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Application of the IUMSS Methodology in an R&D-oriented Nanotechnology Setting

by

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Abstract

The purpose of this research was to study the applicability of management system standards (MSSs) in a research and development (R&D)-oriented nanotechnology setting. Since multiple quality and R&D-specific standards were found to be relevant in such environments, a methodology for the integration of MSS requirements into an organization's management system (MS), found in the recently published "Integrated Use of Management System Standards" (IUMSS) Handbook, was also tested in the study. The steps within the IUMSS methodology were applied to integrate the requirements of two R&D MSSs (UNE 166002:2006 and EARTO:2000) into the existing ISO 9001-based quality management system (QMS) within a Case Study Organization (CSO). Recommendations for achieving full compliance with the standards were also provided to the CSO. This research provides significant contributions for any organization using or intending to use the IUMSS methodology for building and integrating standardized management systems in an R&D-oriented setting such as nanotechnology.

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Glossary of Abbreviations and Terminology

CSO – **Case Study Organization**: A Canadian MEMS foundry and research case study used in this project.

HMSS – Hybrid Management System Standard: The output from conducting IUMSS Sub-Step B4.2 in this project, which consisted of a table containing the combined requirements of ISO 9001:2000, UNE 166002:2006, and EARTO:2000, grouped together by category.

IMS – Integrated Management System: A unified management system that consists of the integration of two or more standard-based subsystems.

Integration: The "*process of unifying multiple management system standard requirements into an organization's overall management system"* (ISO, 2008, p.64).

ISO –International Organization of Standardization: A body for the administration and development of internationally accepted standards, based in Geneva, Switzerland.

IUMSS – **Integrated Use of Management System Standards**: ISO's handbook that provides organizations with "*guidance on how to integrate the requirements of multiple MSSs into their [existing] MS*" (ISO, 2008, p.3)

MEMS – Micro-electro-mechanical systems: A closely related area to nanotechnology (National Academy of Sciences, 2002) that "*combines mechanical and electrical function in devices at very small scales*" (Spearing, 2000).

MS - Management System : The system that an organization uses "*to manage its processes, or activities, so that its products or services meet the objectives it has set itself"* (ISO, 2009a)

MSS - Management System Standard: A document that specifies requirements or guidelines to follow in setting up and operating a management system (adapted from ISO, 2008, p.39).

Nanotechnology: "*The collective term for a range of technologies, techniques and processes involving the understanding and manipulation of matter at dimensions of roughly 1-100 nanometers*" (NNI, 2008).

QA - Quality Assurance: "*Part of quality management focused on providing confidence that quality requirements will be fulfilled*" (*ISO 9000:2005*)

QM- Quality Management: "*Coordinated activities to direct and control an organization with regard to quality"* (*ISO 9000:2005*).

QMS - Quality Management System: "*A management system to direct and control an organization with regard to quality*" (*ISO 9000:2005*).

QS - Quality System: Various authors use the terms "quality system" and "quality management system" interchangeably in the literature. In this thesis, these two terms will signify the same concept.

R&D - Research and Development: "*Creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications*" (OECD, 2009)

R&D&I – Research, Development and Innovation: A concept broader than R&D and includes the "*development of new products (goods or services), new processes, new marketing and organizational methods*" (CEN, 2008).

R&D&I MS - Research, Development and Innovation Management System: A management system to direct and control an organization with regard to R&D&I (adapted from ISO 9000:2005).

1. Introduction

1.1 Nanotechnology

Nanotechnology is the "*collective term for a range of technologies, techniques and processes involving the understanding and manipulation of matter at dimensions of roughly 1-100 nanometers*" (NNI, 2008). According to Davies (2006, p.3), "*materials at the nanoscale often exhibit very different physical, chemical, and biological properties than their normal size counterparts*". These different characteristics can generate a considerable array of novel products and features. A closely related area to nanotechnology is "micro-electro-mechanical systems", otherwise known as "MEMS" (National Academy of Sciences, 2002). MEMS "*combine mechanical and electrical function in devices at very small scales*" (Spearing, 2000).

The scope of nanotechnology is vast, with implications for almost every type of manufacturing process, product, and industrial sector (Davies, 2006, p.7). By 2015, it is estimated that nanotechnology will represent $3.1 trillion in manufactured goods (Howard and Murashov, 2009). For example, nanotechnology-containing products have been reaching the market in a variety of forms, such as paint coatings, cosmetics, pharmaceuticals, microelectronic devices, food products, and composite materials (Tegart, 2004 ; Florini *et al*, 2006). However, nanotechnology is still an emerging field (Blind and Gauch, 2008), with many applications still under research and development (R&D) (Jakeway *et al.*, 2003).

According to Friedrichs and Schulte (2007), the growth of nanotechnology has led to an unprecedented R&D effort in both the public and the private sectors. Worldwide, an increasing number of research laboratories, fabrication and manufacturing plants are developing or applying novel nanometre-sized materials for applications (Friedrichs & Schulte, 2007). Most large companies in the Dow Jones Industrial Index are pursuing nanotechnology applications (Baker and Alston, 2005), although according to Garrett (2005), the "*vast majority of nanotech companies worldwide are small startups or university-led initiatives*". These companies would likely be focused on R&D and innovation (R&D&I) activities.

In this thesis, the terms "nanotechnology setting" and "nanotechnology environment" refers to any R&D-oriented setting in which nanotechnology applications are being developed. The terms "nanotechnology organization" and "nanotechnology company" refers to any organization that pursues nanotechnology applications. However, these terms will signify the same concept in this thesis, and will be used interchangebly.

1.2 Standardization in nanotechnology

The market success of nanotechnology applications will depend on the development of the corresponding standards, which clarify not only terminology, measurement and testing methods, but will also help regulate safety and health aspects (Blind and Gauch, 2008; Hatto, 2007). Blind and Gauch (2008) have also suggested that standardization and standards are an "*effective and efficient channel of technology transfer from research to the diffusion of innovative products*". In fact, they argue that delayed standardization activities in emerging technologies, especially in nanotechnology, can even hinder progress in research. Fanning (2007) supports this view and believes that "*standards encourage innovation through knowledge transfer, plus cost and risk reductions, enabling organization to get product to the market faster and creating avenues to provide for further innovations*".

Fortunately, steps toward nanotechnology standardization have started around the world (Nembhard, 2007), with standardization bodies such as ISO (International Organization for Standardization), BSI (British Standards Institution), ANSI (American National Standards Institute), and ASTM International (American Society for Testing and Materials) taking the lead. The initial focus has been on the following three aspects (*Bergholz et al.*, 2006):

- Terminology and labeling;
- Environmental, Health and Safety (EHS) issues;
- Analysis, measurement, and characterization techniques

However, no literature in this area discusses the standardization of managing other aspects of nanotechnology, such as quality or the interfacing of nanotechnology devices, despite evidence of the need for such standards. Given the absence of nanotechnology-specific quality standards or guidelines, it is hypothesized that organizations involved in nanotechnology might turn to the

existing standards for managing quality. An example of such a standard is ISO 9001:2008, a well-known "Management System Standard" (MSS), which provides requirements for a "Quality Management System" (QMS).

1.3 Management systems and management system standards

A management system (MS) "*refers to what the organization does to manage its processes, or activities, so that its products or services meet the objectives it has set itself*" (ISO, 2009a). In general, every organization has an overall MS by which it manages its resources and conducts its business activities. This overall MS can be divided into a number of interrelated parts, also called "subsystems", which manage specific functional areas (such as quality, environment, health and safety, finance or R&D), in order to fulfill the needs and expectations of different stakeholders (ISO, 2008, p.5).

MSSs are documents that specify requirements or guidelines to follow in setting up and operating an MS (ISO, 2008, p.39). They provide a systematic "*framework for analysis and implementation of internationally recognized good business practices*" (ISO, 2008, p.43). Many MSSs address specific aspects of an organization's MS (ISO, 2008, p.39), such as such as quality (ISO 9001), the environment (ISO 14001) or health and safety (OHSAS 18001). More recently, MSSs have emerged for a wide range of applications and functions. Examples include improving corporate social responsibility (SA 8000), the security of information systems (ISO 27001), supply chains (ISO 28000), and even road safety (ISO 39001).

However, specific MSSs for nanotechnology do not currently exist. Studies on the application of MSSs in MEMS or nanotechnology settings could not be found either, although some nanotechnology companies are ISO 9001- or ISO 14001-registered. Examples of these include: Nanosys (ISO 9001), Zyvex (ISO 9001), Oxonica (ISO 9001), MultiProbe (ISO 9001), Nanophase (ISO 9001 and ISO 14001), and Nanogate (ISO 9001 and ISO 14001). However, a substantial amount of literature exists today on the application of quality-related MSSs in R&D. Standards designed specifically for managing R&D&I (e.g., the Spanish national standard UNE 166002:2006) and for research & technology organizations (e.g., the European standard EARTO:2000) are also available, although literature on their usage is very limited. Given that

nanotechnology development involves innovation, with many of its activities taking place in an R&D environment, it would be interesting to see whether or not the MSSs for R&D are applicable for firms involved in nanotechnology.

1.4 Integration of MSS requirements

Although MSSs for nanotechnology are not available, a search of the existing literature revealed that QMSs in R&D can be built using a combination of requirements from multiple MSSs and guidelines. However, details on the process used to incorporate these requirements is lacking in the available research studies. Furthermore, since some nanotechnology companies may already have existing MSSs in place (e.g., ISO 9001 or ISO 14001), the implementation of R&D MSSs points to the need for a methodology for the integration of multiple MSS requirements.

Recently, ISO published a handbook called "*The Integrated Use of Management System Standards*" (IUMSS), which describes a seven-step methodology for the application of multiple MSSs in an organization's MS. Up to date, there has only been one study in the literature validating the IUMSS methodology in practice (see Borkovič, 2009). Therefore, the testing of this methodology by applying its steps to integrate the requirements of R&D MSSs into a nanotechnology company presents a valuable research opportunity.

1.5 Organization of the thesis

The remainder of this thesis is divided into six chapters. Chapter Two investigates the existing literature covering the currently-available standards for nanotechnology, QMSs in R&D, relevant MSSs for R&D, and the integration of the requirements of multiple MSSs in organizations. This information serves as a background on the application of QMSs in R&D, and provides a validation for the usage of R&D-related MSSs in nanotechnology settings. The rest of the thesis follows the seven steps of the IUMSS methodology and shows how it could be applied in a Case Study Organization (CSO) for integrating the requirements of R&D MSSs into the CSO's MS. The purpose is to produce comprehensive instructions to guide an organization involved in nanotechnology in applying R&D MSSs to its MS.

Chapter Three starts with an explanation of the approach taken to carry out this research project, followed by a description of the CSO selected to represent the nanotechnology setting. This is followed by an in-depth assessment of the current state of the QMS at the CSO, as well as a discussion of the existing issues and challenges.

Chapter Four presents a study of the application of the first three steps of the IUMSS methodology, which involves addressing the benefits and potential challenges of integration, determining the MSSs to be implemented, and developing a plan for the integration. Two standards are introduced at the CSO, namely the R&D standards UNE 166002:2006 and EARTO:2000.

With the groundwork for the integration now developed, Chapter Five focuses on how the requirements of the two new R&D MSS can be connected to the CSO's current QMS. Also incorporated in this chapter are discussions of the issues and challenges that may be encountered during this fourth step of the IUMSS methodology.

Chapter Six takes a further look at how the new R&D MSS requirements can be incorporated into the CSO's QMS. This QMS is compared against the UNE 166002:2006 and EARTO:2000 requirements, and improvement suggestions to assist the CSO in complying with those requirements are offered.

In Chapter Seven, it is shown how the improvement suggestions in Chapter Five can be verified and validated, should they be implemented. Also included are opportunities within the CSO to create an Integrated Quality and R&D&I MS. This chapter also presents a summary of the main lessons learned from studying the application of the IUMSS methodology at the CSO.

The thesis concludes with Chapter Eight. Here, the results and contributions of this research are summarized, limitations of research are presented, and possibilities for future work are offered.

2. Literature Survey

2.1 Introduction

This chapter presents the literature survey which was conducted to provide the foundation and justification for the original work presented in the thesis. More specifically, the following topics were investigated:

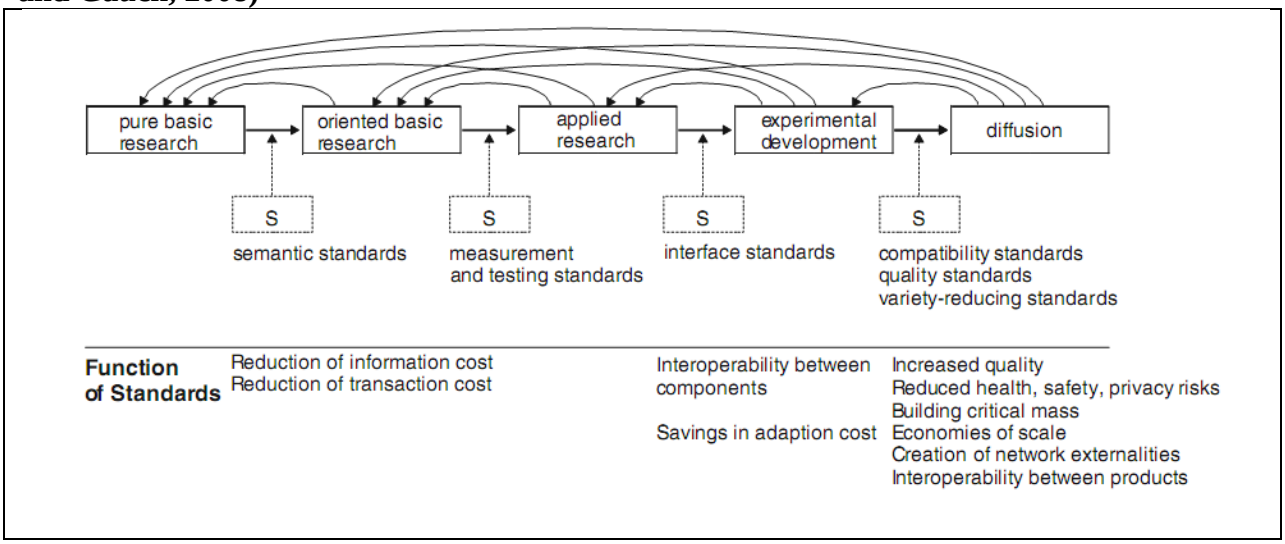
- Standardization activities in nanotechnology;
- The implementation of QMSs in R&D and the possible implications for nanotechnology;
- Relevant MSSs that can be applied in R&D and nanotechnology settings;
- Methodologies for the integration of multiple MSS requirements.

2.2 Standardization activities in nanotechnology

Firstly, a literature search focused on MSSs for nanotechnology and MEMS was conducted. However, no such standards could be found. An examination of other currently-available nanotechnology-specific standards was also conducted through the ISO, BSI, ANSI and ASTM websites. The standards found in this search were categorized according to the three main focuses of nanotechnology standardization described by Bergholz *et al.* (2006), which are "*Terminology and labeling*","*Environmental, Health and Safety Issues*", and "*Analysis, measurement and characterization*". These standards and their categorization are listed in *Appendix A-1*. It should be noted that the search results represent only nanotechnology-specific standards and guidelines developed by ISO, BSI, ANSI and ASTM. They do not include other general documents that are related to nanotechnology, such as the use of an electron microscope.

According to Blind and Gauch (2008), standards play various roles within the different phases of the research and innovation process. This is illustrated in the conceptual model developed by Blind and Gauch (2008), shown in *Figure 2.1*.

Figure 2.1: **The various roles of standards in the research and innovation process (Blind and Gauch, 2008)**



Blind and Gauch (2008) argue that the development of nanotechnology standards can be related to the model represented by *Figure 2.1*. Since nanotechnology is still in an emerging phase, the emphasis has been on the terminology standards ("semantic standards" in *Figure 2.1)* in nanotechnology, as a consistent set of terminologies is "*necessary to allow efficient communication between researchers and to build the basis for all the following phases in the innovation cycle and the following standardization processes*" (Blind and Gauch, 2008). It also helps avoid the vast and confusing set of definitions and labeling that has evolved as corporations choose their own terms to describe their interests in nanotechnology (Willis, 2007). Standards on nanotechnology analysis and characterization have also been a focus of the current standardization activities, as agreements on measurement and testing methods are "*crucial for a technology moving to a new size dimension*" (Blind and Gauch, 2008).

Blind and Gauch's (2008) model suggests that as nanotechnology matures, its standardization will evolve from purely technical issues (e.g., terminology, measurement and testing) to the management of broader aspects (such as quality, safety and interoperability between products). Such standards will become more important in the near future, when more products utilizing nanotechnology will enter the market (Blind and Gauch, 2008).

Indeed, as seen in *Appendix A-1*, ISO, BSI and ASTM have already issued guidelines addressing environmental, health and safety risks of nanotechnology. This is not surprising, in light of the

growing concerns that have been raised over nanotechnology's potential toxicity and adverse effects for human health and the environment (Davies, 2006; Florini *et al.*, 2006; Friedrichs & Schulte, 2007; Howard and Murashov, 2009; Bowman and Hodge, 2008). .

In contrast to the already-numerous initiatives undertaken in the area of terminology, measurement and testing, and environmental, health and safety standards, standardization for managing other aspects of nanotechnology, such as quality, compatibility or interfacing, has been lacking (Blind and Gauch, 2008). In fact, ISO's Technical Committee for Nanotechnology (TC 229) has not identified either one of these aspects as high priority areas for their plans in nanotechnology standardization (ISO, 2009b).

However, there is evidence for the need for such standards, in particular quality. For instance, Nembhard (2007) notes that nanotechnology commercialization has been hampered by concerns about the quality of the products, and that nanotechnology companies often experience problems with contaminated batches of nanoparticulates which may occur during production or shipping. Furthermore, one of the primary challenges nano-manufacturing faces is that of "scaling up", or moving scientific discoveries from the laboratory to large scale commercial production (Mazzola, 2003; Nembhard, 2007). Reports from the National Science Foundation (NSF), the Food and Drug Administration (FDA) and other agencies in the United States identified several key problems for the mass production of nanotechnology, namely low reliability and yield for nanoscale devices, lack of repeatability and reproducibility in yielding a particular product, and lack of robustness and control of the manufacturing process (Nembhard, 2007). Blind and Gauch (2008) claim that "*compatibility and interface standards [serve] to reduce product variety, which then allows cost savings in mass production*". All of these issues are inherently related to quality management (QM).

Given that nanotechnology is still an emerging field (Blind and Gauch, 2008), with much of its activity taking place in R&D environments (Jakeway *et al.*, 2003), an examination of the literature on MS implementation in R&D was carried out, with a focus on QMSs. In many of these articles (e.g., Auer *et al.*, 1996; Kumar and Boyle, 2001), the scope of "R&D" also includes activities such as applied research, engineering, and product design and development. These are activities found in most high-technology environments such as nanotechnology.

Therefore, the research from the QM literature on R&D should also be applicable for firms involved in nanotechnology.

A literature search was also conducted on the usage of MSSs in the semiconductor industry, as this is an area which is connected to MEMS. However, the articles found were generally not as detailed as the available research on QMSs in R&D. Furthermore, articles related to MSSs in biotechnology were not found. Since nanotechnology has implications for almost all industrial sectors (Davies, 2006, p.7), it seemed prudent to focus the literature search on settings that are applicable for any nanotechnology-oriented company, rather than individual industry sectors, such as microelectronics or pharmaceuticals.

2.3 QMSs in R&D

2.3.1 Definition of quality in an R&D context

Since the focus of the literature survey is on QMSs in R&D, it is first important to define the meaning of quality in an R&D context. However, the concept of quality in R&D can be difficult to define (Mathur-De Vre, 2000; Kumar and Boyle, 2001), and different authors have discussed its meaning from various perspectives.

Bire (2004) and Mathur-De Vre (2000) discuss the general aspects of "quality in R&D". Bire (2004) makes the distinction between "quality in research" and "quality of the research". The former focuses on the way the research activity is conducted in terms of quality requirements. The latter refers to the excellence of the work in terms of the results and progress of knowledge. Mathur-De Vre (2000) expands upon the notion of both "quality in research" and "quality of the research" and states that "*quality in R&D can imply: reliability of the basic scientific and technology aspects of the project, appropriate choice of quality criteria, scientific value of the results (originality and novel exploitations), achieving the objective in relation to the available resources and pre-defined terms (i.e., cost and delay) and an efficient quality system".*

Both Kumar and Boyle (2001) and Patino (1997) provide an actual definition of what "quality" means in R&D. Patino (1997) writes that quality in R&D involves doing *"it the right way the first time, learning from and improving it each time and getting the results the company needs"*.

Kumar and Boyle (2001) states that it involves *"an understanding of who the R&D client is and what his/her values and expectations are, what the key technologies are and how they can be used to meet client expectations and the needs of the entire organization, and who the competitors are how they will respond to emerging customer needs. This is achieved by doing things right once you are sure you are working on the right things, concentrating on continually improving your system, enabling people by removing barriers and encouraging people to make their maximum contribution."*

Auer *et al.* (1996), Mathur-De Vré (1997), and Cammaann and Kleibohmer (1998) provide characteristics of quality in R&D. Auer *et al.* (1996) listed five quality metrics for R&D projects: "*overall client satisfaction, fulfilment of project objectives, accuracy of timetable, accuracy of budget and usefulness of project".* Mathur-De Vré (1997) listed the following important criteria for quality in R&D.

- *"Originality, sound fundamental concepts, and rigor in experimental design, planning and performance*
- *Combination of scientific knowledge, intellectual competence and technical skills*
- *Adequate and reliable technology and methodology employed*
- *Intrinsic quality of raw data and scientific value of results*
- *Full knowledge of uncertainty and validity limits of final results*
- *Dedicated spirit of innovation, creativity and initiative*
- *Well constructed and documented project*
- *Potential for application of results in different domains*
- *Scientific prestige and dissemination of scientific and technical knowledge through publications and patents."*

Cammaann and Kleibohmer (1998) also agree with these criteria and add two of their own:

- *"Feedback-controlled variations during the course of the project.*
- *Complete mastery of related scientific principles combined with some elements of self-criticism*."

These definitions provide an idea of the general principles that MSSs might address in managing the quality of R&D.

2.3.2 Implementation of QMSs in R&D

A QMS in R&D refers to the general organization of an R&D environment in terms of quality requirements in order to ensure proper management and organization (Mathur-De Vré, 1997). Kumar and Boyle (2001) state that "*quality management systems that are successful in manufacturing environments are well known and widely published*". However, many traditional manufacturing QM practices, such as implementing process improvement teams and documentation, are also applicable to R&D (Kumar and Boyle, 2001).

Many authors (see for instance, Auer *et al.*, 1996; Jayawarna and Holt (2009); Krapp, 2001; Kumar and Boyle, 2001; Mathur-De Vré, 1997, 2000; Robins *et al.*, 2006) have written about the need to have systematic processes to manage quality in R&D environments. Empirical research has also been carried out (see for example, Munir and Phillips, 2005; Endres, 1997; Jayawarna and Pearson. 2002; Prajogo and Sohal, 2006; Prajogo and Hong, 2008) which suggests positive relationships between the effective implementation of QM practices and R&D performance.

It should be noted that various authors in the literature use the terms "quality system" and "quality management system" interchangeably. In this thesis, these two terms were taken to signify the same concept, but the term "QMS" will be used hereafter.

2.3.3 Benefits of implementing a QMS within an R&D environment

The implementation of a formal QMS in R&D oriented organizations (such as those involved in nanotechnology) provides multiple advantages. These advantages are listed below.

2.3.3.1 Record keeping and documentation of research

A QMS in R&D helps facilitate the transfer of knowledge (Mathur-De Vré, 1997) through the eventual exploitation of the results (Mathur-De Vre, 2000). It leads to the creation of a formal documented system that helps ensure that results do not get lost, and also provides a disciplined way of capturing the R&D results that may need to be referred to during the product's life cycle (Jayawarna and Pearson, 2001, Vermanercke, 2000). Records and documentation also aid in the training of new personnel, which is an advantage in a research environment where the staff turnover may be high (Krapp, 2001).

The importance of good record keeping has crucial implications for nanotechnology. Given the current lack of information regarding nanotechnology quality, safety, environmental and health risks (Institute for Food and Agricultural Standards, 2007), any type of recorded information based on working experiences provides research data for nanotechnology risk assessment.

2.3.3.2 Improvement of R&D processes

A QMS encourages a continutal improvement of the R&D processes (Ferguson et al, 2006; Pellicer *et al.*, 2008) through:

- Audits, where inefficiencies in the processes can be evaluated in a systematic manner, and be brought to management attention (Joubert, 1998)
- Improved training of new staff with standard laboratory practices (Auer *et al.* 1996)
- Lessons learned from post project reviews (Jayawarna and Holt, 2009)

Furthermore, QMSs can lead to improved problem solving as a result of utilizing systematic quality tools and methods (Jayawarna and Holt, 2009), which is often lacking, especially in pure research environments (Krapp, 2001).

2.3.3.3 Quality assurance

The existence of a formal QMS helps promote mutual confidence among all parties involved, by removing potential uncertainties concerning how the research was conducted (Biré et al, 2004; Mathur-De Vré, 1997; Petit and Muret, 2000; Robins *et al.*, 2006) and the reliability of the scientific results (Krapp, 2001, Vermanercke, 2000). A QMS improves the transparency of data, methodologies and instrumentation, which helps lessen the chances of manipulation of experimental data and fraud (Cammann & Kleibohmer, 1998). This point is of particular relevance when dealing with "hot" research areas such as nanotechnology.

Also, a QMS results in better uniformity of documents and plan templates (Auer *et al.* 1996), improves reproducibility and comparability of R&D results from one location to another (Cammann & Kleibohmer, 1998; Krapp, 2001), and also enhances the compatibility between different phases of the research project and in the various facilities involved (Mathur-De Vré, 1997).

Furthermore, a QMS in R&D provides substantiated data to back up performance claims to customers and can be used as an effective tool in promoting sales (Krapp, 2001). Especially for costly first-of-a kind or custom-built products (such as those commonly found in nanotechnology and MEMS), it provides confidence to a customer that the item will perform as intended. Accurate data is also required for justifying specific design concepts and investing in expensive equipment (Roberts, 1983, p.2). This is particularly important in capital-intensive environments such as nanotechnology/MEMS test and fabrication facilities.

QMS registration also helps enhance company reputation and market recognition amongst customers (Jayawarna and Holt, 2009). It provides a proof of competence and credibility, which may be essential when it comes to selecting partners for performing research and obtaining investment capital for projects (Krapp, 2001; Vermaercke, 2000a; Petit and Muret, 2000). This is particularly important due to globalization of R&D activities and competitiveness (Mathur-De Vré, 1997).

For some nanotechnology companies with ISO 9001 registration, MSS implementation seems to be primarily motivated by the promotion of company image, at least based on information gathered from company corporate websites. For instance, Nanophase states that ISO 9001:2008 registration "*demonstrates commitment to service quality and customer satisfaction, as well as continuously improve the quality management systems and integration due to the realities of a changing world*." (Nanophase, 2009). Oxonica claims that the ISO 9001 standard reassures customers and investors that" *rigorous quality control procedures [are] in place…at all stages from consultation through research and development to final products*" (Oxonica, 2009).

2.3.3.4 Enhancing communication

A QMS in R&D facilitates communication between different parties involving multiple organizations and multi-disciplinary fields (Mathur-De Vré, 1997 ; Valcarcel and Rios, 2003; Robins *et al.*, 2006). Effective channels of communication are particularly important for nanotechnology research and development, which involves a great deal of collaborative effort between industry sectors. QMSs can also improve the ability to communicate with customers and respond directly to requests and can help match expectations between client and organizations (Jayawarna and Holt, 2009).

2.3.3.5 Improved quality of research through planning

Despite widespread views that R&D&I thrives on unstructured processes and accidental discoveries (see for instance, Jayawarna and Holt, 2009; Krapp, 2001; Kumar and Boyle, 2001; Mathur-De Vre, 2000; Valcarcel and Rios, 2003), Pellicer *et al.* (2008) argue that careful planning, organizing, directing and controlling of R&D&I activities is critical - "*a spontaneous and random approach to innovation is not viable*". By planning ahead, organizations can identify possible problems in early project phases (Jayawarna and Pearson, 2001), which helps improve predictability of R&D projects, especially in terms of costs and schedule (Auer, 1996; Jayawarna and Holt, 2009 Ferguson et al, 2006).

Planning assists with developing an organizational and overall project structure in order to:

- Clearly define the objectives and goals, working plan and resources (Mathur-De Vré, 1997), leading to increased efficiency (Robins *et al.*, 2006)
- Ensure R&D projects stay focused (M.M. McTeer and B.G. Dale, 1994) and evolve according set objectives, planning, and deliverables linked to time schedules (Mathur-De Vré, 1997; Vermanercke, 2000).
- Develop efficient problem-solving strategies during the project (Mathur-De Vré, 1997)
- Lower the risks of doubtful results (Mathur-De Vré, 1997)
- Increase project time efficiency and reduce overall costs (Mathur-De Vré, 1997; Robins *et al.*, 2006)
- Proactively to meet changing customer requirements (Jayawarna and Holt, 2009)

2.3.3.6 Reducing legal uncertainty

Standardization is also a strategy to reduce legal uncertainty in new and emerging technologies (Blind & Gauch, 2008). For example, document control of a formal QMS helps protect proprietary information, intellectual property, and "*the way results are to be made available to others*" (Krapp, 2001).

Well-kept records required from a QMS help facilitate efficient patent applications (Jayawarna and Holt, 2009) and would help substantiate conclusions and recommendations from an R&D project or product in the event that the R&D is subject to scrutiny by customers or public

(Roberts, 1983, p. 1).

2.3.4 Challenges of implementing QMSs in R&D

Although the benefits are numerous, there have also been reservations about the use of QMSs in R&D. Some of the challenges of implementing QMSs in R&D are described below.

2.3.4.1 Unique characteristics and peculiarities of R&D

The many unique characteristics of R&D activities and their environments have made the implementation of standardized QMSs more challenging compared to other areas in an organization (Kumar and Boyle, 2001; Prajogo and Hong, 2008). In fact, authors such as Valcárcel and Rios (2003) have suggested that certain aspects of QMSs and R&D activities can be contradictory.

Valcarcel and Rios (2003) and Krapp (2001) noted that conventional QMSs are based on predictable and controllable factors, whereas R&D activities thrive on flexibility and unexpected events. In R&D, there is an emphasis on creativity, innovation and experimentation, rather than on repetitive manufacturing activities (Jayawarna and Holt, 2009; Mathur-De Vre, 2000). R&D projects often involve a high level of variability (Kumar and Boyle, 2001) and often lack a well-defined structure (AENOR, 2006).

The starting conditions and objectives of an R&D project often change during the process (Vermaercke, 2000), leading to uncertainties in fixing the targets and complying with pre-planned time schedules and resources (Jayawarna and Holt, 2009). As a result, documented procedures for R&D projects are usually very generic and are constantly modified (Rodriguez-Ortiz, 2003), since the knowledge obtained is continuously evolving (Jayawarna and Holt, 2009). Also, researchers tend to rely a lot on their memory, and often do not often document their work, making it difficult to implement QMS documentation requirements (Vermaercke, 2000).

Monitoring and measuring the impacts of an implemented QMS in R&D are challenging, given the non-repetitive character of the R&D process (McAdam, 2004). Furthermore, in a research

project, the technology is complex and new, the staff may be inexperienced in the research area, and the quantities of supplies and production items are relatively small (Willborn, 1989).

The quality of the end product of a research project (e.g., a report, presentation or publication) is often intangible, making it difficult to employ classical quality control concepts during the project or final inspection (Vermaercke, 2000). Products are usually customized and are not mass-produced (Koksaldi and Iyigun, 1997; Rodriguez-Ortiz, 2003). Furthermore, there are also high levels of uncertainty in terms of the impact of the product on the market and the revenue it will eventually generate (Rodriguez-Ortiz, 2003). An additional challenge in R&D is that the final results may differ significantly from the initial expectations (Pellicer *et al.*, 2008), or can even be unknown, without affecting the validity or the relevance of the results, as other worthwhile findings may have emerged (Mathur-De Vre, 2000; Robins *et al.*, 2006). Bire (2004) refers to scientific contributions arising from unexpected or apparently negative results as "positive non-conformities" and cites the accidental discovery of penicillin by Dr Alexander Fleming as an example. As a consequence, Vermaercke (2000) suggests that it becomes much more difficult to define and measure the cost of "poor quality" in R&D (e.g., unexpected results and inefficiency). Efficiency is also related to R&D, since, as Mathur-De Vre (2000) suggests, quality in R&D can imply "*achieving the objective in relation to the available resources and pre-defined terms (i.e., cost and delay)"*.

2.3.4.2 Rigidity of standards

The primary argument cited against setting up formal a QMS in R&D environments is that its rigid requirements may restrict freedom (Jayawarna and Pearson, 2001; Mathur-De Vre, 2000) and creativity (e.g. Jayawarna and Pearson, 2001; Jayawarna and Holt, 2009; Kondo, 2000; Krapp, 2001Mathur-De Vré , 1997) in research work, and hence innovation (Prajogo and Sohal, 2004, 2006). However, other research findings have supported the notion that QM and innovation are compatible concepts (e.g. Bossink, 2002; López-Mielgo *et al.*; 2009**;** Naveh and Marcus, 2004) and that MSSs do not hinder innovation processes (Castillo *et al.*, 2008; Leticia *et al.*, 2007).

2.3.4.3 Administrative maintenance of the QMS

The maintenance of the QMS, in particular the increased bureaucracy and administrative paperwork that often comes along with its implementation, is also a commonly-cited concern (Jayawarna and Pearson, 2001; Jayawarna and Holt, 2009). Some authors feel it may even lead to the loss of research time and extra overhead costs (Mathur-De Vré, 2000). Concerns for hindering progress are particularly relevant for researchers at the leading edge of technology, as setbacks may cause them to lose any advantage they had initially. Robins *et al.* (2006) suggests imposing the minimum possible level of control during research activities to avoid unnecessary bureaucracy. For example, it is important to demonstrate the competence of all those involved in the project, but this can be achieved by managers making an informal assessment of an individual's ability to conduct the tasks required, and recording that the assessment took place (Robins *et al.*, 2006).

2.3.4.4 Difficulty of adapting QMS principles for R&D

Most authors agree that, due to the unique characteristics of R&D, manufacturing-based QM techniques should not be blindly applied to R&D (Jayawarna and Holt, 2009; Krapp, 2001; Kumar and Boyle, 2001; Robins *et al.*, 2006; Valcárcel and Rios, 2003). For instance, Krapp states that "*a quality approach for a research area must be tailor-made to be fit for purpose"*. Valcárcel and Rios (2003) believe that a common error when creating QMSs for R&D is the "*direct extrapolation of well-established quality systems from routine to R&D activities [and] the straight application of inflexible quality standards*". Robins *et al.* (2006) emphasized that "*quality systems must be adapted to the characteristics and peculiarities of R&D*". In particular, it is essential to build flexibility into a QMS for R&D (Krapp, 2001; Mathur-De Vre, 2000; Robins *et al.*, 2006). "*Flexibility implies the ability to alter and adapt the research plans and experimental procedures on the basis of scientific and technology knowledge acquired*" (Mathur-De Vre, 2000) during the project, and "*allowing deviations from planned programs to pursue unexpected avenues*" (Robins *et al.*, 2006). Developing a system that satisfies the requirements of QMS standards, while at the same time allowing for flexibility and creativity indispensable for research processes is often a major challenge (Biré et al, 2004 ; Ferguson et al, 2006; Mathur-De Vré, 1997 ; Robins *et al.*, 2006). For example, Mathur-De Vré (1997) writes that the "*real challenge for implementing a [QMS] system in R&D concerns the development of standards*

specifying quality requirements that allow flexibility and originality indispensable for R&D".
All of this suggests that, although a research project is similar to any other project, requirements from generic standards for QMS need to be adapted or tailored for R&D.

In addition, Jayawarna and Holt (2009) emphasize the importance of designing QMSs that:

- focus on creating conditions that foster inquiry, rather than well-crafted procedures (e.g., by fostering an innovative environment and developing problem solving skills of employees).
- develop procedures that "*assist in the exploration for and exploitation of strategically relevant knowledge*".

2.3.4.5 Selection of suitable standards

Lastly, the selection of a suitable MSS is an essential element for establishing a QMS in R&D (Mathur-De Vre 1997, 2000). This is not an easy task, since there relatively few internationally-accepted MSSs specifically designed for R&D. As Biré et al (2004) mentions, requirements from traditional QMS standards that work well in analytical laboratories (e.g., pre-defined methods) can be limiting when applied to R&D work.

2.4 Relevant standards for R&D and nanotechnology settings

Although R&D and technology innovation are often considered to be unique, creative processes lacking a structure, standardization techniques used in other activities, such as quality or environmental MSs, are also applicable for managing R&D&I (Research, Development and Innovation) (AENOR, 2006). Pellicer *et al.* (2008) note that one of the main advantages of systematizing and standardizing R&D is the enhanced integration with other ISO standards, e.g., from the ISO 9000 and ISO 14000 families.

As mentioned in Subsection 2.3.4.5, the selection of an appropriate MSS for R&D is an important issue. This section presents an overview of the currently-available standards and guidelines which were identified to be relevant in R&D environments and high-technology organizations involved in areas such as nanotechnology.

2.4.1 Quality-related and R&D-specific standards

The standards that were found to be applicable for R&D and nanotechnology settings were divided into two main categories: "generic quality standards and laboratory guidelines" and "R&D standards and guidelines". The first category includes quality standards and guidelines that various authors (e.g., Biré et al, 2004) have used as a starting point for the development of QMSs in R&D. A list of these standards and a brief commentary for each are provided in *Table 2.1*. A more detailed survey of the literature on these standards is provided in *Appendix A-2*. The second category consists of the standards specific to R&D. Researchers such as Biré *et al.* (2004) believe that these standards are preferred when performing and managing research activities. The R&D standards and guidelines were further divided into two sub-categories: "guidelines for R&D" and "standards for R&D". The first sub-category includes guidance documents and best practice frameworks that have been mentioned in the literature and are not intended for registration purposes. While a summary of these guidelines is provided in *Table 2.2*, more details are given in *Appendix A-3*. The second sub-category is a group of European national R&D standards identified in a report on innovation written by the European Committee for Standardization (CEN, 2008). The reason for the prevalence of European standards in R&D is because the European Union considers R&D&I as a vital issue (with standardization identified as a key priority), in order to maintain the European competitiveness in the global market (CEN, 2008). In this group are MSSs containing requirements for setting up an R&D&I MS. An overview is provided in *Table 2.3* and more details are found in *Appendix A-4*.

Table 2.1: **Generic quality standards and laboratory guidelines**

Standard	Comments
ISO 9001	Most widely used MSS for setting up a QMS.
	Limited reference to technical and scientific competence, which is essential for the critical interpretation and evaluation of R&D results (Mathur-De Vré, 1997; Vermaercke, 2000).
	Too much focus on repetitive actions (Vermaercke, 2000).
	Rigidity of standard requirements, in particular with regards to final product conformity (i.e., research results) (Biré *et al*., 2004).
ISO 17025	MSS containing requirements for testing and calibration laboratories.
	Requirements too restrictive to apply to research activities (Biré *et al*, 2004)
	Does not describe how to record and organize data for experiments, or how to implement a working atmosphere favorable to research (Biré *et al*, 2004)
OECD GLP:1999	Set of guidelines containing principles of Good Laboratory Practice.
	Highly record-orientated, imposes excessive control and restrict flexibility (Holcombe, 1999).
	Concentrates more on the integrity of data than validity (Holcombe, 1999).
ISO 10006: 2003	Guidelines for QM in projects.
	Does not incorporate notions of prime importance to research activities, such as the distinction between "*positive and negative non-conformity*" (Biré et al, 2004).

Table 2.2**: Guidelines for R&D**

Standard	Comments
EARTO:2000	Guidelines for the operation of research and technology organizations
	Covers criteria from multiple guidelines and standards (ISO 9001, ISO 17025, EURACHEM/CITAC Guide 2:1999, and OECD GLP:1999).
Joint Code of Practice for Research	General framework for the proper conduct of research
	Too brief and generic, and seems to serve only as a basic starting point for developing an MS.
EURACHEM/CITAC Guide 2:1999	Guidelines for quality assurance in research and non-routine chemical analysis.
	Requirements are too focused towards analytical chemistry.
	General R&D requirements contained within this standard are also covered in EARTO:2000.
ANSI/ASQ Z1.13-1999	Specifies quality guidelines for research
	Standard could not be obtained. due to inaccessibility
DOE standard ER-STD-60001-1992	Guidelines for developing and implementing quality assurance programs for research work.
	May not be particularly useful for nanotechnology companies with product commercialization goals in mind, since the document is mainly focused on "*research work that produces new knowledge usually published in professional journals*" (DOE, 1992).

Table 2.3: **Standards for R&D**

Standard	Comments
Spanish standards (UNE 166000:2006 series)	A series of five standards available with English translations.
	UNE 166002:2006 aims to systematize R&D&I management, especially in small to medium enterprises (Pellicer *et al.*, 2008; Veras *et al.*, 2008). This makes it particularly relevant to nanotechnology and other high-technology startup companies.
French standards (X50 series)	A series of five R&D standards which were not available in English translations. Specific details regarding the content of the standards could not be obtained.
Portuguese standards (NP 4400:2007 series)	A series of four R&D standards which were not available in English translations. Specific details regarding the content of the standards could not be obtained.
British standard (BS 7000-1:2008)	Standard for the managing innovation and the design and development of innovative products.
	Could not be obtained due to high cost.
Denmark (pDS xxxxx)	Innovation standard.
	Still under development at the time of writing.

The R&D standards and guidelines (i.e., the second category studied) were found to be more appropriate for this study, since they addressed specific aspects of R&D that are not detailed in the traditional quality standards. In particular, EARTO:2000 and UNE 166002:2006 seemed to be the most promising, and will be analyzed in detail in the next sub-section..

Although there are a number of available standards targeting R&D&I activities, the European Commission (2008) identified several challenges in their application. These include:

- "*The existence of too many competing standards addressing similar needs,*
- *The lack of standards in national languages,*
- *The excessive number of cross-references between standards,*
- *The complexity of the language of the standards,*
- *The difficulty in identifying the group of standards relevant for a product or process, and*
- *The cost of purchasing standards".*

These issues, in particular the cost, are important concerns for small organizations with limited resources, such as nanotechnology start-up companies. Furthermore, even if the appropriate standards have been identified and are available, implementing and using standards is often a challenging for those unfamiliar with the language contained in the documents.

2.4.2 Analysis of EARTO:2000 and UNE 166002:2006 standards

2.4.2.1 EARTO:2000

In their paper, Biré *et al.* (2004) mentioned the guidelines developed by the European Association of Research and Technology Organizations (EARTO). This document establishes general guidelines a research and technology organization (RTO) should follow in its practical work, with the emphasis on industrial and applied research (EARTO, 2000). The content of the document is derived from a combination of ideas from multiple guidelines and standards, such as ISO 9000 series, ISO 17025, EURACHEM/CITAC Guide 2:1999, and OECD GLP:1999 (EARTO, 2000).

EARTO:2000 is structured to address the QMS requirements of ISO 9001, the technical competence requirements of ISO 17025, as well as guidelines specific to research projects (Biré *et al.*, 2004). The document is divided into five sections:

Section 1 outlines a code of conduct for RTOs, which generally addresses principles such as fair employment rules and sustainable development. These aspects are not covered in either ISO 9001:2008 or UNE 166002:2006. *Section 2* discusses general contractual and legal aspects, with contractual procedures and intellectual property rights being the focus. *Section 3* outlines the issues related to the QMS. It covers many of the elements from ISO 9001:2008, such as document and record control, sub-contracting and procurement, non-conforming work and corrective and preventive actions. However, the *Design and Development* section of ISO 9001:2008 is noticeably missing from EARTO:2000. This is probably due to the fact that, since the focus of EARTO:2000 is on providing guidelines for operating a technology organization as a whole, there is less emphasis on the product development process. *Section 4* on technical capabilities deals with the competence of personnel, facilities, experimental methods, equipment, measurement traceability, sample and handling of research items. Again, most of these topics are touched upon in ISO 9001:2008 and UNE 166002:2006, but in much less detail. *Section 5* describes general project management and professional judgment issues. In particular, the responsibility for quality in project work, monitoring project progress, and reporting of results is discussed.

EARTO:2000 should be used as a set of supplementary guidelines when additional information is required for a particular aspect of a project, such as details on "handling of research items" (Section 4.8 EARTO:2000), or "intellectual property rights" (section 2.2 EARTO:2000). Since product-realization is the main business process for all organizations (ISO, 2008), a more product development-focused standard, such as ISO 9001:2008 or UNE 166002:2006, should be implemented first as a framework in a nanotechnology or high technology company,

2.4.2.2 UNE 166002:2006

Published by AENOR, the Spanish Association for Standardization, the purpose of UNE 166002:2006 is to provide guidelines that go beyond the requirements established in other MSSs, in order to "*increase both the effectiveness and efficiency of an R&D&I management system, leading to a potential improvement in the results and optimization of the technological innovation processes of the organization*" (AENOR, 2006). Intended to be used by organizations and certification bodies, the document sets up a framework for the systematization of R&D&I (Pellicer *et al*., 2008) and supports the optimization of R&D&I activities (UNE 166002:2006).

UNE 166002:2006 introduces some of the characteristics of the R&D process, as well as a listing of the benefits of implementing an R&D&I MS using the standard. These include (AENOR, 2006):

- Promoting R&D&I and related activities as a competitiveness factor,
- Improving the effective organization and management of R&D&I,
- Ensuring that no activities that can generate technologies and patents are lost,
- Saving of resources through improvement in the planning, organization and control of R&D&I units, and increase in employee motivation,
- Providing organizations with the ability to recognize emerging or new technologies not applied in their sector, their assimilation and development (through the technology watch and foresight activities). This is particularly important for hi-tech companies involved in rapidly evolving areas such as nanotechnology.

Like with ISO 9001 or ISO 14001, the requirements of UNE 166002:2006 are generic and applicable to any organization, regardless of its type, size or industry sector (AENOR, 2006). This suggests that the application of the standard is not restricted to R&D organizations or departments, but is rather intended for any organization looking to systemize their R&D&I activities. Furthermore, it does not establish precise criteria or specific demands for R&D&I performance.

Unlike EARTO:2000, which merely provides guidelines for the operation of an R&D-based organization, UNE 166002:2006 presents requirements for the implementation of an R&D&I MS. It thus fits the definition of a "management system requirements standard", i.e., a "*standard that is intended to provide the market place with relevant specifications for the management system of an organization to demonstrate its capability to meet internal and external requirements*" (ISO Guide 72: 2001)

An interesting feature of UNE 166002:2006 is its compatibility with ISO 9001 and 14001. The requirements are aligned with ISO 9001:2008 and ISO 14001:2004. In fact, the standard seems to share the same structure and layout as ISO 9001:2008, and also has many of the same requirements. Pellicer *et al.* (2008) states that UNE 166002:2006 was designed to integrate R&D&I MSs with other MSs already existing in the company: quality (ISO 9001), environment (ISO 14000), or health and safety (OHSAS 18000).

Like ISO 9001:2008, there are five major components: "R&D&I (instead of "quality") management system and model"; "management responsibility"; "resource management"; "R&D&I activities" (i.e., "product realization"); and "measurement, analysis and improvement".

However, there are notable differences, since UNE 166002:2006 contains some unique aspects of the requirements for an R&D&I MSs. Table 2.4 shows a comparison of the elements between UNE 166002:2006 and ISO 9001:2008.

Table 2.4: Comparison between UNE 166002:2006 and ISO 9001:2008

UNE 166002:2006	ISO 9001:2008
R&D&I policy and objectives	Quality policy and objectives.
R&D&I management unit and an R&D&I unit.	Company-wide responsibilities
Employee creativity, motivation and teamwork (essential elements for R&D according to authors such as Jayawarna and Holt, 2009; Cammann and Kleibohmer, 2001).	Not covered.
R&D&I activities: R&D&I "tools", which include "Technology watch", "Identification of information needs", "Search, treatment, and dissemination of information", "Information assessment", "Technology foresight", "Creativity", "External and internal analysis". "Identification and analysis of problems and opportunities" "Analysis and selection of R&D&I ideas" "Planning, monitoring and control of the project portfolio" "Technology transfer" "R&D&I product" - provides supplementary information for product design and development	Generic Product Realization requirements
Documentation of R&D&I results.	Design and Development outputs
"Unexpected" or "non-conforming research results".	Product/Service Non-conformities
Protection and exploitation of the results of R&D&I activities.	Not covered
Monitoring and measurement of the R&D&I processes and products	General Monitoring and measurement of the processes and products

Veras *et al.* (2008) believe that the success in R&D&I depends on the proper choice of R&D ideas to be developed and effective project management, both of which are factors addressed by UNE 166002:2006.

2.5 Application of multiple standards in R&D settings

Many researchers (e.g., Holcombe *et al.*, 1999; Robins *et al.*, 2006; Mathur-De Vré, 1997; Vermaercke, 2000) believe that no single existing standard is ideal and provides complete guidance for designing a QMS for R&D. It must be noted, however, that the newer European national R&D standards were not studied by those authors. Nevertheless, a combination (i.e., integration) of the criteria from standards and supplementary items from R&D guidelines is recommended (Holcombe et. al, 1999, Vermaercke, 2000, Valcárcel and Rios, 2003). For

example, Mathur-De Vré (2000) believes that a combination of the following types of standards is ideal to assure the flexibility and specificity necessary for different types of research facilities:

- Generic standards with minimal requirements covering project management, QM, and technical competence;
- Sector-specific standards providing complementary recommendations for R&D

Several authors have implemented QMSs in R&D environments, using combinations of requirements and guidelines from multiple standards. For instance, Ferguson et al. (2006) presented an implementation of a QMS in a cereal quality laboratory involved in R&D activities. This QMS was based on the requirements of ISO 9001:2000, with certain guidelines of ISO 17025:2005 incorporated into the procedures where a higher level of control was required. Biré et al (2004) described a QMS established at a Food Process Quality Research Laboratory of the French Food Safety Agency. Like other researchers, they were unable to find a single standard to comply with all their quality requirements, and therefore had to create a "*system [that was] a hybrid incorporating the requirements of several standards, dedicated to both routine [e.g. ISO 17025] and research activities [e.g. EARTO:2000]*" (Bire *et al*., 2004). However, Biré *et al.* (2004) do not provide details in their paper as to how the integration of the requirements was actually carried out. Henri *et al.* (2009) followed up on the work conducted by Biré *et al.* (2004) and developed a QMS system for research in an university laboratory setting for a PhD student project. Their system was based on the requirements of ISO 17025 for the execution of tests associated with the research, on good laboratory practices (GLP) for the description of studies, and on ISO 10006 for the requirements associated with the management of a project. In establishing their system, Henri *et al.* (2009) also referred to the guidelines of ANSI Z1.13-1990 and the French standards FD X 50-550:2001 and FD X 50-551:2003. They describe the features of their system, and the associated benefits and limitations at length. However, like Biré *et al.* (2004), they do not provide details on the methodology or procedure they went through to incorporate the components of those standards and guidelines.

2.6 Integration of multiple MSS requirements

As discussed in the previous sub-section, the combination, or "integration" of the requirements and guidelines of multiple standards is often required when developing an MS for R&D. Especially in companies with pre-established MSs that contain different objectives and focus (e.g., quality, environment, health and safety), incorporating an additional R&D standard to the mix can be a challenging task. Furthermore, to establish an effective MS, most authors believe that quality processes, if introduced in R&D, must also be integrated, or at least aligned with organizational objectives and processes (Jayawarna and Holt, 2009; Prajogo and Sohal, 2006; Jayawarna and Pearson, 2002). Karapetrovic (2002) argues that the integration of MS processes is a more difficult task than integrating MSS requirements.

The integration of MSs and the related standards is a broad topic and has been studied extensively in literature. Readers can refer to Jonker and Karapetrovic (2003), Karapetrovic and Willborn (1998), Karapetrovic and Casadesús (2009) and Wilkinson and Dale (1999), for detailed discussions on the concepts and theories. Much has also been discussed regarding the benefits (e.g., Douglas and Glen, 2000; Jonker and Karapetrovic, 2003; Karapetrovic, 2002; Salomone, 2008; Zutshi and Sohal, 2005) and challenges (e.g., Karapetrovic, 2002; McDonald, 2003; Wilkinson and Dale, 2002) of integration. Borkovič (2009) provides a detailed literature survey on the subject in general.

2.6.1 Integration methodologies

The case studies in the literature on implementing QMS systems in R&D environments have all focused on presenting the features of the standardized system, the overall setup, and the related benefits and challenges. Discussions on how the requirements of the standards were incorporated or integrated (i.e., the methodology), are noticeably missing. This is not surprising, as comprehensive studies on integration methodologies seem to be much more limited in the literature, compared to the discussions on integration theories, models and issues of establishing an Integrated Management System (IMS).

Several authors have presented outlines of various integration methodologies which can be used for any organization. For example, Karapetrovic (2003) explained that an integration

methodology should provide a general procedure for integrating MS, while at the same time allowing for differing initial conditions, routes and ultimate objectives for integration. In the same paper, Karapetrovic (2003) briefly described a seven-step process for integration that takes into consideration factors such as scope, level, and sequence. Unfortunately, the presented methodology is very generic and does not provide guidance on what is involved in each step.

Heinloth (1999) provided a summary of the best practices of four companies which established their IMSs, and proposed an outline of a five-step methodology. Again, there is very little guidance or examples of how each step can be performed.

The British Standards Institution (BSI) has published two books providing guidance and practicing advice on integrating systems, based on using its integrated MSS, PAS 99:2006 (BSI, 2007a; BSI, 2007b). However, not much is known about these resources, as they were not available for use in this research study.

In general, there has been a lack of methodologies in the literature regarding the integration of standardized MSs. The few that exist are basic and generic, and have not been developed into a comprehensive set of instructions that organizations can readily utilize. A concise and generic outline of an integration methodology might be enough, or even desired by larger organizations with well established systems in place (supported by professionals trained in QM) or with the ability to hire external consultants. A small high-technology company (such as a nanotechnology startup), on the other hand, might not have in-house expertise and knowledge on QMSs, nor the resources for professional assistance. In their situation, a more complete set of guidelines, or even step-by-step instructions, would be welcomed.

Fortunately, in 2008, ISO published a handbook called "The Integrated Use of Management System Standards" (IUMSS), with the purpose of providing organizations with "*guidance on how to integrate the requirements of multiple MSSs into their [existing] MS*" (ISO, 2008, p.3). It presents the most thorough integration methodology for organizations to date, and seems to combine the features of the methodologies proposed by Heinloth (1999) and Karapetrovic (2003).

2.6.2 IUMSS Handbook

The IUMSS Handbook provides a detailed seven-step methodology for the integrated use of management system standards (hereafter referred to as the "IUMSS methodology"). A feature of the IUMSS Handbook are the real-life case-study examples used to illustrate the practices, tools and methodology involved, and how MS implementation can be carried out. These can be useful for nanotechnology organizations that do not have experience with implementing MSs.

