DEVELOPMENT OF A QUALITY FRAMEWORK TO MONITOR, EVALUATE AND CONTROL BROAD-BASED ENGINEERED NANOMATERIALS.

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2018

DEVELOPMENT OF A QUALITY FRAMEWORK TO MONITOR, EVALUATE AND CONTROL BROAD-BASED ENGINEERED NANOMATERIALS.

by

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Submitted in fulfilment of the requirement for

DOCTOR OF PHILOSOPHY

IN MANAGEMENT SCIENCES

QUALITY MANAGEMENT

In the

Department of Operations and Quality Management

Faculty of Management Sciences

at

Durban University of Technology

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24 January 2019

DATE

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BComm; LLB; LLM; LLD

25 January 2019

DATE

May 2019

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ABSTRACT

Predictions of new technologies are often difficult to make, however Engineered Nano Materials (ENMs) is undoubtedly a novel technology and a revolutionary science that has the potential to bring substantial change to society. Scientists and researchers have demonstrated the ability to manipulate atoms and convert them to be lighter, more resilient, durable, high precision with superior strength qualities. Studies have indicated that although ENMs have been used in many products for several years, a formal, practical, systematic and robust system of assessment of risks with validated quality protocols are absent globally and are urgently required.

There are inherent risks relating to ENMs which include environmental, toxicity, societal impacts and economic uncertainty. Very often all it takes is one incident, one oversight or one mistake (such as the recent listeriosis outbreak) to put an entire community and industry at risk. The volatility, mobility and increased reactivity of the ENMs is what presents risks for users and they need to be aware of such risks. Hence, it would be prudent for researchers, scientists and manufacturers to find and implement measures to mitigate and eliminate these risks. Globally, products that contain ENMs are not subject to any special legislation or regulations relating to research, production, handling and disposal of these materials which compels users to take precautionary measures. In the absence of compulsory regulation, voluntary or self-implemented measures may be effective in reducing risks. Thus the aim of this study was to develop an integrated quality framework that will assist in understanding, predicting and managing the risks associated with ENMs.

The methodology comprised of an empirical study using a mixed method research approach. Questionnaires were administered and interviews were conducted with experts in the field of nanotechnology. The literature review and the results of this study confirmed the areas of risks that required to be addressed. The findings from the study were then used to develop a first generic or broad-based framework to ensure compliance with safety, health, environment, quality and nanotechnology risk standards. This

framework combined and integrated several management systems which allows an organisation to work such systems as a single unit with unified objectives. The integrated management framework that was developed included international standards for safety, health, environment, quality and nanotechnology (which included ISO 9001-2015; ISO 14000-2015; OHSAS 18001; ISO 17025; ISO TR 13121: 2011 and ISO TR 12885: 2008). The framework was designed to guide an organisation in improving efficiencies and reducing costs as duplication of management systems are avoided.

The proposed name for the new framework is Safety, Health, Environment, Quality and Nanotechnology (SHEQN) which incorporated technical reports with international standards.

Further, as part of this study, a computer programme was developed to classify the human risk exposure to ENMs. This computer application would assist the organisation in establishing and implementing their “Risk Management Strategy” at an accelerated pace.

It is hoped that the SHEQN Framework presented in this study will serve as a theoretical platform for organisations wanting to formalise their management of ENMs to facilitate commercialisation and ultimately promote the use of safer nanotechnology.

ACKNOWLEDGEMENTS

I wish to record my deepest gratitude and appreciation to all those who have supported, assisted and guided me in obtaining this qualification.

Firstly to my family – my wife Sundri who was my main inspiration and support. Throughout my academic career, you have been the most supportive and caring partner. Through your fervent prayers and divine blessings my academic journey has finally been fulfilled. To my daughters Vishantham and Myurie and sons-in-laws Martino and Kevlyn - thank you for your patience, encouragement, support and motivation throughout this process.

This PhD thesis would not have been possible had it not been for my Supervisor, Professor Shalini Singh and co-supervisor Professor Karunanidhi Reddy whose expertise, guidance and constructive advice certainly made this work something I can be proud of. I would also like to thank Mr. D. Singh for his assistance with the statistical aspects of this thesis.

My colleagues Mr. Rajen Moodaliyar and Mr. Robin Ramlagan for their kind support and encouragement during this journey.

My close friend and confidant Mr. Bavan Naicker, whose advice and knowledge was a constant source of inspiration.

Above all, I would like to thank God Almighty for giving me the strength, courage and fortitude to complete this study through His interventions.

DECLARATION

I hereby declare that the thesis submitted for the Doctor in Philosophy Degree in Management Sciences: Quality Management in the Department of Operations Management, Faculty of Management Sciences at the Durban University of Technology is my original work in the text and the bibliography has not been submitted to any other institution. I further declare that all sources cited or quoted are indicated and acknowledged in the bibliography.

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LIST OF ACRNOYMS

CNT	Carbon Nano tubes
DNA	Deoxyribonucleic Acid
ENMs	Engineered Nanomaterials
EU	European Union
GLP	Good Laboratory Practice
GMO	Genetically Modified Organism
ISO	International Standards Organization
KMO	Kaiser-Meyer-Olkin Measure
NIOSH	National Institute of Occupational Health and Safety
nm	Nanometre
OECD	Organization for Economic Corporation and Development
PDCA	Plan, Do, Check, Act
PPE	Personal Protective Equipment
QA	Quality Assurance
QMS	Quality Management System
REACH	Registration, Evaluation, Authorization and Restrictions of Chemicals
SECQA	Safety, Environment, Corporate Governance, Quality and AIDS
SHEQ	Safety, Health, Environment and Quality
SHEQN	Safety, Health, Environment, Quality and Nanotechnology

SIDS	Screening Information Data Set
SPC	Statistical Process Control
SPSS	Statistical package for Social Sciences
SQP	Strategic Quality Planning
TQM	Total Quality Management
µg / m^3	Concentration of air pollutant approximately one-millionth of a gram per cubic metre

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CHAPTER 1 - Introduction

Background and Overview of the Study

The history of nanotechnology can be traced back to prehistoric times. Evidence of this can be seen in cave walls where early civilizations used naturally occurring carbon sized nanoscale materials which integrated with porous surfaces to form what is known today as “rock paintings”. The 1960’s and 1970’s saw the birth of the first Engineered Nanomaterials (ENMs) in the form of metallic nanopowders used in magnetic recording tapes (Choi and Mody, 2009).

The potential benefits of ENMs are undoubtedly immense, but so too are the hazards and risks. Sokull-Kluettgen (2012) emphasise that the risks of ENMs on human health and the environment is still relatively unknown. Whilst scientists and researchers race to develop this technology, health, safety, environmental and risk issues are often neglected (Aithal and Aithal, 2016). According to Qui (2016), a study of this nature becomes important as the risks relating to ENMs cannot rely on traditional risk management approaches because of the unique and unknown characteristics of these nano engineered materials.

This chapter addresses the aims, objectives and rationale of this study. Throughout the study, evidence is presented on the hazards and risks of ENMs. Thereafter and based on the literature review and the research conducted, an integrated quality framework incorporating quality, health, safety, environment and risk management and a computer software program will be developed to asses, mitigate, reduce and control health, environment and safety risks.

1.1 Introduction to Nanotechnology

According to Staggers, McCasky, Brazelton and Kennedy (2008), nanotechnology is defined as the design and manipulation of materials at the atomic and molecular scale. At the heart of nanoscience is miniaturisation, that is, the ability to make materials or products smaller, faster and cheaper without losing functionality. The rapid growth of nanoscience over the past few years has resulted in a significant impact on the development of new materials and products. This technology has the potential to be a major economic driver in the near future.

The ensuing commentary supports the notion that materials science must play an important role for nanotechnology to reach its full potential. Consequently, it was deemed necessary to introduce the understanding of size, description, application, risks and behaviour, among others, of ENMs, before engaging with their management.

1.1.1 Size

To understand the unusual world of nanotechnology, an understanding of the units of measure is required. Corbett, McKeown, Peggs, and Whatmore (2000) define a nanometre (1nm) as 10^{-9} meter and is approximately 80,000 times less than the diameter of an average human hair and 10 times the diameter of a hydrogen atom. According to Bronsor and Strickland (2007), a nanometer (nm) is one-billionth of a meter, smaller than the wavelength of visible light and a hundred-thousandth the width of a human hair. Barnard (2006), describes ENMs as the study of objects that are between a thousandth and a millionth of a millimetre in size.

1.2 Engineered Nano Materials (ENMs)

This section outlines the description, application, associated risks and the behaviour of ENMs. The intention for including these sections is to contextualise ENMs.

1.2.1 Description of ENMs

Delgado (2010) claims that, through the versatility in product applications and chemical structure, ENMs application can be endless, making it difficult to understand and control. Due to this nano-scale, the properties (electronic, mechanical, biological and chemical) can change radically, resulting in the creation of new functional materials. Yehia (2012) states that materials engineered to the nano-scale can show different properties when compared to what they exhibit on a macro-scale, thus enabling unique applications. For example, opaque substances become transparent (copper) or stable materials turn combustible (aluminium) or insoluble materials become soluble (gold). The Organization for Economic Corporation and Development (OECD) proposes that new approaches for testing ENMs need not be developed however, adjustments to existing sampling methods and dosimetry for testing them may have to be adopted when working with ENMs.

Barnard (2006) reports that ENMS could soon significantly impact this technology, its materials and devices on a global scale. Whilst an understanding of ENMS, can create new opportunities it can also generate substantial threats to existing technologies and mankind, especially people who have some form of contact with ENMS (Kumar and Kumbhat, 2016).

1.2.2 Application

Barnard (2006) acknowledges that the versatility and durability of ENMs has made it a favourable component in the food, construction, packaging, medical, biomedical, electronic and pollution control industries. In comparison, Linkov and Stevens (2009) suggest that most benefits of nanotechnology depends on its ability to tailor the essential structures of materials required, at the nano-scale, to achieve specific properties, thus greatly extending materials science. By using nanotechnology, materials can be made stronger, lighter, more durable, reactive, sieve-like and better electrical conductors, among many other traits.

1.3 Novel and Revolutionizing Industry

Aithal and Aithal (2016) and Sekhon (2010) contend that there are over 800 commercial products that rely on nano-scale materials and processes. These include:

- Polymer additives in composite materials used in equipment such as, bats, rackets, helmets, car bumpers, bags, and power tool housings can make them lightweight, firm, durable, and robust.
- Additives to fabrics help to resist discoloration, creasing and bacterial growth.
- A thin film can be imposed on glass that can be used on computer screens camera lens and windows that make them water-repellent, anti-reflective, self-cleaning, resistant to ultraviolet or infrared light, anti-fog, antimicrobial, scratch-resistant, or electrically conductive.
- Cosmetic products use ENMs to provide better cleansing, absorption and health properties.
- ENMs are used in the food industry primarily in food containers to minimize leakage and prevent bacterial growth which will keep food safer, fresher and with a longer shelf-life. Nano-sensors built into packaging can detect spoiled food.
- ENMs are being tested on rechargeable battery systems, tyres, solar panels and catalytic converters for cleaner exhaust and extended range.

1.4 Associated Risks

Delgado (2010) suggests that quality management standards are very important, especially, when considering the impact of manufactured ENM and its repercussions on fauna and flora. He claims that in 2007 seventy seven (77) patients were intoxicated by a German bath product containing ENMS, two (2) people died while five (5) others were very sick from pulmonary diseases. Similarly, the National Institute for Occupational Health and Safety (NIOSH, 2013) claims that airborne particles can be inhaled and deposited in the respiratory tract and enter the bloodstream and translocate to other organs. Aschberger, Christensen, Rasmussen,

Jensen, Xing, Vecitis and Senesi (2016) observe that there are several other incidents exhibiting negative effects of nanotechnology on fauna and flora. This will be discussed further in Chapter 2.

1.5 Unusual Behaviour

According to Cockburn, Neil, Constable and Edwards (2012), studies has indicated that although ENMs have been used in many products for several years, a formal, practical, systematic and a robust system of assessment with validated quality protocols is absent and is required. Furthermore, Hock, Gamer, Landsiedel, Leibold and Frechen (2007) argue that due to the novelty and uniqueness of the material its effects in application are unknown especially in terms of risk-assessment, toxicology and quality assurance.

The challenge of having a prescribed standard for ENMs is also premature and difficult as there is no universal definition for ENMs with only the European Union and Switzerland having a fixed definition.

1.6 The Need for Quality Management

This study attempts to provide a framework to monitor, evaluate and control broad based ENMs. Quality management and quality engineering has typically been used in traditional practices to continuously manage and improve products and processes (Goetsch and Davis, 2014). Due to the lack of information and the uncertainty exhibited in the behaviour and risks of ENMs presented in the foregoing sections, it is envisaged that the discipline of Quality can be used as a platform for managing and controlling this technology.

1.7 Quality Defined

Heizer and Render (2014) define quality as the totality of features and characteristics of a product or service that bears on its ability to satisfy stated or implied needs. However, there are different views, and these include Jones (2012) who is of the view that Quality is user-based implying better performance and additional features whilst Foster (2007) explains

that Quality is manufacturing-based and refers to conformance to standards “making it right the first time”, whereas Stevenson’s (2007) theory is that Quality is product-based which is specific and measures the attributes of the product.

For this study, quality will be considered to be compliant with selected management systems (in terms International Standards Organization) and prescribed quality metrology (good measurement practices in terms of good laboratory and good manufacturing practices).According to the literature review, the importance of Quality Assurance (QA) should be introduced very early in the development of a product (Jones, 2012). According to Heizer and Render (2014) it makes good business sense to develop a quality framework to ensure that quality related activities are included in the product development stage. The thought behind introducing quality early in the development phase and even as early as in the design phase will encourage better management of the ENM, its quality, impact on health, safety, environment and risk.

Chase, Jacobs, Aquilano (2004) imply that developing quality specifications of a product stems from the initial design characteristics and the ability of processes to conform to its design. Furthermore, they explain that the dimensions of design quality include: performance, features, reliability, durability, serviceability, response, aesthetics and reputation whilst Stevenson (2007) argues that quality of conformance is affected by issues such as capability of equipment used, employee skills, motivation and training of the worker, the extent to which the design lends itself to the ease of manufacture and taking remedial action when necessary. In considering the views of the commentary above perhaps the dimensions and conformance to quality should be addressed in the design stage of the development of any ENM.

1.7.1 The Importance of Total Quality Management (TQM)

Quality management is important as it ensures the provision of superior quality of products or services (Goetsch et al., 2014). Weingarten and Pagell (2012) observe that quality management practices and programs such as Total Quality Management (TQM), Six Sigma and ISO Certification programs have been used extensively in virtually all organizations. According to Heizer et al. (2014), ethics and quality management are one of the most important functions through which organisations can deliver healthy, safe and reliable products to customers. They contend that the development of poor quality products because of inadequate design and quality assurance produces results not only in higher production costs but could also lead to injuries, lawsuits and increased government regulations.

Jones et al. (2012) emphasise that quality management is the process of controlling, ensuring, maintaining and improving products or services. Therefore, a well-functioning quality management system should be a pre-requisite for the implementation of ENMs in order to build quality into the product.

1.7.2 The Need for Quality Assurance for ENMs

Foster (2007) and Goetsch et al. (2014) explain that Quality Assurance (QA) covers all matters that individually or collectively influence the quality of a product. QA is also considered as the sum of the arrangements made with the intention of ensuring that finished goods are of the quality required for their intended use. According to Foster (2007) “Quality Assurance refers to the activities associated with guaranteeing the quality of a product or service”. Taylor and Russel (2011) describe QA as a process- driven approach that sets and defines goals relating to product design, development and ultimately production. The main objective of QA is to identify and resolve quality problems prior to manufacture. Nanjwade (2009) confirms that QA processes include the following items: technology transfer, validation and documented control. Each of these items presented

in figure 1.1 is discussed as it is useful in managing ENMs, in view of the poor commercialization of nanotechnology applications.

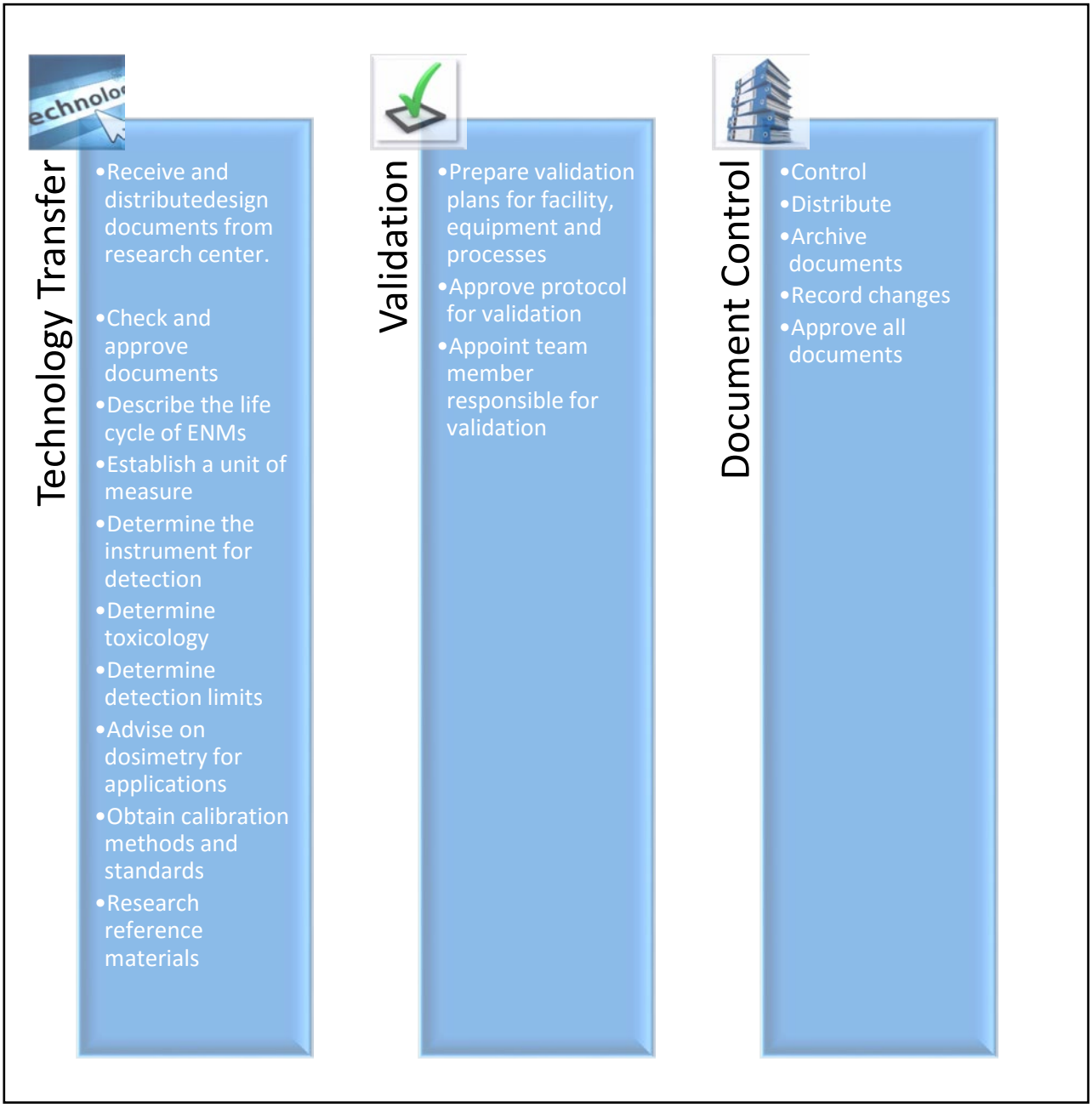

Figure 1.1: Q.A. Processes for ENMs

Source : Adapted from Nanjwade (2009)

Nanjwade (2009) is of the view that technology transfer includes design, approval of design specifications, establishing measurements, determination of toxicology and calibration limits. Furthermore, validation includes facility plans for equipment and processes, providing validation protocols and appointing employees responsible for such validation. Document control includes recording of document changes, approving documents, distribution, control and archiving functions.

Sroufe and Curkovic (2008) state that a properly managed Quality Management System (QMS), not only ensures meeting regulatory and performance goals but also serves as a foundation to set a strategic direction for quality. In general, current studies assessing the safety level of nanomaterials provide inadequate health and safety reassurance. The literature above suggests that the discipline of quality can support the gap of knowledge in the management of ENMs.

1.8 The Need for a Quality Framework

Berger (2007) states that whilst ENMs have the ability to transform the future of science and chemical properties of products, there are potential risks associated with this technology. In general, a framework can best be described as a series of interlinked management systems supporting an approach to achieving specific objectives. In this regard, Jones, Gibb, Goodier and Bust (2017) suggest that adherence to proper procedures will ensure that:

- Risks of the ENMs are known, monitored, controlled and\or mitigated.
- Standards, metrology and accurate measurements are established to provide mechanisms to maintain them.

Leech and Scott (2017) and Amoabediny, Naderi, Malakootikhah, Koogi, Mortazavi, Naderi and Rashedi (2009) acknowledge that there is a lack of standards governing the manufacture and use of ENMs. Standards are documents that contain technical specifications and other prescribed criteria used to guide the development and manufacturing phases of

production. The introduction of a quality framework for ENMs will be established in accordance with international technical reports and ISO standards.

From the foregoing discussion it can be deduced that quality and quality management could form the foundation for the development of a framework upon which ENMs can be monitored, evaluated and controlled. The road-map for the integration of these systems will be highlighted in detail as the thesis develops.

1.9 Risk Assessment

Berger (2007) and Ganguly, Roshanak and Farr (2017) found that a problem with nanotechnology lies in the huge gap between the public perception of what its novelty promises and the scientific and commercial reality of what the technology delivers. Some ENMs, including carbon nanotubes, although offering tremendous opportunities, also may pose risks which have to be addressed sensibly so that the full benefits can be realised.

Mankind has learnt to handle electricity, gas, steam engines, aero-planes and mobile phones in a safe manner because of the benefits they provide. Most ENMs will be perfectly safe, embedded within other materials, such as polymers (NIOSH, 2013). There is, however, some possibility that free nanoparticles of specific length scales may pose a health hazard if inhaled. Hallock et al. (2009) emphasizes that industries and governments, are aware of these hazards and are funding research into identifying particles that may pose a hazard to health or the environment. They are also investigating how these risks may be quantified and minimised over the whole lifecycle of a given nanoparticle (Hischier and Walser, 2012). Berger (2007) argues that although nanotechnology has great potential to bring benefits to society over a wide range of applications, care must be taken to ensure that these advances come about in as safe a manner as possible.

Tyshenko and Krewski (2008) confirm that governments in the European Union, United States of America and Japan are developing new risk management frameworks for ENMs. Morgan (2005) argues that the extent of research required to fully understand the risks relating to ENMs may take years or even decades to complete. Vladimir, Schulte, and Howard (2012) suggest that risk assessments should be synchronised in accordance with the ENM's unique behaviour. They also suggest that risk control strategies be adopted very early in the process so that engineering controls, elimination or substitution can be implemented. This is synonymous with the preceding discussions on building Quality early in the design phase (Chase, Jacobs, Aquilano, 2004; Stevenson, 2007 and Heizer and Render, 2014). An example of a risk assessment framework is presented in figure 1.2 below.

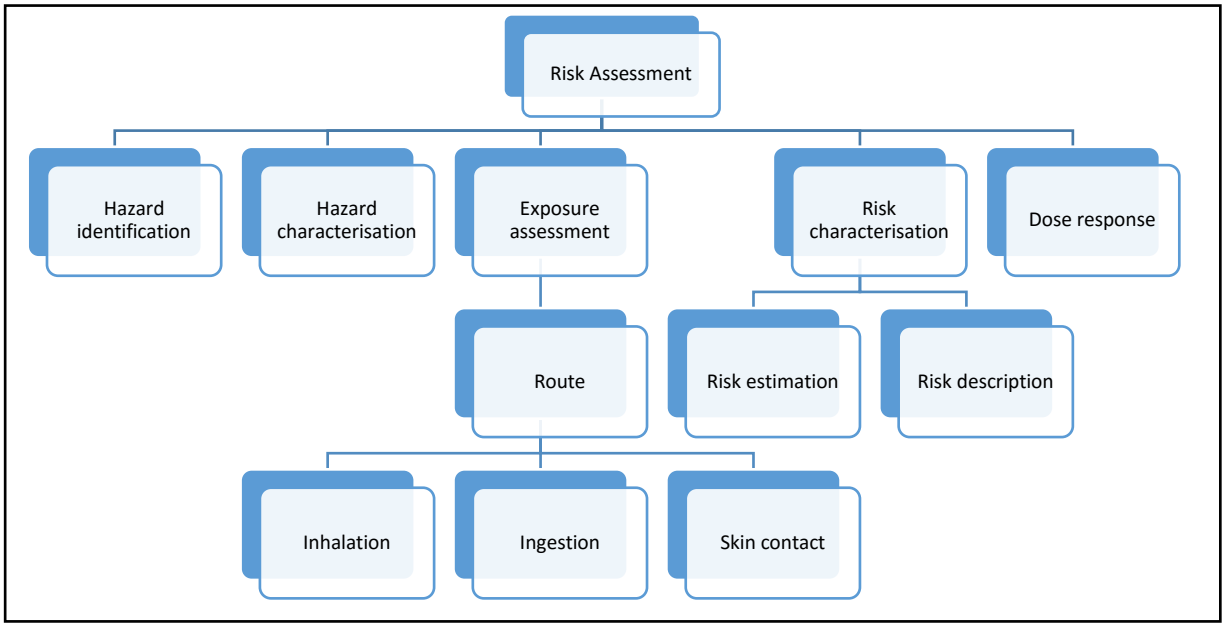

Figure 1.2: Activities to consider in Risk Assessment

Source: Singh (2016)

Figure 1.2 illustrates the steps which should be undertaken for risk assessment. It covers the activities from hazard identification, hazard characterisation, exposure assessment, risk characterisation and dose response. Assessment of these steps will provide users with a better understanding of what hazard is manifesting, how it can be characterised, the levels of exposure, the various possible routes it follows and risk

controls required. This framework was considered during the development of the integrated quality framework and software application during this study.

1.10 Current Regulations, Standards and Technical Reports governing ENMs

There are several technical reports, guidelines and frameworks developed globally for use and risk assessments relating to ENMs. These documents have been developed by researchers, licencing bodies and governmental departments including Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) EC No. 1907/2006, Organization for Economic Coperation and Development (OECD) and National Institute for Occupational Safety and Health (NIOSH).

Sokull-Kluettgen (2012) asserts that the legislation explicit to ENMS in both the European Union as well as the United States of America is not mandatory at this stage with adherence being voluntary. The challenge, however, lies in which guidelines to follow and how they could be managed when multiple guidelines are applicable for products made by a facility, thus suggesting a need for an intervention.

Traditionally when multiple management systems were required, organisations typically integrated them. These were generally ISO 9001, ISO 14001 and OHSAS 18001. Singh (2006) argues that integration creates the opportunity to manage multiple systems by providing a snap shot of the organisation without the duplication of resources thereby saving time and money. Currently ENMs at the research and development stage are produced in accordance with supplier requirements only. The extent of compliance of these requirement protocols from technical reports is still to be established. Linkov et al. (2009) suggest that researchers, developers, manufacturers, governments and regulatory bodies must be able to predict ENMs specific adverse outcome\s to exposure, estimate its probability and

its impact on humans, fauna, flora and the environment. Herein lies the justification to develop a generic or broad-based platform that incorporates and integrates international standards in the disciplines of health and safety, environmental and quality (Kumar et al., 2016).

Jorgensen, Krogstie and Guttorm (2006) and Hristozov, Gottardo, Semenzin, Oomen, Bos, Peijeneburg, van Tongeren, Nowack, Hunt, Brunelli and Scott-Fordsmand (2016) argue that there have been several attempts in integrating management systems (ISO 9000, ISO 14000, OSHAS 18001 and SA 8000) where the key focus has been on alignment and integration which seeks to reduce administration and audit costs. Furthermore, ISO have recently created a path towards more compatible management standards with cross references and integration of systems elements. However, a pre-requisite for integration is the understanding of generic management processes.

Medley (2008) proposes one of the first Nano Risk Frameworks as shown in Figure 1.3 which provides a risk assessment cycle commencing with the description and application of the ENMs, profiling its life cycle and then evaluating and managing the risk, followed by the documentation and reviewing of ENM’s risk profile.

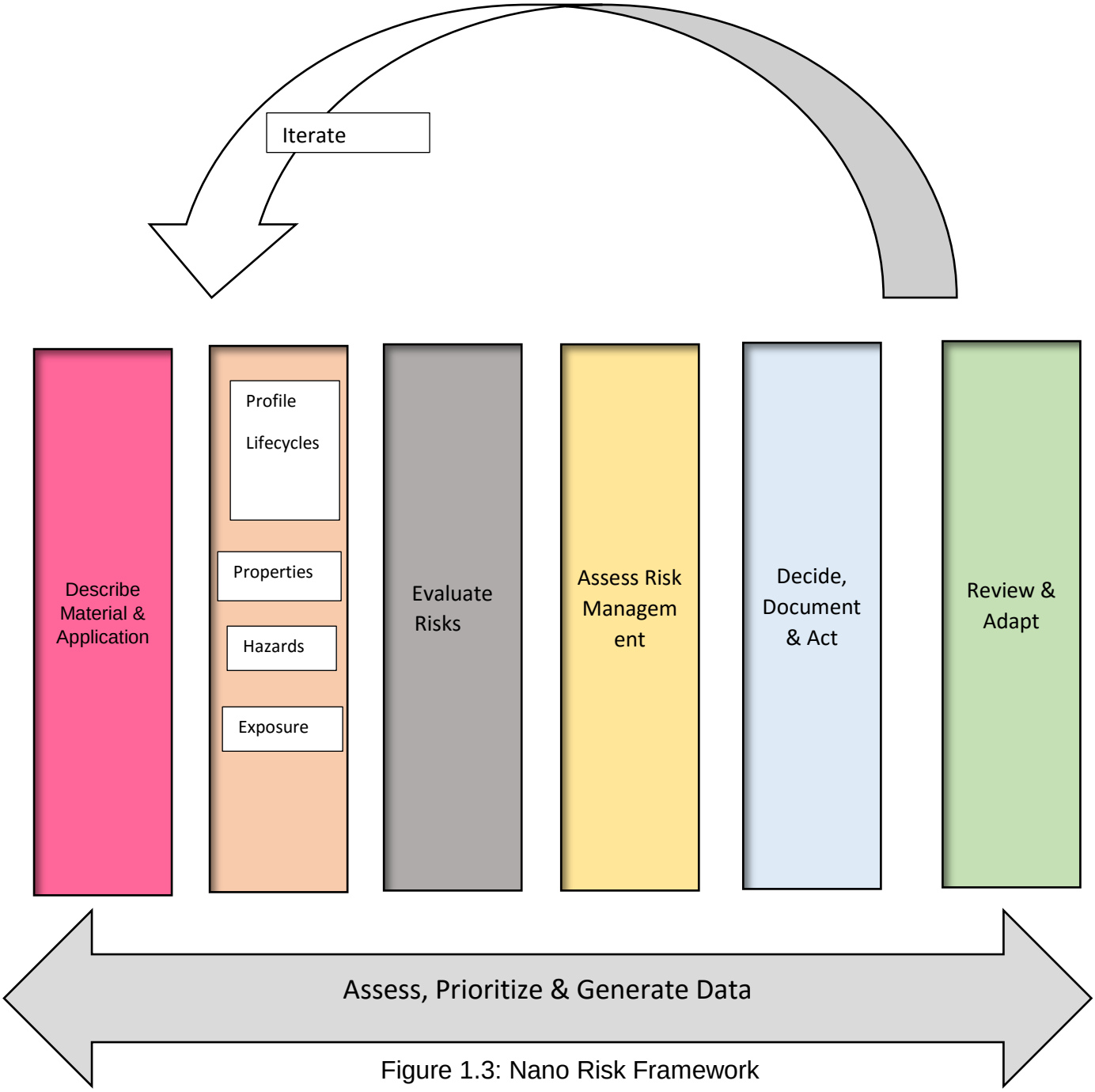

Figure 1.3: Nano Risk Framework

Source: Adapted from Medley (2008)

A review of the framework above is aligned to the discussions and inferences made in the foregoing sections, particularly in seeking the information required to develop a framework for this study. Medley (2008) suggests a continuous cycle in his nano risk framework. This suggestion is also aligned to Deming's plan, a well-known quality guru who proposed the Plan, Do, Check and Act (PDCA) Cycle, which is highly recommended by

several management systems (Kruger and Ramphal, 2009) and (Heizer et al., 2014).

1.11 Statement of the Problem

Although the usefulness of nanotechnology is acknowledged, the potential risks, harm and lack of uniform management structures has prevented this technology from reaching its full potential and commercialisation.

1.12 Aim of the Research

The aim of this study is to investigate selected risk assessment and quality management practices in order to develop an integrated quality framework to monitor, evaluate and control broad-based ENMs.

1.13 Research Objectives

This quality framework will be generic, covering ENM related risks and quality features required.

From a risk perspective the following will be addressed:

- To use literature, technical reports and selected risk assessments to identify the characteristics (for example: source, characterization and exposure assessment) of the risk in ENMs
- To predict the probability, severity, and estimation of the likelihood and magnitude of risk that can be detrimental.

This will form the point of departure for the development of the integrated quality framework in this study. All these above factors will be consolidated from Technical Reports (ISO/TR 13121-2011 and ISO/TR 12885-2008) to inform the quality framework.

Objective 1: To use literature to establish current practice from technical reports, experts and researchers, for developing and manufacturing ENMs.

Objective 2: To conduct interviews with researchers and manufacturers to determine their current practice used in the field of ENMs.

Objective 3: To establish via surveys the current level of understanding of integration, storage procedures and risks associated with ENMs.

Due to the novelty of nanotechnology and the lack of established data, peer reviewed research will serve as preliminary data to establish the risk perspective in Objectives 1 and 2 above.

Objective 4: To develop a Quality framework which is presented in a graphical format showing the integrating of management systems.

Objective 5: To develop a computer application to predict the risks associated with ENMs.

1.14 Significance of the Research

Firstly, this study seeks to highlight the importance of the discipline of Quality in nanotechnology and to create an awareness of the hazards and risks to improve the safety while working with ENMs. It is envisaged that this will be achieved through developing an integrated quality framework that serves as a foundation to better understand, predict and manage the challenges of nanotechnology. The computer software developed as part of this study will assist uses working with ENMs to identify their personal risk profile and take corrective action to minimise or eliminate such risks.

1.15 Understanding Quality and Quality Assurance (QA)

Most industries subject raw materials, semi-finished goods, components and finished goods to some sort of testing / inspection procedures. Ferris (2015) maintains that testing ENMs is somewhat different from traditional materials in that the reactivity of the ENM can depend heavily on the shape of the particle considering that two particles from the same batch may perform differently in test conditions.

Foster (2007) and Goetsch et al. (2014) suggest that QA tools be used extensively in the design phase of material development. Each of these tools is shown in Figure 1.4 below.

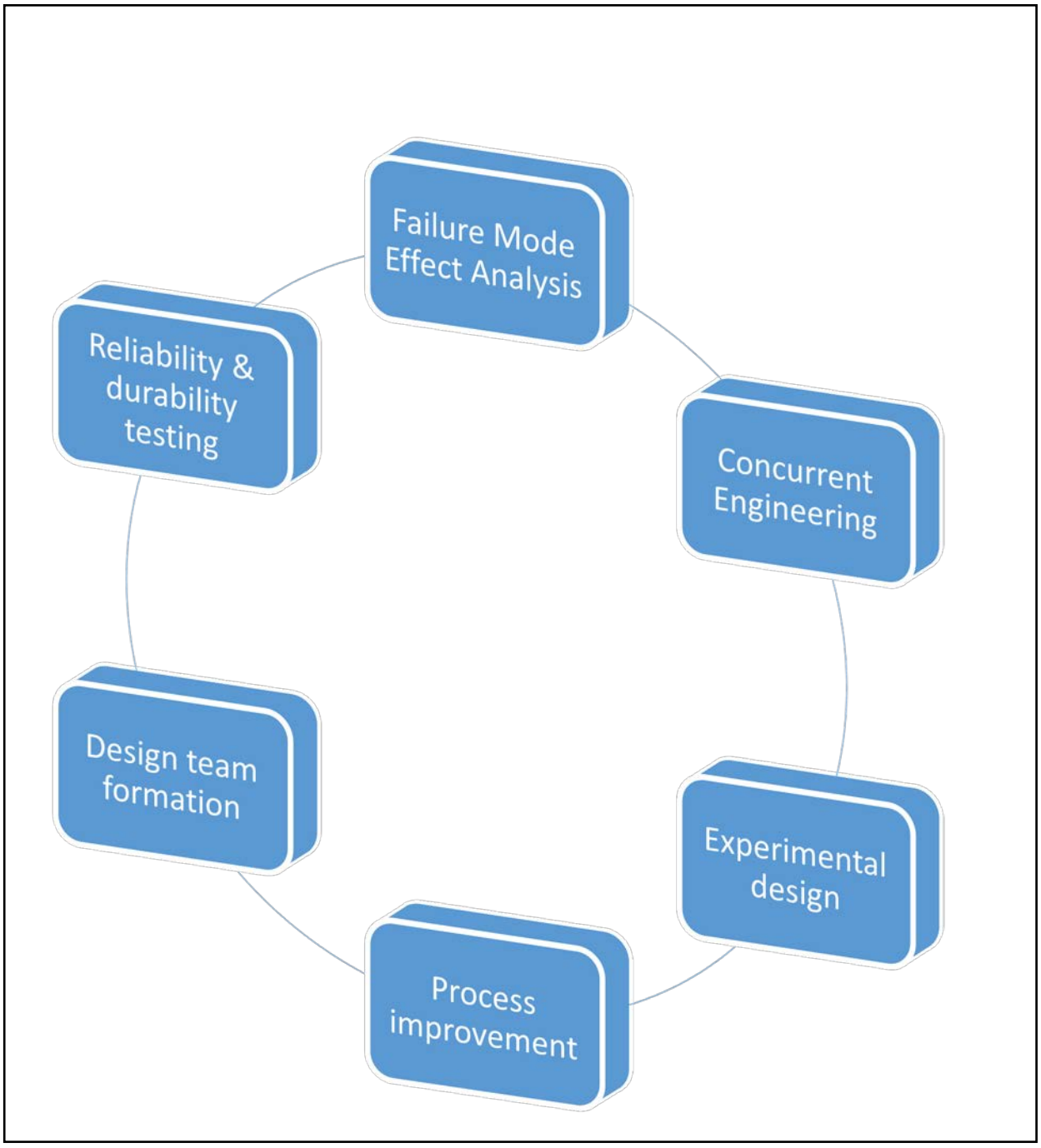

Figure 1.4: Tools for Assuring Quality in the Design and Manufacture of ENMs.

Source: Adapted from Foster (2007) and Goetsch et al. (2014)

- Failure Mode Effect Analysis is a risk assessment tool that identifies possible ways that a product or process can fail.
- Concurrent engineering is where several functions of the organization such as technical, research and design, engineering and manufacturing are integrated to speed up product development and manufacture.
- Experimental design refers to predicting an outcome by introducing a change to the preconditions and observing the outcomes.
- Process improvement analyses existing products or process with the intention of increasing efficiencies or reducing costs.
- Design team formation deals with structuring a team so that it can function effectively and efficiently by addressing team dynamics.
- Reliability and durability testing aims to the test the performance of products under review.

From an assessment of the uses and applications of the tools in the section above and the opportunities, deficiencies and needs of ENM to mature as a technology, established earlier in the chapter, it is evident that quality tools can be adapted and are useful for nanotechnology, particularly for ENMs.

1.16 Research Methodology

This study adopts an empirical strategy, follows by a mixed method approach. The qualitative aspect of the study will be based on literature and interviews with selected experts, researchers and manufactures of ENMs. Their opinions regarding the suitability of the factors will be included in the framework. The quantitative aspect of the study will be determined via questionnaires which will ascertain the suitability of integrating management systems and the level of adoption of recommended protocols for ENMs. Questionnaires will be administered to in-house laboratories at Durban University of Technology (DUT) that deal with glass fibre, carbon fibre, polymers, nano-induced clays and nano-induced silver materials.

The integration of the ENMs protocols with Safety, Health, Environment and Quality (SHEQ) will be based on the safety and health, environmental, corporate governance, quality and AIDS (SECQA) Model developed by Singh (2006) in a previous doctoral study.

Thereafter, the development of the framework and the results of the quantitative aspects will be used to triangulate the validity of the design of the quality framework.

- Population: The sample population will include researchers, experts, quality technicians and manufacturers.
- Sample size: A minimum of 75 responses will be required to conduct the factor analysis (Mundfrom, Shaw, Lue, 2005).
- Triangulation will include known experts and manufacturers. This study will adopt a “mixed method” research, as it is the act of combining several research methods in the study. In the case of this study it will include stakeholder interview, examination of quantitative data and qualitative surveys.

In developing the questionnaire, the first part will be validated using content validity by an expert in ENMs. The second part will be designed in accordance with the ENMs technical reports (ISO/TR 13121 and ISO/ TR 12885).

Reliability will be measured using the Cronbach Alpha Test and Kaiser-Meyer- Olkin (KMO). According the Melville and Goddard (2006), the KMO is the prescribed method to measure reliability. Due to the uniqueness of the study, the need of the latter will only be established as the study progresses.

As part of this study a computer application will be developed that allows a risk profile to be constructed for any person working with ENMs.

As far as ethical considerations for the study are concerned, there were no vulnerable populations that were interviewed. The experts, researchers and manufactures were treated with respect and due consideration was given to the confidentiality of information.

1.17 Delimitation of the Study

This study is limited to the most commonly used management systems that are currently being used by Industry for compliance purposes. They include ISO 9001:2015, ISO 17025:2005, OHSAS 18001: 2007and ISO 14001: 2015.

1.18 Outline of Chapters

In Chapter 2, the literature on nanotechnology and Quality Management Systems is reviewed focusing on the toxicology and the inherent risks of ENMs. The literature review seeks to establish current practices governing ENMs and thereafter determine the need for a Quality Management System.

Chapter 3 describes the research methodology used for this study, describing the research design, the population and sample and data collection methods. It also includes the validity and reliability of the study.

Chapter 4 commences with an examination of the results from the literature and the technical reports. Thereafter, the results from the survey and interviews are presented with graphs and tables. Significant patterns in the data are identified and analysed. The results was used as basis to develop the framework and the computer application proposed in this study.

Chapter 5 will explicate how the framework and the computer application works. It will also present conclusions, recommendations and suggestions for future research.

1.19 Summary of the chapter

In conclusion, this chapter introduced nanotechnology with specific reference to engineered nanomaterials (ENMs). The risks and unusual behaviour patterns of ENMs were explored and the need for quality management and a quality framework was established. Current standards and regulations governing ENMs were discussed and the aims objectives and rationale for this study was presented. Chapter 2 reviews the literature on ENMs and Quality Management Systems.

Chapter 2 – Review of Literature

This chapter will explore the background of nanomaterials, commonly used management systems and selected risk analysis models. The theories of health and safety, compliance and social justice will also be discussed.

2.1 The Nature of ENMs

According to Corbett et al. (2000) the rapid growth of nanoscience over the past few years has resulted in a significant impact on the development of new materials and products. As such, this science has the potential to be a major economic driver soon. At the heart of nanoscience is miniaturisation, that is, the ability to make materials or products smaller, faster and cheaper without losing functionality.

This literature review informed the basis for establishing the current practice of researchers in identifying inadequacies. Hence, this presents an opportunity for developing, managing and controlling the use of ENMs through the adoption of a Quality Management System (QMS). These opportunities obtained from the review of related literature will be discussed in this section.

The overall goal of this chapter is firstly to establish from the available literature the nature, structure and challenges of ENMs and secondly to determine the need for Quality Management Systems to govern this technology. In this chapter, for providing a background to the understanding of ENMs, a theoretic synopsis is detailed on the structure of ENMs, the health, safety, environmental hazards, the handling and disposal of ENMs. An overview of the two technical reports (TR 13121 and 12885) is interrogated. This is followed by a discussion on Quality Management Systems. The literature focuses on the structure, the types and composition of ENMs. A discussion on the hazards and toxicology is then presented which culminates in the conceptual framework proposed for this study.

Barnard (2006) argues that due to its small size, the properties of ENMs, such as electronic, mechanical, biological and chemical can change radically, resulting in the creation of new functional materials. Therefore, it could be suggested that applied ENMs, in the not distant future, have the ability to significantly impact on technology, materials and devices on a global scale. Of concern, Boldrin, Hansen, Baun, Hartmann and Astrup (2014) and Aschberger et al. (2016) argue that whilst an understanding of ENMs can create new opportunities it can also generate substantial threats to existing technologies and mankind, especially those people that have some form of contact with ENMs.

There are two schools of thought on the categorization of ENMs. The first one looks at bulk, surface and particle whilst the second looks at powder, nanocomposite, solid nanofoam, nanoporous material and fluid nanodispersion. These are illustrated in figure 2.1.

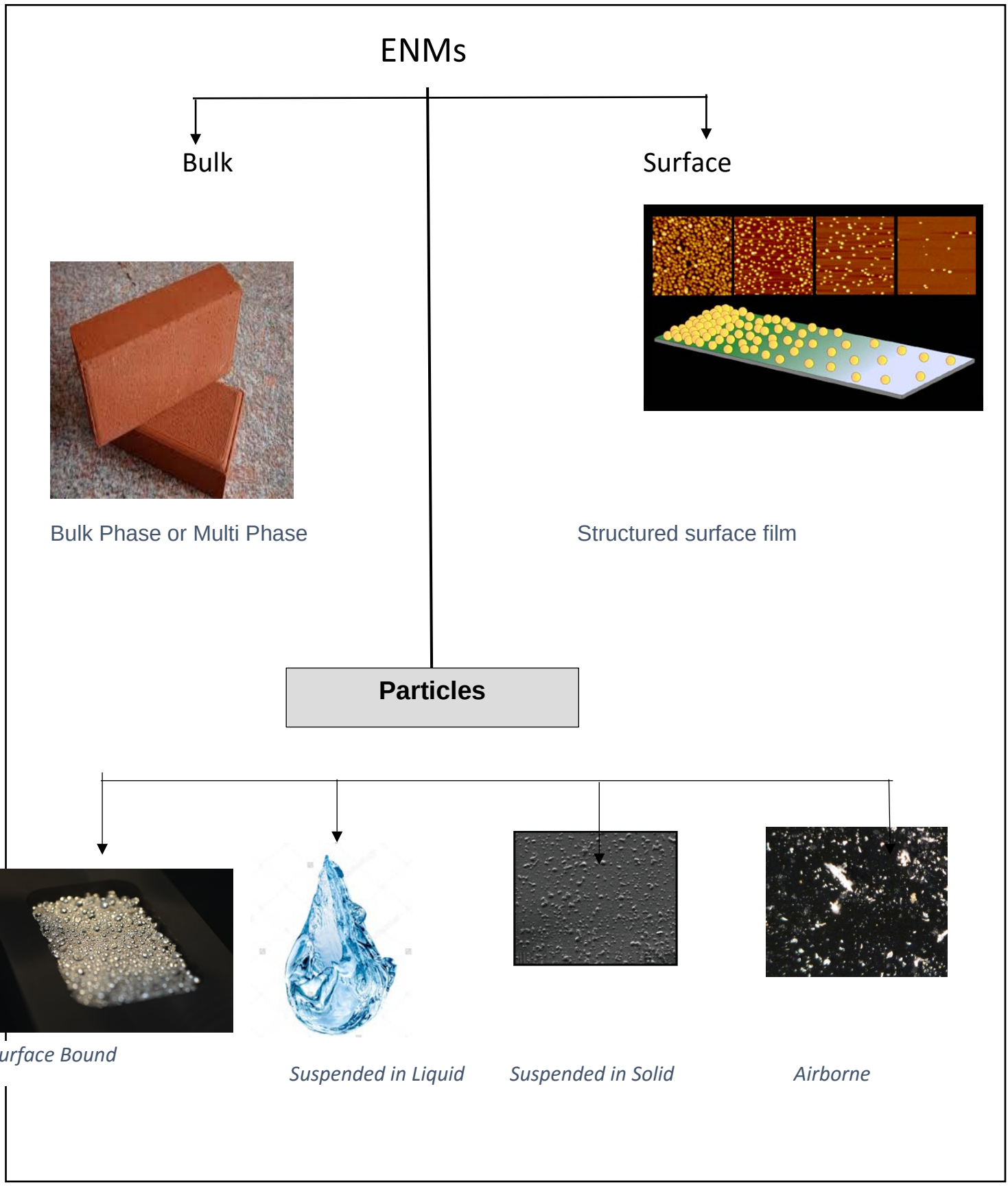

Figure 2.1: Structure of ENMs
Source: Adapted from Hansen, Larsen, Olsen and Baun (2007)

Hansen et al. (2007) suggest that ENMs can be categorized into three subsectors namely: ENMs materials in bulk; materials that have ENM attached to the surface and materials that contain ENMs particles. The reason for this categorization is that it provides a system for dividing ENMs into identifiable parts that can simplify material testing. A different point of view on the structure of ENMs is presented in the ISO/TS 80004-4 report as shown in figure 2.2.

