME V&V 40	Assessing Credibility of Computational Models through Verification and Validation: Application to Medical Devices
R3	ANSI/AAMI/ISO 14937:2009 (R2013)	Sterilization of healthcare products -General requirements for characterization of a sterilizing agent and the development validation and routine control of a sterilization process for medical devices
R1	ANSI/AAMI/ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (supersedes ST81)
R3	AAMI TIR37:2013	Sterilization of health care products-Radiation-Guidance on sterilization of biologics and tissue-based products
R2	ASTM F2475-11	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials
R1	ASTM F2847-10	Standard Practice for Reporting and Assessment of Residues on Single Use Implants and Single-Use Sterile Instruments
R2	IEEE 3333.2.1-2015	IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling
R1	ISO 19227:2018	Implants for surgery -- Cleanliness of orthopedic implants -- General requirements
Design		
R3	IEEE P3333.2.5	Standard for Bio-CAD File Format for Medical Three-Dimensional (3D) Printing
R1	FDA Stat	Design Control Guidance For Medical Device Manufacturers (This Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001)

Process		
R2	ASME V&V 50	Verification and Validation of Computational Modeling for Advanced Manufacturing
R1	ASTM WK60552	Additive Manufacturing-Finished Part Properties-Standard Specification for Additive Manufacturing Titanium Alloys via Powder Bed Fusion
R1	AWS D20.1	Standard for Fabrication of Metal Components using Additive Manufacturing
R1	ISO/ASTM WD 52942	Additive manufacturing -- Qualification principles -- Standard guideline for qualifying machine operators of powder bed based laser beam machines in aerospace applications
R3	SAE AMS7011	Additive Manufacture of Aerospace Parts from T-6Al-4V using the Electron Beam Powder Bed Fusion (EB-PBF) Process
R3	ANSI/AIHA/ASSP Z9.7-2007	Recirculation of Air from Industrial Process Exhaust Systems
R1	ASTM F3091/F3091M-14	Standard Specification for Powder Bed Fusion of Plastic Materials
R3	ANSI B11.21-2006 (R2012)	Safety Requirements for Machine Tools Using Lasers for Processing Materials
R1	ANSI Z136.9-2013	American National Standard for Safe Use of Lasers in Manufacturing Environments
R1	MSFC-SPEC-3717	Specification for Control and Qualification of Laser Powder Bed Fusion Metallurgical Processes
Raw materials		
R1	ASTM WK53878	New Specification for Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 1: Feedstock materials
R2	ASTM WK55610	New Test Methods for the Characterization of Powder Flow Properties for Additive Manufacturing Applications
R2	ASTM D4000-16	Standard Classification System for Specifying Plastic Materials
R2	Batelle Memorial Inst.	Metallic Materials Properties Development and Standardization (MMPDS) Handbook
R1	FDA 21CFR 820.140	Handling
R1	FDA 21CFR 820.150	Storage
R1	ISO 3953:2011	Metallic powders - Determination of tap density
R2	ISO 9276:Parts 1-6	Representation of results of particle size analysis
R1	NFPA 484-2015	Standard for Combustable Metals
R2	NIST AMMD	Additive Manufacturing Material Database
R1	SAE AMS4998E	Titanium Alloy Powder 6Al 4V
R1	SAE AMS7002	Process Requirements for Production of Powder Feedstock for use in Laser Powder Bed Additive Manufacturing of Aerospace parts
Post-processing		
R1	ASTM WK60265	New Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder-bed Fusion
R1	ISO/ASTM PWI 52908	Additive manufacturing -- Post-processing methods -- Standard specification for quality assurance and post processing of powder bed fusion metallic parts