The first chapter of the IUMSS Handbook ("*The Management System*") discusses the characteristics of a MS, its main components, and their interrelationships. This chapter seems to be most useful for new organizations (for example, nanotechnology startups) looking to set up a MS. A number of guiding questions are presented to get the organization thinking strategically about the business, addressing aspects such as "Stakeholders and their needs/expectations" and "Organizational structure and resources". For example, in the sub-section discussing "Organizational structure and resources", one of the guiding questions is "*How is teamwork and competence fostered throughout the organization*" (ISO, 2008, p.18). Teamwork is particularly important in nanotechnology research, since it often involves input and collaboration from workers of different disciplines and expertise. This chapter can also be useful for organizations that are already up and running. Although the organization should already have a system in place for managing its business, the guiding questions can serve as a useful reminder for organizations (especially nanotechnology startups), that place the majority of their focus on R&D and product development activities that they lose sight of other aspects of the business.

Chapter 2 ("*Management System Standards*") explains the main features of MSSs, their importance, and the way an organization should apply them. This chapter is relevant for nanotechnology organizations that may not be familiar with MSSs and their significance. In particular, this chapter addresses two challenges of R&D&I standardization identified by the European Commission (2008), which are "*the existence of too many competing standards addressing similar needs*" and "*the difficulty in identifying the standards relevant for a product or process*". Guiding questions such as "*How does the MSS fit into the organization*" (ISO, 2008, p.47) facilitate the selection of a suitable MSS for an R&D-oriented or a nanotechnology organization.

Chapter 3 ("*Integration of Management System Standard Requirements*") introduces the idea of "integration" and presents the actual IUMSS methodology. This chapter is organized according to the seven steps in the IUMSS methodology, and is outlined in *Appendix A-5*. Each sub-chapter is devoted to a step of the methodology, with ample details and guidance provided for the reader. The steps of the IUMSS methodology and their relevance for nanotechnology organizations are provided below.

3.1: Lead the integration. Identify business case considerations for integration (i.e. benefits and risks), and obtaining top management's commitment to initiate project. "Leading the integration" and obtaining management/employee support is of particular importance to R&D-oriented organizations as there are usually reservations towards standardization in R&D.

3.2: Determine the scope of integration. Determine the MSSs to be implemented, the order in which they will be implemented, and the extent of integration in the organization. This step is also of particular relevance, since, as mentioned earlier, the selection of an MSS for R&D is an important, yet challenging task.

3.3: Plan the integration. Develop a project plan for the integration. As mentioned in sub-section 2.3.3 of the thesis, planning is crucial for when R&D activities are involved.

3.4: Connect MSS requirements and the MS. Determine how the requirements of the selected MSSs apply to the organization's MS. There are three sub-steps:

> ***3.4.1: Structure the MS.*** Develop a model for the MS and organize the system according to the model. Numerous examples of how different organizations have structured their MSs are provided. "Structuring the MS" is useful for determining where R&D processes fit relative to the rest of the organization. This is important since quality processes involved in R&D should also be integrated or aligned with the rest of the organization's objectives and processes (Jayawarna and Holt, 2009; Prajogo and Sohal, 2006; Jayawarna and Pearson, 2002).

3.4.2: Structure the MSS requirements. Understand the requirements contained in the MSS and analyzing them for commonalities. An efficient method of analyzing commonalities and unique requirements is important because:

- Developing an MS for R&D often involves incorporating the requirements of multiple R&D standards and guidelines (resulting in a "hybrid system" as described by Biré et al (2004)).
- R&D&I MSSs (e.g. UNE 166002:2006) share many of the same requirements of ISO standards that may have already been implemented in an organization.

3.4.3: Map MSS requirements against the MS. Relate the requirements of the selected MSSs (determined in 3.4.2) to the corresponding components in the MS (structured in sub-step 3.4.1). Structuring the MSS requirements and mapping them against the MS facilitates the selection and adoption of relevant clauses in guideline standards such as EARTO:2000, where criteria need not be adopted in totality. If a particular guideline cannot be mapped onto the current MS, and is also found to be irrelevant to the organization, then the organization can choose not to implement it.

3.5: Incorporate MSS requirements into the MS. Integrate the requirements of the MSSs into the organization's MS in order to achieve compliance. For instance, a nanotechnology organization can assess its management practices against an R&D MSS. The organization can then determine whether certain requirements should be adapted or added to its MS in order to improve it. To accomplish this, three sub-steps are performed:

3.5.1: Identify and analyze gaps. The gaps exist between the MS components and the related requirements of the MSSs.

3.5.2: Close the gaps. Create new and/or modify existing components within the MS in order to eliminate the identified gaps and establish full compliance with the MSS. The result is "integration" of the MSS requirements into the MS.

3.5.3: Confirm gap closure. Verify that all the identified gaps have been closed and close any gaps that still exist.

3.6: Maintain and improve integration. Continual system maintenance and improvement may be required in fast growing and ever-changing environments such as nanotechnology.

3.7: Apply lessons learned in the organization. Review the lessons challenges learned from the integration project. Understanding these may help the nanotechnology organization overcome similar issues faced in future integration projects.

Because of its newly-published status, there has only been one study (see Borkovič, 2009) illustrating the IUMSS methodology in practice to date. Borkovic (2009) adapted the IUMSS methodology for the implementation of two standards (ISO/IEC 17025:2005 and ISO/TR 10013:2000) in a testing and calibration laboratory, and created a slightly-modified version, calling it the "AI-IUMSS methodology".

2.7 Motivation for the proposed research

The motivation for this research project stems from two main directions, specifically the academic opportunities made visible during the literature survey and the practical implications for the Case Study Organization (CSO).

From the academic viewpoint, the need for research exists in two areas identified in the literature:

A) The application of MSSs in R&D and nanotechnology environments
B) The integration of the requirements of multiple MSSs

With respect to the application of MSSs in R&D, and particularly in nanotechnology organizations:

- The literature survey validated the importance of the standardization of nanotechnology, especially regarding the definitions, testing and safety (Blind and Gauch, 2008; Hatto, 2007). In contrast, standardization of other aspects of nanotechnology, such as quality, has not been a thoroughly-researched area, despite evidence of the need for such work (e.g., Nembhard, 2007). Therefore, a study of quality standardization in nanotechnology is warranted.
- Research on the application of MSSs in nanotechnology environments was not found in the literature. However, many researchers (e.g. Jayawarna and Holt, 2009; Kumar and Boyle, 2001; Robins *et al.*, 2006) have written about the importance of implementation of QMSs and the related MSSs in R&D. While a substantial amount of literature exists today on adapting QMSs in R&D environments (e.g. , Biré *et al.*,2004; Ferguson *et al*, 2006), not much has been written about the practical usage of R&D-specific MSSs. Therefore, further research in this area can improve our understanding on how these particular MSSs can be implemented. In particular, it would be interesting to see if MSSs for R&D are also applicable in firms involved in nanotechnology.
- Castillo et al (2008) suggested that quality (e.g. ISO 9001) and innovation (e.g. UNE 166002:20060) standards be compared and analyzed in order to see how complementary they are. The similarities between ISO 9001:2008 and UNE 166002:2006 (see

Subsection 2.4.2.2) suggest that the new R&D&I requirements can be used to expand or "augment" the scope of a QMS. A study of the application of R&D&I MSSs in an ISO 9001-registered company will help in assessing their compatibility with quality MSSs.

With regards to the integration of multiple MSS requirements:

- Researchers (e.g., Biré *et al.,*2004; Henri *et al.,* 2009; Vermaercke, 2000) believe that no single existing standard provides complete guidance for managing a standardized R&D system. A combination (i.e., integration) of the requirements of multiple standards and supplementary items from R&D guidelines is recommended. Biré *et al.,* 2004 refers to these systems as "hybrids". However, details on the actual procedure that had been used to incorporate these multiple sets of requirements was not found. Therefore, a study describing the process or methodology involved with integrating the requirements and guidelines from multiple MSSs in an R&D environment also presents a unique research opportunity.
- Some nanotechnology companies are ISO 9001:2008 or ISO 14001:2004 registered, and therefore with the implementation of R&D MSSs, integration is likely required. This is facilitated by the emergence of R&D&I MSSs such as UNE 166002:2006, which are designed to be integrated with other pre-existing MSs in an organization. Therefore, as stated earlier, there is an opportunity to study whether R&D&I MSSs can be used to augment existing the existing MS in a nanotechnology company.
- The literature on integration primarily focuses on quality, environmental and safety management systems. Therefore, the integration of quality and R&D MSs provides an atypical integration scope that is novel.
- Literature describing the integration of MSSs using the methodology described in the ISO IUMSS Handbook (ISO, 2008) is scarce. The integration of multiple R&D MSS into the CSO's MS will be the second known practical application of the IUMSS Handbook, and will be a study for evaluating the IUMSS Methodology itself. The methodology contained within the Handbook is well-suited for a nanotechnology company, as it is flexible and can be applied to all sorts of organizations, yet detailed enough to provide the necessary guidance for a company inexperienced with of management systems and the integration of standards.

From a *business viewpoint*, the CSO, a Canadian MEMS foundry, can obtain the following benefits from this research project:

- Suggestions for improvement to its current ISO 9001-based QMS through the integration of R&D&I MSSs. A major reason for such motivation is that R&D is an area where the CSO encounters problems and challenges.
- Comprehensive guidance on how to integrate the requirements of the new R&D MSSs (and other future MSSs) into its current QMS.

To sum up, three main areas of motivation (two academic and one business) form the basis for this research:

Motivation #1: The application of MSSs in R&D and nanotechnology environments.
***Motivation #2*:** The integration of multiple MSS requirements using the IUMSS methodology.
***Motivation #3*:** Details on how to integrate the new R&D MSSs into the CSO's QMS and suggestions for its improvement.

2.8 Objectives of the proposed research

Three primary objectives can be drawn from the three main areas of research motivation listed in sub-section 2.7.

***Objective #1*:** Investigate the application of R&D-specific MSSs (in particular, UNE 166002:2006 and EARTO:2000) in a nanotechnology setting and their compatibility with quality MSSs (ISO 9001:2008). This is addressed throughout Chapters 4-6.

Objective #2: Test the IUMSS methodology in a real life nanotechnology setting (represented by the CSO) by showing how its steps can be applied to integrate the requirements of R&D&I MSSs into an existing QMS:

Sub-Objective 2.1: Address the need for integration, and the benefits and potential challenges (Chapter 4).

Sub-Objective 2.2: Select appropriate R&D MSSs to incorporate into the CSO's MS and determine their impact (Chapter 4).

Sub-Objective 2.3: Determine how the selected MSS requirements apply to the CSO's MS (Chapter 5).

Sub-Objective 2.4: Conduct a gap analysis of the CSO's QMS against the R&D MSSs, and develop ideas to close the gaps found (Chapter 6).

Sub-Objective 2.5: Describe the activities required to maintain and improve the IMS (Chapter 7).

Objective #3: Make recommendations to improve the QMS in the CSO:

Sub-Objective 3.1: Determine the current state of the QMS and assess issues and opportunities for improvement (Chapter 3).

Sub-Objective 3.2: Develop suggestions to assist the CSO in complying with the R&D MSS requirements, and in creating a fully-integrated Quality/R&D&I MS (Chapters 6 and 7).

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3. IUMSS methodology application at the CSO

3.1 Introduction

As mentioned in the previous chapter, one of the main research goals was to test the IUMSS methodology in nanotechnology oriented organizations. To accomplish this, a case study approach was taken, using the CSO as the subject. Initially, the choice of the CSO was a university facility, where pure nanotechnology research was carried out. However, the director of this facility suggested that a MEMS development company based in Western Canada would provide a closer representation of the type of environment one would find in a commercial nanotechnology company (i.e., a company that is very much focused on R&D efforts, but also conducts fabrication and other traditional manufacturing activities). Also, the CSO was selected because it already had a standardized ISO 9001-based QMS in place, with quality manuals, documentation and procedures available.

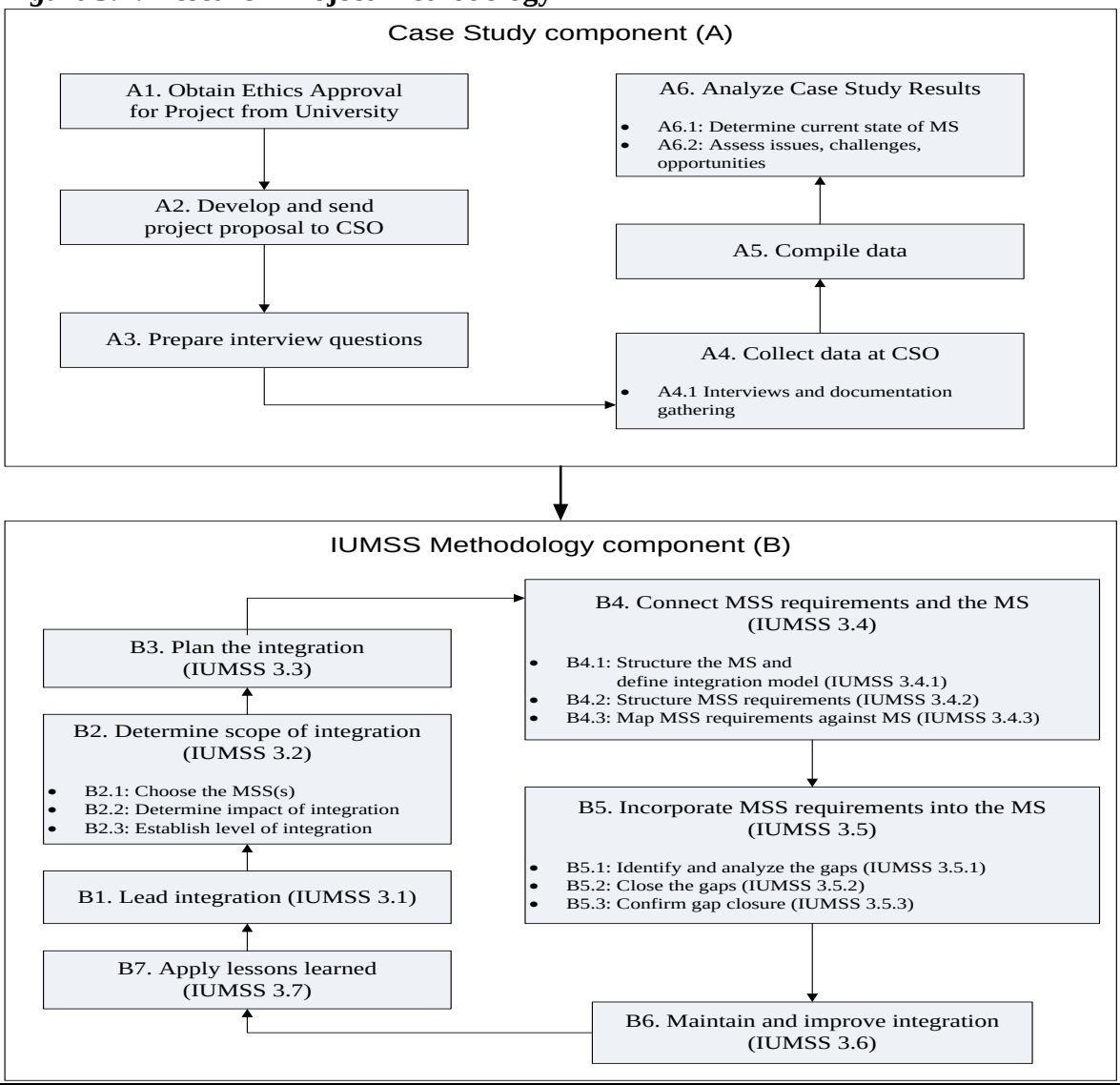
Since a QMS was already established at the CSO, the project of applying an R&D MSS into the organization meant incorporating new requirements into the existing system. As alluded to in section 2.6 of the thesis, this meant that the requirements of the new R&D MSS needed to be combined, or integrated, with the requirements of the existing ISO 9001-based QMS. Furthermore, the associated MS processes would also need to be integrated as much as possible. The methodology from IUMSS Handbook (ISO, 2008), presented in Subsection 2.6.2, was chosen as a framework for integrating the requirements of the R&D&I MSSs into the CSO's QMS. Since the CSO was purely used as an academic case study, the application of the MSSs was solely intended to provide suggestions to the CSO on how the standard requirements could be integrated within their existing QMS. The scope of the project did not include implementing any actual changes to the system.

The flowchart illustrated in *Figure 3.1* details the Research Project Methodology that was used in this study. The case study component of the project involved six steps (labeled A1 through A6), the most important of which was the collection of the practical data at the CSO (Step A4), necessary for applying the steps of the IUMSS Methodology. The steps followed in the IUMSS

Methodology component of the project (labeled B1 through B7) were based on the sections from Chapter 3 of the IUMSS Handbook. For example, Step B2 in the Research Project Methodology corresponds to sub-chapter 3.2 of the Handbook. The research steps referred to throughout the remainder of this thesis correspond to the steps outlined in the Research Project Methodology (*Figure 3.1*).

The remainder of this chapter will discuss Part A of the Research Project Methodology (the Case Study component). Chapter 4 covers Steps B1 to B3, Chapter 5 addresses Step B4, Chapter 6 discusses Sub-Steps B5.1 and B5.2, and Chapter 7 covers Sub-Step B5.3, Step B6 and Step B7.

***Figure 3.1*: Research Project Methodology**



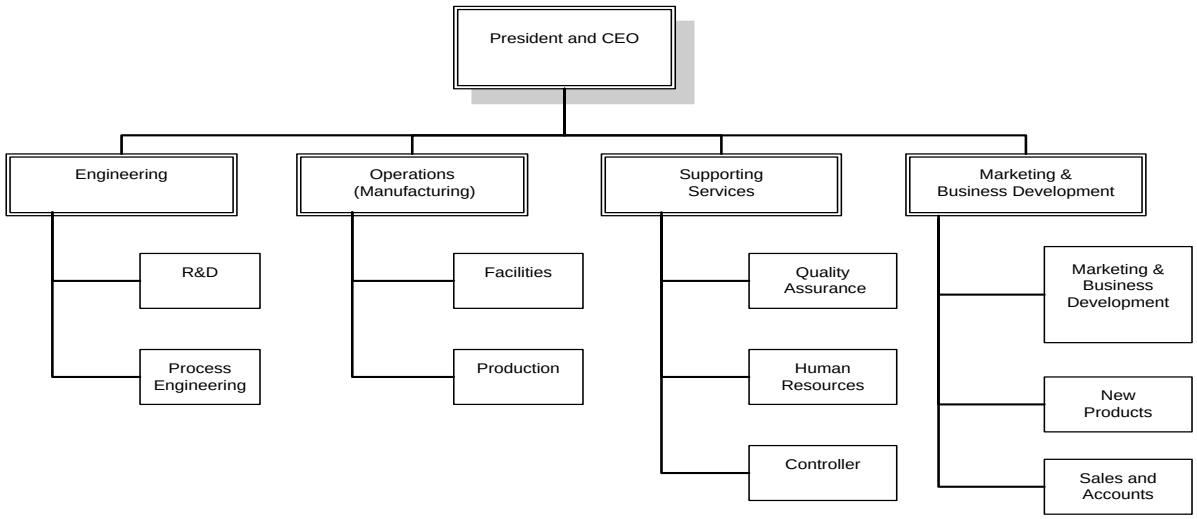
3.2 CSO Background

The organization being studied is one the largest independent MEMS foundries in the world, and employs more than 200 people at its headquarters in Western Canada. The CSO's core business is the development and manufacturing of miniature MEMS components. The company provides a combination of both MEMS development for customized applications and fabrication/manufacturing services for standardized processes. The foundry is a partner for a diverse set of clients, which includes both the Fortune 500 firms and high-technology start-up companies in the communications, energy, life sciences, and transportation markets (CSO's website, 2009). More specifically, the CSO's products are found in emission sensors for automobiles, electronic guidance systems for jets, optical switching technology in telecommunication networks, lab-on-a-chip devices for drug discovery, and commercial prepress equipment for printing magazines (CSO's website, 2009).

The CSO regularly partners with the University of Alberta in licensing technologies developed by the university for commercialization purposes. Unlike a typical pure nanotechnology R&D company or a semiconductor manufacturer, the CSO has the capability and experience to produce products at both high and low volumes.

Figure 3.2 shows the corporate structure of the CSO (extracted from the CSO's QMS documentation). Namely, the CSO is organized into four main departments (Engineering, Operations, Supporting Services, and Marketing & Business Development), which are broken down into business units.

***Figure 3.2*: CSO Corporate Structure**



3.3 Data Gathering at the CSO

Before the IUMSS Methodology could be applied, it was necessary to gather and compile the relevant data at the CSO in order to understand the current status of its QMS. This set of activities formed the first part of the Research Project (Part A). Information about the CSO's MS was obtained through a series of interviews with employees involved in the MS, and from the existing QMS- related documentation at the CSO. Since the data gathering process in the project involved human subjects, a Request for Ethics Review (RER) was sought and approved prior to the project start (Step A1). *Appendix B-1* details the RER application.

A proposal summarizing the project, the objectives and the schedule was prepared and sent to the CSO prior to the onsite data collection (Step A2). In the Project Proposal sent out to the CSO, interviews with the QA Coordinator and other representatives from the areas related to quality, environment, and health and safety, were planned for the case study. However, the final selection of the interviewees was finalized by the CSO, depending on their familiarity and involvement with the MS, as well as their availability.

To help with the interview process, a list of questions was prepared (Step A3) prior to the meetings (see *Appendix B-2* for a list of sample questions that were used). During the interview, these questions were generally adhered to. However, relevant questions were added during the course of the interview and irrelevant questions were subtracted. Brief notes of the interviews were recorded during the meetings. Care was taken in drafting interview questions to ensure a descriptive answer was required in order to obtain optimal information regarding the MS activities and processes. Therefore, open ended questions were designed, rather than questions that merely required "yes/no"-type answers. Furthermore, the questions asked were non-personal and strictly related to the company's quality and other MSs, which helped prevent biased answers.

The following data collection activities were carried out onsite at the CSO (Step A4):

1) **Preliminary meeting with the QA Coordinator**
   In this meeting, the thesis project was introduced to the CSO and topics for discussion were set up. The onsite meeting schedules were also finalized.
2) **Interview with a QA employee**
   During this meeting, the CSO's expectations for the project were discussed. The current QMS practices at the CSO were introduced. Some challenges and issues that were present were also identified.
3) **Interview with the QA Coordinator and gathering of QMS documentation**
   In this meeting, views of the QMS from the QA Coordinator were collected.
4) **Interviews with other employees involved in MSs**
   An R&D employee was interviewed and views of the QMS from the R&D perspective were collected in this session. The Health and Safety (H&S) coordinator was also interviewed and brief information about the H&S MS was obtained.

The interviews were all semi-structured interviews conducted face-to-face. Before each meeting, all interviewees read an information letter containing details of the project (*Appendix B-3*), and signed a consent form (*Appendix B-4*).

The Quality Manual, as well as the related QA procedures and flowcharts depicting the processes deployed along the product life cycle at the CSO were collected. Technical documents (which include quality plans, work orders, work instructions and specifications) and record forms were not available for the study. This company documentation was used to obtain the details on the QMS, and supplied the bulk of the information for the thesis project. The main purpose of the interviews was to identify some of the challenges and issues that were perceived to exist at the CSO regarding the usage of an ISO 9001-based QMS, which otherwise could not be determined solely from company documentation. After the employees' answers and opinions were recorded, the information from the meetings was compiled and transferred into an electronic file (Step A5). *Table 3.1* provides an excerpt of some of the interview answers that were obtained.

Table 3.1: **Sample of interview answers**

What are some of the direct benefits that stem from the use of management system standards at your organization?
• ISO 9001 provides a structure for quality, consistency, and set procedures to follow for the employees. • Processes are standardized with the suppliers. • Provides quality assurance and confidence to customers. • However, there does not seem to be much direct link to decreasing non conformities. • Continuous improvement is a clear benefit. • Advantage of regular reviews is helping to evaluate how effective the system is.
What are some of the challenges involved with the use of standards in a nanotechnology setting?

• ISO 9001 is primarily set up for manufacturing settings, and not for innovative R&D environments (which are regularly found in nanotechnology companies).
• Several challenges exist in R&D with regards to QMS standardization:
  • Different needs and requirements from product to product.
  • End result often unclear.
  • Many products made are just one-off production items. The rigor of ISO 9001can mean too much work for the items that are not mass produced.
  • Many R&D outputs are in the form of reports, experimental data and drawings.
  • ISO 9001 requirement for document control, when applied to R&D can be very time consuming and since many procedures are performed only once.
  • ISO 9001 does not fully cover elements of R&D.

Table 3.1: **Sample of interview answers (Continued)**

What are some of the challenges involved with the use of standards in a nanotechnology setting?
• ISO 9001 is not geared towards innovative R&D activities. Therefore R&D work has been exempted from the ISO 9001:2000 requirements, which occasionally causes complications. During R&D work, standardized procedures are not used. New procedures are created as needed by the company during the development of customized products. • Since R&D is exempted from the QMS requirements, requirements that are not met up front at the R&D stage carry through to the manufacturing stage (which is not excluded from the QMS). This sometimes leads to a lot of work being redone in order to meet the standard documentation requirements, leading to delays and extra work.
How could these standards be better tailored towards a research intensive and high-tech environment such as nanotechnology?
○ Not too many specific improvements to ISO 9001 can be made to aid R&D. ○ ISO 9001 is too general, therefore specific guidelines for R&D would be helpful. • Because of the exemptions/exclusions that are sometimes made, the standard needs a mechanism to ensure that certain requirements are met at all stages of the product life cycle.

3.4 Case Study Results

From the answers provided in the interviews, along with the data extracted from company documentation, the current state of the QMS at the CSO was estimated (Step A6.1). Although interview data regarding the Health and Safety MS was also obtained, this information was not used since the focus of the project was on QM. The following sections also summarize the issues and challenges the CSO is facing, and provide a listing of some of the potential improvement opportunities that stem from those issues. QMS procedures at the CSO are prefixed with the letters "*QASP*". This abbreviation will be used throughout the remainder of the thesis. A full list of the QMS procedures referenced in the thesis is provided in *Appendix C-1*.

3.4.1 Current QMS status at the CSO

The QMS at the CSO is currently registered to ISO 9001:2008 and has been in place for more than 10 years. However, the 2008 edition of ISO 9001 was not available at the time this research study was conducted, and therefore ISO 9001:2000 was used

Since the CSO is ISO 9001 registered, all basic QMS requirements and documentation are in place. For example, the CSO's quality policy statement reads: "*To meet or exceed both internal and customer requirements 100% of the time and continually improve the effectiveness of the quality system. Objectives: Outstanding customer feedback, no product returns, on-time*

delivery". "Internal requirements" refers to the requirements of Internal Research projects (which are occasionally carried out by the CSO), that lack an external customer. An example of such a project would be a MEMS fabrication technology developed internally by the CSO that has the potential of enhancing its existing methods.

Most noteworthy, R&D projects (called "research contracts" at the CSO), are excluded from the scope of the QMS and ISO 9001:2000 registration. "Research contracts" at the CSO are a group of projects that are not ready for manufacturing and include investigative work to determine the feasibility and requirements of a concept. Products developed at this stage primarily consist of one-off production items and experimental prototypes with high design variability. Furthermore, some of the outputs at the research stage are intangible (i.e., in the form of reports, experimental data and design drawings).

It is believed by the CSO that the rigor of ISO 9001 is not warranted for R&D work, as most of the outputs produced are of limited volume and are highly variable, with requirements greatly differing from project to project. This has led to research contracts being exempted from the QMS. Once feasibility of a concept has been established and the requirements are understood, a decision is made to move into the next stage of development (i.e., "Engineering Build") where the design activities are controlled by the QMS.

The CSO has also adapted "Advanced Product Quality Planning" (or APQP) concepts to support their product design and development processes. The APQP concepts were compiled into a procedure (QASP-037), which the CSO has named "MPQP".

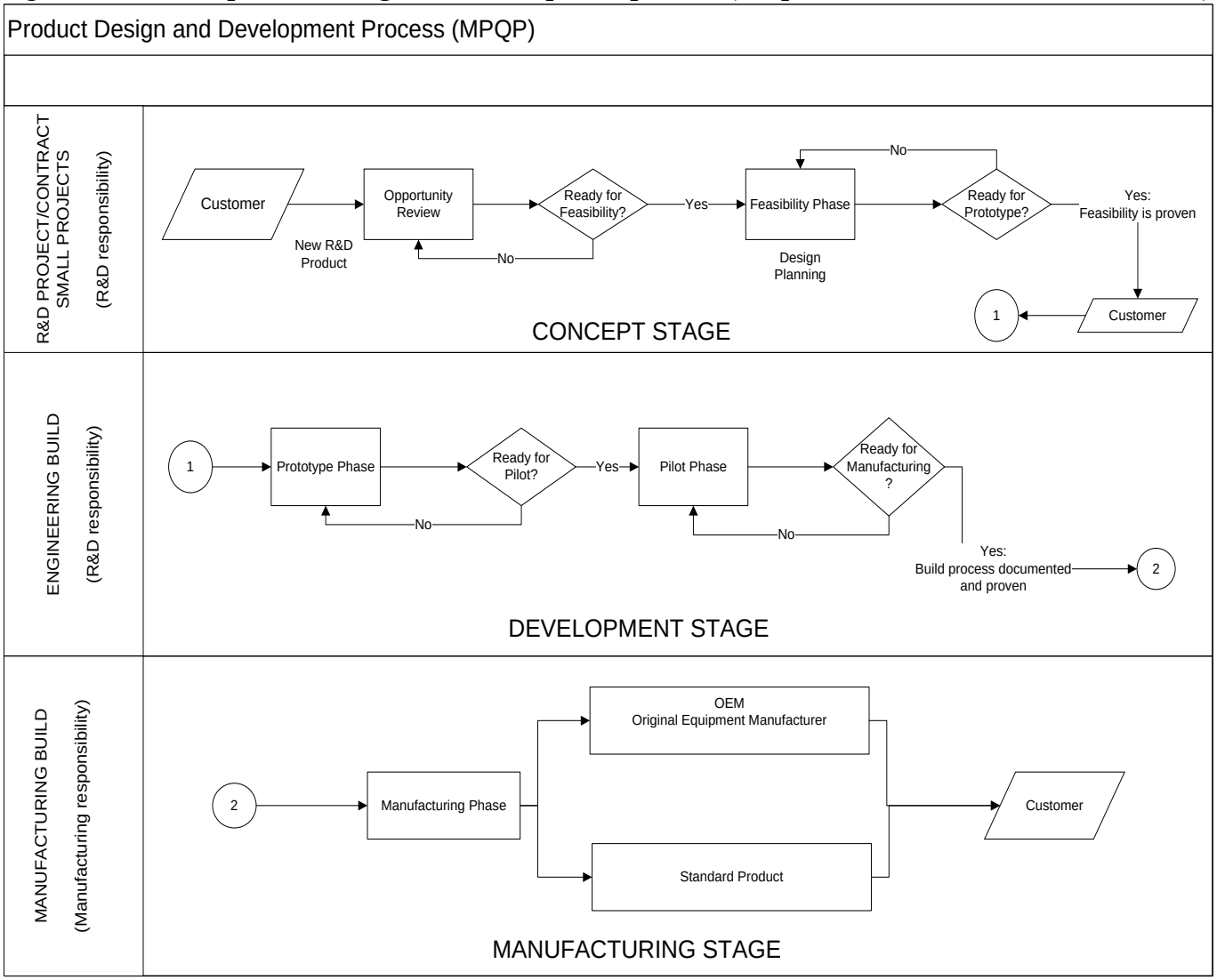
In MPQP, all new projects and product lines progress through series of development phases from the "Opportunity Review" to the "Manufacturing phase". In order to move to the next stage, the project must meet certain pre-determined requirements (called "gate requirements"). Furthermore, prior to commencing each stage, requirements for review, verification and validation are determined. The CSO believes that this strategy helps minimize risk in projects. By reviewing a project at the end of each phase or stage of development, the company can identify projects or products that are unlikely to be successful before resources are wasted. If the

project or product fails to meet established criteria, the project is scrapped. If it meets them, resources sufficient to enable it to reach the next development stage are allocated.

Figure 3.3 shows the flowchart of the entire product design and development process with the various development phases.

According to the CSO, APQP improves upon ISO 9001 by providing additional guidelines for the product design and development process (in particular, R&D work benefits the most from these guidelines). It was later found (specifically, during Step B5.1 of the project) that the guidelines adopted from APQP (listed in QASP-037) allowed the CSO to meet many of the design and development requirements from the R&D standards. Furthermore, APQP has helped streamline the CSO's product development operations. For example, it has helped project managers determine when projects are profitable and should be continued, facilitated project management and ensuring deadlines and milestones are met, and improved the logistics of projects. In the thesis, the APQP guidelines found in QASP-037 were analyzed. More details on the QMS will be provided in Section 5.2 of the thesis, where the MS is structured (Sub-Step B4.1).

***Figure 3.3*: CSO's product design and development process (adapted from the CSO documentation)**



3.4.2 Assessment of issues, challenges and opportunities

Based on the employees' opinions and the answers collected from the interviews, several issues that exist in the CSO regarding its QMS were identified (Step A6.2). Potential solutions to these issues that present improvement opportunities to the MS were formulated. *Table 3.2* shows an analysis of issues/challenges and the opportunities that stem from them.

***Table 3.2*: Assessment of issues and challenges at the CSO and the related opportunities**

Issue/Challenge	Opportunity
Research contracts are excluded from the current standardized QMS requirements. This is seen as a problem since documentation that is not prepared up front at the R&D stage affects product life cycle stages down the line (which are bound by QMS requirements). At times, it is not until the manufacturing stage that a particular documentation is found to be missing, leading to rework and delays in production.	Include R&D work in the standardized quality system, keeping in mind that the system should be tailored for R&D (Kumar and Boyle, 2001), with procedures designed to be as flexible as possible (Mathur-De Vre, 2000, Robins *et al.*, 2006).
Given that R&D contracts are excluded from the scope of the QMS, standardized operating procedures are not used in R&D work. Instead, new procedures are created as needed by the R&D staff. Furthermore, as most of the outputs in an R&D project are one-off production items, most of these procedures are never used again.	The application of a MSS with documentation requirements will aid greatly with the CSO's documentation issues.
Since R&D employees are given the freedom to craft their own procedures, documented procedures supporting the R&D processes are non-structured, inconsistent and sometimes non-existent. Currently, R&D procedures consist of documents with list of generic steps involved in the process (with lots of blanks). The missing information (blanks) are filled in as the project is carried out.	The generic nature of the procedures is necessary to maintain flexibility in R&D work, however, these documents can be standardized using generic templates, which will provide a basic structure and help establish consistency.
According to the R&D employee interviewed, ISO 9001 does not address many elements of R&D, and is therefore perceived to be primarily set up for manufacturing settings, and not innovative R&D environments. The same employee also believes that a set of specific R&D/Nanotechnology/MEMS development guidelines would be desired at the company.	Opportunity to select and implement a new MSS more suitable for R&D, which can be integrated on top of the existing ISO 9001:2000 based QMS.

Table 3.2: **Assessment of issues and challenges at the CSO and related opportunities (Continued)**

Issue/Challenge	Opportunity
Procedures are in place, but are occasionally not followed, especially in the R&D business unit (e.g. In one instance, the R&D personnel were not aware of a procedure and used the wrong revision of a document. This led to an incorrect mask design sent to accounting, which resulted in the wrong mask being ordered).	Include R&D work in the scope of the QMS, and reacquaint R&D staff on the responsibilities, policies, objectives and procedures of the quality system. This can be accomplished through mandatory attendance to information sessions which will review the applicable manuals and system procedures.
The bureaucratic nature of QMS (e.g. documentation requirements such as filling out forms) is often cumbersome and time consuming. However, these documentation requirements also lead to more complete records.	The CSO's goal is to move to a paperless (electronic) documentation system once the technical aspects can be sorted out (e.g. not having enough computers on shop floor)
Value-added benefits of MSSs not perceived by some personnel (from R&D and H&S).	Create employee commitment to the standardized MS by involving them in its design. Ensure they understand the benefits of an MSS, and the relationship of the MSS requirements to their jobs (e.g. through workshops and training)
CSO would like to see the integration of ISO 9001, 14001, APQP, and other related standards in the future (e.g. ISO 16949 for their automotive customers)	Provide comprehensive methodology for the integration of multiple MSSs, and explain how the methodology can be used.

3.5 Summary

This Chapter presented the overall Research Project Methodology to be used in this study. The Case Study Organization (CSO) was introduced, and a summary of the current state of its QMS presented. Based on the data collected from the CSO, an assessment of issues, challenges and opportunities for improvement was made.

4. Establishing the Integration

4.1 Introduction

This chapter will present the first three steps of Part B of the Research Project Methodology (The IUMSS Methodology component) - namely Step B1: Lead the integration, Step B2: Determine the scope of integration, and Step B3: Plan the integration.

Once the current state of the CSO's MS was determined, and an assessment of issues and opportunities performed, it was possible address both the benefits and potential challenges of integration. This was the main activity carried out in Step B1.

After making the decision to integrate the requirements of multiple R&D MSSs into the MS, the scope of the integration process was established (Step B2). Using the guiding questions provided in IUMSS Handbook (ISO, 2008, p.78), three aspects of determining the scope of integration were addressed:

a) Choosing the specific MSSs to be implemented
b) Determining the impact of integration on the existing MS
c) Establishing the level of integration

4.2 Lead the integration (Step B1)

Three main opportunities for enhancing the current MS were identified after the assessment of issues and challenges identified in Subsection 3.4.2:

a) Extend the QMS requirements to cover all R&D work.
b) To address the issue of ISO 9001:2000 being deficient in terms of R&D specific guidelines, the requirements of a new R&D-focused MSS could be incorporated (i.e. integrated) into the existing QMS.
c) Provide the CSO with details on how to apply the IUMSS methodology for integrating the requirements of the new R&D MSSs and other future MSSs into the existing MS.

The following issues and opportunities were outside the scope of this research, and could not be seized due to the limited interaction with the CSO:

- The design of specific content on procedural templates.
- The implementation of an electronic documentation system.
- Creating employee commitment and understanding of the standardized MS.

4.2.1 The need to integrate

According to the IUMSS handbook, the implementation of MSSs in an organization is driven by the customers and stakeholders, as well as the regulatory or internal organizational needs (ISO, 2008, p.80). The Handbook further explains that reasons for implementation are either reactive (where the organization is confronted with the requests from the customer or other stakeholders) or proactive (where the organization is interested in internal improvement and anticipation of future customer or stakeholder demand) (ISO, 2008, p.51). In this study, the decision to integrate was proactive and driven by internal organizational needs. The CSO was looking to improve performance in a particular functional area (i.e., R&D).

4.2.2 Benefits and challenges of integration

4.2.2.1 Benefits

The benefits of implementing a standardized MS in R&D were presented in Subsection 2.3.3, while benefits of implementing some of the specific MSSs were mentioned in Subsection 2.4.2. In addition, the IUMSS Handbook mentions two other benefits of integration:

- "*Establish consistency*" (ISO, 2008, p.71): The standardization of R&D work at the CSO may promote more structured documentation and procedures design at the R&D stage, through the usage of standardized procedures and records. This will eliminate the issues of missing or inconsistent documentation downstream at the manufacturing stage, which may lessen the delays in processing and improve efficiency. Consistency may also be reflected in the "*communications of policy and direction"* (ISO, 2008, p.71), since an IMS requires the creation of a common policy, and helps ensure that all employees are working towards the same strategic goals at the CSO. Due to improved consistency

under a single IMS, communication between R&D and the other departments may improve.

- "*Facilitate decision making*" (ISO, 2008, p.76): The MSS requirements include performing MS maintenance and improvement activities, such as regular audits and management reviews. Including all R&D activities in these reviews may help the CSO obtain a "*more complete view of the functional needs and performance of the business*" (ISO, 2008, p.76), especially with regards to R&D performance and needs.

The integration of R&D MSS requirements into the existing ISO 9001-based QMS should theoretically create a system more suitable for R&D processes and ensure a better coverage of nanotechnology development issues (e.g., novel products having unique requirements and the aspect of innovation).

4.2.2.2 Potential challenges

The challenges and limitations of QMS implementation in R&D were discussed in Subsection 2.3.4. *Table 4.1* relates some of those challenges to the CSO. It can be seen that these issues are also relevant for companies involved in nanotechnology development.

Table 4.1: **Limitations of implementing QMSs in R&D and how they affect the CSO**

Potential challenge/limitation identified from the literature	***Applicability to the CSO***
The idea that certain aspects of QMSs and R&D activities can be contradictory (Valcárcel and Rios (2003).	R&D personnel at the CSO perceive that ISO 9001 is primarily set up for manufacturing settings, and not innovative R&D environments.
Inflexibility and rigidity of standard requirements might restrict freedom (Jayawarna and Pearson, 2001; Mathur-De Vre, 2000), creativity (e.g. Jayawarna and Pearson, 2001; Jayawarna and Holt, 2009; Kondo, 2000; Krapp, 2001; Mathur-De Vré , 1997), and innovation (Prajogo and Sohal, 2004, 2006).	Since research work at the CSO is currently excluded from QMS requirements, this could become a challenge if QMS requirements are extended to cover all R&D work.
	As for the manufacturing aspects of nanotechnology development, the inflexibility of standards is not seen to be an issue at the CSO (as perceived by quality assurance team). They felt that ISO 9001 is very generic and dependent on how the company interprets the requirements. Changes can be made depending on how the standard is viewed.
Requirements from generic standards for QMS need to be adapted carefully or tailored for R&D (Krapp, 2001; Kumar and Boyle, 2001).	It has been perceived by the CSO that ISO 9001 is not entirely suitable for R&D environments. As mentioned earlier, this can be addressed through the introduction of the R&D MSSs.
The importance of designing quality systems that focus on creating conditions that foster inquiry; and developing procedures that "*assist in the exploration for and exploitation of strategically relevant knowledge*" (Jayawarna and Holt, 2009)	Innovation and problem-solving is important for any R&D intensive environment (such as MEMS/nanotechnology development). An even more important concern for nanotechnology companies is the commercialization of R&D results (i.e. the "exploitation of relevant knowledge"). The CSO's business philosophy is to "*always have in mind the end goal of commercialization and to successfully bring each customer's product into the marketplace"* (CSO's website, 2009).
Increased bureaucracy and administrative paperwork (Jayawarna and Pearson, 2001; Jayawarna and Holt, 2009).	The CSO also believes that additional documentation requirements can be time consuming.
Selection of a suitable MSS for R&D (Mathur-De Vre 1997, 2000).	Particularly relevant, since the implementation of a new R&D focused MSS has been proposed as an opportunity for MS improvement.

4.3 Determine the scope of integration (Step B2)

4.3.1 Choose the MSSs to be implemented (Sub-Step B2.1)

The first task was to determine which MSSs would be implemented in the CSO. A number of relevant MSSs and guidelines for R&D environments were identified in the literature review (Section 2.4) and an assessment for their suitability for integration was performed. Factors such as cost of the standard, availability, and comprehensiveness were taken into account. Based on the assessment, it was decided that UNE 166002:2006 and EARTO:2000 be used for the reasons provided below.

4.3.1.1 UNE 166002:2006

UNE 166002:2006 was one of the few MSSs made specifically for R&D&I that were available in English. BS 7000-1:2008 was also seen as an alternative, but was later found to be too costly for use. This is a point of particular importance for smaller nanotechnology start-ups, which might not have the resources to purchase highly-priced standards. Furthermore, UNE 166002:2006 can be used for managing the R&D&I activities in any organization. It contains all the requirements needed to design a complete MS and is fairly up to date (published in 2006). Its use in several countries also suggested that the standard's applicability has been validated. Most importantly however, the requirements and structure of UNE 166002:2006 are closely aligned with ISO 9001:2000, which is already in place at the CSO. This increases the compatibility of the standards and greatly facilitates integration, as it becomes much simpler to make direct comparisons between the respective requirements.

4.3.1.2 EARTO:2000

The EARTO (2000) guidelines are free for public use and were found to address QM, technical competence, and project management, aspects which Mathur-De Vré (2000) believed to be important in an R&D standard. Its requirements also encompassed the elements of other R&D guidelines (namely EURACHEM/CITAC Guide 2:1999, ISO 17025, and OECD GLP:1999). Furthermore, EARTO:2000 is catered for research and technology organizations, which the CSO (being a nanotechnology company), is an example of. Like UNE 166002:2006, EARTO:2000 is

designed to be compatible with ISO 9001 and other related QMS standards. According to the document, the guidelines "*have been formulated so that they do not contradict the requirements that stem from other documents that the RTO may have to follow*" (EARTO, 2000).

4.3.1.3 Using two MSSs instead of one

In general, these two documents complement each other. UNE has a strong focus on product design and development, whereas EARTO addresses organizational wide issues not found in UNE 166002:2006/ISO 9001:2000, such as ethical codes of conduct. As was mentioned in the literature survey, EARTO:2000 supplements and provides additional guidelines for ISO 9001:2008 and UNE 166002:2006.

If we recall the discussions of quality in the R&D context (Chapter 2.3.1), both UNE 166002:2006 and EARTO:2000, in a sense, can be viewed as a quality MSS for R&D&I functions in an organization. For example, taking Bire's (2004) ideas of "quality in research" and "quality of research", it can be seen that Sections 3 and 4 of EARTO:2000, addressing "QMS requirements" and "Technical Competence" respectively, are related to "quality in research", or the way research activity is conducted. Section 5.3 of EARTO:2000 touches on "quality of research", since it addresses how the quality of completed research work is reviewed. UNE 166002:2006, although designed for managing R&D&I, is also related to the QM of R&D. *Table 4.2* shows how some of Kumar and Boyle's (2001) criteria of quality in R&D can be connected to the related clauses in UNE 166002:2006.

***Table 4.2*: Kumar and Boyle (2001) quality criteria and UNE 166002:2006**

Kumar and Boyle (2001) quality criteria:	**Related UNE 166002:2006 section(s)**
"What the key technologies are and how they can be used to meet client expectations and the needs of the entire organization"	4.4.1.1: Technology Watch 4.4.1.2: Technology Foresight 4.4.1.4: External and internal analysis 4.4.2: Identification and analysis of problems and opportunities
"Who the competitors are how they will respond to emerging customer needs"	4.4.1.4.1: External analysis
"Doing things right once you know you are working on the right things, concentrating on continually improving your system"	4.5.7: Improvement
"Enabling people by removing barriers and encouraging people to make their maximum contribution"	4.3.2.2: Motivation of the personnel 4.4.1.3: Creativity
"An understanding of who the R&D client is and his/her values and expectations"	4.2.2: Interested parties approach

The close relationships of these R&D&I MSSs with QM suggested that they should be integrated with the CSO's QMS. It further implies that UNE 166002:2006 and EARTO:2000 can be used to augment ISO 9001:2000.

4.3.2 Determine the impact of the integration (Sub-Step B2.2)

After determining which standards will be integrated into the MS, the IUMSS handbook advises that the impact of the integration on various organizational areas and the existing MS be determined (ISO, 2008, p. 78). Only the impact on the CSO's QMS was analyzed, since other MSs, such as Health and Safety or the Environment were not considered. This was because:

- the majority of the case study data collected was related to the CSO's QMS
- the QMS was the only MS in the CSO that was standardized (i.e., an informal health and safety MS exists at the CSO, but does not follow a particular standard)
- as mentioned in the previous subsection, the two R&D MSSs chosen to be implemented are closely related to quality management in R&D.

The Handbook provides a series of questions (ISO, 2008, p. 80) to consider that proved useful in analyzing the impact of integration. Two of those questions are addressed below.

What parts of the organization will be impacted?

As both UNE 166002:2006 and EARTO:2000 have an organization-wide scope, all parts of the organization were thought to be affected by the new requirements of the MSSs. The policies of the CSO would also be impacted, as UNE 166002:2006 introduces an R&D policy requirement.

Who will be impacted by the integration?

Any personnel involved with the company's QMS would be impacted. It was suspected that the most impact would be felt by the R&D business unit, since R&D processes were excluded from the standardized QMS requirements.

4.3.3 Establish the level of integration (Sub-Step B2.3)

Lastly, the IUMSS handbook specifies that the degree or level of integration be established (ISO, 2008, p.78). The Handbook does not go into much detail regarding the level of integration. However, Bernardo *et al.* (2009) provide an overview of this topic in detail. In general, they mention that various authors have different views on the degree to which an organization may decide to integrate their MS, ranging from "no integration" ("level 0") to complete integration ("level 3").

The level of integration is a management decision, and since interaction with the CSO's management was limited, it could not be established with certainty. It is possible that the CSO might choose to integrate company documentation and common MS processes found in both the existing QMS and the new R&D&I MSS.

With regards to integrating documentation, it is likely that a common IMS manual (containing both quality and R&D MS elements) would be created, since the R&D MSS requirements are to be integrated throughout the entire company, and not just the R&D business unit. This IMS manual would make reference to both the relevant quality and R&D&I MS procedures. Policies and objectives might also be integrated, as Bernardo *et al.* (2009) suggest that these strategic elements of the MS are most likely to be the first documentation sources to be integrated. Furthermore, it would make sense for the CSO (being an R&D-oriented organization), to incorporate R&D aspects into its IMS manual and corporate policies.

Examples of common MS processes the CSO might integrate include internal auditing, document control, and management review. More suggestions of where integration can occur are provided in Subsection 7.3.2.

4.4 Plan the integration (Step B3)

After determining the scope of integration (Step B2) and determining the MSSs to be implemented into the MS, a general plan for the actual integration was developed (Step B3). Since the IUMSS handbook was available as a guide, the remaining steps of the project (B4 to B7) were planned by applying the methodology as prescribed. *Figure 3.1* shows the steps that were to be followed. The Research Project Methodology shown in *Figure 3.1* formed the plan for the whole project and Step B3 ("Planning the integration") was considered as a sub-step of the overall project.

4.5 Summary

This chapter presented the activities involved in the first three steps of the IUMSS methodology, namely "Lead the Integration" (Step B1), "Determine the scope of integration" (Step B2), and "Plan the integration" (Step B3). In Step B1, the benefits and challenges for integration were addressed. In Step B2, two R&D&I MSSs (UNE 166002:2006 and EARTO:2000) were selected for integration. The impact of implementing these two MSSs in the CSO, and the extent to which integration would likely be established, were also discussed. In Step B3, a general plan for the integration of the MSS requirements into the QMS was prepared. With the current state of the MS determined, and the MSSs to be implemented selected, the next chapter will look at how the MSS requirements and the MS will be connected.

5. Connect MSS requirements with the MS (Step B4)

5.1 Introduction

The previous chapter established the state of the existing QMS at the CSO, and presented the first two steps of the IUMSS methodology. This chapter will present how the requirements of the selected MSSs apply to the organization's MS (Step B4). As suggested by Sub-Chapter 3.4 of the IUMSS handbook (ISO, 2008, pp.90-111), three sub-steps were performed:

a) Structure the MS (Step B4.1)
b) Structure the MSS requirements (Step B4.2)
c) Map the MSS requirements against the MS (Step B4.3)

Structuring the MS involved understanding all the components of the MS, and graphically depicting their relationships (forming a structured model of the MS, or a "QMS map"). Structuring the MSS requirements involved understanding the requirements contained in the MSSs and analyzing them for commonalities. Lastly, this chapter will outline how the MSS requirements were mapped against the MS. This involved relating the requirements of UNE 166002:2006 and EARTO:2000 (structured in Step B4.2) to the corresponding components in the MS (modeled and mapped out in Step B4.1).

5.2 Structure the MS (Sub-Step B4.1)

5.2.1 Activities performed in Sub-Step B4.1

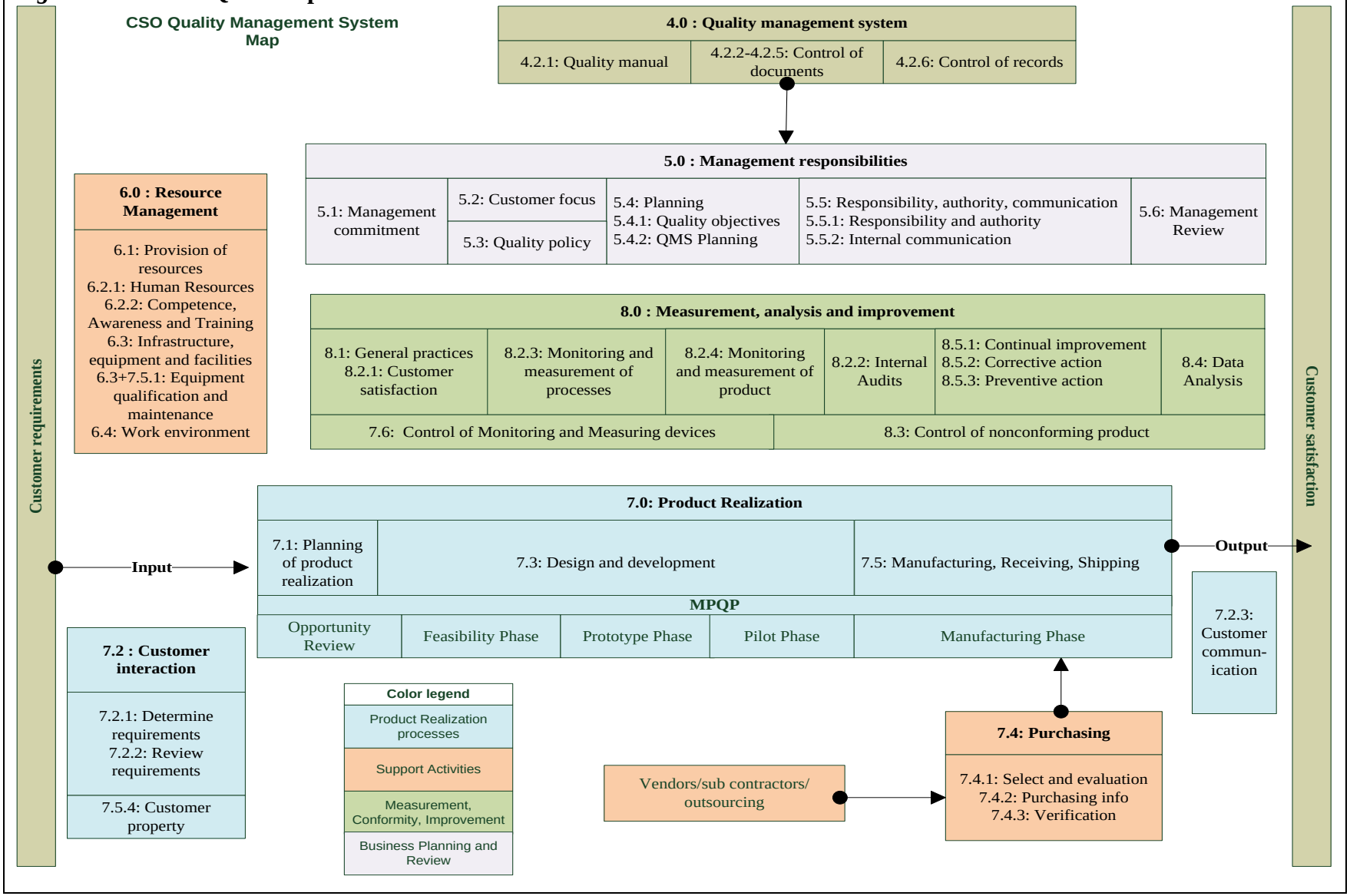
This step involved a detailed study of the CSO's QMS documentation in order to analyze the organization of the QMS and their components. Since the CSO was ISO 9001:2000 registered, most of the information was readily available in the Quality Manual. For instance, a quality process flowchart (also known as a "process map"), showing the sequence and interaction of the main QMS processes, was provided in the Quality Manual. This flowchart can be found in *Appendix C-2*. However, the flowchart was incomplete due to three primary reasons:

- Since its focus is on the procedures involved in product realization, it does not provide a high level overview of the entire QMS. As a result, certain processes of the QMS (e.g., monitoring and measurement of processes and the product) that were not linked to a specific procedure are not represented, and organizational resources (e.g., Human Resources and Work Environment) are not mapped,
- The product design and development phases described in MPQP (QASP-037-*Figure 3.3*), which the CSO heavily relies on during product design and development, were not incorporated.
- It is not clear where research, design and development activities are carried out.