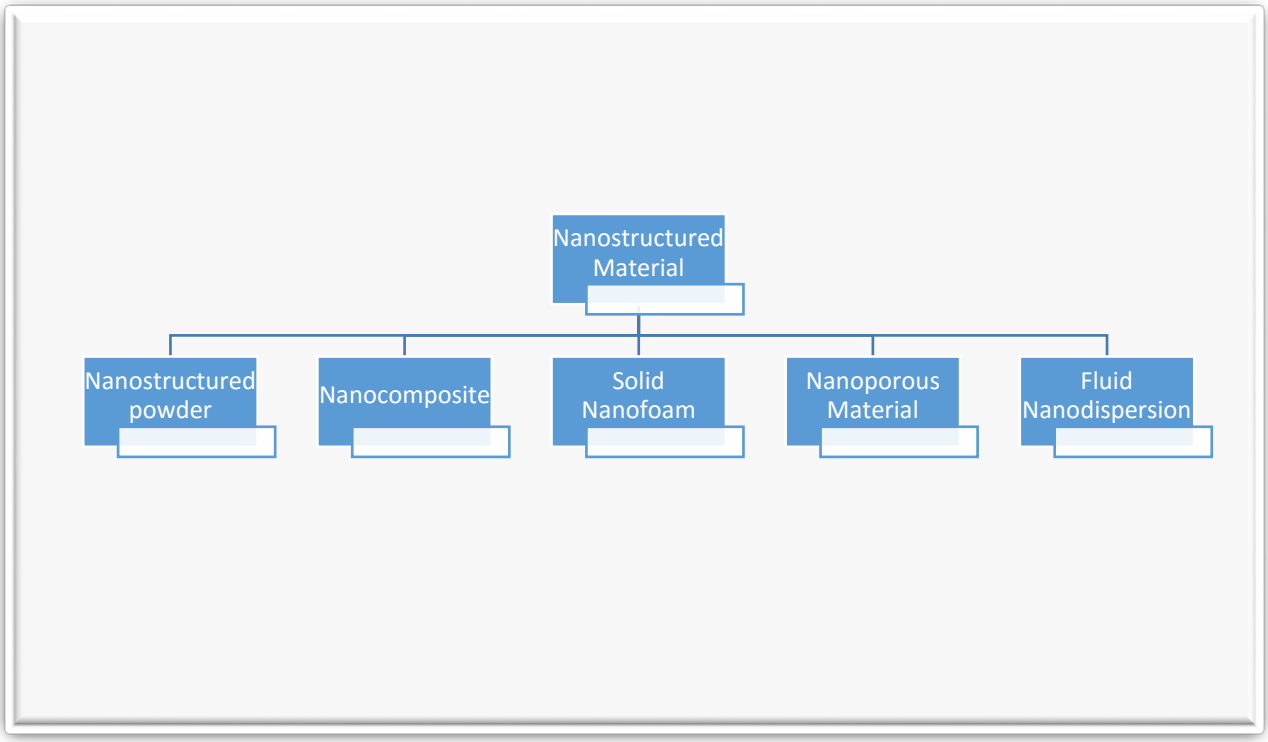

Figure 2.2: Categories of Nanostructured Materials

Source: ISO/TS 80004-4 (2011).

Sweeney, O Brien, Dunne, McHugh, and Leen (2015) argue that material testing is conducted to confirm whether a specific material is suitable for an application.

In a recent study conducted by Tan, Yussof, Abas, Mirhosseini, Nehdi, Tan (2016), it was found that nanopowders and fluid nanodispersion ENMs are arranged in a non-random distribution. These will interact with the molecules in the liquid and form a thin boundary layer on the surface of each particle as reflected in figure 2.2.

Nanostructured powder is an assembly of discrete particles, usually less than 1mm in size, nanocomposite is a mixture of two or more phase-separated materials, solid nanofoam is a matrix filled with a second gaseous phase resulting in a material of much lower density, nanoporous materials have a small fraction of the pores covered which overlap and fluid nanodispersion is a gaseous matrix with at least one liquid or solid nanophase (ISO/TS 80004-4 2011).

According to Prihar, Chudasama, Singh and Ingole (2016), uncontrolled ENMs can create inherent problems. For example, disposal of ENMs into municipal landfills may result in serious environmental issues although the long-term effect of how such particles disintegrate are yet unknown. Furthermore, due to the size, shape, structure, unpredictability and toxicity of ENMs, the literature reviewed in this chapter seeks to confirm the risks associated with this technology and affirms the need for such a study to find ways to control, evaluate and predict the risks of ENMs.

Understanding of the categories of ENMs is useful in developing the integrated framework in Chapter 5.

2.2. Overview of Engineered Nanomaterials (ENMs)

Stern and McNeil (2007) categorise ENMs as either being engineered or incidental depending on its origin. Engineered nano particles are manmade materials and are commonly seen as nanotubes, dendrimers and quantum dots.

Barnard (2006) acknowledges that the potential hazards associated with engineered materials are significant suggesting valid concerns. The key to address the future challenges is through proper management systems when dealing with ENMs. Hence, understanding the scope and diversity of nanomaterials is one way to protect against emerging hazards.

This section presents an overview of the structure, composition and manufacturing methods of ENMs. Scientists and researchers are fully

aware of the material properties and chemical reactions of macro particles or solid matter particles. However, the properties of ENMs such as melting point, fluorescence, electric conductivity and chemical reactivity change significantly as a function because of the size of the nanoparticle (Barnard, 2006). Thus, ENMs pose a serious challenge as far as risk and unpredictability is concerned.

The size of a nanoparticle (in comparison with other products) is shown in figure 2.3.

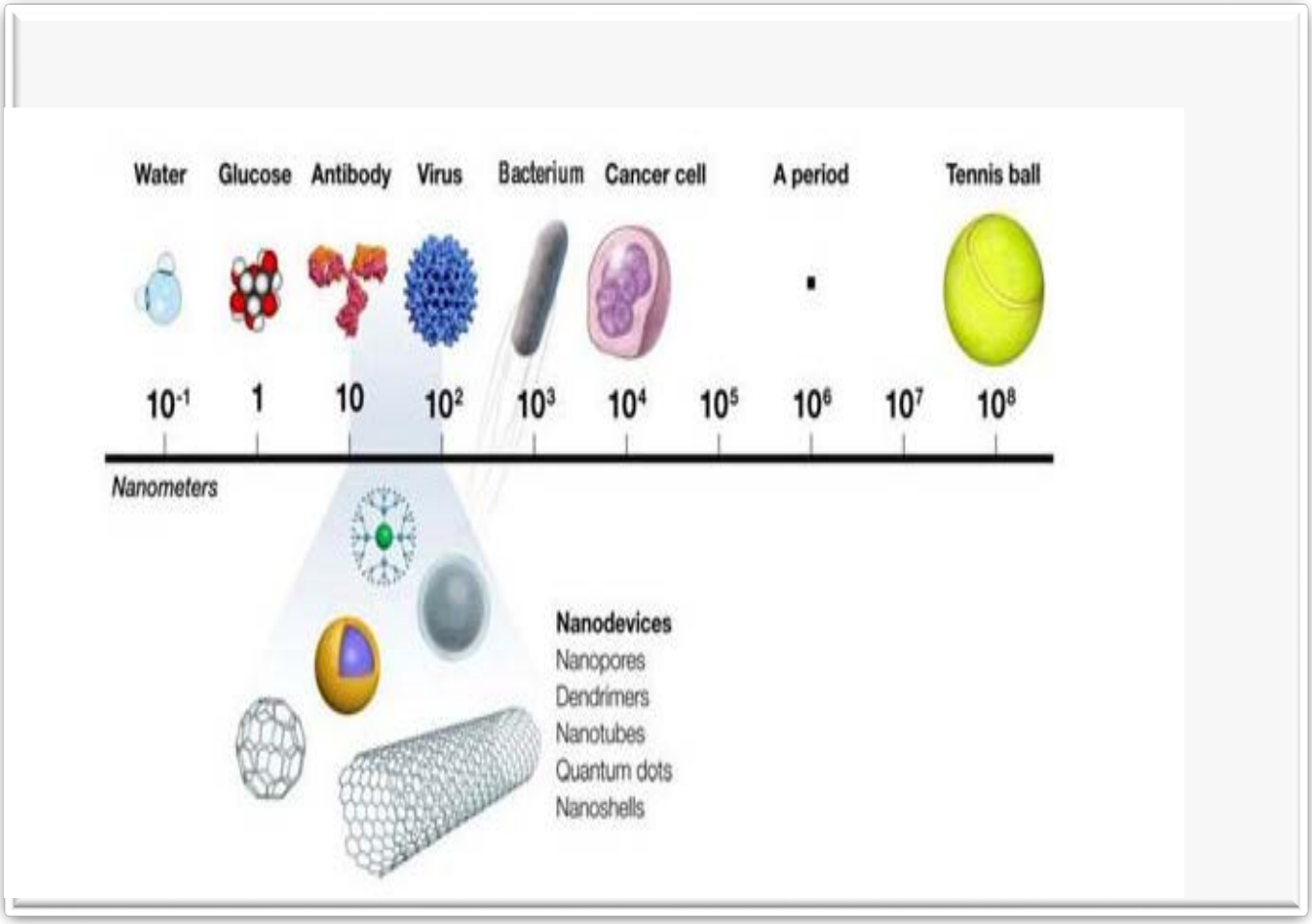

Figure 2.3. Engineered Nanomaterials Size

Source: Particle Sciences (2012).

Figure 2.3 provides a context of how the size of ENMs compares with other objects. This diagram depicts how small a nanoparticle is. Comparing the size of ENMs with traditional objects provides measurement through a scale or reference point. Jones (2007) points out that properties change at the nanoscale due to quantum mechanics. Thus, according to Sun, Fernandez and Barnard (2016) this complexity of ENMs poses a challenge especially because precision at this level is often unavailable. To address the challenges, scientists, researchers and manufacturers must understand the structural diversity of ENMs.

Lam, James, McCluskey, Arepalli and Hunter (2006) suggest that ENMs can be generated to exploit their size-related properties. For example, Carbon Nanotubes (CNTs) have thermal and electrical properties and are lightweight with a high tensile strength expected to be 100 times stronger than steel.

The review of literature provides a platform to understand the structure, composition and manufacturing methods of ENMs and provides a context within which risk assessment is explored. The following is an overview of the various forms of ENMs, focusing on the composition, structure and methods used in manufacturing ENMs.

2.2.1 Fullerenes

D'Souza and Bhainsa (2006) reported that fullerenes are chemical entities which look like spherical cages built from carbon atoms chemically bonded to three nearest neighbours. Cylindrical ENMs are known as nanotubes. Fullerene molecules can contain from 28 to more than 100 carbon atoms. The potential application of such molecules include: Solar cells, Fuel cells, Lithium-ion batteries, oxygen and methane storage materials, additives to plastics, oil and rubber and cancer and AIDS treatment.

2.2.2 Carbon Black

Kushnir and Sanden (2008) found that carbon black consists of fine black particles, organized into spherical shapes fused together to give aggregates, interrelating weakly to form agglomerates. They have an average aggregate diameter of 80-500 nm and average primary particle size of 11-95 nm. The main industrial uses include:

Colouring and reinforcing filler for rubber particles for example tyres, thickening agents for liquid systems and heat insulation materials. Understanding the chemical composition and properties of ENMs, will provide a better understanding on how to predict and control these materials.

2.2.3 Metals

D'Souza et al. (2006) claim that since gold nanoparticles are sensitive to environmental changes the particles can be used in several applications including optical markers and thermal targeted cancer treatment. Durán, Durán, de Jesus, Seabra, Fávaro, Nakazato (2016) point out that in metal nanoparticles, silver ENMs are produced in large volumes and can be used in a variety of application ranging from disinfectants to dressings for wounds. Metal nanowires such as cobalt, gold and copper based can either be conductive or semi-conductive and used as interconnectors for the transport of electrons in nano-electronic devices.

2.2.4 Quantum Dots

Astley, Kataoka, Ford, Barnes, Anderson, Jones, Farrer, Ritchie, and Pepper (2007) define quantum dots as circular nanocrystals ranging in size from 1 to 10 nm in diameter, comprising of semi-conductor materials and often retain exceptional optical properties. The number of atoms in quantum dots makes them neither an extended solid structure nor a molecule entity. The light discharged can be adjusted to the chosen wavelength by changing the overall dimension. Quantum dots are used as fluorescent probes in diagnostic medical imaging and in therapeutics.

2.2.5 Organic Polymer Nanomaterials

Oaki, Kijima, and Imai (2011) note that dendrimers are a new class of controlled-structure multi-branched polymers with nanoscale dimensions. They allow exact, atomic level control of the amalgamation of nanostructures according to the desired shape, dimensions, and surface chemistry.

2.2.6 Aerosol Generation Methods

Schmoll (2009) confirms that this method is used to produce an extensive range of ENMs. The creation of vapour occurs within an aerosol reactor at high temperatures where often a super saturate of a solid is cooled into the background of gas. The methods used to produce ENMs are usually categorized by the heating or evaporation process and include laser induced pyrolysis, flame pyrolysis and furnace/ hot wall reactors. Hence, workers who do not use proper personal protection and safety equipment can be exposed to respiratory pathogens.

2.2.7 Vapour Deposition Methods

Schmoll, Elzey, Grassian and O'Shaughnessy (2009) contend that vapour is formed in a reaction chamber by pyrolysis, reduction, oxidation and nitration. Hence, the vapour deposition of polymers can pose a potential risk for people working with this technology.

2.2.8 Colloidal/ Self-assembly Methods

Hallock et al. (2009) report that colloidal/ self-assembly methods are well-established conventional wet chemistry precipitation processes in which solutions of dissimilar ions at required concentrations are mixed under controlled conditions of pressure and temperature which form insoluble precipitates. Chalcogenides, metals and alloys including gold, cobalt and nickel as well as carbon and titanium nanotubes have been created using this method.

2.2.9 Electrodeposition

Corbett et al. (2000) claim that polymer nanofiber and metal nanowire films can be fabricated on a substrate through a controlled electro polymerization (polymers) or electrodeposition (metals) process.

2.2.10 Electro-Spinning

Oaki et al. (2011) agree that the electro-spinning method is used in the manufacture of polymer nanofibres. It uses an electrical force to produce polymer fibres from polymer solutions or melts.

2.2.11 Agglomeration Methods

Khandekar, Joshi and Metha (2008) mention that in agglomeration size reduction is accomplished by grinding and milling of materials such as clay, coal and metals have been produced.

Understanding the composition, structure and manufacturing methods of ENMs will provide a better understanding of their biological impact and the risks involved with this technology. Whilst nanotechnology is of great scientific interest through its introduction of new and diverse products, ENMs, unlike traditional bulk materials, are often unpredictable. Understanding the structure and behaviour of the ENMs listed above will assist in incorporating health and safety considerations in the design phase of any new product development in nanotechnology.

The following section of the study explores the risks and storage of ENMs which is aligned to objective 3 of the study.

2.3 Challenges, Hazards and Risks in the use of ENMs

Uniform particle size plays an important part in any manufacturing process. The lack of uniformity (or non-uniformity) could result in increased levels of toxicity in ENMs (Brouwer, 2010).

Schulte, Roth, Hudson, Murashov, Hoover, Zumwalde, Kuempe, Geraci, Stefaniek, Castronova and Howard (2016) argue that, whilst some

measures have been taken to ensure the safety and health of people working with ENMs, there are still significant gaps in the knowledge systems relating to this technology. Responsible development of nanotechnology must go “hand-in-hand” with appropriate quality management systems to ensure adequate safeguards and safety standards for not only workers but also end-users of ENMs products.

2.3.1 Unusual Behaviour

According to Corbett et al. (2000) ENMs are designed around specific properties which include nano-objects and nano-structured materials. Nano-objects are materials with one nanoplate, two nanorod or three external dimensions approximately between 1 and 100 nm. They contend that nanofabrication includes a variety of production processes that yield patterns or layers of material to form micro or nano-structures. ENMs are manufactured using manufacturing processes which function at an atomic level. To attain suitable control of the motion of systems that are used in atomic manipulation, displacements and dimensions must be known at the atomic level and below. Current restrictions in dimensional nanometrology include the lack of two dimensional and three dimensional nano-probing systems and the lack of sub-nanometre calibration equipment, traceability and procedures highlighting the relative accuracy gap to ultra-precision measurement (Stohr, Michael-Linhard, Simons, Poulsen, Hubner. Hansen, Garnaes, and Jensen, 2015).

Such restrictions pose a challenge around measurement and support the uncertainty of behaviour of ENMs which is strongly enunciated in the literature (Barnard, 2006). This also presents challenges for quality assurance and quality control purposes in research and development and in the manufacture of nano-enabled products (Ferris, 2015).

ENMs incorporate several types of products and offers great promise for new technological breakthroughs. However, ENMs is a developing technology and the potential health and safety risks have yet to be quantified (Hallock et al., 2009). As highlighted earlier Brouwer (2010)

contends that it would therefore be wise for organisations to mitigate potential risks to both humans and the environment in the design stage of manufacture. Accordingly, Morose (2010) articulates five design principles for use during the design stage for products that contain ENMs. These include surface size and structure, alternative materials, functionalization, encapsulation and reduction of material quantity. He believed that the use of these design principles, may mitigate or eliminate the risk factors in dealing with ENMs.

Healy, Dahlben and Isaacs (2008) contend that there are two approaches to achieve safer ENMs. These are the design approach and non-design approach. The design approach is beneficial during the design stage of ENMs. Healy et al. (2008) found that non-design approaches can be used during subsequent stages in the product life cycle such as materials processing, product manufacturing and end-of-life use of products. Non-design approaches are important for increasing the safety of ENMs, and often incorporate multi-disciplinary systems and approaches including occupational hygiene, cleaner production, and product management.

A study conducted by Vogelsberger, Schmidt and Roelofs (2008) found that solid ENMs are often brought into contact with liquids during the manufacturing processes. The ENMs displayed an unusual behaviour in relation to the kinetics of the dissolution process. This is of significance as the structure of the finished product may not have uniform measurements. Hallock et al. (2009) believe that ENM's unique behaviour poses new challenges for scientists as the technology can be quite unpredictable. This could, according to Brouwer (2010), result in increased levels of toxicity.

2.3.2 Toxicology, Exposure, Disposal and Handling of ENMs

Toxicology as defined by Zhao, Zhang and Feng (2016), is the study of biological effects of chemicals, drugs and other agents (such as ENMs) in living organisms. This section explores the toxicology, sources of exposure, disposal and handling of ENMs. The inclusion and discussion of these

topics under this section is important because it is a prerequisite for ISO 14001 and OHSAS 18001 which are standards included in the integration of management systems and in the development of the quality framework for this study.

Amoabediny, Naderi, Malakootikhah, Koohi, Mortazavi, Naderi and Rashedi, (2009) emphasized that nanotechnology is advancing at a rapid pace and is likely to transform a broad range of materials including consumer products, packaging, medical technologies, construction and manufacturing. Therefore, whilst this technology may bring significant improvement, researchers are uncertain about its effect on occupational health and safety.

Schulte et al. (2016), confirm that carbon nanotubes appear to rapidly promote interstitial fibrosis and lung cancer. They argue that scientists and researchers have been unable to extrapolate toxicity results of ENMs from petri dish and laboratory studies to its impact on humans and the environment.

An understanding of the effects on occupational health and safety is important for this study because ISO 9001 and OHSAS 18001 both consider the latter as requirements for the standards. Hence these effects will be considered in the development of the quality framework and the computer application in this study.

According to Amoabediny et al. (2009), possible routes of nanparticle exposure include oral and dermal inhalation as illustrated in figure 2.4. However, inhalation or ingestion of nanoparticles are likely to be the major route in humans. ENMs can be deposited in the lungs and onward transmission into the blood stream, translocating to other organs such as the brain.

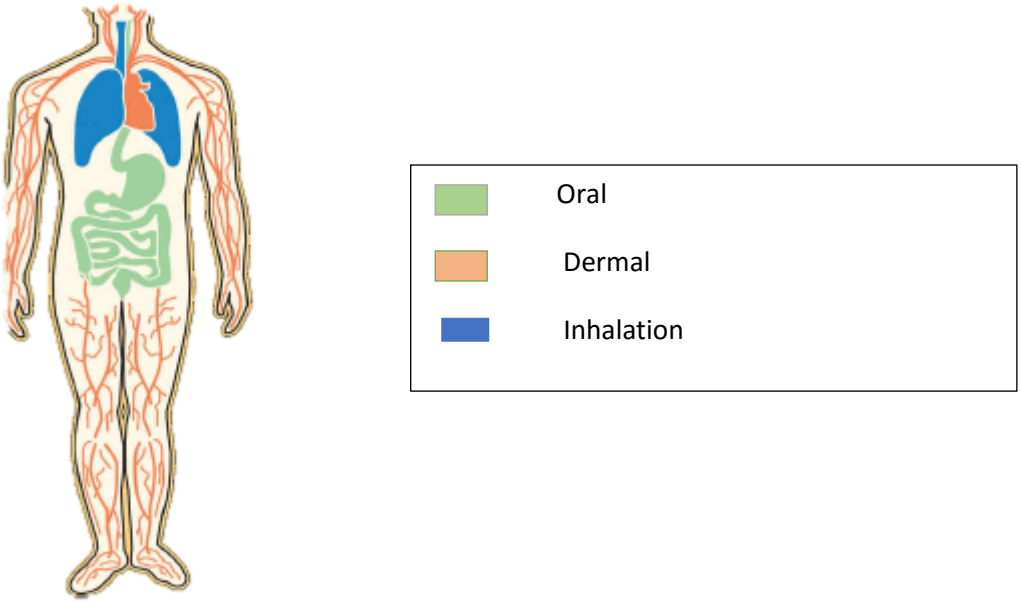

Figure 2.4. Possible Routes of Nanoparticle Exposure.

Source: Amoabediny et al. (2009)

According to Brouwer (2010) particles with an aerodynamic diameter of 1 nm, or 0.001 micrometer, reaches the alveoli (tiny air sacs of the lungs), whilst 80% is deposited in the nose and pharynx hence the retention of inhaled nanoparticles is almost 100%. For particles larger than 5 nm, the deposition is predominantly in the alveolar region of the lungs. Of concern, Warheit (2008) asserts that once deposited, ENMs, due to their size may remain in the lungs longer than the larger particles. Particle deposition in these regions may be responsible for the development of airway diseases, such as chronic obstructive pulmonary disease (COPD) or asthma. These studies also support a direct role for inhaled nanoparticles in systemic infections, such as cardiovascular diseases. Hence there is a need to re-examine how safety is managed in a nano-environment which reinforces the need for a study of this nature.

Oberdorster, Zhu, Blickley, McCellan-Green and Haasch (2006) agree that some types of ENMs can be transferred to other organs, including the

central nervous system. Silver and carbon nanoparticles showed systemic availability after exposure by inhalation. Significant amounts of 13 C-labeled carbon particles (22-30 nm diameter) were found in the liver of rats after 6 hours of exposure by inhalation at 80 or 180 µg / m^3 (concentration of air pollutant approximately one-millionth of a gram per cubic metre). They also found that 13C-labeled inhaled carbon particles reached the olfactory bulb, the brain and cerebellum, suggesting that translocation to the brain occurred through the nasal mucosa along the olfactory nerve.

Khandekar, Joshi and Metha (2008) observed that the capability of ENMs to move about the body may depend on their chemical reactivity, surface characteristics, and ability to bind to body proteins. However, Brouwer (2010) reported that there was no consensus about the ability of ENMs to penetrate through the skin. Particles in the micrometre range are generally thought to be unable to penetrate through the skin. The outer skin consists of a 10- um thick, tough layer of dead keratinized cells (stratum corneum) that is difficult for particles such as ionic compounds, and water-soluble compounds to pass through. However, Brouwer (2010) further found that 0.5 and 1 um dextran spheres penetrated ‘‘flexed’’ human skin in an in vitro experiment. Particles penetrated the epidermis and a few entered the dermis only during flexing of the skin. Particles 2 and 4 micrometers (um) in diameter did not penetrate. From the literature that was reviewed above, it can be inferred that particles in the nanometer range will penetrate the skin.

Ryman-Rasmussen, Riviere and Monteiro-Riviere (2006) found that nanometer-sized quantum dots penetrated through pig skin which is like human skin, thus suggesting the likelihood of penetration of these particles through human skin. Titanium dioxide size (40 nm) is currently used in sunscreens and cosmetics. The nano-particles are transparent and do not give cosmetics the white and calcareous appearance that the thicker preparations do. Hallock et al. (2009) argue that ENMs have been found to penetrate the stratum corneum and more deeply into the hair follicles and sweat glands. There is also concern that the particles of nano- titanium

dioxide have a higher photo-reactivity than the coarser particles and can generate free radicals which can cause cell damage. Some manufacturers have addressed this issue by coating the particles to prevent the formation of free radicals.

The literature reviewed suggests that attention should be given to potential inhalation and penetration of particles by researchers and workers in manufacturing, indicating that adequate and appropriate precautions are essential in the management of ENMs. Cognisance of such precautions will be taken during the development of the quality framework and the computer application.

Kumar and Kumbhat (2016) identify seven (7) studies relating to the toxicological effects of ENMs. They are as follows:

- Nanoparticles may be toxic to cells in vitro – in this study cadmium-selenium quantum dots were found to be toxic in monkey and human cell lines resulting in cell death.
- Cytotoxicity may be modified or reduced by coatings or substituent groups – this study confirmed that Cd-Se quantum dots coated with ZnS or polyethylene glycol do not cause cell death during 2-week incubation in liver hepatocytes.
- Nanoparticles may be more toxic than micron sized particles in short term animal tests – this study confirmed that Nanosized titanium dioxide (20 nm) produced 43-fold more inflammation than 250nm size particles in short term tests of pulmonary toxicity in rats.
- Nanoparticles may translocate to other organs in the body – this study proved that radioactive carbon particles were found in the liver after 6 hours of inhalation exposure in rats.
- Nanoparticles may enter the brain through nasal epithelium olfactory neurons – the results of this study indicated that radioactive carbon reached the olfactory bulb, cerebellum and cerebrum via olfactory neurons in rats.

- Nanoparticles may cause pulmonary inflammation, granulomas and fibrosis in short term animal tests. In this study CNTs caused inflammation, granulomas and fibrosis after single dose instillation in mice. It also decreased breathing rate and bacterial clearance.
- Nanoparticles may penetrate skin. It was proven that quantum dots penetrate to living dermis in isolated pig skin bioassay.

All seven studies above confirm how traces of ENMs were found in the various organs of the subjects tested.

Xia, Zhu, Mu, Zhang and Liu (2016) observed how ENMs could cause respiratory infections and impair immune functions of the lungs. They found evidence that the hazardous potential of ENMs is determined by their physicochemical properties. The physical properties, shape, size, aspect ratio and solubility can translocate to the lungs quite easily via inhalation. Using this study as a basis for safety considerations, it becomes evident that adoption of suitable safety protocols such as the use of N95 respirator mask should be mandatory.

Buzea, Blandino, Robbie (2007), also provided a theory on how ENMs in the lungs can result in cardio-vascular deaths. This is detailed in figure 2.5.

2.3.3 Hypothetical pathways for ENMs

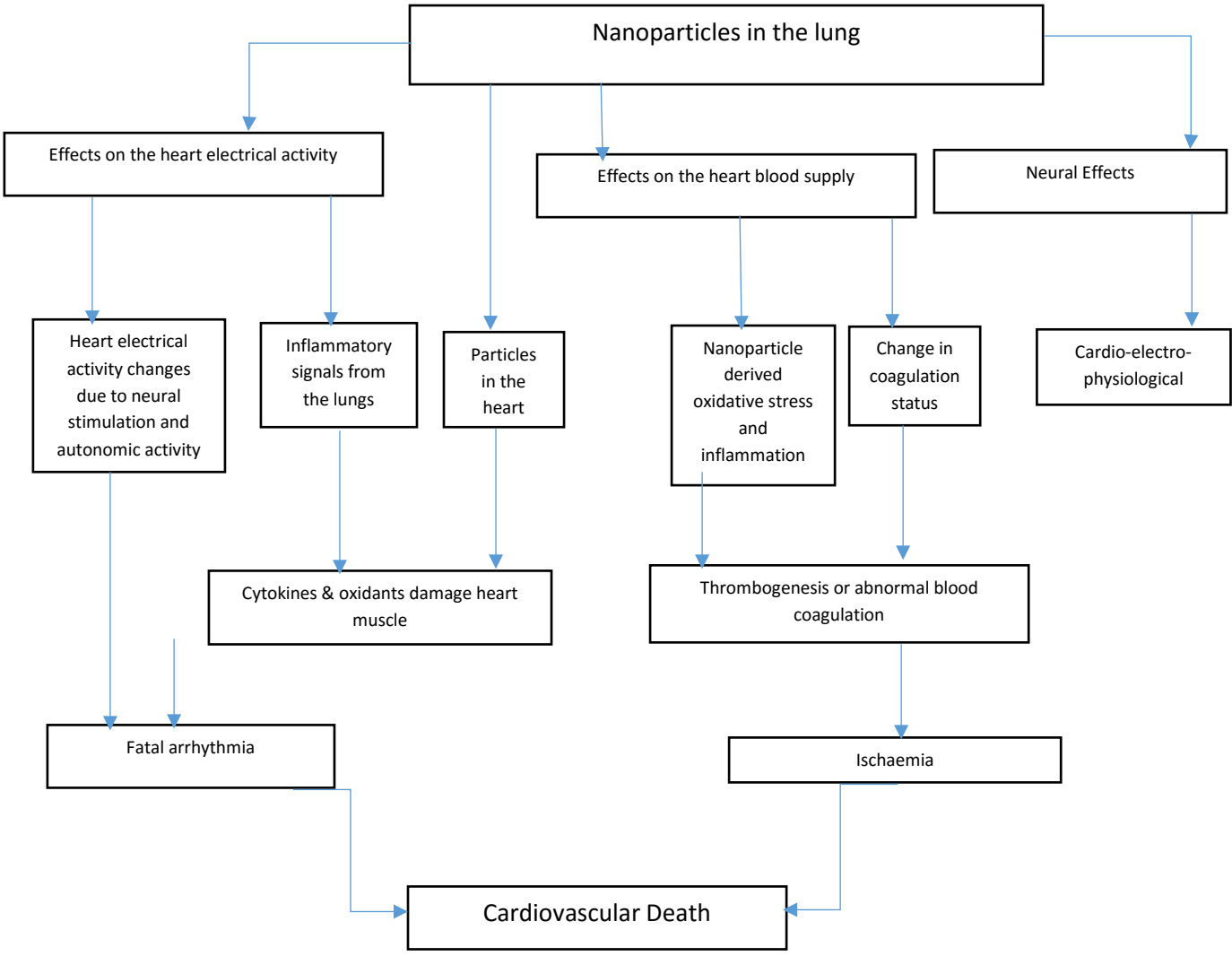

Figure 2.5: Diagram of Hypothetical Mechanisms and Pathways that link ENMs in the Lung with Adverse Cardiovascular Effects.

Source: Buzea et al. (2007)

Buzea et al. (2007) submit that ENMs are created through several physical processes with health risks ranging from lethal to benign. Whilst the dermis of the skin is an effective barrier to foreign particles, the lungs and gastro-intestinal tracts tend to be more vulnerable to ENMs. Figure 2.5 provides a hypothetical scenario on how ENMs, due to their size, can translocate from entry portals into the blood stream and ultimately to organs and body tissue, resulting in cardio-vascular death.

It is evident, from the literature reviewed above on the toxicology and potential hazards of ENMs, that there is an urgent need for a Quality Management System to govern the control, evaluation, manufacturing and disposal of ENMs.

2.4 Sources of Exposure

Amoabediny et al. (2009) in Table 2.1 provide a synopsis of how ENMs can be a potential source of exposure to workers.

Table 2.1: Potential Sources of Occupational Exposure to ENMs

Process Synthesis	**Particle Formation**	**Exposure Source or Worker Activity**	**Primary Exposure Route**
Gas Phase	In Air	Direct Leakage from reactor; especially if the reactor is operated at positive pressure	Inhalation
		Product recovery from bag filters in reactors	Inhalation/dermal/ ingestion
		Processing and packaging of dry powder	Inhalation/dermal/ ingestion
		Equipment cleaning and maintenance	Inhalation/dermal
Vapour Deposition	On substrate	Product recovery from reactor/ dry contamination of workplace	Inhalation/ ingestion
		Processing & packaging of dry powder	Inhalation/dermal
		Equipment cleaning and maintenance	Inhalation/dermal
Colloidal	Liquid suspension	If liquid suspension is processed into a powder, potential exposure during spray drying to create a powder & the processing & packaging of the dry powder.	Inhalation/dermal
		Equipment cleaning and maintenance	Dermal
Attrition	Liquid Suspension	If liquid suspension is processed into a powder, potential exposure during spray drying to create a powder & the processing & packaging of the dry powder.	Dermal/ ingestion
		Equipment cleaning and maintenance	Dermal

Source: Amoabediny et al. (2009)

From table 2.1, it is evident that Amoabediny et al. (2009) confirm that ENMs in the gas phase, vapour disposition, colloidal and attrition phases can be dispersed through air, or substrate or through liquid suspension respectively. The primary route of exposure according to them could be through the processing of ENMs and cleaning of equipment. This is through the skin (dermis), inhalation (nose) and ingestion (mouth).

Abbott and Maynard (2010) argue that the monitoring of ENMs is somewhat complicated because of the lack of proper detection techniques and the unavailability of standardised metric data. They suggest that an exposure metric database be created for ENMs that will identify exposure pathways such as dermal, inhalation or ingestion. These findings are consistent with the literature that has been presented throughout this study. It can be concluded that ENMs are potentially toxic and that anyone working with this technology should be warned. Hence, this information could assist researchers and workers in identifying the potential risks and institute precautionary measures to minimize or eliminate such risks.

2.5 Improving Safety in the use of ENMs

Hallock et al. (2009) argue that as nanotechnology emerges and advances, governments will have to develop legislation to deal with this technology and its impact on human health and the environment. Safety of ENMs covers a wide scope of topics, however, for the purposes of this study only the storage, handling and disposal will be discussed.

2.5.1 Storage of ENMs

The ISO/TR 12885:2008 technical report suggests the following storage protocols:

- Storage containers for ENMs should accommodate the different granulometric characteristics;
- Tightly sealed reservoirs should be used to avoid leakage and contamination;

- With certain ENMs, it may be possible to store in inert gas or in anhydrous (removal of water) conditions;
- It is also possible to surround certain ENMs with a protective layer of salts or polymers. These layers can be removed prior to using the product;

Dhawan, Shanker, Das and Gupta (2011) advocate that ENMs:

- Be stored in a demarcated area in separate cabinets;
- Have danger labels that boldly emblazoned on such cabinets;
- Have danger labels like that of toxic, carcinogenic or flammable materials.

Thus, if proper storage procedures are adopted, dangers to personnel could be minimised and ENMs will be prevented from being externally contaminated. This view is supported by Carey (2016).

2.5.2 Handling of ENMs

Hallock et al. (2009) contend that the use of ENMs does raise questions regarding possible health risks to manufacturers and workers. They proposed a list of handling procedures in several common potential exposure routes.

Hallock et al. (2009) maintains that there are six routes of possible contamination, namely:

- Inhalation exposure;
- Dermal exposure
- Laboratory contamination
- Spillage ENM waste and
- Lack of toxicity information

According to Hallock et al. (2009), the possible prevention of inhalation exposure include:

- Using a fume hood, biosafety cabinet or other exhausted enclosures.
- Mixture in furnace or reactor: exhaust reactor gases – purge before opening, have an exhaust ventilation for emission points.

- Perform part maintenance in fume hood.
- Reduce or eliminate the use on open laboratory bench.
- Transport within laboratory in sealed containers.

To prevent dermal exposure, Hallock et al. (2009) suggest the following:

- Use of sturdy gloves for dry particulate.
- Use of gloves resistant to solvent if nanoparticles are in suspension.
- If skin contamination is likely, use double gloves or gloves with gauntlets or extended sleeves.
- Use of laboratory coats, preferable disposable.
- Use of appropriate eye protection.

To prevent laboratory contamination:

- Wet wipe hood & other laboratory surfaces after use or at end of day.
- Avoid using compressed air for cleaning.
- Use bench liners or vacuum cleaners

To prevent spillage:

- Have spill kit on hand; wet wipe for dry spills.
- Use appropriate absorbent for spills or suspensions.
- Use vacuum cleaner for larger spills
- Use respirator (disposable P100 or elastomeric half-mask with P100 cartridges) if there is a possibility of inhalation exposure.

To minimize ENM waste:

- Dispose of nanomaterials and nanomaterial-contaminated laboratory materials as hazardous waste until specific regulations are developed.
- Label waste as nanoscale.

Obtaining, updating and communicating of toxicity information and reports regularly.

From an analysis of literature, particularly around the calls for personal protective equipment and good laboratory practice with ENMs (Dhawan et al., 2011) and, Hallock et al. (2009) suggest plausible methods for handling materials and infrastructure.

From the commentary above and in developing methods to identify and analyse ENMs risk including the use of a computer application, the following routes of contamination must be considered:

- Inhalation exposure
- Dermal exposure
- Laboratory contamination and
- Disposal of ENM waste

2.5.3 Disposal of ENMs

Hallock et al. (2009) further advise that ENMs waste material including paper, wipes, PPE or other items should be placed in a sealed plastic bag after use. The bag, when full, should be sealed and placed it into a second plastic bag. Furthermore, the bag must be labelled indicating that it contains ENMs waste and proper disposal protocols must be adhered to. Boldrin et al. (2014) maintain that there is a lack of guidelines and protocols specifically addressing disposal of waste nanomaterials. Waste ENMs streams consist of carbon nanotubes, contaminated ENMs for example: wipes/personal protective equipment (PPE), ENMs in liquid suspensions, ENMs that have solid matrixes that are powdery or are loosely attached to the surface can be expected to break free or leach out when in contact with air or water and nano- dust generated from cutting, milling or grinding procedures. Ounoughene, LeBihan, Debray, Chivas-Joly, Longuet, Joubert, Lopez-Cuesta, and Le Coq (2016) claim that the disposal procedures for ENMs is increasingly drawing the attention of authorities due to its potential toxicity and emissions into the environment. Hence, through the model proposed in this study, suitable disposal protocols would be embedded in the Quality Management System.

Based on the review of the literature on the structure, composition and challenges of ENMs, it is evident that there is a need for strategic interventions in respect of health and safety of employees. This study attempts to propose such intervention through the development of a quality framework which will cover monitoring, evaluating and controlling ENMs.

The next section deals with the regulations and technical reports governing ENMs.

2.6 Intervention Strategies for Developing and Manufacturing ENMs

Several technical reports were developed by International Standards Organisation (ISO) relating to the management, safety and risk evaluation of ENMs. The reports that are discussed below formed the basis for the research questionnaire developed and used for this study.

2.6.1 Regulations/Technical Reports – Guiding Principles for Ethical and Safe Working Conditions

The Technical Reports (TR 13121:2011 and TR 12885: 2008) were used to inform this study. Whilst these reports have no legal or regulatory compliance standing, they are useful to guide organisations in dealing with ENMs to participate in ethical and safe working conditions (TR 13121:2011 and TR 12885: 2008).

2.6.2 Technical Report ISO/TR 13121 (2011) – Steps in Risk Management

The ISO/TR 13121 (2011) technical report describes a process for identifying, evaluating, communicating and decision making relating to the potential risks of developing and using ENMs in order to protect health and safety issues for all those that are potentially exposed to this technology. The risk management suggested in this report comprises six (6) steps represented in Figure 2.10:

Figure 2.6: Steps in Risk Management

Source: Adapted from the International Organisation for Standardisation (2011). ISO/TR 13121.

As indicated in Figure 2.6 above, ISO/TR 13121 entails 6 steps, which are described below.

Step 1 – Description of Materials and Applications

This step describes the ENMs and includes the stage of development, source of ENM, identifies who is responsible for its procurement or

manufacturing, means of transportation, length of existence and the intended use of the ENM.

There is also a need to determine the benefits of manufacturing this material in the nanoscale, the handling, processing and disposal of the ENM and any other potential application for this material.

It can be inferred that step 1 deals with the management of the ENM on a broad scale. It included the activities and involvement of the entire Supply Chain ranging from procurement, incoming raw materials through to disposal. This step is aligned to the requirements of ISO 9001 thus highlighting the quality management aspects of ENMs.

Step 2 – Develop a profile

Step 2 develops a profile of ENMs properties, hazards and exposures. This includes the routes of occupational exposure, the laboratory equipment, for example, the fume-hood, extractors, the personal protective equipment (PPE), emergency procedures and the environmental fate of the ENMs.

The required information includes the number and location of manufacturing sites, the annual volume of ENMs to be manufactured, the manufacturing methods (technical specifications, work instructions) and the number of employees that could be exposed to the ENM.

From the discussion above, Step 2 aligns to the requirements of safety (OHSAS 18001) and environmental management (ISO 14001) standards.

Step 2 also details the distribution, delivery, packaging, storage and post use management of ENMs. Guidelines for measuring and monitoring exposure to ENMs include workplace monitoring, sampling procedures, data collection and accident reporting. The relevance of ISO 9001 is also apparent from the foregoing section.

Step 3 – Evaluate risks

Step 3 involves the evaluation of risks and includes exposure levels, identification of possible risks, identification of knowledge gaps and planning for worse case scenarios.

Step 4 – Assess risk management options

Risk management options are assessed by determining the best practice, evaluating safety procedures and measuring the efficacy of how airborne ENMs are captured by ventilation systems. Administrative issues, PPE and communication is also included in this step.

Both steps 3 and 4 cover the requirements of ISO 9001 and OHSAS 18001.

Risk assessment is the analysis of the potential adverse health effects (current or future) caused by a hazardous agent. Risk assessments in occupational settings include hazard identification, hazard assessment, exposure assessment and risk characterization (ISO/TR12885:2008). Schmidt (2009) is of the view that conducting a Risk Assessment (RA) of ENMs is becoming more important and relevant, especially since an estimated 2000 ENMs are in commercial use today. Another school of thought offered by Singh (2016) presents a model for risk assessment.

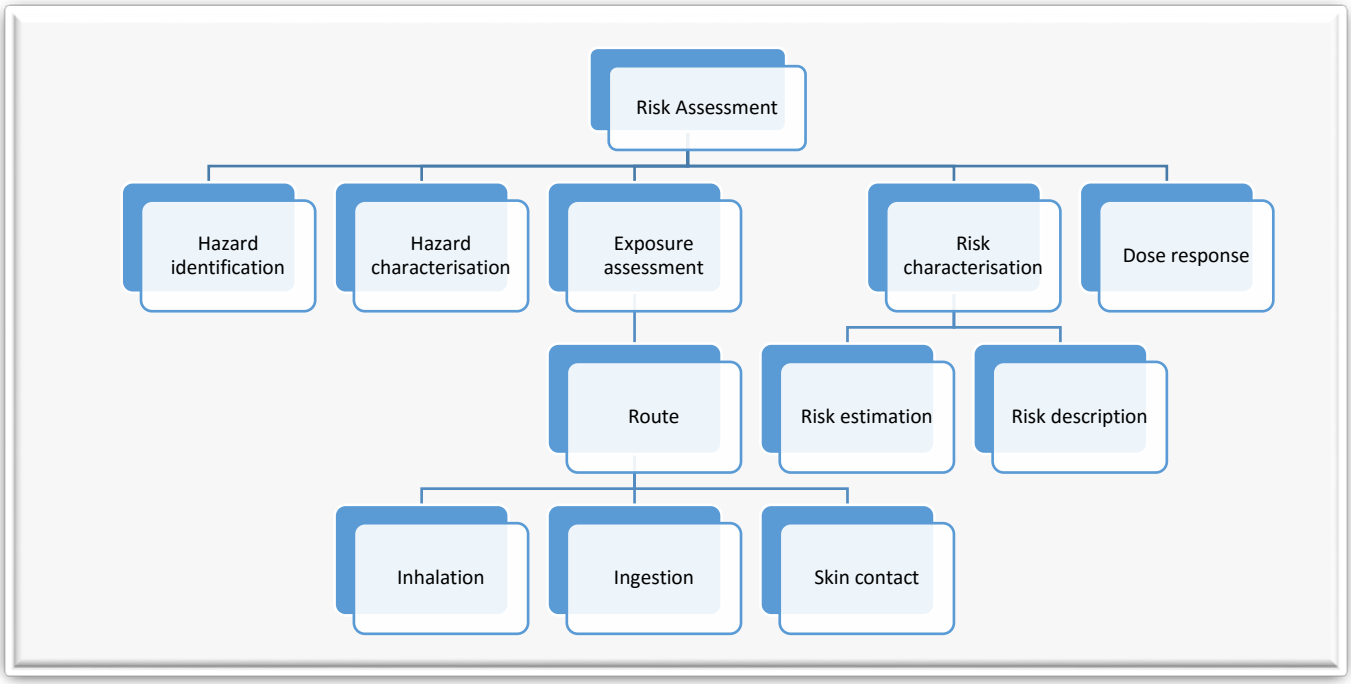

Figure 2.7: Activities to consider in Risk Assessment

Source: Singh (2016)

Figure 2.7 proposes the steps which should be undertaken when conducting a risk assessment for ENMs. It commences with hazard identification as the first step of the assessment and then progresses to hazard characterisation, exposure assessment, risk characterisation and finally dose response. It was perceived that adherence to figure 2.8 will enable step2, step 3 and step 4 of the ISO/TR 13121 ultimately contributing to developing the Quality framework.

To further assist with identifying the factors to be considered in the development of the Quality framework, Kuempel, Castranova, Geraci and Schulte (2012) was reviewed. Their study provides current information on occupational, health and safety relating to ENMs. Furthermore, they claimed that ENMs can be measured by using:

- Standard measuring methods (respirable mass or number concentration);
- Engineering controls for risk management;
- Appropriate personal protective equipment (PPE);
- Risk assessment methodologies (Research and Tools) to test toxicity and
- Risk characterisation to confirm severity and likelihood, variability and uncertainty. An overview of their study on the research tools, risk characterization, risk management and workplace actions is presented in figure 2.8.

Figure 2.8: Components for Assessing, Characterizing, Communicating and Managing Risks.

Source: Keumpel et al. (2012).

Step 5 – Decide, document and act

Documentation allows those absent at meetings to understand the decision-making process, its outcomes and resulting actions. The organisation must decide who will have access to such documentation. The documentation should include an introduction, any modifications, methods of manufacture, termination of redirection of ENMs, implementation timelines for the risk management, a monitoring and compliance process, and the determination of the product review cycle including timing and conditions for the next review. A comprehensive communication plan must be developed for all stakeholders. Step 5 is applicable to all the standards

that will be used in the integration and development of the Quality framework.

Step 6 – Review and Act

The ISO standards provide a mechanism to check processes to confirm whether they are functioning properly according to plan. In this stage the monitoring, measuring, analysis and evaluation of products or services is done in order to meet customer expectations.

Action must be taken to address non-conformances and it must be the role of senior management within an organization to conduct regular follow-ups to ensure the continuous improvement of the systems.

Hence these six (6) steps outline the risk when dealing with ENMs. It highlights the importance of identifying, assessing and managing ENMs' risks right from the procurement, manufacturing, transportation through to disposal. Developing a profile of ENMs is useful in determining potential routes of exposure, identifying knowledge gaps and ultimately developing safety protocols. It is worth noting that the steps outlined in this technical report will be considered in the development of the integrated Quality framework for this study.

2.6.3 Technical Report: ISO/TR 12885 (Health and Safety Practices in Occupational Settings Relevant to Nanotechnology (2008)

This technical report provides a framework for adopting good health and safety practices in the use of ENMs.

2.6.3.1 Overview of related clauses of the ISO/TR 12885 (Health and Safety Practices in Occupational settings relevant to Nanotechnologies) technical report

This report proposes practices to control operations in ENMs responsibly. It covers the sub-themes: Hazard Characterisation, Risk Exposure and Risk Assessment. Each of these sub-themes and their contribution to the development of strategies to address the issues relating to risk in ENMs, is presented in the following section.

2.6.3.2 Hazard Characterisation

This sub-theme focuses on monitoring health effects and physical hazards. Typically, the health effects of a hazard is characterised by its duration, magnitude, inherent toxicity and the health condition of a person being exposed (ISO /TR 12885). However, with the novelty of ENMs, these effects have not been established. Suggestions have been made to relate the possible behaviour of ENMs to their bulk counterparts (Hansen et al., 2007).

Makowitz, Levin, Miller and Morabia (2013) claim that, asbestos has proved to cause lung disorders (including pulmonary interstitial fibrosis, pleural plaques, calcification and thickening). The harmful effects of fibres are driven by three important factors: diameter, length, and persistence. Whilst it is difficult to draw conclusions regarding the health effects of engineered nanoscale fibres based on asbestos studies, researchers suggest that particle properties of size, shape and composition are important factors that can influence the toxicity of nanoparticles. Carbon nanotubes' needle like shape has similar properties with asbestos. This is of importance because researchers and manufacturers are starting to make significant use of carbon nanotubes in bulk quantities and there could be possible health and safety risks attached to such use.