R1	ANSI/AIHA/ASSP Z9.4-2011	Abrasive-Blasting Operations – Ventilation and Safe Practices for Fixed Location Enclosures
R3	ASTM B600-11(2017)	Standard Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces
I	ASTM E407-07(2015)e1	Standard Practice for Microetching Metals and Alloys
R1	ASTM F3301-18	Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion
R1	SAE AMS2801B	Heat Treatment of Titanium Alloy Parts
R1	SAE ARP1962A	Training and Approval of Heat-Treating Personnel
Testing		
R1	ASTM WK47031	New Guide for Nondestructive Testing of Additive Manufactured Metal Parts Used in Aerospace Applications
R1	ISO/ASTM CD 52905	Additive Manufacturing — Non-Destructive Testing and Evaluation — Standard Guideline for Defect Detection in Metallic Parts
R1	UL 2904	Standard Test Method for Particle and Chemical Emissions from 3D Printers
R3	ASTM B946-11(2016)	Standard Test Method for Surface Finish of Powder Metallurgy (PM) Products
R3	ASTM D638-14	Standard Test Method for Tensile Properties of Plastics
R1	ASTM E1226-12a	Standard Test Method for Explosibility of Dust Clouds
R2	ASTM E1316-18a	Standard Terminology for Nondestructive Examinations
R1	ASTM E1447-09(2016)	Standard Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method
R1	ASTM E2375-16	Standard Practice for Ultrasonic Testing of Wrought Products
R2	ASTM E647-15e1	Standard Test Method for Measurement of Fatigue Crack Growth Rates
I	ASTM B646-17	Standard Practice for Fracture Toughness Testing of Aluminum Alloys
R1	ANSI B11.TR5-2006 (R2017)	Technical Report for Machines -Noise Level Measurement Guidelines - A guide for measuring
Quality management		
R1	ASTM WK59813	New Guide for Hazard Risk Ranking and Safety Defense
R1	ABS Volume 4	Guide for Software Systems Verification
R1	ABS Volume 5	Guidance Notes on Software Provider Conformity Program
R1	ANSI/ASSP Z10-2012 (R2017)	Occupational Health and Safety Management Systems
R1	ANSI/ASSP Z590.3-2011 (R2016)	Guidelines for Addressing Occupational Hazards and Risks in Design and Redesign Processes
R3	ANSI/ASSP Z690.1-2011	Vocabulary for Risk Management (National Adoption of: ISO Guide 73:2009)
R1	ANSI/ASSP Z690.2-2011	Risk Management - Principles and Guidelines (Identical National Adoption of: ISO 31000:2009)
R2	ANSI/ASSP Z690.3-2011	Risk Assment Techniques (National Adoption of: IEC/ISO 31010:2009)

R1	ANSI B11.TR6-2010	Safety Control Systems for Machines
R1	ANSI/ISO 12100:2012	Safety of Machinery - General Principles for Design – Risk Assessment and Risk Reduction
R2	ANSI B11.20-2017	Safety Requirements for Integrated Manufacturing Systems
R3	ANSI B11.TR7-2007	Designing for Safety and Lean Manufacturing: A guide on integrating safety and lean manufacturing principles in the use of machinery
R3	FDA 21CFR 820.186	Quality System Record
R1	FDA 21CFR 820.65	Traceability
R3	FDA 21CFR 820.70	Production and process controls
R1	FDA Reg	Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
R2	ANSI Z136.7-2008	American National Standard for Testing and Labeling of Laser Protective Equipment
R2	NFPA 68-2013	Standard on Explosion Protection by Deflagration Venting
R1	NFPA 69-2014	Standard on Explosion Prevention Systems
I	SAE EIA649C	Configuration Management Standard

E.2 Case Study 2 Implementation Planning

Table E. 2 - PKR implementation planning.

Act #	Activity	Requires regulation	Require standard	High risk act.	Related regulation	Related standards	Existing SOP	Implementation order
1	Doctor request for medical devices		No			SOP	Y / N	
2	Receive CT/MRI scan files		Yes			IEEE P3333.2.5		Round 2
3	Do planning and risk assessment	X	Yes	X		ASME V&V 40; ASTM WK59813; ANSI/ASSP Z10; ANSI/ASSP Z590.3; ANSI/ASSP Z690.1; ANSI/ASSP Z690.2; ANSI/ASSP Z690.3		Round 1
4	Convert CT/MRI data to STL format		Yes			See Case Study 1.		Round 2
5	Contact doctor for correct scans		No			SOP		
6	Estimate cost for required quantity		No			SOP		
7	Send quote to doctor		No			SOP		
8	Receive signed purchase order confirmation	X	No			SOP		
9	Update order book and complete order form		No			SOP		
10	Design plastic knee replica		Yes	X		FDA Stat 1; IEEE 3333.2.1		Round 1
11	Design plastic model cutting guide		Yes	X		See activity 10		Round 1
12	Design plastic model implant		Yes	X		See activity 10		Round 1
13	Complete pre-operative design		No			SOP		