A table of correspondence between the CSO's procedures and its ISO 9001-based QMS component(s) was also found in the Quality Manual. This table showed the linkages between processes and relevant procedures and was used as the basis for establishing the QMS structure. *Appendix C-3.1* shows a modified version of the original table found in the Quality Manual. The table illustrated in this appendix was modified by changing some the labels of the QMS elements to more descriptive names that reflected the actual processes. For example, QMS component 7.5, which was originally named "Production and Service Provision" was renamed to "Manufacturing, Receiving and Shipping". QMS component 7.2, originally named "Customer-related Processes" was renamed to "Customer Interaction". Also, some of the QMS components were broken down into sub-processes. For instance, the Customer interaction component was further divided into four processes (i.e., Determine requirements, Review requirements, Customer communication, and Customer property). Lastly, it was found that some procedures that are relevant to a particular process were not listed in the original table. For example, the Project Management procedure (QASP-006) was related to QMS component 7.1: Planning of Product Realization, yet this procedure was not listed.

Using the table presented in *Appendix C-3.1* as the underlying structure, the CSO's QMS components were graphically depicted into a QMS map (*Figure 5.1*).

***Figure 5.1*: CSO's QMS Map**



This QMS map, adapted from the Mandarin Oriental Hotel Case Study in the IUMSS Handbook (ISO, 2008, p.137), shows a graphical depiction of all the components in the QMS, and allows a better visualization of the entire system as a whole. The numbers in the map correspond to the ISO 9001:2000 clause numbers and can be used to reference a particular QMS component. As mentioned by the IUMSS Handbook, the product realization process provides the foundation and "the backbone" of the MS (ISO, 2008, p. 28). The Mandarin Oriental Hotel model was used because it contained many of the similar processes already found at the CSO, and provided an effective way of overlaying ISO 9001:2000 clauses on top of those processes.

5.2.2 Issues and lessons learned

The QMS map (*Figure 5.1*) helped address the three issues found with the CSO's QMS process flowchart by:

- Providing a high level overview of all components of the QMS (including processes and elements not associated with a particular procedure, such as Human Resources and Work Environment),
- Incorporating the product design and development phases described in the MPQP, a procedure that the CSO follows extensively for product realization,
- Including the MPQP phases in the system map, which also helps clarify where research, design and development activities are carried out during product realization. As illustrated in *Figure 3.3*, research and design work (in the form of research contracts/projects) is conducted during the "Opportunity Review" and "Feasibility Phases". Product development is carried out during the "Prototype" and "Pilot" phases.

Structuring the MS and developing the QMS Map (*Figure 5.1*) was important, since it provides a model of the CSO's QMS where the "*relationship of the MSS to the organization's MS can be described using this structure*" (ISO, 2008, p.90). As illustrated in *Figure 5.1*, the ISO 9001:2000 requirement clause numbers were juxtaposed with the related QMS components. The QMS Map was also used later as the basis for mapping the MSS requirements (from the R&D standards) onto the MS (Sub-Step B4.3). Furthermore, an in-depth analysis of company documentation, which was necessary in order to structure the MS, also improved the overall

understanding of the MS in terms of identifying the core product realization and support processes and their relationship.

Lastly, the design of the structured QMS Map was useful in order to establish a "snapshot" of the MS (i.e., *Figure 5.1*) before the new R&D MSSs are introduced. After the R&D MSS requirements are integrated into the MS, comparing the original QMS Map to the updated MS (with the newly integrated requirements) can reveal where improvements or changes have been made (i.e., the "before" and "after" pictures of the MS). Thus, the system maps generated in Sub-Step B4.1 can be used as a record for an organization to keep track of the evolution of their MS. This can be particularly relevant in nanotechnology, due to the potentially large number of nanotechnology standards that will issued in the future (e.g., for health and safety or nanotechnology quality), which, if adopted by an organization, will likely alter its MS.

5.2.3 Define the path of integration

Before proceeding further, it was deemed useful to determine the path of integration, or how the MSS requirements would be integrated. The "subsystem path" was taken. This is an approach where an existing subsystem of the organization's MS (e.g., a QMS) forms the basis for the integration of other subsystems (Karapetrovic, 2005). This is in contrast to a "systems path", where "*subsystems are [put] together using a shared or juxtaposed model*" (Karapetrovic, 2005). In this project, the ISO 9001-based QMS implemented at the CSO was used as the foundation of the MS. The components of an R&D&I MS subsystem (available through UNE 166002:2006 and EARTO:2000) were then incorporated into it. The newly incorporated R&D MSS requirements provided an expanded set of requirements for the QMS system (*Figure 5.2*), leading to the creation of an "Integrated Quality/R&D&I MS".

The "subsystem path", with the QMS acting as the foundation for integration, was chosen because:

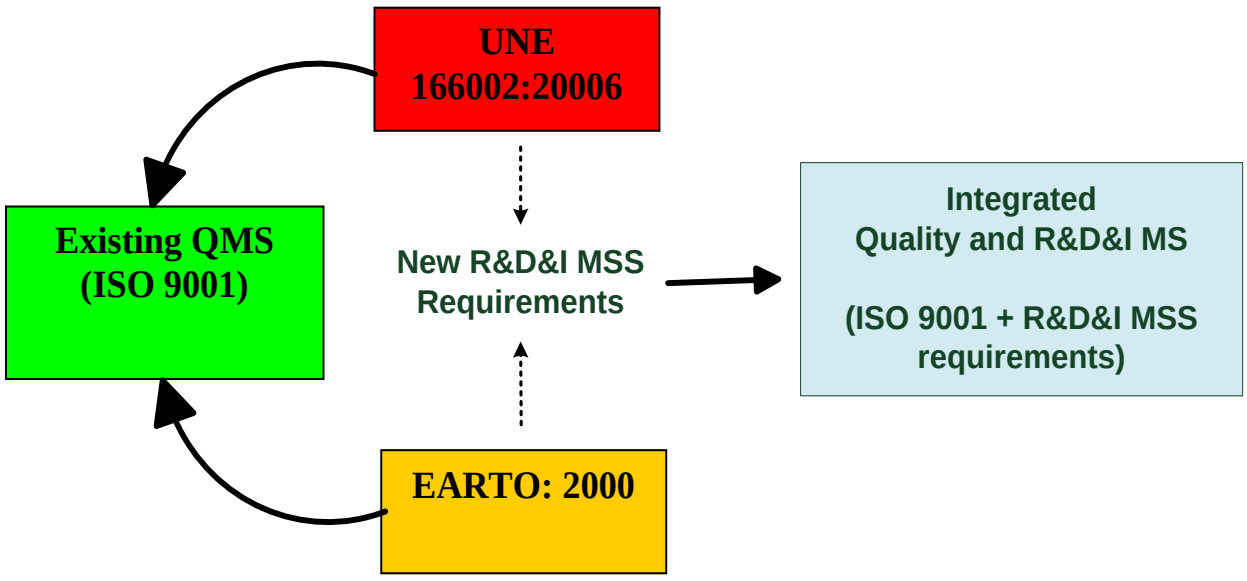
- The CSO's existing ISO 9001-based QMS was the only MS in the company that was standardized, and the main business processes are also built around its structure.

- As was alluded to in Subsection 4.3.1**,** both UNE 166002:2006 and EARTO:2000 are related to managing quality in R&D, and would therefore be appropriate for integration with the CSO's QMS.

- Many of the R&D&I MSS requirements are common or aligned with the elements of ISO 9001:2000 (e.g., document control, management review, and internal audits), which facilitates integration.

- Apart from the common requirements, a number of the unique requirements in UNE 166002:2006 and EARTO:2000 impact and would benefit the entire organization, not merely the R&D business unit (e.g., motivation and creativity of employees).

***Figure 5.2*: Path of integration**



5.3 Structure the MSS requirements (Sub-Step B4.2)

5.3.1 Activities performed in Sub-Step B4.2

After the CSO's QMS is structured and mapped out, the next step in the integration process was to structure or configure the MSS requirements to be integrated. This is known as "structuring the MSS requirements" (Sub-Step B4.2). It involved mapping out the various standards to be

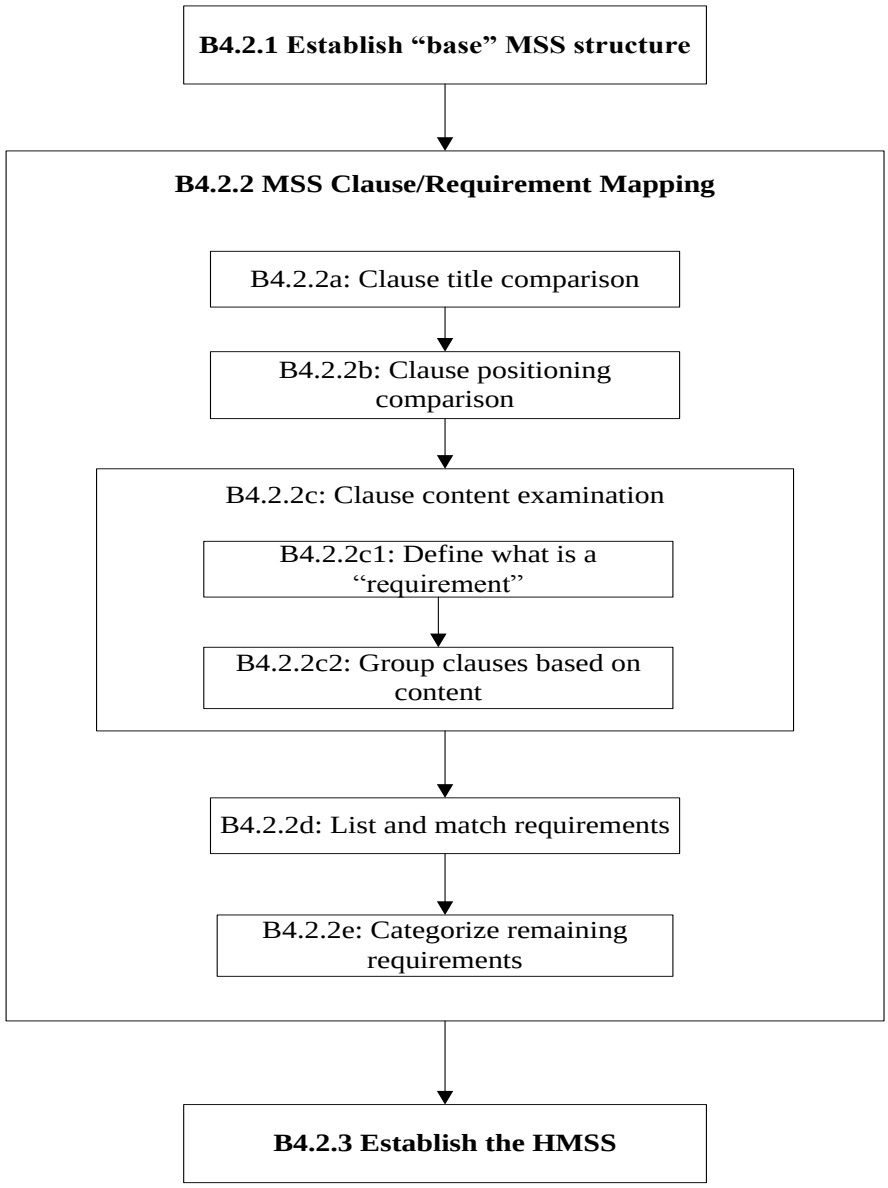
incorporated into the MS, and merging the requirements of the MSSs (i.e. ISO 9001:2000, UNE 166002:2006) into a combined set of criteria.

The main purpose of Sub-Step B4.2 was to create a homogenous scheme or a framework for the requirements of all three standards to be integrated. This was particularly important in the project, since multiple R&D standards of different formatting and configurations were to be applied at the same time. The result of structuring the requirements was a table containing the combined requirements from ISO 9001:2000, UNE 166002:2006, and EARTO:2000. This table was referred was to as the "hybrid" MSS (HMSS). It forms the basis of a "hybrid system" (made using multiple MSSs) that researchers such as Biré *et al.* (2004) deemed necessary for R&D.

It should be noted that the requirements in the HMSS were only summarized, thus not fully written out, in order to keep the table as concise as possible. Therefore, the HMSS represents the author's own interpretation of the MSS requirements.

Figure 5.3 shows the activities that were performed in order to structure the MSS requirements. Each activity will be explained separately in the following sub-sections.

***Figure 5.3*: Structuring the MSS requirements process**



5.3.1.1 Activity B4.2.1: Establish "base" MSS structure

This involved listing all the ISO 9001:2000 requirements that already existed in the current QMS, forming the initial framework of the HMSS (see *Table 5.1*).

***Table 5.1*: Activity B4.2.1: Establish "base" MSS structure**

ISO 9001:2000 clauses
4.2.3 Control of documents
a) Document approval
b) Review and update
c) Changes and current revision status identified
d) Availability of relevant versions
e) Legible and identifiable
f) External documents identified and distribution controlled
g) Prevent unintended use of obsolete documents and identify them if kept
…

It should be noted that the base MSS structure need not be ISO 9001, since the idea of establishing such structure is to set up a starting framework for the requirements to be compared against. In fact, any existing MSS implemented in the company can be used. For companies without a standardized MS in place (such as nanotechnology startups), one of the new MSSs to be implemented can be used for the base structure.

5.3.1.2 Activity B4.2.2: MSS Clause and Requirement Mapping

The next activity was the actual merging of multiple MSS requirements into the HMSS. This involved connecting, or mapping, related MSS clauses and requirements together. Five sub-activities were carried out:

Activity B4.2.2a: Clause title comparison

Activity B4.2.2b: Clause positioning comparison

Activity B4.2.2c: Clause content examination

Activity B4.2.2d: List and match requirements

Activity B4.2.2e: Categorize remaining requirements

5.3.1.2.1 *Activity B4.2.2a: Clause Title Comparison*

Since some R&D MSS section headings were titled very similarly to that of ISO 9001:2000, a simple comparison of those headings (also referred to as "clauses") was a useful strategy for grouping similar clauses together. Clauses that share similar titles were grouped together, and assigned a section label (Column B in *Table 5.2*). The first column (Column A) was reserved for labeling the overall MS area. These areas are discussed further in Subsection 5.3.1.3.

***Table 5.2*: Activity B4.2.2a: Clause title comparison**

B	C	D	E
	ISO 9001:2000 clauses	**UNE 166002: 2006 clauses**	**EARTO: 2000 clauses**
Document control	*4.2.3 Control of documents*	*4.1.2.1 Control of documents*	*3.3 Document control*
…	…	…	…
Policies and objectives	*5.3 Quality policy*	*4.2.3 R&D&I policy*	
…	…	…	…
MS Planning	*5.4.2 Quality management system planning*	*4.2.4.2 R&D&I management system planning*	
…	...	...	…
Internal audits	*8.2.2 Internal audits*	*4.5.2 Internal audits*	*3.12 Internal audits*

5.3.1.2.2 *Activity B4.2.2b: Clause positioning comparison*

Determining where the clause was positioned relative to the base ISO 9001:2000 MSS structure was a useful technique for mapping the UNE 166002:2006 requirements, since the sections of this MSS were laid out in the same order to that of ISO 9001:2000.

For example, it was not apparent where UNE 166002:2006 clause *4.2.2: Interested parties Approach* would fit in the HMSS solely by looking at the title. However, this clause was located in section *4.2: Responsibility of top management,* and was positioned in between *4.2.1: Commitment of top management* and *4.2.3: R&D&I policy*. Therefore, it could be deduced that it was related to ISO 9001:2000 section *5.2: Customer Focus*. A comparison of the content within the clauses confirmed that the assumption was correct. As another example, the requirements in UNE 166002:2006 clause *4.3.2.2*: *Motivation of the personnel* seemed to be unique to that MSS. However, it was found under the main section *4.3.2: Human Resources*, which was also a component in ISO 9001:2000. Therefore these requirements were grouped together. The grouping of these two examples (highlighted in blue), is shown in *Table 5.3*.

***Table 5.3*: Activity B4.2.2b: Clause positioning comparison**

B	C	D	E
	ISO 9001:2000 clauses	**UNE 166002: 2006 clauses**	**EARTO: 2000 clauses**
Management commitment	*5.1 Management commitment*	*4.2.1 Commitment of top management*	
Stakeholder Focus	*5.2 Customer focus*	*4.2.2 Interested parties approach*	
Policies and Objectives	*5.3 Quality Policy*	*4.2.3 R&D&I policy*	
	…	…	
Human resources	*6.2.1 General*	*4.3.2.1 General*	
	6.2.2 Competence, awareness, and training	*4.3.2.3 Competence, awareness and training*	
		4.3.2.2 Motivation of personnel	

Many of the UNE 166002:2006 clauses could be grouped by simply comparing their titles and relative positioning, since its structure and format was very similar to ISO 9001:2000. However, not all the clauses could be mapped this way (especially with EARTO:2000). Therefore, a more thorough examination of the content within each clause was required.

5.3.1.2.3 *Activity B4.2.2c: Clause content examination*

Sub-Activity B4.2.2c1: Define what is a "requirement"

In order to examine the content contained within the clauses, it was necessary to break down each clause into individual requirements or criteria. According to Borković (2009, p.74), an individual requirement or guideline refers to a "*single statement, usually given in one sentence, that expresses a specific need or expectation from the specific component of the MS*". This was seen to be a suitable definition for both ISO 9001:2000 and UNE 166002:2006.

For example, UNE 166002:2006 clause *4.1.2.1: Control of documents* can be broken down into individual requirements 4.1.2.1a) through 4.1.2.1g):

"4.1.2.1: Control of documents
A documented procedure shall be established to define the necessary measures to:
a) Approve documents in terms of their suitability before they are issued.
b) Review and update documents whenever necessary and approve them once again…

…g) prevent the unintended use of deprecated documents and identify them in the event they are kept for any reason."

For EARTO(2000), this definition was more complicated, since the sections in the standard are lengthy and contain very detailed descriptions. In addition, the guidelines are not clearly organized into separate requirements. Instead of assigning each individual statement in the document as a requirement, the requirements were thus grouped into paragraphs or sections of text. Each paragraph in the section that addressed a particular aspect or idea (e.g., "validation of research methods") was designated a letter for referencing purposes. For example, "validation of research methods" is addressed in section 4.3 of the standard, and was labeled 4.3(f). Such labeling of each "requirement" in EARTO:2000 may be useful only for the individual performing the MSS structuring activity, as each reader may label the requirements differently.

Sub-Activity B4.2.2c2: Group clauses based on content

Once the content in the clauses could be categorized into requirements, it became a much easier task to relate the remaining clauses together (see *Table 5.4*). For instance, it was found that EARTO:2000 clause *3.2: Quality System* contained information regarding the Quality Policy, and therefore was grouped together with the policy-related clauses in ISO 9001:2000 and UNE 166002:2006.

The clauses in the R&D standards associated with Design and Development (section 7.3 in ISO 9001:2000) were also identified. For example, for UNE 166002:2006 clause *4.4.6: R&D&I product*, the clause title and positioning within the standard suggested that it was related to product design and development. An examination of the content (i.e., the requirements) confirmed this. Clause *4.4.8*: *Results of R&D&I process* was actually not positioned with the other clauses in R&D&I product. However an examination of its content revealed that the requirements addressed R&D&I results, and therefore it was mapped into this area of the HMSS.

Although UNE 166002:2006 clause *4.4.2: Interested parties approach* was initially linked with the ISO 9001:2000 clause *5.2 Customer Focus*, the requirements contained within the clause indicated that it was also associated with obtaining the needs and requirements of stakeholders. Therefore, UNE 166002:2006 clause 4.4.2 was also mapped into this section.

***Table 5.4*: Activity B4.2.2c2: Group clauses based on content**

B	C	D	E
	ISO 9001:2000 clauses	**UNE 166002: 2006 clauses**	**EARTO: 2000 clauses**
Policy and objectives	*5.3 Quality policy*	*4.2.3 R&D&I policy*	*3.2 Quality System - Quality Policy Statement*
	…	…	…
Gather and assess stakeholder requirements	*7.2.1 Determination of product related requirements*	*4.2.2 Interested parties approach*	
	…	…	…
Design and Development	*7.3 Design and Development*	*4.4.6 R&D&I product*	
Design and Development Planning	*7.3.1 Design and Development Planning*	*4.4.6.1 Basic design* *4.4.6.2 Detailed design*	
Design/Development Inputs	*7.3.2 Design and development inputs (relating to product requirements)*		*5.2a) Initial project phase: Data/information collection*
Design/Development Outputs	*7.3.3 Design and development output*	*4.4.8 Results of R&D&I process* *4.4.8.1 Documentation of the results*	*5.4 Reporting the results*
…	…	…	…

5.3.1.2.4 *Activity B4.2.2d: List and match requirements*

Next, the requirements contained within the clauses were listed underneath the corresponding clauses. This allowed the related requirements to be quickly compared side by side for differences (see *Table 5.5*).

For example, requirements 4.2.3(a) of ISO 9001:2000, 4.1.2.1(a) of UNE 166002:2006, and 3.3b) of EARTO:2000 all addressed document approval. In fact, the entire set of requirements regarding Document Control was found to be identical in content.

ISO 9001:2000 clause 5.4.2 and UNE 166002:2006 clause 4.2.4.2 addresses QMS and R&D&I MS planning, respectively. Therefore, they were grouped together based on the "Clause Title Comparison". However, the listing of the individual requirements revealed that this particular clause in UNE 166002:2006 contained an extra criterion not found in ISO 9001:2000, namely the "R&D&I Investment Policy" (requirement 4.2.4.2c).

Table 5.5: **Activity B4.2.2d: List and match requirements**

B	C	D	E
	ISO 9001:2000 clauses	**UNE 166002: 2006 clauses**	**EARTO: 2000 clauses**
Document control	*4.2.3 Control of documents*	*4.1.2.1 Control of documents*	*3.3 Document control*
	a) Document approval	a) Document approval	b) Reviewed and approved prior to use
	b) Review and update	b) Review and update	b) Documents reviewed and revised
	…	…	…
MS Planning	*5.4.2 Quality management system planning*	*4.2.4.2 R&D&I management system planning*	
	a) Meets quality objectives and general QMS requirements	a) Meets R&D&I objectives and general R&D&I MS requirements	
	b) QMS integrity maintained during changes	b) R&D&I MS integrity maintained during changes	
		c) R&D&I investment policy set	
	…	…	…

5.3.1.2.5 *Activity B4.2.2e: Categorize remaining requirements*

It was found that some other UNE 166002:2006 and EARTO:2000 requirements could not be related to a specific 9001:2000 requirement, even after comparing their clause section titles and examining their relative position and content. These were categorized into separate groups in the HMSS, listed below in *Table 5.6*.

***Table 5.6*: Activity B4.2.2e: Categorize remaining requirements**

B	C	D	E
	ISO 9001:2000 clauses	**UNE 166002: 2006 clauses**	**EARTO: 2000 clauses**
Teamwork, creativity and motivation	N/A	*4.3.2.2 Motivation of personnel* 4.3.2.1b) Ability to work in team, motivation and enthusiasm to obtain results *4.4.1.3 Creativity*	N/A
Information gathering, technology assessment, analysis and selection of ideas	N/A	*4.4.1.1 Technology watch* *4.4.1.2 Technology foresight* *4.4.1.4 External and internal analysis* *4.4.2 Identification and analysis of problems and opportunities* *4.4.3 Analysis and selection of R&D&I ideas*	5.2a) Project Information collection
Technology transfer, exploitation of results and intellectual property	N/A	*4.4.9 Protection and exploitation of results of R&D&I activities* *4.4.5 Technology transfer*	5.2 g) Transfer of knowledge and technology to client *2.2: Intellectual Property Rights*
Experimental/Calculational methods	N/A	*N/A*	*4.3 Experimental/calculational methods* *5.3d) Methods to ensure quality of outgoing results*

5.3.1.3 Activity B4.2.3: Establish the HMSS

The requirement and clause mapping ultimately led to a structured table containing the combined (integrated) requirements of ISO 9001:2000, UNE 166002:2006, and EARTO:2000. This was referred to as the "hybrid" MSS, or the HMSS. An extract of the HMSS is shown below in *Table 5.7*. The full HMSS can be found in *Appendix D*.

Section labels that had been created previously (Column B in *Table 5.7*) were renamed, if necessary to reflect the content of the requirements, reordered according to the sequence of the ISO 9001:2000 clauses, and numbered. These section labels can be thought of as the components or elements of the integrated QMS and R&D&I MS (i.e., the clauses of the integrated HMSS). Lastly, these sections were placed into larger overall QMS areas (e.g., 1.0 Quality Management System, 2.0 Management Responsibilities, and 3.0 Measurement, Analysis, and Improvement) that reflect the current structuring of the MS (*Figure 5.1*). These overall MS areas are represented by Column A in *Table 5.7***.**

The horizontal strip (colored in green) in *Table 5.7* refers to the listing of requirements that have commonalities and that impact the same or similar processes. The vertical strip (colored in yellow) refers to the processes and other resources that are impacted by the particular requirements (i.e., the integrated MS components).

Table 5.7: **Extract of the HMSS**

A	B	C	D	E
		ISO 9001:2000 requirements	**UNE 166002: 2006 requirements**	**EARTO: 2000 requirements**
1.0 Quality Management System	1.2.2 Document Control	*4.2.3 Control of documents* a) Document approval	*4.1.2.1 Control of documents* a) Document approval	*3.3 Document control* b) Reviewed and approved prior to use
		b) Review and update	b) Review and update	b) Documents reviewed and revised
		c) Changes and current revision status identified	c) Changes and current revision status identified	c) Changes be reviewed and approved by original reviewer c) Changes identified c) Procedure for electronic documentation changes
		d) Availability of relevant versions	d) Availability of relevant versions	c) Appropriate documents available at suitable locations
		e) Legible and identifiable	e) Legible and identifiable	a) Documentation simple and easy to understand
		f) External documents identified and distribution controlled	f) External documents identified and distribution controlled	
		g) Prevent unintended use of obsolete documents and identify them if kept	g) Prevent unintended use of obsolete documents and	c) Prevent unintended use of obsolete documents and identify them if kept
…	**…**	…	…	…
2.0 Management Processes and Responsibilities	2.3 Management system planning	*5.4.2 Quality management system planning* a) Meets quality objectives and general QMS requirements b) QMS integrity maintained during changes	*4.2.4.2 R&D&I management system planning* a) Meets R&D&I objectives and general R&D&I MS requirements b) R&D&I MS integrity maintained during changes c) R&D&I investment policy set	
	…	…	…	…
5.0 R&D&I analysis	5.0 Information gathering, technology assessment, analysis and selection of ideas	*N/A*	*4.4.1.1 Technology watch* *4.4.1.2 Technology foresight* *4.4.1.4 External and internal analysis* *4.4.2 Identification and analysis of problems and opportunities* *4.4.3 Analysis and selection of R&D&I ideas*	*5.2a) Project Information collection*

5.3.2 Issues and lessons learned

5.3.2.1 Clause/Requirement Mapping

The difficulty of structuring MSS requirements largely depended on how each MSS was structured relative to the base MSS adopted by the company (in our case, ISO 9001:2000). For instance, structuring and integrating the requirements of UNE 166002:2006 was relatively straight forward, as the standard was written to be aligned with ISO 9001:2000. The similarities between the structure and format allowed clause mapping to be conducted quite efficiently.

However, it is perceived that structuring MSS requirements may prove to be challenging for nanotechnology organizations looking to implement R&D-specific standards or guidelines that do not share similar structuring and content with the existing MSSs like ISO 9001. As seen in the literature survey, many "standards" for R&D are not published by ISO, and may not be compatible with the ISO standards. For example, figuring out where EARTO:2000 requirements fit with respect to the base MS was challenging as the standard was structured differently than ISO 9001:2000 or UNE 160002:2006.

Another challenge was encountered when performing the mapping activity for EARTO:2000, since the sections of the document were not organized and numbered into individual requirements. A single section of this document would sometimes contain requirements that fit into different areas of the MS. For example, section 5.2 of EARTO(2000), called "*Project Work*", contained statements which were related to the Monitoring and Measurement of Product (MS Component 3.2.2), R&D&I Analysis (MS Component 5.0), Project management and Planning" (MS Component 6.1.1), Review of Product Requirements (MS Component 6.1.3), Design and Development Inputs (MS Component 6.2.2) and IP and Exploitation of Results (MS Component 6.4). This was an instance where separating sections of the standard into individual requirements (i.e., performing Activity B4.2.2c1) was useful.

After structuring the MSSs, it was found that most of the elements from the two R&D standards could be mapped with corresponding elements from ISO 9001:2000. This suggests that, content-wise, both R&D standards share many elements with the ISO 9001:2000-based QMS used in the CSO. Overall, the R&D standards provided additional criteria for maintaining an R&D&I MS.

Generally, most of the new requirements expanded or augmented the scope of the existing QMS activities to include R&D&I components (e.g., the extension of the quality policy to include an R&D&I Policy and Code of Conduct).

5.3.2.2 MSS translation issues

Language translation was also perceived to be an issue. As the literature survey revealed, many R&D standards are published in European languages other than English. For instance, UNE 166002:2006 was translated from Spanish to English by the publisher (AENOR), and it was found that with some of the requirements were translated poorly. This led to ambiguity and difficulties in interpreting the MSS requirements. An example is clause 4.4.6.5: *Marketing*, which is misleading, as it relates more to the validation of the R&D product, rather than to the sales aspect of product marketing. This is an example of where looking at the positioning and content of the requirement, rather than just the title of the clause, was especially helpful in mapping the requirement into the correct area of the HMSS. By just looking at the title, it was unclear as to where the clause could be mapped into the HMSS. However, the clause is positioned just before the sections *Change Control* and *Purchasing* and after *Redesign, Demonstration and Production.* The corresponding requirement in ISO 9001:2000 would be *7.3.6 : Design and development validation,* which suggested that *Marketing* was related to R&D product validation. An examination of the requirement content (which reads "*…the new development faces up to the market to see how the [product] satisfies the interested parties."*) implied that this requirement was indeed related to validation.

5.3.2.3 HMSS design

The primary purpose for HMSS design is not to fully write out and design an entirely new integrated standard, but to merely group related MSS components together. The HMSS represents the integration or merging of MSS requirements from various standards into a common structure or framework. Establishing this common framework makes it easier to comprehend the requirements of multiple MSSs that are often formatted and structured differently from one another. Structuring the MSSs is important since the R&D&I standards that a nanotechnology organization can be interested in implementing may consist of a variety of different layouts and configurations.

When listing the HMSS requirements, only keywords and short bullet points were used to maintain readability and brevity. Users can then consult the full standard for details when performing gap analyses and gap closure activities. The crucial idea is that all the requirements are present in the HMSS, not a particular order or location of a requirement in the HMSS.

It is obvious that the structuring of the MSS requirements leading up to the creation of the HMSS is subjective, and will vary between users. Different users may group requirements in different areas of the HMSS, structure the EARTO:2000 requirements differently, and organize the HMSS in different ways. Dale (2000, p.295) agrees and points out that the requirements where linkages are weak are open to a range of interpretations, and that there is always a danger of trying to find links that do not exist.

Other slightly simpler approaches were considered, which did not involve the creation of a full HMSS with a listing of the requirements and reorganization of the sections. Two of these approaches are briefly illustrated below.

One approach was to create a generic matrix for analyzing requirement commonalities, with only the section headings included and without listing individual requirements (as in *Table 5.8*).

Table 5.8: Generic matrix for analyzing requirement commonalities

UNE 166002:2006	ISO 9001:2000	EARTO:2000
4.1.2.1 Control of documents	*4.2.3 Control of documents*	*3.3 Document control*
4.2.4.2 R&D&I management system planning	*5.4.2 Quality management system planning*	*N/A*
4.4.1.1 Technology watch	*N/A*	*5.2a) Project Information collection*

These matrices are analogous to the "tables of correspondence" found in the appendices of some ISO standards such as ISO 14001:2004, which show the correspondence between the clauses of different MSSs. These tables, unfortunately, were not available for R&D&I MSSs. The approach itself may work quite well if only the standards that are formatted similarly to ISO 9001:2000 (such as UNE 166002:2006) are used. Since the guidelines in EARTO:2000 were not clearly organized into separate requirements, along with lengthy sections that sometimes

contained requirements that belonged to multiple areas of the MS, listing out the actual requirements was needed, and this approach would not have been appropriate.

Another approach would be proceeding straight to the gap analysis. Since mapping R&D MSS requirements onto the ISO 9001-based MSS was a form of gap analysis, this was another alternative that might have saved time. This approach may work well if only one additional standard were to be integrated. With the addition of multiple standards, however, going directly to the gap analysis stage may lead to details missed out, and require multiple re-readings of the standards. In addition, this approach would not be possible for an organization that did not have an existing standardized MS in place.

5.3.2.4 Additional benefits of the HMSS

There were also other benefits that were found in structuring the MSS requirements to form a HMSS.

Firstly, the HMSS could be used as an input for mapping the MSS requirements against the MS (Sub-Step B4.3). This was actually done in the research, since the R&D MSS requirements were related to corresponding clauses in ISO 9001:2000, which the existing MS had been based on. Furthermore, the HMSS presented a succinct way for mapping MSS requirements against MS. Namely, instead of having multiple MSS requirements mapped onto a particular process area, there would be only one integrated HMSS requirement to map.

The creation of the HMSS also facilitates quick comparisons between the standards. For instance, it can be seen from the HMSS that requirements from section *7.5 Production and Service Provision* in ISO 9001:2000 are not found in UNE 166002:2006. On the other hand, sections 4.4.5 and 4.4.9 in UNE 166002:2006 addressing Technology Transfer and the Protection and Exploitation of R&D&I Results are not considered in ISO 9001:2000. However, the requirements for Document Control are addressed in both standards and in the HMSS. Therefore, the HMSS provides an efficient and simple way of identifying commonalities (overlaps) and differences between MSS requirements, which avoids duplication. It can also serve to help identify any conflicting requirements between MSSs. Listing the requirements in the HMSS helps ensure that none are missed out during the integration.

The HMSS presents a detailed view of the entire MS structure, the processes that lie within each area, and where new MSS requirements may be integrated. This particularly applied to the CSO, as its MS had been structured almost identically as ISO 9001:2000. Therefore, the HMSS can be used as a tool to "*assess the current state of the organization's MS in applying either new or existing MSS requirements*" (ISO, 2008, p.104).

Lastly, the HMSS can be used as a framework in which additional MSs can be built onto in the future. For instance, shared requirements from other MSSs, such as ISO 14001, can be directly "plugged" onto appropriate sections of the framework. Requirements specific to an MS may be placed in a functional sub-section, or what Karapetrovic (2002) calls "sub-modules". Adding other MSs would simply increase the number of modules, and the HMSS can be expanded to encompass as many MSSs as needed.

5.4 Map the MSS requirements against the MS (Sub-Step B4.3)

5.4.1 Activities performed in Sub-Step B4.3

The next step in the IUMSS methodology was to determine how the new R&D MSS requirements fit and can be integrated into the organization's existing QMS. This involved linking the MSS requirements against the CSO's existing MS processes, resources and objectives in order to understand their impact, a process also known as "mapping the MSS requirements against the MS" (ISO, 2008).

The first step taken to map the MSS requirements against the MS of the CSO was a modified version of the "matrix approach" (ISO, 2008, p. 104), or the "applicability map" approach (Borković, 2009, p.75). This method involves placing the requirements of the MSS to be incorporated in the organization against its MS in a matrix (in which the x-axis encompasses the selected standards and their common requirements and the y-axis lists the MS components), and subsequently denoting the relationship between each MSS requirement and each MS component by inserting the requirement clause numbers in the crossing field of the axes.

Evidently, an "applicability map" is in fact the matrix that was generated for the HMSS (*Table 5.7*). Therefore, much of Step B4.3 was already carried out in Step B4.2 (Structure the MSS

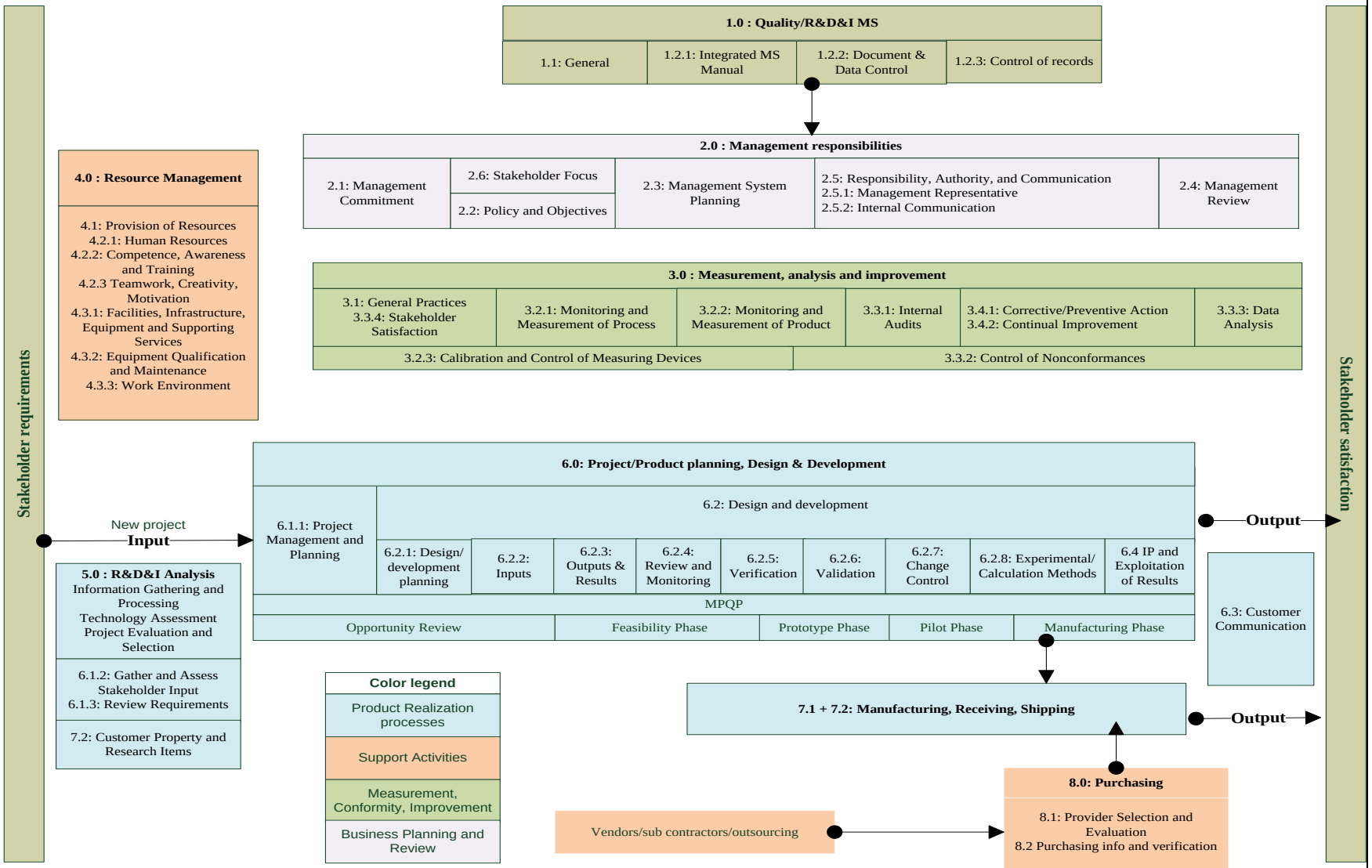
requirements). This is because the HMSS itself was created from the ISO 9001:2000 structure, which is, coincidentally, also the structure from which the existing QMS at the CSO had been built. By relating the requirements of new MSSs against this base MS, Step B4.3 mapping was already conducted. In the situation where an organization does not have an established ISO 9001 QMS, the HMSS will simply represent a table with all the structured MSS requirements.

Another form of MSS to MS mapping was also performed by overlaying the integrated HMSS requirement clauses on top of the impacted processes and elements in the MS structure map developed in Sub-Step B4.1 (*Figure 5.1*). The result is an Integrated Quality and R&D&I MS Map, shown in *Figure 5.4*. This map is a graphical representation of the relationships between the HMSS requirements or guidelines and the impacted MS components. For instance, requirements in clause 2.2 of the HMSS addressing "Policy and Objectives" correspond to, and are mapped against, the Policy and Objectives component of the MS. The MSS requirement number also serves to label the various components of the MS. For instance, the Measurement, Analysis and Improvement components are labeled as "3.0". Throughout the remainder of this thesis, the various components of the MS will be numbered according to *Figure 5.4*.

As seen in *Figure 5.4*, the original QMS map (*Figure 5.1*) was expanded to assimilate the new integrated R&D&I requirements in the following manner:

- Components containing more detailed requirements, e.g., Design and Development, were broken down into the different activities involved.
- New R&D specific requirements were added, e.g., Activities involved in R&D&I Analysis were added as an additional input for product development.
- Components were renamed, e.g., Quality Policy was renamed as Policy and Objectives, since R&D&I Policies and Objectives are also now required.

Figure 5.4: Integrated Quality and R&D&I MS Map



The HMSS requirements were also mapped against the impacted CSO's MS processes and internal procedures. A sample can be found in *Table 5.9* below. This matrix was generated using the table given in *Appendix C-3.1* by replacing the former column containing the ISO 9001:2000 elements with the HMSS requirements. Subsequently, this table provides an input into the gap analysis later, and the full version can be found in *Appendix C-3.2.*

***Table 5.9*: Correspondence between HMSS requirements and CSO procedures**

Key processes/practices in the organization		***Associated Organizational Documents***	**Impacted HMSS requirements clauses**
1.0) Quality Management System	General QMS practices	Quality system process flow QASP-037: Product Quality Planning	1.1 General Requirements
	Documentation practices	Quality Manual QASP-003: Document & Data Control QASP:-030: Internal Drawing Control QASP-014: Quality records	1.2 Documentation 1.2.1 Quality Manual 1.2.2 Document Control 1.2.3 Record Control
…	…	…	…
4.0) Resource Management	Provision of resources		4.1 Provision of resources
	Human Resources	QASP-016: Training	4.2.1 Personnel 4.2.2 Competence, awareness and training 4.2.3 Teamwork, creativity, and motivation
…	…	…	…

5.4.2 Issues and lessons learned

Sub-Step B4.3 can help an "*organization understand how the MSS requirements fit into its MS*" (ISO, 2008, p.102). For example, the Integrated Quality and R&D&I MS Map created in Sub-Step B4.3 helps the CSO visualize which parts of the MS would be impacted by the new R&D MSS requirements. Mapping the MSS requirements onto the MS provides a systematic method for connecting the MSS requirements with components of the MS.

As mentioned in the IUMSS handbook, the mapping of MSS requirements against the processes "*requires knowledge of both the MSS requirements and the organization's processes…and often demands collaboration through input and judgment of the process owners*." (ISO, 2008, p.104). The "knowledge of the organization's processes" was one of the limitations in the study (see

Section 8.2). Namely, since contact with the CSO was limited, some details regarding the QMS and R&D processes had to be extrapolated from the company documentation provided.

5.5 Summary

This Chapter presented how the new MSS requirements can be connected to a current MS in the case of a nanotechnology and R&D-oriented organization, i.e., the CSO. The applicability of these steps to organizations involved with nanotechnology in general and the issues that they could encounter were also discussed.

Structuring the MS (Sub-Step B4.1) involved understanding of all the components of the MS and their relationships, as well as graphically depicting these in a QMS map. Also included in this step was the determination of the path of integration. In this study, the "subsystem path" was taken, where the existing QM subsystem formed the basis for the integration of the R&D&I subsystem. Next, MSS requirements were structured (Sub-Step B4.2). This sub-step involved structuring all the MSS requirements together into a common scheme, and resulted in a "hybrid" MSS (HMSS) containing the requirements of all three standards. Lastly, HMSS requirements were mapped against the structured MS (Sub-Step B4.3). The result of this mapping was the development of an Integrated Quality and R&D&I MS Map. With the HMSS requirements now connected to the MS, the next chapter will look at how these requirements can actually be incorporated into the MS.

6. Incorporate MSS requirements into MS (Step B5)

6.1 Introduction

The previous chapter demonstrated how mapping establishes linkages between the CSO's MS and the corresponding HMSS requirements. This chapter addresses whether or not new processes would be needed in order to meet the new requirements. In addition, its purpose is to illustrate how the CSO can effectively integrate these requirements into its MS.

Firstly, as suggested by the IUMSS handbook (ISO, 2008, p. 112), the extent of the differences between the existing MS and the requirements given in the standards was evaluated. This assessment, known as "gap analysis" (Sub-Step B5.1), involved comparing the various components of the MS against multiple sets of related standard requirements (which were established during Sub-Step B4.3) and determining how well the MS components comply with the requirements. The differences (called "gaps in compliance") were addressed in the next step (Sub-Step B5.2: Gap closure) with appropriate policies, processes and procedures.

After the gaps were identified through gap analysis, a list of suggestions describing the actions required to fill these gaps was derived, in order to establish a full compliance between the standards and the MS. This is known as "gap closure" (Sub-Step B5.2), and was achieved by creating new and/or modifying the existing components of the MS (which were mapped in Sub-Step B4.3).

During the process of integrating requirements from multiple standards, "gaps in integration" might also crop up in the form of duplicated, redundant or non-efficient processes. These are different from the gaps in compliance with a particular standard mentioned previously. Following the suggestion given in the IUMSS handbook (ISU, 2008, p. 105), three different actions of eliminating "integration gaps" were performed:

- identifying commonalities between the requirements of the HMSS impacted by the same MS process
- identifying commonalities between MS processes impacted by the same HMSS requirement

- Looking for redundancies, synergies and integration possibilities.

The goal of the gap analysis is to identify where value can be added to the organization's infrastructure and decision-making processes (ISO, 2008, p. 113). For example, the incorporation of R&D&I Analysis activities such as "Technology Watch" (through compliance with UNE 166002:2006 requirement 4.4.1.1) can improve the decision-making processes at the CSO by alerting them about technology innovations that can create market opportunities or threats.

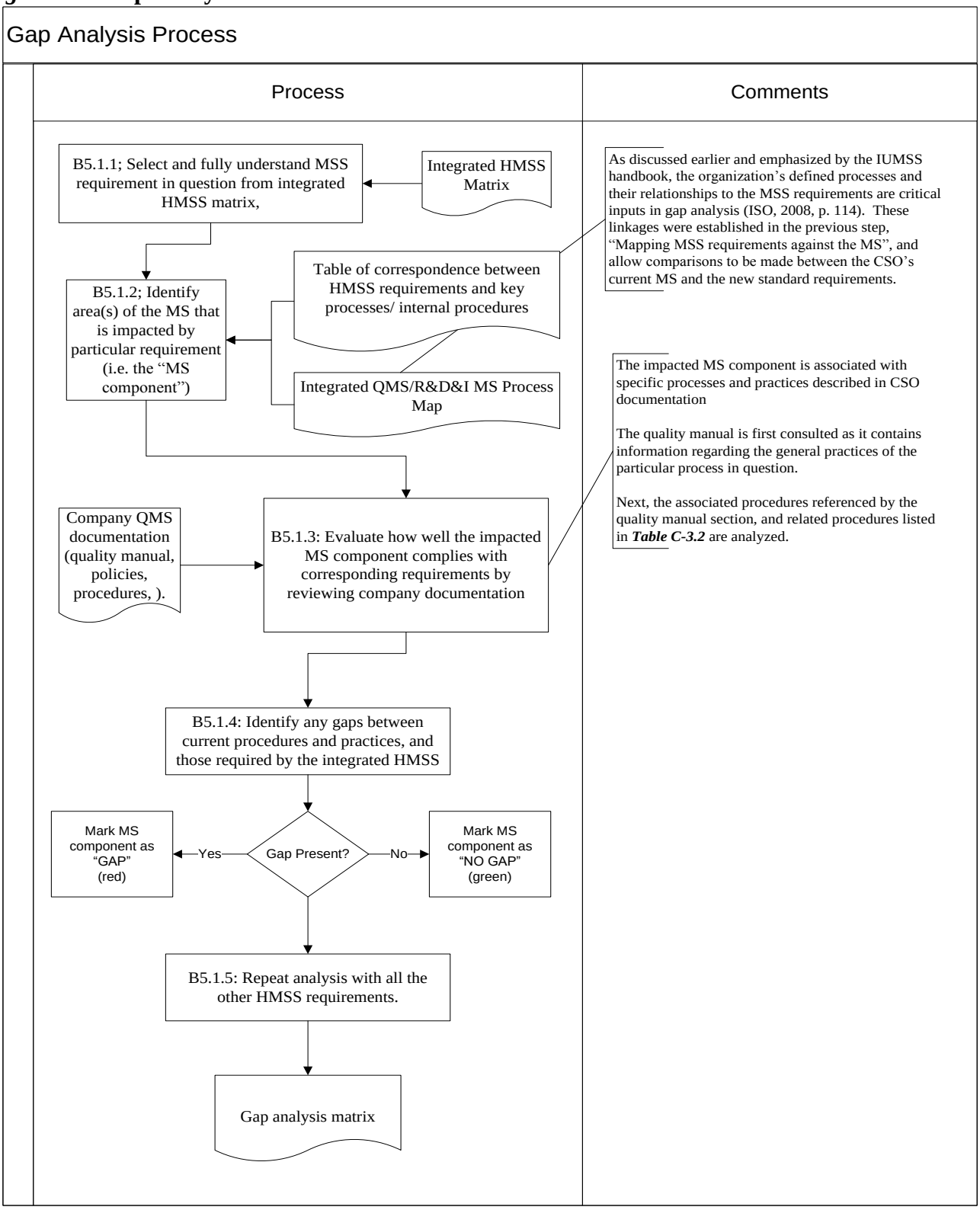
The integration of new or changed MSS requirements brings changes to process, resources and objectives of the MS, though the underlying structure of the MS should remain intact (ISO, 2008, p.97). This was guaranteed by establishing a structure for the MS (Sub-Step B4.1) before integrating the new requirements into the system.

6.2 Identify and analyze gaps (Sub-Step B5.1)

6.2.1 Gap Analysis Process

The following sequence of activities (*Figure 6.1* below) was realized for gap analysis, which was carried out in all the areas of the QMS (mapped in Sub-Step B4.1 in *Figure 5.1*). The entire Gap Analysis was performed by document review of the CSO's QMS documentation.

***Figure 6.1*: Gap Analysis Process**



6.2.2 Gap Analysis Matrix

The output of the gap analysis was a completed gap analysis matrix (*Appendix E*). This matrix summarizes the gaps between the integrated HMSS requirements and the current QMS activities of the CSO. *Table 6.1* shows an extract of the filled gap analysis matrix for two areas of the MS which were compliant with the HMSS requirements (Document/Data Control and Design and Development Verification), and two areas which contained a gap (Policy and Objectives and Management Review).

The vertical column on the left lists the major components in the integrated QMS/R&D&I MS. These were directly extracted from the processes established in the Integrated Quality/R&D&I MS Map **(***Figure 5.4***).** The horizontal row at the top of the matrix lists the HMSS clauses impacting the process or activity in question. Color coding was used to indicate whether a gap was found (green = no gap; red = gap found), and justification of the analysis is provided in the right-most column.

The justification column consists of :

- A reference field, which contains links to information (e.g., procedures or sections in the quality manual) that verifies the component's compliance or non compliance with the HMSS requirement.
- A "comments" field, which contain comments on the compliance level.

For example, as seen in *Table 6.1*, the Document/Data Control processes in the MS were determined to be compliant (green - no gap) with the associated HMSS requirement 1.2.2. Four sections from the Quality Manual (sections 4.2.2 through 4.2.5), and the Document & Data Control procedure (QASP-003) were analyzed and provided as evidence for the gap analysis findings (References field). A brief comment justifying the analysis is listed below the references. In this case, the explanation given was that the CSO's MS compliance to ISO 9001:2000 also met the requirements for UNE 160002:2006 and EARTO:2000.

Table 6.1: Extract of the filled gap analysis matrix

1.0) Quality and R&D&I Management System

HMSS Clauses	1.1	1.2	1.2.1	1.2.2	Justification
MS Component					
Document/Data Control					**Reference(s):** • *Quality Manual sec. 4.2.2: Control of documents* • *Quality Manual sec. 4.2.3: Document Identification* • *Quality Manual sec. 4.2.4: Indexes* • *Quality Manual sec. 4.2.5: Controlled Document Approval* • *QASP-003: Document & Data Control* **Comments:** All criteria for document control met through ISO 9001:2000 compliance.

2.0) Management Responsibilities

HMSS Clauses	2.1	2.2	2.3	2.4	Justification
MS Component					
Policy and Objectives					**Reference(s):** • *Quality Manual sec. 5.3: Quality Policy* • *Quality Manual sec. 5.4.1: Quality Objectives* • *QASP-033:* Policy and Objectives (QASP-033) **Comments:** • R&D&I policy and objectives not set by the CSO • General quality policy exists in the CSO, but elements addressing ethical codes of conduct environmental/sustainable development not included.
Management Review					**Reference(s):** • *Quality Manual sec. 5.6: Management Review* **Comments:** • Management reviews are carried out at CSO, but does not cover R&D&I MS and the related R&D standard requirements.

6.0) Project/product planning, design & development

HMSS Clauses	6.2.1	6.2.2	6.2.3	6.2.4	6.2.5	6.2.6	Justification
MS Component							
Design and Development							
Verification							**Reference(s):** • *Quality Manual sec. 7.3.5: Design and Development Verification* • *QASP-002: Design Control* • *QASP-037: Product Quality Planning* **Comments:** • Design verification is an activity in the Design Control process (QASP-002). • Additional details of design verification activities provided in QASP-037 ("Prototype Phase" of product design).