Furthermore, a study was undertaken by Treumann, Ma-Hock, Groters, Lindsiedel and van Ravenzwaay (2013) to test the effects of single walled carbon nanotubes and multi-walled carbon nanotubes on the lungs of laboratory tested rodents. The study showed unusual inflammatory and fibrogenic reactions in the lungs, including transient inflammation followed by early onset of fibrosis. Craig, Duffin, Kinloch, Maynard, Wallace, Seaton, Stone, Brown, MacNee and Donaldson (2008) also suggest that some forms of CNTs could be as harmful as asbestosis if inhaled in sufficient quantities.

Physical hazards such as fire, catalytic reactions, radiation emitting devices, among others, also require consideration under this technical report.

Figure 2.9 describes the possible health effects of ENMs including the paths it follows and how it can be managed and controlled.

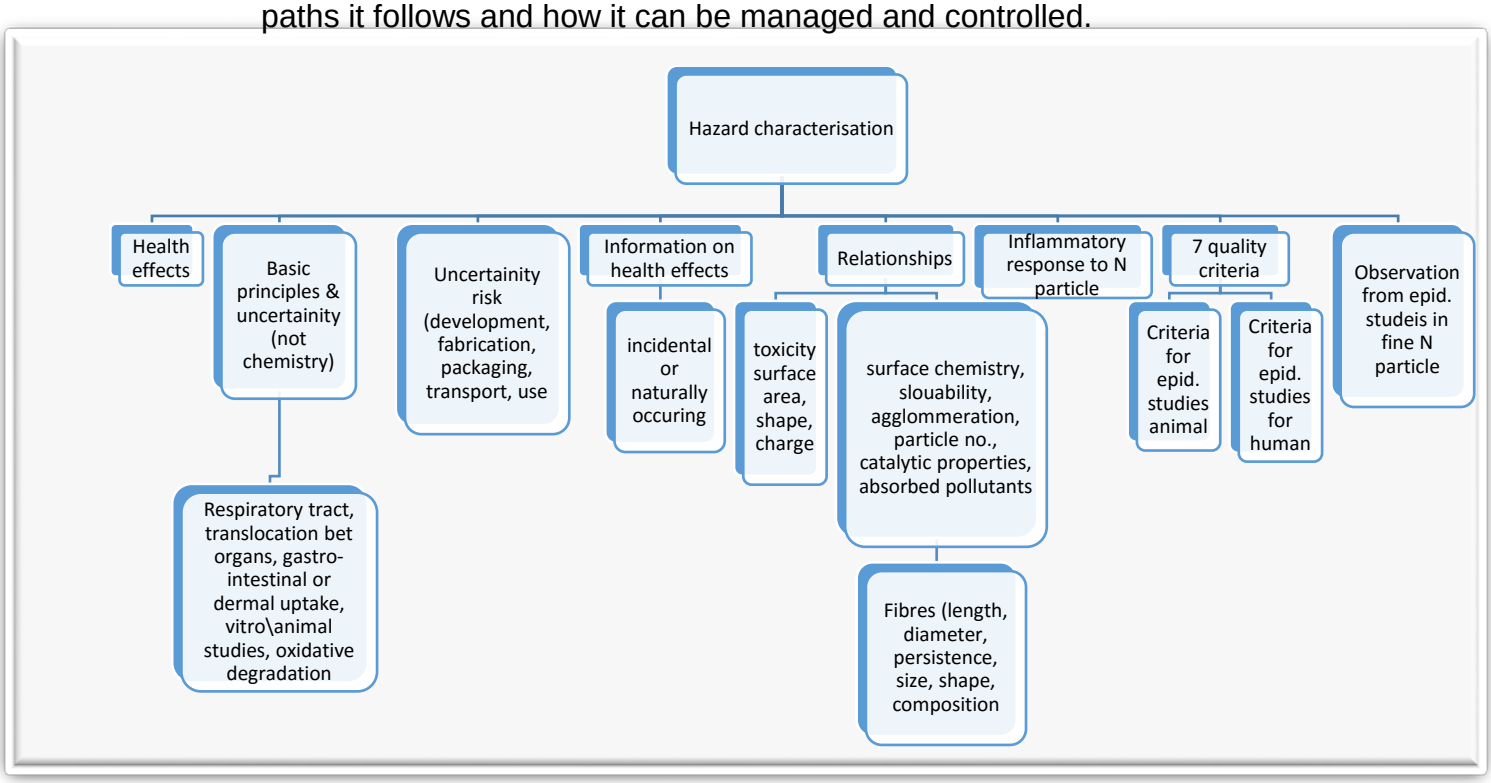

Figure 2.9: Activities to Consider During Hazard Characterisation

Source: Singh (2016).

Figure 2.9 also provides an understanding of the source, the composition, the possible behaviour and effects of the ENMs. It can be inferred that hazard characterisation is an important requirement in ISO 9001 and OHSAS 18001, hence both of these systems will be considered during the development of the Quality framework and computer application.

2.6.3.3 Dermal Exposure Assessment of ENMs

The ISOTR 12885 (2008) report outlines the procedures that could be followed to test for dermal exposure to ENMs. Firstly, a sample of ENMs deposited on the skin must be taken. Tests must be performed to establish contamination. Thereafter, corrective action be taken. The technical report falls short of providing possible procedures for inhalation and ingestion even though the literature suggests that inhalation could cause potential harm (Amoabediny et al., 2009).

2.6.3.4 Risk Assessment for ENMs

The components of risk assessment have been highlighted by Boldrin et al. (2014) and Singh (2016) in the foregoing sections and is applicable to ISO/TR 12885:2008 hence it has been omitted in this section.

An analysis of the related literature and both technical reports reveal important factors that should be considered in controlling ENMs. It is crucial that such factors be considered in any management initiative of ENMs. Therefore, these factors were used in the development of the research questionnaire administered in this study. The factors are presented in Table 2.2 below:

Table: 2.2 Factors to be considered in managing ENMs.

Singh (2016); Kuempel et al. (2012); ISO/TR 13121 (2011); Schmidt (2009),	Singh (2016), Boldrin (2014), Makowitz et al. (2013), Treumann et al. (2013); ISO/TR 12885: 2008
Health hazard data set	Physicals hazards
Description of nanomaterials and its applications	Routes of exposure
Risk evaluation	Risk assessment
Material safety and handling	Risk characterization
Description of nanomaterials	Record keeping
Description of applications	Storage
Investigating environmental-exposure potential	Evaluating the work environment
	Dermal protection

Source (Adapted: by Researcher).

From Table 2.2 we observe that the inclusion of ISO/ TR 13121: 2011 and ISO/TR 12885:2008 in the proposed framework will allow organizations to track routes of exposure; conduct risk assessments; describe applications; investigate potential environmental-exposure; systems to evaluate the work environment and focusing on dermal protection.

2.7 Code of Conduct for Nanotechnology Principles (EC 2005)

The European Union (EU) Commission (2005) recommends a code of conduct for responsible research into nanotechnology. This code focuses on a safe, integrated and responsible strategy to good governance when working with ENMs. The code comprises of seven (7) principles:

Figure 2.11: EU Code of Conduct for Nanotechnology Principles.

Source: Adapted from Nanowerk (2005)

According to Nanowerk (2005), the EU Code of Conduct for Nanotechnology Principles (2005) suggests the following principles:

- The Principle of Public Well Being

  ENM research needs to be mindful about respecting fundamental human rights and this needs to be addressed in the design, manufacturing and disposal phase of this technology. The public needs to be informed about the use of nanotechnology.

- The Principle of Sustainability
  Nanotechnology needs to be managed in a safe, ethical and sustainable manner. There should be no harmful effects on people, animals, plants or the environment at present or in the future.
- The Principle of Precaution
  ENM research activities should be able to anticipate the potential harmful impact on safety, health and environment. Hence a precautionary approach should be adopted by building adequate safety features.
- Principle of Democracy
  Nanotechnology must be guided by the principles of openness and transparency. All stakeholders should have a legitimate right of access to information.
- Principle of Excellence
  ENM research and manufacturing activities should conform to acceptable scientific and manufacturing standards. It is suggested that organisations involved with this technology subscribe to ISO 9000 and ISO 17025.
- Principle of Innovation
  The development of nanotechnology should foster maximum creativity, flexibility and innovative practices.
- Principle of Responsibility
  Researchers developing this technology must act in a responsible manner and should remain accountable for the environmental and social impact this technology may impose on present or even future generations.

Based on the literature above, the EU code places certain obligations on the researcher which include research that is of public interest, using ethical principles and identifying risks prior to applying for research funding.

It is of particular concern that this code has no legal standing amongst EU states and is merely a guideline for nanotechnology research. However, it must be noted that the EU's code of conduct articulates the principles of public well-being, taking adequate precautions, being excellent and innovative, ensuring sustainability, democracy and ultimately being responsible when using ENMs.

The underlying EU principles of public well-being, precaution, excellence and responsibility will be used in developing the Quality framework presented in this study as it is in keeping with each ISO standard in the integration process.

The following section is aligned to objective 4 of the study which attempts to integrate management systems for ENMs.

2.8 Management Systems

Stevenson (2007) believes that the challenges facing organisations include complying with customer requirements, adhering to regulations, instituting best practices and growing the organisation. Pardy and Andrews (2010) and Sroufe and Curkovic (2008) assert that one way of achieving these objectives is through an effective management system. According to Heizer et al. (2014), management systems is a set of procedures that an organisation uses to achieve its objectives. The benefit of using a management system is that it improves the use of existing resources, facilitates the identification and management of risks, improves safety, customer satisfaction and profitability.

The structure of quality management systems typically follows a generic format and can be adapted to suit the context of the organisation in which it is implemented. The next section deals with management systems in relation to ENMs.

2.9 Quality Management Systems (QMS) for ENMs

According to Rocha-Lona, Garza- Reyes and Kumar (2013), a QMS is an integrated business approach to plan and deploy models, methods and tools across the organisation that aligns to strategy. The structure of a QMS is shown in Figure 2.12

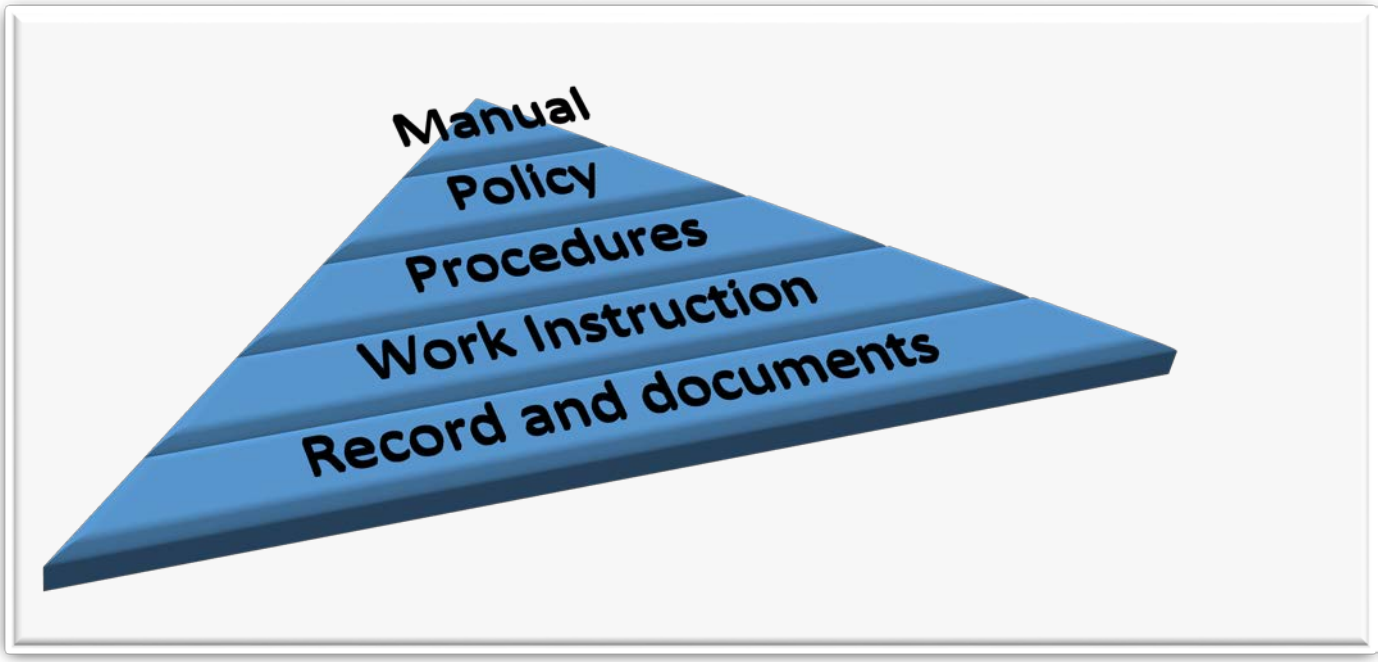

Figure 2.12: Structure of a QMS

Source: Mitra (2016).

Mitra (2016) explains the structure of a QMS as follows:

- The manual includes the scope, references to relevant documents, and the business process model. It could also contain policy, organisational objectives and definition of responsibilities.
- Policies are statements that reflect the commitment to continual improvement. It defines quality objectives to which the organisation hopes to achieve. This includes, title, purpose, scope, responsibilities, records and description of activities.
- Procedures define the policy in terms of who, what and where? It also includes responsibilities.

- The work instruction is very similar to procedures but define specific steps to accomplish a task, for example, the activities, the sequence of steps, the equipment required and the methods to be used.
- Records and documents include what, where, when, who and how documents are stored.

The above literature provides fundamental documents required in the development typical quality management systems and will thus be used in the development of the quality framework proposed for this study.

Currently, there is very little formal quality practice in nanotechnology. Pries and Quigley (2013) and Rebelo, Santos and Silva (2014) observe that the structure of a QMS provides opportunities for organisations to establish policies, procedures, work-instructions and records. Adherence to this structure will provide direction for an organisation in terms of uniformity and standardised practices.

According to Jones (2012), the following elements contribute to the success of a QMS.

- Labour – this includes work ethics, education levels, experience, skills, attitude to quality, turnover, absenteeism and health and safety.
- Processes - consistent results are achieved more effectively when process activities are easily understood and managed. The focus is to achieve customer satisfaction and must be aligned to the organisations objectives. In improving processes, the following concepts can be used.
- Failure Mode and Effects Analysis (FMEA), Concurrent engineering, Experimental design, Process Improvement, Design team formation and management, Off-line experimentation, Reliability and durability product testing.
- Quality tools include Plan-Do-Check-Act (PDCA), Cause and Effect diagram, Check Sheet, Control charts, Pareto charts and Statistical Process Control (SPC) and Flow charts.
- Organisational strategy – if an organisation decides to focus on quality to give it a competitive edge, it becomes the central strategic issue. In

order to achieve this, it must foster a culture of quality within the organisation.

From the above-mentioned commentary these suggestions for quality concepts and practices and their importance are noted.

Furthermore, Jones (2012) suggests that Strategic Quality Planning (SQP) has become essential in any organisation as it provides direction to implement quality practices. It encompasses both internal and external analysis of the organisation, the generation of plans and objectives, implementation measures and monitoring of outcomes.

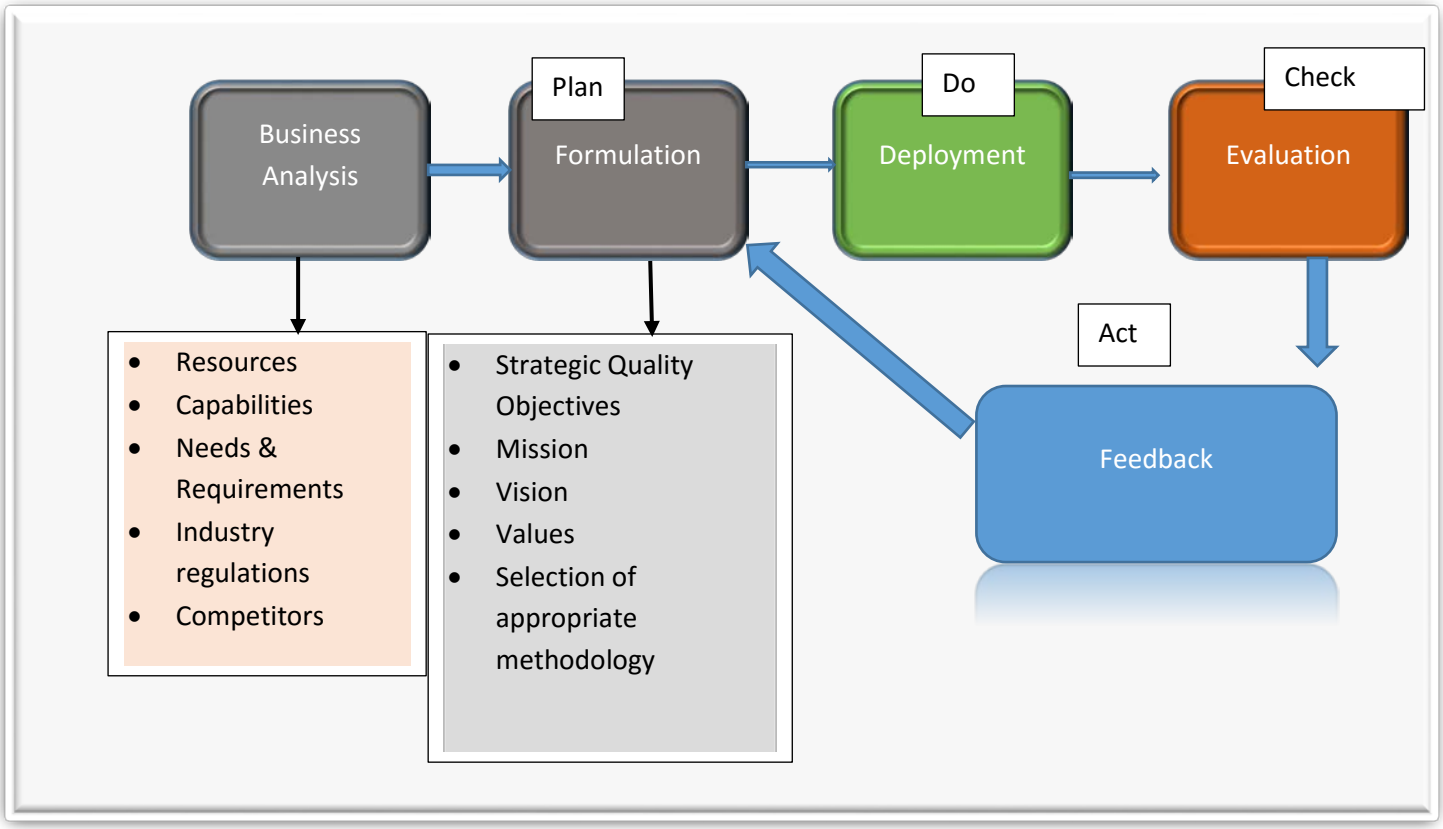

Figure 2.13: SQP Model for a QMS

Source: Jones (2012)

It can be inferred from figure 2.13, that the strategy is underpinned by the Plan-Do-Check-Act (PDCA) quality tool. Initially the organisation needs to be analysed in terms of resources, capabilities, customer requirements, legislation and competition. In the planning stage, strategic quality objectives must be identified that are in line with the organisations' mission,

vision and values. Thereafter the correct methodology is selected as discussed in figure 2.14.

An alternative view for the implementation of a business model for a QMS is presented by Rocha-Lona et al. (2013) in figure 2.13

Figure 2.14: Business Model for a QMS

Source: Rocha-Lona et al. (2013)

Rocha-Lona et al. (2013) suggest the following elements for their model:

- Knowledge management organizes information systematically for the purpose of creating value and meeting strategic objectives. It includes researching latest information, creation and sharing of information.

- Information Technology (IT) includes system software, hardware, internet, networks and databases. From a quality perspective, IT should provide systems support, improve customer - supplier relationships, enhancing process controls, measuring quality costs and facilitate real-time information flow.

Jones (2012) and Rocha-Lona et al. (2013) outline important elements that that are required to ensure the success of a QMS. An assessment of their elements is synonymous with the EU Code of Conduct which was discussed in the previous section, which possibly implies that a QMS together with a business model can be used as a fundamental foundation for an organisation working with nano-enabled products.

Rocha-Lona et al. (2013) provide a methodology in the form of a QMS and business model in figure 2.14. This methodology illustrates how an organisation can select an appropriate model, method or tools to build its QMS. The model commences with the QMS diagnostics which leads to strategic planning, introduction of a model, cost benefit analysis, resource requirements and capabilities of the organisation. At each point in the process, a ‘yes-no’ question is answered leading to the adoption of the final model.

The quality diagnostics investigate the feasibility of whether the model can be implemented or not. If this is possible, a strategic plan is compiled. The quality strategic plan includes identifying customer needs, conducting a gap analysis, aligning the plan to the organisation’s mission and vision and an implementation plan. A cost-benefit analysis is then undertaken. Roosen (2014) defines a cost-benefit analysis as a comparison between the benefits that the organisation can realise in monetary terms versus the investment of estimated costs. If the model is not cost effective, then an

alternative solution needs to be sought. Resources which includes labour, equipment, materials, capital, energy and information are analysed to identify potential problems. If the organisation has adequate resources, it can then do a capability study, if not, the organisation can seek ways of acquiring resources through capital expenditure.

Organizations developing, and manufacturing nano-products must be mindful of ensuring long term sustainability and profitability. However, organisations must take cognisance that strategy must be aligned with a suitable a business model before initiating a QMS.

Figure 2.15 documents a flow process for the selection and adoption of a QMS. The process commences with a strategic plan which encompasses the need for a QMS.

Several QMS models are proposed for the organization. If the model does not meet the specified criteria and needs of the organization, the implementation is halted, and an alternative model is evaluated. Once a suitable model is accepted, a cost-benefit analysis is conducted. If the model does not yield significant benefits, an alternative model is then sought. If the cost-benefit analysis is acceptable, then resources and capabilities are interrogated. For example, does the organization have the right skill set (labour), correct machinery and appropriate systems. If these are found lacking, then they must be either acquired or developed prior to adopting a QMS.

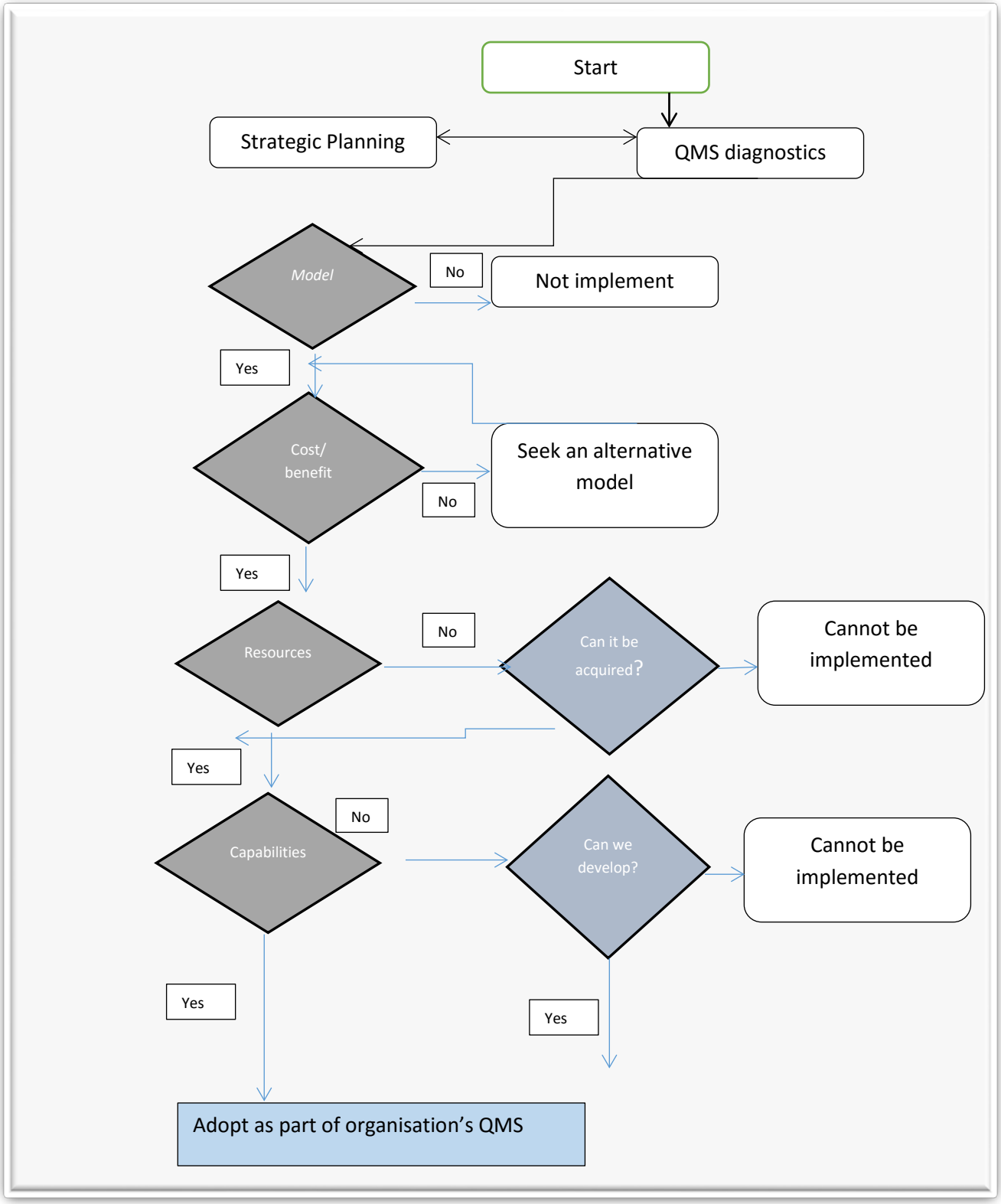

Figure 2.15 Selection Method for a QMS.

Source: Adapted from (Rocha-Lona et al., 2013)

Delgado (2010) and George and Shoemaker (2000) observe that in the race to be part of the nanotechnology frenzy, there are many novel nano-enabled products mostly in the Research and Development phase. Wiek, Foley, Gunston and Bernstien (2016) point out that several of these products have not matured to the stage of commercialisation because of the lack of the researchers' business acumen. They also state that researchers who work towards innovation are distracted from the organisational strategic plans. Quite often these innovations are not feasible for commercialisation. Application of QMS models as illustrated in figures 2.13, 2.14, and 2.15 could help to assess the feasibility of new innovations to evolve within the scope of the organisational plans.

The review of the literature presented serves two purposes in this study. Firstly, it provides an organisation with a basic platform to situate their quality practices. Secondly, it highlights the important considerations in the development of strategies to address health and safety in a Quality framework.

2.10 Implication of Quality Costs of ENMs

According to Heizer et al. (2014), one of the most important tasks is to deliver safe, healthy and quality products to markets. In order to achieve this, a culture of quality must be embedded within the organisation. Every layer of the organisation must be aware of the consequences, costs and implications of poor quality.

As discussed earlier nanotechnology is in its infancy and as such is confined to R & D and in selected manufacturing organisations with little commercialisation in place compared to its envisaged potential. In an attempt for organisations to mature in their commercialisation sustainably, Westgard and Westgard (2014) suggests that the Cost of Quality must be identified.

Goetsch et al. (2014) and Heizer et al. (2014) maintain that an understanding of the Cost of Quality is important as it allows an organisation to do things right the first time. They categorize the costs of quality as follows: Prevention costs, Appraisal costs, Internal and External failure costs. Prevention Costs – which include trying to prevent quality problems, quality failures and errors from occurring in the first place. They can be summarised as follows:

According to Chase, Jacobs, Aquilano (2004), prevention costs include:

- The identification of potential problems and correcting them before defects occur.
- Designing better products, services and processes to eliminate or diminish quality problems.
- Upskilling employees through training and development initiatives to ` ensure better qualified personnel.

In a nanotechnology environment, prevention costs will eliminate defects before production commences. This will improve the profitability of the organization, especially if it is in its initial stage of business.

Mitra (2016) explains that Appraisal Costs are costs related to measuring and controlling quality. The costs occur mainly for checking, inspection and testing activities before, during and after the production process. They include:

- Implementing statistical process control (SPC) programmes and administering sampling plans.
- Inspection time relating to inputs, outputs and processes.
- Verifying and obtaining of processing inspection records and test data sheets.
- Examining quality problems and compiling quality reports.
- Administering customer surveys and conducting quality audits.

Appraisal costs cannot be overlooked for ENMs. The testing and verification is crucial as the risks of this technology is still relatively unknown.

According to Foster (2007), Internal failure costs – relate to errors picked up whilst the product is within the operation, and include:

- Material, scrapped parts and sub-assemblies.
- Reworking of material, parts and sub-assemblies.
- Production time lost as a result of errors.
- Time spent fighting fires (trouble-shooting) rather than improvement efforts.
- External failure costs – are those which are associated with errors that have reached the customer. These costs include:
- Cost of customer goodwill.
- Unhappy customers.
- Lawsuits and litigation.
- Guarantee and warranty costs.

External failure costs will be the most problematic for ENMs as this entails recalling products that have already been sold or distributed to consumers. The negative advent of a recall will attract the interest of the public since it has to be advertised in national or sometimes international media.

Based on the literature above, it would be prudent for organisations to focus their attention on prevention costs rather than failure and appraisal costs as this would yield significant benefits in terms of less scrap and rework.

Jones and Robinson (2012) argues that quality assurance is best described as the maintenance of a desired level of quality. Quality assurance considers acceptable standards, regulations, best practices, policies and procedures.

2.11 The Need for Quality Assurance of ENMs

In keeping with the philosophy of prevention, Jones et al. (2012) noted that Quality Assurance (QA) is a concept that is designed to ensure errors and faults do not occur or are minimised. In the case of ENMs the philosophy below "prevention is better than cure" could be adopted by the QA program in figure 2.16.

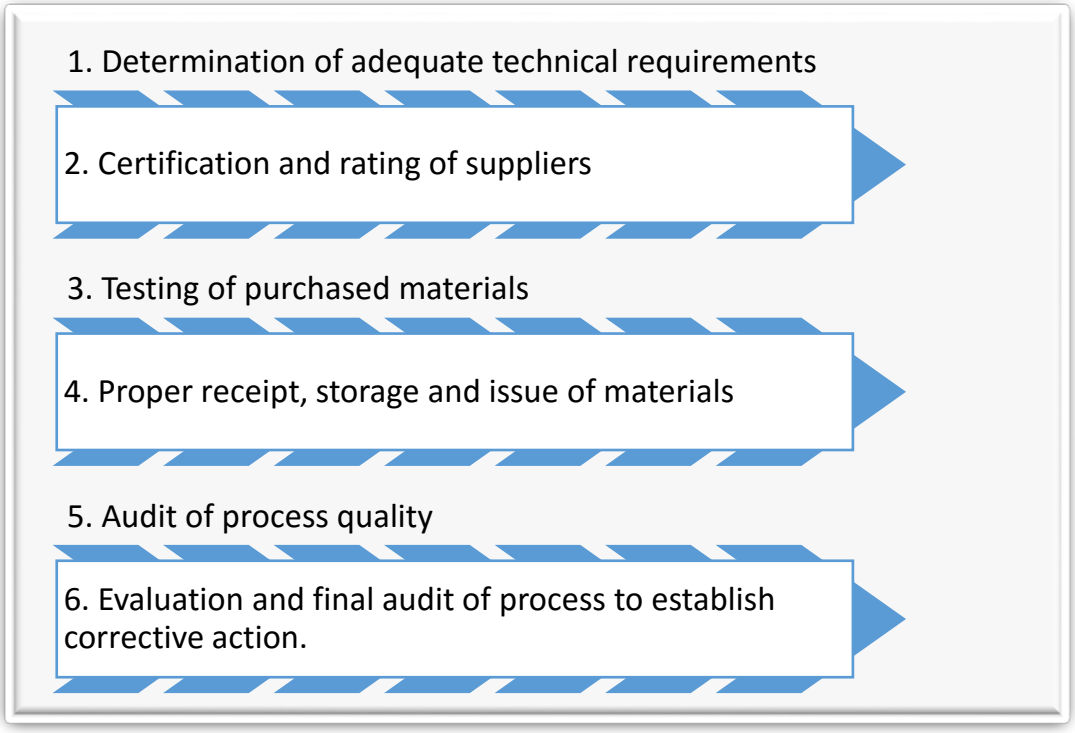

Figure 2.16: Steps in the Quality Assurance process.

Source: Jones et al. (2012)

Jones et al. (2012) propose that determining technical requirements, certifying suppliers, material testing, storage of materials audits and evaluations must be controlled via policies and procedures.

Specifically, for nanotechnology, Nanjwade (2009) confirms that the Quality Assurance for processes should include the following items:

- Technology transfer which includes product design documentation, distribution of documents, product validation, establishing units of measurement, calibration of equipment and researching reference materials.
- Validation consists of preparing validation plans, approval of validation protocols and team responsibilities.
- Document Control which includes approval, control, distribution and archiving.

Furthermore, Singh (2016) provides a comprehensive framework (figure 2.17) for QA activities in nanotechnology.

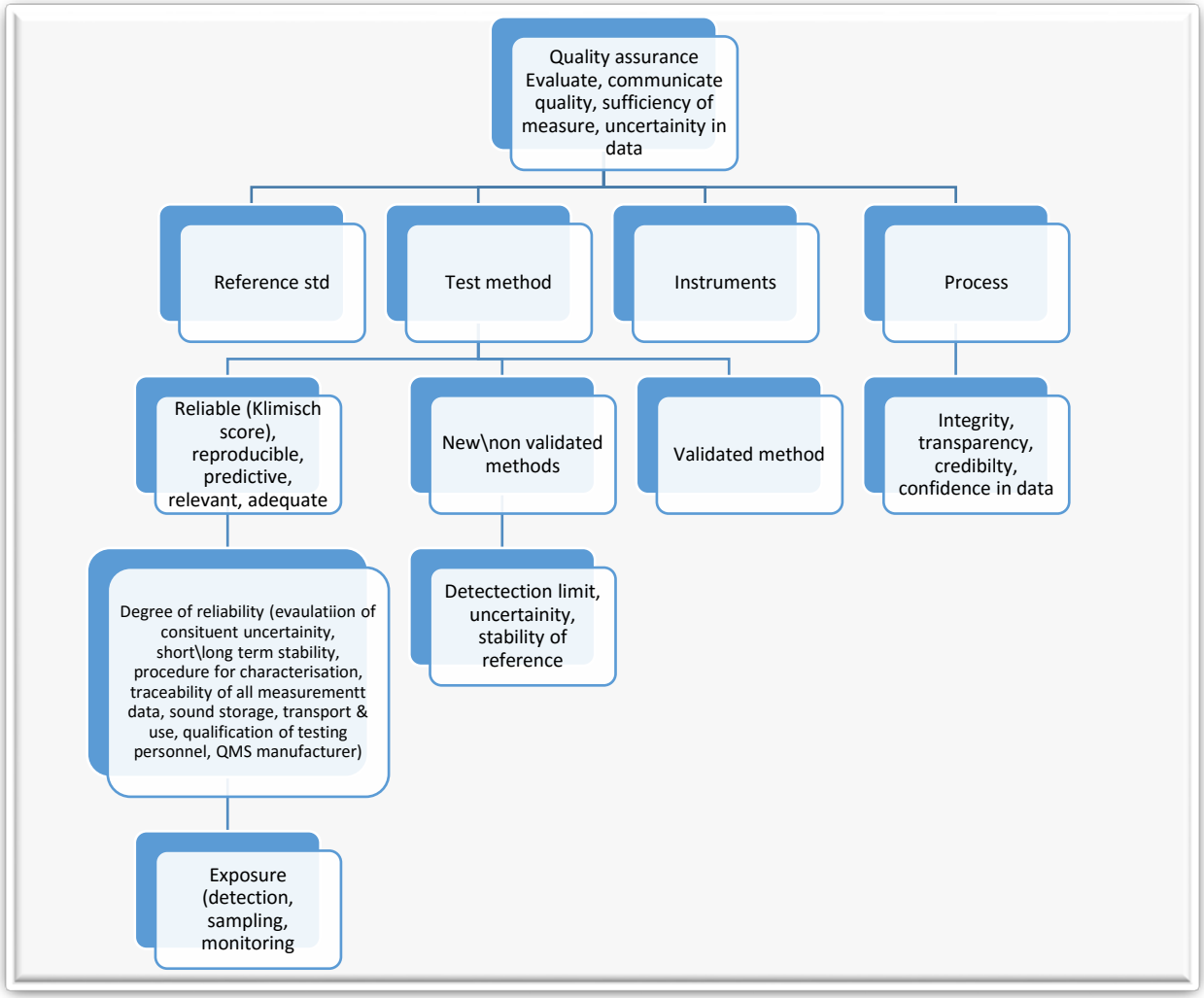

Figure 2.17: Activities to Consider for Quality Assurance

Source: Singh (2016).

Figure 2.17 provides the roadmap for users and organisations to produce sound, reliable and accurate test results. It includes stages from sampling, development of test methods, validation of data, degree of reliability and exposure monitoring.

The researchers have highlighted different aspects of QA which will be considered in the development of the Quality framework for this study, although the standards proposed in the integration are not specific to nanotechnology.

2.12 Additional Theoretical Considerations in Developing the Framework

Several theories that underpin Health, Safety, Compliance, Social Justice and Risk Management are presented below.

2.12.1 Health and Safety

According to Yorio and Moore (2017), Health and Safety Management (HSMS) generally exists as an objective of an organization's safety culture. The theoretical expansion of HSMS as a safety philosophy has created confusion within certain sectors of the safety research community. Two (2) general approaches are used to assess HSMS with regard to individual and organization perceptions and these are confirmed in the following studies:

Studies conducted by Vinodkumar and Bhasi (2010) on HSMS measurement at a worker level in the context of an empirical operation found a bottom-up worker-derived perceptual construct. This entailed asking workers to document their perceptions of the elements and/or practices used within the HSMS.

Studies undertaken by Fang and Wu (2013) on HSMS at a manager level revealed a top-down organization derived structural construct. In this study managers or supervisors were requested to supply information on the organization's HSMS. The data provided was used to derive estimates of the importance of HSMS outcomes. Based on these studies, it can be concluded that HSMS is operationally, a bottom-up, worker-derived perceptual construct or conversely, a top-down management derived structural concept.

Health and Safety theorists, Guldenmund (2010) and Christian, Bradley and Burke (2009), state that, although the bottom-up approach is appealing, it is often neglected because HSMS is generally the domain of management.

2.12.2 Compliance Theory of Regulations

Fiene (2016) states that the theory of regulatory compliance outlines the importance and significance of complying with regulations, laws and rules. This theory is premised on the fact that when rules and regulations are too minimal to comply with, it is difficult to differentiate between good and mediocre practices. Whilst this may lead to oversight of such rules, Fiene (2016) suggests that statutory bodies should not try to deregulate or over-regulate but rather strike the right balance.

2.12.3 Social Justice Theory

Sensoy and DiAngelo (2017) argue that social justice is based on the principles of fairness and equality for everyone as a basic human right. They explain that the theoretical perspectives of social justice is stratified in society, that is in most instances, divided and unequal based on race, gender, class, religion, ability and sexuality. The following are some important shared principles:

- Even though people are individuals, they are also members of social groups.
- Most social groups are valued unequally throughout the world.
- The more highly the social group is valued the greater the access to resources.
- Social injustice results in unequal access to resources between groups of people.
- If organizations want to address social injustice their commitment must be ongoing and a lifelong process.

2.12.4 Risk Management Theory

Reason (2000) argues that human error is based on two (2) approaches, the person approach and the system approach. The person approach focuses on an individual's errors most often resulting from inattention, forgetfulness, negligence, carelessness or recklessness, whereas the

system approach focuses on the conditions under which people work. Progressive organizations, which have low rates of accidents, recognize that human variability can lead to errors.

The person approach tends to focus on unsafe acts, human errors and violations of operating procedures. Organizations tend to rectify human behaviour through disciplinary measures, litigation or dismissals. The system approach, on the other hand, is based on the philosophy that humans are fallible, and errors can be expected. Actions to address this include, improving working conditions, identifying hazardous technologies and developing appropriate safeguards.

Reason (2000) further states that researchers, who study human factors, are constantly developing tools and systems for managing unsafe behaviour. According to Heizer et al. (2014), the Japanese use a tool known as Poka Yoka (mistake-proofing) to eliminate human error. Managing errors can be divided into two components, eliminating or limiting the incidence of dangerous errors and developing systems that are able to predict and contain errors. Even high reliability organizations, who operate in hazardous conditions rely on models to ensure a resilient and safe operating system.

Risk management in high reliability organizations (that is, organizations that have succeeded in circumventing disasters in a work environment where normal accidents are expected due to high risk factors) evolves around anticipation of worst case scenarios and preparing themselves to deal with such risks. This philosophy of high reliability provides staff with the comfort that the organization is committed to health and safety.

The theories discussed above relate to an organization's role and responsibilities in ensuring safe working conditions for its employees. This would also apply to organizations developing and manufacturing ENMs.

2.13 Choosing a Suitable Management System for ENMs

Rebelo et al. (2014) claim that models are useful as they provide a systematic approach to problem solving. Stevenson (2007) and Westgard et al. (2014) are of the view that the following requirements should be considered prior to the introduction of a model:

- Determine the purpose of the model;
- Identify how the model would be used to generate results;
- Analyse and interpret the results;
- List the assumptions and limitations of the model.

According to Rebelo et al. (2014) as the number of ISO standards increase, integration becomes a necessity as it promotes cost saving and synergies. As part of her doctoral study, Singh (2006) developed a management system (SECQA model) which integrated Safety, Environment, Corporate Governance, Quality and HIV/ AIDS. The following management systems were used in the SECQA model: OHSAS 18001:1999; EMS ISO 14001: 2005; King II report; ISO 9001:2000 and AMS 16001:2003. This formed the basis for a conceptual framework that integrated quality management into a holistic system rather than individual parts.

The SECQA model was considered to be most acceptable framework for this study because it addressed the challenges presented by integrating multiple management systems (standards) and used the systems that are currently most commonly used in R & D and manufacturing. The integration is reflected figure 2.18. The Process Approach formed the foundation of the SECAQ Model. Heizer et al. (2014) contend that the Process Approach in ISO 9001 includes a code of practice for developing, implementing and improving the effectiveness of management systems.

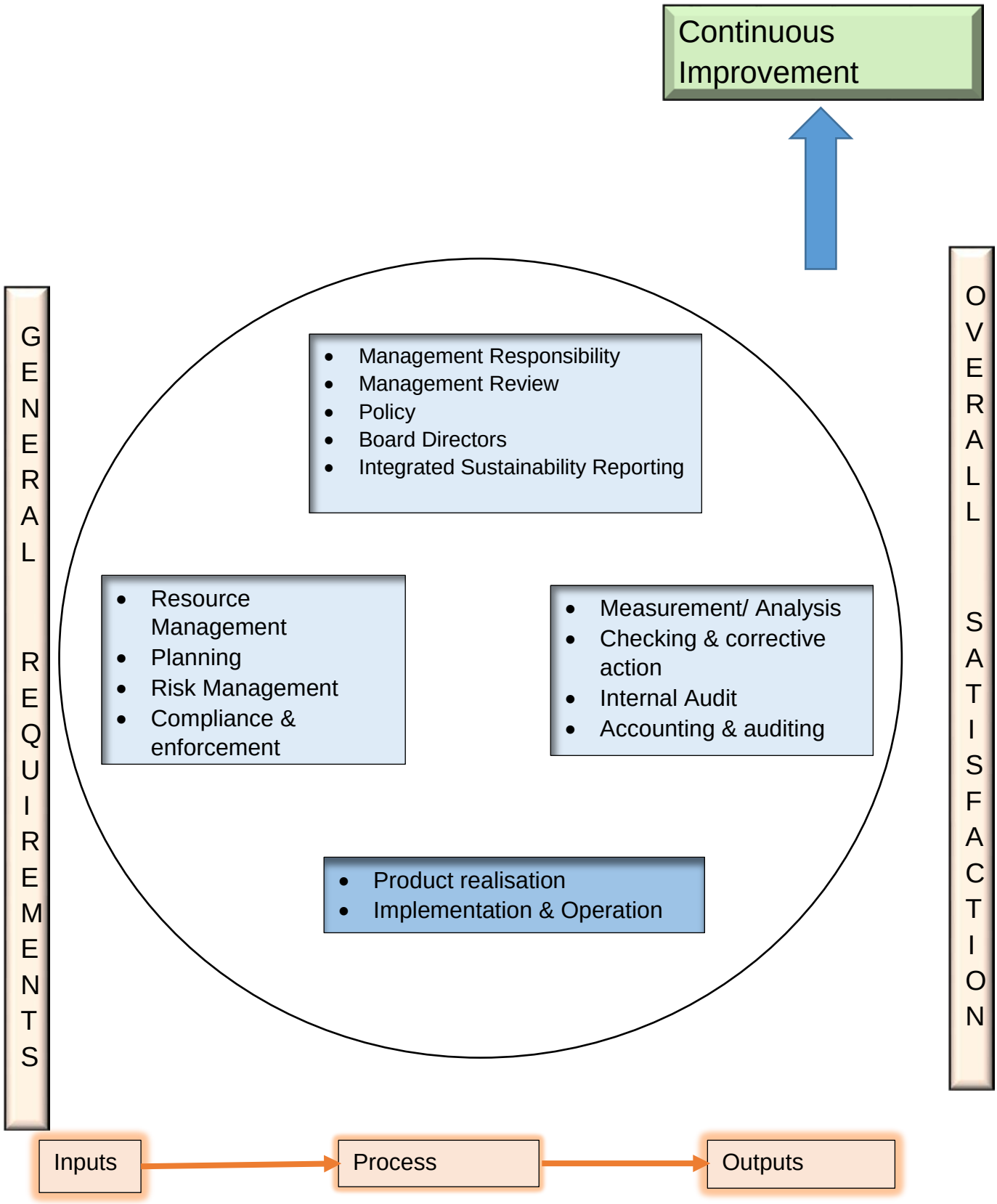

Figure 2.18: The SECQA Model
Source: Singh (2006)

Slack, Chambers and Johnston (2007) claim that an understanding of customer requirements is one of the key factors in sustainability because an organisation manufactures products or delivers services according to customer wants and needs. Singh (2006) presents the integration of management systems (standards) in the SECQA model as listed below:

Table 2.3 – Integration of Management Systems

Safety (OHSAS 18001:1999)	Environment (EMS ISO 14001:2004)	Corporate Governance (King II Report)	Quality (ISO 9001:2000)
Management Review Policy	Management Review Policy	Management Review Policy Board of Directors Integrated Sustainability Report	Management Review Policy
Planning	Planning	Planning	Planning (Resource Management)
Implementation and Operation Risk Assessment Compliance and enforcement	Implementation and Operation Risk Assessment Compliance and enforcement	Risk Assessment Compliance and enforcement	Implementation and Operation (product Realisation)
Corrective action and check	Corrective action and check		Corrective action and check

Internal Auditing	Internal Auditing	Accounting and Auditing	Internal Auditing
Continuous Improvement	Continuous Improvement	Continuous Improvement	Continuous Improvement

Source (Singh, 2006)

The salient features of SECQA model is:

- The general requirements include information outlining organisational processes, outsourcing and documentation.
- That management responsibility includes support and commitment for the integrated system, the roles and responsibilities of the Board of Directors and integrated sustainability reporting.
- That product realization comprises of customer requirements, statutory regulations and product safety.
- That resource management focuses on the resources required, competence of employees and operational controls such as risk management, emergency preparedness and environmental management.
- That measurement/ analysis and implementation includes inspection, corrective action, identification of non-conforming products, prevention strategies, internal auditing and adherence to financial standards.
- That continuous improvement documents show how policies, objectives and processes are improved within the organisation.
- That documentation required include policies, procedures and work instructions**.**

Table 2.3 shows how the above-mentioned standards was used as a basis for the QMS framework presented in this study.

2.14 The Rationale for including selected Management Systems (standards) in the Quality Framework developed in this study.

Management Systems show how inter-related activities can improve performance of the organization. In this study the following Management Systems have been used as a basis for the proposed Quality Framework.

2.14.1 ISO 9001: 2015

Heizer et al. (2014) state that ISO 9000 can best be defined as a family of standards that address issues such as a QMS, concepts and definition, customer satisfaction, quality plans and measurement systems. The objective of ISO 9001:2015 is to ensure that products and services are reliable and of acceptable quality that align to international standards.

2.14.2 ISO 17025: 2005 – General requirements for the competence of testing calibration laboratories.

ISO 17025:2005 standard is commonly used by laboratories performing tests and calibrations. It deals with the competencies and reliability to conduct tests and/ or calibrations (ISO/IEC 17025: 2005).

According Singh (2016), although ISO 17025 provides a means to produce reliable results, Good Laboratory Practices (GLP) have additional requirements that may be useful in the nanotechnology context as illustrated in figure: 2.19.