14	Add serial number for all 3 medical devices		No			SOP		
15	Add support if it is required		No			SOP		
16	Send to doctor for confirmation and specs sign-off		No			SOP		
17	Create and save job file		No			SOP		
18	Complete job card for build		No			SOP		
19	Prepare machine according to set-up protocol		Maybe	X		ASTM WK53878; ASTM D4000; iso 9276; NIST AMMD; FDA 21CFR 820.140; FDA 21CFR 820.150		Round 2
20	Build plastic patellofemoral implant		Yes	X		ANSI B11 TR6; ANSI B11.20; ANSI B11.TR7;FDA 21CFR 820.70; ASME V&V 50; ANSI Z136.9; ASTM F3091		Round 1
21	Build plastic cutting guide		Yes	X		See activity 21.		Round 1
22	Monitor job where applicable		No			SOP		
23	Remove platform from machine		No			SOP		
24	Save EOSTATE report		No			SOP		
25	Courier pre-operative medical devices to doctor		No			SOP		
26	Receive trial run report from doctor		No			SOP		
27	Complete non-conformance report and do failure analysis	X	Yes			ANSI/ISO 12100; FDA 21CFR 820.65; FDA REG; ABS VOL 4; ABS VOL 5		Round 2
28	Design final cutting guide		Yes			See activity 10		Round 2
29	Design final patellofemoral implant		Yes			See activity 10		Round 2

30	Complete final design		Yes			See activity 10		Round 2
31	Add serial number		No			SOP		
32	Add support if required; save file		No			SOP		
33	Send files to doctor for confirmation		No			SOP		
34	Position parts on platform, merge and rescale		No			SOP		
35	Slice platform and save file		No			SOP		
36	Transfer file to machine		Yes			See Case Study 1.		Round 2
37	Add sample parts for testing platform		Yes			ASTM WK47031		Round 2
38	Create and save job file		No			SOP		
39	Complete job card for build		No			SOP		
40	Prepare machine according to set-up protocol		Yes			See activity 19		Round 2
41	Build cutting guide		Yes	X		ASTM WK60552; AWS D20.1; ISO/ASTM WD 52942; SAE AMS7011; ANSI Z9.7ANSI B11.21; MSFC-SPEC-3717; ASTM WK55610; Batelle MMPDS; ISO 3953; NFPA 484; SAE AMS7002; UL 2904; ANSI B11.TR5; NFPA 69		Round 1
42	Build patellofemoral implant	X	Yes	X		See activity 41.		Round 1
43	AM part and recycle used powder		Yes			See activity 41.		Round 2
44	Outsource lining	X	Yes			See Case Study 1.		Round 2
45	Monitor job where applicable		No			SOP		

46	Remove platform from machine		No			SOP		
47	Save EOSTATE report		No			SOP		
48	Perform maintenance		No			SOP		
49	Log maintenance		No			SOP		
50	Check parameters	X	Yes			See Case Study 1.		Round 2
51	Perform stress relief/annealing		Yes	X		See Case Study 1.		Round 1
52	Perform density testing with archimedes method		Yes			See Case Study 1.		Round 2
53	Perform destructive testing of sample parts (tensile and wear test)		Yes			ASTM D638; ASTM E1447; ASTM E647; ASTM B646		Round 2
54	Perform non-destructive testing (micro ct scan)		Yes			ISO/ASTM CD 52905; ASTM E1316; ASTM E2375; ASME B89.4.23		Round 2
55	Do heat treatment for 12% ductility		Yes	X		ASTM F3301; SAE AMS2801B; SAE ARP1962A		Round 1
56	Perform final quality verification	X	Yes	X		FDA 21CFR 820.186; FDA REG; ISO/ASTM PWI 52908		Round 1
57	Fit final cutting guide on final implant on knee replica		No			SOP		
58	Check quality		Yes			See activity 56.		Round 2
59	Outsource cleaning, packaging and sterilisation		Yes	X		ANSI/ISO 14937; AAMI TIR37; ASTM F2847; ISO 19227		Round 1
60	Receive report		No			SOP		
61	Complete job card for post build		Maybe			SOP		
62	Quality check	X	Yes			See activity 56.		Round 2

63	Non conformance report and preventative action		Maybe			See activity 27.		Round 3
64	Packaging and labeling of medical device	X	Maybe			ASTM F2475; ANSI/AAMI/ISO 17664.		Round 3
65	Prepare waybill list		No			SOP		
66	Ship package		No			SOP		
67	Send tracking number to customer		No			SOP		
68	Complete waybill list		No			SOP		
69	Complete job card for packaging		No			SOP		
70	Submit job card		No			SOP		
71	Complete invoice and delivery note		No			SOP		
72	Follow up invoice and archive job card		No			SOP		
73	Implant delivered and inserted during surgical procedure	X	No			SOP		
74	Follow up recorded and information evaluated	X	Yes			See Case Study 1.		Round 2
<u>Customer and company requirements</u>								
1	Implant and cutting guide should fit together perfectly.		No	X		SOP		Round 2
2	Cutting guide should be non-toxic and not cause adverse reactions in surgery.	X	Yes			See activity 64; ASTM WK60265		Round 1