6.2.3 Results from the Gap Analysis

From the gap analysis, it was seen that many elements of an R&D&I MS were already present in the CSO's MS, suggesting a close relationship with the existing ISO 9001-based QMS. This is not surprising, as the two R&D standards deal largely with quality in R&D and UNE 166002:2006 itself was modeled after ISO 9001.

There were quite a few instances where no gap was found. *Table 6.2* outlines the areas of the MS which were fully compliant to the integrated HMSS requirements. Brief comments pertaining to why these particular areas contained no gap are also provided.

***Table 6.2*: Areas of MS where no gap was found**

MS Component	***HMSS Requirement***	***Comments***
1.0) Quality/R&D&I Management System		
Document/Data Control	1.2.2	All criteria for document control met through ISO 9001:2000 compliance
Quality Manual	1.2.1	ISO 9001 and EARTO:2000 requirement. Related to quality and not R&D&I.
2.0) Management Responsibilities		
Internal Communication	2.5.2	Existing channels of communication at the CSO can also be used for the R&D&I MS.
3.0) Measurement, analysis and improvement		
Corrective/preventive action & improvement	3.4.1, 3.4.2	Same mechanisms for addressing non-conformities and potential causes of conformities can be used as the basic process is the same for both the QMS and R&D&I MS.
		Provisions made for continual improvement are the same for both QMS and R&D&I MS.
Calibration and control of measuring devices	3.2.3	Criteria not covered in UNE 166002:2006. All equipment at CSO (including those used in R&D activities) are calibrated as required by the QMS.
4.0) Resource Management		
Facilities, infrastructure, equipment and supporting services	4.3.1	The entire CSO can be considered to be an R&D&I environment, R&D requirements covering infrastructure and equipment are all met.
Equipment qualification and maintenance	4.3.2	
6.0) Project/product planning, design & development		
Review requirements	6.1.3	Corresponding requirement not found in UNE 166002:2006. EARTO:2000 guidelines specify criteria for developing and reviewing a project contract, which is covered by ISO 9001:2000.

Table 6.2: **Areas of MS where no gap was found (continued)**

MS Component	***HMSS Requirement***	***Comments***
Design and Development Inputs	6.2.2	R&D&I "input" processes from UNE 166002:2006 (e.g. information from technology watch) were placed in its own section of the MS (R&D&I analysis).
Design and Development Verification	6.2.5	Being an R&D and product design focused company, both the verification and validation processes are described in much more detail in CSO documentation than specified by the standards.
Design and Development Validation	6.2.6	
Change Control	6.2.7	Generic processes at the CSO can be reused for approving changes and keeping records.
6.3) Customer communication	6.3	No new R&D&I requirements.
7.0) Manufacturing, Receiving, Shipping		
Receiving	7.2	These processes were outside the "R&D&I" planning, design and development, and measurement phases of product development, and thus were not affected by the requirements of the MSSs.
Manufacturing	7.1	
Shipping	7.2	
8.0) Purchasing		
Purchasing info and verification	8.2	Purchasing information and verification process was generic and can be reused.

Table 6.3 outlines the areas of the MS where gaps were found between the HMSS requirement and its associated MS components. Brief comments pertaining to why these particular areas contained gaps are also provided.

Table 6.3**: Areas of MS where gap was found**

MS Component	***HMSS Requirement***	***Comments***
1.0) Quality/R&D&I MS		
Control of Records	1.2.3	CSO has a record keeping processes as required by ISO 9001:2000, but it is not adequate, for it does not fully address the preparation and layout of R&D project records (since R&D projects are excluded from the QMS)
General QMS/R&D&I MS requirements	1.1	R&D&I MS is an entirely new system to be standardized at the CSO, and therefore
2.0) Management Responsibilities		
Policy and Objectives	2.2	Documented R&D&I policy and objectives not set by the CSO as R&D&I was not a area of the business that was standardized.
Responsibility and Authority	2.5, 2.5.1	R&D&I management structure and units not formally defined, although it was clear from the organizational chart which employees would be involved.
Management Review	2.4	Management reviews are carried out at CSO, but does not cover R&D&I MS and the related R&D standard requirements.
Management Commitment	2.1	Many R&D&I MS specific requirements from UNE 166002:2006 not implemented in these MS areas (e.g. policy for protection/exploitation of results, R&D&I budgeting, R&D&I investment policy).

Table 6.3: **Areas of MS where gap was found (Continued)**

MS Component	***HMSS Requirement***	***Comments***
Management System Planning	2.3	The planning of R&D&I MS, such that it meets the R&D&I objectives and general requirements, is not defined.
Stakeholder Focus	2.6	The needs/expectations of *all interested parties* in the R&D&I process was required by UNE 166002:2006.
3.0) Measurement, analysis and improvement		
General practices and stakeholder satisfaction	3.1, 3.3.4	Monitoring and measurement of R&D&I activities not fully defined in this area of the MS, as they were previously not standardized.
Monitoring and Measurement of processes	3.2.1	
Monitoring and Measurement of product	3.2.2	
Internal Audit	3.3.1	Internal audit process already exists at CSO, but does not cover new R&D&I MS requirements of UNE 166002:2006 and EARTO:2000.
Control of non-conformances	3.3.2	Since research tasks are not covered under the scope of the QMS, "deviations from the expected R&D results" are currently not considered when handling nonconformances.
Analysis of Data	3.3.3	The implementation of the new standardized R&D&I MS requires that additional data related to the monitoring/measurement of R&D&I processes and results needs to be gathered, and analyzed.
4.0) Resource Management		
Provision of resources	4.1	Although resources required for the R&D&I management unit and the work environment required to achieve R&D&I objectives already exist in the CSO, they are not defined in the MS documentation.
Work Environment	4.3.3	
Human Resources	4.2.1	EARTO:2000 contains criteria such as employee integrity, professional conduct, and good reputation as part of employee competence, elements that are not specified in ISO 9001:2000.
Teamwork, creativity, motivation	4.2.3	Aspects such as teamwork, creativity, and motivation (which were cited as essential elements of R&D in the literature survey) are new requirements from UNE 166002:2006 that are not specified in ISO 9001:2000.
Competence, Awareness, and Training	4.2.2	CSO staff need to be aware of how they contribute to the achievement of the newly documented R&D&I objectives.
5.0) R&D&I Analysis	5.0	Currently, there no documented processes in place that manage the R&D&I activities described in 4.4.1 of UNE 166002:2006. These activities include: • Technology watch and technology foresight • System to carry out external and internal analysis • Identification/analysis of problems and opportunities Analysis and selection of R&D&I ideas

Table 6.3: **Areas of MS where gap was found (Continued)**

MS Component	***HMSS Requirement***	***Comments***
6.0) Project/product planning, design & development		
Project management and planning	6.1.1	System for planning, monitoring and control of the global project portfolio was not documented in the QMS. This is probably because management of the overall project portfolio is more of a top level strategic concern, whereas the QMS is more associated with issues at the individual project level.
Gather and assess stakeholder requirements	6.1.2	The gathering and assessment of needs/expectations of *all interested parties* in the R&D&I process was required by UNE 166002:2006.
Design/Development Planning	6.2.1	Design team communication structure was an additional element required by UNE 166002:2006 that the CSO had not considered before.
Outputs and results	6.2.3	Since "research contracts" are excluded from the scope of the CSO's quality system, a standardized system for the documentation of research results is not defined in the CSO's QMS.
Review and monitoring	6.2.4	In the current ISO 9001:2000 based QMS, product features is the main element that is reviewed during the monitoring of design and development. However, the overall surveillance of the project progress, particularly with regard to costs and timeframes is not documented as aspects to be monitored (although it is highly likely that the project manager will keep track of these during project execution).
Experimental/Calculational methods	6.2.8	Guidelines for Experimental and Calculational methods are not defined in the QMS documentation, as these are mainly carried out during R&D.
Exploitation of results and intellectual property	6.4	The exploitation of results and technology transfer is another R&D&I specific requirement, which is not addressed in ISO 9001:2000.
7.0) Manufacturing, Receiving, Shipping		
Customer property and research items	7.2	EARTO requirement: Retention period for client supplied research items was not defined in CSO documentation. The reason for this is unclear, however it it is not an ISO 9001:2000 requirement.
8.0) Purchasing		
Select and Evaluation	6.4	The selection of providers based on needs of R&D&I management unit was not specified as a criteria in Quality Manual, since the R&D&I MS was not originally considered.

6.2.4 Issues and Lessons Learned

The examples of gap analysis matrices shown in the IUMSS handbook (ISO, 2008, pp.116-119) contained different levels of compliance for each gap (i.e., the extent to which each MS component complies with each of the MSS requirements). However, defining this level was an issue that presented some unexpected challenges. Different scales of compliance levels that were considered in the analysis:

- A four-level division (ISO, 2008, p.123) and a five-level division similar to the "maturity levels" described in Table A.1 of ISO 10014:2006. Subdividing partial compliance down to such a detail was found to unnecessarily complicate the analysis, as it became increasingly difficult to distinguish between the different gap levels.
- A three-level compliance scale (ISO, 2008, p.116), based on the extent of corrective actions needed to achieve compliance.
    - No Gap - MSS requirement completely fulfilled by the CSO's existing processes or practices.
    - Partial Gap - Modifications to an existing process or amendments to CSO documentation required to close gap.
    - Major Gap - A new process or practice needs to be added to close the gap.
- Two level scale: MS component fully compliant (no gap) or not compliant (gap)

The three-level compliance scale was initially used for carrying out the gap analysis, as it was believed to have the advantage of providing the CSO with a better idea of the actions required to close each gap and perhaps help them set priorities for the gaps that they would focus on first.

However, it was found during gap closure (Sub-Step B5.2) that certain requirements which had been originally considered as "partial" gaps turned out to be "major" gaps, and vice versa. For example, the Monitoring and Measurement of Product process was originally declared as a "partial gap", since a process of monitoring and measuring products already existed at the CSO. However, during gap closure, it was found that a new process needed to be added in order to close the gap, changing the gap into a "major gap". As a result, to accurately use the three-level compliance scale for gap analysis required having an idea of how to actually close the gap,

which was a future step in the IUMSS methodology.

In the end, a two-level scale was used in the final analysis, for the following reasons:

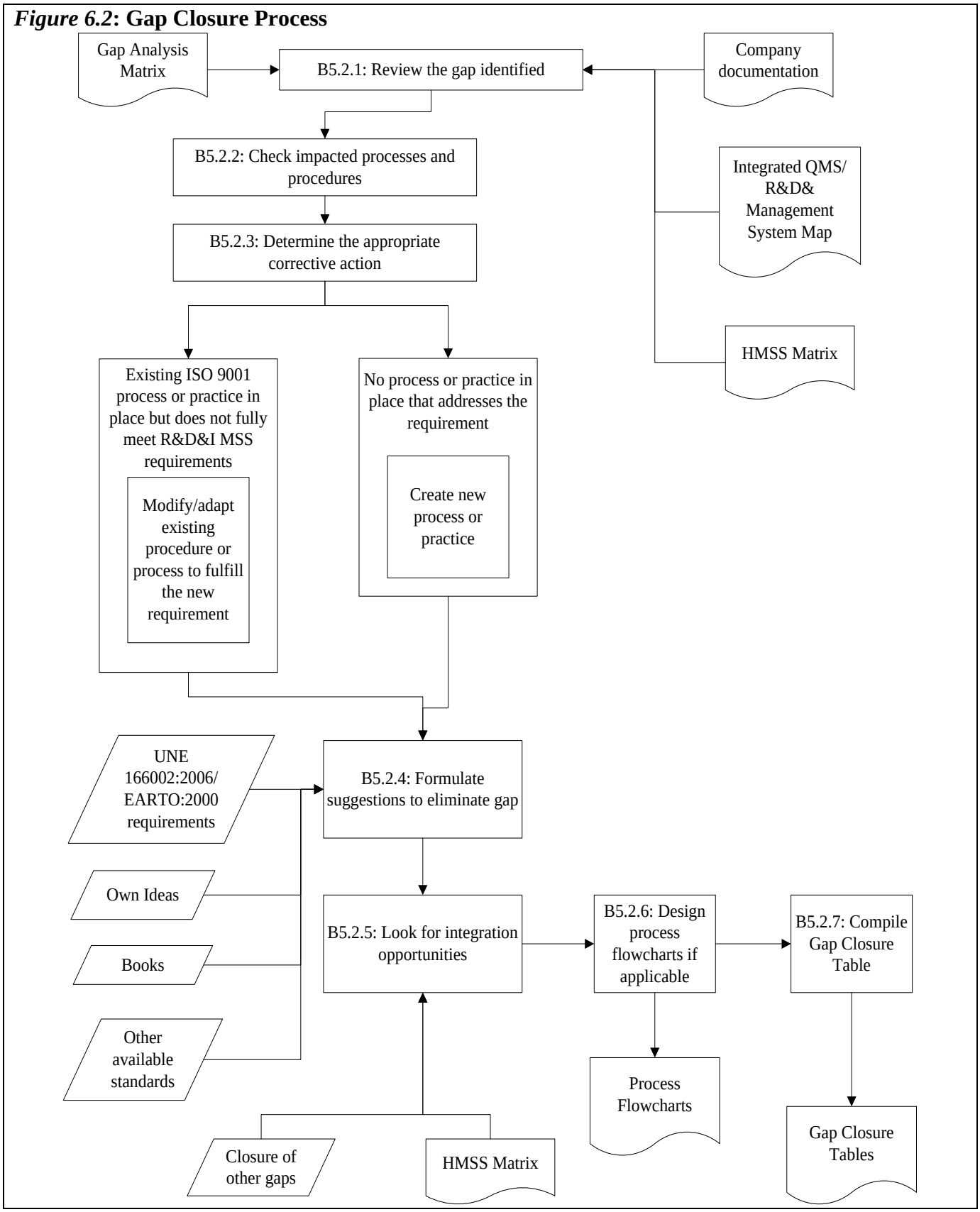
a) Determining the compliance level became a simple question of determining whether or not there was a gap. Difficulties with, and inaccuracies in, establishing the divisions in between these levels were eliminated.
b) Establishing the level of compliance for each gap did not affect the outcome of gap closure. Whether or not a particular MS component contained a "partial" or a "major" gap did not change the fact that the gap had to be addressed or how it was addressed.
c) The gap analysis was conducted against a standard which had only binary-type requirements (i.e., either the requirement was fulfilled by the MS process or not), unlike Business Excellence Models which use a multi-level scale.

6.3 Gap Closure (Sub-Step B5.2)

6.3.1 Gap Closure Process

After the gaps were identified, a list of suggestions describing the actions required to fill them was derived, in order to establish full compliance of the MS with the HMSS. *Figure 6.2* shows the sequence of activities carried out to close the identified gaps.

***Figure 6.2*: Gap Closure Process**



6.3.2 Overview of Gap Closure

This section illustrates how the gap closure activities outlined in *Figure 6.2* were performed, by using Policy and Objectives as an example.

6.3.2.1 Activity B5.2.1: Review the gap identified

From the Comments field in the filled gap analysis matrix, it was found that the Policy and Objectives component of the MS (2.2) contained two main gaps in compliance with the R&D MSSs:

- R&D&I Policy and Objectives not set by the CSO (UNE 166002:2006 requirement)
- General Quality Policy exists in the CSO, but elements addressing ethical codes of conduct environmental/sustainable development not included (EARTO:2000 requirement)

6.3.2.2 Activity B5.2.2: Check impacted processes and procedures

A quick check of the impacted QMS documentation specified in the References field in the gap analysis matrix confirmed the existence of the gaps:

- Quality Manual sec. 5.3: Quality Policy
- Quality Manual sec. 5.4.1: Quality Objectives
- QASP-033*:* Policy and Objectives (QASP-033)

6.3.2.3 Activity B5.2.3: Determine the appropriate corrective action

R&D&I Policy and Objectives and Company Code of Conduct did not exist at the CSO. Thus, the appropriate corrective action was to create a new process or practice. More specifically, an R&D&I Policy and a Company Code of Conduct needed to be developed by the CSO.

6.3.2.4 Activity B5.2.4: Formulate Suggestions to close gap

A list of action steps for closing the compliance gaps was developed. In this particular case, the two main actions suggested to fill the gap were to establish an R&D&I Policy and Objectives and to develop a Code of Conduct. Since it was outside the scope of this research to write out the full policy or code, general ideas for their content was provided using information from UNE 166002:2006 and EARTO:2000.

6.3.2.5 Activity B5.2.5: Look for integration opportunities

One of the guiding questions posed in the IUMSS handbook is: *"Are there other areas or other systems in the organization where gap closure might apply?*" (ISO, 2008, p.129). Thus, opportunities for integration were also considered to address the "integration gaps". As suggested by the IUMSS handbook (ISO, 2008, p. 105), possibilities for both the integration of MSS requirements and MS processes were examined.

***Table 6.4*: Policy Integration Opportunities (highlighted in green)**

	MSS Requirements		
	ISO 9001 clauses	UNE 166002:2006	Requirement UNE 166002:2006
2.1 Management Commitment		Policy for protection/exploitation of R&D results	
...	…	…	…
2.2 Policy and Objectives	Quality Policy	R&D&I Policy	Company Code of Conduct
…	…	…	…
2.3 Management System planning		R&D&I Investment Policy	

Integration possibilities between MSS requirements were a matter of examining the requirements of all three standards listed in the same clause of the HMSS matrix. For instance, as shown in *Table 6.4* above, it was evident that there was an opportunity for integrating the Quality and R&D&I policies and the Company Code of Conduct. The final suggestion was to merge the Quality and R&D&I policies into a single policy, and place it into a single document along with the Company Code of Conduct. This was logical, since the CSO is a MEMS/nanotechnology company with a large emphasis on R&D&I.

Integration possibilities between MS processes was a more complex task as it involved examining how other gaps were closed. For example, it was found that the Policy for the Protection and Exploitation of R&D Results (developed when closing the gap for MS Component 2.1) could also be integrated into the R&D&I Policy as it is related to the overall strategy for R&D&I (see *Table 6.4*). It should be emphasized that identifying integration opportunities between MS processes was only truly possible after suggestions were formulated

for the closure of all the gaps. For instance, looking at the HMSS, it was initially believed that the R&D&I Investment Policy (from MS Component 2.3) could also be integrated into the R&D&I policy. However, the closure of that gap indicated that the investment policy was more of a strategic concern, and therefore the details would probably not be made available to regular employees in the Integrated Quality/R&D&I MS manual.

More details on integration possibilities between the existing QMS and the R&D&I MS are discussed in Subsection 7.3.2**.**

6.3.2.6 Activity B5.2.6: Design process flowcharts if applicable

Generic flowcharts were designed where graphical depictions would aid the understanding of the processes described in gap closure. These process flowcharts can be found in *Appendix G*. *Appendix F* shows the flowchart symbols used. For this gap, three process flowcharts were designed:

- Developing the R&D&I Policy and Company Code of Conduct (*Appendix G-1.1*)
- Integrating and deploying the policies (*Appendix G-1.2*)
- Verifying the policy implementation (*Appendix G-1.3*)

6.3.2.7 Activity B5.2.7: Compile Gap Closure Table

The main output from gap closure consisted of 22 gap closure tables (*Appendix H*). The tables were set up as shown in *Table 6.5*. A description of the content of each column is also provided.

***Table 6.5*: Gap Closure Table Setup**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
The identified gap	Corresponding clause number in the integrated HMSS. This number is also used for referencing the gap.	The area of the MS, and related documents that are impacted	A list of suggestions to close the gap. Only brief guidelines for gap closure were provided.	The rationale behind the gap closure suggestions and other relevant details.

An extract of the gap closure table for closing the Policy and Objectives (2.2) gap is shown in *Table 6.6*. The full gap closure table can be found in *Appendix H-2.1*.

***Table 6.6*: Extract of Gap Closure Table - Policy and Objectives**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
R&D&I policy and objectives not set by the CSO General quality policy exists in the CSO, but elements addressing ethical codes of conduct environmental/sustainable development not included.	Clause #2.2 : Policy and objectives	*Management Responsibilities: Policy and Objectives* Quality Manual (Section 5.3: Quality Policy) Quality Manual (Section 5.4.1: Quality Objectives) Policy and Objectives (QASP-033) Training (QASP-016)	For a graphical representation of the corporate policy development and deployment process, refer to *Figure G-1.1* and *Figure G-1.2* A) Establish a top level policy for the R&D&I activities and set overall R&D&I objectives for the organization. … B) Develop *Company Code of Conduct*, covering aspects such as environmental and sustainable development, ethics and professional business practice … C) Look for integration opportunities between policies, and develop an Integrated Quality/R&D&I Policy.	A) The R&D policy is a statement that formalizes the company's commitment to R&D performance . It "*provides a reference framework to establish and review the R&D&I objectives*" (4.2.3: UNE 166002:2006). B) Section 1 of EARTO:2000 covers ethics and general principles for a "Code of Conduct" (for the organization). These are brief set of guiding principles/behaviors that the company and all employees must follow to uphold the company's ethical standards. It helps to resolve ethical dilemmas. C) Since the CSO is a MEMS/nanotechnology company (with a large emphasis on R&D&I), it is logical that the R&D&I policy be combined with the Quality Policy (ISO 9001:2000 requirement 5.3) to create an integrated policy.

To close this gap, a process for developing an R&D policy and Company Code of Conduct was designed. A gap closure table for this gap was created (*Appendix H-2.1*) along with a new generic process for developing an R&D policy and Company Code of Conduct (*Appendix G-1.1*). It was also determined that the quality policy, and the Quality and R&D Policy could integrated into a single policy, and the organized into a single document along with the Code of Conduct. A process for integrating the policies, deploying and verifying them is shown in *Appendix G-1.2* and *Appendix G-1.3.*

6.3.3 Selected examples of gap closure suggestions

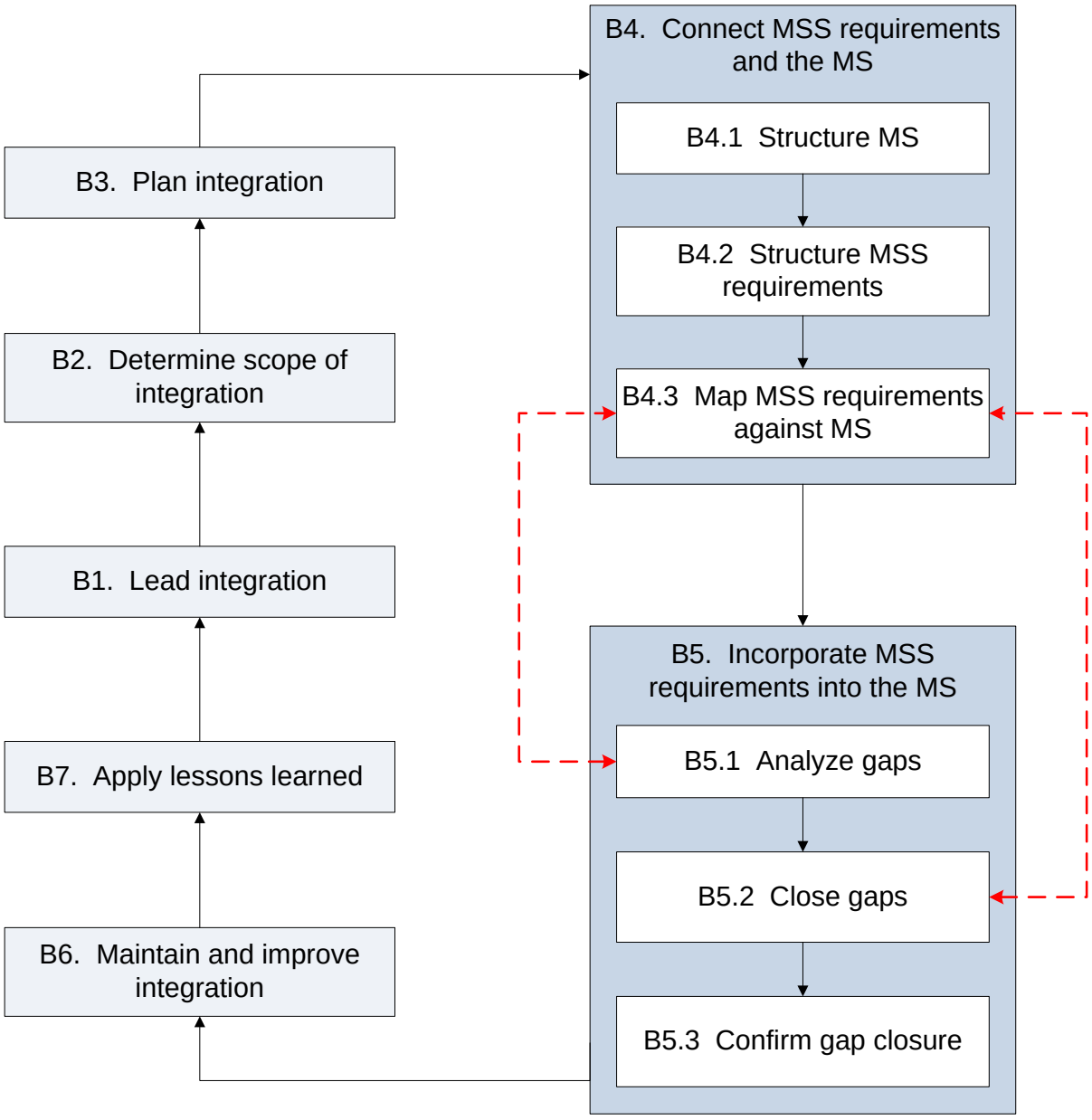
Five examples of the gap closure suggestions were selected from various parts of the MS, and are discussed in the following subsections. Each gap is identified by the name of the corresponding MS area, with its number in brackets (see *Figure 5.4*). These examples represent the range of corrective actions that were suggested for closing the gap, from modifying a single line in a procedure (Subsection 6.3.3.3), to creating entirely new processes (Subsection 6.3.3.5). The details of all the gap closure suggestions can be found in *Appendix H.*

6.3.3.1 Policy and Objectives (2.2)

The compliance gap in Policy and Objectives was closed as outlined in the previous subsection. Since a Quality Policy already existed at the CSO, there was also an integration opportunity to combine the R&D and Quality Policies, which was an example of closing an "integration gap".

This example also illustrates an important discovery that was made which has important implications for the IUMSS methodology. During gap closure, it was found that some parts of the MS were affected by certain MSS requirements that were not initially identified during Sub-Step B4.3. For instance, the development of a new R&D Policy and Code of conduct also affected the Training procedure. This finding suggests that the IUMSS process can be modified as shown in *Figure 6.3* below.

Figure 6.3: **Modified IUMSS with feedback loop back to mapping step**



The red dashed feedback loops indicates that if a particular MSS requirement is found to impact a new area of the MS not initially identified, after the corresponding analysis in the mapping step (Sub-Step B4.3), the CSO can go back to the mapping step and revise. This can occur during Sub-Step B5.1 (Analyze gaps) or Sub-Step B5.2 (Close Gaps), although in the case of this example, it was the latter.

As an illustration, the Policy and Objectives example will be used again. As stated before, the development of a new R&D Policy and Code of Conduct also affected the Training procedure (since employees needed to be trained on the new Integrated Policy). Therefore, a revision of the 'Table of Correspondence between HMSS requirements and CSO procedures" (*Appendix C-3.2*) compiled during Step B4.3 can be made. As shown in *Table 6.7*, the Training procedure (QASP-016) and MS Area 4.2.2 (Competence, Awareness and Training) are added to reflect the changes (shown in red text).

Table 6.7: **Revision to Table of Correspondence between HMSS and procedures**

Key processes/practices @ organization		***Associated Organizational Documents***	**Impacted HMSS requirements clauses**
2.0) Management responsibilities	Policy and Objectives	QASP-033: Quality Policy and Objectives QASP-016: Training	2.1 Management commitment 2.2 Policy and objectives 4.2.2 Competence, Awareness and Training

Going back to the Sub-Step B4.3 and making the appropriate revisions can facilitate future integration efforts. For instance, if ISO 14001:2004 (which also contains Policy and Objectives requirements) were to be also implemented by the CSO, it would be clear immediately that not only would Policy and Objectives be affected, but also Training. The gap analysis conducted would now involve the examination of both the Policies and Training procedures.

6.3.3.2 Management Review (2.4)

The existing Management Review process at the CSO was identified to contain a gap, since the review did not cover the R&D&I MS and the related R&D standard requirements. The existing process was modified to include additional R&D&I review input, the sitting in of the R&D director during the meetings, and R&D&I review results (output). This criterion was all provided in UNE 166002:2006. Details of the additions are listed in *Appendix H-2.5*.

A flowchart for the Management Review process (*Appendix G-1.5*) was also designed for the CSO, as one was not found in the QMS documentation. This flowchart is believed to provide a better visualization of the Management Review process, as it shows in a single figure the inputs and information needed to be collected, the people involved in the meetings, record forms used,

and the outcomes to be expected. The gap closure table for the Management Review gap is shown in *Appendix H-2.4*.

This was another example of closing an "integration gap" by examining integration possibilities between MSS requirements. Since a Management Review process already existed at the CSO (ISO 9001 requirement), it would be redundant to design an entirely new process. As per the suggestions above, the existing process was re-used, with additions made in order to comply with the new R&D MSS requirements.

6.3.3.3 Customer Property and Research Items (7.2)

The gap was identified in the Control of Customer-Supplied Product process was that the retention period for customer delivered research items was not specified. The gap was closed by modifying the existing procedure to specify a minimum retention period time of three months as suggested by the EARTO:2000 guidelines. In this case, the addition of a single line in an existing procedure was all that was required to establish compliance with the standards. The gap closure table for this gap is shown in *Appendix H-7.1*.

6.3.3.4 Control of Records (1.2.3)

The Control of Records component of the MS was found to contain a gap, since it did not fulfill the new MSS requirement of addressing the preparation and layout of R&D project records (EARTO:2000 requirement). A new section was created in the existing Quality Records procedure (*QASP-014*) providing guidelines for the "Preparation of R&D project and technical records", with information obtained from both the EARTO:2000 guidelines and a book on Quality Assurance in R&D (Roberts, 1983). Since requirements provided by MSSs are usually general and do not provide much guidance for implementation suggestions, information from additional sources can be helpful. For instance, Roberts (1983, p.121) contained detailed information on formatting project records which was used as suggested content for the new section on R&D records.

Developing a procedure for the preparation of R&D records is important for three main reasons:

a) Documentation generated by the R&D staff at the CSO is currently unstructured and inconsistent
b) Keeping good records helps ensure that results do not get lost, and provides a disciplined way of capturing the R&D results that may need to be referred to during the product's life cycle (Jayawarna and Pearson, 2001, Vermanercke, 2000).
c) Well kept records help facilitate an efficient patent application (Jayawarna and Holt, 2009) and would help substantiate conclusions and recommendations from an R&D project or product, in the event that the R&D is subject to scrutiny by customers or a public court (Roberts, 1983, p. 1).

Full details of closing this gap can be found in *Appendix H-1.1*

6.3.3.5 R&D&I Analysis (5.0)

These were new requirements from Section 4.4 of UNE 166002:2006, and include the use of R&D&I Tools (see Subsection 2.4.2.2), the Identification and Analysis of Problems and Opportunities, and the Analysis and Selection of R&D&I Ideas. These processes provide the management with additional information for making decisions in planning the company's project portfolio and MS. For instance, implementing technology watch and foresight activities can help the CSO be more aware of changes in technology, the marketplace, and new standards that may have an impact on R&D, and to make sure these changes are taken into account in order to keep the R&D&I management system up to date.

All these processes constituted an entirely new area of the MS (5.0: R&D&I Analysis) that was not previously documented, although many of the activities were likely to be informally conducted by the CSO during product development. New processes flowcharts for Technology Watch (*Appendix G-3.1*) Technology Foresight (*Appendix G-3.2*), External and Internal Analysis (*Appendix G-3.3*), the Identification and analysis of problems and opportunities (*Appendix G-3.4*) and the analysis and selection of R&D&I ideas (*Appendix G-3.5*) were designed, using the criterion provided by UNE 166002:2006. Full details of these processes are provided in *Appendix H-5*.

6.3.3.6 Summary of gap closure suggestions

The five examples discussed above illustrate the range of suggestions that were formulated to close the gaps identified during gap analysis. Some of the recommendations only required minor modifications to existing procedures (Subsection 6.3.3.3), whereas some required entirely new processes to be designed (Subsection 6.3.3.5)

These examples also emphasize that the recommendations provided for gap closure were not made simply for the sake of fulfilling standard requirements (i.e., closing the "gaps in compliance"), but are actually useful for improving the MS in a nanotechnology company. For instance, as revealed in the literature survey, the careful planning, organizing, direction and controlling of R&D activities is considered to be critical for R&D work by researchers such as Pellicer *et al.* (2008). The establishment of an R&D&I Policy and Objectives (Subsection 6.3.2.1) can help provide a basic starting framework for developing R&D plans. The R&D&I Analysis processes presented in Subsection 6.3.3.5 can provide input and additional information for R&D planning. Documentation features required by the R&D MSSs (see for example, Control of Records in Subsection 6.3.3.4) can also be highly beneficial for the CSO and any other nanotechnology company. In general, the R&D MSSs and the gap closure suggestions generated to meet their requirements expands the existing ISO 9001:2000 based MS to better accommodate R&D aspects.

Lastly, these gap closure examples illustrated how common QMS and R&D&I MS processes, such as Management Review (Subsection 6.3.3.2) and Policy (Subsection 6.3.3.1) could be integrated. These are two examples of "integration gaps" that were addressed.

6.3.4 Issues and lessons learned

One of the challenges a company might encounter in gap closure is how to formulate the corrective actions to close a gap, since the requirements in MSSs are usually very generic and do not provide much guidance. For instance, UNE 166002:2006 requires that a company sets a suitable R&D&I policy, yet does not specify exactly what the policy should contain. As mentioned in the literature survey, the interpretation of the MSS requirements can be a challenge for small organizations (such as a nanotechnology startup), which are often unfamiliar with the

terminology and language of the standards (European Commission, 2008). This is further exacerbated by the fact the usage R&D MSSs have been not been extensively studied, and unlike MSSs such as ISO 9001 or ISO 14001, guides for their implementation are not readily available.

A finding that was mentioned in Subsection 6.3.2.1 was that if a particular MSS requirement is found to impact an area of the MS not initially identified, after the corresponding analysis in the Mapping step (Sub-Step B4.3), one can go back to the mapping step and revise. As illustrated in *Figure 6.3*, this can occur during Sub-Step B5.1 or Step B5.2. Going back to the Sub-Step B4.3 and making the appropriate revisions to outputs generated during that sub-step can facilitate future MSS integration efforts. As explained in sub-section 6.3.3.1, updating the "Table of Correspondence between HMSS requirements and CSO procedures" (*Appendix C-3.2*) may help the company better target which processes to analyze in future gap analyses.

It was also learned that multiple gaps can be closed through common corrective action. For example, Gap 4.2.1 (Human Resources) requiring that employees show integrity and professionalism, was fulfilled by closing Gap 2.2: Policy and Objectives, through training with the newly developed Company Code of Conduct. Checking for the closure of multiple gaps using the already-developed corrective action is another example of closing an "integration gap" through "integration between MS processes" (Activity B5.2.5).

6.4 Summary

This Chapter presented how the new MSS requirements can be incorporated into the CSO's current MS through the IUMSS steps of Gap Analysis (Step B5.1) and Gap Closure (step B5.2). The Gap Analysis Process was presented first, followed by the introduction of the Gap Analysis Matrix and a summary of the gap analysis results. Issues related to defining a compliance level for the gap were also discussed. Next, the Gap Closure process was introduced and discussed in detail. Five selected examples of the gap closure suggestions from various parts of the MS were discussed. These examples illustrated the range of suggestions formulated to achieve compliance with the MSS requirements (i.e., "compliance gaps"). Several examples of closing "integration gaps" were also illustrated. The chapter finishes with a brief discussion of some of the lessons learned during gap closure.

7. Post Implementation Activities

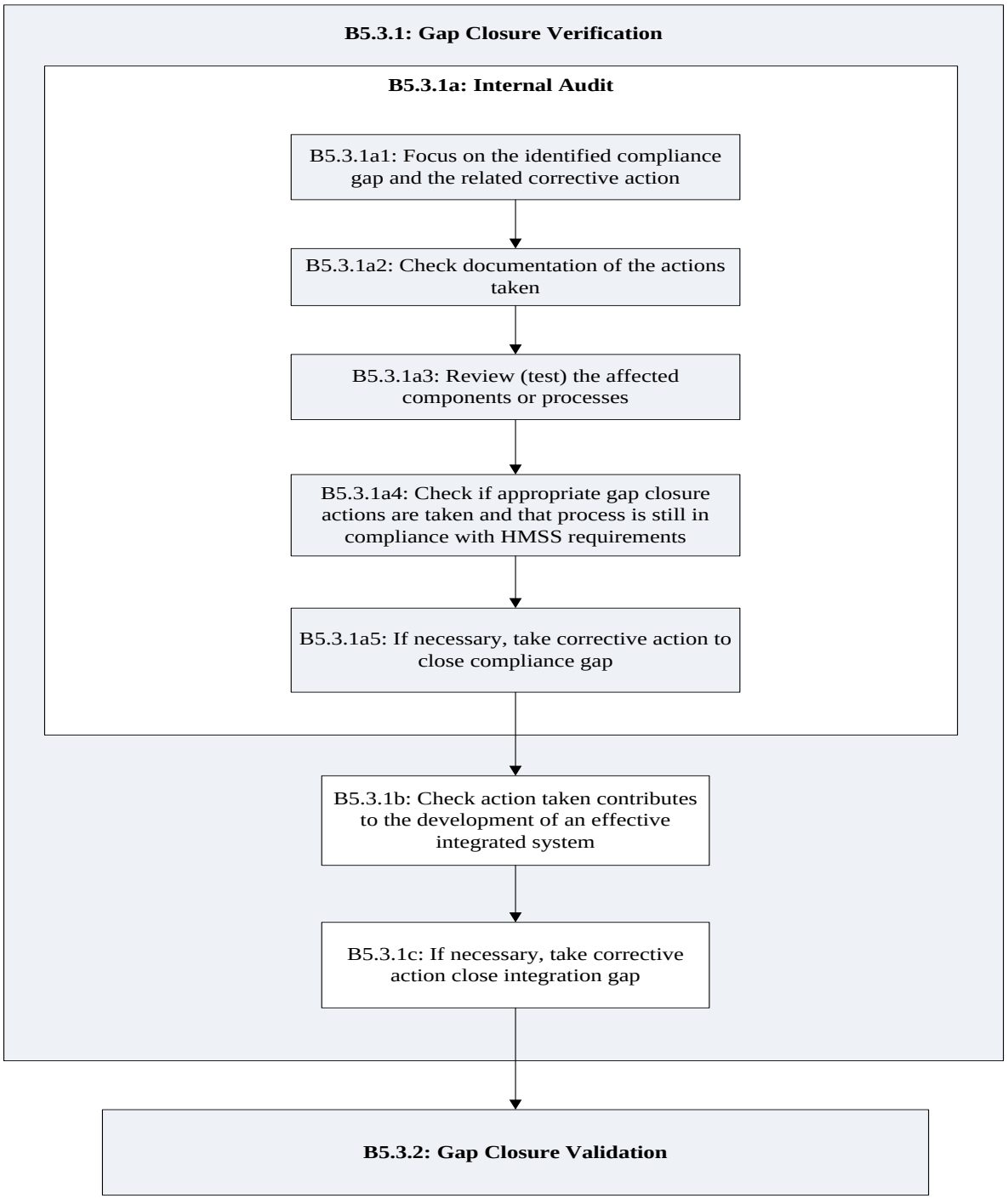
7.1 Introduction

After gap closure suggestions are made and planned out, the next step would be to actually close the gaps. This involves implementing the changes to the company processes, creating and updating the appropriate documentation, training employees, and recording the actions taken. However, these actions were outside the scope of this research. Instead, this chapter will briefly describe the activities involved in "Confirming gap closure" (Sub-Step B5.3) and maintaining and improving integration (Step B6), should the CSO decide to implement the gap closure suggestions. An overview of the possibilities for creating an integrated MS is also presented in Step B6. Lastly, a summary of the lessons learned and challenges encountered during the IUMSS process carried out in this research study will be provided (Step B7).

7.2 Confirm Gap Closure (Sub-Step B5.3)

Figure 7.1 shows the sequence of activities that can be carried out to confirm gap closure.

***Figure 7.1*: Confirm gap closure**



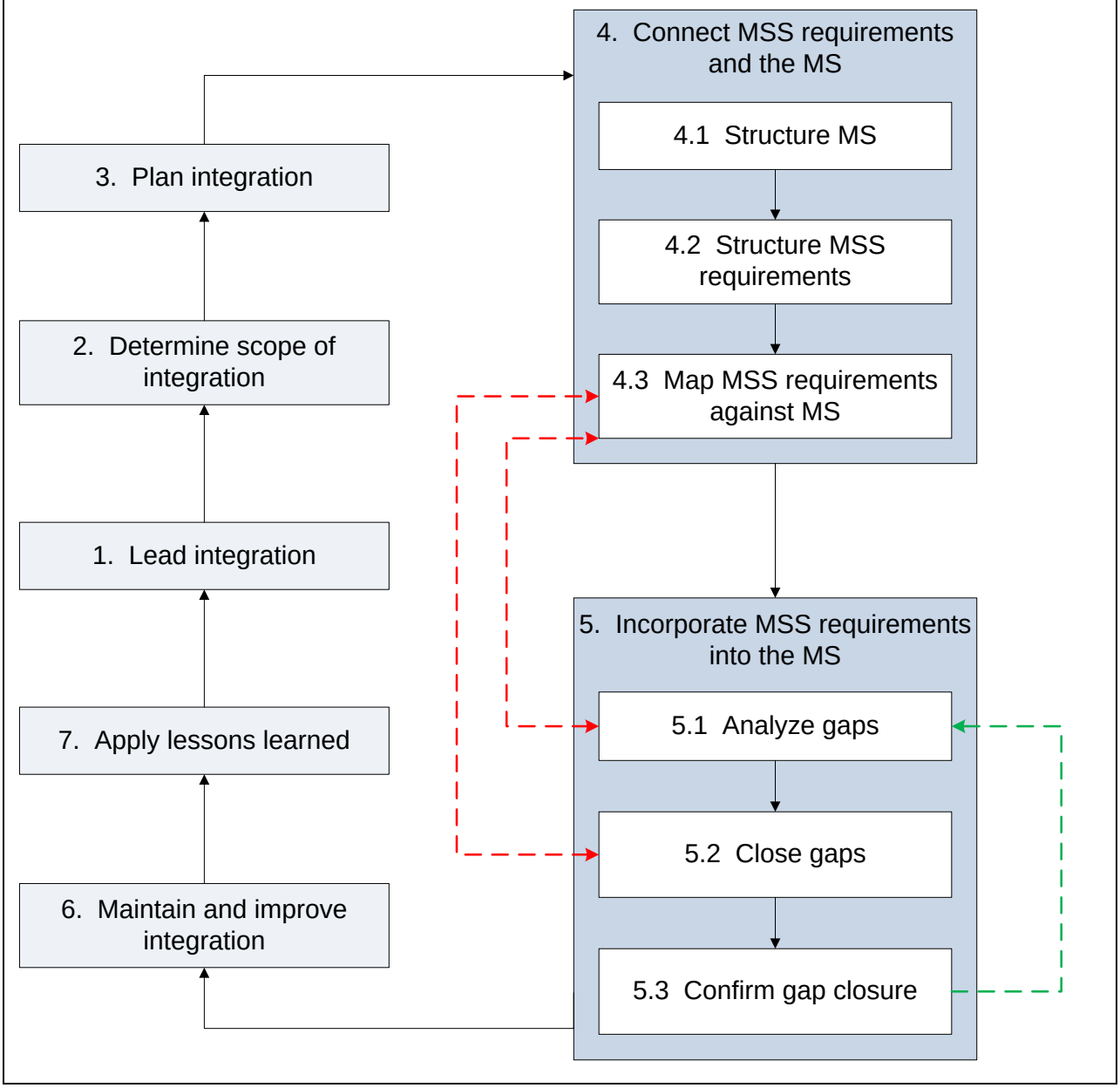
7.2.1 Activity B5.3.1: Gap closure verification

Following guidance provided in the IUMSS handbook (ISO, 2008, pp.129-131), the CSO should confirm that:

a) gap closure actions have been taken and were effective
b) the actions taken fully satisfy the MSS(s) requirements
c) the actions taken contributes to the development of an effective IMS

Confirming that action has been taken, was effective, and fully satisfies the MSS(s) requirements can be accomplished through an internal audit (Activity B5.3.1a in *Figure 7.1*). For example, the Control of Customer Supplied Procedure (QASP-005) procedure was modified to include the requirements for a three-month retention period for client supplied research items, as specified in EARTO:2000 (Gap 7.2). An audit to confirm that the gap in compliance was closed would involve checking that client-supplied research items were indeed being retained for at least three months and verifying that the other requirements in HMSS Clause 7.2 were still complied with. Evidently, this activity is analogous to performing a gap analysis on a particular MS component. In the case the internal audits show that the gaps still exist within the MS, corrective action should be initiated to close them. This last point suggests that yet another modification can be made to the IUMSS process, as shown in *Figure 7.2***.**

Figure 7.2: **Modified Process of IUMSS Methodology**

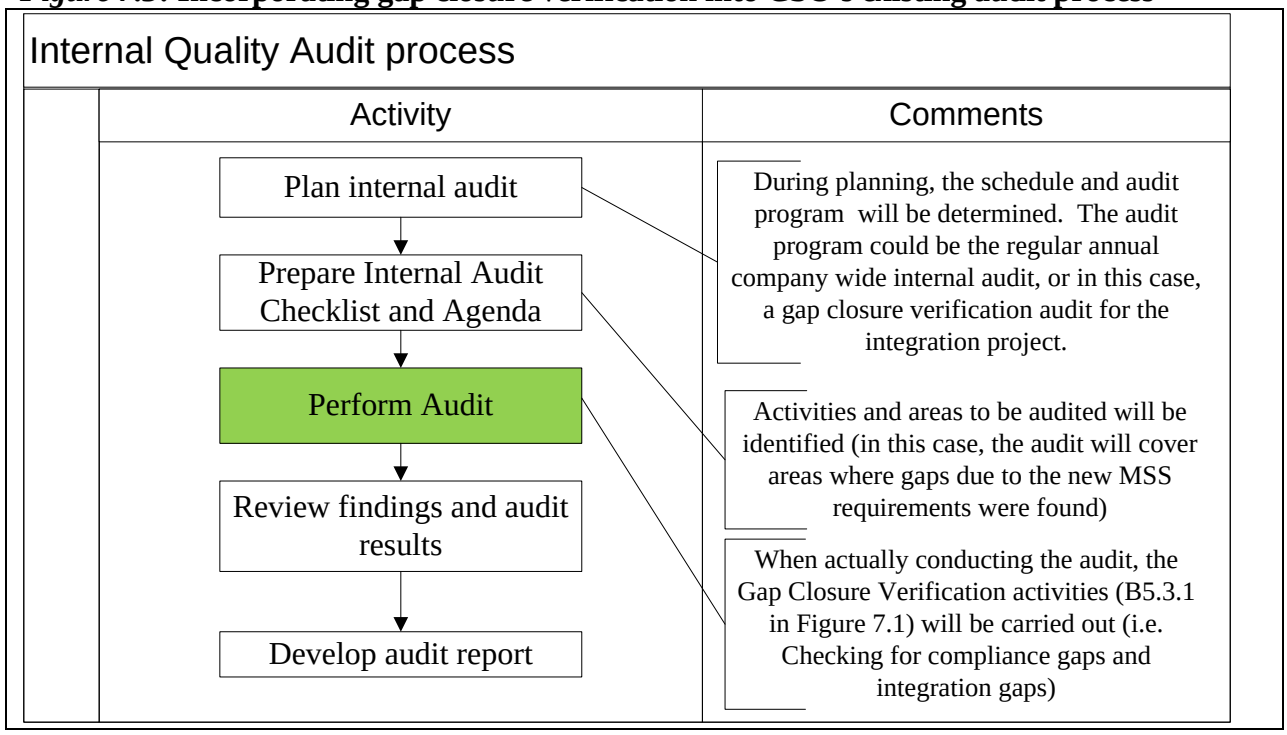


The addition of the green-dashed feedback loop indicates that verification activities performed during Step B5.3 may require revisiting previous sub-steps of the IUMSS methodology. Gap analyses (Sub-Step B5.1) are carried out on particular MS components that were modified by the new MSS requirements. Areas where gaps still exist will require corrective action to be taken again (i.e. Sub-step B5.2), which implies that the gap closure tables and process flowcharts developed earlier may need to be revised. The loop also suggests that the process of fully

closing the gaps (especially the identification of all integration gaps), can take several passes to complete.

It should be noted that the existing Internal Quality Audits process at the CSO (found in QASP-015) can be used for the gap closure verification (*Figure 7.1*). The CSO's Internal Quality Audit process is generic and can be tailored for auditing an IMS. *Figure 7.3* shows in general how the CSO's audit process could be used for gap closure verification.

***Figure 7.3*: Incorporating gap closure verification into CSO's existing audit process**



"Self assessments" (ISO, 2008, p.130) conducted by the R&D team to confirm gap closure was also considered as an option. However, it was decided that the verification activities (in the form of internal audits) would be best carried out by the QA Team at the CSO, as they are more experienced with auditing procedures and MSSs overall. The R&D team would have the responsibility of implementing gap closure changes, but the verification of the gap closure would be performed by the QA Team.

Finally, gap closure verification involves checking to see if the gap closure action taken contributes to the development of an effective IMS with no unnecessary duplication of processes (Activity B5.3.1b). This refers to addressing the "gaps in integration", which, for the purposes of

this research, was performed during Activity B5.2.5 of Sub-Step B.5.2 (see *Figure 6.2*), since the implementation of the MSSs was not actually carried out. However, addressing "gaps in integration" can also be conducted at a later stage. The IUMSS handbook suggests doing so during Sub-Step B5.3 and Step B6.

Nevertheless, the first pass of closing the "gaps in compliance" needs to be performed before "gaps in integration" can be addressed, since a better idea of where MS components can be combined would be available at this time. For example, as was mentioned earlier in Chapter 6.3.2, the Policy for the Protection and Exploitation of R&D results (developed when closing Gap #2.1) could also be assimilated into the R&D&I Policy (Gap #2.2), as both policies are related to the overall strategy for R&D&I. After this integration possibility was realized, the gap closure tables and process flowcharts developed earlier had to be revised, to reflect the new input content for developing an R&D&I Policy. The activity of addressing these "gaps in integration" further emphasizes the need for the feedback loop running between gap closure confirmation and the earlier steps of gap analysis and gap closure. A full list of possible integration opportunities is presented later in Subsection 7.3.2.

Another note of importance is the possibility of finding requirements from multiple MSSs that are conflicting. In this study, no such requirements were found, since both UNE 166002:2006 and EARTO:2000 were designed to be compatible with ISO 9001:2000. In the event that such conflicting requirements did exist, they would be dealt with early during Sub-Step B4.2, since they would be visible when included in the HMSS table. At this point, the organization might decide to choose to adopt one of the requirements, but not the other one that conflicts with it. It is likely that the organization would choose the requirement from an MSS meant for MS registration purposes (e.g, UNE 166002:2006), as opposed to guideline standards (e.g., EARTO:2000). The effective identification of conflicting requirements is one of the benefits of developing the HMSS.

7.2.2 Activity B5.3.2: Gap closure validation

Aside from verification, the effectiveness of the implementation (whether or not the integration added value to the CSO) needs to be determined. The true indicator of whether the integration is working successfully is an improved performance of the organization's MS over time (ISO,

2008, p. 129). Therefore, validation would involve establishing indicators of MS performance before the integration project, and measuring any improvements after the integration.

The general benefits of implementing a QMS in R&D were mentioned in Subsection 2.3.3. Benefits of implementing some of the specific MSSs were mentioned in Subsection 2.4.2. Specific opportunities stemming from the issues and challenges identified at the CSO were listed in Subsection 3.4.2. Performance indicators can be developed for the particular aspects of the business where benefits were to be expected or where issues/challenges were found. Some possible performance indicators that can be used for gap closure validation are listed below in *Table 7.1*. These indicators will likely be assessed during the quarterly management reviews.

Table 7.1: **Possible performance indicators for gap closure validation**

Business Aspect to be measured	Possible indicator(s) of performance
The standardization of R&D work at the CSO is believed to promote more structured and consistent documentation/procedural design at R&D stage, which was previously not standardized.	• Percentage of project time devoted to rework due to missing or inadequate documentation from R&D • Average product development time spent at the "Concept" and "Development" stages (see *Figure 3.3*.
Including R&D work in the QMS is believed to improve procedural awareness and compliance, due to employee training requirements.	• Instances of project delays due to procedures not followed.
Improved planning of R&D projects (including the introduction of R&D&I "tools") required by R&D&I MSS implementation is believed to improve the predictability of the projects and overall R&D performance.	Kerssens-van Drogelen *et al.* (2000) list a number of metrics that can be used for R&D performance. Some of these include: • Patent output. • Technology and business awards received. • Percentage of successful research design to production transfers. • Product development cycle times and research costs. • Percentage of sales that come from new products introduced over a period of time. R&D performance measurement is outside the scope of this thesis. For details, readers can refer to Garcia Valderrama *et al.* (2008) or Kerssens-van Drogelen *et al.* (2000).
One of the specified benefits of implementing UNE 166002:2006 is improved employee motivation and R&D awareness.	• General survey of employee perception of new standardized system.

7.3 Maintain and improve integration (Step B6)

7.3.1 Integration Maintenance and Improvement

After completing the gap analysis and successful closing the identifying gaps through verification, the organization should ensure that the requirements of the MS remain properly implemented. Regular monitoring and review of the system is a key part of maintaining and improving an effective MS over a sustained period of time (ISO, 2008, p. 132).

Furthermore, the MS must also be continually updated and improved in order to maintain effectiveness. For example, the CSO may choose to monitor key performance indicators in order to continuously improve or maintain a standard that is above average in the industry. This data can be benchmarked against other organizations that have successful Quality and R&D programs. At the very least, ongoing assessments of the MS to uncover weaknesses need to be conducted, and appropriate corrective actions incorporated. Assessments should also identify strengths and what is working well (ISO, 2008, p.144).

Awareness of the external environment and impact on the organization is also important in keeping the MS current and effective (ISO, 2008, p.144). For instance, monitoring of the system includes being continually aware of new and changing requirements from customers and stakeholders, as well as external sources from international standards and industry best practices, legislatures and NGOs (ISO, 2008, p. 133). This is particularly important in rapid growth areas such as nanotechnology.

7.3.2 An Integrated Quality and R&D&I Management System

As mentioned in Subsection 4.3.1**,** both UNE 166002:2006 and EARTO:2000 are inherently related to QM (of R&D), suggesting that Quality and R&D&I management systems can be integrated. Both of the R&D&I MSSs were very similar to ISO 9001:2000 (containing many of the same components, and therefore their elements could be directly inserted into the QMS. The compatibility of UNE 166002:2006 with ISO 9001:2000 further facilitates their integration.