An ISO recognition gives consumers confidence that products are safe to use, properly tested and are of good quality hence the rationale to use these standards in the proposed framework of this study.

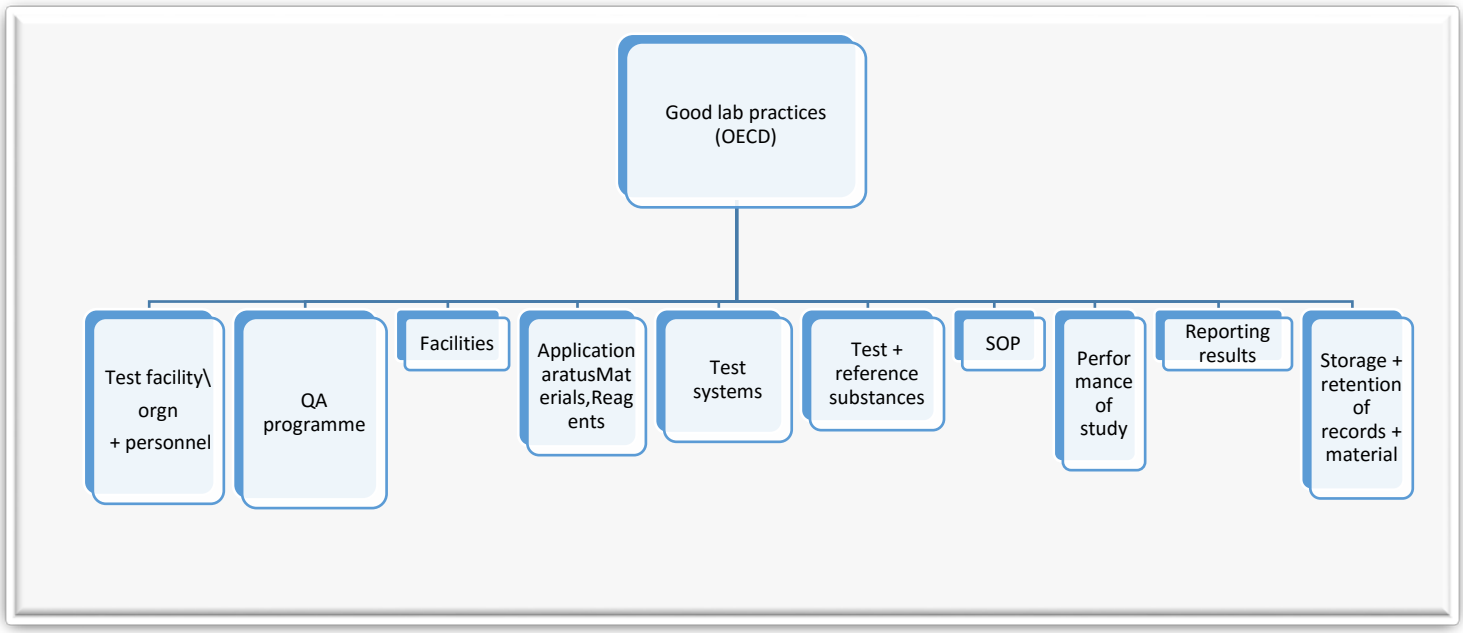

Figure 2.19: Activities to Consider for Good Laboratory Practices

Source: Singh (2016).

Adherence to the requirements proposed by Singh (2016), as indicated in Figure 2.19, in combination with ISO 17025 could ensure that an organisation has the infrastructure, expertise, equipment, training and communication mechanisms in place for providing sound practices relevant to nanotechnology. It also shows that results have been obtained in accordance with international standards and norms and can regarded as reliable, uniformly analysed and acceptable between countries.

The inclusion of the ISO17025:2005 standard in the framework is to ensure laboratory facilities are accredited and that the test equipment is technically proficient to produce precise and accurate test data.

2.15 OHSAS 18001: 2007 - Health and Safety Standard

According to Occupational Health and Management Systems (2012), OHSAS 18001 is a global occupational health and safety management standard which allows organisations to monitor health and safety risks and promote a safe work environment. Organisations adopting this standard are less likely to fall foul of health and safety regulations whilst creating an environment that supports safe working conditions.

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2.16 ISO 14001: 2015 - Environmental Management System

ISO 14001-2015 is that part of the overall management system that includes organisational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining an organisations environmental policy. To do this, environmental targets must be defined. These may include products or services that can interact with the environment, for example, waste generation, air emissions, chemical operations, water and energy use operations, use of natural resources and disposal. It encompasses air, water, natural resources, flora, fauna, humans and their interrelations (ISO 14001:2015) Environment Management Systems).

The amendments to the standards in section 2.16.1 – 2.19 from 2000 to 2015 have to be considered in the development of the framework. Consequently, the SECQA Model cannot be adopted in its current format for the development of the Quality framework because of several changes to the nomenclature of the requirements from the 2000 version. Although the amendments have similar broad meaning to the older version, for example in the ISO 9001 the " Management Responsibility" from the old standard and "Leadership" from the new standard, there are new nuances in the most recent version that require noting and possible inclusion in the Quality framework. The integration of all the standards is shown in chapter 5 (see Annexure 5.1).

These management systems listed above were used to build the integrated Quality framework presented in Chapter 5 of this study. An integrated management system provides all the components necessary to support an organisations' objectives and goals. The aim is to provide a single structure that transforms inputs into outputs that satisfy quality, health and safety, environment and good laboratory practices. Pardy and Andrews (2010) argue that to successfully integrate management systems, a single system

concept should be used. The organisation must have a fundamental culture based on commitment to quality, teamwork, employee involvement, education, training and strong leadership for the integration to succeed Pardy et al. (2010) and Weingarten et al. (2012).

The next section aligns to objective 5 of this study.

2.17 Developing the Computer Software Application

Bystrzejewska-Piotrowska, Golimowski and Urban (2009) claim that there are several computer software systems that relate to ENMs and these cover areas such as imaging of materials, molecular modelling software, design of ENMs and simulation of materials. To date only the technical aspects of nanotechnology have been addressed in computer software. This study identified an opportunity to develop a computer software application that specifically address the health, risk and safety considerations for nanotechnology. This will enable any person working with this technology to identify their risk profile in terms of handling, storage, PPE, emergency protocols and equipment usage. According to Renn and Roco (2006) risk profiling allows the user to identify, collect data, analyse and take preventative actions. The computer application in this study will attempt to predict the risk profile so that mitigation and corrective actions could be taken. A detailed analysis of the software is presented in Chapter 5.

2.18 Positioning Nanotechnology as a Disruptive Technology

According to Conole, deLaat, Dillon, and Darby (2008), disruptive technologies are ‘pedagogically innovative’ and act as a catalyst for change, whilst, Hall and Martin (2005) describe disruptive technologies as the ability of organisations to acquire and assimilate new technologies without disrupting the existing value chain. It can be inferred that these new technologies bring about complex and uncertain challenges which may have environmental, health and social side-effects. Hence, the management of these technologies are crucial as the disruptive potential of these innovations should be recognised (Wiek et al., 2016). This is required to protect an organization, to avoid liabilities, and prepare for emergencies.

According to Millis (2006) scientists used the deoxyribonucleic acid (DNA) from one plant species (donor) and introduced it to another species (host) which gave rise to Genetically Modified Organisms (GMO). This novel species acquired new properties which would not have been possible through conventional breeding. The first GMO was constructed in the year 1972. Research into the impact of this technology was lacking and with this in mind, the Australian Government, in 1981, introduced a series of legislation for regulating these products. Due to the novelty of this technology and its ability to transform food production, scientists and researchers surged ahead with research with little or no concern of the potential risks involved. The introduction of the Gene Technology Act of 2000 provided a basis for the risks from GMO to be identified and managed. Sandler and Kay (2006) claim that GMO products have met with widespread public resistance. The lack of communication and disclosure of the risks of GMO's led to public suspicion and a backlash against this technology.

For example, GMO allows the manipulation of DNA to produce crops that grow faster with a longer shelf life and more resilient to attack from insects or weather damage. Conole et al. (2008) quotes the case of a US based chemical company, Monsanto, which believed that it could apply this revolutionary technology to agriculture by bio-engineering seeds to allow for more efficient production. Whilst this technology, at first, seemed to be financially rewarding and environmentally promising, stakeholders including academics and advocacy groups warned about long-term health implications. By the year 1999, there was widespread opposition to GMO in Europe, United States and developing countries which still persists today. Philip (2008) states that like GMO's, ENMs pose risks to human health and the environment.

It can be inferred that ENMs, if not managed properly, have the potential of suffering the same fate as GMOs because the side effects of ENMs are still relatively unknown, (Barnard, 2006).

2.19 Summary of the Chapter

From the review of the related literature it is evident that ENMs pose certain risks and potential harm if not properly managed and controlled. The significant uncertainties associated with ENMs cannot be overlooked as scientists and researchers race to develop new and exciting products for the consumer market. Reliable information of safe levels of exposure and the behaviour of ENMs within the human body are yet to be established. The literature presented in this chapter presents overwhelming evidence for the introduction of structured quality management systems to govern this technology. The structure and composition of ENMs was included to show how these particles can enter either through the dermis, inhalation or ingestion. Toxicology, hazards and sources of exposure were discussed, and this formed the basis for the development of the software application presented in Chapter 5 of this study.

Management systems including ISO, Good Laboratory Practice, Health, Safety and Environmental standards were examined. The existing SECQA model was used as a basis for the integrated model presented in Chapter 5.

The next chapter outlines the research methodology that will be used in this study.

Chapter 3 - Research Design and Methodology

Chapter 2 outlined the literature relating to ENMs and Quality Management systems. In this chapter the research methodology is introduced and justification for the research is explained. The research design will compare the two main research patterns and provide an argument why the mixed method model was chosen for this study. This chapter documents the population and sample, which is followed by describing the data collection methods. This is further divided into two sub-sections, specifically primary and secondary data collection. An explanation of the approaches used for data analysis is presented followed by a dialogue on the credibility (validity and reliability) of the measuring instrument used.

Welman and Kruger (2005) and Baumgarten (2010) claim that research is a process which involves the use of objective methods and procedures to obtain scientific knowledge and excludes any personal feelings of the researcher. Mouton (2008) and Collis and Hussey (2014), observe that people have a natural tendency to obtain more knowledge about specific objects of interest through research. One of the primary objectives for this research was to develop an integrated management framework and to establish a risk profile for people working with ENMs. The development of the framework was dependent on the primary data (through an empirical study using questionnaires) and secondary data gathered.

3.1 Structure of the Study

Since a mixed method approach was adopted for the purposes of this study, a discussion of the qualitative, quantitative and mixed research paradigms is included in this chapter. Furthermore, details on the design of the questionnaire, the target population and sampling techniques used in this study are also presented. Finally, the researcher presents the various statistical techniques that were used to conduct the research in this study.

3.2 Research Design

Creswell (2013) and Brace (2008) regard research design as a plan that provides the framework for collecting information from the respondents, outlining the various steps involved in the study, and providing the required guidelines for collecting information from them. According to Mouton (2008), research design targets the problems and objectives of a study. Researchers in the design phase, try to maximise the validity of information by anticipating the appropriate types of research available in order to provide the most effective answers to research questions. The research data is subsequently analysed with the objective of obtaining results and reaching conclusions about the problem being investigated.

Collis and Hussey (2014) submit that research design can be considered as a plan for collecting, measuring, and analysing information. Walliman (2011) also regards research design as a plan which indicates the manner in which the research should proceed. Quinlan (2011) is of the opinion that the research design is a structured investigation to obtain information in order to answer research questions. In addition, he states that the research design indicates the methods that will be used in collecting information. Trochim and Donnely (2008) are also of the opinion that the research design is used in structuring the research, indicating the way in which the main areas of the research problem work together in addressing the primary research investigation.

An outline of the research process followed in this study is presented in figure 3.1

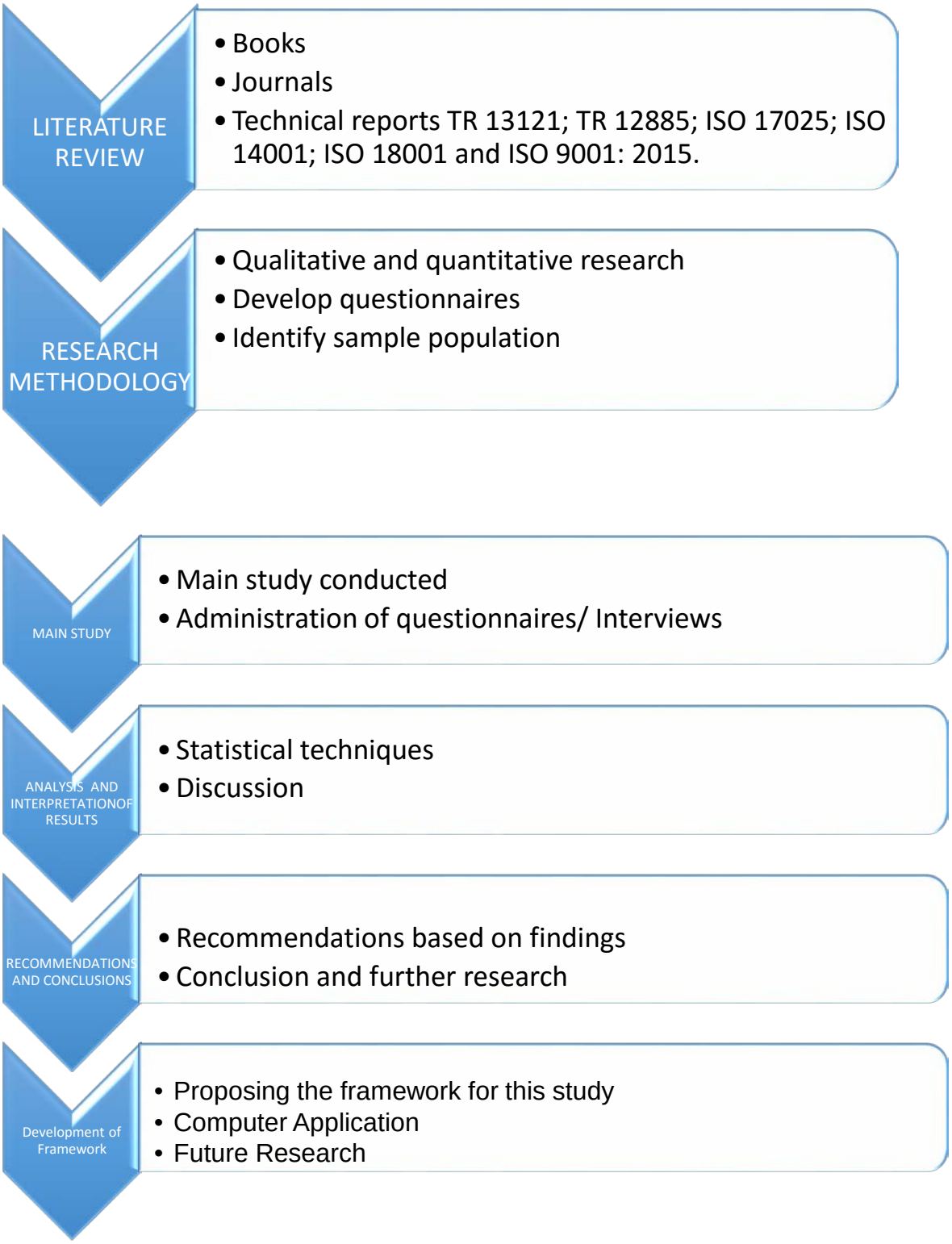


Figure 3.1. Outline of the Research Process

Source: Adapted from Srivastava, Thomson (2009)

According to Jesson, Matheson and Lacey (2011) the literature review justifies the need for the study, develops the thesis position and identifies gaps in existing knowledge. It also helps the reader understand how this study fits into a broader context, in this instance, in the field of ENMs. Creswell (2013) proposes that research methodology outlines the methods used in studying the research problem and the process of data collection. In this main study, interviews, questionnaires and surveys are used to collect data which is processed and analysed. This will culminate in drawing conclusions and making recommendations.

3.3 Research Methodology

Scruggs, and Mastropieri, (2006) define research methodology as the method that a researcher uses in studying a research problem. Bhattacharyya (2006) adds that the methodology used in research indicates the way in which researchers identify the respondents of a research study, and the method in which information is be collected from the respondents. Newman (2013) regards research methodology as an operational framework within which information is presented so that its meaning is more clearly defined.

The two main approaches of conducting research, according to Kumar (2011), are the qualitative and quantitative research paradigms. While empirical studies have traditionally been based on these two approaches, many researchers now consider the mixed-methods research approach (both quantitative and qualitative) a viable option.

These approaches are discussed in the sub-sections that follow.

3.3.1 Research Paradigms

According to Johnson and Christensen (2012) and Gray (2017), a paradigm is a set of patterns, and common beliefs that identifies problems with the intention of understanding and solving them. They identify two main

research paradigms or philosophies, namely the qualitative and the quantitative paradigms.

Maxwell (2005) and Gray (2017) state that research paradigms are made up of ontology, epistemology and methodologies which, in simple terms, is a holistic view of how knowledge is used and created. Collis et al. (2014) submit that the ontological dimension refers to a research paradigm's assumption about the nature of reality. They further suggest that in positivistic research, science is one way of understanding the world so that predictions can be made and actions taken to control events. In the positivistic paradigm, the assumption is that reality can be captured objectively and separate from the researcher. Manen (2014) states that in the phenomenological paradigm, the approach is to identify phenomena and see how they are perceived by researchers in a particular situation. Reality is seen as subjective and located in research respondents. According to Antwi and Hamza (2015), a positivist paradigm is based on observation and reason as a means of understanding human behaviour, where true knowledge is gained through experiences obtained via observation and experimentation. Positivism can thus be explained as uncovering the truth and presenting it by empirical means. Hence this study used both qualitative and quantitative methodologies to develop the framework.

3.3.2 The Quantitative Research Approach

Creswell (2013) argues that quantitative research uses numerical values to test the theory of an identified problem. This enables the researcher to measure or quantify the variables being investigated. Typically, the results of the investigation are evaluated using mathematical and statistical techniques.

A number of scholars have used the quantitative approach in their research studies. For example, Molina-Azorin and Cameron (2010) synthesised their findings from a scan of six business and management journals in

seven different areas of business and management. They found that the quantitative approach dominated all seven areas (76% of empirical articles). Their findings concluded that the quantitative approach is the most commonly used research method. In this study the quantitative approach will be used to explore numeric data such as the percentage of respondents who were provided with protective equipment, had an awareness of safety procedures or were familiar with emergency procedures.

3.3.3 The Qualitative Research Approach

Johnson et al. (2012) and Kothari (2004) maintain that qualitative research involves the collection of data in the form of descriptions and the analysis of such data non-numerically. Whilst Kumar (2011) submits that this approach is generally used to study the interaction between and amongst organisations, groups, and individuals from a multiple perspective, with the objective of obtaining an overall picture of the phenomenon of interest.

Table 3.1: Comparison of Qualitative and Quantitative Research

Criteria	**Qualitative research**	**Quantitative Research**
Purpose	To understand underlying reasons and motivations	Quantify data, analyse and make predictions from a sample.
Objective	Explore, discover and construct	Describe, explain and predict
Sample size	Usually a small number of respondents selected to fulfil a given quota.	A large number of respondents randomly selected representing a population of interest.
Data collected	Normally words, images or objects	Numbers and statistics
Data collection method	Unstructured or semi-structured techniques, for example, individual interviews or focus groups.	Quantitative data using structured and validated data-collection instruments, for example, questionnaires, surveys or on-line reviews.
Data analysis	Non-statistical	Statistical data is analysed which is conclusive and usually descriptive in nature.
Research orientation	Process focused	Outcome focused
Nature of research	Biased	Unbiased
Nature of results	Outcomes that are context specific	Outcomes generalised to a theoretical population
View of human behaviour	Dynamic, situational, personal and social	Regular and predictable

Source: Adapted from Creswell (2013)

Table 3.1 provides a comparison between qualitative and quantitative research.

Ling Pan (2016) contends that whilst qualitative research is narrative based and quantitative is more statistics based, both these methodologies have an obligation to:

- Define key terms and introduce terms
- Establish the importance of the research
- Describe how the literature search was conducted and
- Identify the gaps in the literature

Zayer and Neier (2011), in examining the brand relationship of young, heterosexual male consumers of fashion and grooming products, employed three qualitative techniques, namely, collage construction, in-depth interviews, and shopping trip observations. In a different study of business and management journals, Molina-Azorin et al. (2010), found that the qualitative approach constituted only 10% of articles. Similarly Newman (2013), in exploring the process of institutionalisation of human resource management practices in Russian subsidiaries of German multinational organisations, also used three qualitative techniques, namely, interviews, participative observations, and an analysis of documents.

It can be concluded from the foregoing discussion that the data collected in qualitative research is based on human experience which was the rationale for including a range of qualitative questions in the interviews conducted in this study.

3.3.4 The Mixed-Method Research Paradigm

Klenke (2008) and Creswell (2013) define the mixed-methods paradigm as one which involves the collection and analysis of data, incorporating the results, and drawing inferences using both qualitative and quantitative approaches in a single study. Trochim et al. (2008) observed that the collection of data becomes more efficient when using both qualitative and quantitative research approaches. Walliman (2011) is of the opinion that

the qualitative and quantitative research approaches are more powerful when combined.

Maxwell (2005) found that the best way of combining the qualitative and quantitative research approaches were through:

- A combination of the two approaches to obtain better measurements;
- Sequencing information for a better analysis of that information
- Merging the findings of the study to obtain better results.

In his review of literature on the mixed-methods approach, Bhattacharyya (2006) argues that the reasons for using the mixed approach were to improve the validity of the proposed theory to be tested, and to obtain an unbiased and a better overall picture of the case that was being studied. He also found that the mixed method approach was useful in specifying research questions, enabling the researcher to be familiar with the subject matter of the study, and ensuring that respondents have the same understanding of the concepts and measures used in the study.

Murphy and Maguire (2011), in evaluating the benefits and costs of conducting clinical trials in a New Zealand public hospital, found that collecting quantitative and qualitative data was time consuming, and hence, had to restrict the quantity of data collected for the study. Furthermore, they found that their study required researchers with different skills.

According to Bryman and Bell (2015), a quantitative research strategy consists of a deductive approach in the relationship between theory and research, incorporates the norms of the natural sciences model of positivism and adopts a view of social reality as an external, objective reality. By contrast qualitative research emphasises an inductive approach to the relationship between theory and research where the emphasis is based on the generation of theories and rejects the practices and norms of the natural sciences model of positivism, instead placing emphasis on the way humans interpret their social world.

The review above showed that a large percentage of researchers have used the quantitative approach, and a much smaller percentage used the qualitative approach. It also shows that interest in the mixed-method approach [14% of empirical studies as identified by Molina-Azorin et al. (2010) is much higher than the qualitative approach as a standalone approach. In this study, the majority of the data is collected using a quantitative approach. The questionnaire designed for this study consisted of both qualitative and quantitative type of questions. The quantitative approach used statistical analysis for analysing and interpreting data. The qualitative data was used to develop a risk profile for people working with ENMs. The data collected for this study was derived from both primary and secondary sources.

3.4 Sources of Data

Ling Pan (2016) and Kumar (2011) describe data as a collection of facts and statistics with qualitative or quantitative variables. This section defines primary and secondary data. Zikmund, Babin, Carr and Griffin (2013) identify a number of primary data collection methods, such as the following:

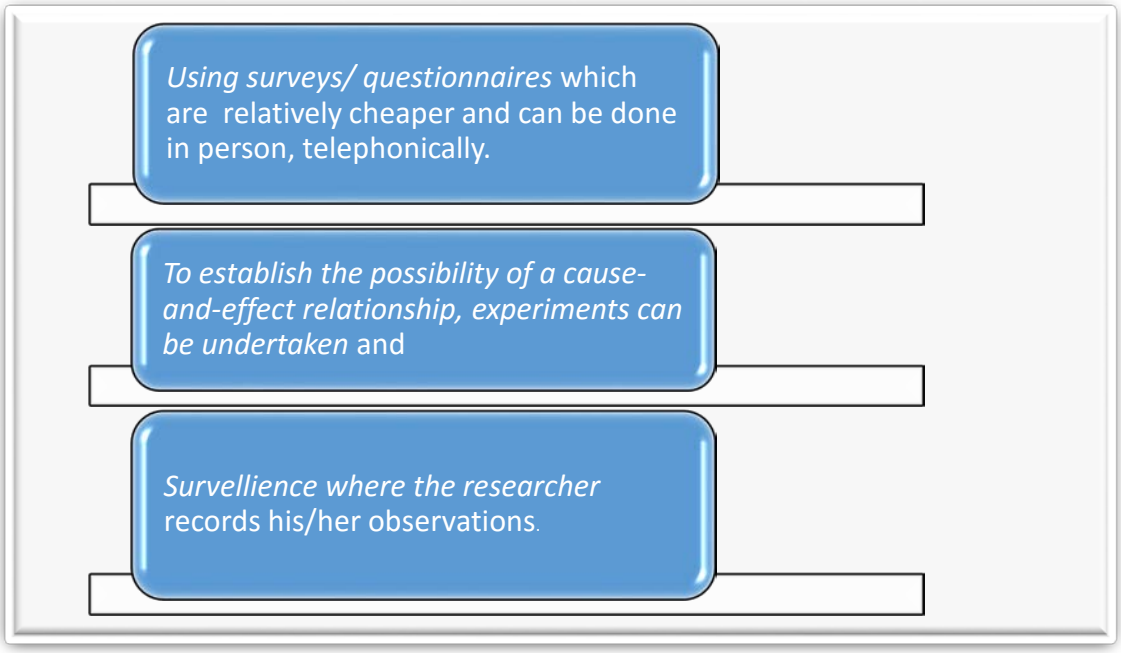


Figure 3.2: Data Collection Methods

Source: Zikmund et al. (2013).

This study used questionnaires and interviews to collect data.

3.4.1 Primary Data

Johnson and Christensen (2012) state that primary data is data that is collected for the first time and published by the person or organisation responsible for its collection. On the other hand, Newman (2013) is of the opinion that the advantage of using primary data is that the researcher can define the variables to be used in the research and the techniques that will be used to measure these variables so that a valid result is obtained

Primary data is data collected which is subjected to statistical analysis with the objective of finding a solution to the research problem. Primary data for this study was obtained through a questionnaire and interviews administered to scientists, researchers, technical and management staff working in the field of ENMs.

Ling Pan (2016) confirms that researchers often use a variety of data collection methods based on research circumstances. For example, administering questionnaires are relatively cheaper than experiments or direct observations. According to Jogulu and Pansiri (2011) mixing the information collection techniques improves the findings to allow inferences to be made with a degree of confidence. Fan and Lau (2015) confirm that questionnaires are one of the most common methods used by researchers to acquire data. Moses and Kalton (2016) concur that questionnaires are extremely useful in investigating the problem and collecting data so that hypotheses can be tested.
Hence the survey method was chosen to conduct the primary research in this study as this seemed most appropriate.

3.4.2 Secondary data

Secondary data, according to Collis and Hussey (2014), is data that has already been collected and published by the person or organisation not responsible for its collection. They add that, in using secondary data, the researcher has little or no control over the data collection method or the

limitations that exist in their use. However, using secondary data can save much time and cost.

The main sources of secondary data for this study were research articles obtained from peer reviewed academic journals, technical reports and textbooks. These secondary sources provided the background to the literature review in Chapter 2 and it also provided the preliminary data which served as a point of departure for data collection in Chapter 3.

3.5 Methods of Collecting Data

Data can be collected from a variety of sources using methods which include personal interviews, telephonic interviews and emailing of questionnaires. These methods are discussed below:

3.5.1 Personal Interviews

Molina- Azorin et al. (2010) are of the opinion that the personal interview method of data collection is used by a number of scholars in their research studies. Mouton (2008) believes that the research interview can be used to canvass the views, experiences and beliefs of respondents. For this study a total of five (5) interviews were conducted. This included three (3) researchers and two (2) manufacturers. A structured interview with predetermined questions was verbally administered. The use of this method was designed to elicit the depth of detail from the respondents that a quantitative methodology would not normally yield.

3.5.2 Telephonic Interviews

According to Farooq and de Villiers (2017) a telephonic interview is similar to personal interviews except that the interviews are conducted over the telephone which is usually a less expensive method than the personal interviews. Of the five interviews, telephonic interviews were conducted with two (2) respondents due to distance constraints.

3.5.3 Self-administered Questionnaire

According to Mouton (2008), a self-administered questionnaire offers several advantages which include, respondents completing the questionnaire at their convenience, as absence of the interviewer eliminates bias in the respondents' answers and it is an economical way to collect large amounts of research data. For this study a total of 117 questionnaires were administered which included the 10 pilot study questionnaires.

3.5.4 Emailing of Questionnaires

According to Neuman (2013) and Boynton and Greenhalgh (2004), emailing questionnaires to respondents is another common method of collecting data. The questionnaire must be designed to receive quick responses, preferably through check marks or a few words. Although this method is the least expensive of the data collection methods, its main disadvantage is that the percentage of usable returns is usually lower than the other methods. However, it does cover a wider geographical location. Thirty questionnaires were emailed and 10 were completed and returned for this study.

In summary, for this study, the personal interview, the self-administered questionnaire survey method as well as the emailing of questionnaires was used to collect data. The purpose of administering a questionnaire was to seek current practice to help to develop a Quality framework to monitor, evaluate and control broad based ENMs as well as to develop a computer application software program that could identify its risks.

3.6 Design of the Questionnaire

Collis et al. (2014) state that a questionnaire is a list of carefully considered questions designed to extract specific information that aims to find reliable responses.

Kumar (2011) advises researchers to concentrate on three focus areas when designing a questionnaire, namely, the wording of the questions, the manner in which responses are to be categorised and coded, and the general appearance of the questionnaire. Saras and Gallhofer (2014) are of the view that questionnaires must be designed to collect data in a systematic and ordered manner that enables responses to be quantified, categorised, and analysed statistically. This formed the basis for the questionnaire used in this study.

3.6.1 Characteristics of a Questionnaire

Questionnaire design is of utmost importance as it forms an integral part of the research process. This is how the essential data is collected. Brace (2008) argues that the design of the questionnaire necessitates the researcher to concentrate on the following:

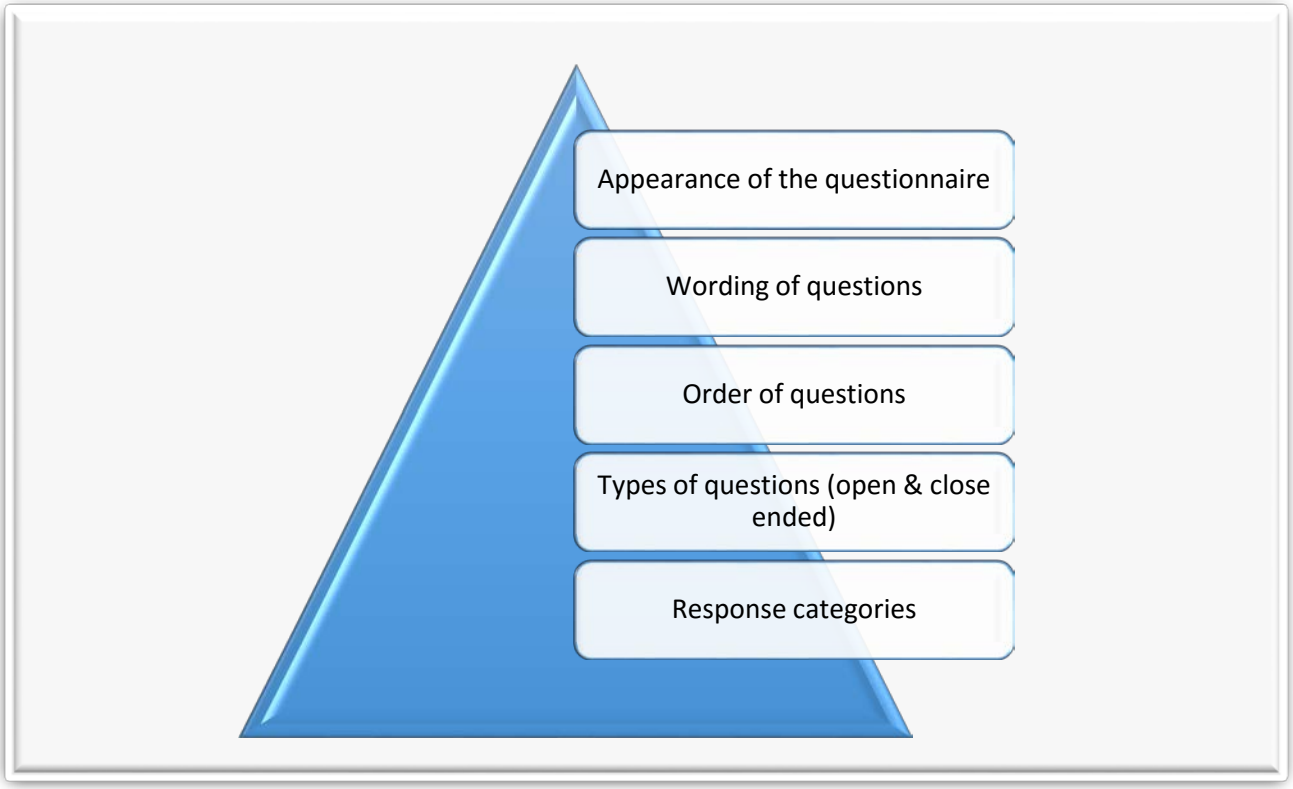


Figure 3.3: Characteristics in the Design of a Good Questionnaire.

Source: Brace (2008)

Figure 3.3 outlines the characteristics in designing a good questionnaire. Brace (2008) asserts that the physical appearance of the questionnaire should include creative use of space and typeface, colour coding (if possible), be easily understandable language, incorporate correct sequencing of questions, include both open and close ended questions.

For the design of a questionnaire, Saris et al. (2014) further contend that:

- Questions must be able to provide only one interpretation.
- Eliminate technical terms unless the questionnaire is addressed to experts.
- The questionnaire should not be too lengthy.
- Questions should not require the respondent to do any calculations.
- Questions should have an exact answer, if possible in the form of yes/no, a number, measurement or quantity.
- Questions must not contain words of unclear meaning.
- Avoid biased or leading questions.

- The questionnaire should cover the precise subject of the inquiry.

The above characteristics were considered when compiling the questionnaire for this study. The draft questionnaire was informed by a review of literature from Chapter 2, including the technical report ISO/TR13121 and ISO/TR 12885.

3.6.2 Open-ended and Close-ended Questions

According to Saris et al. (2014) the two common approaches for obtaining responses are through the use of open-ended questions and close-ended questions. Additionally, open-ended questions are used in eliciting an opinion from respondents whereas close-ended questions require respondents to make a choice from a number of alternatives supplied by the researcher. Also, close-ended questions are standardised, making it easier to interpret and to analyse statistically.

This study used questionnaires that consisted of both open-ended and close-ended questions. A self-administered questionnaire (see annexure 3.1) was used for data collection.

Brace (2008) claims that in order to gauge attitudes or strength of feelings of the respondents, the researcher often use scales. The questionnaire designed for this study used a five-point Likert scale. According to Nemoto and Belgar (2014) and Hill and Alexander (2006), the data produced by this scale is of interval data. The Likert scale is a rating scale which has numbers associated with sub-statements. Typically a questionnaire which uses the Likert scale will contain a number of statements with which respondents are required to agree, remain neutral, or disagree. Schmee and Oppenlander (2010) contend that the reliability of Likert scale is preferable to other measuring scales since it allows for a wide variety of answers from respondents. Table 3.2 indicates the response section of a questionnaire which uses the Likert scale.

Table 3.2: The Likert scale

1	2	3	4	5
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Source: Schmee et al. (2010)

3.7 Statistical Analysis of Data

Before discussing the specific statistical measures and techniques that is applied to this study, it is necessary to explain some of the concepts and terms used in the statistical analysis of data. These concepts and terms also assist in identifying the population and sample of this study. This is followed by a discussion on the various statistical techniques used in the analysis and interpretation of data.

3.7.1 Population and Sampling

The Composite Research Group (CRG) from the Department of Mechanical Engineering at the Durban University of Technology, South Africa hosted their Second International Conference on Composites, Biocomposites and Nanocomposites (ICCBN) from the 28th to the 30th October 2015. This conference brought together international experts in the field of nanotechnology and included scientists, researchers, technologists, manufacturers and quality management specialists and thus provided an ideal opportunity to administer the research questionnaire for this study. A list of 131 conference delegates (see annexure 3.2) made up the first group for the convenience sample. One hundred and seventeen questionnaires were handed out at the ICCBN conference and a total of 62 responses were received.

A further, 30 questionnaires were electronically mailed to experts in the field of ENMs. The contact details for the second sample was obtained from the 7th International Symposium on Nanotechnology (Occupational and

Environmental Health) held in October 2015 in Limpopo, South Africa. A list of conference delegates (see annexure 3.3) is attached. From the second sample a total of (ten) 10 responses were received. Ten questionnaires were received from the pilot group.
The response rate of questionnaires returned from both samples was 70%, and this was acceptable for the purposes of the study (Hill et al., 2006).

3.7.2 Sample

Collis et al. (2014) deduce that a population is a set of people or a group of items under consideration. Manen (2014) and Quinlan (2011), on the other hand, claim that the population of a research study can be defined as individuals, items or units pertinent to a study. Newman (2013) argues that it is irrational to study the complete population which explains why researchers consider using a sample. The sample, however, must be valid to extrapolate results for the entire population. The respondents from both samples and the pilot group used in this study comprised 82 respondents including 61 researchers, 19 experts and 2 manufacturers for both the questionnaires and the interviews. For the questionnaire respondents were selected using a convenience (taking into availability and willingness to participate) and a judgemental sample based on factors such as experience in the manufacturing sector.

3.7.3 Sampling Techniques

Myers, Well and Lorch (2010) agree that the choice of a sampling technique depends on the requirements and objectives of the research and the availability of funds. In addition, a sample of respondents to be included in a study can be selected by means of probability sampling or non-probability sampling.

Researchers have a choice between a probability and non-probability sampling methodology. In probability sampling, according to Myers et al. (2010), each respondent in the population has a non-zero chance of being included in the sample. They add that probability sampling, in a statistical

sense, provides estimates of precision. Furthermore, they state that selecting a simple random sample, in which each respondent in the population has an equal chance of being selected, is the simplest form of probability sampling. They identified systematic sampling, stratified sampling, cluster sampling, and area sampling as more complex probability sampling techniques. However, for this study non-probability techniques were used.

3.7.4 Non-probability Sampling

Myers et al. (2010) state that this type of sampling is non-random and subjective in nature but does offer practical advantages in that it is less costly and less time consuming or that it may be the only alternative available to the researcher.

Furthermore, Meyers et al. (2010) argue that, non-probability sampling is useful in exploratory research where the researcher wishes to contact only certain respondents. Mouton (2008) identified the four main types of non-probability sampling techniques as convenience sampling, quota sampling, snowball sampling and purposive sampling. In these sampling techniques, the researcher has freedom of choice in the selection of the sample.

Etikan, Abubakar, and Alkassimr (2016) confirm that convenience sampling is a non-probability sampling technique whereby people of a particular population that meet certain criteria are available at a given time.

Convenience sampling was used in this study as the ICCBN (2015) conference provided an opportunity to elicit responses from leading scientists, researchers, laboratory technicians, quality practitioners and manufacturers of ENMs from all over the world.

3.8 Descriptive Statistics

Descriptive statistics, according to Holcomb (2016), describes data through tabular and graphical presentation, as well as descriptive measures such as the mean and standard deviations. In this study, descriptive analysis was used to investigate the overall level of perception with respect the risks associated with ENMs. For this purpose, the mean of the dimensions listed is summed up. Thereafter the total for each dimension is summed up and divided by the total number of responses.

Table 3.3: Calculation of Scores

Mean Score	Category
1.0 – 3.33	Low
3.4 – 5.5	Moderate
5.6 – 7.8	Good
7.9 - 10	Excellent

Source: Holcomb (2016)

Halcomb (2016) states that ranking the mean scores will indicate the impact that each of the dimensions has on the construct. Also, it becomes necessary to calculate the variances and standard deviations since these measures will be used extensively in the inferential statistical analysis of the data. Both these measures evaluate variability, that is, the extent to which the individual scores are dispersed around the mean. A high value indicates greater variability in the data set.

3.9 Data Analysis – Quantitative Research

Neuman (2013) articulates that in the quantitative research approach, data must be gathered using structured research instruments and all aspects of the study must be carefully designed prior to data collection. The following methodologies are used by researchers to analyse and interpret quantitative data:

3.9.1 Factor Analysis

Brown (2015) argues that Factor Analysis is a model that measures the relationship between observed measures and predefined factors. Whilst Yong and Pearce (2013) contend that Factor Analysis is used to summarize data so that relationships and patterns can be interpreted and understood. In this methodology, variables are regrouped into clusters which helps to isolate constructs and concepts.

Brown (2015) confirms that Factor Analysis is a statistical tool used to investigate variable relationships. Factor Analysis is used primarily in survey research, where a researcher desires to represent a number of questions with a small number of hypothetical factors. For example, as part of an international survey on global warming, respondents may answer three separate questions regarding green manufacturing that impact at provincial, national and international level. Individual questions may not be an adequate measure of attitude towards global warming but combined they may provide a more focused measure of the attitude. Brown (2015) advises that factor analysis can be applied to find out whether the three measures above do measure the same thing. If so, they can then be converted to create a new variable, that is, a factor score variable that comprises a score for each respondent for the factor. Factor techniques can be applied to a multiplicity of conditions. Factor analysis is used primarily for the Likert scale questions.

3.9.2 Correlation

Cohen, Cohen, West and Aiken (2010) contend that correlation analysis is used most often to measure the strength of a relationship between two variables. The correlation can be either positive, which is, higher level of one variable in relation to the other or negative, which simply means lower levels of one variable to another. For example, a correlation of r = 0.8 would suggest a strong, positive relationship between two variables. On the other hand, a correlation of r = -0.3 suggests a negative or weak association. A correlation close to zero tends to suggest that no linear relationship exists

between two variables. The detailed results of the correlation for this study are presented in annexure 4.3.

3.9.3 Analysis of Variance (ANOVA)

According to Rouder, Engelhardt, McCabe and Morey (2016) ANOVA is a statistical method used to examine the variance of a dependent variable. The test can be conducted to identify whether a significant difference exists between means of two sets of data.

3.9.4 Regression Analysis

Chatterjee and Hadi (2012) describe regression analysis as a method for investigating if a functional relationship exists between variables. It can be used to detect whether a casual relationship exists between an independent and dependent variable. The methodology allows the researcher to measure, for example, levels of satisfaction and what events or variables influenced such satisfaction.

3.9.6 Kaiser-Meyer- Olkin (KMO)

Sharma (2005) explains that the KMO test is used to measure how suitable the data collected is for factor analysis. The test is designed to measure sampling adequacy for each variable. For example, it measures the proportion of the variance and hence the lower the proportion, the more suitable the data is for factor analysis. The KMO test results for this study is included in Table 4.3.

3.9.7 Rotated Component Matrix

Neuman (2013) and Kumar (2011), suggest that a Principle Component Analysis be used as the extraction method for the data, with the rotation method being Varimax with Kaiser Normalization. This is an orthogonal rotation method that minimizes the number of variables that have high

loadings on each factor. It simplifies the interpretation of the factors through:

- Factor analysis/loading to show inter-correlations between variables.
- Items of questions that loaded similarly imply measurement along a similar factor. An examination of the content of items loading at or above 0.5 (and using the higher or highest loading in instances where items cross-loaded, at greater than this value) effectively measured along the various components. This means that where there is more than one component, the highest value above 0.5 is chosen in that component.

For the purposes of this study, the following quantitative methodologies were used for analysis and interpretation of data; Cronbach Alpha; Factor Analysis and Rotated Component Matrix and were conducted on each of the dimensions of ENMs which include:

- Understanding of ENMs
- Safety
- Storage
- Quality Assurance
- Description of ENMs
- Application of ENMs

The reason of this analysis is to ensure that the dimensions used in measuring each of the constructs were reliable indicators.

3.10 Data Analysis – Qualitative Aspects

The following methods were used to analyse qualitative data:

3.10.1 Content Analysis

Elo, Kaariainen, Kanste, Polkki, Utriainen and Kyngas (2014) agree that qualitative content analysis is one of many methods used in analysing data and interpreting meaning. This is an objective and systematic method of describing data. In order to use this method, data must be reduced to concepts that describe the research phenomenon through the creation of categories such as concepts, models or maps.

3.10.2 Narrative Analysis

Smith (2015) contends that narratives are stories that are shared by people who relive an experience or event. Narrative analysis can be expressed in the following ways:

- Be written or oral;
- Be elicited during an interview;
- Could be long or short;
- Could focus on events and the interpretation of such events for those experiencing them.

The results of the narrative analysis for this study is included in section 4.10.

3.10.3 Thematic Analysis

According to Smith (2015), thematic analysis focuses on recording and examining patterns or themes within a set of data. This methodology allows for some degree of flexibility in the researchers' choice within a theoretical framework and hence can be used to expand the theory the researcher chooses. This methodology allows for rich, complex and detailed description of data. The results of the thematic analysis are included in section 4.11.

3.10.4 Discourse Analysis

Johnstone (2018) refers to discourse analysis as instances of communication through the medium of language, photography, music, art and dance. This methodology tries to study the organization of language used in social contexts through the interaction or dialogue between speakers.

3.10.5 Framework Analysis

Srivastava and Thompson (2009) conclude that framework analysis is best suited for applied policy research. In this methodology data is sifted and sorted using key issues and themes involving a five-step process:

- Familiarisation;
- Identifying a thematic framework;
- Indexing;
- Charting;
- Mapping and interpretation.

Framework Analysis can be used very effectively in a context where the researcher wants to assess how policies and procedures affect respondents. For this study, framework analysis was used to develop policies and procedures relevant to nanotechnology. An example of a policy and procedure can be found in section 5.2.

3.10.6 Grounded Theory

According to Rubin and Babbie (2014), grounded theory can best be described as a research method that allows the researcher to develop a theory that explains the main concern of the research and ultimately process or resolve such concerns. For example, this method not only enables documentation of change with social groups but also allows the researcher to examine data that reflects the core processes central to such changes.

In this study the following qualitative methods were used: content analysis; thematic analysis, framework analysis and grounded theory.

3.11 Coding of Data

Bernard, Wutich and Ryan (2016) imply that researchers create data by grouping responses into recordable units. In research methodology a code is normally expressed as a "short-word" of phrase which describes the meaning of a sentence, paragraph or phrase. Coding is done to make the process of data analysis easier. To ensure anonymity for this study, each questionnaire was allocated a letter of the alphabet.

The qualitative data from the completed questionnaires of this study was re-typed using the exact words provided by the respondents. Thereafter, data was analysed and evaluated.

3.12 Validity

Baumgarten (2010) articulates that the validity of a measuring instrument is the extent to which the instrument measures what it is intended to measure. Validity can be grouped under three main categories, namely, content validity, criterion validity, and construct validity.

3.12.1 Content Validity

Krishnaswamy, Sivakumar and Mathirajan (2009) are of the view that a measuring instrument has content validity if the measurement dimensions of each construct covers all aspects of the construct being measured. They argue that content validity cannot be measured quantitatively and that it is established through a review of literature and detailed evaluations by scholars and practitioners. In terms of content validity, the measuring instrument for this study has met the requirements, since it was developed based on extensive review of the literature and reviews by academics in the field of quality and nanotechnology.

3.12.2 Criterion-related Validity

Krishnaswamy et al. (2009) state that criterion-related validity is the extent to which the measuring instrument is related to the criterion outcome, either in the present time (concurrent validity) or in the future (predictive validity).

3.12.3 Construct Validity

Klenke (2008) postulates that a measuring instrument has construct validity if it measures the construct it was designed to measure. For this study, the validity of each construct was evaluated through Principal Components Factor Analysis. Factor analysis validates a construct by demonstrating if its individual dimensions load on the same common factor. The measurement dimensions for each construct will be analysed using factor analysis.

The foregoing section discussed the validity of the measuring instrument. The following sections will use statistical techniques to determine the relationships between the ENMs constructs.

3.13 Reliability

Raheja and Gullo (2012) define reliability as the consistency in measurement. This means that similar results should be produced with different measures of the same concept or with the same measures over different time periods. Kuo and Zhu (2012) identified four different ways of measuring the reliability of a dimension, namely, test-retest reliability, alternate-forms reliability, split-half reliability, and internal consistency. In this study, internal consistency will be used as a measure of reliability.

A measure is considered internally consistent if it gives the same results when the measurement is repeated (Kuo et al., 2012). Raheia et al. (2012) state that Cronbach's alpha is the coefficient that is used to obtain a measure of internal consistency and is based on the average correlation

among dimensions within a construct. The authors believe that an alpha value of 0.80 or above is acceptable since it shows that the dimensions produce reasonably reliable results. However, a value below 0.60 is regarded as unacceptable.