E.3 Partial Knee Replacement Process Chain

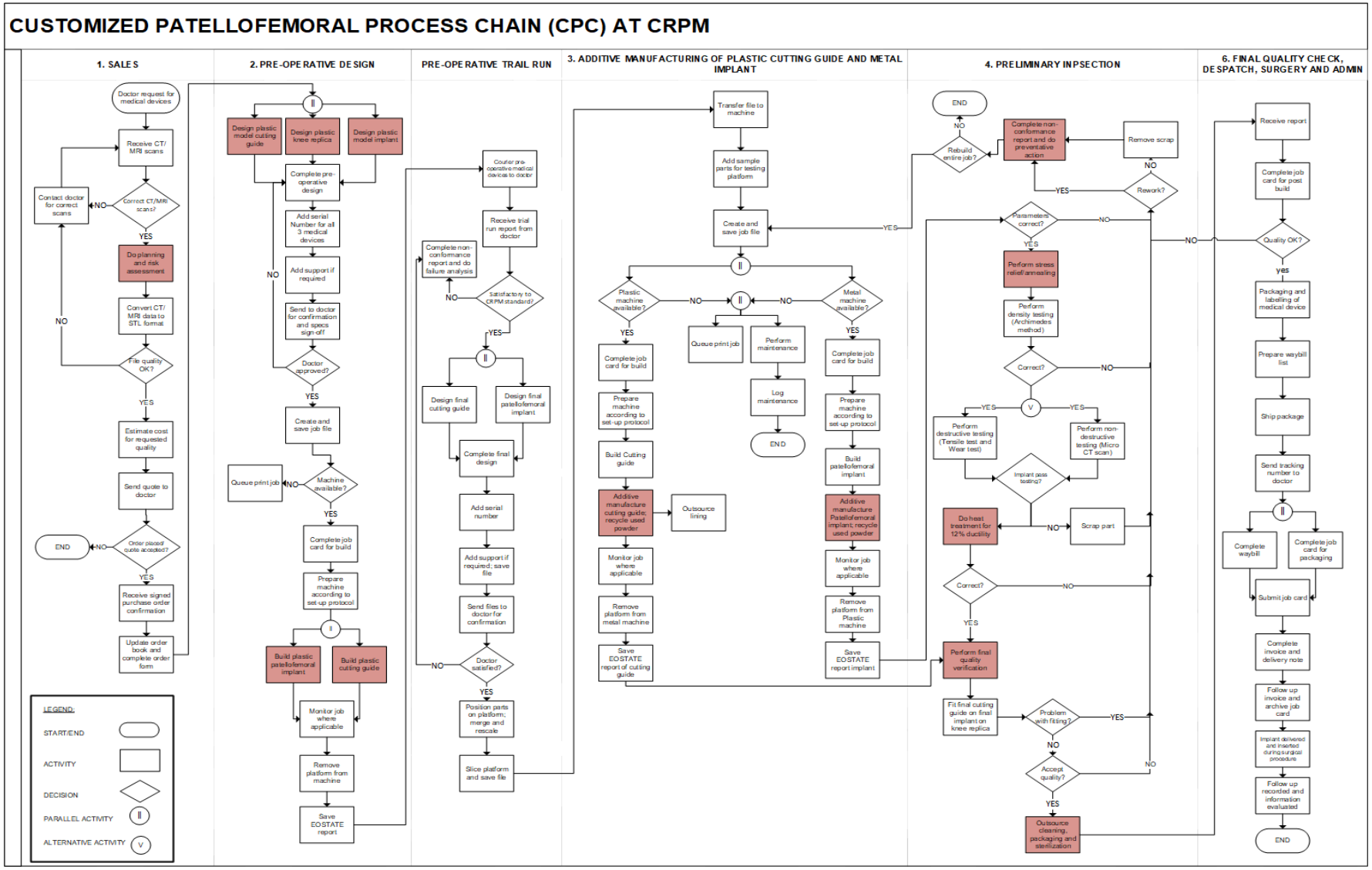


Figure E. 1 - Partial Knee Replacement process chain (adapted from (Henning, 2018)).