As emphasized throughout the IUMSS Handbook and this thesis, it was essential to determine

whether the system is integrated as much as possible by looking for redundancies and synergies in the MS processes and resources (i.e. the "integration gaps"). These integration gaps were determined during Activity B5.2.5 of Gap Closure (see Subsection 6.3.2.5).

A summary of the possibilities creating an integrated MS are provided below. These stem from areas of the MS where no gaps were found (i.e. existing processes at the CSO which can be re-used), and from the closing of integration gaps.

Possibilities for integration have been divided into three main categories as described by Bernardo *et al.* (2009):

- Integration of Human Resources,
- Integration of Goals and Documentation Resources
- Integration of Processes

7.3.2.1 Integration of Human Resources

As the CSO is a small company, it is likely that the existing QA Coordinator (who currently manages the QMS) will also be assigned the responsibility of managing the R&D&I MS. Representatives for quality and R&D will be separately appointed though, as the R&D Top Management Representative (e.g., the R&D Director) would be more familiar with the developments and issues faced in the R&D business unit.

7.3.2.2 Integration of Goals and Documentation Resources

Integrated Quality/R&D&I Policy and Objectives

The "goals" refers to the Quality and R&D&I Policies and Objectives, which will be integrated as mentioned in Subsection 5.3.3. The related gap closure suggestion was to create a single document (QASP-033) for containing the Integrated Quality/R&D&I Policy and Objectives (meeting ISO 9001:2000 and UNE 166002:2006 requirements), along with the Company Code of Conduct (EARTO:2000 requirement). An Integrated Quality/R&D&I Policy and Company Code of Conduct may help ensure that all employees are working towards the same strategic goals at the CSO, and improve communication and cooperation (Karapetrovic, 2003).

Integrated Management System (IMS) Manual

An integrated manual containing both Quality and R&D MS elements should be created, since the R&D&I MSS requirements impact the entire company, and not just the R&D business unit. As evident throughout the Gap Closure tables, most of the new R&D&I MSS requirements were built on top of the existing sections in the Quality Manual. Hence, the "Quality Manual" should be renamed the "IMS Manual". This manual would describe the processes in both systems, and make reference to all relevant procedures. The IMS Manual will also contain the Integrated Quality/R&D&I MS Map (*Figure 5.4*), which shows how and where R&D&I elements fit into existing QMS. In the future, the IMS Manual can be expanded to encompass environmental and other management systems as needed.

As Bernardo *et al.* (2009) revealed, strategic elements of the MS such as Policy and Objectives are most likely to be the first areas to be integrated. Furthermore, it would make sense for the CSO (being an R&D-oriented organization), to incorporate R&D aspects into its IMS Manual and corporate policies.

Work instructions and records

These items will probably not be integrated at first due to the difficulty in standardizing the CSO's operational working procedures, and the fact that different records and instructions are involved at each stage of product development. For instance, quality record forms (containing inspection results, inspection status and authority responsible for release of the product) are currently used at the CSO for manufactured products. With the implementation of the R&D&I MS, records for R&D activities will also be kept (see *Appendix H-1.1*). The instructions used for product manufacturing are called "Work Order Travelers" at the CSO, whereas "Design Plans" are used during R&D.

7.3.2.3 Integration of Processes

The CSO might also decide to integrate a number of common MS processes found in both the existing QMS and the new R&D&I MSS. Many requirements of the three MSSs can be satisfied by having a single shared process, thus reducing the number of procedures that need to created.

Document and record control

This was one of the MS areas that did not contain a gap (see *Table 6.2*). Therefore the same processes can be used for both the Quality and R&D&I MS.

Internal Communication

Existing channels of communication at the CSO can be used by the employees involved with the R&D&I MS. This includes verbal communication at staff meetings or through emails.

Corrective/preventive action & improvement

The existing processes for addressing non-conformities and potential causes of non-conformities can be used for both the QMS and R&D&I MS. For example, the process of corrective and preventive action can respond to customer complaints (strictly related to ISO 9001), or non-conformities related to R&D products (e.g. prototypes). The provisions made for continual improvement are also the same for both QMS and R&D&I MS.

Product Realization

Since R&D is a stage of the overall Product Realization process, many of the new elements from the R&D&I standards are an extension of the Design and Development processes in ISO 9001:2000, and can be built into the QMS (see *Figure 5.4*). For example, the information gathered from the R&D&I Analysis (e.g., Technology Watch) acts as additional input that is fed into project and product planning (along with the existing ISO 9001 Determination of Requirements process). Existing Design and Development processes are further developed by the incorporation of new requirements from the R&D standards (e.g., the Outputs and Results component now includes a process for the documentation of research results).

Training

The same training process will be used by all the personnel at the CSO, as everyone needs to be aware of the Integrated Policy and Company Code of Conduct. The material each employee will be trained on, however, will differ depending on their roles. The training procedure is contained in a single document (QASP-016), and covers both Quality and R&D&I.

Purchasing

As pointed out in gap analysis (Subsection 6.2.3), the existing purchasing information and verification processes can be reused for the R&D&I MS. The revised Provider Selection and Evaluation process (*Appendix H-7.1*) can also be applied for both the QMS and R&D&I MS,

Control of non-conformances

This process can be used for both the QMS and R&D&I MS after gap closure, by specifying that "deviations from the expected R&D results" will also be considered as a "non-conformance". For example, a single record for the initiation and follow-up of preventive and corrective actions can be used, with the possibility to indicate the specific area of concern, i.e. quality or R&D&I.

Internal auditing

An integrated internal audit covering the requirements of both the QMS and R&D&I standards can be performed. An integrated audit has the ability to identify linkages, redundancies and synergies among systems, as well as reducing costs (Pojasek, 2006). As mentioned by Pojasek (2006), cost savings can occur since the CSO's internal auditor will only need to consider one audit sample (e.g., management review, document control and training) for common processes. Furthermore, an integrated audit will require an auditor to receive specific training on both Quality (ISO 9001) and R&D (UNE 160006:2006 and EARTO:2000) MSSs. Having the knowledge of both systems can help the auditor identify linkages between them. This is the same sort of activity as described in Subsection 6.3.2.5, where opportunities for gap closure integration were sought. The HMSS developed during Sub-Step B4.2.2 can facilitate the internal audit, since it contains the combined requirements of both the Quality and R&D MSSs. Instead of auditing against three separate standards, the internal auditor can simply audit against the HMSS, and refer to the individual standards if necessary.

Management Review

The management review of the both the QMS and R&D&I MS can be combined into one business meeting, as implied by the new Management Review Process Flowchart designed for the CSO (*Appendix G-1.5*). An integrated management review can save time (Pojasek, 2006), since a single meeting can be held to review both systems together. More importantly, with perspectives from both Quality and R&D, managers will be able to use information in an

integrated fashion, allowing them to identify how issues overlap, and incorporate action items from the Quality and R&D MSSs into "*one overall action plan that addresses multiple problems*" (Pojasek, 2006).

7.4 Summary of Lessons Learned (Step B7)

The final step in the IUMSS methodology is to identify and understand some of the challenges faced during the entire integration process. This may help in overcoming potential issues that the CSO may come across during other integration efforts in the future. To this end, a summary of the main issues encountered and lessons learned through applying the IUMSS methodology is provided in *Table 7.2*.

***Table 7.2*: Main Lessons Learned**

Issue	***Lessons Learned***
Structuring the MSS requirements	
R&D&I MSSs that a nanotechnology might be interested in are often configured and structured differently from one another, and contain different content (see Subsection 5.3.2.1).	Structuring the MSS requirements into a "HMSS" establishes a common framework that makes it easier to comprehend the multiple sets of requirements.
	Since many nanotechnology organizations are registered under ISO 9001:2000 or ISO 14001:2000, it is recommended that MSSs that are designed to be compatible with the ISO standards (such as UNE 166002:2006) be used when choosing the MSSs to be implemented. This will greatly facilitate MSS Clause/Requirement mapping (Subsection 5.3.1.2), and reduce the chances of conflicting MSS requirements.
	If any MSS requirements do conflict, laying them out side by side in the HMSS will reveal them.
The structuring of the MSS requirements leading up to the creation of the HMSS is subjective, and may vary between users (see Subsection 5.3.2.3).	There is always a danger of trying to find connections between requirements that do not exist, especially where linkages are weak and open to a range of interpretations.
Many R&D standards are published in European languages other than English, which may lead to misleading translations and wording (see Subsection 5.3.2.2).	Requirements in R&D MSSs should always be carefully analyzed depending on its positioning and content, and not merely its title.
Defining different scales to use for the level of compliance of the gap (see Subsection 6.2.4).	Simplify the analysis by using a two level scale (gap or no gap) whenever possible.

Table 7.2: **Main Lessons Learned (Continued)**

Issue	***Lessons Learned***
Gap Closure	
Formulating the appropriate corrective actions to close a compliance gap was a challenge, since the standards were generic and did not provide much guidance. Furthermore, the usage of R&D MSSs have not been extensively studied compared to more popular MSSs such as ISO 9001:2000 or ISO 14001:2004 (see Subsection 6.3.4).	Resources and guides for R&D MSS implementation are not readily available. This can pose a problem for nanotechnology organizations that may lack experience in interpreting MSS requirements.
Determining opportunities for integration - closing the integration gaps (see sub-section 6.3.2.5).	Search for integration possibilities between MSS requirements, by examining the requirements of all three standards listed in the same clause of the HMSS matrix.
	Search for integration possibilities between MS processes, by examining how other gaps were closed. Should be performed after closing the integration gaps, since a better idea of where MS components can be combined would be available at this time.
During gap closure, parts of the MS were found to be affected by certain MSS requirements that were not initially identified during Sub-Step B4.3 (see Subsection 6.3.3.1).	If a particular MSS requirement is found to impact a new area of the MS not initially identified after the corresponding analysis in the Sub-Step B4.3, one can go back to the mapping step and revise (see Figure 6.3)**.**
Multiple gaps can be closed through common corrective action (see Subsection 6.3.4).	Checking for "integration opportunities between MS processes" right after gap closure can result in multiple gaps being closed through the same corrective action.
Confirm Gap Closure	
Activities performed in Sub-Step B5.3(such as addressing compliance and integration gaps that still exist) may require revisiting and redoing previous sub-steps of the IUMSS methodology, for example Sub-Steps B5.1 and B5.2 (see Subsection 7.2.1).	IUMSS process can be modified by including a feedback loop running between gap closure confirmation and the earlier steps of gap analysis and closure (see *Figure 7.2*). This loop also suggests that the process of fully closing the gaps (especially the identification of all integration gaps), can take several passes to complete.

7.5 Summary

This Chapter presented how the suggested actions in Chapter 6 can be verified and validated should they be implemented. Next, the activities involved with maintaining and improving the integration were discussed. Suggestions for how an Integrated Quality/R&D&I Management System were given. The chapter concludes with a summary of the main lessons learned by applying the steps of the IUMSS methodology. Most of the challenges were encountered during Steps B4 and B5, where the new MSS requirements were actually connected and incorporated into the CSO's MS.

8. Conclusions

This chapter concludes the thesis by summarizing the main contributions of the research and its limitations, and finally recommends topics for future work.

8.1 Contributions of the research

The purpose of this research was to study the applicability of MSSs in an R&D-oriented nanotechnology setting. This setting was represented by the CSO used in the research, a Canadian MEMS developer. Since multiple quality and R&D-specific standards were found to be relevant in such environments, the IUMSS methodology (ISO, 2008) was used. The IUMSS methodology was tested by applying its steps for integrating the requirements of two R&D MSSs into the CSO's existing QMS. Overall, the IUMSS methodology can be adapted for use in a nanotechnology environment. Throughout the integration process, suggestions for improvements to the QMS can also be generated. The integration of the requirements of R&D MSSs into an existing ISO 9001-based QMS should theoretically create a system more suitable for R&D-intensive environments such as nanotechnology. For instance, suggestions can be made for improving creativity and innovation, as well as standardizing R&D-specific processes such as intellectual property and technology transfer.

Chapter Two provided the background and justification for the research work presented in the thesis. A literature search was conducted on standardization in nanotechnology, which revealed that quality is not an area that has been thoroughly researched, despite the evidence that there is a need for standardization. Research on the application of MSSs in nanotechnology or MEMS could not be found, although the importance of QM in R&D is well published. Because much of nanotechnology development takes place in an R&D environment, it was hypothesized that the research on implementing QMSs in R&D would also be applicable for nanotechnology settings. Therefore, a literature survey was conducted on QMSs and relevant MSSs for R&D. It was found that many QMSs in R&D are built using a combination of requirements from multiple MSSs and guidelines, although the details describing the actual process or methodology used are clearly lacking. As a result, an opportunity to test the newly-published IUMSS methodology

exists. The findings of the literature survey may be particularly useful to researchers or practitioners interested in building standardized management systems for R&D-oriented environments such as nanotechnology.

Chapter Three began with details on the plan for carrying out the research project. The project activities were divided into the two main components - the Case Study component (Part A), where practical data for the project was collected and analyzed; and the IUMSS Methodology Component (Part B), where the application of the IUMSS Methodology was discussed. The steps followed in the IUMSS Methodology component of the project (labeled B1 through B7), corresponded to the sections from Chapter 3 of the IUMSS Handbook. The remainder of this chapter provided a thorough analysis of the CSO's QMS, which was used as the subject for studying the application of the IUMSS methodology. Some of the findings may also be of interest to other nanotechnology companies, as many of these organizations likely experience similar challenges and issues.

Chapter Four provided a discussion of the activities conducted to follow the first three steps of the IUMSS methodology. In Step B1, a business case for integration, as well some the potential limitations, were discussed, using the data gathered from the CSO. Identifying the benefits for the integration project is of particular importance to R&D-oriented nanotechnology organizations since, as authors such as Valcárcel and Rios (2003) have noted, there are usually reservations towards standardization in R&D. In Step B2, two R&D standards, UNE 166002:2006 and EARTO:2000, were selected for integration into the CSO's QMS. A careful selection of a suitable MSS is essential for a nanotechnology organization, due to the existence of many standards addressing similar needs and the consequential difficulty in identifying the relevant standards (European Commission, 2008). It was also suggested that UNE 166002:2006 and EARTO:2000 addresses QM in R&D, and therefore should be integrated into the CSO's QMS. In Step B3, a general plan for the remaining four steps of the IUMSS methodology (Steps B4 to B7) was developed.

Chapter Five presented how the requirements of these two new MSSs can be connected to the CSO's current QMS (Step B4). This step was broken down into three sub-steps, as suggested by the IUMSS handbook.

Sub-Step B4.1 involved gaining an understanding of all the components of the MS and their relationships. Consequently, a model of the CSO's QMS was graphically depicted. This model presented a visual depiction of the QMS as a whole, showed where R&D processes were carried out and provided a framework that the MSS requirements could be mapped onto. Furthermore, Sub-Step B4.1 establishes a "snapshot" of the MS, which can be used as a record for an organization to keep track of the evolution of their MS. This can be particularly relevant in nanotechnology, due to the potentially large number of new standards a company might choose or be required to adopt. A path of integration was also established, and it was decided that the ISO 9001-based QMS implemented at the CSO be used as the foundation of the MS. The components of an R&D&I MS subsystem (available through UNE 166002:2006 and EARTO:2000) would then be incorporated into the QMS, leading to the creation of an Integrated Quality and R&D&I MS.

In Sub-Step B4.2, the requirements of ISO 9001:2000, UNE 166002:2006, and EARTO:2000 were merged together into a combined set of criteria, referred to as the "hybrid" MSS (HMSS). This step is particularly relevant for nanotechnology organizations, since designing an MS for R&D often involves a combination of requirements and guidelines from multiple standards (Biré *et al.*, 2004). Furthermore, the structuring of these MSS requirements into a common framework is important since R&D standards often have different configurations and formatting.

The HMSS provides several other benefits to the CSO. Most notably, since it succinctly combines multiple (common) requirements into a single requirement, it facilitates the gap analyses conducted in Sub-Step B5.1 and internal audits performed in Sub-Step B5.3. Instead of auditing against three separate standards, the internal auditor can simply audit against the HMSS, and refer to the individual standards if necessary. The HMSS, which serves as a detailed "Table of Correspondence" between ISO 9001:2000, UNE 166002:2006 and EARTO:2000, can also be used to make quick comparisons between these MSSs.

Structuring of the MSSs revealed that most of the elements from the two R&D standards could be mapped with the corresponding elements from ISO 9001:2000, thus suggesting that content-wise, the standards share many elements. In general, it was found that the R&D standards are compatible with ISO 9001:2000 and provide additional criteria for maintaining an R&D&I MS. Furthermore, UNE 166002:2006 and EARTO:2000 complement each other. UNE 166002:2006 has a strong focus on product design and development, whereas EARTO addresses organization-wide issues not found in UNE 166002:2006 or ISO 9001:2000, such as ethical codes of conduct. It is suggested that these R&D-specific standards can be used to augment an ISO 9001-based QMS. These results contribute to the future work suggested by Castillo *et al*. (2008), which involve comparing and analyzing a quality MSS (i.e., ISO 9001:2000) and an innovation management standard (i.e., UNE 166002:2006).

Lastly, Sub-Step B4.3 showed how MSS requirements can be mapped against the MS. The main output was the Integrated Quality and R&D&I MS Map, which graphically depicted all the components of the Quality and R&D&I MSs and their connections with the HMSS. This map helped visualize which parts of the MS would be impacted by the new R&D MSS requirements. Sub-Step B4.3 provides a systematic method to connect the MSS requirements with components of the MS.

Chapter Six illustrated how the new MSS requirements can be incorporated (i.e.integrated) into the CSO's current ISO 9001-based QMS (Step B5). A gap analysis of the QMS was conducted against the HMSS (Sub-Step B5.1). This IUMSS step allows nanotechnology organizations to evaluate their MS practices against the requirements provided in R&D MSSs, and then use these requirements for improvement in the next sub-step.

Details of a gap closure process (Sub-Step B5.2) were also provided. In particular, it was shown how the CSO would establish full compliance between the selected standards (closing the compliance gaps), as well as look for redundancies, synergies and integration possibilities (addressing the integration gaps). A detailed set of recommendations, along with flowcharts of modified and newly-added processes were designed for the CSO. Results from Sub-Step B5.2 may improve understanding on how R&D MSSs can be implemented in nanotechnology organizations, and the types of benefits they can provide for them.

An important discovery regarding the IUMSS methodology was illustrated in Chapter Six, namely that during gap closure, particular MSS requirements may be found to impact areas of the MS that were not identified initially. This led to a modification of the IUMSS methodology (see *Figure 6.3*), which incorporated a feedback loop between Sub-steps B4.3 and Sub-Steps B5.1/5.2. Going back to the Step B4.3 and making the appropriate revisions to mapping outputs can facilitate future MSS integration efforts, since it prompts organizations to examine certain procedures that would not have otherwise been considered. In addition, this chapter also discussed how during gap closure, multiple gaps can sometimes be addressed using the same corrective action.

Finally, Chapter Seven provided ideas on how gap closure suggestions can be verified and validated, should they be implemented. It was found that activities performed during this step, such as addressing compliance and integration gaps, may require revisiting and redoing previous sub-steps of the IUMSS methodology, for example Sub-Steps B5.1 and B5.2. Therefore, a further modification to the IUMSS methodology was proposed, by including a loop running from Sub-Step B5.3 back to Sub-Step B5.1 (see *Figure 7.2*). A short list of performance indicators of how the CSO could assess the effectiveness of the implementation was also provided, along with some examples of integration maintenance and improvement activities. This chapter also contained a discussion on the possibilities for creating an Integrated Quality and R&D&I MS at the CSO. Due to many similarities, it was found that there are opportunities to integrate the requirements of quality and various R&D-specific standards. These suggestions may also be relevant for other nanotechnology organizations, especially those that are already ISO 9001-registered. The chapter concludes with a summary of the main lessons learned through this study, which will be valuable to organizations using or intending to use the IUMSS methodology.

In summary, the main contributions of the work in this thesis are:

- testing of the IUMSS methodology and demonstration of its applicability in an R&D-oriented nanotechnology setting.
- introduction of modifications to the IUMSS methodology with respect to gap closure, which provide an improved process for future applications.
- further investigation into the compatibility of R&D-specific standards with ISO 9001:2000,

and their suitability in nanotechnology environments.

- development of a HMSS framework, which illustrates how the requirements of ISO 9001:2000, UNE 166002:2006, and EARTO:2000 can be combined and organized into a common scheme.
- provision of suggestions for improvements in the CSO's QMS, through the integration of two R&D MSSs, and the creation of a fully-integrated Quality and R&D&I MS.

8.2 Limitations of the research

A number of limitations should be considered while interpreting the results of this research:

- Beside the literature survey and the Author's own ideas, the results of this research were primarily based on the experience from only one case study organization. Therefore, fully generalized conclusions cannot be established, as some of the issues found at the CSO were specific to the company. For example, R&D processes at the CSO were excluded from the scope of the QMS, which might not be the case for other organizations.
- The research was focused mainly on the QM sub-system within the MS. Other sub-systems, such as environmental or safety MSs, were not analyzed.
- Due to the time constraints, interaction and contact with the CSO was limited. As a result, it was not possible to perform a complete, full-scale audit of the QMS. Such an audit would involve interviews with, and observations of, operational-level employees from all areas of the organization, and would provide a more detailed analysis of the CSO's QMS. As a result, the structuring of the MS and the subsequent gap analysis was performed solely using the information extracted from the CSO's QMS documentation.
- The actual implementation of the gap closure suggestions was not performed. As a result, the subsequent application of the "Confirm gap closure" and "Maintain and Improvement Integration" steps of the IUMSS methodology could not be fully developed.

8.3 Recommendations for future work

During this research project, several areas for further investigation were highlighted.

Specifically, the following recommendations can be made for the CSO:

- Conduct a full-scale audit of the QMS and identify all gaps between the system and UNE 166002:2006 and EARTO:2000.
- Implement gap closure suggestions discussed in Section 6.3, in order to create an Integrated Quality and R&D&I MS described in Subsection 7.3.2.
- Establish R&D&I performance metrics as described in Subsection 7.2.2, in order to validate the effectiveness of the gap closure corrective actions.
- Apply other MSSs (such as ISO 14001:2004), according to the identified needs in the future.

In addition, future research work can include:

- Applying UNE 1660002:2006 and EARTO:2000 (or other R&D&I-focused MSSs) to other nanotechnology organizations, in order to develop a more comprehensive understanding of the suitability and effectiveness of R&D&I MSSs in nanotechnology.
- Develop performance indicators to measure the effect that R&D&I MSSs have on company R&D&I performance.
- Explore opportunities for integrating quality, R&D, environmental, and health and safety MSs.
- Investigate the application of other MSSs (e.g., ISO 27001 for information security) in nanotechnology.
- Further studies on the integrated use of MSSs in other "high-tech" environments, such as biotechnology.

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List of referenced standards

Generic Quality Standards and Laboratory Guidelines

- *ISO 9001:2000 - Quality Management Systems – Requirements*
- *ISO 9001:2008 - Quality Management Systems – Requirements*
- *ISO 17025:2005 - General requirements for the competence of testing and calibration laboratories*
- *OECD GLP:1999 - Principles of Good Laboratory Practice*
- *ISO 10006: 2003 - Quality management systems - Guidelines for quality management in projects*

Guidelines for R&D

- *EARTO:2000 - General guidelines for the operation of research and technology organizations*
- *Joint Code of Practice for Research:2003*
- *EURACHEM/CITAC Guide 2:1999 - QA best practice for research and development and non-routine analysis*
- *ANSI/ASQ Z1.13-1999 - Quality guidelines for research*
- *DOE standard ER-STD-60001-1992 - Implementation guide for quality assurance programs for basic and applied research*

Standards for R&D

- *UNE 166000:2006 - Research, Development and Innovation (R&D&I) Management - Terminology and definitions*
- *UNE 166001:2006 - R&D&I management - R&D&I project requirements*
- *UNE 166002:2006 - R&D&I management - R&D&I Management System*
- *UNE 166005:2003 - R&D&I management - Application guide of UNE 166002:2002 EX to equipment sector.*
- *UNE 166006:2006 - R&D&I management - Technological Watch System*

- *FD X50-551:2003 - Research-sector quality - Recommendations for organizing and conducting a research activity in project mode, particularly with the framework of a network.*
- *FD X50-901:1991 - Project management and innovation. Memorandum for the use of the actors of an innovation project*
- *FD X50-550:2001 - Research quality approach - General principles and recommendations*
- *GA X50-552:2004 - Quality management systems - Implementation guide for ISO 9001 within research units - Specificities of the research activity and implementation examples from ISO 9001*
- *XP X50-053:1998 - Watch services - Watch services and watch system introduction services*

- *NP 4456:2007 - Management of Research, Development and Innovation (RDI)- Terminology and definitions of RDI activities*
- *NP 4458:2007 - Management of RDI - Requirements for a RDI project*
- *NP 4457:2007 - Management of RDI - Management system requirements of RDI*
- *NP 4461:2007 - Management of RDI - Competence and assessment of RDI management system auditors and RDI project auditors*

- *BS 7000-1:2008 - Design management systems- Part 1: Guide to managing innovation*

- *pDS xxxxx - User-oriented innovation*

Other referenced ISO standards

- *ISO Guide 72:2001 - Guidelines for the justification and developments of management system standards.*
- *ISO 9000:2005 - Quality management systems - fundamentals and vocabulary*
- *ISO 10001:2007 - Quality management - Customer satisfaction - Guidelines for codes of conduct for organizations*
- *ISO 10002:2004 - Quality management - Customer satisfaction - Guidelines for complaints handling in organizations*
- *ISO 10014:2006 - Quality management - Guidelines for realizing financial and economic benefits.*

Appendix A : Addendum for the literature survey

A-1 Currently available nanotechnology-specific standards

Standardization Body	*Publication*	*Title of document*
Terminology and labeling		
ISO	ISO/TS 27687:2008	*Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate,*
BSI	PAS 130	*Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles*
	PD 6699-1:2007	*Nanotechnologies. Good practice guide for specifying manufactured nanomaterials*
	PAS 71	*Vocabulary. Nanoparticles*
	PAS 131	*Terminology for medical, health and personal care applications of nanotechnologies*
	PAS 132	*Terminology for the bio-nano interface*
	PAS 133	*Terminology for nanoscale measurement and instrumentation*
	PAS 134	*Terminology for carbon nanostructures*
	PAS 135	*Terminology for nanofabrication*
	PAS 136	*Terminology for nanomaterials*
ASTM	E2456-06	*Standard terminology relating to Nanotechnology*
Environmental, Health and Safety Issues		
ISO	ISO/TR 12885:2008	*Health and safety practices in occupational settings relevant to nanotechnologies*
BSI	PD 6699-2:2007	*Nanotechnologies. Guide to safe handling and disposal of manufactured nanomaterials*
ASTM	E2535-07	*Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings*
Analysis, measurement and characterization		
ASTM	E2490-09	*Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)*
	E2524-08	*Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles*
	E2525-08	*Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies*
	E2526-08	*Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells*
	E2578-07	*Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions*

A-2 Traditional quality standards and laboratory guidelines

ISO 9001: Quality Management Systems - Requirements

Many authors have made their own interpretations of using ISO 9001 as a framework for developing a quality system in R&D (e.g. Auer *et al.*, 1996; Jayawarna and Pearson, 2001; Robins *et al.*, 2006; Rodriguez-Ortiz, 2003).

For instance, Auer *et al.* (1996) presents practical experience in adopting ISO 9001-based QMS framework in an engineering contract research environment. Robins *et al.* (2006) briefly describe the implementation and subsequent registration of a ISO 9001 based QMS system at the Institute of Food Research in Norwich, UK, which handles both fundamental and applied research. Ferguson et al (2006) details the development of a QMS in a cereal quality laboratory based on the requirements of ISO 9001:2000, with certain guidelines of ISO 17025:2005 incorporated into the procedures where a higher level of control was required.

It is generally accepted that R&D activity constitutes a "process"' and as such, process driven quality systems such as ISO 9001 which provide clear requirements for general quality management, are potentially of great value to control the quality of R&D (Jayawarna & Pearson, 2001). Robins *et al.* (2006) believe that ISO 9001's emphasis on customer satisfaction and "fitness for purpose" is valuable in creating quality research work that is aligned with the organization's goals. ISO 9001:2000 is often selected to be the MSS of choice because of its international recognition and generic nature, allowing for flexibility of operations (Ferguson et al, 2006).

Rodriguez-Ortiz (2003) discusses the aspects that should be considered in fulfilling the requirements of an ISO 9001:2000 QMS from an R&D project perspective. His QMS model groups the processes involved in R&D into two groups of activities. This grouping seems to be structured around the ISO 9001:2000 framework.

a) Project life cycle activities grouped into four development phases or stages: *Planning and definition, Project execution, Product delivery, Evaluation*
b) Support activities to complete the compliance of the ISO 9001:2000 requirements: *Management responsibility, Resource Management, Internal Audits, Improvement*

Rodriguez-Ortiz (2003) describes the ISO 9001:2000 requirement(s) related to each process, the associated documentation required and general comments on implementation. However, he does not provide much commentary on R&D specific issues.

Jayawarna and Pearson (2001) also present a similar paper where they discuss ISO 9001 QMS elements and practices in an R&D context, along with the specific benefits.

Authors have written about the limitations of applying ISO 9001 for R&D processes, some of which were already discussed in Chapter 2.3.4**.** For example, Mathur-De Vré (1997) and Vermaercke (2000) find that reference to technical and scientific competence, which is essential for the critical interpretation and evaluation of R&D results, is rather limited in ISO 9001. Vermaercke (2000) also criticizes that the standard focuses too much on repetitive actions. Biré et al (2004) argues that the requirements of the standard to be too rigid, in particular with regards

to final product conformity. He believes that the idea of non-conformity has to be revised when dealing with research projects, as final results that do not match initial expectations (a "non conformity", according to ISO 9001) do not necessarily affect the validity or relevence of the results, and as mentioned earlier, can even be promising for the research.

ISO 17025: General requirements for the competence of testing and calibration laboratories

Some researchers (e.g. Valcárcel and Rios, 2003 and Biré et al, 2004) have tried to determine whether ISO 17025, a standard found commonly in analytical laboratories, could also be applied to research activities. However, Biré et al (2004) has found some of the requirements in this standard to be either incomplete or too restrictive to apply to research activities. For example, validating every method in a research project would be far too constraining, especially if the method was only to be used for a specific part of the research. Furthermore, Biré et al (2004) notes that ISO 17025 does not describe how to record and organize data for experiments, or how to implement a working atmosphere favorable to research.

OECD GLP:1999 : Principles of Good Laboratory Practice

Authors have also analyzed the suitability of the Good laboratory Practice (GLP) guidelines for R&D (Holcombe, 1999; Mathur-De Vré, 2000; Vermaercke, 2000). GLP is often used analytical laboratories in the pharmaceutical, cosmetic, and food industry (Geijo, 2000). GLP places emphasis on the organizational structure and the conditions under which laboratory activities are planned, performed, recorded, monitored and reported in safety testing of chemicals as required by regulatory authorities (Mathur-De Vré, 1997)

However, the guidelines tend to be "*highly record-orientated and seen by some to impose excessive control and restrict flexibility…Furthermore, it concentrates more on the integrity of data than validity*" (Holcombe, 1999). Mathur-De Vré (2000) agrees that GLP is too rigid and detailed to be implemented in full in research activities. According to Vermaercke (2000), GLP is limited in its application and is not suitable for an open and multidisciplinary R&D environment (for example, nanotechnology).

ISO 10006: 2003: Quality management systems - Guidelines for quality management in projects

Project quality management guidelines in ISO 10006:2003 have been used for setting up quality systems for managing a research project (e.g. Biré et al 2004; Henri *et al.*, 2009). ISO 10006:2003 addresses "*progress assessment, budget control, time control, trackability, communication control, risks control, and resources management*" (Henri *et al.*, 2009).

According to Biré et al (2004), ISO 10006:2003 is useful for organizations performing research activities as projects and are not familiar with quality management. However, like ISO 9001:2000, the standard does not incorporate notions of prime importance to research activities, such as the distinction between positive and negative non-conformity (Biré et al, 2004).

A-3 Guidelines for R&D

EARTO:2000 : General guidelines for the operation of research and technology organizations

Details provided in sub-section 2.4.2.1.

Joint Code of Practice for Research: 2003

Robins *et al.* (2006) mentions the Joint Code of Practice for Research for implementing a QMS in a research institute. Developed by the combined efforts of several agencies of the UK government (Biotechnology and Biological Sciences Research Council, National Environment Research Council, Department for Environment, Food and Rural Affairs, and the Food Standards Agency), this document lays out a framework for the proper conduct of research (Joint Code of Practice for Research, 2003). The main advantage of the Joint Code is that there is considerable flexibility in the precise requirements, which means that the controls can be tailored to the specific nature of the research project or activity (Robins *et al.*, 2006).

EURACHEM/CITAC Guide 2:1999: QA best practice for research and development and non-routine analysis

Some authors (e.g. Holcombe, 1999, Vermaercke *et al.*, 2000) have regarded the EURACHEM/CITAC Guide 2 to be suitable for implementing a quality system in R&D. Produced by EURACHEM, a network of organizations in Europe focused on analytical chemistry and quality related issues, EURACHEM/CITAC Guide 2 is a comprehensive document for quality assurance in research and non-routine chemical analysis. Although the guide is focused towards analytical chemistry, Vermaercke *et al.* (2000) applied the criteria in a Belgian Nuclear Research Centre, and found that this guide provides a comprehensive framework for setting up quality system in R&D, since it recommends controls at the organizational, technical and analytical levels.

Other guidelines

In Petit and Muret's (2000) paper, two American R&D guidelines for quality assurance were found in the references:

- ***ANSI/ASQ Z1.13-1999: Quality guidelines for research***
    - This document can be used in the development of a quality system for basic and applied research (ANSI, 2009). Other specific details were not available.
- ***DOE standard ER-STD-60001-1992*: *Implementation guide for quality assurance programs for basic and applied research***
    - This guide is intended to assist management at DOE-ER (Department of Energy Research) sponsored facilities in the process of developing and implementing quality assurance programs that satisfies the requirements of DOE Order 5700.6C (DOE, 1992). DOE Order 5700.6C was a former quality assurance standard used by DOE. The guide is written primarily for scientists and technical managers, and purposely uses scientific and technical examples and terminology. Furthermore,

the guidelines are mainly focused on research work that produces new knowledge usually published in professional journals; the “development” aspect of R&D for practical application is beyond the scope of the document (DOE, 1992).

A-4 Standards for R&D

The following European national R&D standards were mentioned in the CEN (2008) report.

Spanish standards

- *UNE 166000:2006 - Research, Development and Innovation (R&D&i) Management - Terminology and definitions*
- *UNE 166001:2006 - R&D&I management - R&D&I project requirements*
    - This is a reference for defining, documenting, developing, and systematizing R&D&I projects (Pellicer *et al.*, 2008). According to Pellicer *et al.* (2008), the standard helps organizations identify innovative activities, develop and document them in a methodical way. Additional, UNE 166001:2006 serves as a means to certify R&D&I projects in Spain, which facilitates access to tax reductions and subsidies that the government grants to innovative companies (Veras *et al.*, 2008)
- *UNE 166002:2006 - R&D&I management - R&D&I Management System*
    - Details provided in sub-section 2.4.2.2.
- *UNE 166005:2003 - R&D&I management - Application guide of UNE 166002:2002 EX to equipment sector.*
- *UNE 166006:2006 - R&D&I management - Technological Watch System*

The UNE 166000 standards are not limited to just R&D organizations, but can be used by any organization to manage their R&D&I functions. As a matter of fact, Pellicer *et al.* (2008) discuss the application of the UNE 166000 standards in the construction industry, which typically does not invest much into R&D. Pellicer *et al* (2008) also performed an empirical study on R&D&I standardization in the Spanish construction industry. They highlight the characteristics of the UNE 166000 series of R&D management standards, but do not discuss how the standard requirements were implemented. These standards have mainly been used in Spain, however, they have also been recently introduced in Mexico, Brazil, Italy and Portugal (Pellicer *et al.*, 2008).

French standards

- *FD X50-551:2003 - Research-sector quality - Recommendations for organizing and conducting a research activity in project mode, particularly with the framework of a network.*
- *FD X50-901:1991 - Project management and innovation. Memorandum for the use of the actors of an innovation project.*
- *FD X50-550:2001 - Research quality approach - General principles and recommendations*
- *GA X50-552:2004 - Quality management systems - Implementation guide for ISO 9001 within research units - Specificities of the research activity and implementation examples from ISO 9001*
- *XP X50-053:1998 - Watch services - Watch services and watch system introduction services*

Portuguese standards

- *NP 4456:2007 - Management of Research, Development and Innovation (RDI)- Terminology and definitions of RDI activities*
- *NP 4458:2007 - Management of RDI - Requirements for a RDI project*
- *NP 4457:2007 - Management of RDI - Management system requirements of RDI*
- *NP 4461:2007 - Management of RDI - Competence and assessment of RDI management system auditors and RDI project auditors*

Lopes (2009) wrote a brief summary of NP 4457:2007, and states that "*the objective of the standard is to encourage and support companies operating in Portugal…to develop innovation in a more systematic and efficient manner, in order to reinforce their competitive advantages in an increasingly global and knowledge-based economy*". The standard is applicable to all organizations irrespectively of size, complexity or sector in which it operates, and is designed to be simple, flexible and adaptable, (Lopes, 2009). It contains five main sections: a) General Requirements; b) Management Responsibilities; c) Planning RDI; d) Implementation and Operation; e) Evaluation of Results and Improvement (Lopes, 2006). Like UNE 166002:2006, Lopes (2006) claims that the standard is designed to be compatible to other MSS, namely ISO 9001, ISO 14001, OHSAS 18001, and ISO 22000.

British standard
BS 7000-1:2008 - Design management systems- Part 1: Guide to managing innovation

The following information on the content of from BS 7000-1:2008 was made available through email correspondence with Anne Ferguson of BSI (Ferguson, personal communication, September 11, 2008). BS 7000-1:2008 gives "*guidance on managing innovation, specifically the design and development of innovative and competitive products that satisfy customers' perceived needs and aspirations in the long-term future*". The document covers the "*total experience and benefits of innovating, as well as the application of general principles and techniques to the management of innovation, from conception, creation, fabrication, delivery and sustenance in markets, right through to withdrawal, final disposal, recycling and the development of subsequent generations of offerings*". It should be noted that BS 7000-1:2008 takes the form of a "*guide rather than a specification, therefore the criteria need not be adopted in total…effective use can be achieved through the smart selection of relevant clauses and adapting them to an organization's particular circumstances*".

Danish standard
pDS xxxxx - User-oriented innovation

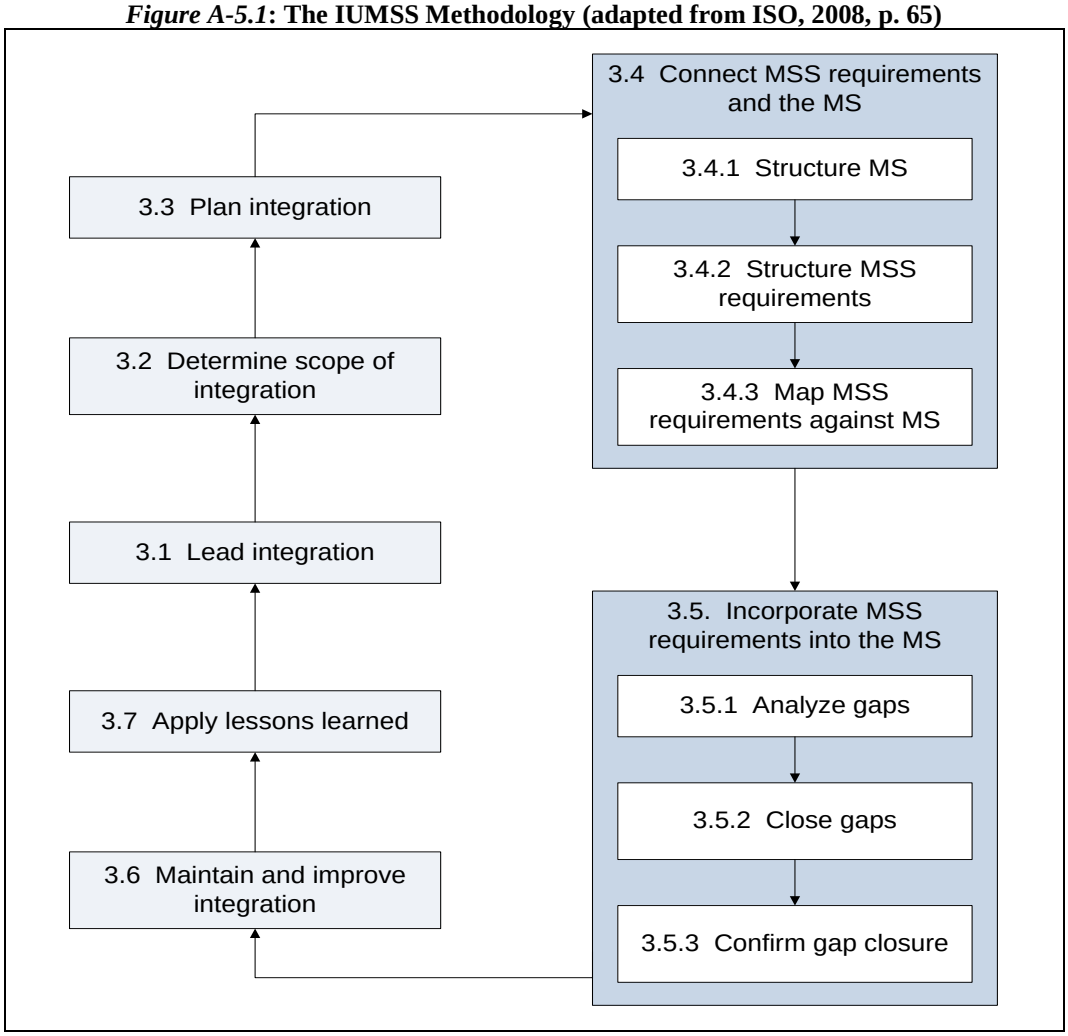
This standard was still under development at the time of the CEN (2008) report.

A-5 The IUMSS Handbook

The information contained in the IUMSS Handbook is based on the collective experiences of organizations that have successfully implemented multiple MSSs through an integrated approach. The benefits, challenges and lessons learned from these organizations are also reported, providing additional insight into issues that may be encountered. Furthermore, "practice" questions at the end of each sub-chapter act as a checklist and help ensure that the MS implementation is effective and well thought out.

According to the IUMSS Handbook, integration is the "*process of unifying multiple management system standards requirements into an organization's overall management system*. *The result…is a single management system that meets the requirements of multiple management system standards*" (ISO, 2008, p.64). Integration has been found to be an effective and efficient approach for implementing multiple MSSs, as it allows the organization to cross-functionally consider the impact of the multiple standards and their requirements (ISO, 2008, p.63).

***Figure A-5.1*: The IUMSS Methodology (adapted from ISO, 2008, p. 65)**



Appendix B : University of Alberta application for study approval and Case Study Data

B-1 Request for Ethics Review (RER) Application

Ethics Review Template
Faculty of Engineering, University of Alberta

REQUEST FOR ETHICAL REVIEW OF ACTIVITIES INVOLVING HUMAN SUBJECTS

Specify Research Type: (Ph.D., M.Sc., M.Eng., Contract, Course Project, other -)
M.Sc.

Project Title: Application of Standardized Management Systems in the Nanotechnology Industry

Principal Investigator(s) and Degree(s): Norman Law

Advisor (if applicable): Stanislav Karapetrovic

Status or Rank: Graduate Student **Office Phone:** 2-8684

Department: Mechanical Engineering **Faculty:** Engineering

Building and Room: Mechanical Engineering 6-27

Sponsoring Agency: The CSO/University of Alberta **Budget:**

Project Period: April 2008 – October 2008 **Budget Period:**

Please provide answers to all of the following questions. **All projects submitted for review must be typed (no handwritten proposals accepted)**. Only one copy is required and will be retained for the Ethics Committee files and eventually reproduced for Committee use.

PURPOSE, OBJECTIVES and EXTERNAL INTERACTIONS

- What are you doing?
  As a case study component of the research on my M.Sc. thesis regarding the application of standardized management systems in the nanotechnology industry, I will perform a study on the quality management system at The CSO, and the possibilities for its augmentation with different standards. The purpose of the study is to analyze the suitability and the possibility of integration of existing standardized management systems (e.g. ISO 9001:2000) in a high tech research environment such as nanotechnology/MEMS.

- Why? What **benefits** are there to the participants, to society, or to further research? What are you trying to find out?
  The research is aimed at the application and evaluation of quality and other management system standards in the nanotechnology/MEMS industry.

  The expected benefits for the company include:
  - better understanding of interrelations among different internal systems;
  - possibility to build more effective connections among those systems;
  - introducing the company to other standards which might improve its operations
  - feedback on the suitability of ISO9001:2000 and other standardized systems in a nanotechnology/MEMS production setting.

  The researchers will benefit from the development or adaption of a model for the integration of standardized management systems in the nanotechnology industry and the ability to validate its suitability

in a real-life setting. As a result, the overall body of knowledge regarding the development and use of integrated standardized management systems will be enhanced.

- Where will the study take place?
  The study will take place at The CSO's company site, located in Western Canada.

- How are you going to do it (e.g., interviews, physical testing, or videotaping)?
  I will perform the study of the current quality management system and related systems at The CSO through the analysis of the relevant standards, documentation and interviews with the employees and managers. To facilitate this analysis, I will perform interviews that will be used in information gathering. The questions asked will be non-personal and will be strictly related to the company's quality and other management systems. An example of the types of questions that will be used is provided in *Appendix A* of this application. As a result of the analysis performed, I will study and evaluate the suitability of standardized systems in the nanotechnology industry. In addition to this, I will also analyze the implication of integrating an additional standardized management system into the company's operations (e.g. CSA Z1000), and analyze potential issues and problems. Feedback to The CSO is planned to be given through a written report and/or presentations. The actual implementation of the proposed model is outside of the scope of this study.

- How long will it take (each part of the study; total time required of participants)?
  The length of the entire project will be from April 2008 to December 2008.

- Is the activity directly funded? If so, provide brief details of the arrangements.
  This project is directly funded by the Mechanical Engineering Department, at the University of Alberta.

- Might any of the research team have, or be reasonably perceived to have, a conflict of interest, including personal, family or financial interests, in the research? If so, explain the situation in detail.
  No conflicts of interest are involved.

DESCRIPTION OF METHODOLOGY AND PROCEDURES

8) Where will the project be conducted (room number or area; if not U of A location, site authorization allowing this research must be provided)?
   The data collection stage of the project will take place at the The CSO facility in Western Canada. Analysis of the gathered data will be conducted at the University of Alberta.

9) How will the project be explained to the subjects?
   The project will be explained to by providing the interviewees a copy of the Participant Information Letter (Appendix B).

10) If the subjects are minors, how will assent be secured:
    No subjects are minors.

11) How will you make it clear to the subjects that their participation is voluntary and that they may withdraw from the study at any time they wish to discontinue participation?
    Informed consent is asked from all participants at the time of the interview. The participants are also informed that the participation in the study is completely voluntary and that the purpose of the study is to better understand the current company's quality management system and to recommend opportunities for improvement. The voluntary nature of the interview is assured by making a statement that the participant can refuse to participate at any time before or during the interview, and that such a decision will bear no negative consequences for the participant.

12) Will your project utilize (check):

    - Questionnaires (submit a copy) - No.
    - Interviews (submit sample of questions) – Yes.

- Observations (submit a brief description, stating your role in the activities observed) – Possibly. Flowcharts or process maps, together with the quality manual and related procedures depicting the actual processes deployed along the product life cycle, are required to better understand the current quality management system. Most of this information is likely to be available in the existing documentation at the company or be gathered through interviews. However, observations of company laboratories and fabrication facilities to understand how this documentation is used may occur. I may also perform sample product tracking (e.g., to track product labeling and consistency).
- Medical records review - No.

PERSONNEL

13) Describe the **qualifications** of research personnel if special conditions exist within the research that could cause physical or psychological harm, or if participants require special attention because of physical or psychological characteristics, or if made advisable by other exigencies
No special conditions exist, no special attention is required, and there are no other exigencies.

DESCRIPTION OF POPULATION

14) Number of subjects to be involved:
The number of interviewees is expected to be between one to four.

15) Description of population to be recruited and rationale for their participation (indicate age range):
The interviewees are chosen from the managers and the employees of The CSO, depending on their involvement with the quality management system and the other related systems under study.

16) How are the subjects being recruited?
The interviewees will be recruited and the interviews will be scheduled through the company's quality manager.

17) What are the criteria for their selection?
The interviewees are selected on the basis of their knowledge and familiarity with the processes under study.

DATA

18) Who will have access to the gathered data?
The data will be available to the investigators (Norman Law and Stanislav Karapetrovic).

19) How will confidentiality of the data be maintained?
The anonymity is assured by coding the interview data sheets with a non-personally identifiable code. Therefore, no individual-specific information gathered from the interviews will appear in the thesis and/or any reports provided to the company or research papers that will be publicly available.

20) How will the data be recorded (instruments or notes)?
The data will be recorded in the interview data sheets by taking notes during an interview.

21) What are the plans for retention of data?
The coded interview data sheets will be kept in a locked drawer accessible to Mr. Law only for the duration of the study, and then transferred to the University of Alberta, where it will be kept locked in the AIMS Research Laboratory, 6-27 Mechanical Engineering Building, for a period of one year after the last publication regarding this study.

22) What are the plans for future use of data beyond this study?
If the company is interested in further work on this topic, the information provided in Mr. Law's thesis or the published papers stemming from the project may serve as background.

23) How will the data be destroyed and at what point in time?
If the participant withdraws during the study, the information provided will be removed from the study upon the participant's request. The related paper documents will be shredded and electronic documents will be erased at that time. The code interview data sheets and electronic versions will be destroyed after five years of the completion of the study or one year after the last publication, whichever comes later.

24) Where will the signed consent forms be stored (list administrative office and room number)?
In the AIMS Research Laboratory, 6-27 Mechanical Engineering Building, University of Alberta.

BENEFITS, COSTS, RISKS

25) What are the potential benefits to the subjects?
- Better understanding of the existing management system;
- Learning about new standards;
- Learning how to integrate different standardized systems.

26) What may be revealed that is not currently known?
- How to effectively deal with assimilating standards, and
- How to use them in an integrative manner.
- The suitability of standardized management systems in the nanotechnology industry, or related high tech environments.

27) Will monetary or other compensation be offered to the subjects?
No monetary or other compensation will be offered to the subjects.

28) What are the costs to the subjects (monetary, time)?
Each interview with the subjects (the interviewees) is expected to last two hours.

29) What specific risks to the subject are most likely to be encountered (physical, psychological, sociological)? If none, state none.
None.

30) What approach will you make to minimize the specific risks?
No specific risks are expected in this research study.

B-2 Sample questionnaire

The types of questions that will be asked during the interview (these are provided simply to reflect the non-personal nature of the questions):

1. What are the products/services you provide to your customers?
2. What are the needs/requirements of your stakeholders?
3. What processes do you use to adapt to the ever-changing requirements of your customers and other stakeholders? (governmental regulations, application of "lean manufacturing" concepts).
4. What are the internal systems that you use in the laboratory (e.g. quality management system, health & safety management system, environmental)?
5. What are the processes used in the laboratory and how are they related together (Process map)?
6. What are the management standards already used in the company and how do they relate to the processes? (standard technical micro-fabrication process steps are most likely employed).
7. What are some of the direct benefits that stem from the use of these standards (e.g. decreasing nonconformities, customer satisfaction, etc.)?
8. What are some of the key manufacturing/development challenges you experience today in the nanotechnology industry?
9. What are some of the challenges involved with the use of standards in a nanotechnology setting (and are there elements in the standard which pose particular difficulties, or are rarely addressed)?
10. How could these standards be better tailored towards a research intensive and high tech environment such as nanotechnology (any specific areas/issues not covered by existing standards)?
11. What is your opinion on the need for a specific nanotechnology standard (addressing issues such as nanotechnology terminology, toxicity effects, environmental impact, risk assessment, test methods, safe handling of nanomaterials)?
12. What process is used to ensure employee competence (especially those directly involved with fabrication)?
13. What process is used to specify and label manufactured nanomaterials/products (product identification and traceability). Is there an industry standard/guide that is followed?
14. How are records/documentation used and maintained?
15. How do your staff and product managers address development changes/challenges when they arise (formal documentation and records made)?
16. What is the process for handling both high and low volume orders?
17. Does the top management review the company's management system at planned intervals to ensure its continual adequacy, effectiveness, and suitability (especially in a fast changing environment such as MEMS)
18. Describe your product testing and validation procedure.
19. What is the procedure in the case of nonconformance between specifications and actual tests?
20. How do you audit your systems? (internally or through 3rd party).
21. How often are your systems audited, and what is the process of evaluating audit effectiveness?
22. Are the changes/recommendations from audits actually implemented)?
23. How do you communicate with your customers/stakeholders, and collect feedback?
24. How do you improve your system based on customer feedback and changing environments?
25. How do you benchmark for quality and reliability in MEMS fabrication?
26. What other standards would you consider to be useful?
27. How do you control occupational exposures to nanomaterials (what health and safety management system do you have in place)?
28. How do you handle, control and dispose of nanomaterials/waste (any good practice guides followed)?
29. How do you assess occupational health and safety risk? (risk assessment system in place?)

B-3 Participant information letter

Study title:
Application of standardized management systems in nanotechnology

Research Investigators:

Norman Law
AIMS-RL, Department of Mechanical Engineering
University of Alberta
T6G 2G8 Edmonton, Alberta
nmlaw@ualberta.ca
Phone: (780) 951-0457

Stanislav Karapetrovic
Department of Mechanical Engineering
University of Alberta
T6G 2G8 Edmonton, Alberta
stanislav@ualberta.ca
Phone: (780) 492-9734

Research Information:

Hello, my name is Norman Law. I am conducting a study on the application of ISO9001:2000, and the possibilities for its augmentation with different standards in a MEMS/nanotechnology fabrication setting. This research is a part of my Master of Science thesis in the Engineering Management program in the Department of Mechanical Engineering at the University of Alberta.

The purpose of the study is to analyze the suitability of existing management systems (e.g. ISO 9001:2000) in new industries such as nanotechnology. As a case study component of this project, I will be conducting interviews at The CSO to better understand the current quality management system and/or other related systems and processes. The questions asked will be non-personal and will be strictly related to the company's quality management systems.

This study will be purely academic, but may provide The CSO with feedback on the overall effectiveness of their quality management system with regards to nanotechnology development, and suggestions for improvement to the current system. The study may also benefit the nanotechnology community in terms of the implementation and integration of quality and other management systems. Lastly, it may provide input to standardization organizations on the application of the existing management system standards to nanotechnology.

You are under no obligation to participate in this study. The participation is completely voluntary.