Baumgarten (2010) argues that the following issues represent some grave threats to reliability during data collection as shown in figure 3.4:

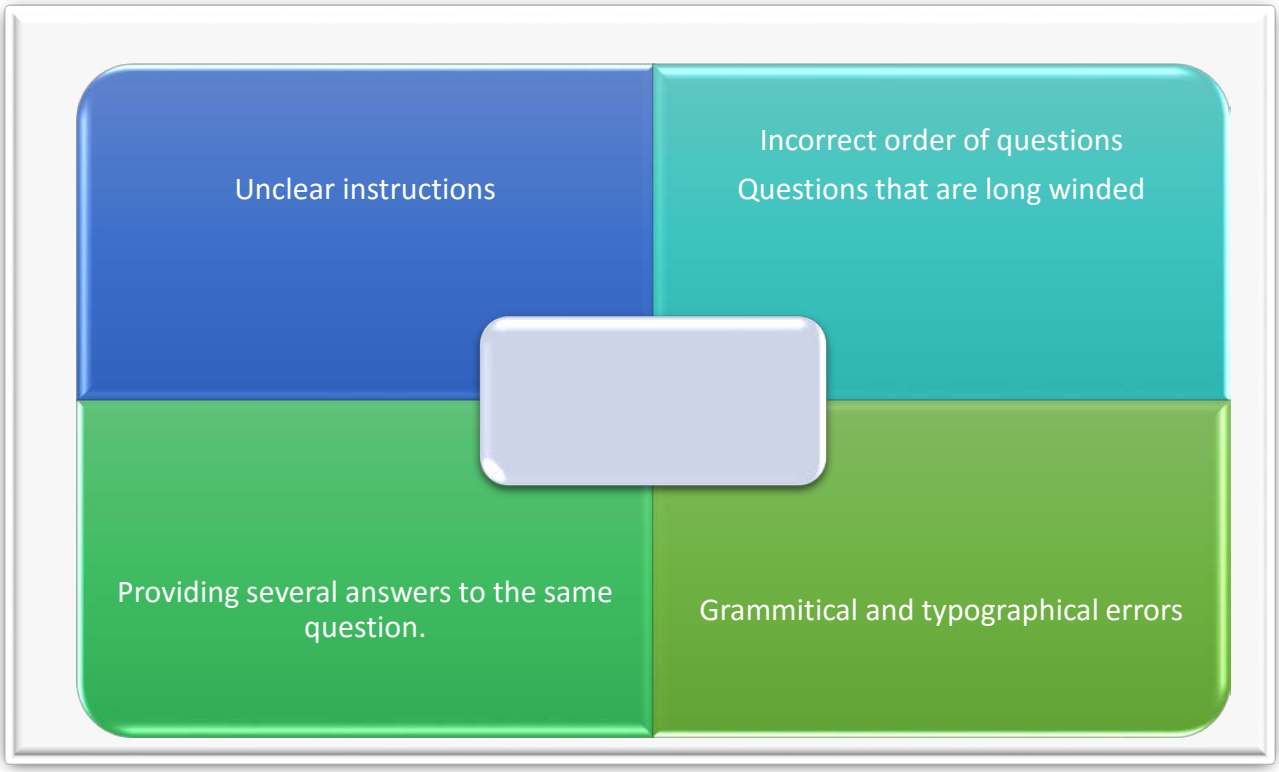


Figure 3.4: Threats to Reliability during Data Collection

Source: (Baumgarten, 2010)

Baumgarten (2010) contends that unclear instructions, incorrect sequence of questions, long winded questions, grammatical and typographical errors and ambiguous questions could distort the data collected in a study.

According to Raheia et al. (2012), Cronbach alpha is used primarily to measure reliability or internal consistency. In other words, it confirms how well a test measures what it was designed to do. It's used to test the reliability of multiple-type questions like a (Likert scale) survey and generally informs the researcher if the test accurately measures the variable of interest.

Cronbach's alpha was used in this study to measure construct reliability. This is supported by Osborne (2008) who claims that it is one of the most widely used coefficients for measuring internal consistency.

For this study, the reliability of the questions in measuring a construct were tested using Cronbach's alpha. The reliability scores for all sections exceeded the recommended Cronbach's alpha value. This indicates a degree of acceptable, consistent scoring for these sections of the research.

3.14 Pilot Work

Rubin et al. (2014) conclude that pretesting a questionnaire is designed to test whether the questions work as intended and are understood by the respondents.

The pilot work for this study involved the testing of the questionnaire before it could be administered to the target population in the main study. The purpose of which was to identify ambiguity in the wording of the questions and to eliminate problematic questions.

The first part of the questionnaire (quantitative) consisted of 19 questions which included the following themes:

- The understanding of ENMs
- Safety issues relating to ENMs
- Storage of ENMs and
- Quality Assurance of ENMs

The second part of the questionnaire (qualitative) focused on the description of and application of ENMS and included:

- Description of ENMs
- Application
- Manufacturing
- Handling

- Disposal
- Annual volume of use and
- General comments

A total of ten respondents were used to pre-test the questionnaire. Based on their responses, amendments relating to safety, storage procedures and personal protective equipment were made to the main study.

3.15 Results of pilot work

The results of the pilot work for all sections of the reliability coefficient exceeded the recommended Cronbach alpha value of 0.7 of acceptance and hence the main study continued.

Table 3.4 indicates Cronbach's alpha score for each of the constructs in this study.

Table 3.4 Reliability coefficients for Pilot Work

Construct	***Number of Items***	***Cronbach's alpha***
Understanding of ENMS	4 of 4	0.731
Safety	4 of 4	0.732
Storage	5 of 5	0.831
Quality Assurance	6 of 6	0.719

3.16 Ethics Clearance

The researcher obtained ethical clearance from the Durban University of Technology. Every effort was made to ensure that ethical standards were adhered to in the course of this research. Considerations included:

- Obtaining consent from all respondents prior to the administration of the questionnaire;
- Confirming transparency and honesty with respondents;

- Ensuring that all information obtained during the research was kept confidential.

3.17 Summary of Chapter

This chapter introduced research methodology and justified the reasons for choosing the mixed method model for this study. The structure of the study was explained together with identifying the population, the sample size and data collection methods. The design of the questionnaire was presented. Both descriptive and inferential statistics was utilised in this study to analyse the data. The descriptive analysis involved the calculation of means and standard deviations together with graphical representations in the form of charts and diagrams.

The next chapter uses statistical techniques to analyse the data, obtain the results, interpret and analyse the results.

Chapter 4- Findings, Results and Discussions

This chapter presents the results and discusses the findings obtained from:

- A review of literature from research studies, technical reports and experts working with ENMs.
- Interviews with researchers and manufacturers using ENMs, in their current practice.
- Surveys using questionnaires to seek the current level of understanding and integration of ENM best practice with SHEQ management systems of researchers, technicians, quality practitioners and managers.

The information obtained from the results above will be used to develop a quality framework illustrating the integration of SHEQ management systems to propose best practices during the use and manufacture of ENM. This quality framework together with the computer application will be presented in Chapter 5.

4.1 Results Obtained from Literature

Two hundred and fifty articles were reviewed during the literature review, and of these fifty-two were directly related to risk. These formed the basis for establishing current practices thus presenting the opportunities and necessity for managing and controlling the use of ENMs. According to Onwuegbuzie and Weinbaum (2017) literature can be used as a basis for data collection in the absence of historical data or evidence. These opportunities obtained from the literature are discussed in the section below.

According to Barnard (2006), the potential hazards associated with nanomaterials are significant and as such, they present valid concerns related to employees' health. Morose (2010) reports that ENMs is a developing technology and the possible health and safety risks have yet to be quantified. Shvedova, Pietroiusti and Kagen (2016) believe that the behaviour of ENMs poses new challenges for scientists. The afore-mentioned authors argue that this technology is unpredictable and

managing the potential adverse effects of risks, exposure and toxicity on both humans and the environment are not yet fully understood. Costa (2016) confirms that it would therefore make sense for organisations to mitigate potential risks to both humans and the environment in the research, development and design stages of manufacturing ENMs.

According to Amoabediny et al. (2009), possible routes of nanparticle exposure include ingestion, inhalation and dermal penetration. However, inhalation and ingestion of nanoparticles are likely to be the major route in humans. Of concern, is that ENMs can be deposited in the lungs and onward transmission into the blood stream, translocating to other organs such as the brain. A study by Ryman-Rasmussen et al. (2006) found that nanometer size quantum dots penetrated through pig skin. Titanium dioxide at a size of 40 nm is currently being used in sunscreens and cosmetics as sun protection. This suggests that despite warnings from research findings, products containing ENMs have been commercialised and are currently in use.

The Technical reports (TR 13121:2011 and TR 12885: 2008) describe the process of identifying, evaluating, communicating and making decisions relating to the potential risks of developing and using ENMs. These reports make a strong argument for having a properly constituted Quality Management System. During the integration of management systems in the present study, the following requirements from the technical reports above have been considered: summary of production processes, ENM profile, ENM hazard and exposure, risk assessments, evaluation of risks, description and manufacturing of ENMs, control methodologies, material sourcing, review of information, health surveillance, risk management, review and adaption.

Ganguly et al. (2017) argue that nanotechnology can be classified as a disruptive technology because it is an emerging technology that changes existing markets by introducing products with a different set of performance attributes. Furthermore, Conole et al. (2008) submit that disruptive technologies are ‘pedagogically innovative’ and act as a catalyst for

change. Ganguly et al. (2017) further argue that these new technologies bring about complex and uncertain challenges which may lead to environmental, health and social side-effects.

Hence, responsible management of these technologies are required as the need to recognize the disruptive potential of ENMs does exists. The level of risk on humans are still relatively unknown as experimental research to date has primarily been conducted on animals (Przygoda, Cingula and Yongqiang, 2017).

4.2 Results obtained from Survey

Of the 117 questionnaires administered, a total of sixty-two (62) responses was received. A further thirty (30) questionnaires were emailed, and ten (10) responses were received. Ten (10) responses were from the pilot study. Of the eighty-two (82) completed questionnaires, sixty-one (61) respondents were researchers, nineteen (19) were experts and two (2) manufacturers. The sample included employees from academia, research and manufacturing organisations. SPSS version 24.0 was used to analyse the data collected. Graphs and cross tabulations were utilized to present the results of the quantitative data that was collected. Inferential techniques included the use of chi square test values and correlations which were interpreted by using the p-values.

4.2.1 The Sample

The total of 82 responses yielded a 70% response rate. According to Patten (2016) a 50% response is deemed to be acceptable. The respondents were selected based on their knowledge, experience and exposure to ENMs.

4.2.2 The Questionnaire Design

The questionnaire consisted of fifty-six (56) questions, with a level of measurement at a nominal or an ordinal level. The questionnaire was divided into 4 themes which measured the following:

Table 4.1: Structure of the Questionnaire

A	Biographical data
B	Understanding of ENMs
C	Description of ENMs
D	Description of application of ENMs

According to Brown (2015), the two most important aspects of precision are validity and reliability. The consideration of both these aspects in this study will be discussed below.

4.3 Content validity

Bernard et al. (2016) and Maxwell (2005) advise that a measuring instrument has content validity if the measurement dimensions of each construct covers all aspects of the construct being measured. In terms of content validity, the measuring instrument for this study meets the requirements, since the dimensions were:

(i) Based on an extensive review of international, current and peer-reviewed literature;
(ii) Reviewed by a researcher and statistician in the field of quality and technical knowledge of ENM.

4.4 Reliability

According to Leontitsis and Pagge (2007) reliability is calculated by taking numerous measurements of the same subjects. A reliability coefficient of 0.70 or higher is considered as “acceptable”. The table 4.2 reflects the

Cronbach's alpha score for all the questionnaires completed in both sample sets that were administered and emailed for this study.

Table 4.2: Cronbach's Alpha Scores

	Number of Items	Cronbach's Alpha
Understanding of Nano-engineered materials (ENMs)	4 of 4	0.842
Safety	4 of 4	0.856
Storage of ENMs	5 of 5	0.848
Quality Assurance of ENMs	6 of 6	0.847

From Table 4.2 the reliability scores for all sections exceeded the recommended Cronbach's alpha value of 0.7 of acceptance. This indicates a degree of acceptable and consistent scoring for these sections of the research (Leontitsis et al., 2007)

4.5. Kaiser-Meyer-Olkin and Bartlett's Test (KMO)

Sharma (2005) contends that a summarised table that reflects the results of Kaiser-Meyer-Olkin Measure (KMO) and Bartlett's Test precedes the matrix tables. The requirement is that KMO Measure of Sampling Adequacy should be greater than 0.50 and Bartlett's Test of Sphericity less than 0.05.

Table 4.3: Kaiser-Meyer-Olkin Measure of Sampling Adequacy and the Bartlett's Test of Sphericity.

	Kaiser-Meyer-Olkin Measure of Sampling Adequacy	Bartlett's Test of Sphericity		
		Approx. Chi-Square	df	Sig.
Understanding of Nano-engineered materials (ENMs)	0.748	144.809	6	0.000
Safety	0.727	177.585	6	0.000
Storage of ENMs	0.712	206.530	10	0.000
Quality Assurance of ENMs	0.728	321.200	15	0.000

For the purposes of this study, the conditions for the KMO were satisfied which allows for the use of the Factor Analysis procedure. DiStefano, Zhu and Mindrila (2009) suggest that the Bartlett Score method is computed by multiplying the row vector of observed variables by the inverse of the diagonal matrix of variances of the unique factor scores. Hence, the advantage of using the Bartlett Score method is that it produces unbiased estimates of the true factor scores.

4.6 Rotated Component Matrix

This section was used to determine whether the statements per theme measured what it intended to measure.

Table 4.4: Understanding of ENMs

Component Matrix[a]	
	Component
B1: Understanding of Nano-engineered materials (ENMs)	**1**
I understand the structure of ENMs	0.742
I have received suitable and adequate training in dealing with ENMs	0.877
There was a practical component to the ENMs training	0.889
I understand the risks associated with ENMs	0.793
Extraction Method: Principal Component Analysis.	
a. 1 component extracted.	

The data in table 4.4 attempted to determine the understanding of ENMs of the respondents in this study. The Principle Component Analysis indicated that the statements above loaded perfectly along a single component. This implies that these statements (above 0.5) measured perfectly to what it set out to measure.

Table 4.5: Safety of ENMs

Component Matrix[a]	
	Component
B2: Safety	**1**
I was given a safety manual for ENMs	0.702
I am aware of the safety procedures when dealing with ENMs	0.894
Protective equipment is provided when I'm dealing with ENMs	0.864
I know what to do in the event of an emergency when dealing with ENMs	0.881
Extraction Method: Principal Component Analysis.	
a. 1 components extracted.	

The data in table 4.5 measured the perceptions of safety of ENMs for the respondents in this study. The Principle Component Analysis indicated that the statements above loaded perfectly along a single component. This implies that these statements (above 0.5) measured perfectly to what it set out to measure.

Table 4.6: Storage of ENMs

Component Matrix[a]	
	Component
B3: Storage of ENMS	**1**
I understand the storage procedures of ENMs	0.598
There are adequate storage facilities for ENMs	0.827
ENMS is stored in a controlled environment	0.855
Access to ENMs is restricted	0.813
Inventory of ENMs can always be accounted for	0.830
Extraction Method: Principal Component Analysis.	
a. 1 components extracted.	

The data in table 4.6 measured the storage aspects of ENMs with the respondents in this study. The Principle Component Analysis indicated that the statements above loaded perfectly along a single component. This implies that these statements (above 0.5) measured perfectly to what it set out to measure.

Table 4.7: Quality Assurance of ENMs

Rotated Component Matrix[a]		
	Component	
B4: Quality Assurance of ENMs	**1**	**2**
There are documented policies and procedures available for the use of ENMs	0.884	0.192
Work Instructions are available for ENMs	0.893	0.153
Documents relating to ENMs are filed in an appropriate manner	0.919	0.105
I know how to use the test equipment for ENMs	0.051	0.940
The equipment is regularly calibrated	0.169	0.936
Non- conformance reports are available	0.507	0.619
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.		
a. Rotation converged in 3 iterations.		

The data in table 4.7 measured Quality Assurance of ENMs for the respondents in this study. It is noted that the variables that constituted Section B4 loaded along 2 components (sub-themes). This means that respondents identified different trends within the section. Within the section, the splits are colour coded. A more in-depth discussion is presented in the next section.

4.7 Descriptive Measures of Demographic Information

This section presents the descriptive statistics based on the demographic information of the study. The results are presented in the form of charts and graphs.

4.7.1 Section A: Biographical Data

This section summarises the biographical characteristics of the respondents. The table below describes the gender composition of the sample.

Table 4.8: Gender Composition

Gender	Frequency	Percent
Male	52	63.4
Female	30	36.6
Total	82	100.0

Table 4.8 sets out the gender composition of this study. Of the 82 respondents 52 were male (63.4%) and 30 were female (36.6%). The significance of gender statistics is discussed in figure 4.1.

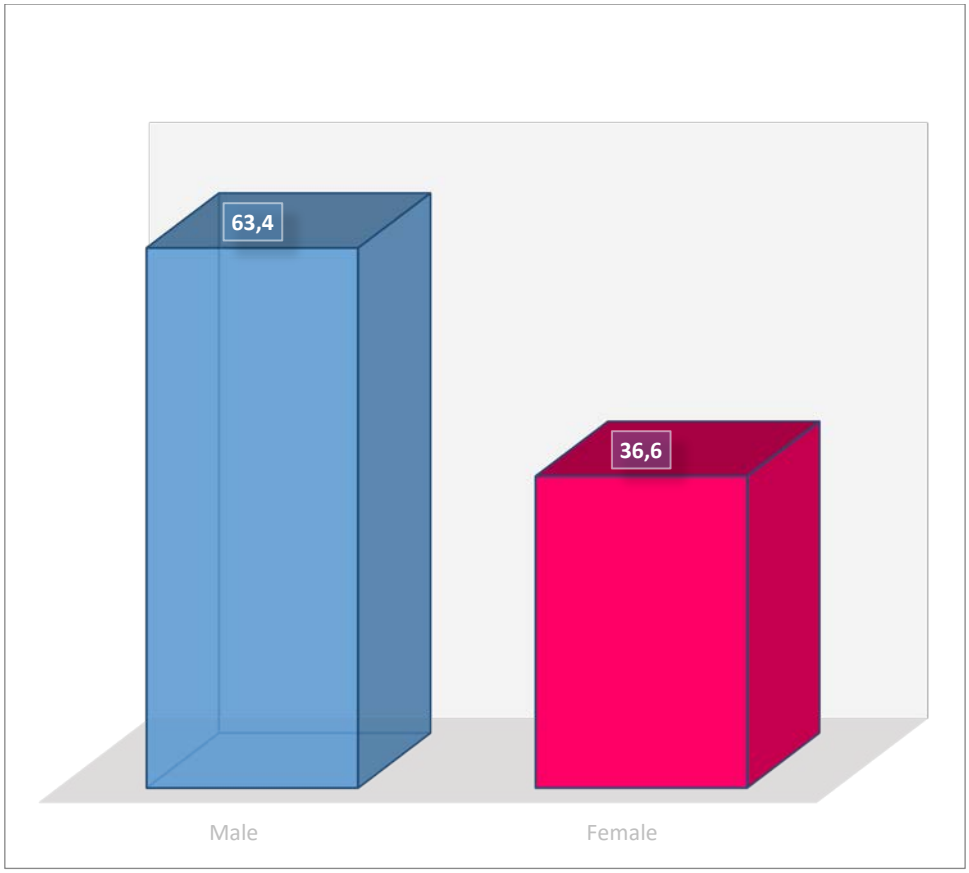


Figure 4.1: Gender Statistics

Figure 4.1 indicates that the ratio of males to females is approximately 3:2 (63.4%: 36.6%). The inference here is that males outnumber females in the field of ENMs for the sample investigated. The reason for gender specific statistics is to detect if any gender differentiated conditions did exist.

4.7.2 Racial Classification

The racial composition of the sample is shown below.

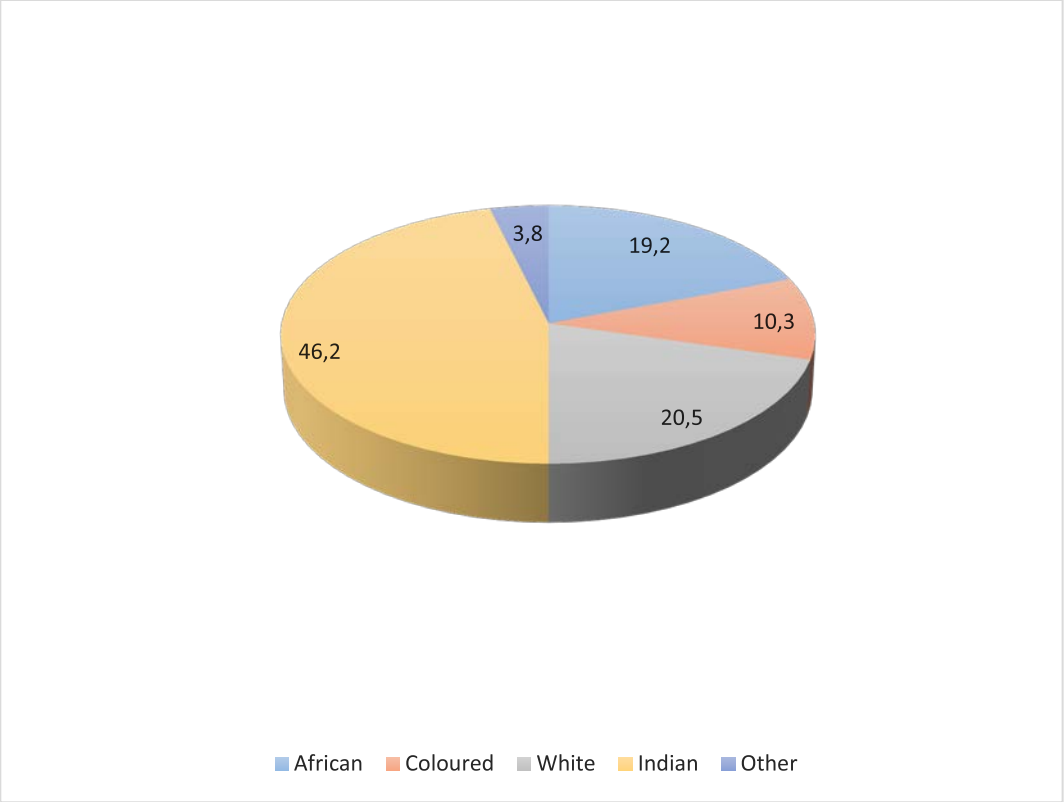


Figure 4.2: Racial Classification

A little less than half of the respondents (46.2%) were Indian, 20.5% were White, 19.2% were Black and Coloureds (10.3%) forming the smallest ratio of the main South African race groups.

According to Nadal, Davidoff, Davis, Wong, Marshall and McKenzie (2015), the question relating to race is to determine whether respondent's ethnicity influences their responses.

4.7.3 Type of Organisations

The type of organisation to which the respondents belonged to is shown in Figure 4.3.

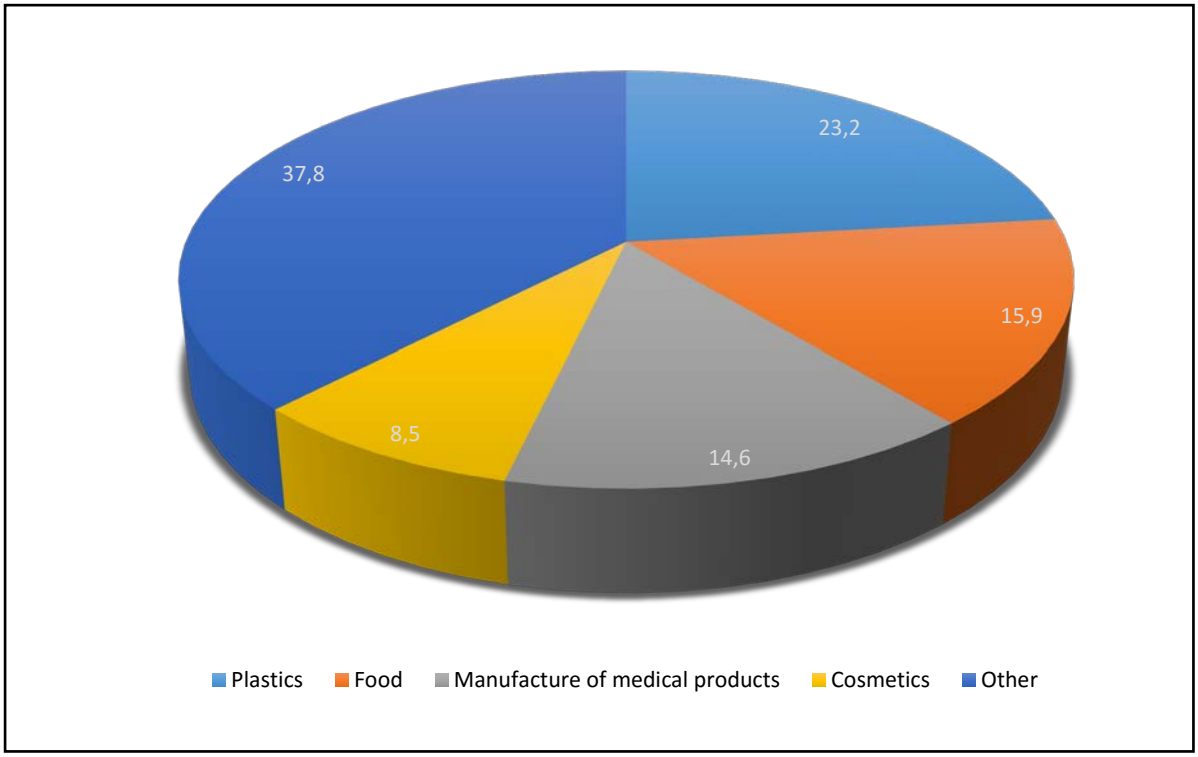


Figure 4.3: Type of Organisations

Approximately 38% of the respondents were in the Plastics Industry, 15.9% from food-based industries; 14.6% from medical products and 8.5% from cosmetics with the balance of 23.2% in research and academic institutions.

Gray (2017) ascertains that the reasons for classifying organisations in research studies is to guide legislators as to which industries to target relating to health and safety should this become necessary.

4.7.4 Length of Service

Figure 4.4 indicates the length of service of the respondents.

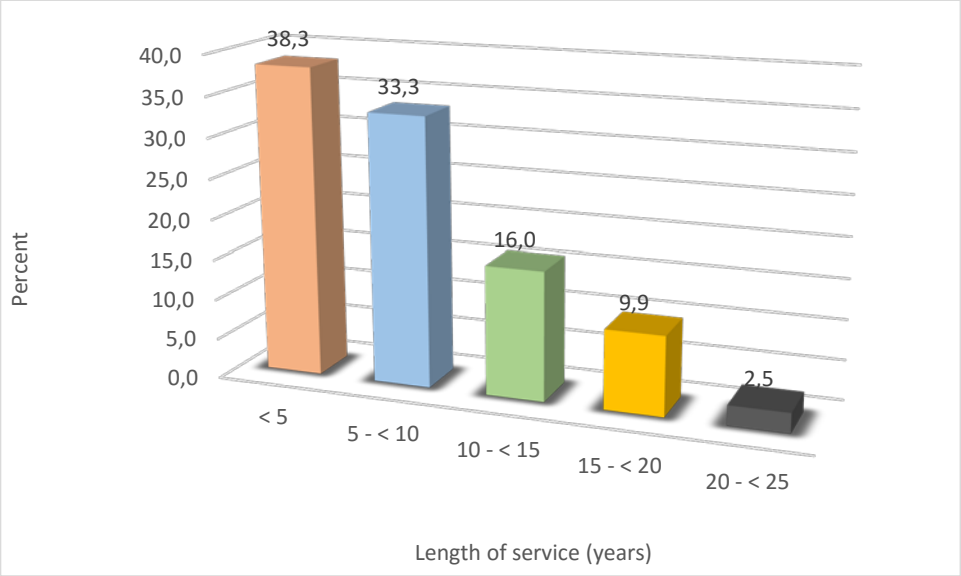


Figure 4.4: Length of Service

Nearly 60% of the respondents had been employed for more than 5 years. It implies that responses received were from experienced workers. The consistency of responses is verified by the high reliability scores obtained (see annexure 4.1).

Length of service can also be an indicator of employee retention and turnover. High staff turnover can affect the stability and loss of knowledge within an organisation (Anitha and Begum: 2016). The data presented in this study does not suggest high staff turnover and this bodes well for organisations working with ENMs as knowledge and systems needs to be retained for growth in this sector.

4.7.5 Positions in the Organisation

The table below indicates the positions of the respondents in their organisations. This question was asked to test the levels of understanding of ENMs at different levels in the organisations.

Table 4.9: Position in the Organisation

Position in Organisation	Frequency	Percent
Management	21	25.9
Technical	34	42.0
Quality	26	32.1
Total	81	100.0

Almost 74.1 % of respondents are actively engaged in either working with, testing or researching ENMs. This is significant as the majority of the respondents are from the technical side and they are the individuals within organisational structures that are most at risk with working with ENMs.

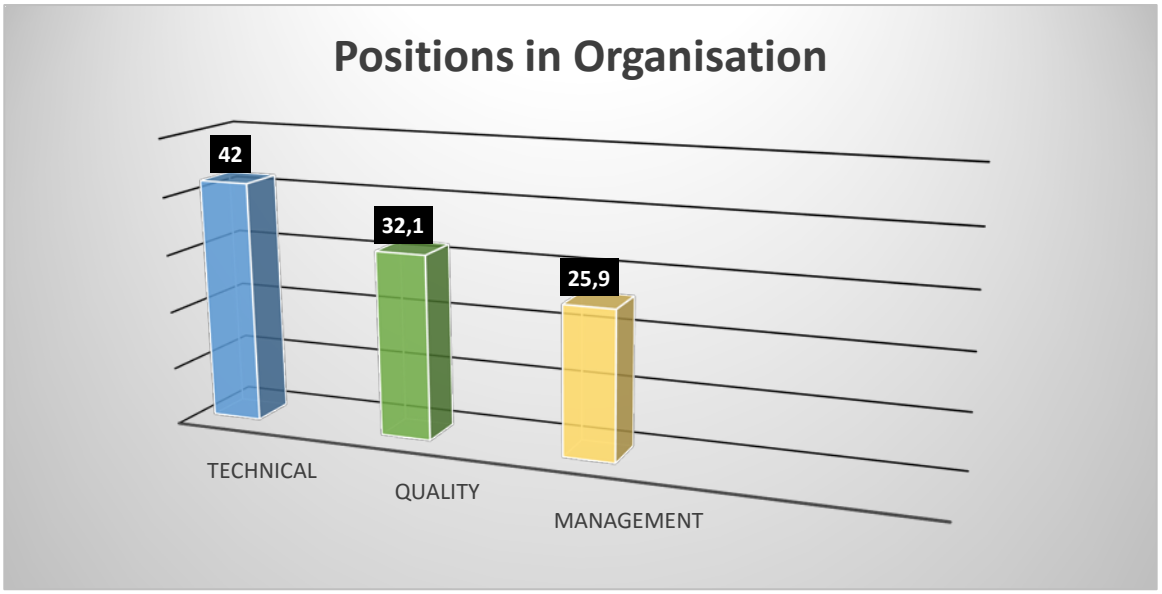


Figure 4.5: Positions in Organisation

4.8 Section Analysis

In the following section, analyses of the scoring patterns of the respondents per variable per section is conducted. Where relevant, negative statements (levels of disagreement) were combined to show a single grouping of "Disagree". Similarly, this procedure was followed for positive statements (the levels of agreement).

The results are first presented using summarised percentages for the variables that constitute each section.

4.8.1 Section B1 – Training and Risks Associated with ENMs

This section deals with the respondents' understanding, training and risk associated with ENMs. According to Koiranen, Nevalainen, Virkki-Hatakka, Aalto, Murashko, Backfolk and Pyrhönen (2017) safety issues have somewhat delayed the massification of ENMs into the commercial market as the material properties of carbon nanotubes has shown similar structural properties to those of asbestos. The reason for asking this question was to find out how much knowledge the respondents had about the risks of ENMs and whether adequate training was administered.

Table 4.10 summarises the scoring patterns for theme training and risks associated with ENMs

Table 4.10: Training and Risks Associated with ENMs

Question		Agree		Neutral		Disagree		Chi Square
		Count	Row N %	Count	Row N %	Count	Row N %	p-value
I understand the structure of ENMs	B1.1	68	82.9%	8	9.8%	6	7.3%	0.000
I have received proper and adequate training in dealing with ENMs	B1.2	46	56.8%	15	18.5%	20	24.7%	0.000
There was a practical component to the ENMs training	B1.3	30	37.0%	20	24.7%	31	38.3%	0.254
I understand the risks associated with ENMs	B1.4	24	29.3%	18	22.0%	40	48.8%	0.009

The following patterns are observed:

- The respondents were asked whether they understood the structure of ENMs. Two of the statements (B1.1 and B1.2) show significantly higher levels of agreement which means that respondents understood the structure of ENMs and had received adequate training.
- Two other statements (B1.3 and B1.4) indicated higher levels of disagreement. The respondents indicated that even though they had received adequate training, there was still a need for more practical training.
- For risks, 48.78% did not fully understand the risks associated with ENMs.
- The significance of the differences is tested and is reflected in the table 4.10.

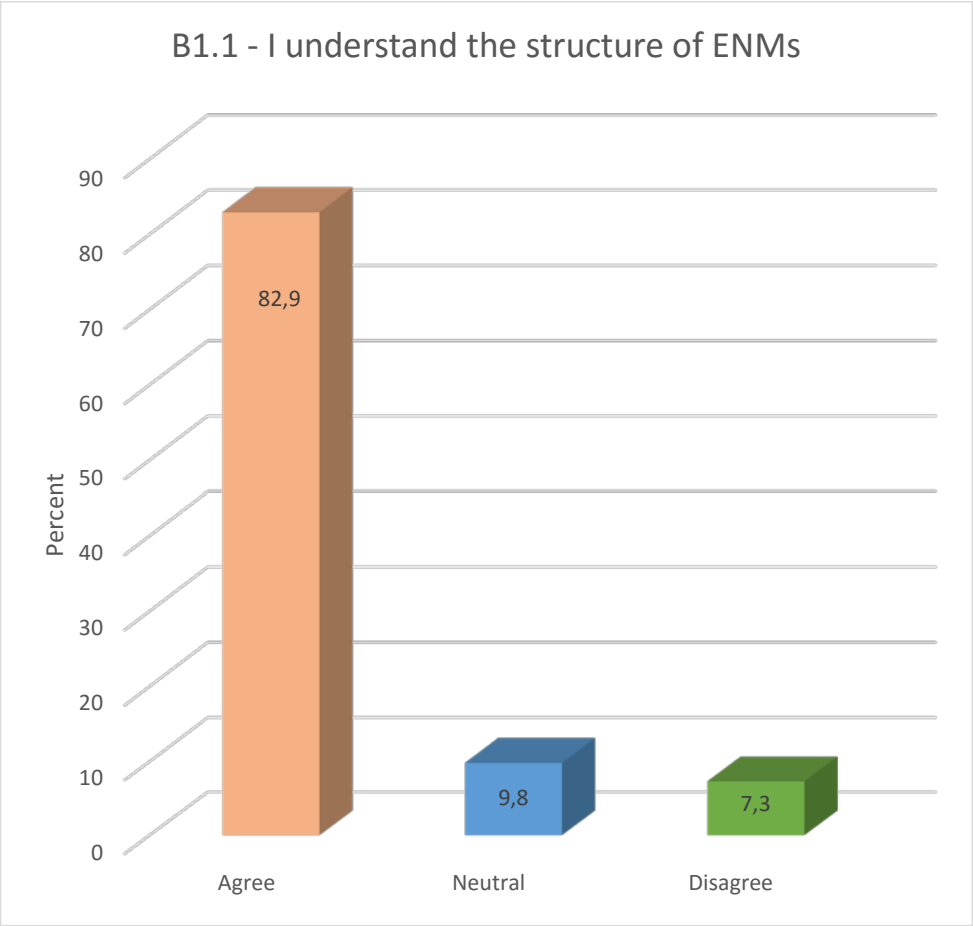


Figure 4.6: Understanding of the Structure of ENMs.

It is observed that the first 2 statements (B1.1 and B1.2) have significantly higher levels of agreement ($p < 0.05$). Figure 4.6 shows that 82.9% of the respondents understood the structure of ENMs, whilst 7.3% indicated that they did not know and 9.8% were neutral. This is an indication that the respondents are well versed with the scientific and chemical properties of the ENMs with which they are working.

Hence understanding the the structure of ENMs is important since bulk properties of materials (atoms and molecules) can change drastically when reduced to nano scale (Boldrin et al., 2014)

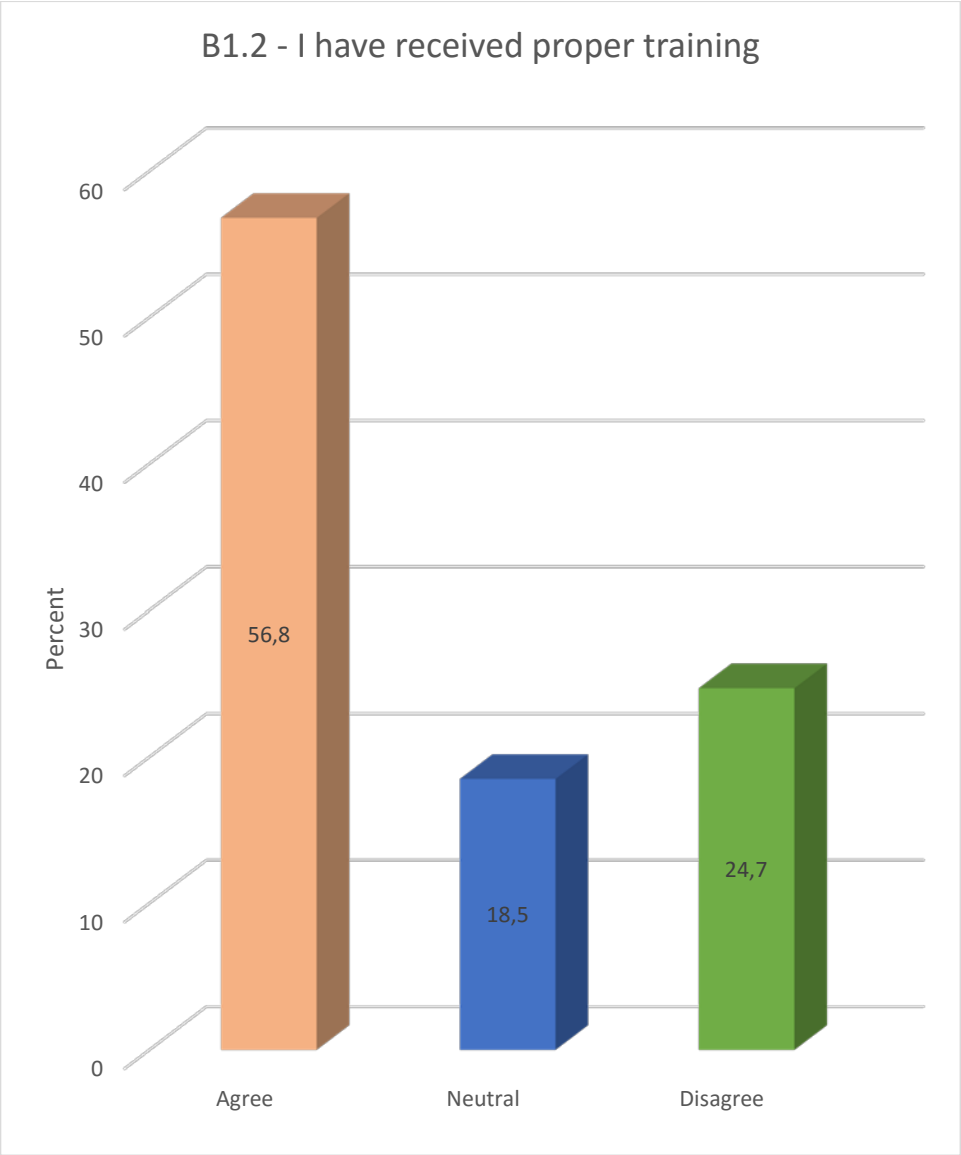


Figure 4.7: Training in ENMs

The respondents were asked whether they received proper training in dealing with ENMs. Figure 4.7 that only 56.8% of respondents have received adequate training whilst 24.7% did not. This needs to be addressed as training should be seen to be of importance in the nanotechnology sector. Hossain, Rony, Das, Majumder, Khandaker and Zhou (2017) claim that untrained workers are inefficient and may not fully realise the dangers inherent in the workplace. Furthermore the lack of proper training can lead to mistakes and due to the uncertainty of ENMs

this could prove costly to an organisation. This suggests that training needs must be priortised in the organisation's safety strategy.

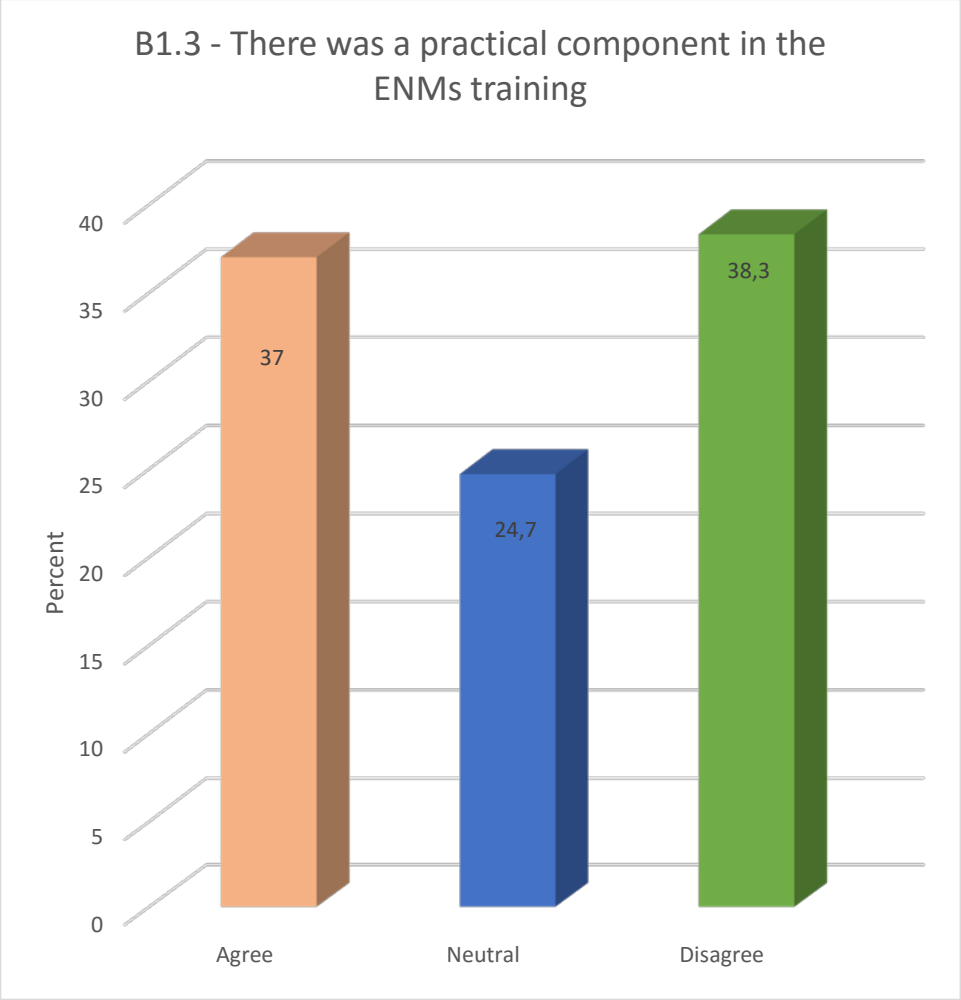


Figure 4.8: Practical Component in the ENMs Training

Statement B1.3 does not show any significant difference in scoring patterns ($p = 0.254$). This means that the respondents were equally split along the options (agree, neutral, disagree).

The respondents were asked to indicate whether there was a practical component in the ENMs training. Figure 4.8 shows that some (37%) of the respondents agreed that there was a practical component to the ENMs training. However 38% of them had received no practical training. Heiskanen, Thidell and Rodhe (2016) contend that whilst theory provides the groundwork for learning, practical training helps individuals to acquire

specific skill sets and competencies which is necessary in the field of nanotechnology.

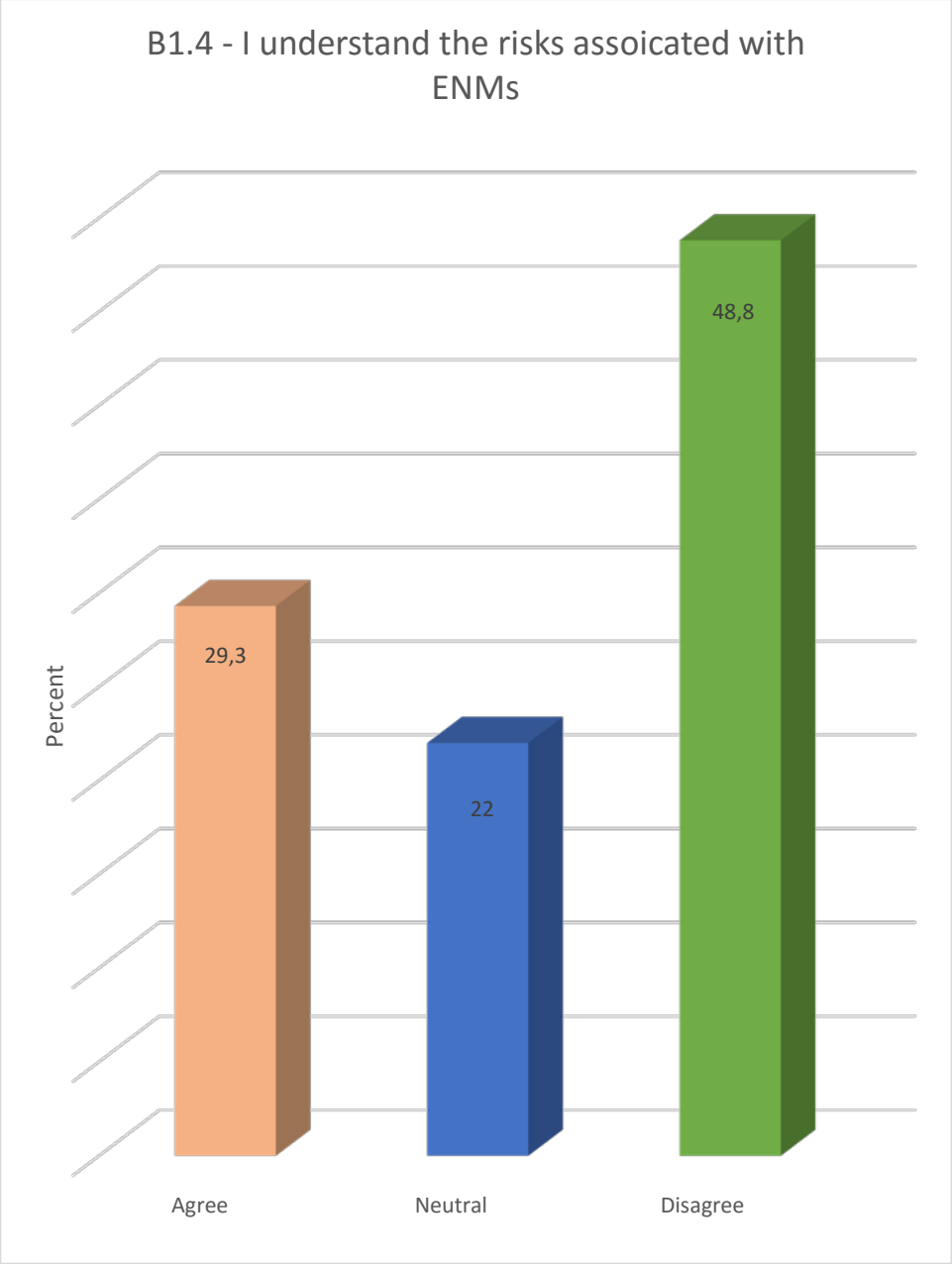


Figure 4.9: Risks Associated with ENMs

There was a significant higher number of respondents who disagreed with statement B1.4 ($p = 0.009$). The respondents were asked whether they understood the risks associated with ENMs. Figure 4.9 shows that some (29.3%) of the respondents understood the risks associated with ENMs while almost half (48.8%) of the respondents indicated that they did not understand such risks. This is of concern as it indicates that risk

identification, monitoring and control procedures seem to be lacking in many organisations.

Gaunt, Picket and Reinert (2017) claim that to determine whether the scoring patterns per statement are significantly different per option, a Chi Square Test can be undertaken (table 4.10).

4.8.2 Section B2 - Safety, PPE and Emergency Procedures

Emergency preparedness including disaster plans are crucial to ensure employee safety, prevention of infrastructure and inventory loss (Renschler, Terrigino, Azim, Snider, Rhodes, and Cox, 2016).

Table 4.11: Safety, PPE and Emergency Procedures

Question		Agree		Neutral		Disagree		Chi Square
		Count	Row N %	Count	Row N %	Count	Row N %	p-value
I was given a safety manual for ENMs	B2.1	52	64.2%	10	12.3%	19	23.5%	0.000
I am aware of the safety procedures when dealing with ENMs	B2.2	43	52.4%	22	26.8%	17	20.7%	0.001
Protective equipment is provided when I'm dealing with ENMs	B2.3	32	39.0%	24	29.3%	26	31.7%	0.530
I know what to do in the event of an emergency when dealing with ENMs	B2.4	20	24.4%	17	20.7%	45	54.9%	0.000

From Table 4.11, the following patterns are observed:

- Three statements (B2.1; B2.2 and B.3) show significantly higher levels of agreement.
- One statement (B2.4) indicates a higher level of disagreement.

- The significance of the differences is tested and is reflected in the table 4.11.

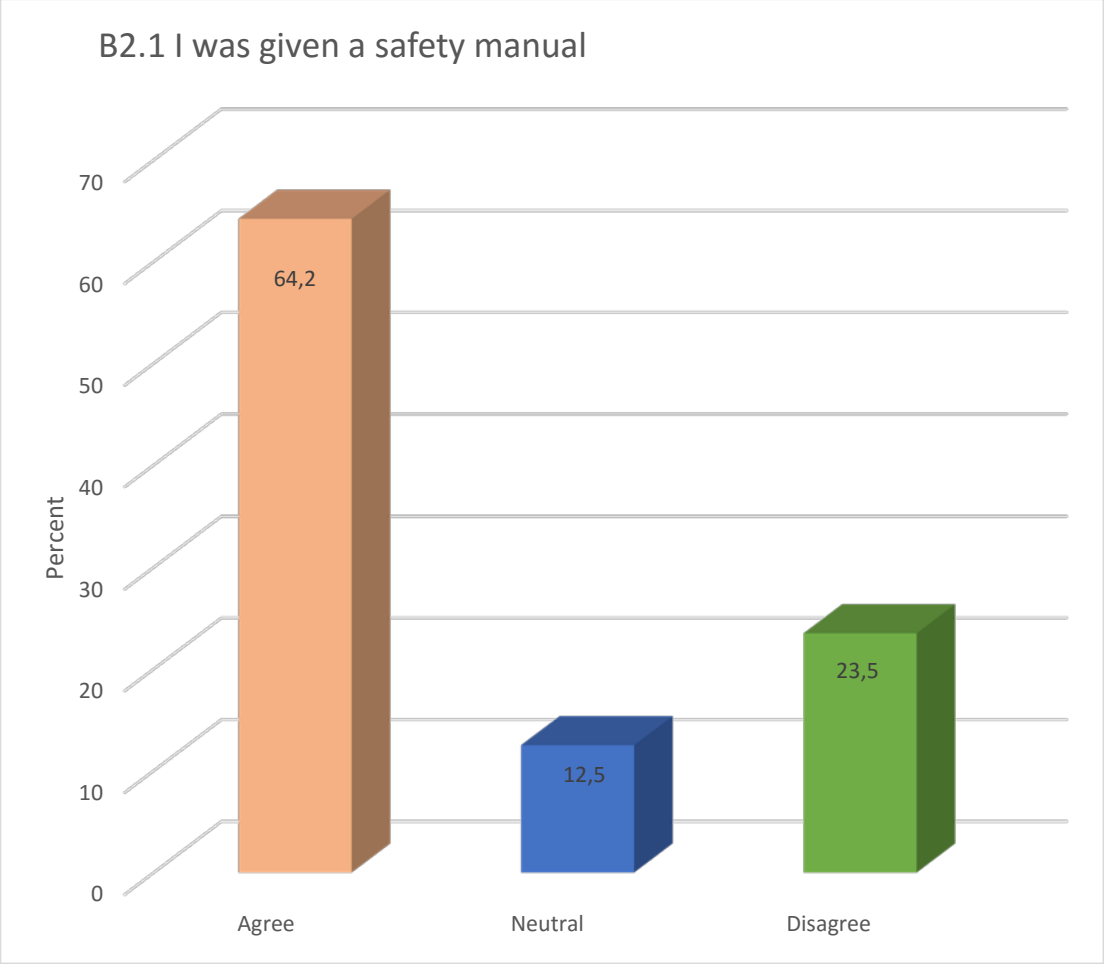


Figure 4.10: Receipt of a Safety Manual

The respondents were asked whether they were given a safety manual. Figure 4.10 indicates that 64.2% of the respondents were given a safety manual, while 23.5% did not receive one. According to Borg (2016), safety manuals are in essence workplace reference guides and may contain life saving information. Safety manuals also contain information about the storage, handling and disposal of ENMs and preventative measures in the case of exposure to hazardous chemicals. Hence through accessing safety manuls workers are more likely to adopt safe working practices resulting in minimizing or eliminating accidents. Furthermore safety manuals can serve as a mechanism when traceability of activities are required (Borg 2016).

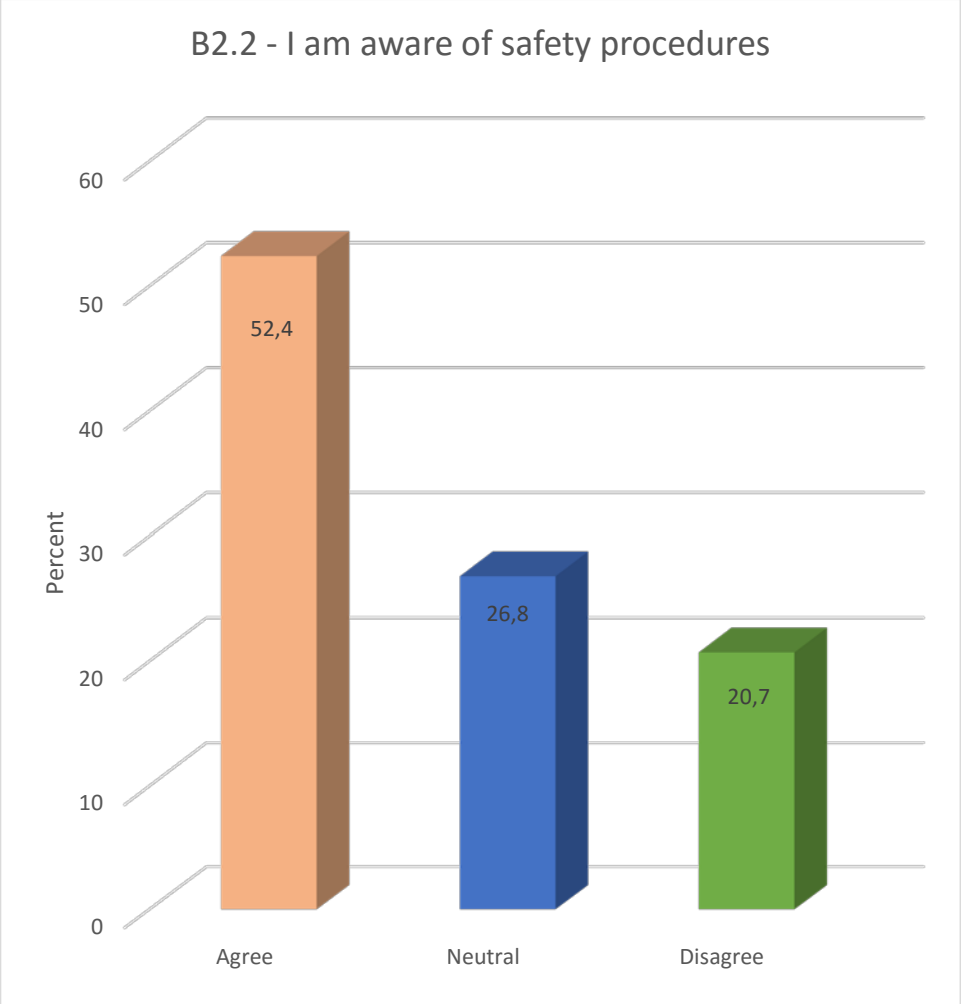


Figure 4.11: Awareness of Safety Procedures

The respondents were asked to indicate whether they were aware of safety procedures when dealing with ENMs. Figure 4.11 shows that about half (52.4%) of the respondents were aware of safe working procedures, while 20.7% were not aware and 26.8% were neutral. Current evidence regarding the toxic effects of ENMs is very limited (Shvedova et al., 2016). There is also a lack of legislation relating to ENMs (Aschberger, et al., 2016). In the absence of legislation, it would be prudent for organisations to build, enhance and promote a safe working environment.

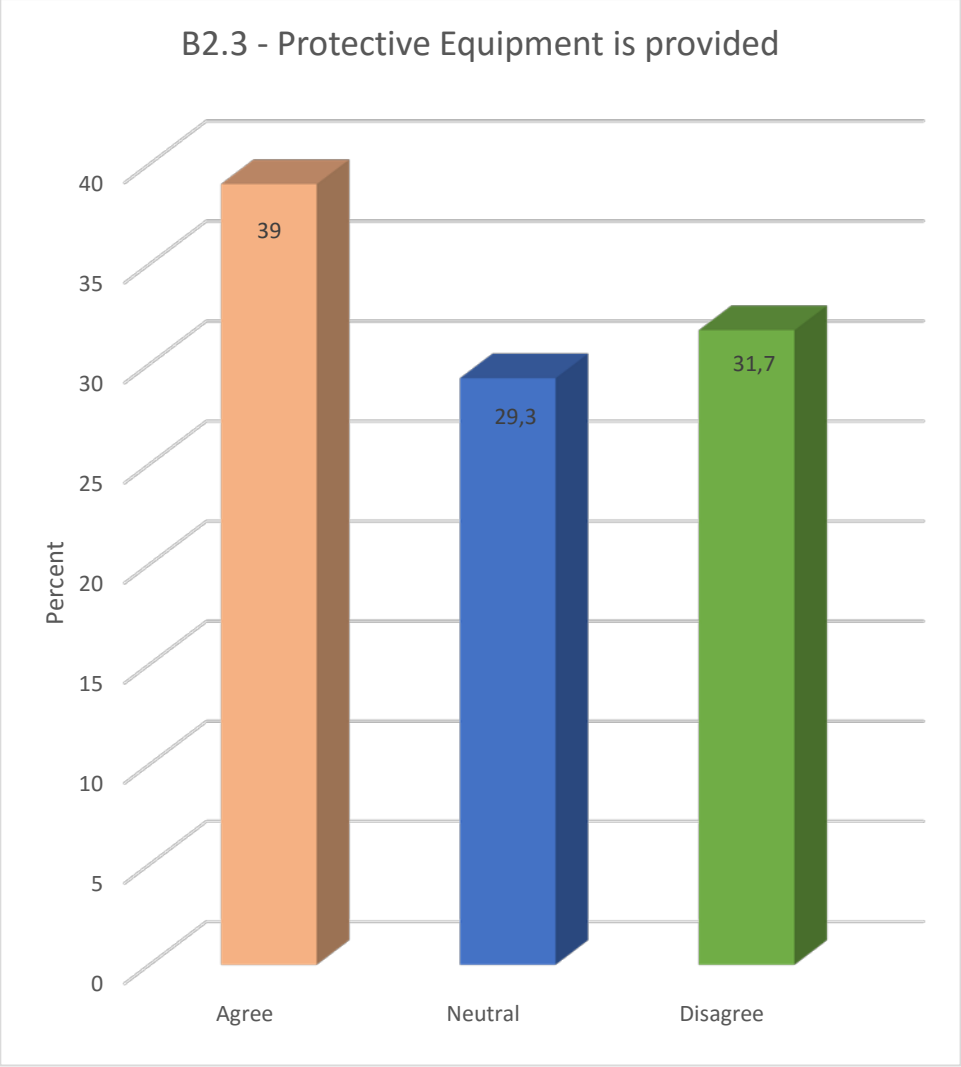


Figure 4.12: Provision of Protective Equipment

Statement B2.3 does not show any significant differences in scoring patterns ($p = 0.530$). This means that the respondents were equally split along the options (agree, neutral, disagree).

The respondents were asked to indicate whether protective equipment was provided whilst working with ENMs. As shown in Figure 4.12, only 39% of respondents indicated that suitable PPE specific for nanotechnology was provided, while 31.7% indicated that such equipment was not provided and 29.3 were neutral. According to Koiranen et al. (2017), employees must be made aware of the dangers of not using the correct PPE.

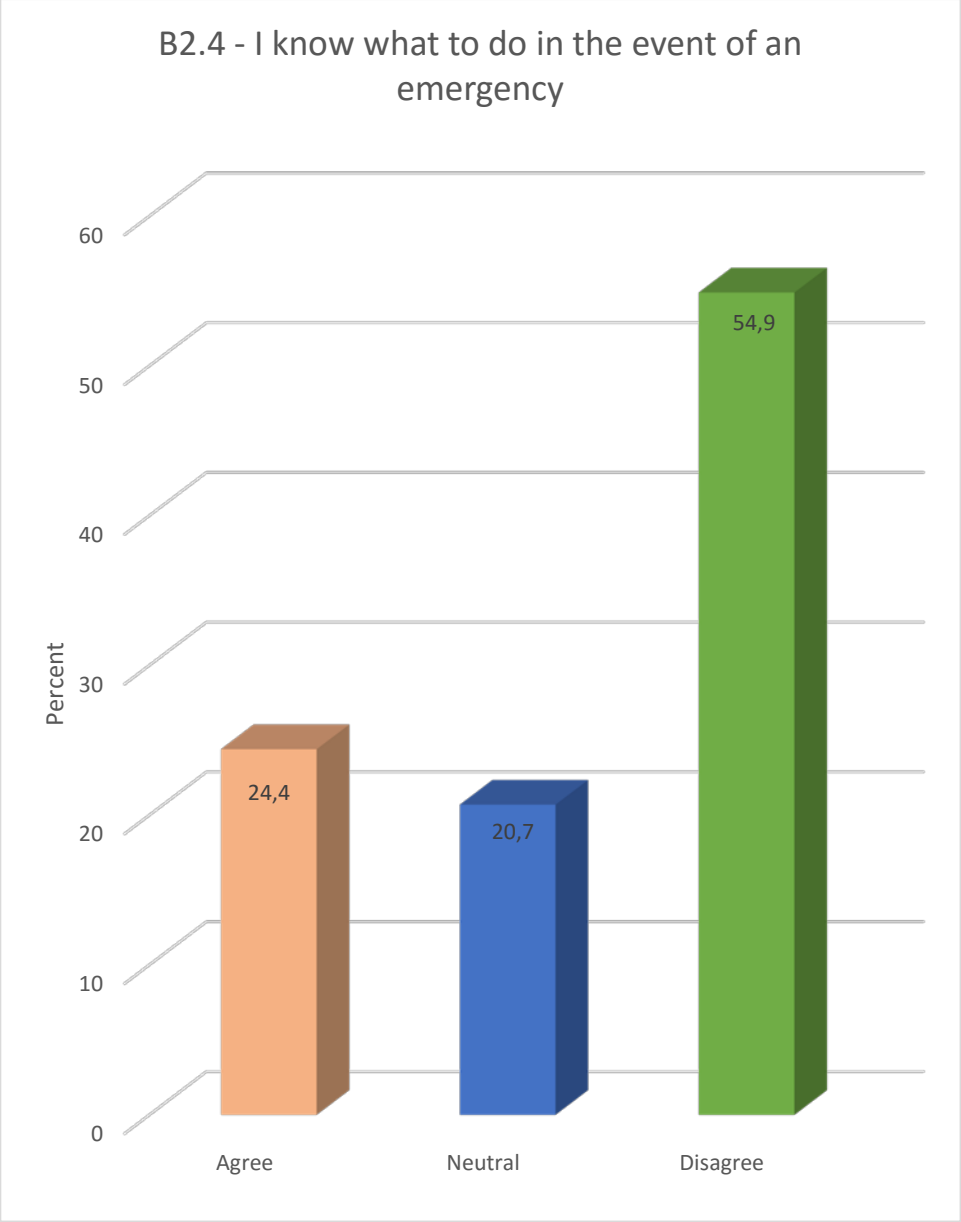


Figure 4.13: Emergency Procedures

The respondents were asked to indicate whether they knew what to do in the event of an emergency. Figure 4.13 indicates that only 24% of the respondents knew what to do in an emergency. 54.9% of the respondents were not aware of what they should do in such situations, while 20, 7 were neutral. The effects of an emergency can be devastating especially if staff are unprepared (Koiranen et al., 2017). Planning, communication and training in emergency procedures are crucial to minimize the impact of emergency situations (Haddow et al., 2017).

4.8.3 Section B3 - Storage and Control of ENMs

ENMs can enter the body in the form of nanoparticles, agglomerates of nanoparticles, and particles from nanostructured materials if they are airborne. People working with ENMs must have a proper understanding of the storage and control procedures of ENMs to minimize accidents (Boldrin et al., 2014). Section B3 of the instrument contained statements relating to storage and control of ENMs which which respondents had to agree/disagree with.

Table 4.12: Storage and Control of ENMs

Question		Agree		Neutral		Disagree		Chi Square
		Count	Row N %	Count	Row N %	Count	Row N %	p-value
I understand the storage procedures of ENMs	B3.1	60	73.2%	16	19.5%	6	7.3%	0.000
There are adequate storage facilities for ENMs	B3.2	50	61.0%	15	18.3%	17	20.7%	0.000
ENMs is stored in a controlled environment	B3.3	45	54.9%	20	24.4%	17	20.7%	0.000
Access to ENMs is restricted	B3.4	35	43.2%	18	22.2%	28	34.6%	0.067
Inventory of ENMs can always be accounted for	B3.5	25	30.9%	22	27.2%	34	42.0%	0.236

As shown in Table 4.12 above, the following patterns are observed:

- Three statements (B3.1; B3.2 and B3.3) show significantly higher levels of agreement about the storage procedures, the adequacy of storage facilities and the control environment of ENMs.
- Two statements (B3.4 and B3.5) indicate higher levels of disagreement relating to access and inventory control of ENMs.

- The significance of the differences is tested and is reflected in table 4.12.

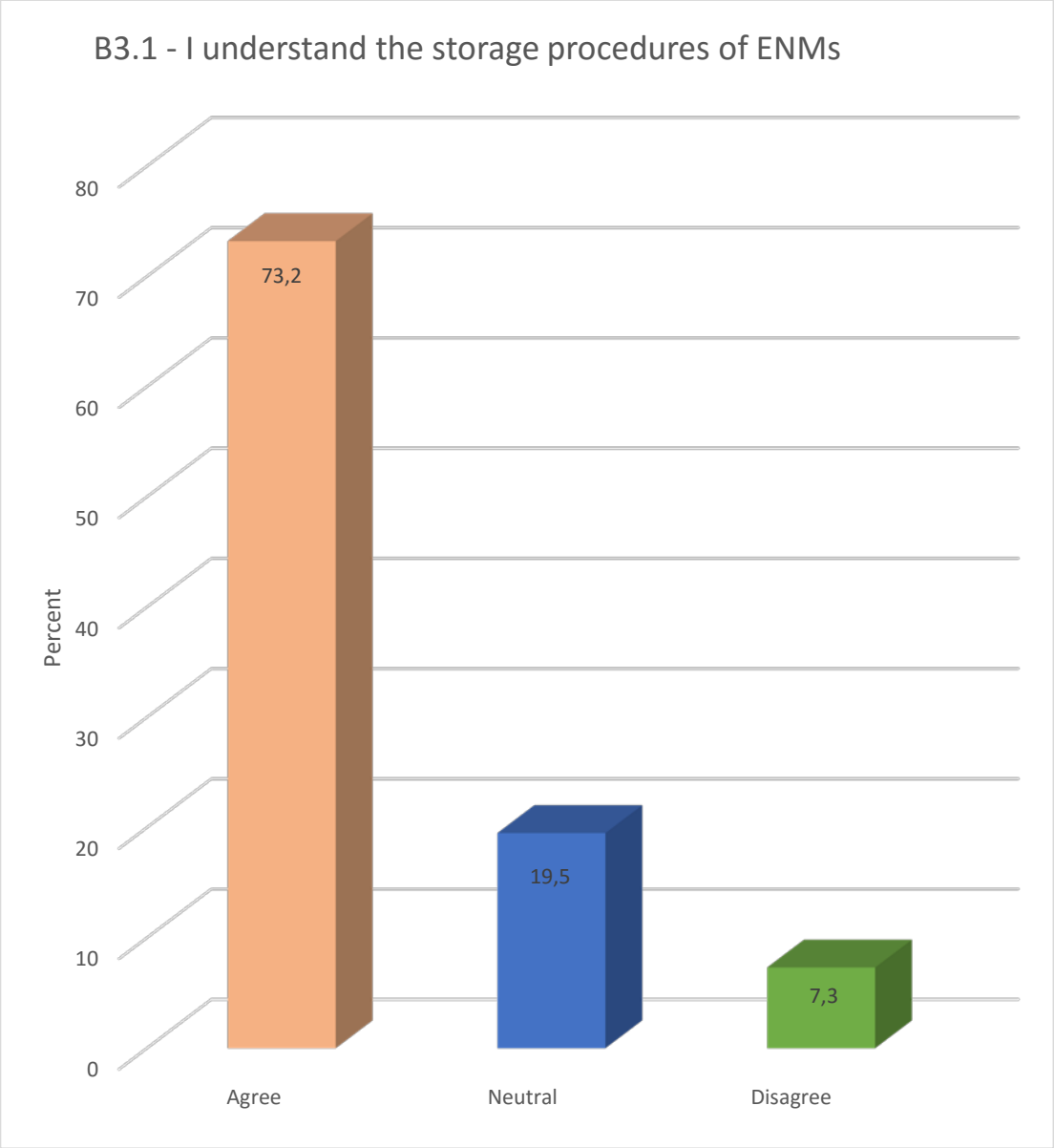


Figure 4.14: Storage and Control of ENMs

Figure 4.14 above shows that the majority (73.2%) of the respondents understood the storage procedures of ENMs, while 7.3% did not and 19.5% were neutral. Engineered nanomaterials must be stored in closed non-breakable containers which are clearly labelled as hazardous materials to ensure that they are not released into the atmosphere (Boldrin et al., 2014).

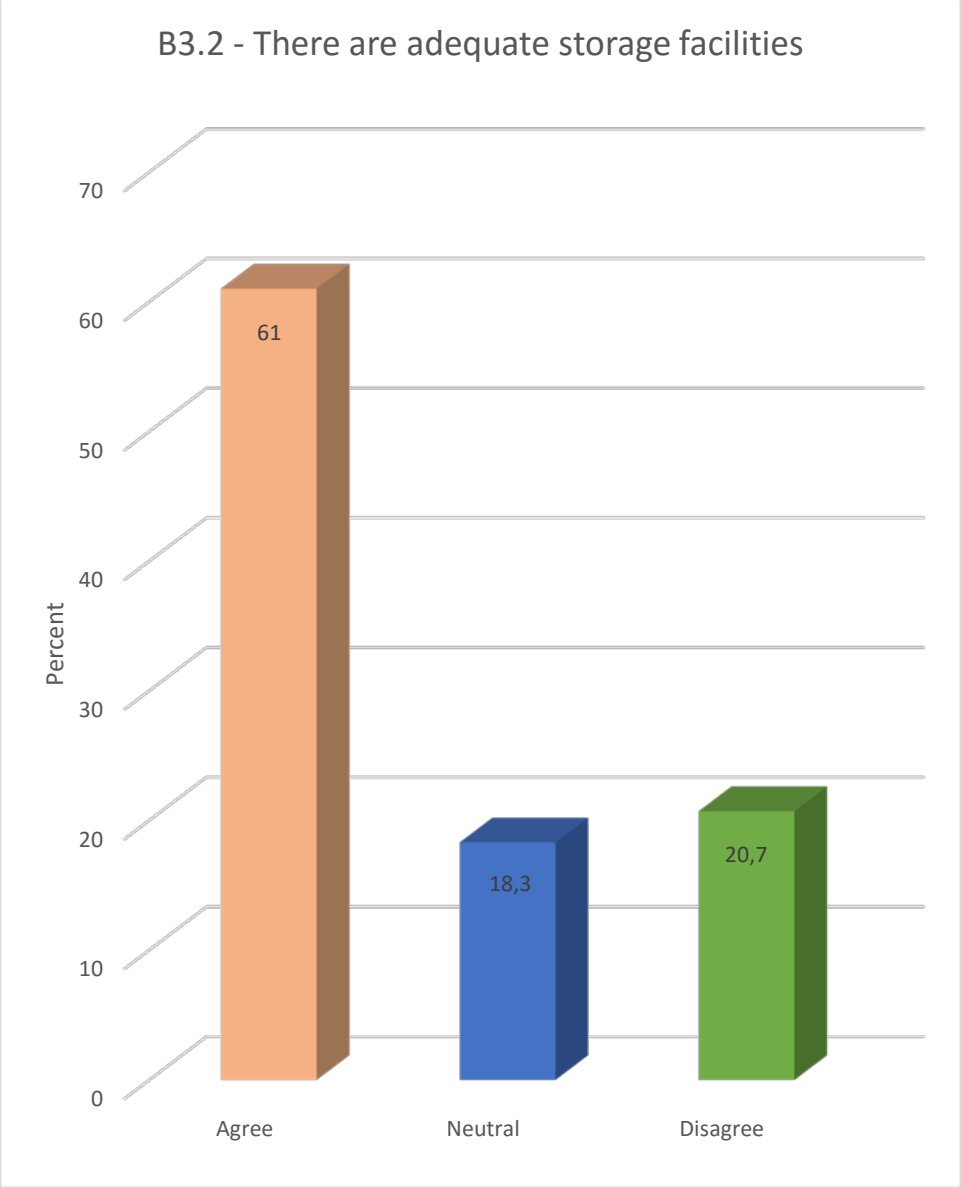


Figure 4.15: Adequacy of Storage Facilities

Figure 4.15 above shows the responses relating to adequacy of storage facilities for ENMs. Only 61% of respondents indicated that there are adequate storage facilities for ENMs. Storage areas must be regularly inspected and individual users should be responsible for completing regular inspections (Kumar et al., 2016).

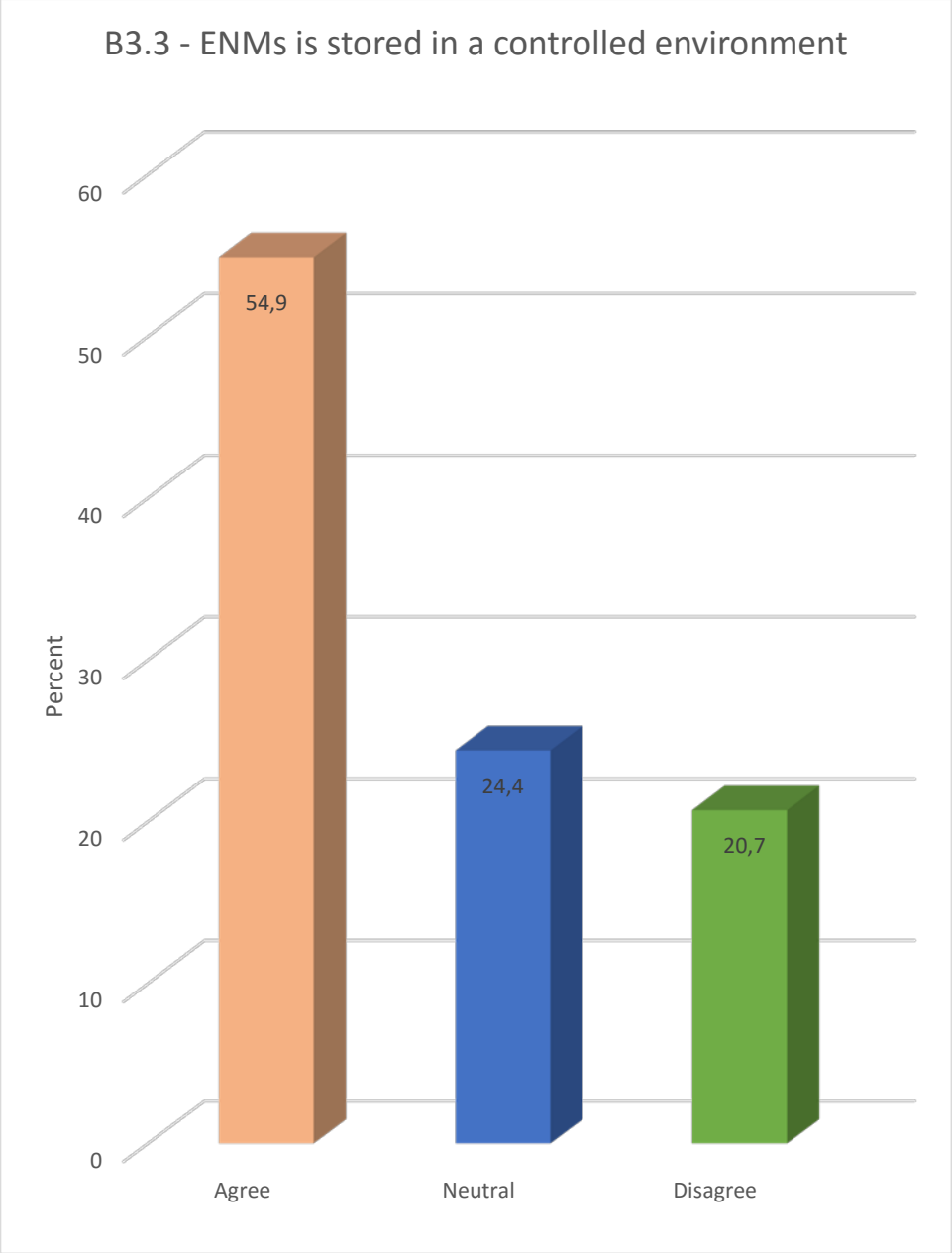


Figure 4.16: Control of ENMs

The respondents were asked to indicate whether the ENMs were stored in a controlled environment. According to Zaloga, Janko, Agarwal, Nowark, Muller, Boccaccini, Lee, Odenbach, Lyer and Alexiou (2015), incorrect handling and storage can change the properties of ENMs due to their high surface to volume ratio.Hence the environment must controlled in terms of humidity and temperature. For example, silver nanoparticles must be stored between 2-8° C.

Figure 4.16 shows that a majority (54.9%) of the respondents indicated that ENMs were stored in a controlled environment, while 20.7% indicated that they were not and 24.4% were neutral. This certainly needs to be addressed as an area of concern and should be incorporated into the training initiatives (Kumar et al., 2016).

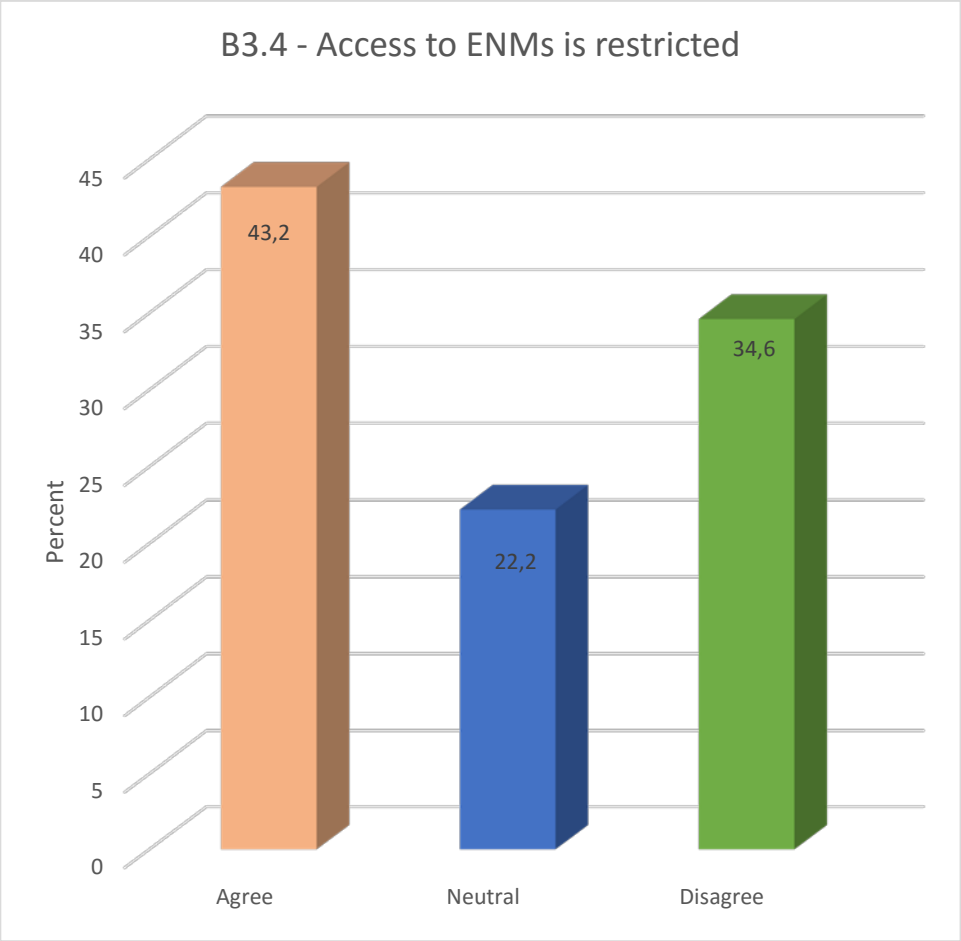


Figure 4.17: Access to ENMs

The respondents were asked whether access to ENMs were restricted. Figure 4.17 shows that only 43.2% of respondents pointed out that access to ENMs is restricted while 34.6% disagreed with this statement. Aschberger et al. (2016) states that given the limited information about health risks of ENMs it would be sensible to restrict access to ENMs.Even though ENMs are becoming increasingly available to commercial markets, their potential toxicity has yet to be properly characterized (Eastlake, Zumwalde and Geraci , 2016).

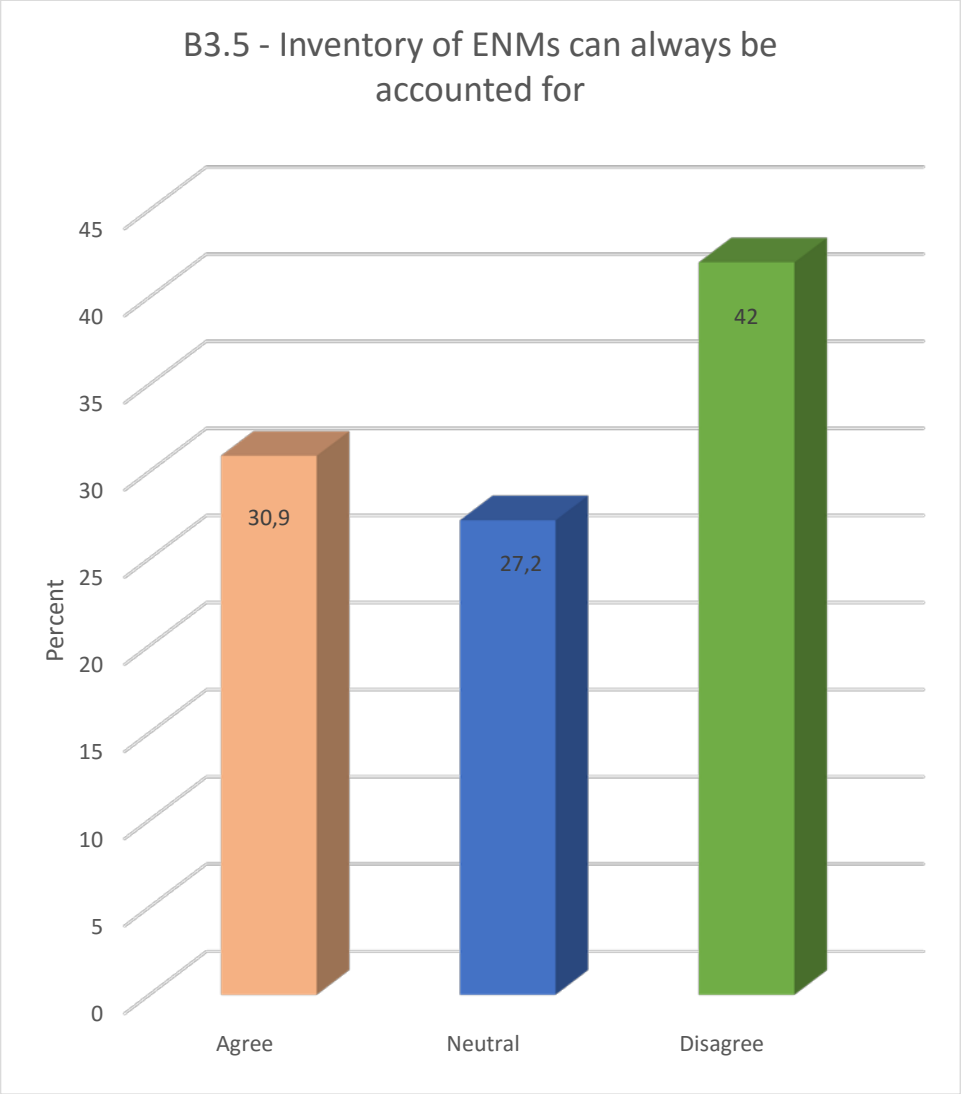


Figure 4.18: Inventory Control of ENMs

The respondents were asked whether inventory control can always be accounted for. Figure 4.18 shows that only 31% of respondents specified that the ENMs can always be accounted for, and 42% indicated that they could not be accounted for, while 27.2% were neutral. According to Cockburn et al. (2012) the inventory must be controlled in an appropriate manner to minimise financial losses.

4.8.4 Section B4 - Documentation and Equipment

Proper documentation provides substance for an organisation's activities in terms of audits, historical records, changes in the process, legal matters or disputes (Hristozov et al., 2016).

Table 4.13: Summary of Documentation and Equipment Related to ENMs

Question		Agree		Neutral		Disagree		Chi Square
		Count	Row N %	Count	Row N %	Count	Row N %	p-value
There are documented policies and procedures available for the use of ENMs	B4.1	57	69.5%	11	13.4%	14	17.1%	0.000
Work Instructions are available for ENMs	B4.2	56	68.3%	15	18.3%	11	13.4%	0.000
Documents relating to ENMs are filed in an appropriate manner	B4.3	48	58.5%	18	22.0%	16	19.5%	0.000
I know how to use the test equipment for ENMs	B4.4	36	43.9%	30	36.6%	16	19.5%	0.021
The equipment is regularly calibrated	B4.5	35	42.7%	27	32.9%	20	24.4%	0.127
Non- conformance reports are available	B4.6	31	38.3%	32	39.5%	18	22.2%	0.104

Table 4.13 is an analysis of documentation and equipment relating to ENMs.

- Three statements (B4.1, B4.2 and B4.3) show significantly higher levels of agreement in terms of availability of policies, work instructions and documents relating to ENMs.
- Three statements (B4.4; B4.5 and B4.6) indicate higher levels of disagreement with refernce to usage and calibration of equipment and the availability of non-conformance reports. The significance of the differences is tested and is reflected in table 4.13.

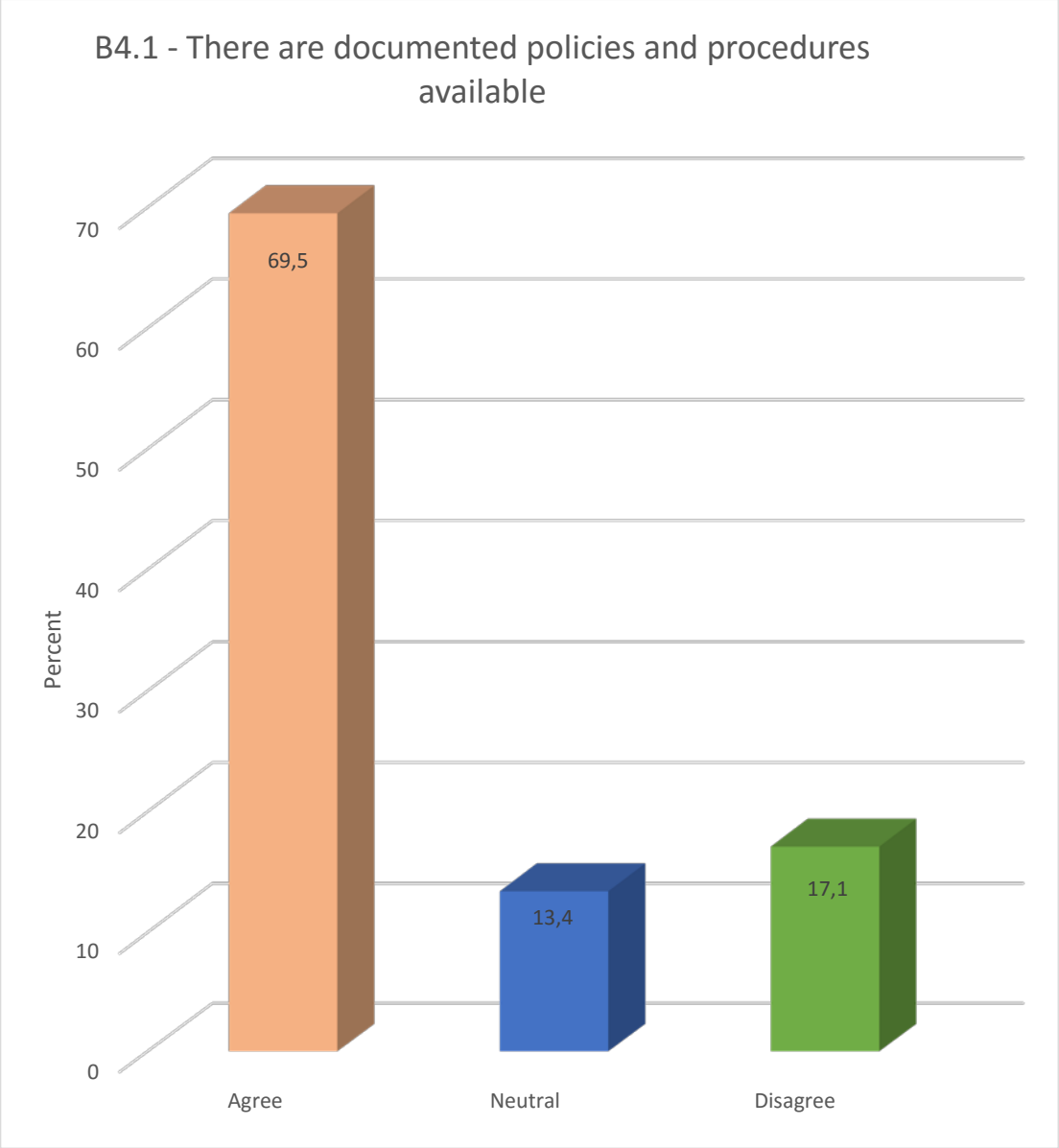


Figure 4.19: Documentation Policies and Procedures

Figure 4.19 shows that 69.5% of respondents indicated that there are documented policies and procedures available for ENMs whilst 17.1% disagreed. According to Amadei (2016) whilst policies are general in nature and identify organisational rules, procedures tend to be more specific and explain the actions that need to be taken. Policies and procedures guide staff in understanding their roles and responsibilities. This reinforces the need for a management system that is relevant, concise, simple and functional.

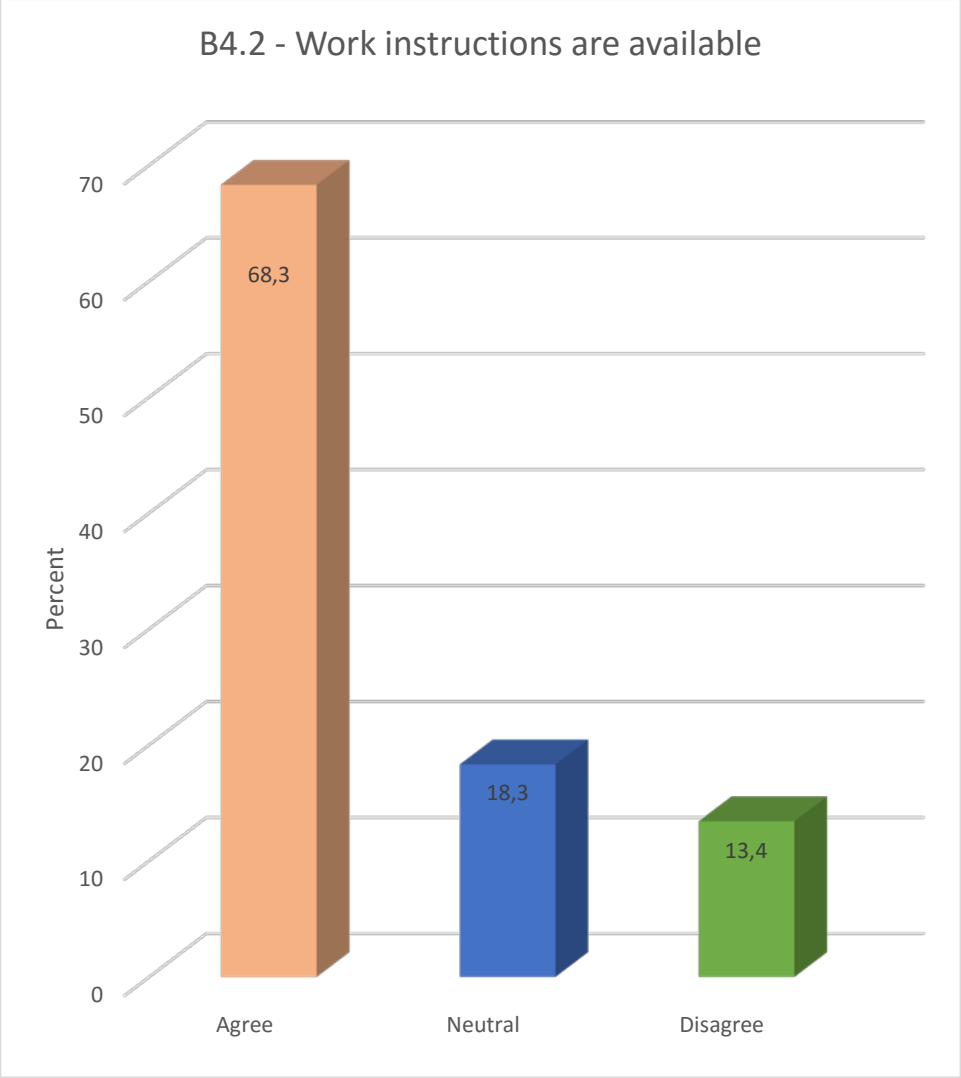


Figure 4.20: Availability of Work Instructions

Figure 4.20 shows that 68.3 % of respondents claimed that work instructions are available. Many staff tend to confuse procedures with work instructions. A work instruction according to Amadei (2016) details how to perform a certain task in a step-by-step fashion. In terms of nanotechnology a work instruction is critical because of the novelty of the technology, its unpredictable behaviour and potential risks to promote uniformity of practice.

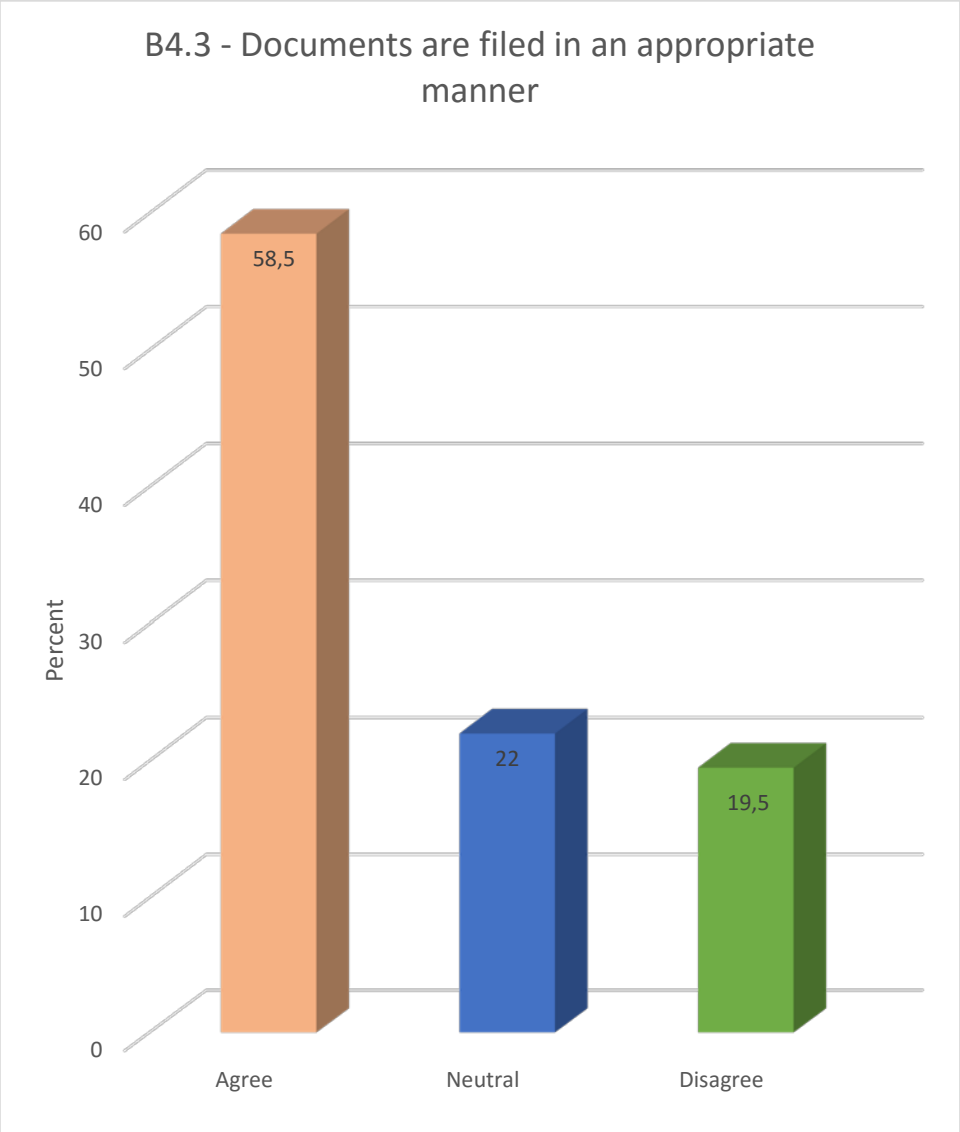


Figure 4.21: Filing of Documentation

Figure 4.21 shows that 58.5% of respondents indicated that documents are filed in an appropriate manner whilst 19.5% disagreed. Proper filing procedures bring efficiency to the organisation. An appropriate manner requires documents to be classified and arranged so that they can be easily retrieved whenever needed. Filing procedures must be included in induction and training programs (Amadei, 2016).