Study participants will not be individually identified in any published or presented material. Data sheets from interviews and observations will be coded with a non-personally identifiable code. Data will be kept in a locked drawer accessible to me only for the duration of the study (April 2008 to December 2008), and then transferred to the University of Alberta, where it will be kept locked in the Auditing and Integration of Management Systems Research Laboratory, 6-27 Mechanical Engineering Building, University of Alberta, for a period of one year after the last publication from this study has been published.
If you decide to participate, please read and sign the enclosed "Consent to Participate" form.

If you decline to continue or you wish to withdraw from the study, your information will be removed from the study upon your request.

If you have any questions regarding this study, please do not hesitate to contact me or Dr. Stanislav Karapetrovic. Any questions or concerns regarding the ethical considerations in conjunction with this study should be directed to Dr. James Miller, Chair of the Engineering Faculty Ethics Committee, at 1-780-492-4443. Dr. Miller has no direct involvement with this project.

B-4 Informed consent form

Part 1 (to be completed by the Principal Investigator)

Title of Project: Application of Standardized Management Systems in the Nanotechnology Industry

Principal Investigator(s): Norman Law and Stanislav Karapetrovic

Co-Investigator(s): Include affiliation(s) and phone number(s):
Department of Mechanical Engineering, University of Alberta
T6G 2G8 Edmonton, AB (780) 492-9734

Part 2 (to be completed by the research participant)

Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had an opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you are free to refuse to participate, or to withdraw from the study at any time, without consequence, and that your information will be withdrawn at your request?	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to your information?	Yes	No

This study was explained to me by: _____

I agree to take part in this study:

_____	_____	_____
Signature of Research Participant	Date	Witness
_____		_____
Printed Name		Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____	_____
Signature of Investigator or Designee	Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY OF BOTH FORMS GIVEN TO THE PARTICIPANT.

Appendix C : CSO procedures and process maps

C-1 List of CSO's QMS documentation used

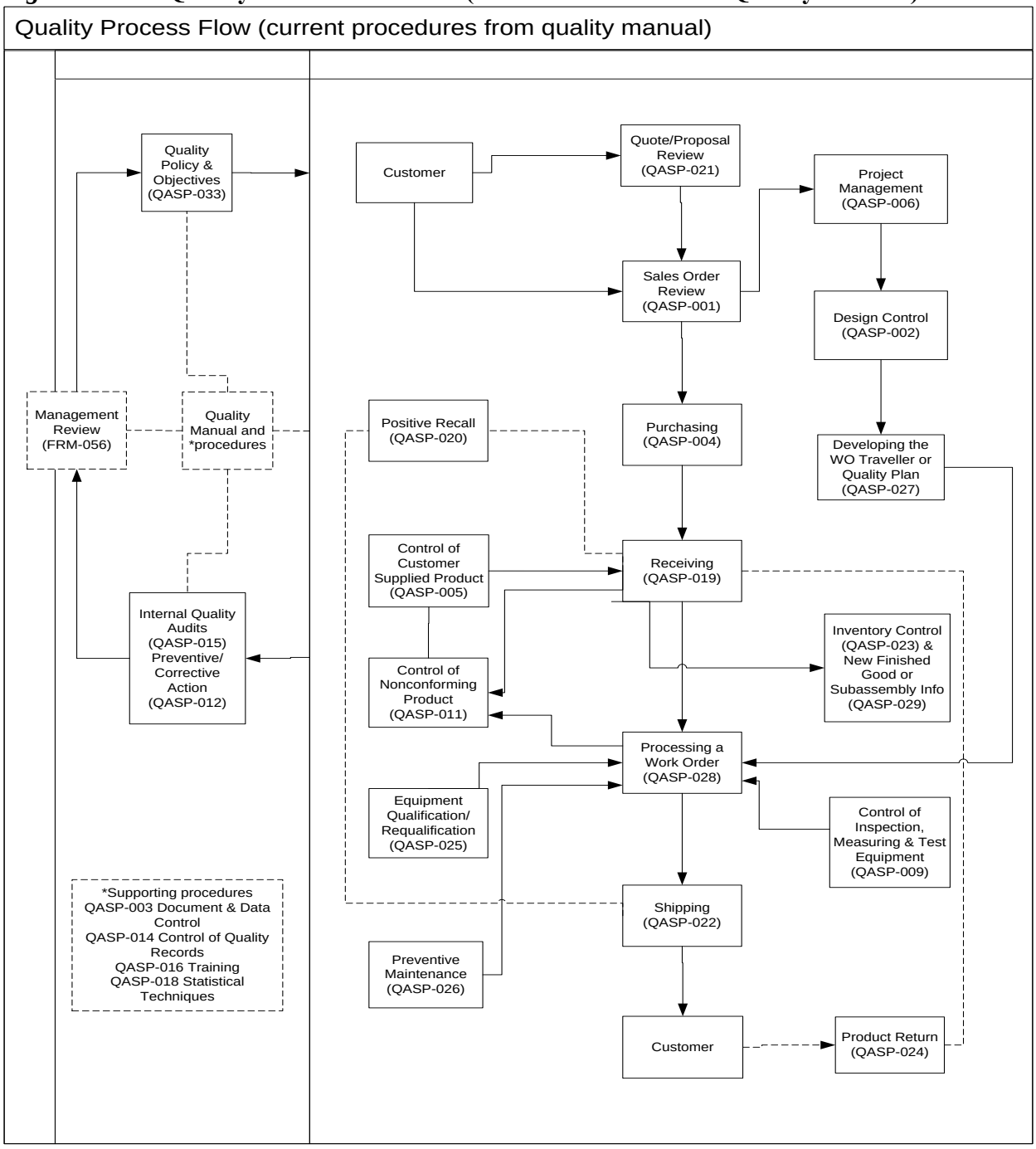
CSO Quality Manual

Procedures
QASP-001: Sales Order Review
QASP-002: Design Control
QASP-003: Document & Data Control
QASP-004: Purchasing
QASP-005: Control of Customer Supplied Product
QASP-006: Project Management
QASP-009: Inspection, Measuring & Test Equipment
QASP-011: Control of Nonconforming Product
QASP-012: Corrective/Preventive Action
QASP-014: Quality records
QASP-015: Internal Quality Audits
QASP-016: Training
QASP-018: Statistical Techniques
QASP:019: Receiving
QASP-020: Positive Recall
QASP-021: Quote/Proposal Review
QASP-022: Shipping
QASP-023: Inventory Control
QASP-024: Return Material Authorization
QASP-025: Equipment Qualification & Re qualification
QASP-026: Preventative maintenance
QASP-027: Developing the Work Order Traveler or Quality Plan
QASP-028: Processing a Work Order
QASP-029: Issuing Part Numbers
QASP:030: Internal Drawing Control
QASP-031: Job Function Listing
QASP-032: Organization Chart
QASP-033: Quality Objectives
QASP-034: Quality System Orientation Package
QASP-036: Control of Process Change
QASP-037: Product Quality Planning (MPQP)
QASP-038: Capital Acquisition
QASP-039: Emergency Sales Order Review

Forms
FRM-056: Management Review Form
FRM-176: Customer feedback form

C-2 CSO Process Map

***Figure C-2.1*: Quality Process flowchart (extracted from CSO's Quality Manual)**



C-3 Tables of correspondence between MSS elements and CSO procedures

***Table C-3.1*: Correspondence between CSO's ISO 9001-based QMS and procedures**

ELEMENT		*ASSOCIATED DOCUMENTS*
4.0) Quality Management System	4.1 General Requirements	Quality system process flow QASP-033: Quality Objectives QASP-004 Purchasing
	4.2 Documentation Requirements 4.2.1 Quality Manual 4.2.2 -4.2.5 Control of Documents 4.2.6 Control of Records	Quality Manual QASP-003: Document & Data Control QASP:-030: Internal Drawing Control QASP-014: Quality records
5.0 Management Responsibility	5.1 Management Commitment	QASP-033: Quality Policy and Objectives QASP-032 : Organization Chart QASP-031: Job Function Listing
	5.2 Customer Focus	
	5.3 Quality Policy	QASP-033: Quality Policy and Objectives
	5.4 Planning 5.4.1 Quality Objectives 5.4.2 QMS planning	
	5.5 Responsibility, Authority and Communication 5.5.1 Responsibility and Authority 5.5.2 Internal communication	QASP-032 : Organization Chart QASP-031: Job Function Listing
	5.6 Management Review	FRM-056: Management Review Form
6.0 Resource Management	6.1 Provision of resources	
	6.2 Human Resources 6.2.1 General 6.2.2 Competence, awareness and training	QASP-016: Training
	6.3 Infrastructure, equipment and facilities	QASP-026: Preventative maintenance
	6.3 + 7.5.1 : Equipment Qualification and maintenance	QASP-025: Equipment Qualification & Re qualification
	6.4 Work Environment	QASP-026: Preventative maintenance
7.0 Product Realization	7.1 Planning of Product Realization	QASP-006: Project Management QASP-027: Developing the Work Order Traveler or Quality Plan QASP-037: Product Quality Planning
	7.2 Customer interaction 7.2.1 Determine requirements 7.2.2 Review requirements 7.2.3 Customer communication 7.5.4 Customer property	QASP-001: Sales Order Review QASP-021: Quote/Proposal Review QASP-039: Emergency Sales Order Review QASP-005: Control of Customer Supplied Product
	7.3 Design and Development	QASP-002: Design Control QASP:-030: Internal Drawing Control QASP-036: Control of Process Change QASP-037: Product Quality Planning
	7.4 Purchasing 7.4.1 Select and evaluation 7.4.2 Purchasing info 7.4.3 Verification	QASP-004: Purchasing QASP-038: Capital Acquisition
	7.5 Manufacturing, Receiving, Shipping	QASP:019: Receiving

		QASP-023: Inventory Control QASP-027: Developing the Work Order Traveler or Quality Plan QASP-028: Processing a Work Order QASP-029: Issuing Part Numbers QASP-022: Shipping QASP-020: Positive Recall
8.0 Measurement, Analysis and Improvement	8.1 General practices 8.2.1 Customer satisfaction 8.2.2 Internal Audit 8.2.3 Monitoring and measurement of processes 8.2.4 Measurement and measurement of product	Customer feedback forms (FRM-176) QASP-015: Internal Quality Audits QASP-027: Developing the Work Order Traveler or Quality Plan
	8.3 Control of Nonconforming Product	QASP-011: Control of Nonconforming Product QASP-024: Return Material Authorization
	8.4 Data Analysis	QASP-018: Statistical Techniques
	7.6 Control of monitoring and measuring equipment	QASP-009: Inspection, Measuring & Test Equipment
	8.5 Improvement 8.5.1 Continual Improvement 8.5.2 Corrective action 8.5.3 Preventive action	QASP-012: Corrective/Preventive Action

Table C-3.2: Correspondence between HMSS requirements and CSO procedures

Key processes/practices @ organization		***Associated Organizational Documents***	**Impacted HMSS requirements clauses**
1.0) Quality Management System	General QMS practices	Quality system process flow QASP-037: Product Quality Planning	1.1 General Requirements
	Documentation practices	Quality Manual QASP-003: Document & Data Control QASP:-030: Internal Drawing Control QASP-014: Quality records	1.2 Documentation 1.2.1 Quality Manual 1.2.2 Document Control 1.2.3 Record Control
2.0) Management responsibilities	Management Commitment, System Planning, and Stakeholder Focus.	QASP-033: Quality Policy and Objectives QASP-032 : Organization Chart QASP-031: Job Function Listing	2.1 Management commitment 2.3 Management system planning 2.6 Stakeholder Focus
	Policy and Objectives	QASP-033: Quality Policy and Objectives	2.1 Management commitment 2.2 Policy and objectives
	Management Review	FRM-056: Management Review Form	2.4 Management review
	Responsibility, Authority and Communication	QASP-032 : Organization Chart QASP-031: Job Function Listing	2.5 Organization and Responsibilities 2.5.1 Management representative 2.5.2 Internal communication
3.0) Measurement, Analysis, and Improvement	General practices		3.1 General requirements 3.3.4 Customer satisfaction
	Internal audits	QASP-015: Internal Quality Audits	3.3.1 Internal Audits
	Monitoring and measurement of processes		3.2.1 Monitoring and measurement of processes
	Measurement and measurement of product		3.2.2 Monitoring and measurement of product
	Calibration and control of measuring devices	QASP-009: Inspection, Measuring & Test Equipment	3.2.3 Equipment calibration
	Control of Nonconforming Product	QASP-011: Control of Nonconforming Product QASP-024: Return Material Authorization	3.3.2 Control of nonconformances
	Analysis of Data	QASP-018: Statistical Techniques	3.3.3 Data Analysis
	Corrective/Preventive Action and Improvement	QASP-012: Corrective/Preventive Action	3.4.1 Corrective/Preventive Action 3.4.2 : Continual improvement
4.0) Resource Management	Provision of resources		4.1 Provision of resources
	Human Resources	QASP-016: Training	4.2.1 Personnel 4.2.2 Competence, awareness and training 4.2.3 Teamwork, creativity, and motivation
	Facilities, Infrastructure, equipment, and supporting services		4.3.1 Facilities, infrastructure, equipment and supporting services
	Equipment Qualification and maintenance	QASP-025: Equipment Qualification & Re-Qualification QASP-026: Preventative maintenance	4.3.2 Equipment qualification and maintenance
	Work environment	QASP-026: Preventative maintenance	4.3.3 Work environment
5.0) R&D&I Analysis	Information gathering, technology assessment, analysis and selection of ideas	N/A	5.0 Information gathering, technology assessment, analysis and selection of ideas

6.0 Project/product planning, design & development	Project Management and Planning	QASP-006: Project Management QASP-037: Product Quality Planning QASP-027: Developing the Work Order Traveler or Quality Plan	6.1.1 Project management and planning
	Gather and assess stakeholder input, review requirements, customer communication	QASP-037: Product Quality Planning QASP-001: Sales Order Review QASP-021: Quote/Proposal Review QASP-024: Product Return QASP-039: Emergency Sales Order Review	6.1.2 Determine and assess input from relevant interested parties 6.1.3 Review of requirements related to product/project 6.3 Customer communication
	Design and Development	QASP-002: Design Control QASP-006: Project Management QASP-027: Developing the Work Order Traveler or Quality Plan QASP-036: Control of Process Change QASP-037: Product Quality Planning Internal Drawing Control QASP:-030	6.2.1 Design/Development Planning 6.2.2 Design/Development Inputs 6.2.3 Design/Development Outputs 6.2.4 Review and monitoring 6.2.5 Verification 6.2.6 Validation 6.2.7 Change control 6.2.8 Experimental/Calculational methods 6.4 Exploitation of results and intellectual property
7.0) Manufacturing, Receiving, Shipping	Manufacturing，Shipping and Receiving	QASP-005: Control of Customer Supplied Product QASP:019: Receiving QASP-023: Inventory Control QASP-027: Developing the Work Order Traveler or Quality Plan QASP-028: Processing a Work Order QASP-029: Issuing Part Numbers QASP-022: Shipping QASP-020: Positive Recall	7.1 Control and validation of production and service 7.2 Handling of product, customer property and research items
8.0) Purchasing	Purchasing	QASP-004: Purchasing QASP-038: Capital Acquisition	8.1 Select and evaluation 8.2 Purchasing info and verification

Appendix D : HMSS Table

***Table D-1*: HMSS**

A	B	C	D	E
		ISO 9001:2000 Requirements	**UNE 166002: 2006 Requirements**	**EARTO: 2000 Requirements**
1.0 Quality Management System	1.1 General Requirements	*4.1 General Requirements* a) Identify processes needed for QMS and their application b) Determine sequence and interaction c) Determine criteria and methods needed d) Ensure availability of resources and information e) Monitor, measure, analyse processes f) Implement actions to achieve results and continual process improvement	*4.1.1 General* a) Identify R&D&I activities b) "……." c) "……." d) "……." e) "…… " f) "…… " g) Establish and document mechanisms for protection/exploitation of results i) Model of the R&D&I process	
	1.2 Documentation	*4.2.1 General documentation requirements* a) Quality policy and objectives b) Quality manual c) Documented procedures d) Documentation for planning, operation and control of process e) Records	*4.1.2 Documentation* a) R&D&I policy/objectives b) Documented procedures c) "……" for R&D&I activities d) Records	*3.2 Quality system* c) Written procedures for major processes
	1.2.1 Quality Manual	*4.2.2 Quality manual* a) Scope of QMS b) Documented procedures for QMS c) Interaction of processes of the QMS	N/A	3.2 b) Quality manual (maintained current)
	1.2.2 Document Control	*4.2.3 Control of Documents* a) Document approval b) Review and update c) Changes and current revision status identified d) Availability of relevant versions e) Legible and identifiable f) External documents identified and distribution controlled g) Prevent unintended use of obsolete documents and identify them if kept	*4.1.2.1 Control of documents* a) "……" b) "……" c) "……." d) "……." e) "……." f) "……." g) "……"	*3.3 Document control* b) Reviewed and approved prior to use b) Documents reviewed and revised c) Changes be reviewed and approved by original reviewer. c) Changes identified Procedure for electronic documentation changes Appropriate documents available at suitable locations a) Documentation simple and easy to understand "……"
	1.2.3 Record Control	*4.2.4 Control of records* a) Records established and maintained for QMS b) Records legible, identifiable, retrievable c) Procedure to define record control for identification, storage, protection, retrieval,	*4.1.2.2 Control of records* a) "……" for R&D&I system b) "……" c) "……."	*3.11 Control of records* Quality records (e.g. audits, management reviews, corrective/preventive action) f) Technical records (data/information from experiments and calculations) e) Records legible, retrievable, identifiable a) "……." b) Records held secure and in confidence

		retention time, and disposition		c) Procedure to protect and backup electronic data d) Layout of records and reports e) Confidentiality during transmission of results
2.0 Management Responsibilities	2.1 Management commitment	*5.1 Management Commitment* a) Communicating importance of meeting customer/regulatory requirements b) Establish quality policy c) Ensure quality objectives d) Conduct management reviews e) Ensure availability of resources	*4.2.1 Commitment of top management* a) Communicating importance of R&D&I activities b) R&D&I policy c) R&D&I objectives d) Management reviews e) Availability of material resources f) Set up R&D&I management unit g) Approve/review R&D&I budget h) Policy for protection/exploitation of R&D results	
	2.2 Policy and objectives	*5.3 Quality policy* a) Appropriate for organization b) Commitment to comply with requirements and continually improve QMS c) Framework to establish and review quality objectives d) Communicated and understood within organization e) Reviewed for continuing suitability	*4.2.3 R&D&I policy* a) Suitable for organization b) "……."…. R&D&I system c) " ……."……R&D&I objectives d) "……" e) "……"	1.0 g) *Environmental/sustainable development policy* *1.0 Code of Conduct and ethical issues* a) Behavior rules upon relationships with clients b) Fairness, social, environmental values c) Free market competition d) Fair employment rules f) Good scientific practice h) Factual and non-misleading advertising and promotion *3.2 Quality System - Quality Policy statement* i) Statement of standard of service ii) Purpose of quality system iii) Personnel be familiar and will implement procedures in quality documentation iv) Commitment to good professional practice and quality
		5.4.1 Quality Objectives	*4.2.4.1 R&D&I objectives*	
	2.3 Management system planning	*5.4.2 Quality management system planning* a) Meets quality objectives and general QMS requirements b) MS integrity maintained during changes	*4.2.4.2 R&D&I management system planning* a) Meets R&D&I objectives and general R&D&I MS requirements b) "……" c) R&D&I investment policy set	
	2.4 Management review	*5.6 Management review* *5.6.1 Review QMS at planned intervals* *5.6.2 Review input* a) Audit results b) Customer feedback c) Process performance/product conformity d) Preventive/corrective actions e) Management review follow-up actions	*4.2.6 Management review* *4.2.6.1 Review R&D&I MS* *4.2.6.2 Review input* a) Audit results b) Interested party feedback c) Monitoring/measurement of R&D&I process d) and the results e) "……" f) "……"	*3.13 Management review* a) Review research activities and QMS b) Review input

		f) Changes that affect QMS g) Recommendations *5.6.3 Review Output* a) Improvement to QMS and processes b) Improvement of product c) Resource needs	g) "……." R&D&I MS h) "……." *4.2.6.3 Review results* a) "……." of R&D&I MS b) Use and need for resoruces	c) Review findings
	2.5 Organization and responsibiltiies	*5.5 Responsibility, authority, communication* 5.5.1 Responsibilities/authorities defined and communicated within organization	*4.2.5 Responsibility, authority, communication* 4.2.5.1 R&D&I management unit creation/roles 4.2.5.2 R&D&I unit responsibilities 4.2.5.3 Establishment and structure of R&D&i units and management	*3.1 Organization* e) Define of organisation and management structure f) Specify authoritities/responsibilities g) Adequate supervision of staff h) Technical management responsible for technical operations i) Quality manager appointment j) Deputies for key managerial personnel 5.1a) Project manager i) responsible for project quality and directing project 5.1b) Steering committee (optional) i) Control and direct execution of project
	2.5.1 Management Representative	5.5.2 Management representative for QMS	4.2.5.4 Top management representative for R&D&i	
	2.5.2 Internal Communication	5.5.3 Internal communication (QMS) a) Appropriate communication processes established	4.2.5.5 Internal communication (R&D&I MS) a) "……."	
	2.6 Stakeholder focus	*5.2 Customer focus* a) Meet customer requirements and enhance customer satisfaction	*4.2.2 Interested Parties approach* a) Ensure needs and expectations of all interested parties in R&D&I process are considered and analyzed a) Demands of providers and customers b) Motivation and involvement of employees c) Demands of shareholders d) Legal and regulatory requirements e) Innovations and technological changes required by the market	
3.0 Measurement, analysis and improvement	3.1 Monitoring and Measurement General requirements	*8.1 General* *Monitor, measure, analyse, improve processes to:* a) Demonstrate product conformity b) QMS conformity c) Continual improvement of QMS effectiveness	*4.5.1 General* *Processes to monitor, measure, analyse, improve:* a) Execution of R&D&I activities b) R&D&I management system c) Continual improvement of R&D&I system Monitor perception of interested parties with regard to fulfillment of needs/expectations	
	3.2 Monitoring and measurement 3.2.1 Monitoring and measurement of processes	*8.2.3 Monitoring and measurement of processes* a) Suitable methods for monitoring and measuring QMS processes that demonstrate ability to achieve planned results b) Correction/corrective action taken if planned results not achieved	*4.5.3 Monitoring and measurement of the R&D&I process* a) "……." R&D&I processes that demonstrate ability to achieve expected results b) Determine required actions if expected results not achieved	

	3.2.2 Monitoring and measurement of product	*8.2.4 Monitoring and measurement of product* a) Monitor and measure product to verify requirements met. b) Carried out at appropriate stages of product realisation process as per plans in 7.1 c) Product release and service delivery proceeds only after planned arrangement (7.1) completed	*4.5.4 Monitoring and measuring results of* R&D&I process a) Monitor and measure results of R&D&I process to verify requirements fulfilled b) Carried out at suitable stages of process according to plans *4.4.8.2 Monitoring and measurement of R&D&I process results* a) Criteria for review, selection, approval of results b) Mechanisms to quantify results achieved and compare with objectives in R&D&I policy c) Monitoring and measuring mechanisms d) Corrective measures/actions required e) Identification of new/expanded R&D&I ideas	5.2 f) Research Project closure i) conditions of contract fulfilled ii) Results presented to client for acceptance iii) Feedback collected from personnel and client iv) Administration of project closure 5.3e) Peer evaluation or independent check of research report 5.3f) Completed research work reviewed by management to evaluate achievements
	3.2.3 Equipment calibration	*7.6 Control of monitoring and measuring devices* i) Determine monitoring and measurement to be undertaken ii) Determine monitoring and measurement devices a) Measuring equipment calibrated and verified at specified intervals or prior to use a) Calibration against measurement standards b) Adjusted or re-adjusted as necessary c) Identified to determine calibration status d) Safeguarded from adjustments e) Protected from damage and deterioration iii) Assess and record validity of previous measuring results when for non-conforming equipment iv) Take action on equipment and product affected v) Records of calibration results/verification		4.4e) Calibration programmes *4.6 Measurement traceability* 4.4i) Equipment calibration/verification status labelled and identified
	3.3 Conformity (measure process and product/service, analyse data concern management, audit system			
	3.3.1 Internal Audits	*8.2.2 Internal audits* Conducted at planned intervals to determine if QMS: a) Conforms to standard and QMS requirements b) effectively implemented and maintained i) Audit programme planned, defined, documented ii) Criteria, scope, frequency, methods defined iii) Selection of auditors/conduct of audits iv) Follow-up actions (verification of actions, reporting of verification results) taken without delay	*4.5.2 Internal audits* "……." for R&D&I management system a) "……." b) "……." iii) "……." i) "……." ii) "……." iv) Results and maintain records	*3.12 Internal audits* Planned intervals with predetermined annual schedule: a) Operations comply with QMS requirements b) Responsibility of quality manager to plan and organize audits c) Trained and qualified auditors d) Timely corrective action, notification of clients in writing if results affected e) Audit findings, corrective actions, followup activities recorded and verified
	3.3.2 Control of nonconformances	*8.3 Control of nonconforming product* a) Actions to eliminate detected nonconformity	*4.5.5 Control of deviations from expected results* a) Deviations from expected results identified and	*3.8 Control of non-conformances* *(in quality system, research methodologies, technical*

		b) Authorizing its use, release, or acceptance c) Action to preclude original intended use i) Records of nonconformities and actions taken ii) Re-verification of corrected products iii) Actions for nonconforming products after delivery	recorded (for future use if appropriate)	*operations and any aspect of research project work)* a) Responsibilites and actions for nonconformity management e) Respnsibility for authorization b) Evaluation of significance c) Remedial actions taken immediately or acceptence d) Client notified and work recalled if necessary
	3.3.3 Data Analysis	*8.4 Analysis of data* i) Determine, collect, analyse appropriate data to demonstrate suitability and effectiveness of QMS ii) Evaluate continual improvement areas Information on: a) Customer satisfaction b) Product conformity c) Characteristics/trends of processes and products d) Suppliers	*4.5.6 Data Analysis* i) "……" of R&D&I management system ii) "……" Information on: a) Satisfaction of interested parties b) R&D&I results conformity c) Characteristics of R&D&I process and results	*4.7 Sampling*
	3.3.4 Stakeholder satisfaction	*8.2.1 Customer satisfaction* a) Methods to monitor customer perception and meeting customer requirements	*4.5.1 General* Monitor perception of interested parties with regard to fulfillment of needs/expectations	N/A
	3.4 Improvement (Corrective/preventive action, continual improvement)			
	3.4.1 Corrective/Preventive Action	*8.5.2 Corrective action* To eliminate cause of nonconformities to prevent recurrence Documented proecedure for: a) Reviewing nonconformities (inc. customer complaints) b) Determining causes c) Evaluating need for action d) Determining and implementing action e) Records of actions taken and results f) Corrective action review *8.5.3 Preventive action* To eliminate cause of potential nonconformities Documented procedure for: a) Determining potential nonconformities and causes b) Evaluating need for action c) Determining and implementing action needed d) Records of results of actions taken e) Review actions	*4.5.7.2 Corrective action* Eliminate cause of nonconformities in R&D&I management system Documented procedure for: a) Review nonconformity b) "……" c) "……" d) "……." e) "……" f) "……." *4.5.7.3 Preventive action* Eliminate causes of potential nonconformities in R&D&I system. Documented procedure for: a) "……." b) "……." c) "……" d) "……." e) "……"	*3.9 Corrective action* Eliminate causes of nonconformities in QMS, technical operations, project work to prevent recurrence a) Determine root cause b) Select and implement action c) Document required changes d) Monitor results *3.10 Preventive action* Proactive process to idenfify improvement , either technical or with QMS a) "……" and opportunities for improvement b) Action plan developed, implemented and monitored c) Results submitted for management review
	3.4.2 : Continual improvement	*8.5.1 Continual improvement* (for QMS, through quality policy, objectives, audit results, analysis of data, corrective/preventive actions management review)	*4.5.7.1 Continual improvement* (for R&D&I management system)	1.0 e) Code of conduct: Continuous improvement of quality of activities.

4.0 Resource Management	**4.1 Provision of resources**	*6.1 Provision of resources* Determine and provide resources needed to a) Implement and maintain QMs b) Meet customer requirements and enhance customer satisfaction	*4.3.1 Provision of resources* Determine and provide resources needed to: a) "……." R&D&I management unit b) Meet needs/expectations of interested parties to enhance their satisfaction c) Foster coorperation with external entities that provide knowledge, methodologies, instruments, funding, etc.	3.1a) Managerial and technical personnel with authority and resources needed to carry out duties
	4.2 Human Resources 4.2.1 Personnel	*6.2.1 General* a) Competent personnel (appropriate education, training, skills, and experience)	*4.3.2.1 General* a) "……."	*4.1 Personnel* a) Competent personnel for all those performing research, operating equipment and making professional judgement d) Appropriate education, training, experience, skills, knowledge, and background b) Supervision of trainees and those not employed or under contract 5.1e) Personnel making professional judgement have integrity and good reputation
	4.2.2 Competence, awareness and training	*6.2.2 Competence, awareness, and training* a) Determine necessary competence for personnel performing work affecting product quality b) Provide training and actions needed	*4.3.2.3 Competence, awareness and training* a) "……." involved with R&D&I activities b) "……."	5.1c) Identify training needs and provide training f) Training by mentoring g) Training of managerial, communication, and interpersonal skills for those with management responsibiltiies h) Personnel certification for technical areas 4.1e) Training should reflect R&D work, which involves collaboration and multi diciplinary personnel
		c) Evaluate effectiveness of actions taken d) Ensure personnel aware of relevence and importance of their activities and contribution to quality objectives e) Records of education, training, skills, experience	c) "……." d) "……." to R&D&I objectives e) "……."	i) Records of qualification, training, experience, job descriptions, CVs
	4.2.3 Teamwork, creativity and motivation	N/A	*4.3.2.2 Motivation of personnel* a) Promote awareness of importance of R&D&i b) Motivate and raise enthusiasm c) Encourage participation of all staff d) Promote creativity and teamwork e) Simplify and facilitate information inputs from different departments 4.3.2.1b) Ability to work in team, motivation and enthusiasm to obtain results *4.4.1.3 Creativity*	N/A
	4.3 Facilities, infrastructure, equipment and environment, 4.3.1 Facilities, infrastructure, equipment and supporting services	*6.3 Infrastructure* Determine, provide, maintain infrastructure needed to achieve product requirements conformity:	*4.3.3 Infrastructure* "……." for the R&D&I process	*4.2 Facilities and environmental conditions* a) Laboratory facilities to facilitate correct performance of research operations

			a) Buildings, workspace, utlilities b) Process equipment (hardware, software) c) Supporting services (e.g. transport, communication)	a) Buildings, working area, associated services b) Equipment for R&D&I activities c) Support services	*4.4 Equipment* a) Availability of required equipment for research
		4.3.2 Equipment qualification and maintenance	Covered under *6.3 Infrastructure* and 7.5.1 Control of production and service provision	Covered under *4.3.3 Infrastructure*	4.4h) Maintenance procedures 4.4b) Purchased equipment checked against specification requirements and standards c) Equipment is labelled and identified d) Equipment capable of providing accuracy required g) Records of equipment and software j) Modification of existing equipment and design of new equipment 4.4f) Equipment operated by competent and authorised personnel 4.4g) Up-to-date instructions on the use and maintanance of equipment
		4.3.3 Work environment	*6.4 Work environment* a) Determine and manage work environment needed to achieve product conformity	*4.3.4 Work Environment* a) "....." R&D&I objectives	b) Sampling, experimental, measurement environment should not adversely affect results c) Monitor, control, record environmental conditions d) Acclimatisation of material to research environment if required e) Measures to prevent cross-contamination f) Access control and good housekeeping of areas affecting quality of results
5.0 R&D&I tools and and analysis	**5.0 Information gathering, technology assessment, analysis and selection of ideas**	N/A	*4.4.1.1 Technology watch* *4.4.1.2 Technology foresight* *4.4.1.4 External and internal analysis* *4.4.2 Identification and analysis of problems and opportunities* *4.4.3 Analysis and selection of R&D&i ideas*	5.2a) Project Information collection	
6.0 Product/project planning, design & development	**6.1 Planning** 6.1.1 Project management and planning	*7.1 Planning of product realisation* Plan and develop processes needed for product realisation Determine:	*4.4.4 Planning, monitoring and control of project portfolio* Definition of R&D&I projects from selected research ideas. Establish system to plan, monitor, control	5.2b) Project planning and preparation (creation of research plan and task planning) 5.1c) Role of project management in large or multidiciplinary projects	

			a) Quality objectives and product requirements b) Processes, documents and resources c) Verification, validation, monitoring, inspection, test activities, and product acceptence criteria d) Records to prove that realisation processes and product meet requirements	project portfolio (details found in this section)	5.1d) Defining the way projects carried out (project guide, manual, checklists)
		6.1.2 Gather and assess stakeholder requirements	*7.2.1 Determination of product related requirements* a) Customer specified requirements, incl. delivery and post-delivery activities b) Requirements not specified by customers c) Statutory and regulatory requirements d) Additional requirements	*4.2.2 Interested Parties approach* a) Ensure needs and expectations of all interested parties in R&D&I process are considered and analyzed a) Demands of providers and customers b) Motivation and involvement of employees c) Demands of shareholders d) Legal and regulatory requirements e) Innovations and technological changes required by the market	
		6.1.3 Review product related requirements	*7.2.2 Review of product related requirements* i) Conducted prior to commitment to supply product Ensure that: a) Product requirements defined b) Contract or order requirements resolved c) Organization can meet defined requirements ii) Records of review maintained		5.2c) Project preparation (project marketing, content, contract, financing, etc.) Organization has required equipment, competence and human resources to carry out project **2.0 Contractual and legal aspect** a) take on project which it is adequately qualified b) Ensure adequate resources c) Professional expertise and scientific care d) Strive to produce sound results e) Define scope of R&D projects with client f) Contract formation and mutual understanding g) Contractual/legal rules h) Personnel formal competence requirements i) Consistent pricing policy j) Liability insurance **2.1 Project contract** a) Establish contract with client for all projects b) Confidentiality level for work c) Projects performed correctly at first attempt in cost-effective manner and results applicable for exploitation as soon as possible d) Deliverables specified clearly in contract e) Liability concerns f) Tender/Contract review g) Risks of a mismatch h) Subcontracting
		6.2 Design and development 6.2.1 Design/Development Planning	7.3 Design and development *7.3.1 Design and development planning* Determine: a) Design and development stages b) Review, verification, validation for each stage	*4.4.6 R&D&I product* *(once projects have been defined)* *4.4.6.1 Basic design* a) Description of design and outline of characteristics b) Resource planning c) Preliminary maps	

		c) Responsibilites and authorities for design and development i) Manage interface between different groups involved to ensure effective communication and assignment of responsibility ii) Planning output updated as appropriate	*4.4.6.2 Detailed design* Modifications and changes to basic design a) Description of design b) Support elements/infrastructure c) Design team d) Communication structure e) How to implement design process	
	6.2.2 Design/Development Inputs	*7.3.2 Design and development inputs (relating to product requirements* a) Functional and performance requirements b) Statutory and regulatory requirements c) Information from previous similar designs d) Other requirements i) Inputs reviewed for adequacy ii) Requirements complete, unambiguous and not in conflict		5.2a) Initial project phase: Data/information collection
	6.2.3 Design/Development Outputs	*7.3.3 Design and development output* Enables verification against input. Outputs shall: a) Meet input requirements b) Provide information for purchasing, production, and service provision c) Contain or reference product acceptance criteria d) Specify safe and proper use of product	*4.4.8 Results of R&D&I process* Enables verification against objectives planned in R&D&I policy *4.4.8.1 Documentation of the results* a) Final project reports b) Protection of the results obtained c) Basic data, diagrams, drawings, intermediate reports d) Problems, and specific solutions e) Written evaluations of project, including knowledge acquired for future activities	*5.4 Reporting the results* (lots of specific guidelines for research report requirements and format)
	6.2.4 Review and monitoring	*7.3.4 Design and development review* Systematic reviews performed at suitable stages to: a) Evaluate ability of results of design/development to meet requirements b) Identify problems and propose necessary actions i) Records of review results maintained	*4.4.6.6 Change control* a) Surveillance of project (especially features, costs, and timeframes)	*5.3 Monitoring project progress* a) Progress of work (completion grade) and expenditure b) Monitoring in co-operation with client and reported to client, steering committee and management in accordance to planning stage c) Changes identified during progress reviewed
	6.2.5 Verification	*7.3.5 Design and development verification* i) Ensure design and development outputs meet input requirements ii) Records of results and necessary actions	*4.4.6.3 Pilot test (prototype to be tested)* Pilot test shall consider: a) Description of actual work situation b) Procedures for changes c) Procedures for prototype validation	
	6.2.6 Validation	*7.3.6 Design and development validation* i) Ensure product meets requirements of specified application or intended use ii) Validation completed prior to delivery or product implementation iii) Records of results and necessary actions	*4.4.6.4 Redesign, demonstration and production* i) Product from R&D&I process manufactured according to approved prototype ii) Define production means and resources iii) Information from real demonstrations recirculated to previous stages *4.4.6.5 Marketing* i) determine how product satisfies	

			interested parties	
	6.2.7 Change control	*7.3.7 Control of design and development changes* a) Changes identified and records maintained b) Changes reviewed, verified, validated, approved	*4.4.6.6 Change control* b) Approval of changes and records kept	
	6.2.8 Experimental/Calculation methods	N/A	N/A	*4.3 Experimental/calculational methods* (details on research method, data collection) a) Use of appropriate experimental and calculational methods for all activites b) Equipment and software instructions c) Research methodologies that meet needs of client and are scientifically appropriate d) Use of standards and recognised specifications e) New research methods or methodologies f) Validation of research methods g) Calculations and data transfers h) Procedure for estimating uncertainty of results 5.3d) Methods to ensure quality of outgoing results
	6.3 Manage customers/clients	*7.2.3 Customer communication* a) Product information b) Enquiries, contracts, order handling c) Customer feedback, including complaints	N/A	*3.6 Service to and feedback from client* a) Co-operation with client requests b) Continual contact with client (inform of any delays or major project deviations) c) Positive and negative feedback *3.7 Complaints* a) Policy to resolve complaints from clients and other parites
	6.4 Technology transfer, exploitation of results and intellectual property	N/A	*4.4.9 Protection and exploitation of results of R&D&I activities* i) Assess viability and opportunity to protect and exploit results a) Define mechanisms for technology transfer b) Implement mechanisms for tech transfer c) Agreements for tech transfer d) Alternatives to protect results e) Patent procedures f) Confidentiality of results and measures to ensure it *4.4.5 Technology transfer* Maintain and document tech transfer system, e.g.: a) Intellectual and industrial property b) Technology acquisition and sale contracts c) Technical assistance d) Creation of joint ventures e) Cooperation and partnerships for projects f) Tech transfer from universities/R&D&I bodies	5.2 g) Transfer of knowledge and technology to client 2.2: Intellectual Property Rights
	Production/ Manufacturing Stage:			

7.0 Manufacturing, **Receiving, Shipping**	7.1 Control and validation of production and service	*7.5.1 Control of production and service provision* Product and service provision under controlled conditions a) Availability of product information b) Availability of work instructions c) Use of suitable equipment d) Use of monitoring and measuring devices e) Implementation of monitoring and measurement f) Implementation of release, delivery, post delivery activities	N/A	5.2 d) Project realisation
		7.5.2 *Validation of processes for production/service*	N/A	N/A
	7.2 Handling of product, customer property and research items	*7.5.3 Identification and traceability* a) Identification of product throughout realisation b) Identify product status according to monitoring and measurement requirements		4.8b) System for identifying research items *4.5 Reagents and laboratory consumables* a) Conformity to purchase order and specified requirements
		c) Control/record product identification for traceability		b) Proper preparation and storage c) Labelling and restrictions of use
		7.5.4 Customer property (including IP) a) Care with customer property b) Identify, verify, protect and safeguard customer property c) Reporting lost, damaged, unsuitable customer property		
		7.5.5 Preservation of product a) Identification, handling, packaging, storage, protection, shipping		4.8a) Practices for transport, receipt, handling, protection, storage, retention and disposal of items 4.8c) Receiving research items 4.8d) Avoiding damage to items 4.8e) Research items kept at least 3 months after results delivery to client (or as otherwise specified by client)
8.0 Purchasing				
	8.1 Procurement and subcontracting **work**	*7.4.1 Purchasing process* a) Ensure purchased product conforms to purchase requirements	*4.4.7.1 Purchasing process* a) Subcontracted personnel & products acquired meet requirements of R&D&I management unit	3.4a) Competent sub-contractor 3.5a) External services and supplies of adequate quality to sustain confidence in results 3.5b) Purchased materials/services comply with requirements
		b) Type and extent of control applied to supplier and purchased product c) Evaluation and selection of suppliers based on organization requirements d) Records and results of evaluations and necessary actions	b) Selection of providers based on needs of R&D&i management unit	
	8.2 Purchasing procedure/documentation **and verification**	*7.4.2 Purchasing information* Describe product to be purchased, including: a) Requirements for approval of product, procedures,	*4.4.7.2 Purchasing information* Describe subcontracted work and product purchased a) Requirements for product approval	3.5c) Procedures for purchase, reception, storage of consumables

		processes, equipment		
		b) Requirements for personnel qualification	b) Requirements for qualification of subcontracted personnel	3.4b) Register of main subcontractors and record of competence 3.5e) Records of main suppliers
		c) QMS requirements		
		7.4.3 Verification of purchased product a) Establish and inplement inspection activities b) Verification arrangements at supplier's premises	4.4.7.3 Purchasing verification a) "……" b) "……" at subcontractor's premises	3.5d) Purchased supplies not used until inspected, calibrated, and verified

Appendix E : Gap Analysis Matrix

Legend:

Requirement does not apply	Gap	No Gap

E-1 MS Area 1.0: Quality/R&D&I Management System

Table E-1.1: **Gap Analysis Matrix - MS Area 1.0: Quality/R&D&I MS General**

HMSS Clauses	1.1	1.2	1.2.1	1.2.2	1.2.3	Justification
MS Component						
Document/Data Control						**Reference(s):** • *Quality Manual sec. 4.2.2: Control of documents* • *Quality Manual sec. 4.2.3: Document Identification* • *Quality Manual sec. 4.2.4: Indexes* • *Quality Manual sec. 4.2.5: Controlled Document Approval* • *QASP-003: Document & Data Control* **Comments:** • All criteria for document control met through ISO 9001:2000 compliance.
Control of Records						**Reference(s):** • *Quality Manual sec. 4.2.6: Control of Records* • *QASP-014: Quality Records* **Comments:** • CSO has a record keeping system as required by ISO 9001:2000, but procedure does not address the preparation and layout of R&D project records.
Quality Manual						**Reference(s):** • *CSO Quality Manual* • *Quality Manual sec. 4.2.1: Quality Manual* **Comments:** • No new requirements from UNE 166002:2006 or EARTO:2000. Quality Manual already exists at CSO
General requirements						**Reference(s):** • *Quality Manual sec. 4.1: Quality Management System Requirements*

						Comments: • Identification of R&D&I activities, their sequence and interaction, criteria and methods needed, are defined in *QASP-037:MPQP*, although not all components included (e.g. technology watch). • Mechanisms for protection/exploitation of results not documented. • CSO has a process map for the quality system (*Quality Manual sec. 9.0: Quality system process* flow), but not a model of R&D&I management system processes. • Research Contracts and Internal Research projects not covered under scope of quality management system.

E-2 MS Area 2.0: Management Responsibilities

Table E-2.1: **Gap Analysis Matrix - MS Area 2.0: Management Responsibilities**

HMSS Clauses	**2.1**	**2.2**	**2.3**	**2.4**	**2.5**	**2.5.1**	**2.5.2**	**2.6**	
MS Component									**Justification**
Policy and Objectives									**Reference(s):** • *Quality Manual sec. 5.3: Quality Policy* • *Quality Manual sec. 5.4.1: Quality Objectives* • *QASP-033:* Policy and Objectives (QASP-033) **Comments:** • R&D&I policy and objectives not set by the CSO • General quality policy exists in the CSO, but elements addressing ethical codes of conduct environmental/sustainable development not included.
Responsibility, authority, and communication									**2.5, 2.5.1** **Reference(s):** • *Quality Manual sec. 5.5.1: Responsibility and authority* • *QASP-031: Job Function listing* • *QASP-032: Organization Chart* **Comments:** • Roles, Responsibilities and structure of R&D&I management and R&D&I unit not fully defined. • Top management representative for R&D&I not designated. **2.5.2** **Reference(s):**

									• *Quality Manual sec. 5.5.2: Internal Communication* **Comments:** • Verbal communication at staff meetings or through emails. •
Management Review									**Reference(s):** • *Quality Manual sec. 5.6: Management Review* **Comments:** • Management reviews are carried out at CSO, but does not cover R&D&I MS and the related R&D standard requirements.
Management Commitment									**Reference(s):** • *Quality Manual sec. 5.1: Management Commitment* **Comments:** • Importance of R&D&I and policies needs to be communicated • Policy for the protection/exploitation of R&D results does not exist. • Process for approving and reviewing R&D&I budget not defined • R&D&I management unit not defined
Management System Planning									**Reference(s):** • *Quality Manual sec. 5.4.2: Quality Management System Planning* **Comments:** • Planning of R&D&I MS, such that it meets the R&D&I objectives and general requirements, not defined • R&D&I investment policy does not exist.
Stakeholder focus									**Reference(s):** • *Quality Manual sec. 5.2: Customer Focus* **Comments:** • Customer requirements are determined and met with the goal of enhancing customer satisfaction; however the needs/expectations of *all interested parties* in the R&D&I process are not fully defined.

E-3 MS Area 3.0: Measurement, analysis and improvement

Table E-3.1: **Gap Analysis Matrix – MS Area 3.0: Measurement, analysis and improvement**

HMSS Clauses	3.1	3.2.1	3.2.2	3.2.3	3.3.1	3.3.2	3.3.3	3.3.4	3.4.1	3.4.2	Justification
MS Component											
General practices and stakeholder satisfaction											**<u>3.1</u>** **Reference(s):** • *Quality Manual sec. 8.1: Measurement, Analysis and improvement – General* **Comments:** • Monitoring and measurement of R&D&I activities not fully defined. **<u>3.3.4</u>** **Reference(s):** • *Quality Manual sec. 8.2.1: Customer satisfaction* **Comments:** • CSO collects information (through quarterly surveys) from a minimum of two customers, related to their perception of the CSO's ability to meet requirements. However, the monitoring and measurement of other stakeholders (apart from customers) is not conducted.
Monitoring and Measurement of processes											**Reference(s):** • *Quality Manual sec. 8.2.3: Monitoring and Measuring of Processes* **Comments:** • Aspects of monitoring and measurement of R&D&I processes in order to achieve planned objectives not defined.
Monitoring and measurement of product											**Reference(s):** • *Quality Manual sec. 8.2.4: Monitoring and Measuring of Product* **Comments:**

											• Aspects of monitoring/measuring R&D&I results and completed research work not fully defined.
Internal Audits											**Reference(s):** • *Quality Manual sec. 8.2.2: Internal Audit* • *QASP-015: Internal Quality Audits* **Comments:** • Internal audit process already exists at CSO, but do not cover R&D&I MS requirements of UNE 166002:2006 and EARTO:2000.
Corrective/preventive action & improvement											**3.4.1, 3.4.2** **Reference(s):** • *Quality Manual sec. 8.5.2: Corrective Action* • *Quality Manual sec. 8.5.3: Preventive Action* • *QASP-012: Corrective/Preventive Action* **Comments:** • CSO has process in place to document all non conformities, potential non-conformities and their causes. • Subsequent follow-up performed to ensure actions taken are timely and effective.
Calibration and control of measuring devices											**Reference(s):** • *Quality Manual sec. 7.6: Control of monitoring and measuring devices* • *QASP-009: Inspection, Measuring & Test Equipment* **Comments:** • No new UNE 166002:2006 requirements addressing this area. • EARTO:2000 requirements already covered by ISO 9001:2000.
Control of non-conformances											**Reference(s):** • *Quality Manual sec. 8.3: Control of*

											Nonconforming Product • *QASP-011- Control of Nonconforming Product* **Comments:** • Since research tasks are not covered under the scope of the QMS, "deviations from the expected R&D results" are currently not considered when handling nonconformances. .
Analysis of data											**Reference(s):** • *Quality Manual sec. 8.4: Analysis of Data* • *QASP-018: Statistical Techniques* **Comments:** • Analysis of data that demonstrates the suitability and effectiveness of the R&D&I MS is not defined (UNE 166002:2006 requirement) • Sampling techniques (EARTO:2000 guidelines) are addressed in QASP-018,.

E-4 MS Area 4.0: Resource Management

Table E-4.1: **Gap Analysis Matrix – MS Area 4.0: Resource Management**

HMSS Clauses	**4.1**	**4.2.1**	**4.2.2**	**4.2.3**	**4.3.1**	**4.3.2**	**4.3.3**	**Justification**
MS Component								
Provision of resources								**Reference(s):** • *Quality Manual sec. 6.1: Provision of resources* **Comments:** • Resources need to be provided for R&D&I management unit; and to meet needs of all interested parties and external entities relevant for project success (not merely customers)
Human Resources								**Reference(s):** • *Quality Manual sec. 6.2.1: Human Resources - General* **Comments:** • Details on integrity, professional conduct, and good reputation of

								personnel currently not included as criteria.
Teamwork, creativity, motivation								**Reference(s):** **Comments:** • Processes that promote awareness and importance of R&D&I not defined • Processes on improving motivation/enthusiasm not defined. • Processes that promote teamwork, innovation, and creativity to obtain results not defined • Processes that simplify information flow between different departments not defined.
Competence, Awareness and Training								**Reference(s):** • *Quality Manual sec. 6.2.2: Competence, Awareness and Training* • *QASP-016: Training* **Comments:** • Processes for determining employee competence meets needs of both QMS and R&D&I MS. • Current training process at CSO is sufficient to meet needs of new standard requirements. However, CSO staff need to be aware of how they contribute to the achievement of both quality and R&D&I objectives.
Facilities, infrastructure, equipment and supporting services								**Reference(s):** • *Quality Manual sec. 6.3: Infrastructure* **Comments:** The entire CSO can be considered to be an R&D&I environment, R&D requirements covering infrastructure and equipment are all met.
Work environment								**Reference(s):** • *Quality Manual sec. 6.4: Work Environment* **Comments:** • Work environment required to achieve R&D&I objectives not defined.
Equipment qualification and maintenance								**Reference(s):** • *Quality Manual sec. 6.3: Infrastructure* • *Quality Manual sec. 7.5.1 Control of Production and Service Provision* • *QASP-025: Equipment Qualification & Re-Qualification* • *QASP-026: Preventative maintenance* **Comments:** • CSO has processes and documented procedures that describe how equipment is maintained and qualified to be meet process

								requirements. • UNE 166002:2006 and EARTO:2000 do not contain additional requirements.

E-5 MS Area 5.0: R&D&I Analysis; MS Area 6.0: Project/product planning, design & development

Table E-5.1: **Gap Analysis Matrix - MS Area 5.0 and 6.0: R&D&I Analysis, Project/product planning, design & development**

HMSS Clauses	**5.0**	**6.1.1**	**6.1.2**	**6.1.3**	**Justification**
MS Component					

R&D&I Analysis: Information gathering and processing; technology assessment; Project evaluation and selection					**Reference(s):**
					• QASP-037: MPQP
					Comments:
					• No documented processes in place that address these activities:
					  • Technology watch and technology foresight
					  • System to carry out external and internal analysis
					  • Identification/analysis of problems and opportunities
					  • Analysis and selection of R&D&I ideas

Project management and planning					**Reference(s):** • *QASP-006: Project Management* **Comments:** • CSO has documented processes for managing individual projects, however a system for planning, monitoring and control of the overall project portfolio is not documented.
Gather and assess stakeholder requirements					**Reference(s):** • *Quality Manual sec. 7.2.1: Determination of requirements related to the product* **Comments:** • Customer requirements are determined and met with the goal of enhancing customer satisfaction; however the needs/expectations of *all interested parties* in the R&D&I process are not fully defined.
Review requirements					**Reference(s):** • *Quality Manual sec. 7.2.2: Review of requirements related to the product* • *QASP-001: Sales Order Review* • *QASP-021: Quotation/Proposal Review* **Comments:**

					• Relevant procedures for contract review and record keeping are included in QASP-021. Procedures for sales order view, amendments, communication and record keeping are included in QASP-001. • Corresponding requirement not found in UNE 166002:2006

Table E-5.1: **Gap Analysis Matrix - MS Area 5.0 and 6.0: R&D&I Analysis, Project/product planning, design & development (continued)**

HMSS Clauses	**6.2.1**	**6.2.2**	**6.2.3**	**6.2.4**	**6.2.5**	**6.2.6**	**6.2.7**	**6.2.8**	**Justification**
MS Component									
Design and Development									
Design/Development Planning									**Reference(s):** • *Quality Manual sec. 7.3.1: Design and Development Planning* • *QASP-002: Design Control* **Comments:** • Design team communication structure not defined in the project "design plan".
Inputs									**Reference(s):** • *Quality Manual sec. 7.3.2: Design and Development Inputs* • *QASP-002: Design Control* **Comments:** • Both the customer and the CSO define requirements of the design. Input includes those listed in ISO 9001:2000 clause 7.3.2. • No additional requirements from UNE 166002:2006 or EARTO:2000.
Outputs and results									**Reference(s):** • *Quality Manual sec. 7.3.3: Design and Development Outputs* • *QASP-027: Developing the Work Order Traveler or Quality Plan* **Comments:** • Since "research contracts" are excluded from the scope of the CSO's quality system, a standardized system for the documentation of research results is not defined in the CSO's QMS. • Existing design outputs consists of drawings, specifications and work order travelers/quality plans for building a product.

Review and monitoring									**Reference(s):** • *Quality Manual sec. 7.3.4: Design and Development Review* • *QASP-006: Project Management* **Comments:** • Surveillance of the project progress, especially with regard to features, costs and timeframes not defined.
Verification									**Reference(s):** • *Quality Manual sec. 7.3.5: Design and Development Verification* • *QASP-002: Design Control* • *QASP-037: Product Quality Planning* **Comments:** • Design verification is an activity in the Design Control process (QASP-002). • Additional details of design verification activities provided in QASP-037 (“Prototype Phase” of product design).
Validation									**Reference(s):** • *Quality Manual sec. 7.3.6: Design and Development Validation* • *QASP-002: Design Control* • *QASP-037: Product Quality Planning* **Comments:** • Design validation is an activity in the Design Control process (QASP-002). • Additional Details of design verification activities provided in QASP-037 (“Pilot Phase” of product design).
Change control									**Reference(s):** • *Quality Manual sec. 7.3.7: Control of Design and Development changes* • *QASP-036: Control of Process Change* • *QASP-037: Product Quality Planning* **Comments:** • Sometimes a customer will ask for extra features in their design, change their specifications, or the CSO will discover new quality requirements that must be met after the original design is determined.

									• When this happens after the feasibility phase, the new quality requirement will be clearly defined to the MPQP review committee by the product line leader, and the committee will document their decision to either: a) Set the product back to a more primitive stage so that the new requirement can be thoroughly integrated into the product via the MPQP procedures; and define new tasks to meet the requirement in the current product life cycle stage. Or b) Accept the new requirement without further action (very strongly discouraged). • Changes to the design plan or final output documents are reviewed and approved by the R&D project manager. • Minor changes (issues that can be resolved with those responsible for imposing them) are marked on the existing plan or input/output document, and initialed as a record of approval. • Major changes (issues that cannot be resolved by making changes to existing design plan) can resolved by developing a new design plan, and then contacting the customer.
Experimental/Calculation methods									**Reference(s):** **Comments:** • Guidelines for Experimental and Calculation methods not defined

E-6 MS Area 6.3: Customer communication; MS Area 6.4: Exploitation of results and IP;MS Area 7.0: Manufacturing, Receiving, Shipping; MS Area 8.0: Purchasing

***Table E-6.1*: Gap Analysis Matrix MS Area 6.3: Customer communication; MS Area 6.4: Exploitation of results and IP; MS Area 7.0: Manufacturing, Receiving, Shipping; MS Area 8.0: Purchasing**

HMSS Clauses	6.3	6.4	7.1	7.2	8.1	8.2	Justification
MS Component							
Customer communication							**Reference(s):** • *Quality Manual sec. 7.2.3: Customer communication* • *QASP-012: Corrective/Preventive Action* • *QASP-024: Product Return* • *QASP-039: Emergency Sales Order Review* **Comments:** • Marketing & business development staff are responsible for communicating with customers regarding product information, enquiries (contracts, order handling, amendments), and customer feedback/complaints. • Customer complaints received are documented as corrective action in accordance with QASP-012. • Customer product returns are conducted in accordance with QASP-024 • Urgent sales orders are addressed in QASP-039. • Related requirement not found in UNE 166002:2006
Exploitation of results and intellectual property							**Reference(s):** **Comments:** • Process for the exploitation of results and technology transfer not documented
Purchasing							
Select and evaluation							**Reference(s):** • *Quality Manual sec. 7.4.1: Purchasing process* • *QASP-004: Purchasing* • *QASP-038: Capital Acquisition* **Comments:** • Approved vendors selected on basis of their ability to meet contractual requirements and quality assurance requirements, but selection of providers based on needs of R&D&I management unit not specified as a criteria in Quality Manual.
Purchasing info and verification							**Reference(s):** • *Quality Manual sec. 7.4.2: Purchasing process* • *Quality Manual sec. 7.4.3: Verification of purchased product*

							• *QASP-004: Purchasing* • *QASP-038: Capital Acquisition* **Comments:** • Purchase orders contain clear descriptions of the item(s) or service(s) required and includes/references all necessary purchasing information. • Purchasing information included is listed in *Quality Manual sec. 7.4.2*, and QASP-004 sec. 3.0 (Purchase Order Content). • Verification requirements are stated in the Purchasing Information (*Quality Manual sec. 7.4.2*); additional details are provided in *QASP-004 sec. 7.1: Verification Upon Receipt*
Manufacturing, Shipping and Receiving							

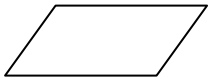
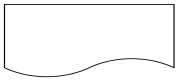
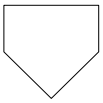
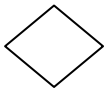
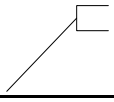
Receiving							**Reference(s):**
							• *Quality Manual sec. 7.5.3: Identification and Traceability*
							• *Quality Manual sec. 7.5.5: Preservation of Product*
							• *QASP:019: Receiving*
							• *QASP-023: Inventory Control*
							
							Comments:
							• Materials are properly identified from receipt and during all stages of product and delivery
							• Materials and products are stored, preserved, handled and packaged in a manner that makes them easy to use and prevents deterioration and damage.
							• EARTO:2000 requirements for reagents and laboratory consumables are all addressed by existing CSO procedures:
							  ○ Conformity to purchase order and specified requirements (QASP-019)
							  ○ Proper preparation and storage (QASP-023)
							  ○ Labeling and restrictions of use (QASP-023)
							• No additional UNE 166002:2006 requirements

Customer property and research items							**Reference(s):** • *Quality Manual sec. 7.5.4: Customer Property* • *QASP-005: Control of Customer Supplied Product* **Comments:** • Retention period for customer supplied research items not defined (e.g. products, materials, samples, specimens)
Manufacturing							**Reference(s):** • *Quality Manual sec. 7.5.1: Control of production and service provision* • *Quality Manual sec. 7.5.2: Validation of processes for production and service*

							provision. • *QASP-027: Developing the Work Order Traveler or Quality Plan* • *QASP-028: Processing a Work Order* • *QASP-029: Issuing Part Numbers* **Comments:** • No new requirements from UNE 166002:2006 or EARTO:2000. ISO 9001:2000 requirements fulfilled through existing procedures.
Shipping							**Reference(s):** • *Quality Manual sec. 7.5.5: Preservation of Product* • *QASP-022:* Shipping **Comments:** • Practices for packaging, shipping and preparation of necessary shipment paperwork contained in QASP-022.

Appendix F : Flowchart symbols

Table F-1: **Flowchart Symbols**

SYMBOL	DESCRIPTION
	INPUT/OUTPUT (e.g. customer, supplier, customer complaint)
	DOCUMENT
	NON-VALUE ADDING ACTIVITY (e.g. inspection)
	ON-PAGE REFERENCE
	OFF-PAGE REFERENCE
	VALUE-ADDING ACTIVITY (e.g. operation)
	MATERIAL/RESOURCE
	DECISION
	COMMENT

Appendix G : Gap Closure Supporting Process Flowcharts and Figures

G-1 Management processes and responsibilities

***Figure G-1.1*: R&D&I Policy and Company Code of Conduct Development process**

***Figure G-1.2*: Policy Integration and Deployment process**

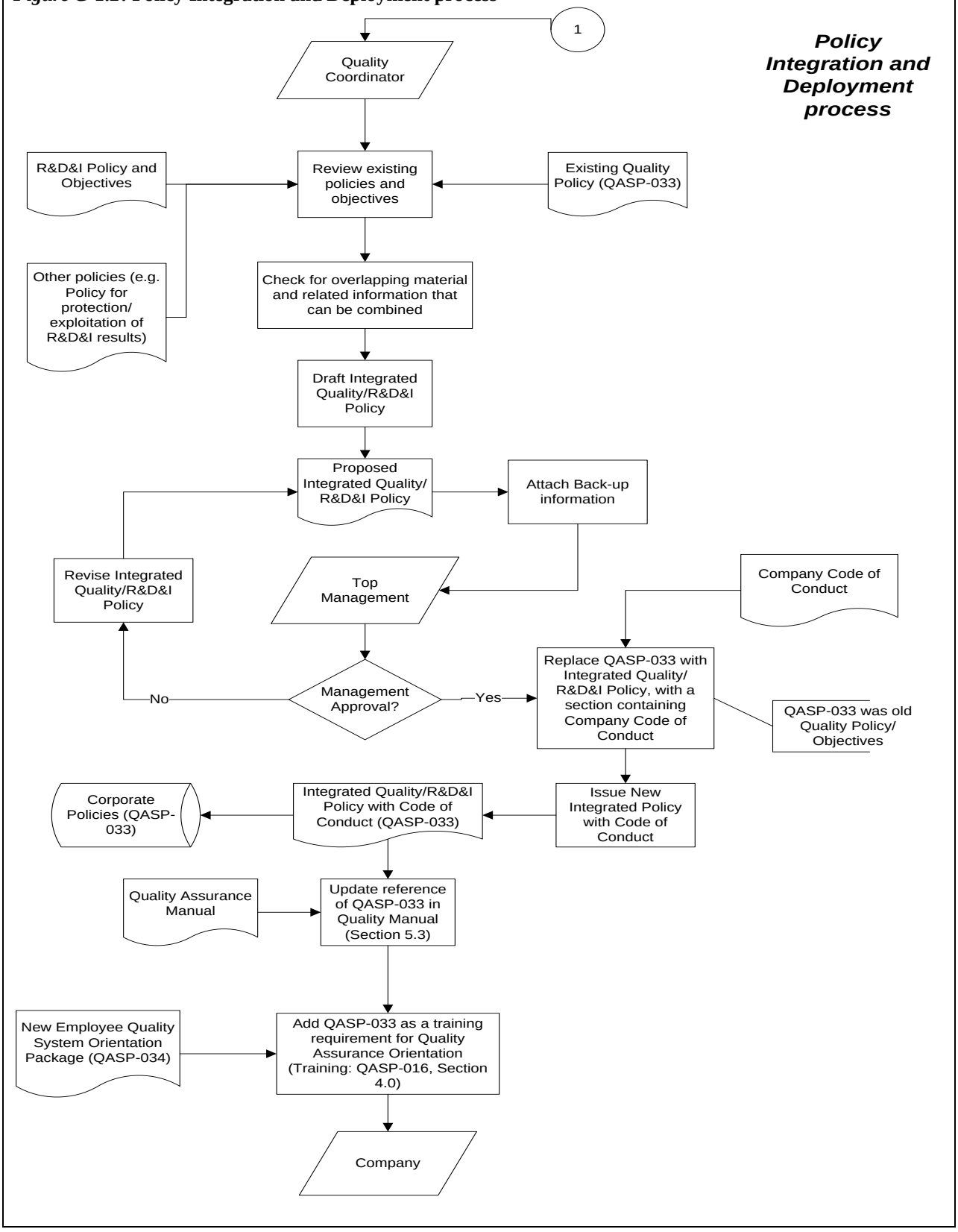


***Figure G-1.3*: Policy Implementation Verification process**

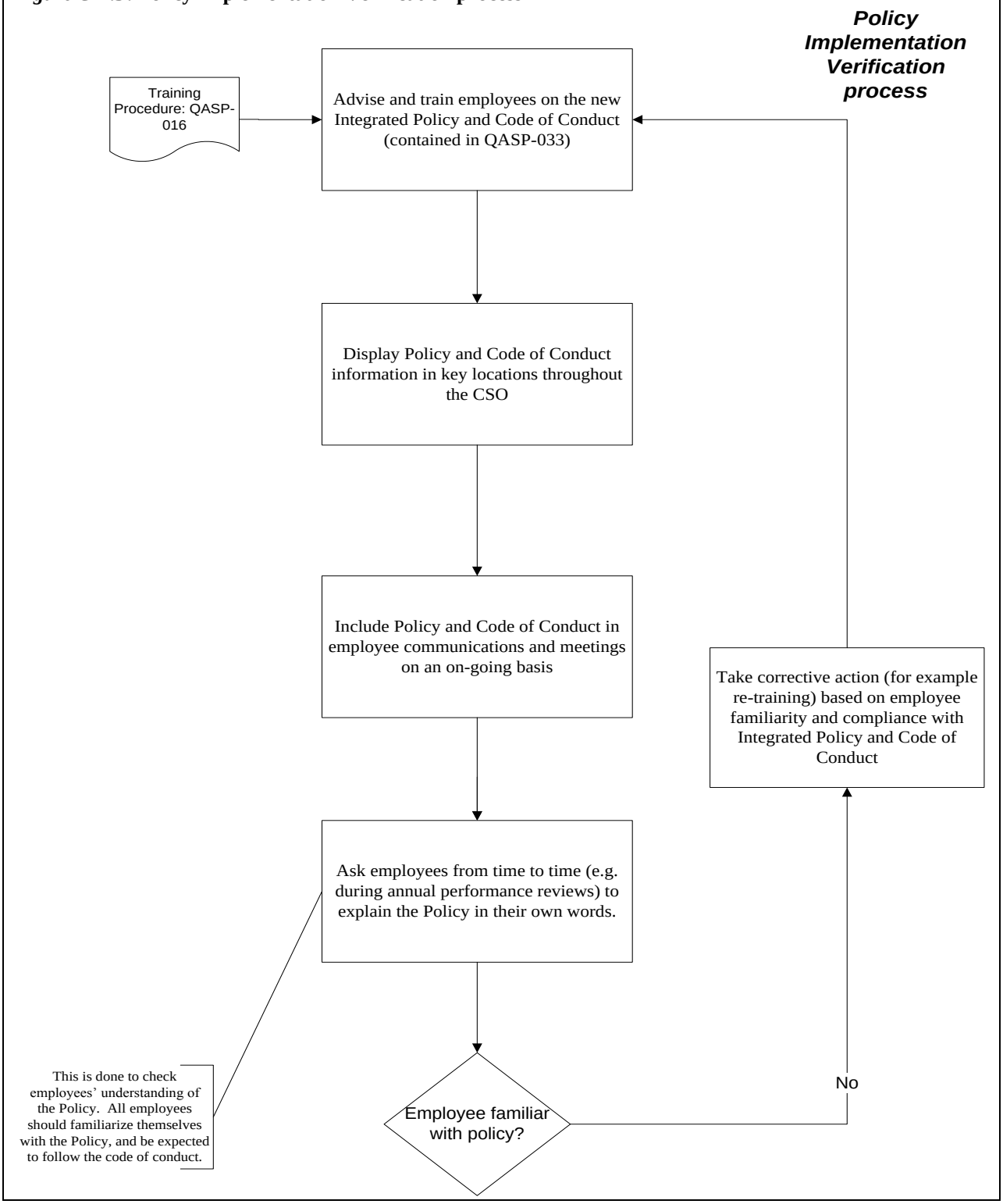


***Figure G-1.4*: Creation of R&D&I units process**

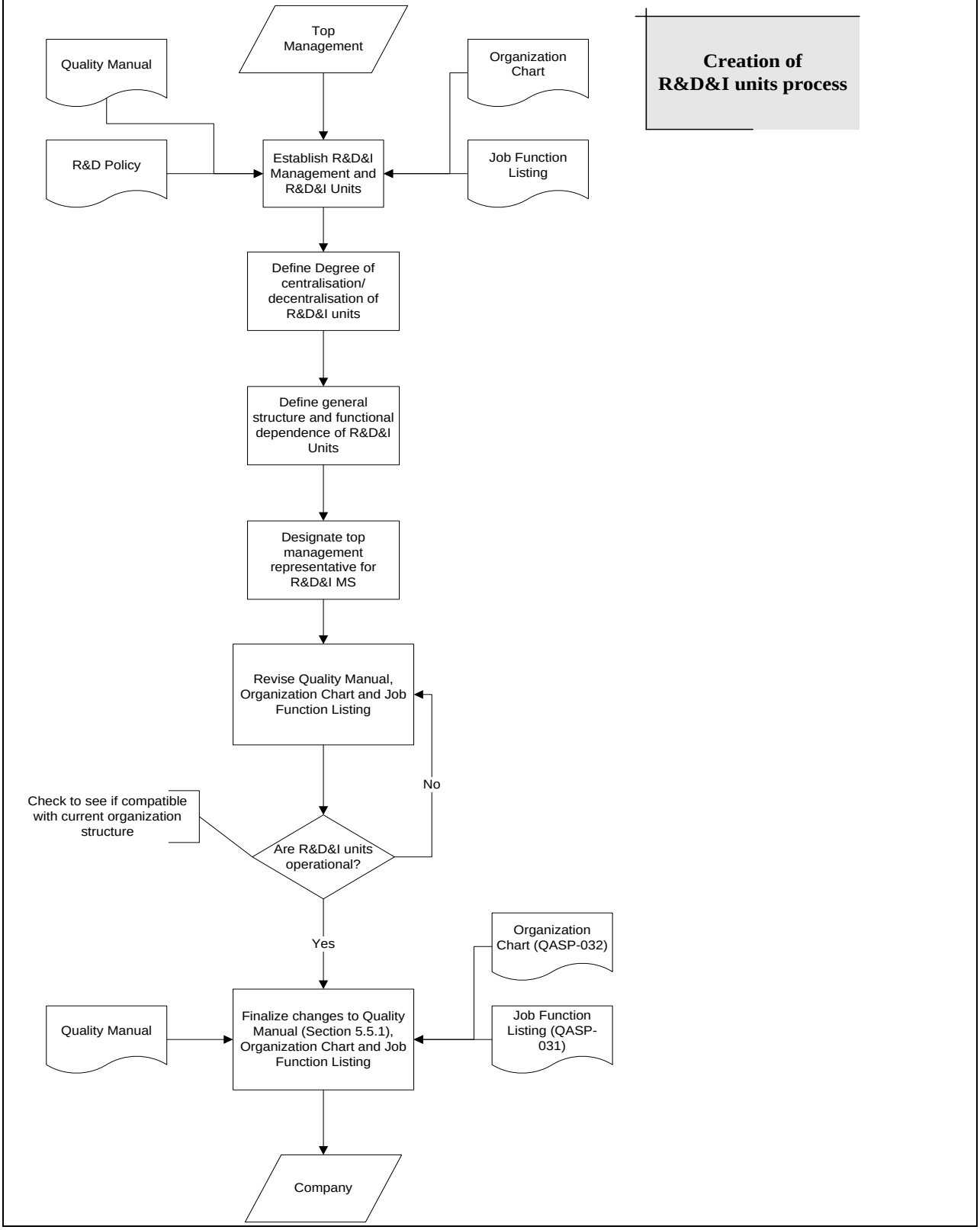


***Figure G-1.5*: Management Review Process**

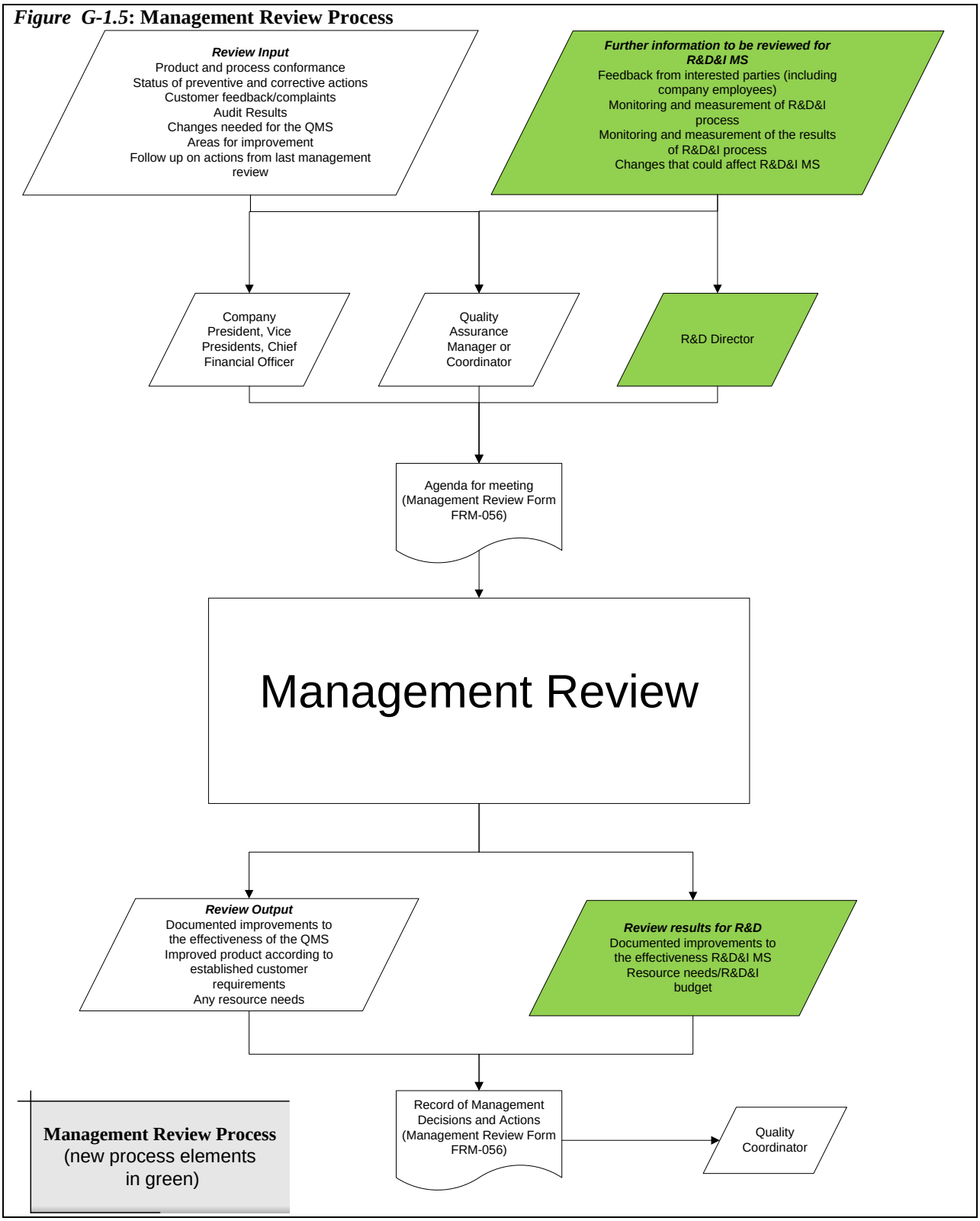
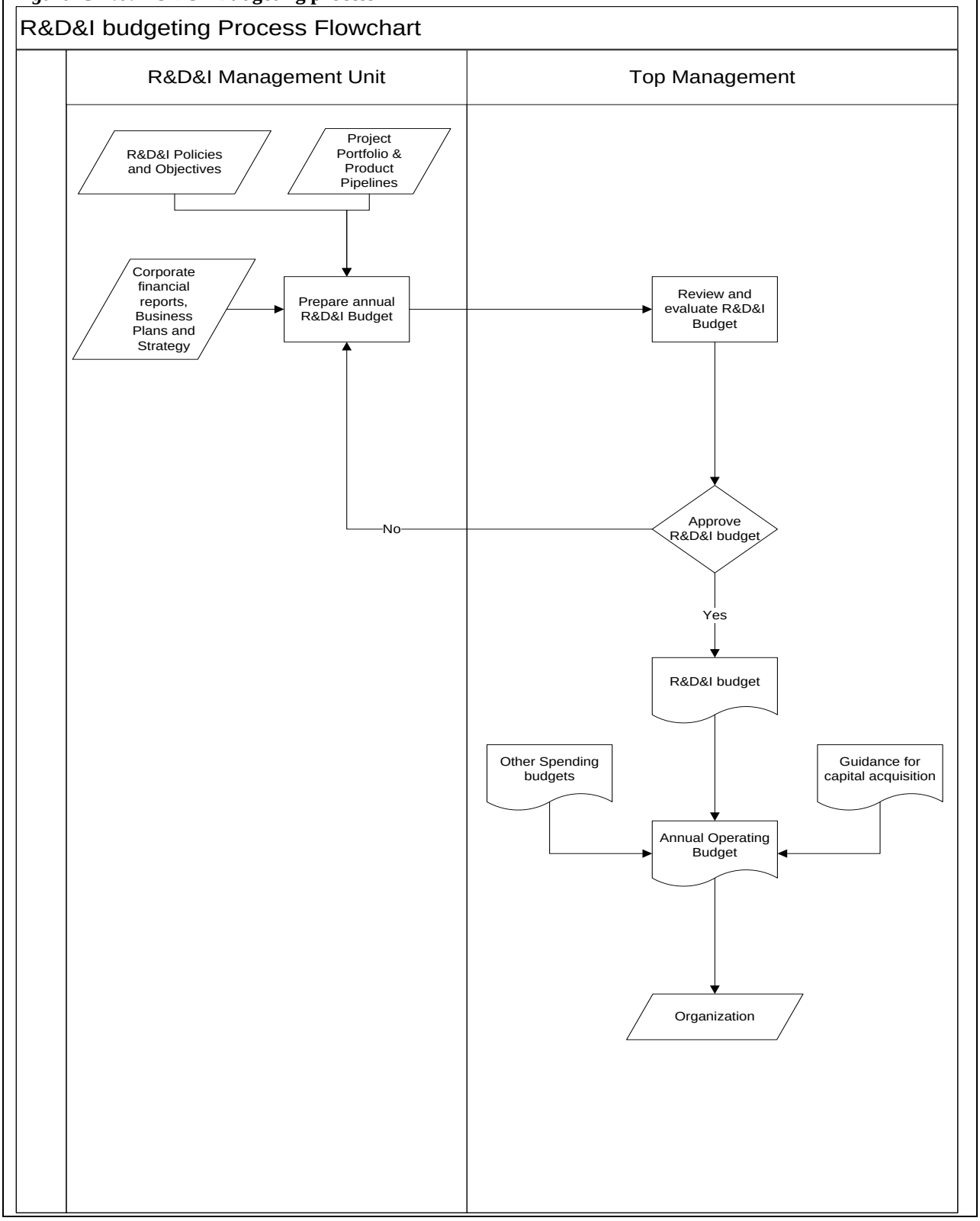
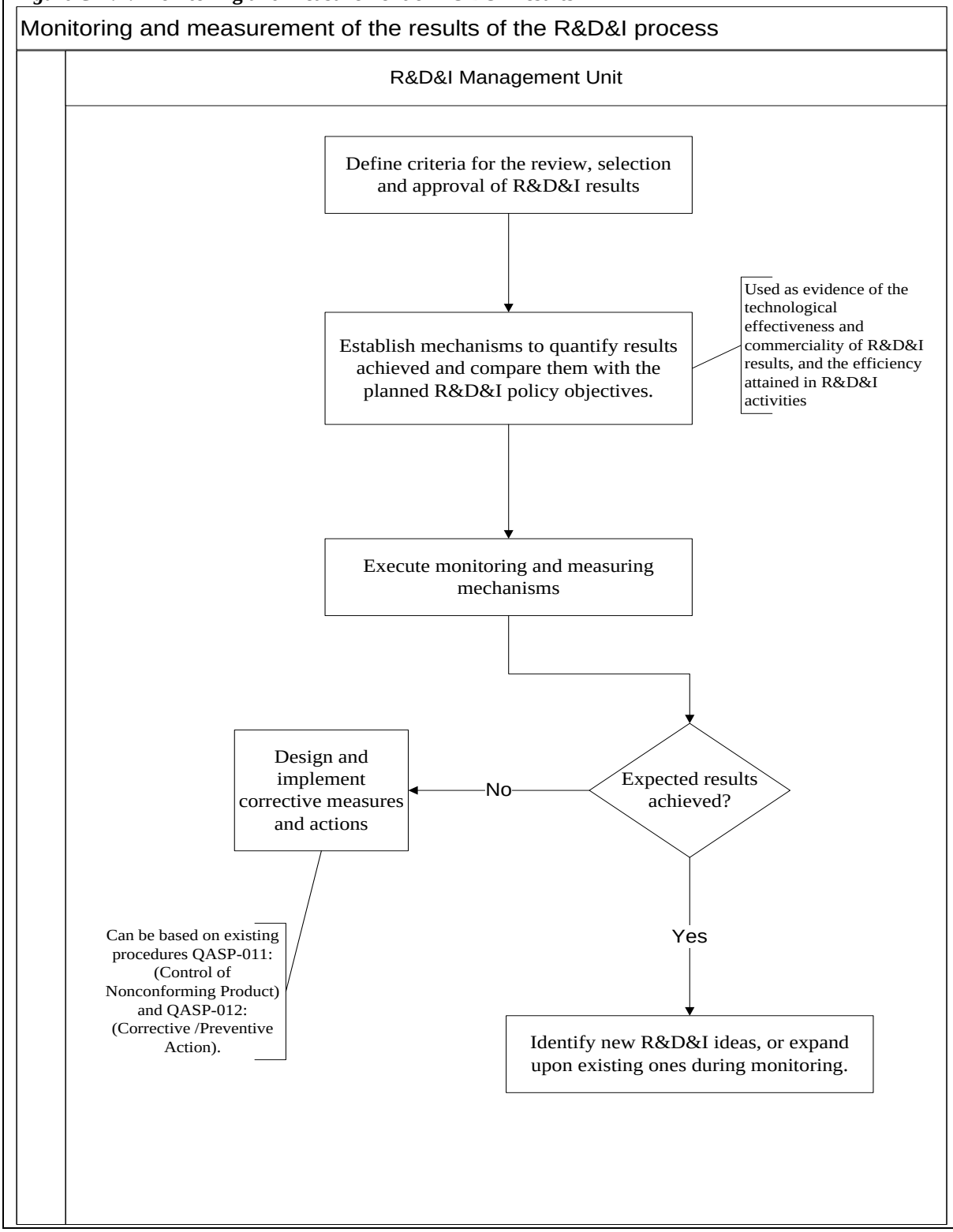


***Figure G-1.6*: R&D&I Budgeting process**



G-2 Measurement, Analysis, Improvement

***Figure G-2.1*: Monitoring and measurement of R&D&I results**



G-3 R&D&I Analysis

***Figure G-3.1*: Technology Watch Process**

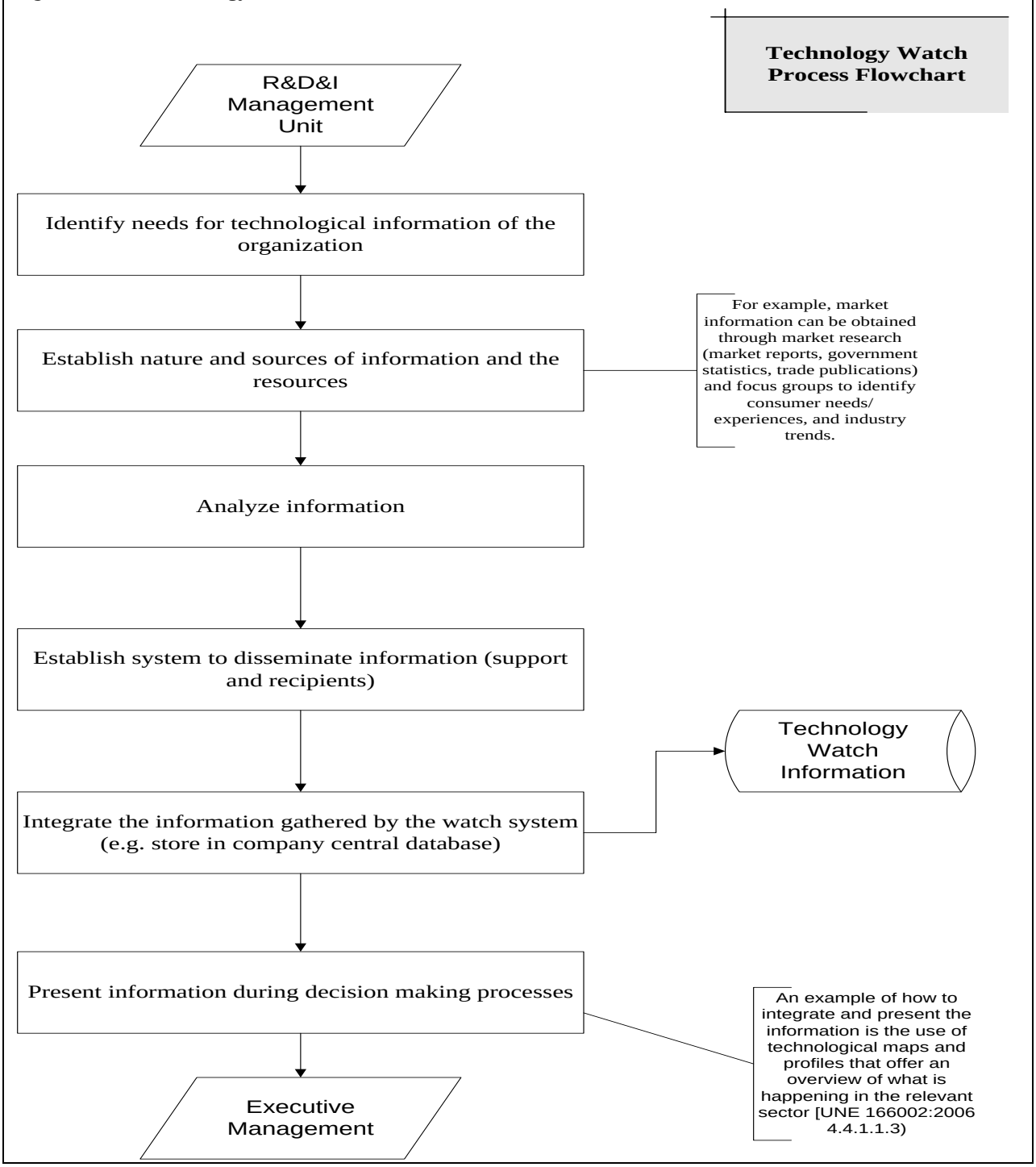


Figure G-3.2: **Technology Foresight process**

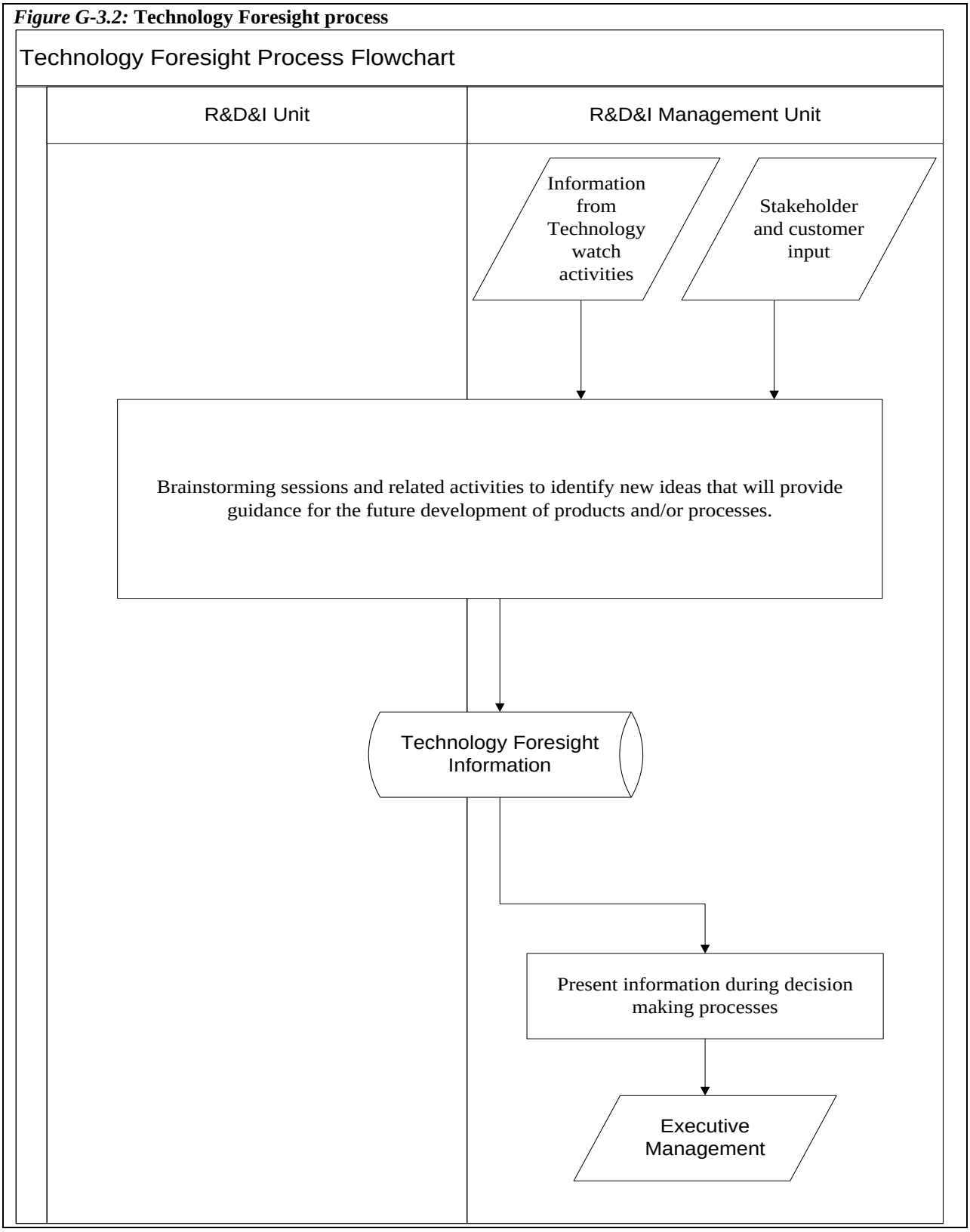


***Figure G-3.3*: External/Internal Analysis process**

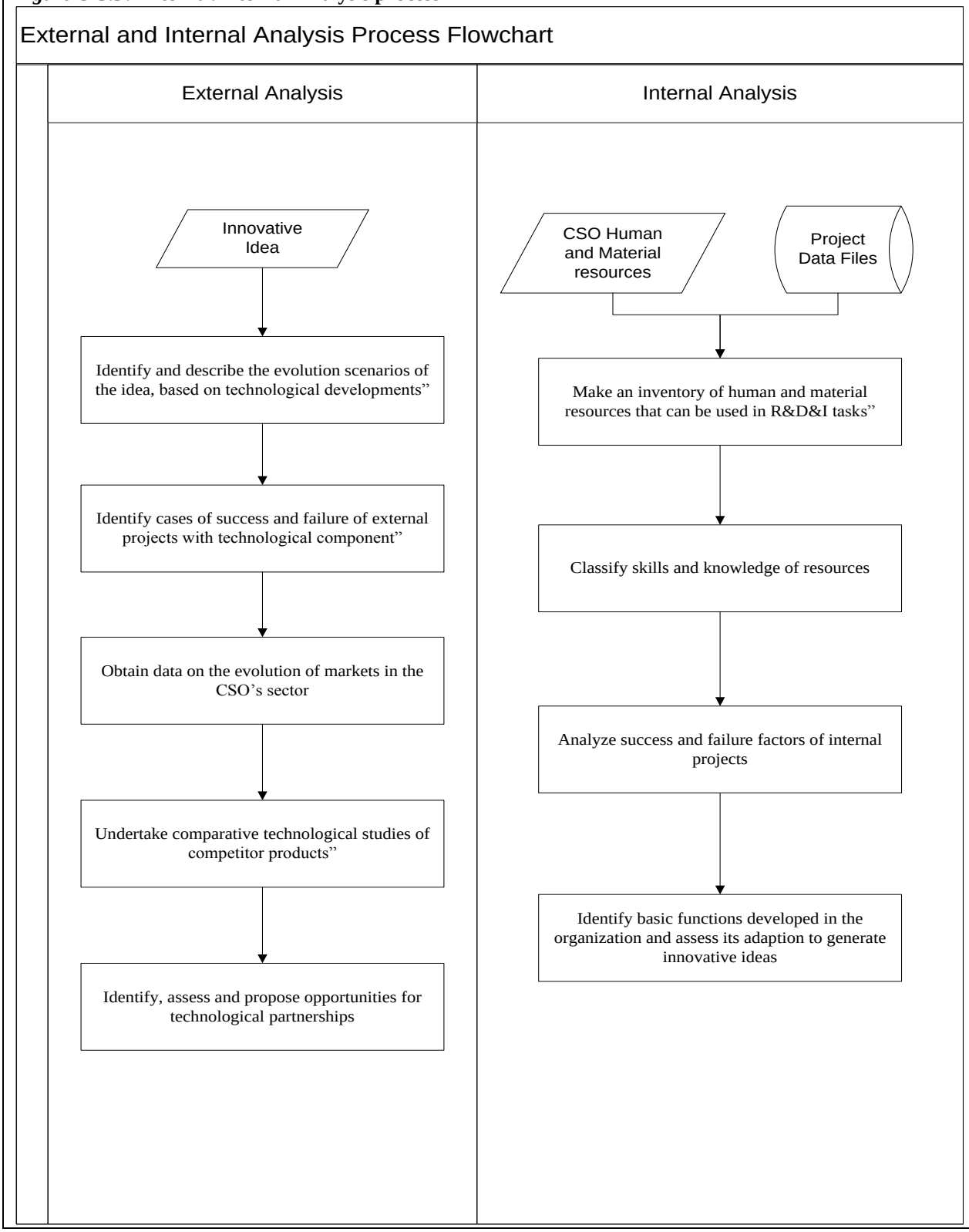


***Figure G-3.4*: Identification/analysis of problems and opportunities process**

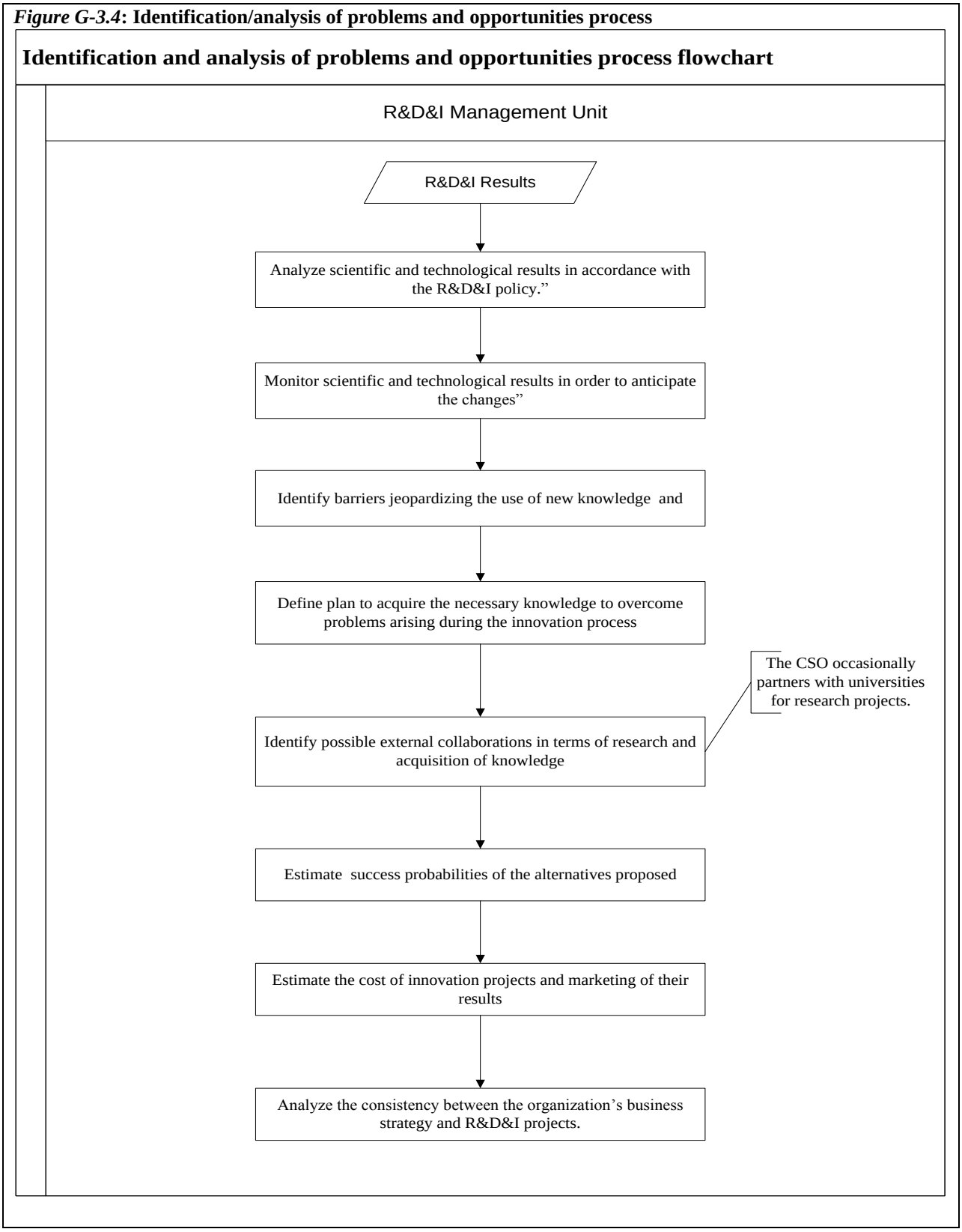
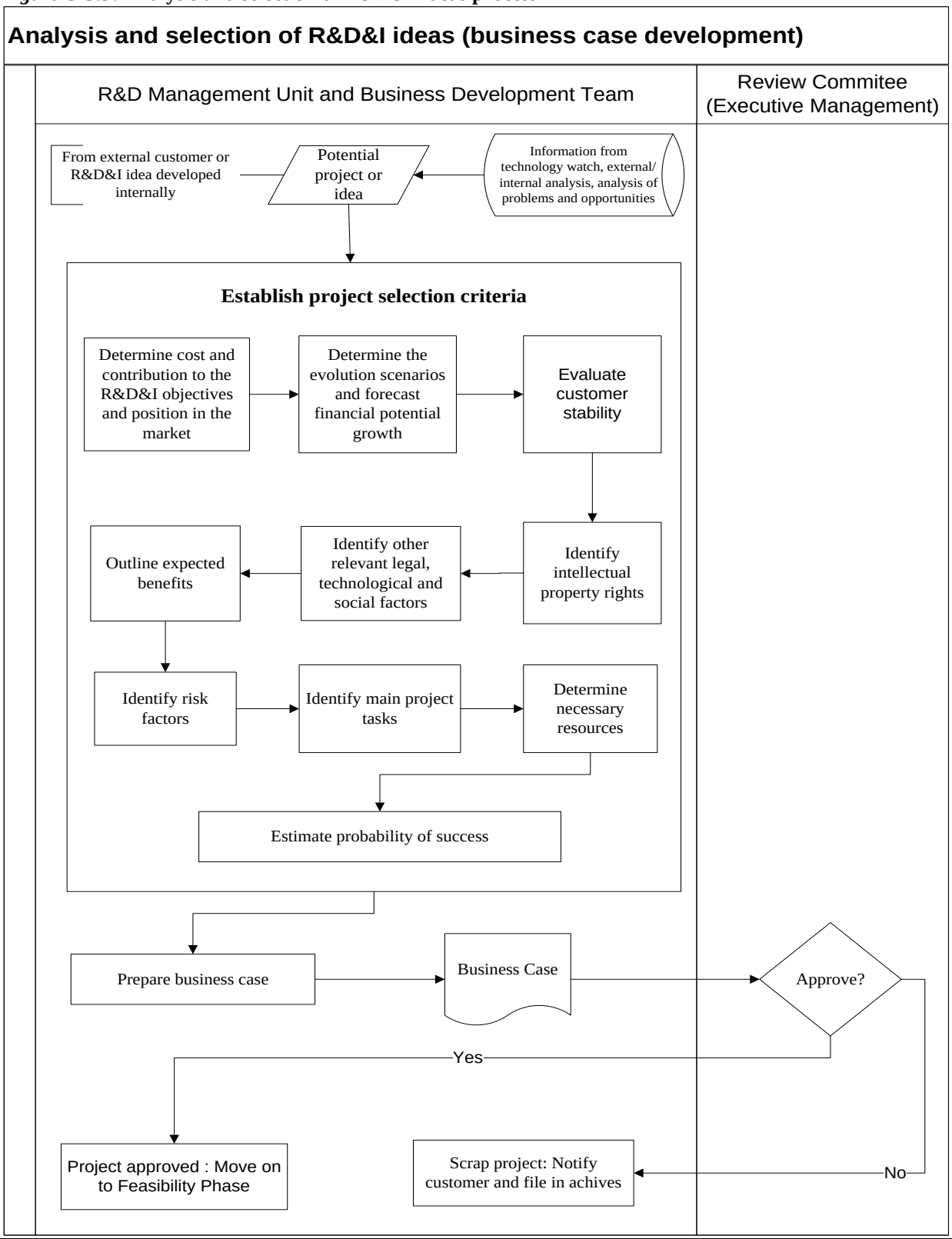


***Figure G-3.5*: Analysis and selection of R&D&I Ideas process**



G-4 Project/product planning, design & development

Figure G-4.1: **Research Project Report Template**

<table>
<tr><td rowspan="2">Report No.
PR-42-0005-01 Rev 00
(PR: “project report”, -42-xxxx is the CSO’s internal classification for “research contract” projects, -01 identifies the report number, and Rev 00 indicates the first revision of the report). This identification will be used on each page of the report</td><td>Report Date</td><td>Date(s) of performance of experiments</td></tr>
<tr><td>Type of Report
Experimental report</td><td>Date of receipt of research item(s)</td></tr>
<tr><td colspan="3">Title of report</td></tr>
<tr><td colspan="3">Author(s) and name of researcher(s)</td></tr>
<tr><td colspan="3">Name and Address of organization (or where work was carried out)</td></tr>
<tr><td colspan="3">Name and Address of Client</td></tr>
<tr><td colspan="3">Description of research task</td></tr>
<tr><td colspan="3">Abstract</td></tr>
<tr><td colspan="2">Key Words
— this will be used for easier searching if needed in the future</td><td>Distribution Statement
No restrictions.</td></tr>
<tr><td colspan="2">Name, title(s), and signature of authorizing person:</td><td>No. of Pages</td></tr>
</table>

Figure G-4.1: Research Project Report Template (continued)

PR-42-0005-01 Rev 01
Description and condition of the research items and the research method(s) applied
Sampling plan and procedures used
Experimental and computation methods, including environmental conditions Deviations from, additions to or exclusions from the normal research methodology/method will also be recorded.
Problems and specific solutions, with the techniques, procedures and equipment used
Results and observations The results of projects should be reported accurately, clearly, unambiguously and objectively. If professional judgments based on the results are included, they must be clearly separated from the measured results. If the report contains results of experiments performed by sub-contractors, these results shall be clearly identified.
Abnormalities related to the results A description of any unexpected results will be highlighted here.
Uncertainties and limitations of results Information on uncertainty is needed in the reports when it is relevant to the validity or application of the results, or when uncertainty affects compliance to a specification limit.
Appendices and references Here, basic data, diagrams, drawings, equations and other references to pertinent documents or resources will be attached
** This research report shall not be published, reproduced, or distributed by the client except in full, without written approval of [the organization ** A more extensive or final report may also include i) executive summary ii) table of contents/list of table and figures iii) a description of the protection of the results obtained, iv) written evaluations of the projects as a whole, including the knowledge acquired for future R&D&I activities.

***Figure G-4.2*: Project Progress Monitoring and Reporting**

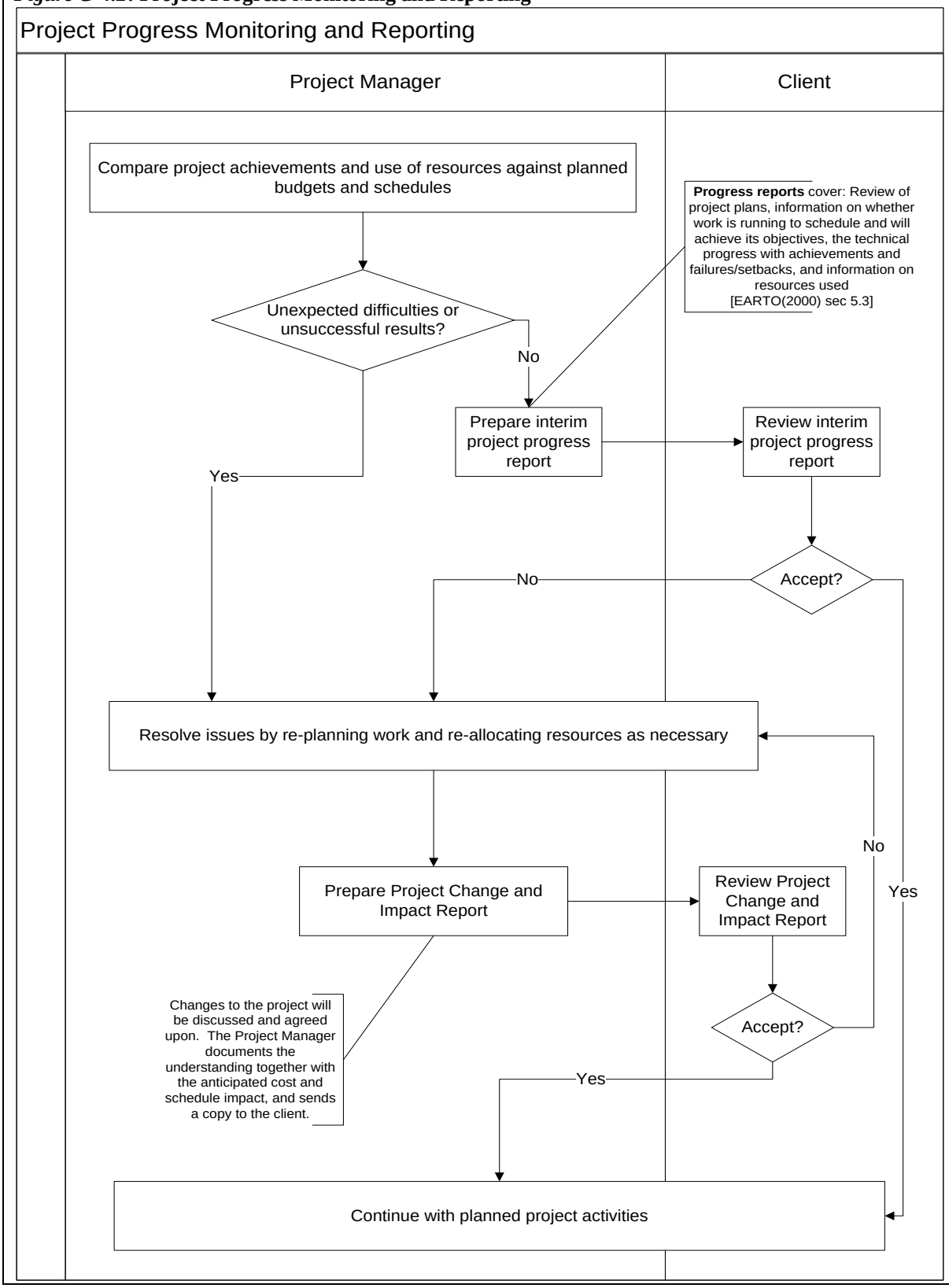


Figure G-4.3: **Updated Project Management Procedure flowchart**

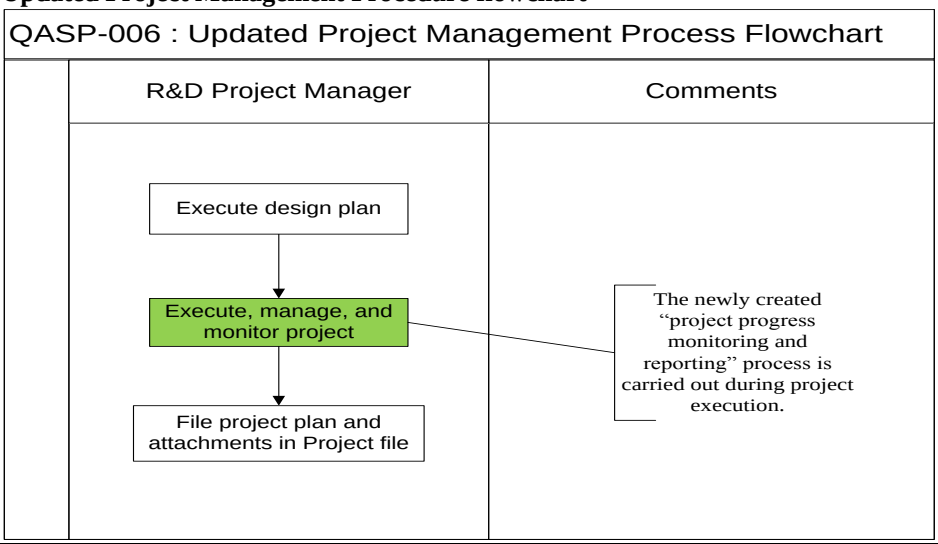


Figure G-4.4: **Protection and exploitation of R&D&I results process**

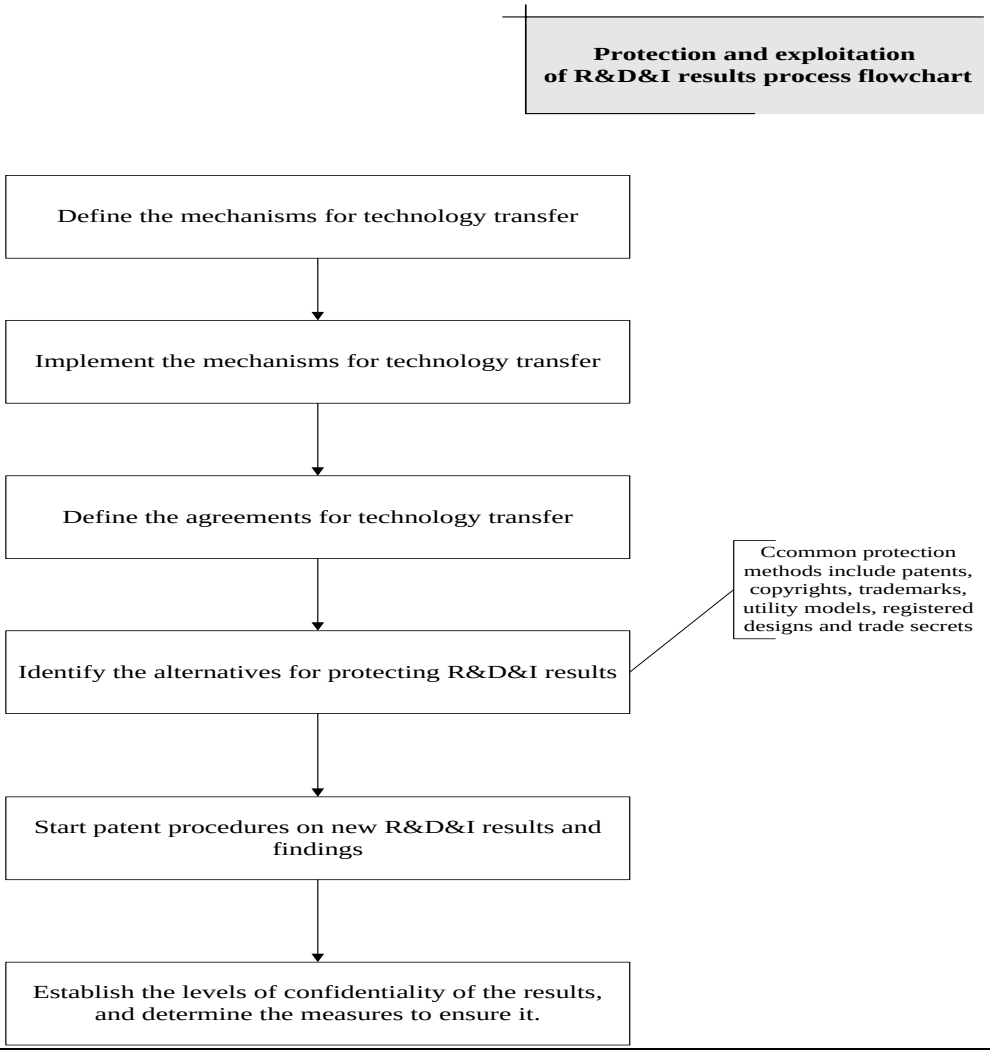


Figure G-4.5: **IP Rights for R&D&I work performed**

Intellectual property rights (IPR) for R&D&I work performed for the client

Extracted directly from EARTO(2000) section *2.2: Intellectual property rights*

"The output of R&D activities performed for clients consists of general information (general knowledge) and specific information (results). The general information can be used freely by the RTO. The specific information should be dealt with so as to protect the client's relevant intellectual property rights. The documents received from the client as well as the reports, expositions and other results related to the project shall be the property of the client if not otherwise agreed.