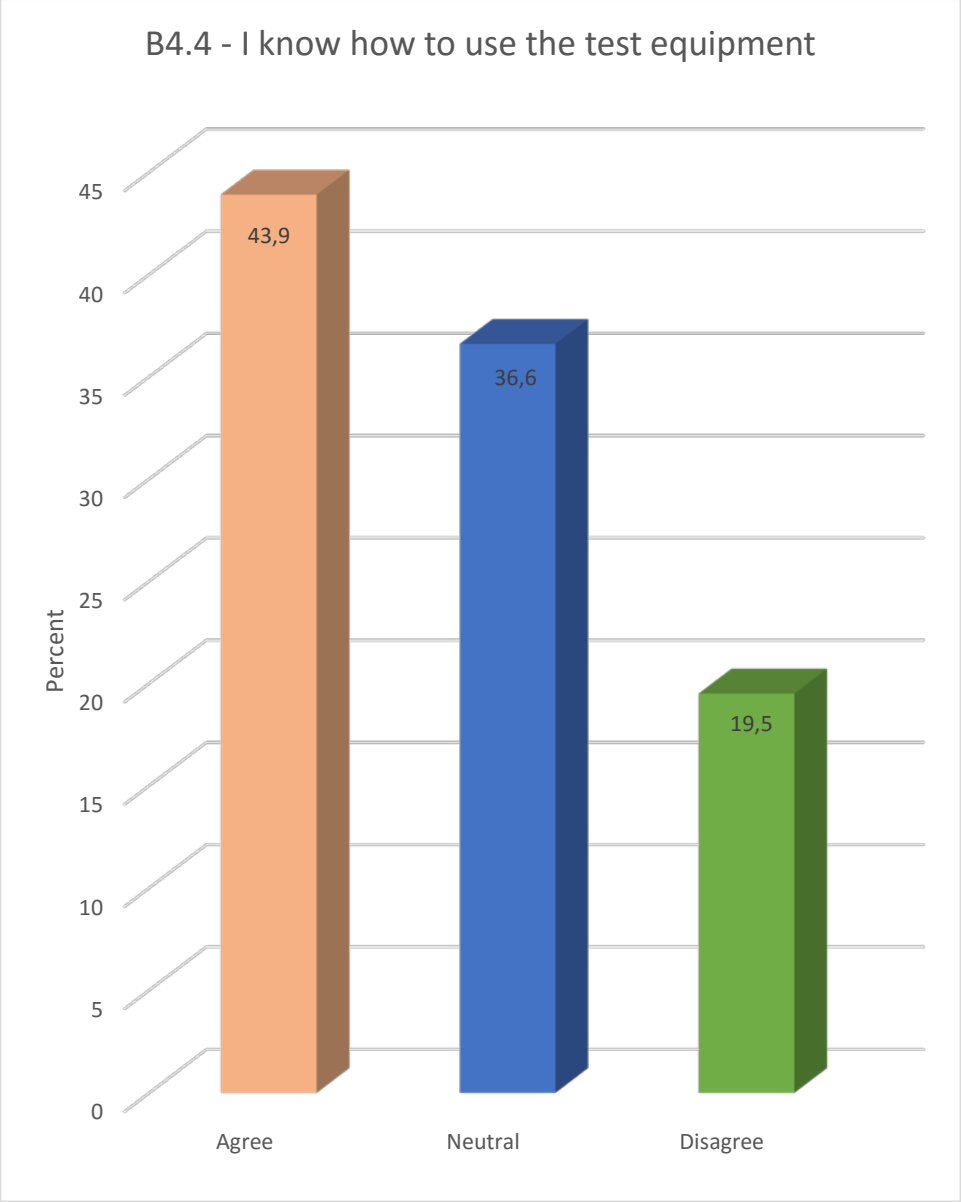


Figure 4.22: Use of Test Equipment

Figure 4.22 indicates that 43.9% of the respondents knew how to use test equipment, whilst 19.5% did not know how to use test equipment properly. Borg (2016) suggests that in many organisations training in proper procedures relating to equipment is lacking. Due to the sensitivity of nanoparticles, optimised operating equipment is essential for reliable results as even very small uncertainties can cause drastic changes in final results.

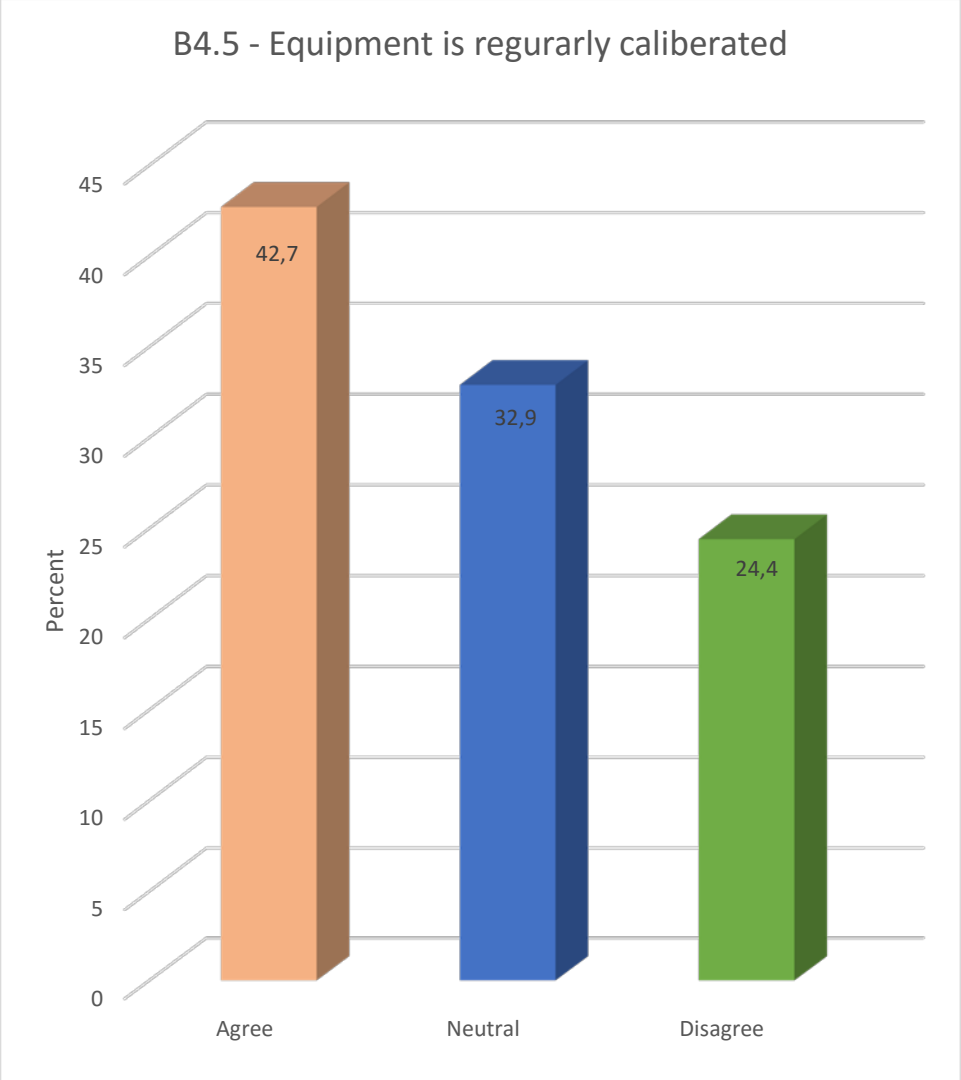


Figure 4.23: Calibration of Test Equipment

Figure 4.23 indicates that 42.7% of respondents asserted that equipment is regurarly calibrated. According to Tielin, Yang and Tenghuan (2016) calibration simply means a comparision between a known measurement (often referred to as a standard) and the actual measurement of the equipment. Calibration checks the accuracy of the equipment and determines the traceability of the instrument. It is of concern to note that 24% of respondents indicated that equipment is not regularly calibrated. This could lead to inaccurate measurements especially in the field of ENMs whose size and structure is in nanoscale.

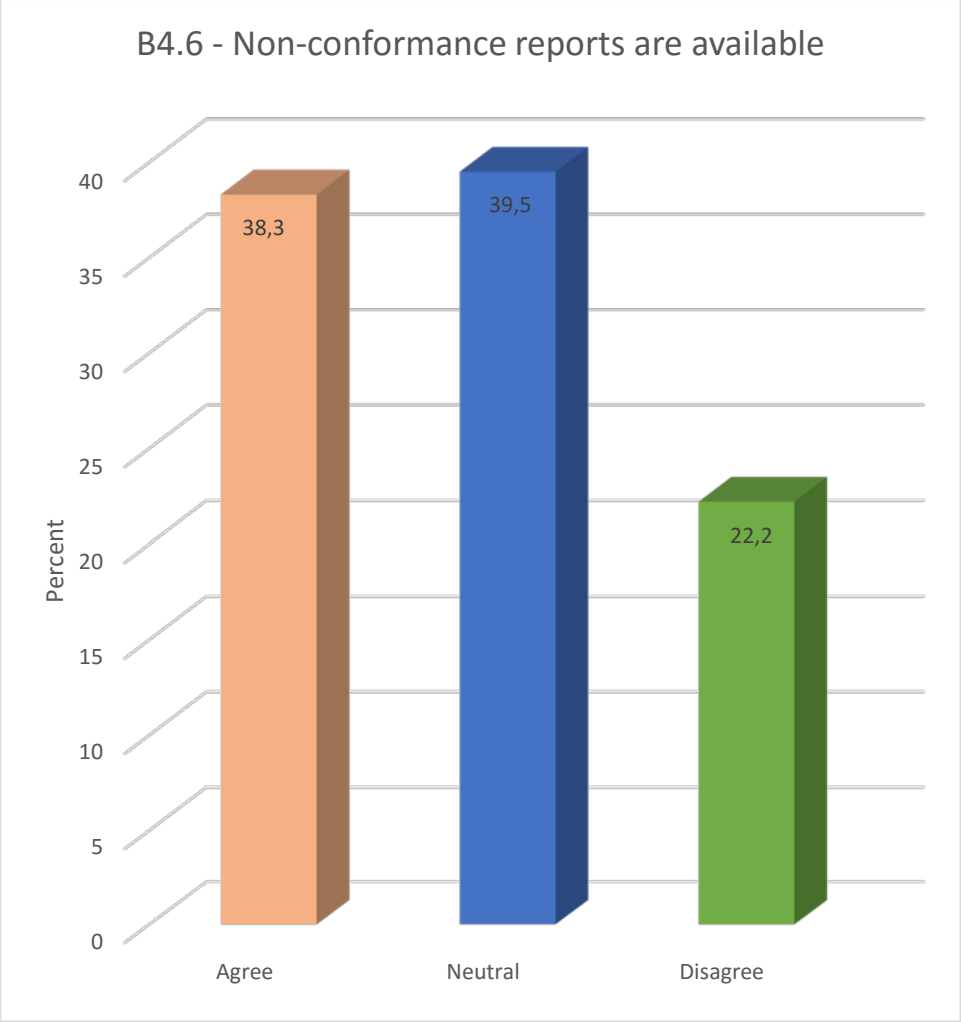


Figure 4.24: Availability of Non-conformance Reports

In figure 4.24 it is noted that 38.3% of respondents indicated that non-conformance reports for ENMs are available. Moren and Morton (2016) state that a non-conformance report is a document that keeps track of any deviation of a process that fails to meet specifications. The fact that 22.2% of respondents are unaware of non-conformance reports should alert management within organisations about the need to address this issue. These are important documents which focus on continuous improvement (Moren et al., 2016), which is also a mandatory requirement of all the management systems.

4.9. Analysis of "Neutral" Responses

A "neutral" response rate from this section implies that the respondents either did not know the technology or did not want to commit themselves. The following neutral responses were recorded:

- Proper training in ENMs - 19%
- Lack of a practical component in the ENMs training - 25%
- Risks associated with ENMs - 22%
- Awareness of safety procedures -27%
- Proper PPE - 29%
- What to do in an emergency situation - 21%.
- Storage and control procedures - 20%
- Restricted access to ENMs - 22%
- Inventory control of ENMs – 27%
- Availability of work instructions – 18%
- Filing of documentation – 22%
- Use of test equipment – 37%
- Calibration of test equipment – 33% and
- Availability of non-conformance reports – 40%

This behaviour is dangerous in both instances because it suggests that there could be serious repercussions from a lack of suitable knowledge or their non-disclosure suggests that they were withholding information.

4.10 Feedback from Open-ended Questions during the Survey

This section represents the feedback arising from the open-ended questions in the survey. The intention of these questions were to illicit information of current practice to inform the risk assessment aspects of this study. There were 31 open-ended questions in the survey. Open-ended questions were included because their feedback provides more detailed responses than closed-ended questions, which this study could have over-looked in the closed-ended section. The feedback will be presented verbatim initially thereafter followed by a discussion.

Question: Briefly describe the source on the ENMs.

Responses:

Carbon, Carbon based, Carbon nanotubes, Chemical synthesis, Copper chromite, Multi walled, carbon nanotube, Nanorods, Nanotubes, obtained directly from supplier, Silver nanoparticles, Southern clay products, Supplied, Synthesized Ti02, Evonile, 510 Wacker, pilot plant production.

Question: How is ENM manufactured?

Responses:

Continuous hydrothermal synthesis (CHS), Combination of sol-gel and combustion method, solnethermal method, Combustion method, Crashing carbon based material to nano size, Electro chemistry, Laboratory, n/a, Not sure, Unknown, Using chemical and electrochemical method and Wet chemical synthesis

Question: What are the known or intended uses for the ENMs?

Responses:

Antifungal, Antifungal agents, As a catalyst in oxidation process, Bio sensors, Carbon nanotube, nanoclay, silicon carbonide, Coatings, Cosmetics, Drugs, Energy storage, drug delivery, water purification, Enhance strength, Enhances strength and growth, Hydrogen storage, can be used for water purification also, Improves strength of materials, Medication, Oxidation, Paint coatings, PDP, WLED, up/down connectors,

Photo-catalysis, drug delivery, coatings, sensors, sunscreens, Silicone-carbide, Storage containers, Strength enhancement of material, Sunscreens, To enhance mechanical and thermal properties of plastics and composites, Versatile and applicable to many industries, Water purification, Water purifiers

Question: What are the known and intended uses of ENMs?

Responses:

Water purification, storage and medical and energy related applications.

Question: What are the extended or intended applications for this ENMs?

Responses:

Dispersion, Intended agriculture, SH coating + photo-catalysis, Strength enhancement of material to make a product, Used in industries.

Question: Why is the material being manufactured and used in nano-scale as opposed to other sizes? The responses were as follows:

Alteration of properties, Because of their novel properties, Better properties due to enlarged surface area, Better storage properties, For photocatalysis, It can get down to the cell level and modify the structure, Nano scale range, Nanomaterials have properties which cannot be found on bulk, New product development, New technologies, Not available commercially and to have high specific surface areas, Not available commercially yet, Research phase, Testing

Question: Why is material being manufactured and used in nano-scale as opposed to other sizes?"

Responses:

Alteration of properties, better storage properties, modification of cell structure and the fact this this is a new technology.

Question: How will employees be handling, processing or using ENMs?

Responses:

By using personal protective equipment like 3m masks, vapour masks, electrostatic nanoparticles precipitator, Fabricating nanocomposites for biosensor to detect TB drugs, follow safety procedures, immobilised on substrates such as carbon fibres or as a coating, looking for methods of compacting nano-powders, not sure, personal protection equipment, planting crops, PPE, protective clothing, protective equipment, safety equipment, safety first, use protective clothing, using in powder state and adding to the processing of material, using latex gloves and dust coats, with care.

Question: How will the ENMs be handled when received by downstream processors?

Responses:

Currently small quantities produced are stored and tested, don't know, no direct handling after our use, not sure, personal protection equipment, safety measures to be taken, sensor will improve operating functions, it will increase sensitivity, sprayed using full face masks, test samples cut into small specimens, with care, with proper masks to avoid inhalation and in properly packed packets

Question: In what form will ENMs be present in the final product?"

Responses:

Antifungal agent, antifungal applicators, as a coating, as a sensor, bulk, bulky form, drugs, filters, in a cylinder, no contact with end user, included/infused with the plastic, liquid, not sure, paint, paint and related products, plastic, powder, powder form, sensor, solid powder, solid powder form, structures, test sample, water purifiers

Question: Will the ENM be agglomerated or bound in matrix in the final product?

Responses:

Agglomerated, as a compacted powder, or shaped pellets, before hardener is added to form a structure, it will be dispersed, bound in matrix, bound into matrix via mixing and heating for one hour at 70 deg, coating is cured in Germany, photo-catalysis are immobilised, de-agglomerated, will be a platform which will enable electron transfer, yes, casting or infusion method, yes, surfactant or coating of the particles to be made

Question: How much of ENMs will be present is the final product?

Responses:

< 1%,< 10%,< 2%,< 3%,< 4%,< 5%,0.2% in weight, 0.02, 0.05, 0.1% to 5% by weight, 0.15 to 0.2% by weight,10 kg, 3% in weight, 5% wt, Kg quantities, Large quantities, not sure, very little.

Question: What types of ENM will be present in the final product?

Responses:

Carbon nanotubes, carbon nanotubes or nanoclays, clay, MMT, MMT - Cloisite 15A, MWCNT, nanoclay, pellets, pellets from compaction, solid powder, various.

Question: What new or different application benefits does this ENM offer compared to existing alternatives for the same application?

Responses:

Can be used as fertiliser, enhanced properties such as change transfer, extra strength and long life cycle, heat retardent, barrier properties, high rate of chemical reaction, Improved water purification, Improves material properties, It contributes to the final product light weight, longer life cycles, longer shelf life, Super hydrophobic, active catalysis with daylight

Question: What are the other potential applications of this ENMs?

Responses:

Biosensors, brake system, car body panels, aerospace, sporting equip, packaging, catalytic reaction in which oxidation is required, cell phone casings, coatings for boats, ships, marine vessels, cosmetics, detergents, generation of white light, medical field sustainability, paint coatings, paints, photo-voltaics, shoe in sales,

Question: How will the ENM be disposed of?

Responses:

By burning it, by dissolving in the solvent or by burning, general waste, in landfills after immobilisation in concrete, landfills, normal general waste post research, lab waste, normal waste, not sure, when it wears off

Question: Are there any general comments you would like to make?

Responses:

Better handling processes required, more research into ppe needed, no education, have to research yourself no storage and access control, use will not be consistent throughout, protection clothing needs to be provided, research in safety is much needed, storage is a growing trend, these particles will have to be shaped as pellets or compacted shape for handling, the use and disposal of the nanomaterial should be handled with care

Question: How will employees be handling, processing or using ENMs?

Responses:

Their responses centred around PPE and using safety equipment.

4.11 Summary of the Feedback from the Open-ended Responses of the Survey:

Some of the key points that emerged from the feedback were:

- Potential uses include energy storage; hydrogen storage, medication and PDP (plasma display panel) /WLED (white light emitting diode) up/down connectors.
- Respondents claimed that by using nano-scale materials as opposed to traditional materials – "*will result in better storage; can get down to cellular level and modify structures and better dispersion of polymers emerged when mixed*".
- Respondents were unsure how ENMs will be handled by downstream processors.
- The form in which ENMs will be present in the final product– included drugs; anti-fungal agents; infused in plastic and water purifiers.
- The benefits of ENMs compared to existing products (Table 4.30) were improved efficiency of fertilizer; extra strength; better heat retardant properties; lighter weight; longer life cycle and shelf life and super hydrophobic.
- The disposal of ENMs included general waste; landfills and respondents were not sure of the current practice adopted.
- General Comments included better handling processes required; more research into PPE; storage and disposal issues need to be addressed.

The salient characteristics that emerged from the open-ended responses suggested that there was an understanding among all respondents around the versatility of applications and the improved strength of ENMs. It can be inferred from this that these respondents would be knowledgeable in proposing future development opportunities around new product development in nanotechnology. However, there is concern that there was a lack of knowledge around the PPE, handling of ENMs and their disposal. It can be gleaned from earlier discussions in literature around the risks of ENMs that more care should be taken by the respondents for their own safety and the environment. This is consistent with the view of Brouwer

(2010) that these materials have the potential to cause harm to the human body and the ecosystems.

The important characteristics that emerged from the survey suggests that the plastic and medical industries dominated in the use of ENMs. The concern is that the majority of the respondents did not have specialised training in ENMs. This is inconsistent with the finding that there were policies, procedures and work-instructions (documentation) available. It could be assumed that the lack of specialised training was due to the absence of specialised documentation for ENMs.

Many respondents did not receive practical training even though they were actively working with ENMs. It also suggests that they were working with ENMs from their theoretical and prior knowledge of nanotechnology and their length of service. This ties in with the responses of the absence of safety manuals and inadequate PPE. There was also evidence of poor emergency response and inventory control.

According to Heizer et al. (2014) the symptoms of poor inventory management suggests that there is a lack of management and control of potentially very dangerous materials. There is also great concern about the absence of regular calibration of measuring equipment because at the nanoscale any small uncertainty in measurement that may have been deemed negligible for bulk material may not be applicable at the nanoscale and may have a great contribution to the behaviour and effects of the ENMs (Wagner, Gondikas, Neubauer, Hofmann and von der Kammer, 2014). This is commensurate with the response of the lack of non-conformance reporting. This brings to the fore the importance of having an active and suitably documented management system.

4.12 Results Obtained from Interviews

Interviews were conducted with 5 respondents, 3 of whom were researchers and 2 manufacturers. Two researchers were South African based while the third was from the EU whilst the manufacturer was UK based. The reason for enquiring about the length of service was to get an overview about experience and knowledge about the interviewees.

Table 4.14: The Length of Service of the Interviewees

Question 1: Years in Service	*Number of Interviewees*
2 – 5 years	2
6 – 8 years	1
>8 years	2

Sixty percent (60%) of interviewees were employed in the nanotechnology sector for more than six (6) years.

Table 4.15: Summary of training

Question 2: Did you receive proper training?	
Response	
No - 4	Yes - 1

Eighty percent (80%) of interviewees indicated that they had not received proper training.

Table 4.16: Reasons for not being trained

Follow-up to question 2: Why were you not trained?
Responses: a. No opportunities for training were available b. This was a new technology and I was not aware of any formal training courses c. I was instructed to work in the laboratory and no further instructions were offered.

It can be inferred that researchers were introduced to their topics and then expected to continue with their study with very little procedural intervention.

Table 4.17: Problems with ENMs

Question: What problems do you foresee with ENMs?
Responses: a. Lack of regulations b. No proper disposal procedures c. Inadequate PPE d. Storage and disposal inadequate e. Emergency procedures unknown f. Insufficient information on risks g. Expertise lacking h. ENMs can be absorbed through the skin and inhalation i. Toxicity – can cause cancer – we don't know

From the responses above it can be inferred that the researchers have developed a more in-depth understanding on ENMs from the time they commenced working with this technology. It shows that with the evolution of time and the extent of their readings their knowledge and conduct when working with ENMs is creating a new awareness within them. This also

suggests that the future of ENMs need not be jeopardised and that researchers read extensively and undergo appropriate training before they are exposed to ENMs and/or poor laboratory practices.

Table 4.18: General Comments

Question: Do you have any general comments regarding ENMs?
Responses: a. This is an exciting technology b. More research into proper PPE needed. c. Cost of PPE too high d. I'm not really worried about the hazards – I just want to get the research done. e. Promising technology f. Must communicate risks to the general public – must not fall into the same trap as GMOs g. Consumer awareness is lacking

The results from the interviews indicate a strong correlation with that of the survey. Based on the above it is evident that, whilst many of the interviewees were excited about their research, there was insufficient training, safety procedures and appropriate PPE used when working with ENMs.

One of the general comments *"I'm not really worried about the hazards – I just want to get the research done"* is of concern as this indicates that the respondent does not understand or appreciate the inherent risks associated with ENMs.

Another response *"I was instructed to work in the laboratory and no further instructions were offered"* indicates a lack of understanding of safety protocols on the part of line managers.

It can be inferred from the response "*More research into proper PPE needed and Cost of PPE too high"* that not enough attention is being given to this very important safety consideration.

However, the positive responses recorded indicated that it is an exciting and promising technology. It should also be noted that communication with the public is vitally important else ENMs may suffer the same fate as GMO's (Martin, Durr, Smith, Finke, and Cherry, 2017).

The feedback from both the open-ended questions as well as the interviews reinforced the need for a Quality framework.

4.13 Relationships between Themes

Lehmann and Romano (2005) contend that the traditional approach to reporting a result requires a statement of statistical significance. A p-value is generated from a test statistic**.** A significant result is indicated with "p < 0.05". These values are highlighted with a *.

A second Chi Square Test was performed to determine whether there was a statistically significant relationship between the variables (rows vs columns) thematic versus biographical variables.

The p-value between "Type of manufacturing organisation" and "I understand the structure of ENMS" is 0.021. This means that there is a significant relationship between the variables highlighted in yellow. That is, the organisation of the respondent did play a significant role in terms of whether respondents understood the structure of ENMs. All values without an * (or p-values more than 0.05) do not have a significant relationship. It is further noted that Plastics and Medical products show much higher levels of agreement than the other organisation types.

4.14 Inter-Correlations Thematic Statements

Bivariate correlation was also performed on the (ordinal) data. The results are found in the annexure 4.3.

The results indicate the following patterns:

Reynaud and Hess (2017) argue that positive values indicate a directly proportional relationship between the variables and a negative value

indicates an inverse relationship. All significant relationships are indicated by a * or **.

The following patterns were observed:

Table 4.19: Inter-Correlation Thematic Statements

Statement	Statement	Correlation
I was given a safety manual	I have received proper and adequate training	0.583
	There was a practical component to the training	0.527
I am aware of safety procedures	I understand the structure of ENMs	0.485
	I have received proper and adequate training	0.539
	There was a practical component to the training	0.595
	I understand the risks associated with ENMs	0.634
	I was given a safety manual	0.655
Protective equipment is provided	There was a practical component to the training	0.424
	I understand the risks associated with ENMs	0.495
	I am aware of safety procedures	0.669
I know what to do in the event of an emergency	I understand the risks associated with ENMs	0.647

	I am aware of safety procedures	0.728
	Protective equipment is provided	0.814
I understand the storage procedures	I have received proper and adequate training	0.517
	I was given a safety manual	0.487
There are adequate storage facilities	I understand the storage procedures	0.549
	I am aware of safety procedures	0.524
	Access to ENMs is restricted	0.507
	ENMs are stored in a controlled environment	0.721
Access to ENM is restricted	Inventory of ENMs can always be accounted for	0.729
There are documented policies and procedures available	There are adequate storage facilities	0.512

To explain, the correlation value between “I have received proper and adequate training in dealing with ENMs” and “I was given a safety manual for ENMs” is 0.583. This is a directly related proportionality. Respondents indicated that the more often they were given training manuals, the more adequate training in dealing with ENMs would be, and vice versa. Negative values, on the other hand, imply an inverse relationship, that is, the variables have an opposite effect on each other.

4.15 Summary of Chapter

The data collected from the survey and interviews confirms the following:

- There seems to be a lack of formalised training initiatives
- Lack of regulations governing ENMs
- Inadequate PPE
- Unknown risks associated with this technology
- On the positive side, there was support for ENMs as it is an emerging and promising technology.

A survey conducted by Simons et al. (2009), found that many people working with ENMs perceived the risks of nanotechnology to be low and that the benefits outweighed the risks.

The responses, with respect to the quantitative information, were presented in the form of charts and diagrams. These responses were analysed in terms of gender, race, type of manufacturing organisation, position occupied in the organisation, and experience in the ENMs field. It is evident that whilst the majority of respondents understood the structure of ENMs, approximately half of them had received proper training.

The results for the disposal of ENMs indicates that these will inevitably end up in municipal solid waste management dumps or landfills. The consequences of ENMs entering waste streams are unclear and these pose potential health hazards for many South African citizens who make a living from these landfill sites. Almost a third of the respondents indicated that they did not have access to appropriate PPE. Preliminary scientific evaluations raise reasonable suspicions that ENMs could have damaging effects on human health. The effects on ENMs on immune systems are still being explored.

Just under half of the respondents knew what to do in an emergency related to ENMs and the majority did not fully understand the risks associated with ENMs.

The findings from the literature, the interviews and survey have been analysed. The salient characteristics applicable to establish, monitor and control management systems have been identified and will be used in the integration of suitable management systems. This feedback informed the development of a computer application program that identifies risks and provide an action plan to eliminate or mitigate such risks.

The computer application program is presented in chapter 5 where the conclusions and recommendations of the study are discussed

Chapter 5 - Conclusions and Recommendations

The conclusions based on the review of the literature, and the results of the study, recommendations with regard to the salient aspects pertinent to the integration process and the development of the quality framework are presented in this chapter. The chapter culminates with a presentation of a computer application which develops a risk profile and an action plan to mitigate or eliminate risks related to ENMs. Such an application will be useful for management systems in the integration process.

The potential benefits of ENMs are undoubtedly immense, but so too are the hazards and risks. Sokull-Kluettgen (2012) emphasise that the risks of ENMs on human health and the environment are still relatively unknown. Whilst scientists and researchers race to develop this technology, health, safety, environmental and risk issues are often neglected (Aithal and Aithal, 2016). According to Qui (2016), a study of this nature is important considering that the risks relating to these unique and unknown characteristics of these nano-engineered materials cannot rely on traditional risk management approaches. . ENMs incorporate several types of products and offers great promise for new technological breakthroughs. However, ENMs is a developing technology and the potential health and safety risks have yet to be quantified.

5.1 Conclusions

Objective 1: To use literature to establish recommended current practices from technical reports, experts and researchers, for developing and manufacturing ENMs. The conclusions obtained from literature presented in this study are as follows:

- There was a lack of legislation governing the research, manufacture and disposal of ENMs across the world;
- There was a lack of management systems governing ENMs, for example, safety manuals, safety procedures, PPE and emergency procedures, and organisations were using systems that were somewhat outdated and did not fully address these requirements.
- There was no integrated framework that incorporates ENMs;

It was also found that the potential hazards of nanotechnology are yet to be quantified. According to Cockburn et al. (2012), studies have indicated that, although ENMs have been used in many products for several years, a formal, practical, systematic and robust system of assessment with validated quality protocols is absent. Furthermore, Hock et al. (2007) argue that due to the novelty and uniqueness of the material its effects in application are unknown, especially in terms of risk-assessment, toxicology and quality assurance.

- Possible routes of nanoparticle exposure include oral, dermal and inhalation;
- ENMs have been found to be toxic to cells in several test subjects. This view is supported by Schulte et al. (2016) who confirm that carbon nanotubes appear to rapidly promote interstitial fibrosis and lung cancer.

ENMs have the ability to translocate to other organs in the body. According to Amoabediny et al. (2009), possible routes of nanoparticle exposure include oral and dermal inhalation. However, inhalation or ingestion of nanoparticles are likely to be the major route in humans. ENMs can be deposited in the lungs, and onward transmission into the blood stream, translocating to other organs such as the brain.

- Monitoring of ENMs was difficult due to the lack of proper detection techniques and the unavailability of metric data.
- Researchers and scientists working with nanotechnology focused on the development of novel nano-enabled products often to the detriment of their personal safety.
- Traditional risk management systems for ENMs are currently being used and this is clearly unsuitable due to the size, shape and chemical composition of ENMs.
- The QA, GLP processes were absent from the SECQA Model but are necessary, for the governance of ENMs.
- The uncertainties relating to ENMs could have adverse health effects on humans, animals and the environment as very little is known regarding the toxicology of this technology.

If nanotechnology is not properly managed and controlled, it can suffer the same fate as GMOs. Whilst GMOs, at first, seemed to be financially rewarding and environmentally promising, stakeholders including academics and advocacy groups warned about long-term health implications. By the year 1999, there was widespread opposition to GMO in Europe, United States and developing countries which persists today. Philip (2008) argues that like GMOs, ENMs pose risks to human health and the environment.

- The lack of a quality management system to govern the research, manufacture, use and disposal of ENMs could have serious health and safety consequences for people working and using this technology. Currently, there is very little formal quality practice in nanotechnology. Pries et al. (2013) and Rebelo et al. (2014) observe that the structure of a QMS provides opportunities for organisations to establish policies, procedures, work-instructions and records. Hence there was a need for a study of this nature to propose a suitable integrated management system.

Objective 2: To interview researchers and manufacturers to determine current practice used in the field of ENMs which included training, safety, PPE, storage, risks, emergency procedures and communication. The conclusions reached are as follows:

- There was a lack of training opportunities in many organisations;
- Regulations relating to safety, handling and storage of ENMs were lacking;
- There were inadequate PPE and storage and disposal procedures specific to ENMs.
- Many interviewees were unaware of the emergency procedures being used.
- Updated information regarding risks in ENMs were not communicated to employees working in laboratories.
- , Scientists and researchers wanted to be the first to develop new products because of the novelty of this technology. This meant that safety and health concerns were sometimes overlooked.
- Consumers were not adequately informed about the dangers, for example, health, usage and disposal of ENM products, although there are many nano-enabled products on the market.

On the positive side the following is noted:

- There is a good understanding of the structural composition of ENMs (83% of respondents).
- 73% of respondents understood storage procedures for ENMs.
- 68% of respondents agreed that there work instructions were available.

Objective 3: To establish, via surveys, the current level of understanding, integration, storage and risks associated with ENMs.

The conclusions reached include:

- 82.9% of the respondents understood the structure of ENMs, but it is of concern that 48.8% of them indicated that they did not fully understand the risks associated with this technology;

- 24.7% of the respondents claimed that they had not received proper nanotechnology training and 38.3% indicated that such training excluded a practical component;
- A further area of concern is that 23.5% of employees were not issued with safety manuals whilst 54.9% of respondents did not know their organisation's emergency procedures.
- Many organisations did not consider the use of proper PPE to be an important issue. This is confirmed by 31.7% of the respondents who claimed that proper PPE was not issued to them.
- 20.7% of the respondents claimed that ENMs are not stored in a controlled environment whilst 34.6% indicated that access to nano materials is unrestricted.
- 24.4% of the test equipment in nano-laboratories are not regularly calibrated and 22.2% non-conformance reports were unavailable.
- Responses from the open ended questions revealed that some organisations dispose ENM waste into municipal landfills. Prihar, Chudasama, Singh and Ingole (2016) argue that uncontrolled ENMs can create inherent problems. For example, disposal of ENMs into municipal landfills may result in serious environmental issues as the long-term effect of how such particles disintegrate are yet unknown.

  This study confirmed that, whilst most respondents understood the structure and composition of ENMs, the health, risk and safety issues were often overlooked by organisations.

Objective 4: To develop a framework, which is presented in a graphical format illustrating the integration of management systems that include Safety, Health, Environment, Quality and Nanotechnology (SHEQN).

The graphical format figure 5.1 was based on a previous study (Singh, 2006) that incorporated Safety, Environment, Corporate Governance Quality and HIV/Aids.

The rationale for integrating management systems is to simplify operating systems so that the time spent by key personnel is freed up and hence they can concentrate on value-added activities of the organisation. The proposed framework for integrated management systems is based on literature reviewed and the empirical research conducted. The graphical format (figure 5.1) shows the overlap between the requirements of the individual systems (Safety, Health, Environment, Quality and Nano). It then demonstrates how these individual systems could be integrated thereby eliminating the duplication of work.

In keeping with the commentaries and findings in this study the development of the framework takes the following facts into consideration:

In accordance with the technical reports and the views of Hristozov et al. (2016), quality management and quality assurance form the foundation upon which ENMs can be monitored, evaluated and controlled. According to Rebelo et al. (2014) management systems such as ISO 9001, OHSAS 18001 and ISO 14001 have been operating as integrated management systems for many years. The framework developed during this study used an existing Safety, Environmental, Corporate Governance and AIDS (SECQA) integrated model (Singh, 2006). According to Singh (2006), several requirements were considered during the developmental stages of the SECQA model including the importance of document control, adhering to documented procedures, the ambiguity in language and avoiding the duplication of requirements. The SECQA model used an interlinking of systems and the Process Approach from ISO 9000 as a generic structure to support other systems. The SECQA Model served as a foundation for

this study. It was modified, and standards were updated to incorporate possible requirements applicable to ENMs.

The integration of the common clauses in a tabular format of the management systems (see annexure 5.1) is included. It outlines the common requirements in the following management systems: ISO 9001, ISO 14001, OHSAS 18001, TR 13121, TR 12885, GLP and ISO 17025. These requirements are not included in the traditional integration of management systems but are deemed pertinent to ENMs and hence included.

During the integration of these management systems, several requirements appeared to be common to all these systems. For example, Introduction, Scope, Normative References, Terms and Definitions, Management Systems, Customer Focus, Documentation, Risk Analysis, Corrective Actions, Personnel Competence, Performance Evaluation, Monitoring/ Measurement, Internal Audits and Management Reviews can be combined.

The proposed name for the framework in this study is Safety, Health, Environment, Quality and Nano (SHEQN). This framework seeks to combine and integrate the aforementioned management systems which would allow the organisation to work as a single unit with unified objectives towards managing and controlling ENMs. The integrated SHEQN framework (Figure 5.1) is presented below:

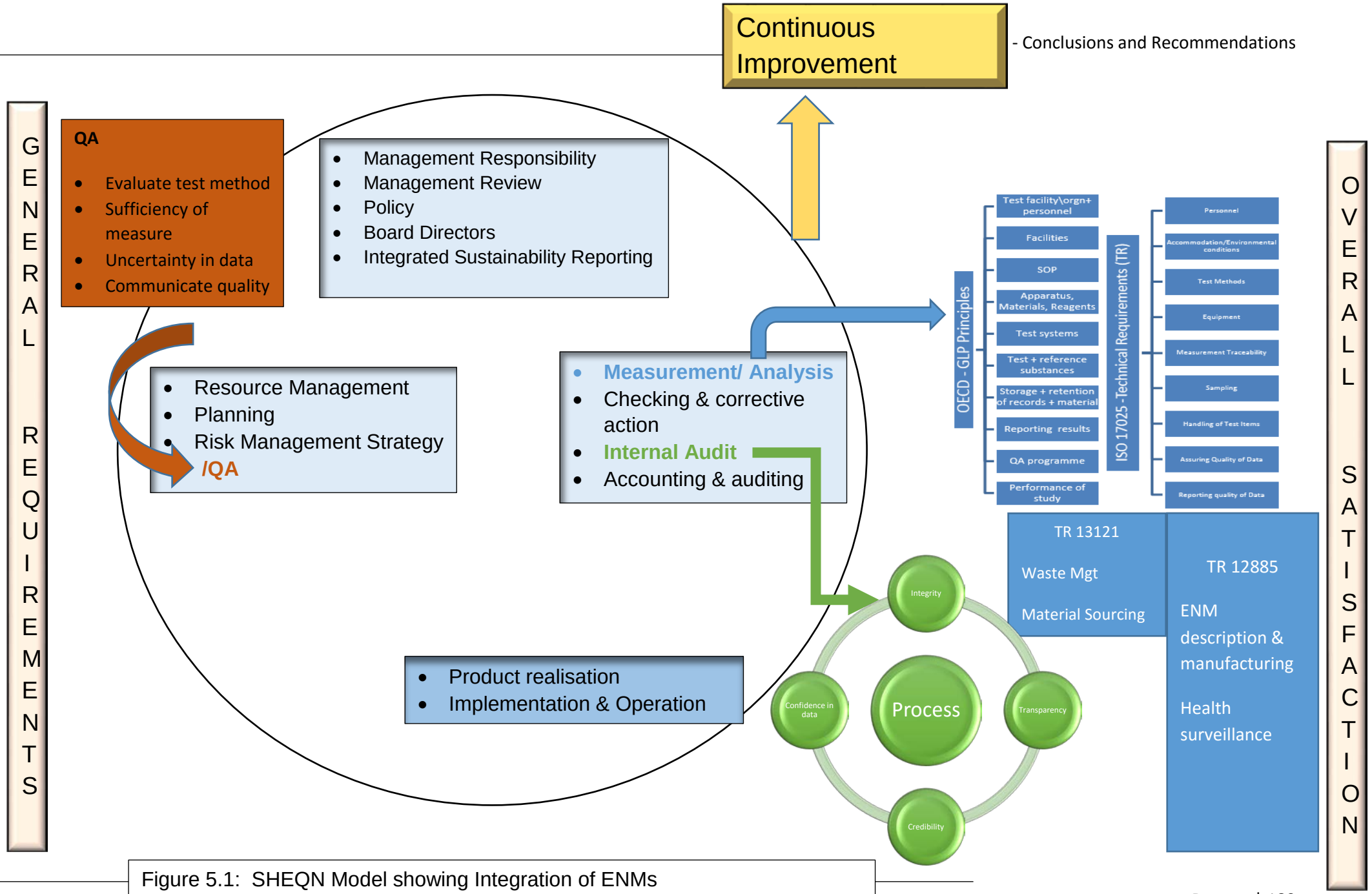


Figure 5.1: SHEQN Model showing Integration of ENMs

Source: Adapted from (Singh, 2006 and 2016)

Organisations that have more than one formal stand-alone management system will realise substantial benefits by merging their systems. According to Nunhes, Motta and Oliveira (2016) there were several benefits observed from integrating systems and they emphasize that the business process can run seamlessly without having to switch between applications. The use of streamlined processes will ensure better use of resources, more productive staff and lower costs. Furthermore, systems become more robust with problems easier to detect. Often the quality and reliability of the integrated framework is improved and documentation (policies, procedures, work instruction and processes) is readily available and easier to track. This results in the harmonizing of methods and processes which can lead to greater efficiency, lower costs and better teamwork.

Mitra (2016) notes that Quality Assurance (QA) is a systematic process that verifies whether a product or service meets required specifications. Therefore, it is recommended that QA processes for the SHEQN framework include:

- Determining the adequacy of PPE
- Evaluation of testing methods
- Identifying uncertainty in data and
- Communicating information relating to quality.

The inclusion of QA in this framework is important to ensure that appropriate measurement units are established, appropriate PPE is provided, and accurate records are documented, stored and maintained. Furthermore, communication mechanisms should be established to raise awareness of all relevant stakeholders.

The inclusion of Good Laboratory Practice (GLP) in this framework is to ensure that there are accredited test facilities that updated Standard Operating Procedures are available, equipment is regularly calibrated, that there is measurement and traceability, approved sampling methods are adhered to and Health and Safety regulations are complied with.

Tague (2005) believes that adherence to GLP will certify that organisations have the necessary infrastructure, knowledge, equipment, training and communication mechanisms in place which will result in acceptable practices. GLP also ensures that results obtained conform to international standards and norms and can be considered reliable.

The ISO/IEC 17025: 2005 standard relates to testing and calibration of equipment in laboratories. It includes the following:

- Having personnel that are well versed and skilled in the use of laboratory equipment.
- Using test methods that are ethical and legally compliant.
- Ensuring that test equipment is adequate and properly maintained.
- Confirming that measurement results are traceable, proper sampling procedures are adhered to and handling of test items are done in accordance with established protocols.
- Certifying the quality of data and compiling non-conformance reports.

To conform with waste management procedures in Report TR 13121, it is expected that organisations address how much, how often and what type of ENMs waste will be disposed of.

In order to manage the procurement process, Report TR 13121 lists the following requirements:

- Details of producer and supplier of ENMs, the manufacturing level of the plant, that is, whether it is a processing, fabrication or packaging plant.
- Identifying the percent of impurities present in the ENM.
- The location of manufacturing sites that shows distance, accessibility, and security.
- Quantifying annual production volumes and identifying methods of delivery and storage.

The TR 13121 Report will help organisations manage the use of ENMs throughout their supply chain as it ranges from suppliers, production, packaging all the way through to waste disposal.

Report TR 12885 suggests that health surveillance should be considered for all workers who are exposed to ENMs. The recommendations include:

- Identifying all employees who are at risk to ENMs exposure. This entails regular health checks for such employees (tests to include pulmonary, renal, liver and hematopoietic functioning) and documenting records of ENMs exposure limits. The report also recommends that workplace exposure assessments are conducted on an annual basis. The TR12885 provides a mechanism to ensure health and safety considerations for employees are built into the management system.

All the salient considerations mentioned in the foregoing sections, particularly regarding the management systems, have been included in the Quality framework in figure 5.1.

The proposed template for integrating these management systems (see annexure 5.1) is included. Common clauses for the standards (ISO 9001-2015; ISO 14000-2015; OHSAS 18001; ISO 17025; ISO TR 13121: 2011 and ISO TR 12885: 2008) are shown. The template will guide an organisation in improving efficiencies and reducing costs as duplication of management systems are avoided.

ISO 9001-2015 introduced a new concept of “risk-based” thinking enter into the narrative. According to International Organisation for Standardization (ISO), risks are ever-present and have to be continuously identified and managed. Table 5.1 below shows the Identification (ID) risk and risk source category as stipulated by this management system:

Table 5.1: Risk ID and Source Category

ID Risk	Risk Source Category
1	Lack of customer requirements and satisfaction analysis
2	Nonconforming technical results from new product design
3	Lack of risk-based assessment
4	Supplier nonconforming product or service
5	Supplier business continuity problem
6	Production planning and control mistakes
7	Production of nonconforming products
8	Information and communication technologies (ICT) failures
9	Machine and equipment failures
10	Workers badly trained, lack of skills and awareness
11	Acts of God

Source: Adapted from Chiarini (2017)

By using the risk categories of ISO 9001-2015, the organisation is provided with a blueprint to categorise and manage such risks. This requires organisations to elicit and record customer feedback, document both technical and supplier non-conformance reports, identify and take corrective action of production mistakes, ICT and equipment failures and monitor poorly trained or skilled workers.

According to Jones et al. (2012) a framework is valid if it is able to accomplish its purpose, if it generates relevant results that are easily interpreted, and assumptions and limitations are known. The SHEQN

framework satisfies these factors, thus making it valid for the integration of the aforementioned management systems and ready for adoption.

The SHEQN framework (Figure 5.1) represents the proposed integrated management systems and can be used by organisations working with ENMs. This framework serves as a guideline to demonstrate the overlap between the Safety, Risk Management, Environmental Management Systems, Nanotechnology (TR 13121 and TR 12885), Quality Assurance and Good Laboratory Practice.

Using the SHEQN framework, documentation such as policies, procedures and work instructions can now be integrated, resulting in saving time, costs and efficiencies.

5.2 Documentation Required to Support the Integrated Framework.

According to Rocha-Lona et al. (2013) policies, procedures and work instructions form the backbone of required documentation for any quality management system (as shown in figure 5.2). These documents can be combined into one manual or listed separately dependent on the volume of documentation.

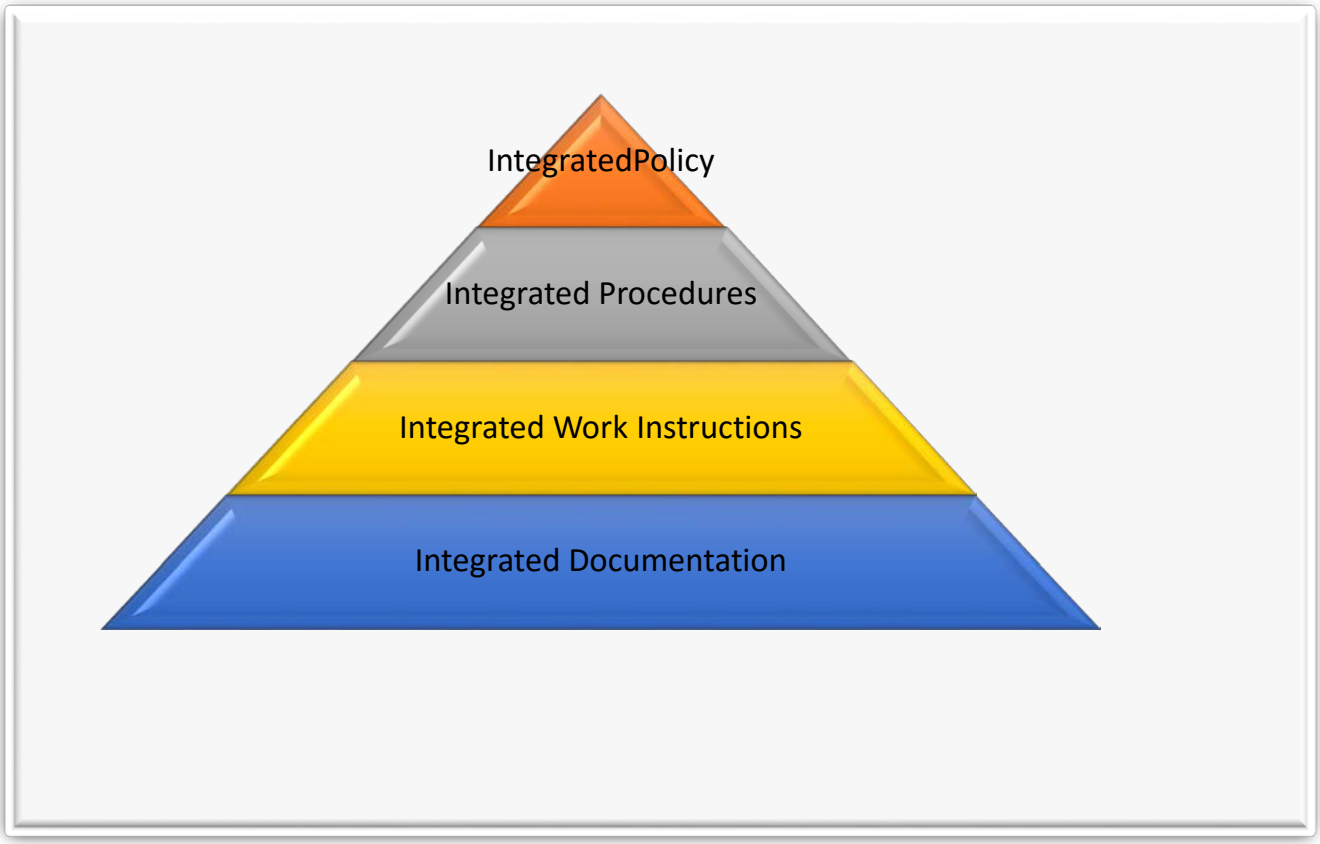


Figure 5.2: Structure of an Integrated Management System

Source (http://www.qualitydigest.com/june05/articles/04_article.shtml)

It is recommended that organisations adopting the SHEQN framework develop the documentation based on the guidelines provided in this section. Examples of Policy, Procedure and Work Instruction which were derived from the framework in figure 5.1. These are mandatory documents required by each management system.

These examples are presented in figures 5.3, 5.4 and 5.5 respectively.

DUT DURBAN UNIVERSITY OF TECHNOLOGY	Department of Mechanical Engineering Faculty of Engineering	Policy	Pol 256
		Revision #	1
		Implementation Date	10 January 2017
Page	1 of 1	Last Reviewed/Update Date	
Policy Owner	M. Kanny	Approval	Dean of Faculty

Policy Statement for an Integrated Management System incorporating Safety, Health, Environment, Quality and Risk

The Durban University of Technology is firmly committed to integrating the above mentioned systems into one comprehensive system. The integration of systems is designed to bring about several sub-systems into one framework. This results in improved use of resources, cost containment and better communication throughout the organization. This gives rise to a centralized approach to managing quality and compliance across all stakeholders. The integrated model will be economical as it provides a consolidated documentation system for all the integrated codes of practice. It will also ensure the ease of traceability should a query arise. By identifying hazards, risks can be prevented, mitigated or eliminated, ensuring a safer use of nanotechnology.

Our intention is to:

- To adhere to legislative and statuary requirements of South Africa.
- Provide a safe working environment for all laboratory staff.
- To communicate will all stakeholders on a regular basis (at least once a month).
- Ensure the proper handling and disposal of ENMs.
- Continuously look for ways to improve safety.
- Become the leader in Nanotechnology in South Africa.

I commit my support for this program and invite all staff to be a part of this new and exciting journey we are undertaking.

_____ _____

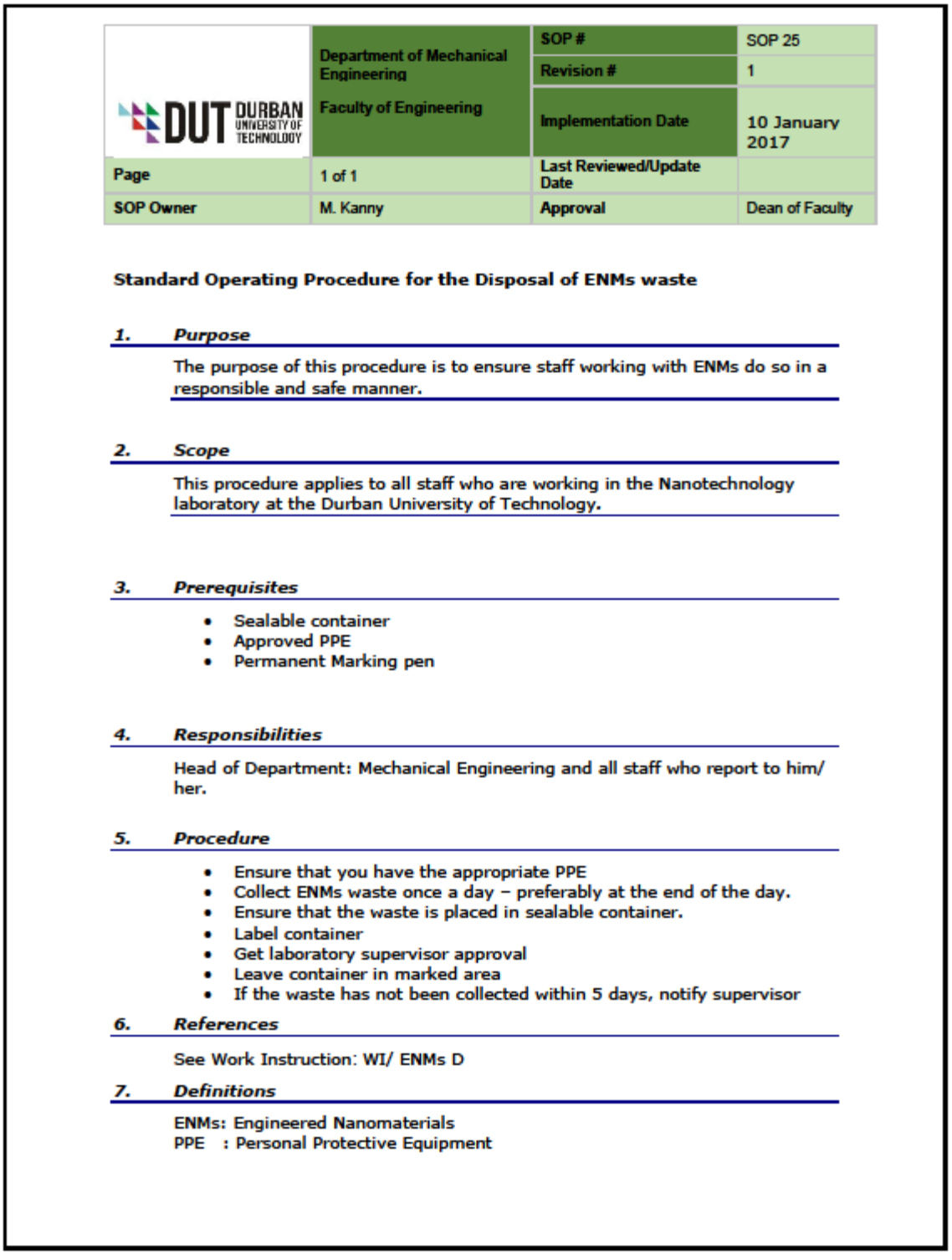
Executive Dean: Faculty of Engineering Date

Prepared by: _____ Issued: 10 Jan 2017

Approved by: _____ Revised:

Figure 5.3 Example of an Integrated SHEQN Policy

Weimer and Vining (2017) state that a policy lays out the basic principles by which an organisation is guided. From figure 5.3 it is evident that the organisation is committing itself to legislative and statutory requirements, providing a safe working environment, ensuring proper communication and waste disposal protocols are adopted.



DUT DURBAN UNIVERSITY OF TECHNOLOGY	Department of Mechanical Engineering Faculty of Engineering	SOP #	SOP 25
		Revision #	1
		Implementation Date	10 January 2017
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SOP Owner	M. Kanny	Approval	Dean of Faculty

Standard Operating Procedure for the Disposal of ENMs waste

1. Purpose

The purpose of this procedure is to ensure staff working with ENMs do so in a responsible and safe manner.

2. Scope

This procedure applies to all staff who are working in the Nanotechnology laboratory at the Durban University of Technology.

3. Prerequisites

- Sealable container
- Approved PPE
- Permanent Marking pen

4. Responsibilities

Head of Department: Mechanical Engineering and all staff who report to him/ her.

5. Procedure

- Ensure that you have the appropriate PPE
- Collect ENMs waste once a day – preferably at the end of the day.
- Ensure that the waste is placed in sealable container.
- Label container
- Get laboratory supervisor approval
- Leave container in marked area
- If the waste has not been collected within 5 days, notify supervisor

6. References

See Work Instruction: WI/ ENMs D

7. Definitions

ENMs: Engineered Nanomaterials
PPE : Personal Protective Equipment

Figure 5.4 Example of an Integrated Procedure

Weimer et al. (2017) assert that a procedure is generally a set of actions that sets out the purpose, scope, prerequisites, responsibilities, references and definitions for a particular process.

DUT DURBAN UNIVERSITY OF TECHNOLOGY

Work Instruction

Department of Mechanical Engineering

Applies to:	All staff who are working in the Nanotechnology laboratory
Objective:	Safe disposal of ENMs waste
Pre-Requisites	Staff must ensure they have the following PPE before entering the workspace: • Nitrile gloves • Splash goggles • Laboratory Coat • Closed Shoes • Marking pen (permanent marker) • Sealable container

Introduction

[Provide a brief explanation of the overall effort, project, or system, including where effort falls in the overall flow, and why it's important. Consider using a graphic to help with setting the context.]

Step	Instruction
1	Ensure you are using the correct PPE
2	Collect ENMs waste and place into sealable container
3	Label container with words "Nanomaterial waste" with a reference code for documentation
4	Log reference code into laboratory disposal register
5	Inform supervisor that the ENMs is ready for disposal
6	Supervisor checks and co-signs the laboratory disposal register

Expected results

The waste container must be collected by an authorized disposal organization within 5 days.

Reference: WI/ ENMs D	Page 1 of 1	Issued: 10/01/2017 Revised: 1st issue

Figure 5.5: Example of an Integrated Work Instruction

The work instruction describes how the task must be performed. From figure 5.5 it is evident that specific steps must be undertaken following a pre-determined order.

Objective 5: To develop a computer application to predict the potential risks associated with ENMs.

As discussed in the foregoing chapters, currently, nano-enabled products are emerging into the market ahead of legislation and mandatory management systems (Ganguly et al., 2017). Therefore, it is crucial for organisations to introduce mechanisms to monitor and control risks that emerge from working with these materials. A computer program was developed to classify the risk exposure to ENMs. It was thought that this computer application would assist organisations in establishing their "Risk Management Strategy" (requirement in figure 5.1) at an accelerated pace.

The questions in the computer application were developed from risk assessment methodologies from the related literature, the technical reports (TR 12885 and TR 13121) and the survey undertaken in this study. The computer application consists of a range of "yes" or "no" questions (table 5.2). On the completion of the questionnaire, a dashboard outlining the respondent's risk profile was configured (figure 5.6). A scoring table was then presented and action plan to reduce the risk was provided (figure 5.7).

Table 5.2: List of Questions to Determine Risk Profile

No.	Question
1	I have received appropriate training relating to ENMs which included a practical component.
2	I know the procedures for safe handling of ENMs
3	I understand hazards and toxicity
4	I have appropriate PPE (closed shoes, laboratory coats, nitrile gloves, splash goggles, N100 or N 95 respirator)
5	I understand equipment usage, calibration and maintenance
6	I am aware of emergency procedures
7	I know storage and disposal procedures
9	I am familiar with laboratory regulations
10	I am familiar with ENMs risks
11	There is a laboratory supervisor present at all times
12	Material data sheets are provided and updated when necessary
13	Work instructions are reviewed and updated
14	Safety manuals are available and accessible
	The workspace has:
15	A Fume hood
16	Restricted access
17	Air filtration and exhaust ventilation systems
18	The laboratory has non-slip tiled floors
19	There are alarms (toxicity monitoring, fire) in the workplace
20	Back-up power is available

On the completion of the questionnaire (Table 5.2) the respondent's risk analysis is displayed in the form of a dashboard as shown in figure 5.6.

5.7.1 Risk Profiling

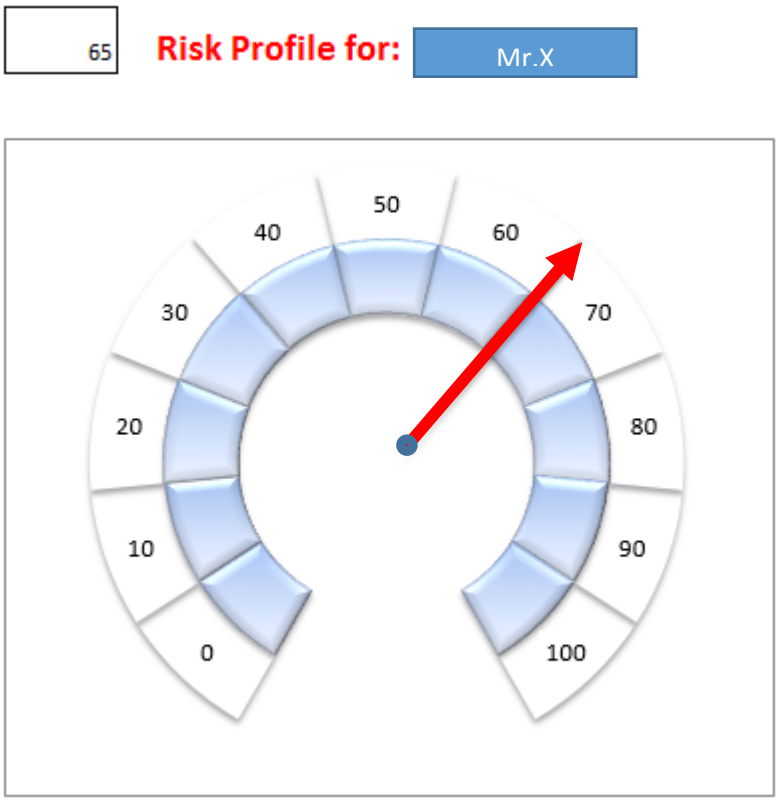

Figure 5.6: Speedometer Showing Respondent's Risk Profile (devised by researcher).

From figure 5.6 based on the risk profile the respondents should then take remedial action/s (figure 5.7) to lower their risk to a more acceptable level, if required.

Auty (2017) quantified the following ENMs risk categorisation:

Table 5.3: Scoring:

<30%	Low risk
31 – 74%	Medium risk
>75%	High risk

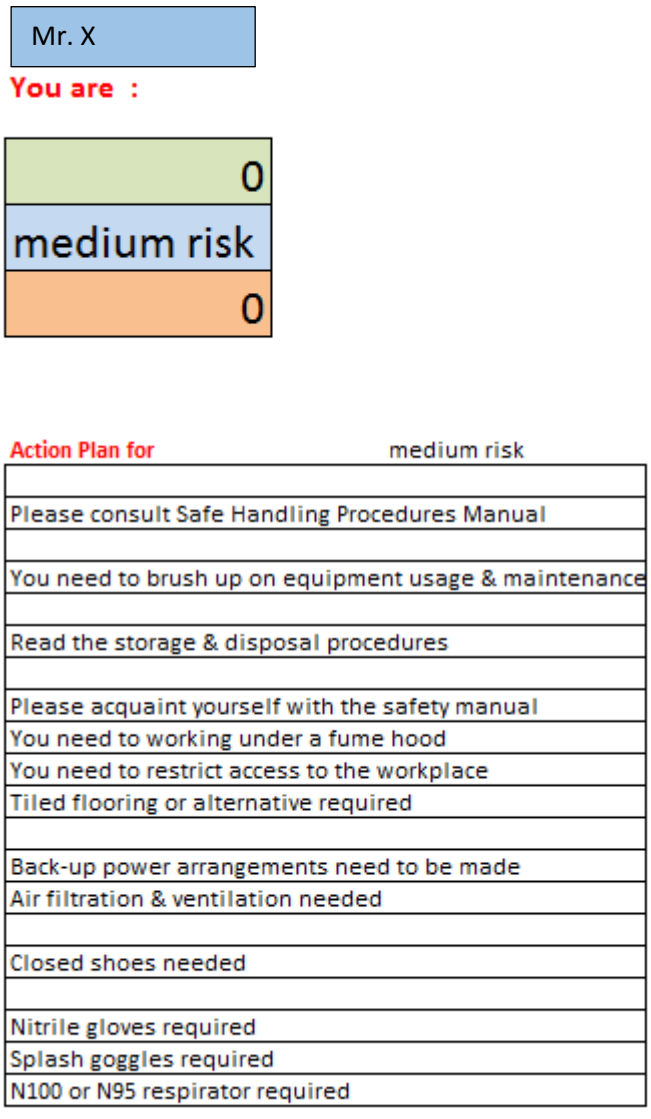

Figure 5.7 – Risk Category and Action Plan to Minimise or Eliminate Risk.

If the actions in Figure 5.7 are addressed, the employee will be able to medium to low risk.

5.3 Explanation of the Computer Application

This section presents an example determining a risk profile for an employee. Figure 5.6 shows that the respondent scored 65%, which is a medium risk profile. An action plan as outlined in figure 5.7 is then provided that displays the items that must be addressed in order to reduce the risks to a more manageable level (which is less than 30%). It is envisaged that the respondent will then consult with the respective managers and discuss methods to reduce risks associated with ENMs.

It is suggested that a short-term action plan for reducing risks should include the following: consulting the safety manuals, equipment usage and maintenance, storage and disposal, appropriate PPE, all of which can be immediately addressed. Medium/ long term action plans will include, inter alia, equipment, restricted access, and back-up power. These action plans should also be agreed upon with realistic dates for implementation.

Bystrzejewska-Piotrowska et al. (2009) confirm that there are several computer software systems that relate to ENMs which cover areas such as imaging of materials, molecular modelling software, design of ENMs and simulation of materials, but there is no software that deals with health, safety and risk management of ENMs. Hence, the computer software application developed as part of this study specifically addresses the health, risk and safety considerations applicable to nanotechnology. This will enable any person working with this technology to identify their risk profile in terms of handling, storage, PPE, emergency protocols and equipment usage.

5.4 Recommendations

Based on the results of this study, particularly with regard to the health, safety and risk factors, organisations need to establish management systems to manufacture, store and dispose of ENMs. The following steps are recommended:

Objective 1: To use literature to establish recommended best practice from technical reports, experts and researchers, for developing and manufacturing ENMs

- Due to the lack of legislation governing nanotechnology, organisations should adopt the principles of EU 2005 code of conduct.
- Adopt the SHEQN framework proposed in this study to address the current lack of management systems as well as integration of such systems.
- Use safety protocols suggested in the computer application to minimise or eliminate risks associated with ENMs.
- Inform researchers, scientists and people working with ENMs of the potential risks. Organisations should use various forms of communication media such as display boards, online platforms, or internal publications to inform staff of any new research relating to the risks of ENMs.
- Keep the public informed about any developments, dangers or safety concerns relating to ENMs.

Objective 2: To interview researchers and manufacturers to determine current practice used in the field of ENMs. As this study concluded that current practices sometimes overlook safety issues, it is recommended that:

- Nano-training must be part of the organisation's Workplace Skills Plan (WSP). Funding for such training can be budgeted for via the Sector Education Training Authority (SETA) grants.
- Emergency drills should be held at least twice a year. Laboratories need to display safety and emergency instructions.

- PPE which includes nitrile gloves, splash goggles, laboratory coat, N100 or N95 respirators must be provided to all employees working with ENMs. It is also recommended that employees use appropriate safety shoes.

Objective 3: To establish, via surveys, the current level of understanding, integration, storage and risks associated with ENMs.

- It is recommended that regular communications relating to nano research be established;
- Employers and employees be made aware of the dangers of disposing ENMs into municipal landfills.

Objective 4: To develop a framework which is presented in a graphical format illustrating the integration of management systems.

It is recommended, in the absence of legislation, all organisations working with ENMs adopt the SHEQN framework. This will make it mandatory for all employees to:

- Receive a training manual.
- Become familiar with safety and emergency procedures
- Follow proper inventory and storage procedures.

Furthermore, the implications for the organisation using the SHEQN framework are that:

- Storage, access and inventory are controlled.
- Test equipment in nano-laboratories must be conducted at least once a year.
- Fume-hoods, tiled flooring, alarms, back-up power, air filtration and proper ventilation must be installed in all nano-laboratories.
- Disposal of ENMs into municipal landfills must be avoided.

Objective 5: To develop a computer application to predict the potential risks associated with ENMs.

- Using the computer application developed as part of this study presents a unique opportunity for employees working with nanotechnology. It empowers them to take the responsibility of improving their working conditions by minimising or even eliminating ENMs risks. Quantifying their risk profiles will alert them to the potential dangers they are exposed to and provide an immediate plan for remedial action.

5.5 Contribution to the field of health, safety and risk management of ENMs.

This study has contributed to the field of health, safety and risk management of ENMs through:

- Highlighting the importance of management systems in developing technologies such as nanotechnology**.** Identifying the health and safety risks associated with ENMs.

- Developing an integrated framework that can be adapted to existing systems such as ISO, which will not only assist in eliminating or reducing risks but also save organisations from duplicating systems.

- Creating a computer application that measures risk for people working with ENMs.

5.6 Contribution to the theories of Health and Safety, Compliance, Social Justice and Risk Management

Studies undertaken by Fang et al. (2013) on Health and Safety Management (HSMS) at management level revealed top-down organisation derived structural construct. In this study managers or supervisors were requested to supply information on the organisation's HSMS. The data provided was used to derive estimates of its effect on the importance of HSMS outcomes. Based on these studies, it can be interpreted that HSMS is operationally a bottom-up, worker derived

perceptual concept or conversely a top-down management derived structural concept.

Health and Safety theorists, Guldenmund (2010) and Christian et al. (2009), concur that the bottom-up approach has certain appeal. However, they argue that since HSMS is mostly the domain of management the bottom-up approach is often neglected. Hence the theoretical underpinnings of health and safety management must be embedded into an organisation's culture. Employees working with ENMs must be part of the development and implementation of HSMS policies and procedures. Report TR12885 also endorses the risk of ENMs exposure. The report suggests regular health checks for such employees (tests to include pulmonary, renal, liver and hematopoietic functioning) and documenting records of ENMs exposure limits. The report also recommends that workplace exposure assessments are conducted on an annual basis.

Fiene (2016) argues that the theory of compliance outlines the importance and significance of complying with regulations, laws and rules. Due to the lack of a regulatory framework governing the research, manufacture and disposal of ENMs, organisations must practice stringent oversight and self-regulations to ensure the well-being of their employees.

Sensoy et al. (2017) state that the social justice theory is based on the principles of fairness and equality for everyone as a basic human right. Therefore, it would be unwise for organisations to overlook this theory in pursuit of fame and fortune, as being the first to introduce new nanotechnology products to the market, without being cognisant of the social welfare of its employees. If organisations want to address social injustice their commitment must be ongoing.

In risk management theory, Reason (2000) propounded that human error is based on two (2) approaches, the person approach and the system approach. The person approach focuses on individual's errors most often resulting from inattention, forgetfulness, negligence, carelessness or

recklessness, whereas the system approach focuses on the working conditions..

Working with ENMs require both these approaches to be constantly evaluated. To address the person approach, regular training, upskilling, communication and safety practices must become mandatory standard operating procedures. The system approach can be addressed through regular system audits to identify non-compliance.

If the recommendations proposed in this study are adopted, most of the above-mentioned theories will be complied with.

5.7 Concluding Remarks

There is no doubt that in the future nanotechnology will impact on all our lives in one way or another. Predictions of new technologies are often difficult to make, however, ENMs is undoubtedly a novel technology and a revolutionary science that has the potential to bring substantial change to society. Scientists and researchers have demonstrated the ability to manipulate atoms and convert it to lighter, more resilient, durable, high precision with superior strength. It is the view of the researcher that it would be prudent for researchers, scientists and manufacturers to have a fully functional Quality Management System (QMS) in place as there are inherent risks relating to ENMs which include environmental, toxicity, societal impacts and economic uncertainty. Very often, all it takes is one incident, one oversight or one mistake (such as the recent listeriosis outbreak) to put an entire community and industry at risk.

5.8 Future Research

The real challenge for nanotechnology is to manufacture nanoscale devices responsibly for public consumption. There is no doubt that this technology presents exciting possibilities that can transform the world as we know it. The technology has the ability to solve contamination of water using molecularly-precise filtration methods which can change the lives of millions of people throughout third world countries and water scare countries. ENMs may also be able to reduce the effect of environmental pollution, especially greenhouse gases which would reduce the impact of global warming. In the health care industry, research into tissue repair and regeneration, bone restoration and cures for diabetes, cancer, and HIV-Aids are being undertaken. However, there is a disturbing side to this technology that may take the form of chemical weapons of mass destruction. Ultimately, the driving force behind this technology must be synchronized with the quest for quality so that potential hazards and risks are eliminated.

Martin et al. (2017) implied that the failure of Genetically Modified Organism (GMO) was in part due to the poor communication (relating to risks) to the public. Therefore, it is of prime importance that ENMs do not meet the same fate. There must be a public discourse on both the advantages and risks of this technology. Industry and science must collaborate to promote this technology in a safe and responsible manner.

The framework presented in this study serves as a theoretical platform for organisations to formalise their management of ENMs, to facilitate commercialisation and promote the use of nanotechnology. It is hoped that the SHEQN framework will be implemented and tested within an organisation to determine its efficacy and usefulness. The computer application is being considered for patenting.

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Questionnaire Annexure 3.1

The Questionnaire has been designed to collect data on Quality Assurance relating to Nano-engineered materials. Your anonymity is guaranteed. The results will be used develop a Quality Assurance framework to monitor, evaluate and control broad based Nano-Engineered Material (NEM).

Please place a (X) in the appropriate box in each of the following.

1. Gender

Male	
Female	

Office Use	

2. Race

African	
Coloured	
White	
Indian	
Other	

Office Use	

3. Type of manufacturing organization

Plastics	
Food	
Manufacture of medical products	
Construction	
Sports Equipment	
Cosmetics	
Other	

Office Use	

4. Length of service in the organization

Under 5 years	
5 – 10 years	
10 – 15 years	
15 – 20 years	
20 – 25 years	
25 and over	

Office Use	

5. Position in organization

Management	
Technical	
Quality	

Office Use	

Please read each statement carefully. Answer each statement by placing an (X) in the appropriate box.

Scale

5 = Strongly Agree, 4= Agree, 3 = Neutral, 2= Disagree, 1 = Strongly Disagree

1. Understanding of Nano-engineered materials (NEM)	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
1. I understand the structure of NEM					
2. I have received proper and adequate training in dealing with NEM					
3. There was a practical component to the NEM training					
4. I understand the risks associated with NEM.					

2. Safety	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
1. I was given a safety manual for NEM					
2. I am aware of the safety procedures when dealing with NEM.					
3. Protective equipment is provided when I'm dealing with NEM					
4. I know what to do in the event of an emergency when dealing with NEM.					

3. Storage of NEM	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
1. I understand the storage procedures of NEM.					
2. There are adequate storage facilities for NEM.					
3. NEM is stored in a controlled environment					
4. Access to NEM is restricted					
5. Inventory of NEM can always be accounted for					

4. Quality Assurance of NEM	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
1. There are documented policies and procedures available for the use of NEM.					
2. Work Instructions are available for NEM					
3. Documents relating to NEM are filed in an appropriate manner					
4. I know how to use the test equipment for NEM					
5. The equipment is regularly calibrated					
6. Non- conformance reports are available					

5. Description of NEM

1. What is the stage of development (lab scale, pilot, demonstration, commercial) of this NM?
2. Briefly describe the source of the material? 3. Is it manufactured in house or purchased? 4. It purchased, who produces the NM?
5. How is the NEM manufactured?
6. How and in what form is it transported to your facility?
7. Is there a larger sized or bulk version of this NEM in commerce?
8. What other NEM exist that are similar to this one?
9. How long has this NEM, or a similar NEM been in commerce?
10. What are sources of additional information of this NEM?

Source: ISO/TR13121: 2011

6. Description of Application on NEM

1. What are the known or intended uses of the NEM based on literature review?
2. What are the extended or intended applications of this NEM (noting especially differences from the uses of incumbent and non- nanomaterial forms of material)?
3. Are these uses new compared to any that are already represented in the literature?
4. Why is the material being manufactured and used in the Nano scale range, as opposed to other sizes?
5. How will you or your employees be handling, using or processing the NEM?
6. How will the NEM be handled when received by downstream processors? 7. How will the NEM be handled when received by end users?
8. In what form will the NEM be present in final product?
9. Will the NEM be agglomerated or bound in matrix in the final product? If so, describe
10. Will the NEM be used by a large number of downstream users? 11. In what form will it be when it is so used?

12. How much NEM will be present in the intended products? 13. What types? 14. What sizes?
15. What volume of NEM will be used on an annual basis?
16. What new or different application benefits does this NEM offer compared to existing alternatives for the same application?
17. What are the other potential applications of this NEM?
18. Are there applications for this NEM that intentionally will not be used?
19. How will the NEM or products be handled? 20. How will the NEM be disposed of? 21. What will happen to the NEM post- use?

Source: ISO/TR13121: 2011

5. General Comments

Please articulate any other comment you may feel is relevant to this study.

Thank for you very much your participation in this study. Your time and opinions are greatly appreciated.

Annexure 3.2

Second International Conference on Composites, Biocomposites and Nanocomposites (ICCBN) from the 28th to the 30th October 2015.
Delegate List

Country	Organization	Department	No. of delegates
Botswana	University of Botswana	Department of Mechanical Engineering	1
China	Fujian Agriculture and Forestry University	College of Material Engineering	1
France	Université d'Artois	Laboratoire de Génie Civil et de géo-Environnement	1
India	Central Institute of Plastics Engineering and Technology (CIPET)	Department of Plastics Technology	1
India	Central Institute of Plastics Engineering and Technology (CIPET)	Laboratory for Advanced Research in Polymeric Materials (LARPM)	3
India	Defence R&D Organization		1
India	Indian Institute of Technology Madras	Department of Aerospace Engineering	1
India	Karunya University	Department of Nanoscience and Technology	1
India	Mahatma Gandhi University	International and Inter University Centre for Nanoscience and Nanotechnology	1
India	Mangalore University	Department of Applied Botany	1

India	Mangalore University	Department of Electronics	1
India	Mangalore University	Department of Materials Science	1
India	Mangalore University	Department of Physics	1
India	Manipal Institute of Technology	Department of Mechanical and Manufacturing Engineering	1
India	Velammal Engineering College	Department of Automobile Engineering	1
Iran	Amirkabir University of Technology	Department of Mechanical Engineering	1
Nigeria	CALEB University	Department of Business Administration	1
South Africa	Cape Peninsula University of Technology	Technology Station in Clothing and Textiles	1
South Africa	Council for Scientific and Industrial Research	Collaborative Fibre Composites Research	1
South Africa	Council for Scientific and Industrial Research	DST/CSIR National Centre for Nanostructured Materials	1
South Africa	Council for Scientific and Industrial Research	HySA Infrastructure	1
South Africa	Council for Scientific and Industrial Research	Materials Science and Manufacturing	4
South Africa	Council for Scientific and Industrial Research	Polymers and Composites	1
South Africa	Durban University of Technology	Composites Research Group (CRG)	9
South Africa	Durban University of Technology	Dental Sciences	2
South Africa	Durban University of Technology	Department of Biotechnology	3

		and Food Technology	
South Africa	Durban University of Technology	Department of Chemical Engineering	5
South Africa	Durban University of Technology	Department of Chemistry	1
South Africa	Durban University of Technology	Department of Chemistry	10
South Africa	Durban University of Technology	Department of Mechanical Engineering	3
South Africa	Durban University of Technology	Department of Operations and Quality Management	1
South Africa	Durban University of Technology	Department of Operations and Quality Management	36
South Africa	Durban University of Technology	Institute for Water and Wastewater Technology	1
South Africa	Nelson Mandela Metropolitan University, South Africa	Renewable Energy Lab	1
South Africa	North-West University	Department of Biochemistry	1
South Africa	Scott Bader	Durban	1
South Africa	Stellenbosch University	Department of Forest and Wood Science	1
South Africa	Tshwane University of Technology	Chemical, Metallurgical and Materials Engineering (Polymers Division)	1
South Africa	Tshwane University of Technology	Department of Mathematics, Science and Technology Education	1
South Africa	Tshwane University of Technology	Department of Mechanical Engineering	2

South Africa	University of Cape Town	Blast Impact and Survivability Research Unit	1
South Africa	University of Fort Hare	Department of Chemistry	1
South Africa	University of Johannesburg	Department of Applied Chemistry	3
South Africa	University of Kwa-Zulu Natal	Biomedical Resources Unit	1
South Africa	University of Kwa-Zulu Natal	Discipline of Mechanical Engineering	1
South Africa	University of KwaZulu-Natal	Discipline of Medical Biochemistry and Chemical Pathology	1
South Africa	University of the Free State	Qwa Qwa Campus	1
South Africa	University of the Western Cape	Department of Chemistry	3
South Africa	University of the Witwatersrand	DST/NRF Centre of Excellence in Strong Materials and RP/Composites Facility	1
South Africa	University of Zululand	Department of Chemistry	1
Tanzania	University of Dar es Salaam	Department of Mechanical and Industrial Engineering	1
Zimbabwe	National University of Science and Technology	Department of Textile Technology	1
South Africa	University of Cape Town		1
South Africa	Council for Scientific and Industrial Research		1
India	Central Institute of Plastics Engineering and		1

	Technology (CIPET)		
South Africa	Advanced Laboratory Solutions		1
South Africa	Labotec		1
South Africa	Perkin Elmer		1

Annexure 4.1

Length of service in the organization

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	< 5	31	37,8	38,3	38,3
	5 - < 10	27	32,9	33,3	71,6
	10 - < 15	13	15,9	16,0	87,7
	15 - < 20	8	9,8	9,9	97,5
	20 - < 25	2	2,4	2,5	100,0
	Total	81	98,8	100,0	
Missing	System	1	1,2		
Total		82	100,0		

CHI - Square tests Annexure 4.2

	Chi-Square	df	Asymp. Sig.
Gender	5,902	1	0,015
Race	40,59	4	0,000
Type of manufacturing organization	20,683	4	0,000
Length of service in the organization	37,951	4	0,000
Position in organization	3,185	2	0,203
I understand the structure of ENMs	90,829	2	0,000
I have received proper and adequate training in dealing with ENMs	20,519	2	0,000
There was a practical component to the ENMs training	2,741	2	0,254
I understand the risks associated with ENMs	9,463	2	0,009
I was given a safety manual for ENMs	36,222	2	0,000
I am aware of the safety procedures when dealing with ENMs	13,927	2	0,001
Protective equipment is provided when I'm dealing with ENMs	1,268	2	0,530
I know what to do in the event of an emergency when dealing with ENM	17,293	2	0,000
I understand the storage procedures of ENMs	60,39	2	0,000
There are adequate storage facilities for ENMs	28,268	2	0,000
ENMs is stored in a controlled environment	17,293	2	0,000
Access to ENMs is restricted	5,407	2	0,067
Inventory of ENMs can always be accounted for	2,889	2	0,236
There are documented policies and procedures available for the use o	48,463	2	0,000
Work Instructions are available for ENMs	45,39	2	0,000
Documents relating to ENMs are filed in an appropriate manner	23,512	2	0,000
I know how to use the test equipment for ENMs	7,707	2	0,021
The equipment is regularly calibrated	4,122	2	0,127
Non- conformance reports are available	4,519	2	0,104

			I understand the structure of NEM
Spearman's	I understand the structure of NEM	Correlation Coe	1,000
		Sig. (2-tailed)	
		N	82
	I have received proper and adequate training in dealing with NEM	Correlation Coe	.590**
		Sig. (2-tailed)	0,000
		N	81
	There was a practical component to the NEM training	Correlation Coe	.482**
		Sig. (2-tailed)	0,000
		N	81
	I understand the risks associated with NEM	Correlation Coe	.403**
		Sig. (2-tailed)	0,000
		N	82
	I was given a safety manual for NEM	Correlation Coe	.270*
		Sig. (2-tailed)	0,015
		N	81
	I am aware of the safety procedures when dealing with NEM	Correlation Coe	.485**
		Sig. (2-tailed)	0,000
		N	82
	Protective equipment is provided when I'm dealing with NEM	Correlation Coe	.292**
		Sig. (2-tailed)	0,008
		N	82
	I know what to do in the event of an emergency when dealing with NEI	Correlation Coe	.345**
		Sig. (2-tailed)	0,001
		N	82
	I understand the storage procedures of NEM	Correlation Coe	.437**
		Sig. (2-tailed)	0,000
		N	82
	There are adequate storage facilities for NEM	Correlation Coe	.231*
		Sig. (2-tailed)	0,037
		N	82
	NEM is stored in a controlled environment	Correlation Coe	.283*
		Sig. (2-tailed)	0,010
		N	82
	Access to NEM is restricted	Correlation Coe	.301**
		Sig. (2-tailed)	0,006
		N	81
	Inventory of NEM can always be accounted for	Correlation Coe	.273*

	Sig. (2-tailed)	0,014
	N	81
There are documented policies and procedures available for the use o	Correlation Coe	0,122
	Sig. (2-tailed)	0,276
	N	82
Work Instructions are available for NEM	Correlation Coe	0,050
	Sig. (2-tailed)	0,658
	N	82
Documents relating to NEM are filed in an appropriate manner	Correlation Coe	0,204
	Sig. (2-tailed)	0,066
	N	82
I know how to use the test equipment for NEM	Correlation Coe	0,012
	Sig. (2-tailed)	0,913
	N	82
The equipment is regularly calibrated	Correlation Coe	0,059
	Sig. (2-tailed)	0,600
	N	82
Non- conformance reports are available	Correlation Coe	-0,016
	Sig. (2-tailed)	0,887
	N	81

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Correlations

I have received proper and adequate training in dealing with NEM	There was a practical component to the NEM training	I understand the risks associated with NEM	I was given a safety manual for NEM	I am aware of the safety procedures when dealing with NEM	Protective equipment is provided when I'm dealing with NEM	I know what to do in the event of an emergency when dealing with NEM	I understand the storage procedures of NEM	There are adequate storage facilities for NEM
1,000								
81								
.747**	1,000							
0,000								
81	81							
.549**	.670**	1,000						
0,000	0,000							
81	81	82						
.583**	.527**	.337**	1,000					
0,000	0,000	0,002						
80	80	81	81					
.539**	.595**	.634**	.655**	1,000				
0,000	0,000	0,000	0,000					
81	81	82	81	82				
.328**	.424**	.495**	.409**	.669**	1,000			
0,003	0,000	0,000	0,000	0,000				
81	81	82	81	82	82			
.368**	.468**	.647**	.415**	.728**	.814**	1,000		
0,001	0,000	0,000	0,000	0,000	0,000			
81	81	82	81	82	82	82		
.517**	.393**	.301**	.487**	.440**	.395**	.381**	1,000	
0,000	0,000	0,006	0,000	0,000	0,000	0,000		
81	81	82	81	82	82	82	82	
.416**	.343**	.290**	.502**	.524**	.513**	.451**	.549**	1,000
0,000	0,002	0,008	0,000	0,000	0,000	0,000	0,000	
81	81	82	81	82	82	82	82	82
.383**	.344**	.380**	.312**	.450**	.393**	.386**	.363**	.652**
0,000	0,002	0,000	0,005	0,000	0,000	0,000	0,001	0,000
81	81	82	81	82	82	82	82	82
.355**	.505**	.514**	.307**	.512**	.419**	.497**	.243*	.507**
0,001	0,000	0,000	0,005	0,000	0,000	0,000	0,029	0,000
80	80	81	81	81	81	81	81	81
.398**	.489**	.573**	.352**	.561**	.585**	.604**	.416**	.529**

0,000	0,000	0,000	0,001	0,000	0,000	0,000	0,000	0,000
80	80	81	81	81	81	81	81	81
.391**	.285**	0,145	.481**	.264*	0,116	0,159	.391**	.512**
0,000	0,010	0,192	0,000	0,017	0,299	0,155	0,000	0,000
81	81	82	81	82	82	82	82	82
.386**	.319**	.219*	.456**	.317**	.233*	.223*	.332**	.471**
0,000	0,004	0,048	0,000	0,004	0,036	0,044	0,002	0,000
81	81	82	81	82	82	82	82	82
.443**	.370**	.278*	.513**	.432**	.242*	.333**	.480**	.519**
0,000	0,001	0,011	0,000	0,000	0,029	0,002	0,000	0,000
81	81	82	81	82	82	82	82	82
0,168	.258*	.343**	.306**	.429**	.427**	.449**	0,137	.466**
0,133	0,020	0,002	0,005	0,000	0,000	0,000	0,219	0,000
81	81	82	81	82	82	82	82	82
.225*	.279*	.376**	.399**	.497**	.473**	.504**	0,214	.472**
0,043	0,012	0,000	0,000	0,000	0,000	0,000	0,054	0,000
81	81	82	81	82	82	82	82	82
0,172	0,167	0,157	.359**	.294**	0,201	.297**	0,147	.465**
0,127	0,139	0,162	0,001	0,008	0,073	0,007	0,189	0,000
80	80	81	80	81	81	81	81	81

Annexure 4.3

NEM is stored in a controlled environment	Access to NEM is restricted	Inventory of NEM can always be accounted for	There are documented policies and procedures available for the use of NEM	Work Instructions are available for NEM	Documents relating to NEM are filed in an appropriate manner	I know how to use the test equipment for NEM	The equipment is regularly calibrated	Non-conformance reports are available
1,000								
82								
.721**	1,000							
0,000								
81	81							
.592**	.729**	1,000						

0,000	0,000							
81	81	81						
.364**	.272*	.315**	1,000					
0,001	0,014	0,004						
82	81	81	82					
.401**	.318**	.373**	.770**	1,000				
0,000	0,004	0,001	0,000					
82	81	81	82	82				
.538**	.379**	.461**	.739**	.810**	1,000			
0,000	0,000	0,000	0,000	0,000				
82	81	81	82	82	82			
.361**	.453**	.578**	.261*	.301**	.232*	1,000		
0,001	0,000	0,000	0,018	0,006	0,036			
82	81	81	82	82	82	82		
.450**	.469**	.608**	.360**	.327**	.304**	.854**	1,000	
0,000	0,000	0,000	0,001	0,003	0,005	0,000		
82	81	81	82	82	82	82	82	
.442**	.400**	.450**	.562**	.451**	.465**	.532**	.616**	1,000
0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	
81	80	80	81	81	81	81	81	81

Annexure 5.1

5.15 Integrating Management Systems

Common clauses

Clause	ISO 9001 – 2015 Quality Management Systems	Clause	ISO 14000 – 2015 Environmental Management Systems	Clause	OHSAS 18001 Occupational health and safety management systems	Clause	ISO 17025 General requirements for the competence of testing and calibration laboratories	Clause	ISO/TR 13121:2011 Nanotechnologies – Nanomaterial Risk Evaluation	Clause	ISO/TR 12885:2008 Nanotechnologies – Health and Safety practices
0.1	Introduction	0.1	Introduction		Introduction		Introduction		Introduction	1	Introduction
0.2	Quality Management Principles	0.2	Aim of the environmental system								
0.3	Process Approach	0.3	Success factors								
0.3.3	Risk based thinking										
0.4	Relationship with other management systems										
1	Scope	1	Scope	1	Scope	1	Scope	1	Scope	2	Scope
1.1	General										
1.2	Application										
2	Normative reference	2	Normative references	2	Normative references	2	Normative reference				
3	Terms and definitions	3	Terms and definitions	3	Definitions	3	Terms and definitions	2	Symbols & abbreviated terms		
4	Context of the organization	4	Context to organization								

4.1	Understanding the organization	4.1	Understanding the organization			4.1	Organization				
4.2	Understanding the needs & expectations of interested parties	4.2	Understanding the needs & expectations of interested parties								
4.3	Determining the scope of the QMS	4.3	Determining the scope of the Environmental management system			4.2	Management system				
4.4	QMS	4.4	Environmental management system	4	Management systems requirements	4	Management requirements				
4.4.1	Determining the processes needed for the application of a QMS							3	Summary of the process	3.2	Production process
4.4.2	Documentation for the QMS			4.4.4	Documentation	4.3	Document control				
5	Leadership	5	leadership								
5.1	Leadership and commitment	5.1	Leadership and commitment								
5.1.1	General										
5.1.2	Customer focus					4.7	Service to customer				
5.2	Policy	5.2	Environmental policy	4.2	OH & S policy						
5.2.1	Developing the quality policy										

5.2.2	Communicating the quality policy										
5.3	Organizational roles, responsibilities and authorities	5.3	Organizational roles, responsibilities and authorities	4.4.1	Structure and responsibility						
6	Planning	6	Planning	4.3	Planning						
6.1	Actions to address risks and opportunities	6.1	Actions to address risks and opportunities	4.3.1	Hazard identification, risk assessment and determining controls	4.11 4.11.2	Corrective action Cause analysis	5 6	Profile of ENM, hazard and exposure Evaluate risks	4 5 6	Hazard characterization Exposure assessment Risk assessment
				4.3.2	Legal requirements						
6.2	Quality objectives and planning	6.2	Environmental objectives and planning to meet them	4.3.3	Objectives, targets and programmes						
6.3	Planning of changes										
7	Support	7	Support								
7.1	Resources	7.1	Resources	4.4.1	Resources, roles, responsibility and authority			4	Materials and applications	3	ENM description & manufacturing
7.1.1	General							4.1 4.2 4.5	General Material description Distribution		
7.1.2	People										
7.1.3	Infrastructure					5.5	Equipment				

7.1.4	Environment for the operation of processes					5.3	Accommodation and environmental conditions	4.7	Waste management		
7.1.5	Monitoring and measuring resources			4.5.1	Monitoring and measurement						
7.1.5.2	Measurement traceability			4.5	Checking						
7.1.6	Organizational knowledge										
7.2	Competence	7.2	Competence	4.4.2	Competence, training and awareness	5.2	Personnel				
7.3	Awareness	7.3	Awareness	4.4.2	Competence, training and awareness						
7.4	Communication	7.4	Communication	4.4.3	Communication, participation and consultation						
7.5	Documented information	7.5	Documented information	4.4.4	Documentation			8	Document		
7.5.3	Control of documented information			4.4.5	Control of documentation	4.3	Document control				
8	Operation	8	Operation	4.4	Implementation and operation						
8.1	Operation planning and control	8.1	Operation planning and control	4.4.6	Operation control					7	Control methodologies
		8.2	Emergency preparedness and response	4.5.2	Emergency preparedness and response						

8.2.1	Customer communication										
8.3	Design and development of products and services										
8.4	Control of external provision of goods and services					4.4 4.5 4.6	Review of requests, tenders and contracts Subcontracting of tests and calibrations Purchasing services and supplies	4.3	Material sourcing		
8.5	Production and service provision										
8.7	Control of non-conforming outputs			4.5.3	Incident investigation, nonconformity, corrective and preventive action	4.9	Control of non-conforming testing and/ or calibration work				
9	Performance evaluation	9	Performance evaluation	4.5.2	Evaluation of compliance	5.4 5.10.2	Test and calibration methods and method validation Test reports and	8.3	Review information		

							calibration certificates				
9.1	Monitoring, measurement, analysis and evaluation	9.1	Monitoring, measurement, analysis and evaluation			4.11.2 4.11.4	Cause analysis Monitoring of corrective action	6 7	Evaluate risks Assess risk management options	7.4	Health surveillance
9.1.2	Customer satisfaction					4.7 4.8	Service to customer complaints				
9.1.3	Analysis of data					5.4.7	Control of data				
9.2	Internal audit	9.2	Internal audit	4.5.5	Internal audit	4.11.5 4.14	Additional audits Internal audits				
9.3	Management review			4.6	Management review	4.15	Management review	9	Review and adapt		
10	Improvement					4.10	Improvement				
10.1	General										
10.2	Non conformity and corrective action										
10.3	Continual improvement										

Source: Adapted (2016)