When the client pays the full cost of the project, the intellectual property rights of specific information and the results obtained by an RTO in the frame of the R&D contract are normally attributed to the client. In such a case the RTO should obtain a ***non-exclusive free licence*** *for its own use.*

When the client does not pay the full cost of the project (e.g., ***jointly funded project****), the intellectual property rights of specific information and results as well as rights to inventions should be decided upon in the contract or in an additional agreement reached before finishing the project. In such a case, the client is normally awarded a non-exclusive licence to use the results within his own sector of activity.*

The RTO may want to safeguard its ***core technologies*** *so that they do not become the property of the client. In such cases, special clauses should be incorporated into the contract so that no misunderstanding between the client and the RTO arises.*

When ***background information*** *belonging to an RTO is used to start an R&D project for a client, the RTO is entitled to claim to be specifically rewarded for such a use.*

In the event an RTO agrees with an industrial partner to jointly exploit the results of R&D projects performed by the RTO, an agreement defining the distribution of the costs and intellectual property rights shall be signed.

Software and design *(e.g., layout of an integrated circuit) developed in connection with a project shall be the property of the RTO. However, if the aim was to develop, e.g., specific software, the client shall have all rights to the software. Rights and liabilities in respect of software and designs should be covered in more detail in the specific contract as the subject is difficult and may be a cause of conflict.*

The RTO shall not have the right to give a third party the results of the project without written consent from the client. An RTO wishing to ***publish results*** *and findings of purely scientific value must obtain the prior consent of the client to publish results and findings when obtained in the frame of the contract for the latter. When the RTO participates in the financing of the project, it could as a benefit of the project, for example, require in the contract that it has the right to publish the results.*

The RTO shall, even after ***termination or expiry of the contract****, keep confidential any confidential information and trade secrets obtained from its clients. The retention time shall preferably be agreed upon with the client, but if that is not done the recommended retention time is three years, unless national legislation or other arrangements impose other requirements.*

RTOs can, in addition to the general secrecy requirements in the employment contract, require from their employees a special ***commitment to secrecy*** *regarding information received from and produced for their clients. This requirement of secrecy should extend beyond the expiration or termination of the employment contract. The client can decide that the information related to the project will become public during the time the secrecy clause is operational. In such a case, the secrecy requirements imposed on the employees are considered to be terminated.*

The client shall have the right to ***inventions*** *generated as a direct result of a project. The inventor in the RTO shall notify his employer in writing of the invention. The RTO shall without delay notify the client in writing of the invention. The client shall notify the RTO in writing of his claim to*

the invention. The claim shall be made within a certain period from the date the client came to know about the invention, or he may risk losing all his rights to the invention. The inventor shall always be accredited to have generated the invention and be entitled to a fair compensation. The costs for patent application and compensation for the inventor shall be paid by the party who has the right to the invention. The RTO must determine the timing and contents of the above actions in relation to the appropriate national legislation."

Appendix H : Gap Closure Tables

H-1 Quality/R&D&I MS General

***Table H-1.1*: Gap Closure Table - Record Control**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
CSO has a record keeping system as required by ISO 9001:2000, but procedure does not address the preparation and layout of R&D project records.	Clause #1.2.3: Record Control	*Control of Records* QASP-014: Quality Records	A) Add the following definition to QASP-014 : **Technical Records** are accumulations of data and information that result from carrying out experiments, tests, or calculations and which indicate whether specified parameters are achieved. They include forms, notebooks, worksheets, experimental or test results, observations, results of calculations and derived data, clients' notes, technical comments and reports. B) Add new section in QASP-014 called **Preparation of R&D project and technical records.** R&D project records section will contain the following content: C) Records will be kept of information that might be needed when continuing the research, repeating experiments or calculations or in a future dispute situation. The records should also include the identity of the personnel responsible for sampling, performing experimental tasks and checking of results. D) Record Layout and Traceability: "The layout of the record should be designed to accommodate each type of record in order to minimize misunderstandings. For example, the headings should be standardized as far as	A) Definition from EARTO(2000) sec 3.11: Control of Records B) This section will address the preparation and layout of R&D project and technical records C) R&D staff should be trained in proper record keeping using QASP-014. D) Roberts (1983, p.121). This allows them to be quickly collected and sorted for future reference. Currently at the CSO, different projects are classified by different numbers (see Quality Manual sec 3.0), and this can be used for record identification. For example, the CSO's "Research Contracts" are assigned "41-xxx" number. E) Roberts (1983, p.26) F) EARTO (2000) sec 3.11.

			possible. Observations, data and calculations shall be recorded and identifiable to the specific job at the time they are made. The unique project number assigned to the project should be used to mark a technical record." E) Entries are to be made in ink, with mistakes and changes crossed out, and the correct value entered alongside. Some organizations require that the laboratory entries be witnessed and initialed daily, which can be advantageous during a patent action in court F) The records should be held secure and in confidence. A procedure should also exist to protect data held on computers to prevent unauthorized access. Measures shall be taken to avoid the loss or change of original data (data should be backed up). Ensure that where clients require transmission of results by telephone, fax or other electronic means, the confidentiality is preserved.	

Table H-1.2: **Gap Closure Table - General Requirements**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Research Contract and Internal Research projects not covered under scope of quality management system.	Clause #1.1 General Requirements	*Entire Quality/R&D&I management system* Quality Manual	A) Remove last paragraph in Quality Manual Section 1.0: Scope. Edit second paragraph to read: "*The scope of this quality system applies to research, design, manufacture and sale of all microfabricated component and instrumentation products".*	A) All projects (including research projects) will be included in the scope of the quality system.

			B) Add UNE 166002:2006 and EARTO (2000) as additional quality standards that the company will follow.	
Identification of R&D&I activities, their sequence and interaction, criteria and methods needed, all defined in QASP-037, although not all components included (e.g. technology watch). CSO has a process map for the quality system, but not a model of R&D&I management system processes.	Clause #1.1 General Requirements	*Entire Quality/R&D&I management system* Quality Manual	A) Develop integrated Quality/R&D&I MS model	A) Existing QMS models at the CSO will be adapted to form an integrated Quality/R&D&I MS model. See *Figure 5.4*. This map was developed during the MS Structuring and MSS to MS mapping step of the MS Integration process. The integrated QMS/R&D&I MS model should be consistent with the model of the R&D&I process.
Mechanisms for protection/exploitation of results not documented.	Clause #1.1: General Requirements	*IP and exploitation of results*	A) Document and add new procedure describing the mechanisms for the protection and exploitation of results.	A) This gap will be closed through Requirement 6.4 (Technology transfer, exploitation of results and intellectual property).

H-2 Management processes and responsibilities

***Table H-2.1*: Gap Closure Table - Policy and Objectives**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
R&D&I policy and objectives not set by the CSO General quality policy exists in the CSO, but elements addressing ethical codes of conduct environmental/sustainable development not included.	Clause #2.2 : Policy and objectives	*Management Responsibilities: Policy and Objectives* Quality Manual (Section 5.3: Quality Policy) Quality Manual (Section 5.4.1: Quality Objectives) Policy and Objectives (QASP-033) Training (QASP-016)	For a graphical representation of the corporate policy development and deployment process, refer to *Figure G-1.1* and *Figure G-1.2* A) Establish a top level policy for the R&D&I activities and set overall R&D&I objectives for the organization. Ideas for content (modified from p.5 of UNE 166002: 2006): • Promotion of R&D&I as a competitive factor • The use of R&D&I system for realization of greater profits through: • Development of innovative production technologies to strengthen core competencies • Creation of technologies connected with new business opportunities that can be commercialized • Sound management of R&D&I project portfolio. B) Develop *Company Code of Conduct*, covering aspects such as environmental/sustainable development, ethics and professional business practice These form a set of the CSO's "Core Beliefs" and could include issues on (adapted and expanded from section 1 EARTO:2000) :	A) The R&D policy is a statement that formalizes the company's commitment to R&D performance (a "mission UNE 166002: 2006 does not specify what an R&D policy or objectives should contain, except that they are suitable and committed to meet the requirements of the R&D standards. R&D objectives might include the identification of R&D needs, which should support the continuing development of new technical knowledge, products, and services for future growth and new ventures. B) Section 1 of EARTO:2000 covers ethics and general principles for a "Code of Conduct" (for the organization). These are brief set of guiding principles/behaviors that the company and all employees must follow to uphold the company's ethical standards. It helps to resolve ethical dilemmas. ISO 10001:2007 provides further guidance on establishing codes of conduct. C) Since the CSO is a MEMS/nanotechnology company (with a large emphasis on R&D&I), it is logical that the R&D&I policy be combined with

			• Professionalism and general behavioral rules on working with clients/customers • Working with one another - respect, teamwork and collaboration, creativity, learning and personal growth • Open and honest communication • Fair employee treatment and employment • Free market competition • Promotion of sustainable business practices to protect the environment and conserve resources • Factual and non-misleading distribution of information, advertising and promotion • Commitment to delivering quality services and products, and continual the improvement of quality • Compliance with laws, regulations, standards • Emphasis on safety and good scientific practice C) Look for integration opportunities between policies, and develop an Integrated Quality/R&D&I Policy. D) Replace QASP-033 with the Integrated Quality/R&D&I Policy, and the Company Code Conduct E) Edit section 5.3 of Quality Manual to reflect the new Integrated Quality/R&D&I policy. E1) Change title of section 5.3 of Quality Manual from "Quality Policy" to "Integrated Quality/R&D&I Policy"	the Quality Policy (ISO 9001:2000 requirement 5.3) to create an integrated policy. D) The policies and company code of conduct that every employee must be familiar with will now all be contained in a single document (QASP-033). QASP-033 will contain four sections: • The Integrated Quality/R&D&I Policy • Company Code of Conduct • Quality Objectives • R&D&I Objectives E) Quality and R&D&I Policies are integrated. F) This section will briefly describe the Company Code of Conduct and its purpose, and will reference QASP-033. G) Quality and R&D&I Objectives will be listed in QASP-033, although unlike the policy, they will be listed separated and not combined since the objectives are specific. H) Management should ensure that the Integrated policy and Company Code of Conduct communicated and understood within organization. See *Figure G-1.3* for details.

			E2) Modify section to read: "The Executive Management is responsible for: o Ensuring that CSO's integrated Quality/R&D&I policy is appropriate. o Formulating and documenting the integrated policy and objectives in document QASP-033, followed by periodic review for suitability o Ensuring that Quality/R&D&I objectives are established at relevant functions o Ensuring that staff are aware of and understand the Quality/R&D&I policy and their contribution to meeting Quality/R&D&I objectives. F) Create new sub-section in Quality Manual 5.4.1 called "CSO Core Beliefs". G) Edit section 5.4.1 of Quality Manual to reflect the new Integrated Quality/R&D&I policy (which also contains the objectives). G1) Change title of section 5.4.1 of Quality Manual from "Quality Objectives" to "Quality/R&D&I Objectives" G2) Modify section to read: "CSO Executive Management will ensure that Quality/R&D&I objectives, including those required to meet product design and development requirements, are established at the appropriate functions and levels, and are measurable and consistent with the Integrated Quality/R&D&I policy" H) Training and Verification.	

Table H-2.2: **Gap Closure Table - Organization and Responsibilities**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Roles, Responsibilities and structure of R&D&I management and R&D&I unit not fully defined Top management representative for R&D&I not designated	Clause #2.5 (Organization and responsibilities) Clause #2.5.1 (Management representative)	*Management Responsibilities: Responsibility, Authority and Communication* Quality manual (Section 5.5.1 : Responsibility and authority) Job Function listing (QASP-031) Organization Chart (QASP-032)	A) Define R&D&I management unit, and if necessary, an R&D&I unit B) Define degree of centralization or decentralization of the R&D&I units C) Define the general structures and functional dependence of the R&D&I units by creating the organizational structure of R&D&I units and R&D&I management D) Define authority and responsibility lines of the R&D&I team. E) Designate top management representative for R&D&I management system (for example, representative can be VP of engineering, who currently leads Research and Development department)	A) R&D responsibilities, job functions, and authorities have already been defined in the Quality Manual. VP Engineering -> (R&D Director) -> R&D Project Manager -> R&D staff Functions of the R&D&I management unit and R&D&I unit are shown below in *Table H-2.3*. B) This involves structuring flexible teams that will adapt to projects of different types and sizes. There might also be the possibility of incorporating external experts to R&D&I unit, and/or subcontract parts of the project (UNE 166002:2006 sec 4.2.5.3.1). C) This can be based on the already existing organizational structure in QASP-032. D) This can be based on based on the descriptions in Job Function descriptions in Quality Manual Section 5.5.1 and QASP-031. E) The top management representative (UNE 166002:2006 sec 4.2.5.4): • Controls R&D&I activities • Ensures necessary activities for R&D&I management system are established, implemented and maintained • Informs top management about the performance of R&D&I management system and improvement needs

				• Ensure awareness of R&D&I activities promoted throughout organization For more details, refer to *Figure G-1.4*

***Table H-2.3*: Functions of the R&D&I Management Unit and of the R&D&I Unit (as defined in UNE 166002: 2006 sec 4.2.5)**

The R&D&I Management Unit

- Uses the R&D&I tools as described in clause 4.4.1 of UNE 166002:2006
- Identifies and analyses problems and opportunities
- Analyses and selects R&D&I ideas
- Plans, monitors and controls the project portfolio
- Monitors and controls the results, as well as prepare result documentation procedures
- Carries out technology transfer, protection and exploitation of results
- Carries out measurement, analysis and improvement

R&D&I Unit

- Uses the R&D&I tools described in clause 4.41 of UNE 166002:2006
- Undertakes R&D&I projects it has been assigned
- Generates knowledge

Develops new technology and improves existing one

***Table H-2.4*: Gap Closure Table - Management Review**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Management reviews are carried out at CSO, but does not cover R&D&I MS and the related R&D standard requirements.	Clause #2.4 (Management Review)	*Management Responsibilities: Management Review* Quality manual (Section 5.6: Management Review) Management Review Form	A) Include review of the R&D&I MS as part of current management review process. B) Update Section 5.6 of Quality Manual (Management review) to include details for reviewing the R&D&I MS. C) Involve R&D director in the management review meetings. D) Add new Management Review	A) UNE 166002:2006 sec 4.2.6 requires that top management review the R&D&I MS at planned intervals. B) See *Table H-2.5* for details. C) R&D Director (currently also the VP of Engineering) will also be present at the management review meetings, where he/she will update Top Management on R&D&I MS process issues.

		(FRM-056)	Flowchart to sec 5.6 of Quality Manual (elements highlighted in green are new additions to the management review process). See *Figure G-1.5*.	D) The Management Review process flowchart gives a visual representation of the management review process and indicates the new R&D&I MS related elements to be considered in the review.

Table H-2.5: **Management Review Updates**

	Existing Management Review (QMS)	**Updated Management Review (QMS + R&D&I MS) will also include**
Scope of review and evaluation	• Quality MS (ISO 9001:2000) • Quality policies and objectives	• UNE 166002:2006, and EARTO:2000 • R&D Policies and Objectives • R&D&I investment policy
Review input	• Product and process conformance • Status of preventive and corrective actions • Customer feedback/complaints • Audit Results, Changes needed for the QMS • Areas for improvement	• Feedback from interested parties, including company employees (e.g. Employee satisfaction surveys, stakeholder feedback) • Monitoring and measurement of R&D&I process and the results [see requirements 3.2.1 and 3.2.2] (e.g. Analysis and results from R&D activities (e.g. technology watch, R&D project portfolio/pipeline, intellectual property), Company R&D&I performance metrics (e.g. innovation, as demonstrated by awards, features in technology trade magazines, filing of patents, internal surveys) • Changes that could affect R&D&I MS
Review output	• Documented improvements to the effectiveness of the QMS • Improved product according to established customer requirements • Any resource needs	• R&D&I resource requirements and budget • Documented improvements to the R&D MS
Frequency of management review meetings	• Once every quarter	• Once every quarter

Table H-2.6: **Gap Closure Table - Management Commitment**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Importance of R&D&I and policies needs to be communicated	Clause #2.1 (Management Commitment)	*Management Responsibilities: Management commitment* Quality manual (Section 5.1: Management Commitment)	A) Add the following to bullet point # 7 in Section 5.1 of Quality Manual : …Management… Responsible for: Communicating the importance of meeting customer requirements **and R&D&I** (as well as statutory, regulatory, and stakeholder requirements if applicable) during employee orientation, training, and regular staff meetings.	A) Management will be responsible for communicating to staff the importance of R&D&I activities (UNE 166002:2006 clause 4.2.1(a)) and the new policies, and how they fit into the company's overall business strategy (this can be accomplished during employee training).
Policy for the protection/exploitation of R&D results does not exist.	Clause #2.1 (Management Commitment)	*Management Responsibilities: Management commitment* *Project/product planning, design, development: IP/Exploitation of Results* *Quality/R&D&I Management System: General Requirements*	A) Establish a policy for protection and exploitation of R&D results. B) Combine content from this policy into the Integrated Quality/R&D&I policy.	A) UNE 166002:2006 clause 4.2.1(h) The standard, however, does not provide any details on the content on the policy. However, it is believed that policy should convey that management will ensure that no activities that can generate technologies and patents are lost, by developing and documenting a process to protect and exploit R&D results whenever possible. Requirement 6.4 provides more details on the exploitation of R&D results. B) Content from the Policy for the Protection/Exploitation of R&D results can also be integrated into the Policy as it is related to the overall strategy for R&D&I.
Process for approving and reviewing R&D&I budget not defined.	Clause #2.1 (Management Commitment)	*Management Responsibilities: Management Commitment* Quality Manual	A) Document new process for R&D&I budgeting. B) Create new section in *Quality Manual sec. 5.1* that states that process for approving and reviewing the R&D&I	A) UNE 166002: 2006 clause 4.2.1(g) requires that top management approve and review the R&D&I budget. An R&D&I budget specifies how much should be spent on R&D&I activities. It

		(section 5.1 Management Commitment)	budget has been developed.	will be depend on a range of factors such as : • Ongoing projects and product pipeline, and their commercial potentials • Anticipated projects from customers. • Market environment (e.g. economic conditions, industry trends, competitor activity, consumer needs). This information is gathered from the R&D&I tools used in Requirement 5.0. • Stakeholder needs/expectations. See *Figure G-1.6* for generic process flowchart.
R&D&I management unit not defined	Clause #2.1 (Management Commitment)	*Management Responsibilities: Management Commitment* Quality Manual (section 5.1 Management Commitment)	A) Define R&D&I management unit	A) Gap closed in 2.5.

Table H-2.7: **Gap Closure Table - MS Planning**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Planning of R&D&I MS, such that it meets the R&D&I objectives and general requirements, not defined R&D&I investment policy does not exist.	Clause #2.3 (Management System Planning)	*Management Responsibilities: Management System Planning* Quality manual (Section 5.4.2: Quality Management System Planning)	A) Modify *Quality Manual sec. 5.4.2 Quality Management System Planning* to cover R&D&I planning. B) Set R&D&I investment policy. C) Create statement in *Quality Manaul sec 5.4.2* that states that an R&D&I investment policy has been set by top management.	A) Planning of the Management system will now cover meeting both Quality and R&D&I objectives/requirements. B) UNE 166002:2006 clause 4.2.4.2 specifies that top management sets the R&D&I investment policy. The standard does not provide details on the content on the investment policy, except that it should be based on risk level criteria. However, it is believed that the policy defines how cash from the R&D&I budget should be spent in order to meet the company's R&D&I policies and objectives. In formulating the investment policy, the objective is to provide managers with guidelines for structuring and monitoring a research project portfolio that possesses the potential to generate maximum returns (in terms of product commercialization potential) within a defined risk tolerance level. C) The investment policy is a top level management strategic concern, and therefore the details would probably not be made available to regular employees in the Integrated Quality/R&D&I management system manual.
Customer requirements are determined and met with the goal of enhancing customer satisfaction; however the	Clause #2.6 (Stakeholder Focus)	*Management Responsibilities: Stakeholder Focus*	A) Consider and analyze the needs and expectations of interested parties (stakeholders) in the R&D&I process. This involves:	A) UNE 166002:2006 Clause 4.2.2 (interested parties approach) requires that "the needs and expectations of all interested parties in the R&D&I process

needs/expectations of *all interested parties* in the R&D&I process not fully defined.		*Input: Gather and assess stakeholder input* *Measurement, analysis, and improvement: General Practices* *Measurement, analysis, and improvement: Stakeholder Satisfaction* Quality manual (Section 5.2: Customer Focus)	B) Determining, gathering and assessing stakeholder information and input prior to product development. C) Collecting information relating to stakeholder perception as to whether their needs and expectations have been met after product has been delivered. D) Edit Section 5.2 of Quality Manual: Replace the word "customer" with "stakeholder". Include a list of "interested parties".	be considered and analyzed. These [include]: • Demands of providers and customers • Motivation and involvement of employees • Demands of shareholders • Legal and regulatory requirements • Innovations and technological changes required by the market" The standard does not specify exactly when or how the requirements of "interested parties" be analyzed. However, this requirement directly maps to ISO 9001:2000 5.2: Customer Focus, which refers to determining and meeting customer requirements in order to enhance customer satisfaction. Quality Manual sec 5.2 focuses on primarily on "customer requirements" and the scope should be expanded to "interested parties" or "stakeholders". B) See gap closure details of requirement 6.1.2 : *Determine and assess input from relevant interested parties* (see *Table H-6.2*). C) See gap closure details of requirement 3.1 : *Monitoring and measurement general requirements)* and 3.3.4: *Stakeholder Satisfaction (* see *Table H-3.1* D) The listing of the "interested parties" will provide the CSO with a more specific list of stakeholder requirements to consider. For instance, "innovations and

				technological changes required by the market" is extremely important for any fast moving high-tech industry. "Motivation and involvement of employees" is not mentioned in ISO 9001:2000 and often neglected, but may be an important factor to consider.

H-3 Measurement, analysis and improvement

Table H-3.1: **Gap Closure Table- Monitoring and Measurement General**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Monitoring and measurement of R&D&I activities not fully defined. CSO collects information (through quarterly surveys) from a minimum of two customers, related to their perception of the CSO's ability to meet requirements. However, the monitoring and measurement of other stakeholders (apart from customers) is not conducted.	Clause #3.1: Monitoring and measurement: General requirements Clause #3.3.4: Stakeholder Satisfaction	*Measurement, analysis, improvement: General practices* *Measurement, analysis, improvement: Stakeholder satisfaction* Quality Manual (Section 8.1: General) Quality Manual (Section 8.2.1: Customer Satisfaction)	A) Implement processes for monitoring, measuring, analyzing and improving the R&D&I MS and the execution of R&D&I activities. B) Monitor stakeholder satisfaction by gathering feedback in regards to whether their needs and expectations have been met. C) In Quality Manual (Sec 8.2.1: Customer Satisfaction), change "customer" to "stakeholder". Add requirement of surveying a minimum of two customers and two stakeholders quarterly. D) Expand scope of measurement, analysis and improvement to include the R&D&I MS (Quality Manual sec 8.1: General).	A) Details are provided in filling gap requirements 3.2.1 and 3.2.2 (*Monitoring and measurement of processes and products*). B) This can be done by sending Stakeholder Feedback Surveys: minimum of two customers and two other stakeholders quarterly. A similar interview and performance scoring scheme used in the CSO's current customer feedback survey can be used for other stakeholders. Data on stakeholder satisfaction is reviewed at Management Review meeting. C) All interested parties (stakeholders) will be considered, not just customers [UNE 166002:2006 clause 4.5.1]

Table H-3.2: **Gap Closure Table- Monitoring and Measurement of processes**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Aspects of monitoring and measurement of R&D&I processes in order to achieve planned objectives not defined.	Clause #3.2.1: Monitoring and Measurement of processes	*Measurement, analysis, improvement: Monitoring and measurement of process* Quality Manual (Section 8.2.3: Monitoring and Measuring of Processes)	A) Edit Quality Manual - Section 8.2.3, first paragraph, to read: "Suitable methods for monitoring and, where applicable, measurement of the QMS **and R&D&I** processes will be applied. These methods will demonstrate the ability of the processes to achieve planned results consistent with the quality **and R&D objectives**. When planned results are not achieved, corrective action will be taken, as appropriate." B) Edit Quality Manual - Section 8.2.3, second paragraph, to read: "The measurement of QMS processes may include product and process nonconformities, corrective and preventive actions, **stakeholder feedback and complaints**, **employee satisfaction surveys,** and audit results. **Additional data to be collected for R&D&I processes may include analysis and results from R&D activities such as technology watch, R&D project portfolio/pipeline and intellectual property generated. Annual R&D&I performance reports will be prepared.** These measurements are reviewed at the Management Review meeting, but may be reviewed more frequently, if appropriate."	A) The capacity of the R&D&I activities to achieve R&D objectives must also be measured [UNE 166002:2006 clause 4.5.3]. The standard does not provide further guidelines on methods and tools for monitoring and measurement. The existing corrective action process defined in the CSO QMS can be used. B) Methods of monitoring and measurement of QMS and R&D&I processes is expanded to include surveys of stakeholders and employees. The measurement of R&D&I processes is also included. Annual R&D&I performance reports will provide a summary of whether R&D&I objectives (and targets) are met. R&D&I performance will be typically reviewed during Management Review meetings, which is detailed in Integrated MSS Requirement 2.4. R&D&I performance can include aspects such as R&D&I efficiency (e.g. product development cycle time, patent output, percentage of sales that come from products introduced over a period of time) R&D performance measurement is outside the scope of this thesis. For details, readers can refer to Garcia Valderrama *et al.* (2008) or Kerssens-van Drogelen (2000).

***Table H-3.3*: Gap Closure Table- Monitoring and Measurement of Product**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Aspects of monitoring/measuring the results of the R&D&I process and completed research work not fully defined.	Clause #3.2.2: Monitoring and Measurement of product	*Measurement, analysis, improvement: Monitoring and measurement of product* Quality Manual (Section 8.2.3: Monitoring and Measuring of Product)	Extend Monitoring and Measurement of Product to include R&D&I results: A) Create process to measure and monitor the results of R&D&I activities (all activities prior to manufacturing). B) A flowchart of aspects to consider when creating a process for R&D&I results monitoring and measurement is provided in *Figure G-2.1*. C) Add new section in Quality Manual 8.2.4: Monitoring and Measuring of Product dealing with "research results".	A) Required to verify that the requirements of the process are fulfilled [UNE 166002:2006 sec 4.5.4]. B) Adapted from UNE 166002: 2006 sec 4.4.8.2: Monitoring and Measurement. C) "Product" in this context refers to "research results and completed research work". R&D performance measurement is outside the scope of this thesis. For details, readers can refer Kerssens-van Drogelen (1999) or Cheisa *et al.* (2009)

***Table H-3.4*: Gap Closure Table - Audits, Nonconformances, Data analysis**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Internal audit process already exists at CSO, but do not cover R&D&I MS requirements of UNE 166002:2006 and EARTO:2000.	Clause #3.3.1: Internal Audits	*Measurement, analysis, improvement: Internal audits* QASP-015: Internal Quality Audits Quality Manual (Section 8.2.2 Internal Audit)	A) Include reference to UNE 166002:2006 and EARTO:2000 standards in Quality Manual Sec 8.2.2 and QASP-015. B) Train the auditor(s) in the newly incorporated R&D standards. C) Conduct periodic audits of R&D projects and activities selected at random.	A) Management system must conform to the requirements of ISO 9001:2000, UNE 166002: 2006 and EARTO: 2000. Future MS audits will be based on the requirements of all three standards. C) The existing internal audit program at the CSO can be used, as it is generic and can be applied to any area of the company. Auditing of activities in the R&D&I MS is also a gap closure verification activity.
Since research tasks are not covered under the scope of the QMS,	Clause #3.3.2: Control of nonconformances	Measurement, analysis, improvement:	Expand scope of "non conforming products" to cover unexpected research results	A) This section will covers unexpected research results (which is often a frequent occurrence in nanotechnology companies

"deviations from the expected R&D results" are currently not considered when handling nonconformances. .		*Control of nonconformances* Quality Manual (Section 8.3 Control of nonconforming product) QASP-011 (Control of Nonconforming Product)	A) Add subsection to Quality Manual Section 8.3 called "Control of deviations from the expected R&D results". B) Identify and record all deviations from expected R&D results.	B) UNE 166002:2006 Clause 4.5.5 requires that deviations from expected results be recorded so they can be reused in the future, if appropriate. In this CSO (the "unexpected results" will be found during the opportunity/feasibility/prototype phase activities). The current process outlined in QASP-011 (Control of Nonconforming Product) can be used for record keeping.
Analysis of data that demonstrates the suitability and effectiveness of the R&D&I MS is not defined (UNE 166002:2006 requirement)	Clause #3.3.3: Data Analysis	Measurement, analysis, improvement: *Data Analysis* Quality Manual (Section 8.4 Data Analysis	A) Add subsection to Quality Manual Section 8.4 addressing the analysis of data that demonstrate the suitability and effectiveness of the R&D&I MS. B) Data will be collected on: • Satisfaction of interested parties (refer to information in gap 3.3.4: Stakeholder Satisfaction) • Conformity of R&D&I results (refer to information in gap 3.2.2: Monitoring and Measurement of product) • Characteristics of R&D&I process and results (refer to information in gap 3.2.1: Monitoring and Measurement of processes)	A) UNE 166002:2006 Clause 4.5.6 B) Details regarding these three items of data were addressed in the closure of previous gaps.

H-4 Resource Management

Table H-4.1: **Gap Closure Table- Resource Management**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Resources need to be provided for R&D&I management unit; and to meet needs of all interested parties and external entities relevant for project success (not merely customers)	Clause #4.1 : Provision of resources	*Resource management : Provision of resources* *Management Responsibilities : Stakeholder Focus* Quality Manual (Section 6.1: Provision of resources)	A) Add to Quality Manual Section 6.1: "…Executive Management will ensure that… **the R&D&I Management unit is implemented and maintained**". B) In Quality Manual Section 6.1, replace the word "Customer" with "Stakeholder". Line will now read: "**stakeholder** satisfaction is enhanced by meeting **stakeholder** requirements".	A) UNE 166002:2006 clause 4.3.1(a) requirement. Once R&D&I management unit defined, the organization needs to ensure they have the required resources to maintain quality of R&D work. Resource requirements are determined and provided at the Management Review meetings. B) UNE 166002:2006 clause 4.3.1(b) requires that the needs and expectations of all interested parties be met, not merely customers. Requirement 2.6 of the integrated MSS provides more details of the stakeholder focus of UNE 166002:2006.
Details on integrity, professional conduct, and good reputation of personnel currently not included as criteria. .	Clause #4.2.1 : Personnel	*Resource management : Human Resources* QASP-016: Training	A) Add the following to Quality Manual Section 6.2.1 : "Personnel making professional judgment must do so in a manner consistent with the Company Code of Conduct." B) Add the *Company Code of Conduct* (incorporated into *QASP-033: Policy and Objectives*) as part of the employee training material. In section 4.0 of QASP-016 (New Employee Training Requirements), add the *QASP-033* as a training requirement applicable to all staff.	A) EARTO (2000) sec 4.1 requires that personnel have "integrity and a good reputation". This is very difficult to ensure. A commitment to ethical professional practice can be demonstrated by having employees abide by the company's newly developed Company Code of Conduct (see Gap 2.2)
Current training process	Clause #4.2.2 :	*Resource*	A) Modify Quality Manual sec. 6.2.2 to	A) The scope of the training process just

at CSO is sufficient to meet needs of new standard requirements. However, CSO staff need to be aware of how they contribute to the achievement of both quality and R&D&I objectives.	Competence, Awareness and Training	*management : Competence, Awareness and Training* Quality Manual (Section 6.2.2: Competence, Awareness and Training) QASP-016: Training	read as follows: "*The Director, Manager or Supervisor is responsible to ensure that operations or processes that can affect quality or R&D&I are listed on the Training requirements index…CSO staff are made aware aware of the relevance and importance of their activities, as well as how they can contribute to the achievement of the quality and R&D&I objectives during the Quality/R&D&I management system orientation…"* B) Inform employees on the R&D&I objectives: In QASP-016 sec. 4.0 (New Employee Training Requirements), edit "Quality Assurance Orientation" to "Quality /R&D&I Management System Orientation".	needs to be expanded to cover the R&D&I MS. B) New employees will be introduced to the R&D&I MS through QASP-033: Policy and Objectives (which contains the integrated Quality/R&D&I Policy and Objectives, along with the Company Code of Conduct).
Processes that: a) promote awareness of the importance of R&D&I b) improve motivation and enthusiasm c) encourages teamwork and participation of all staff d) fosters an environment of creativity and innovation e) simplify and facilitate information flow between different departments	Clause #4.2.3: Teamwork, creativity and motivation	*Resource management: Teamwork, creativity, motivation* Training (QASP-016)	A) *Promoting awareness of importance of R&D&I:* • Train employees on the R&D&I policy and objectives (incorporated into the *Integrated Policy* found in QASP-033: Policy and Objectives) B) *Improving motivation and enthusiasm*: B1) Provide adequate recognition, rewards, and incentives for quality efforts. Recognition and communication of success can be facilitated a number of ways, such as quality news-sheets and bulletins, team competition/celebration days, social gatherings B2) Motivation can be improved by	Sec 4.3.2.1 and 4.3.2.2 UNE 166002:2006 is devoted to the "motivation of the personnel", and specifies that the organization establish the necessary procedures. Full details on closing this gap is an area of Total Quality Management (TQM) and is outside the scope of this thesis, however, some suggestions are provided. A) The R&D&I policy states that R&D&I is part of the company's business strategy. B) "…the key to be successful in R&D&I lies in the ability of the personnel to work as a team and in their motivation and

…are not defined.			encouraging employees to find satisfaction in their own work. For instance, young engineers can be given opportunities to serve as "project leaders" on smaller projects, or assistant project managers for more complex projects. B3) Monitoring and measurement of employee satisfaction: B3a) Administer employee satisfaction surveys. B3b) Develop an employee complaint handling system C) *Teamwork and participation of all levels of staff:* C1) Create a "group culture" where employees are willing to undertake a range of tasks, irrespective of job title, so as to meet customer requirements. Employees should be empowered to make decisions and implement solutions. C2) Organize work units into cells with a great deal of autonomy and the create semi-autonomous work groups. C3) Quality circles which can increase employee participation, and promote creativity. D) *Promoting creativity and innovation:* D1) Create a supportive atmosphere in which people feel free to express their ideas without the risk of criticism or ridicule.	enthusiasm to obtain results" [UNE 166002:2006 sec 4.3.2.1] B1) Dale, 2000, p.86 B2) See Maslow's "Hierarchy of Needs" and Herzberg's "motivation-hygiene theory". B3) Employees are "internal customers" of an organization and their welfare and satisfaction has a considerable impact on product quality, so therefore keeping track of this through measurement is as equally important as measuring external customer satisfaction (Dale, 2000, p.190). B3a) The surveys provide an informal means to gauge staff sentiment in the company and to gather feedback. For instance, they may help managers know what is happening in their functional areas, how employees feel about their work and how they are treated. They may also aid in identifying chief causes of concern for employees, their main complaints, and suggestions for improvements (Dale, 2000, p.86). Results of surveys will be communicated to employees and departmental managers will be required to discuss findings with the staff, in order to develop strategies to deal with problems (Dale, 2000, p.190) Currently, marketing & business development staff obtains customer feedback, however, **employee** feedback regarding their satisfaction/motivation is not analyzed. Surveys should be conducted before and after implementing

			Encourage risk taking and experimentation. D2) Create **processes** and **events** to capture ideas. D3) Stress that people at all levels of the business share responsibility for innovation, so everybody feels involved in taking the business forward. D4) Reward innovation and celebrate success. D5) Look for **imagination** and **creativity** when recruiting new employees. E) Facilitating information flow between departments: E1) Promote openness between individuals and teams. Teamworking, newsletters and intranets can all help staff share information and encourage innovation E2) Keep employees informed of the business "Hits" and "Misses" in the market place (through memos/bulletins). E3) Emphasize teamwork, creativity, and motivation during employee training.	any employee motivation improvement programs, and can be carried out annually. Survey results will be used as data in management reviews and business planning. B3b) ISO 10002:2004 can be consulted. C1) Dale, 2000, p.183 C2) Dale, 2000, 182 C3) Dale, 2000, p.456 D) Innovation and creativity is an important aspect of R&D and is emphasized throughout UNE 166002:2006. "Creativity" is defined as a "mental process contributing to the generation of new ideas…by promoting the ability to discard the usual structured channels and ways of thinking to reach an idea that will allow to solve a specific problem" [UNE 166002:2006 Sec 4.4.1.3] D1) An innovative environment that encourages creative thinking should be created. Supervisors should discourage a "fear of failure", and rather support a "search for failure" (Dale, 2000, p.182). They should actively solicit ideas on problems and solutions from all people in the work group. D2) For example, set up suggestion boxes around the workplace or hold regular workshops or occasional company days to brainstorm ideas.

				D4) Appropriate incentives can play a role in encouraging staff to think creatively. E) Sharing information openly between departments will also foster creativity and encourage growth. E2) This can also help provide a sense of ownership and urgency in resolving customer concerns and preventing customer dissatisfaction in the future. (General Motors Corp. case study, The Integrated use of MSS - Case Study Annex, p.54). E3) The newly created Company Code of Professional Business Conduct (see integrated MSS Req. 2.2) stresses teamwork, creativity, and motivation, and will be a required New Employee Training Requirement in QASP-016
Work environment required to achieve R&D&I objectives not defined.	Clause #4.3.3 : Work Environment	*Resource management : Work Environment* Quality Manual (Section 6.4: Provision of resources)	A) Add to new sub-section in Quality Manual sec. 6.4 that defines the work environment required to achieve the R&D&I objectives, and how it will be managed.	A) R&D&I objectives are to be set by CSO management, and are addressed in Gap 2.2: Policy and Objectives. R&D objectives might include the identification of R&D needs, which should support the continuing development of new technical knowledge, products, and services for future growth and new ventures. Since the R&D objectives primary involve addressing strategic concerns of the business, the “work environment” will likely be the regular offices and meeting rooms at the CSO.

H-5 R&D&I Analysis

Table H-5.1: Gap Closure Table - R&D&I Analysis

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Technology watch and technology foresight activities not defined.	Clause #5.0 Information gathering and processing, technology assessment, project evaluation and selection	*Information gathering, technology assessment, analysis and selection of ideas*	A) Design **technology watch process.** The basic activities involved in a technology watch process are shown in *Figure G-3.1* B Design **technology foresight process**. The basic activities involved in a technology watch process are shown in *Figure G-3.2*	R&D&I unit and management unit uses "tools" to develop their activities [UNE 166002:2006 sec 4.4.1]. These "tools" are Technology Watch, Technology Foresight, Creativity (covered in human resources), External and internal analysis A) The technology watch process provides the CSO with a systematic way to compile, analyze, disseminate, and exploit scientific or technical information that can be useful. It also provides alerts about scientific or technical innovations which can create opportunities or threats [UNE 166002:2006 sec 4.4.1.1]. More details on the Technology Watch Process can be found in the UNE 166006 EX:2006 standard. B) UNE 166002:2006 sec 4.4.1.2: Technology foresight. The technology watch and foresight activities will help the CSO be more aware of changes in technology, the marketplace, and new standards that may have an impact on R&D, and to make sure these changes are taken into account in order to keep the R&D&I management system up to date. With the addition of data from Technology Watch and Technology Foresight activities, not only will the company identify the interested parties and their requirements (an ISO 9001:2000 requirement), they will also assess external information in an anticipative away to identify future expectations of the market. This approach is similar to that in the ISO 10001:2007 (see "Code Framework")

System to carry out external and internal analysis not defined	Clause #5.0 Information gathering and processing, technology assessment, project evaluation and selection	*Information gathering, technology assessment, analysis and selection of ideas*	A) Establish system to carry out **external analysis**. The basic activities involved in external analysis are shown in *Figure G-3.3* B) Establish procedure to carry out **internal analysis**. The basic activities involved in internal analysis are shown in *Figure G-3.3*	A) External analysis helps the organization assess the importance of different innovative ideas by comparing them with the external reality [UNE 166002:2006 sec 4.4.1.4.1: External analysis]. Studies on competitor products and patent searches (an activity in external analysis) can provide useful information, especially to establish a product's level of uniqueness. To ensure the effective and efficient development of new knowledge to solve specified needs of the client, a new project looks for previous knowledge as well as knowledge about the state of the art. "External analysis" is a more detailed assessment of information gathered from the "technology watch". The analysis provides a proactive approach for testing research ideas before further development. B) "Internal analysis helps the CSO analyze the current structure of the organization and integration mechanisms among its different parts, in order to establish the necessary changes for them to effectively contribute to the generation of innovative ideas." [UNE 166002:2006 sec 4.4.1.4.2: Internal analysis].
The identification and analysis of problems and opportunities not fully defined and integrated in MS	Clause #5.0 Information gathering and processing, technology assessment, project evaluation and selection	*Information gathering, technology assessment, analysis and selection of ideas*	A) Establish system to **identify and analyze problems and opportunities** arising from the main R&D&I results of interest for the CSO's target market. The basic activities involved in identification/analysis of problems and opportunities are shown in *Figure G-3.4*	A) UNE 166002:2006 sec 4.4.2 The analysis of problems and opportunities helps the CSO assess the cost of R&D projects, and ensures that they are aligned with the overall business strategy. New opportunities can be determined and existing problems are investigated.
The analysis and selection of R&D&I ideas not fully	Clause #5.0 Information gathering and	*Information gathering, technology*	A) Design method for the evaluation and selection of R&D ideas to be adopted and developed. The basic activities involved are	A) "The selection method shall assess a series of factors that will try to guarantee the success of the idea…economic, productive, legal, social and

defined and integrated in MS	processing, technology assessment, project evaluation and selection	*assessment, analysis and selection of ideas* Product Quality Planning - MPQP (QASP-037)	shown in *Figure G-3.5*. B) Add details on preparing project business cases to QASP-037.	technological factors [should be considered]." (UNE 166002:2006 Section 4.4.3). During the project/R&D idea selection process, the importance of the R&D&I ideas and results are assessed, in order to decide, to plan, and realize their development in the company's product pipeline. The analysis will also aid the CSO in filtering and identifying high priority projects. By filtering ideas before committing to the development of a new product or service, the CSO can avoid wasting resources on products that are unlikely to get off the ground. This allows it to explore a wider range of possible ideas and options in the early stages. Through this process, the management is better able to make its decisions for planning the company's project portfolio. This R&D&I idea analysis and selection process can be integrated as part of the activities involved the "Opportunity Review Phase" of product development), in particular the preparation of the project "business case". A "business case" is defined as "an analysis of the opportunity that includes customer stability, market position, financial potential growth forecast, competitive position and intellectual property rights" (QASP-037 sec 2.5). UNE 166002:2006 Section 4.4.3 provides a list of aspects to identify and define for each R&D&I idea. These aspects, along with the QASP-037 description of a "business case", were used to generate a generic process flowchart for business case development. B) Details on preparing a "business case" are not disclosed in the CSO's QMS documentation,

				however, it is assumed that the CSO has its' own system for preparing project business cases. A flexible documented procedure will ensure that all relevant aspects are considered and that all projects are analyzed fairly using a structured methodology and similar criteria.

H-6 Project/product planning, design & development

***Table H-6.1*: Gap Closure Table - Global Project management and planning**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
CSO has documented processes for managing individual projects, however a system for planning, monitoring and control of the overall project portfolio is not documented.	Clause #6.1.1: Project management and planning	*Project management and planning* Quality Manual (Section 7.0: Product Realization)	A) Create new procedure that addresses how the overall project portfolio will be planned, monitored, and controlled. The following aspects will be included in the procedure: • Review and approval of documents. • Priority proposals • Supervision of global progress and management of periodic reviews • Drafting of reports on the state-of-the-art and progress of projects (data provided by R&D&I unit and project managers for each individual project) • Search for sources of funding • Search for internal and external collaborations • Assessment of the impact caused by the evolution of the state-of-the-art concerning the products B) Create new section in Quality Manual describing the planning, monitoring and	A) UNE 166002:2006 clause 4.4.4.

			control of the overall project portfolio (placed before current section 7.1 : Planning of Product Realization). The procedure created in A) above will be referenced.	

Table H-6.2: **Gap Analysis Table - Gather requirements; Design/Development Planning**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Customer requirements are determined and met with the goal of enhancing customer satisfaction; however the needs/expectations of *all interested parties* in the R&D&I process are not fully defined..	Clause #6.1.2: Gather assess stakeholder requirements	*Gather assess stakeholder requirements* Quality Manual section 7.2.1 (Determination of requirements related to the product).	A) Add list of interested parties to consider in Quality Manual sec 7.2.1. B) Determine, gather and assess stakeholder information and input prior to product development.	A) UNE 166002:2006 sec 4.2.2 (Interested parties approach) specifies that the "needs and expectations of the interested parties in the R&D&I process be considered and analyzed". This suggests that stakeholder input should be considered when determining requirements for a product. UNE 166002:2006 sec 4.2.2 requires that "attention be drawn to following "interested parties": • Demands of providers and customers • Motivation and involvement of employees • Demands of shareholders • Legal and regulatory requirements • Innovations and technological changes required by the market" Although, ISO 9001:2000 does not explicitly specify all of these stakeholder requirements, it covers them in general through 7.2.1d) "any additional requirements determined by the organization". The listing of the "interested parties" will provide the CSO with a more specific list of stakeholder requirements to focus on.

				B) A range of methods can be used for obtaining input from interested parties, including public meetings, focus groups, questionnaires and surveys, advisory committees, workshops and electronic discussion groups (ISO 10001: 2007 Annex E). The information gathered using the R&D&I tools in Clause #5.0 (e.g. technology watch and technology foresight) will also provide useful input for technological changes required by the market.
Design and project team communication structure not defined	Clause #6.2.1: Design/Development Planning	*Design/Development Planning* Design Control (QASP-002)	A) Add "Design Team Communication Structure" as additional content in the Design Plan (QASP-002 sec 3.0).	A) UNE 166002:2006 Sec 4.4.6.2 The standard does not provide details on "communication structure". However, it is believed that it will describe how project design communication will take place (i.e. delivery channels and frequency of communication).

***Table H-6.3*: Gap Closure Table - Documentation of research results**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Since "research contracts" are excluded from the scope of the CSO's quality system, a standardized system for the documentation of research results is not defined in the CSO's QMS.	Clause #6.2.3: Design/Development Outputs	*Outputs and Results* Quality Manual Section 7.3.3 (Design and Development Outputs)	A) Create a new procedure (called "*Documentation and reporting of project results"*) that covers the documentation of the R&D&I results (the "project report") obtained by the project team. This procedure would provide the guidelines for the documentation of research results (as outlined in EARTO:2000 sec 5.4) B) In Quality Manual sec 7.3.3, add "project reports" as an additional "design output".	A) The main "output" of the R&D&I process are the "results". The documentation of R&D&I results include (UNE 166002:2006 Clause 4.4.8.1): • "Final reports on projects • Description of the protection of results obtained • Basic data, diagrams, drawings and intermediate reports • Problems and specific solutions, with the techniques, procedures and equipment used • Written evaluations of the projects as a whole, including the knowledge acquired for future R&D&I activities" Since "research contracts" (and all projects before

				the prototype phase) are excluded from the scope of the CSO's quality system, a standardized system for the documentation of research results is not defined in the CSO's QMS. However, such a system is required, as revealed through the interviews with the CSO. At the very least, a set of guidelines for the proper documentation of project results and reports should be generated. Section 5.4 (Report the Results) of EARTO (2000) provides a set of extensive guidelines for the presentation of a research report. A general format for a project report, based on UNE 166002:2006 and the EARTO:2000 guidelines can be found in *Figure G-4.1* The project report is a quality record and is governed by QASP-014 (Control of Quality Records) and QASP-003 (Document and Data Control)

***Table H-6.4*: Gap Closure Table - Design/Development Review and Monitoring**

Gap(s)	Integrated MSS Requirement(s)	*Area(s) of MS affected*	Necessary Action Plan for Gap Closure	Rationale/Remarks
Surveillance of the project progress, especially with regard to features, costs and timeframes not defined.	Clause #6.2.4: Review and Monitoring	*Review and Monitoring* Project Management (QASP-006)	A) Create new process: "Project progress monitoring and reporting". The monitoring/reporting will typically be performed at regular intervals or on the completion of milestones. See *Figure G-4.2* for details on the process. B) Add new section to QASP-006 called "Project Progress Monitoring and Reporting". Place process flowchart and details in that section. C) Update the Project Management flowchart	A) UNE 166002:2006 sec 4.4.6.6 and EARTO:2000 sec 5.3 addresses project progress monitoring. This involves the "systematic surveillance of the project, especially with regard to features, costs and timeframes" [UNE 166002:2006 sec 4.4.6.6]. **Project** monitoring is larger in scope than "**product monitoring**" required by ISO 9001:2000. Product monitoring involves measuring and monitoring product characteristics to verify that

			in QASP-006 to reflect the project progress monitoring and reporting process **(**see *Figure G-4.3***.)**	product requirements have been met [ISO 9001:2000 sec 8.2.4]. Project monitoring involves monitoring the entire project work progress and status of expenditure by "comparing achievements and the use of resources against the planned budgets" [EARTO:2000 sec 5.3]. A simple flowchart of the project progress monitoring and reporting process was prepared using guidelines provided in EARTO (2000) sec 5.3. B) This gap closure step addresses project progress monitoring/reporting and is part of project management.

***Table H-6.5*: Gap Closure Table - Experimental and Calculation methods**

Gap(s)	Integrated MSS Requirement(s)	*Area(s) of MS affected*	Necessary Action Plan for Gap Closure	Rationale/Remarks
Experimental and Calculation methods not defined or documented.	Clause #6.2.8: Experimental and Calculation methods	*Experimental and Calculation methods* Quality Manual Section 7.3 (Design and Development)	A) Add new section in Quality Manual under section 7.3 of Design and Development called "7.3.8: Experimental and calculation methods". B) Create a new procedure (called "*Experimental and calculation methods"*) that will provide guidelines for the use of appropriate experimental and calculation methods for research activities. Procedure will be referenced in 7.3.8 section of the Quality Manual.	A) EARTO:2000 sec 4.3 refers to the use of appropriate experimental and calculation methods. It is likely that the R&D team members (who are all highly trained), already use suitable experimental and research methodology during day to day research work. The purpose of the documented procedure helps provides formal assurance that proper experimental procedures have been followed by the CSO. B) Guidelines provided in EARTO:2000 sec 4.3 will be used for drafting the new procedure. Some of the requirements are already fulfilled by ISO 9001:2000 (e.g. the availability of work instructions). Only new requirements and guidelines will be included in the procedure. The procedure will be divided into the following sections, which corresponds to the structure of the sequence of guidelines in the standard (further details can be found in EARTO:2000 sec 4.3. i) The use published research methodologies that meet needs of clients and which are scientifically appropriate for the project. ii) The use of newly developed or adopted research methods iii) Validation of research methodologies iv) Control of electronic data and transfers v) Estimating uncertainties in the results

Table H-6.6: **Gap Closure Table – IP and the Exploitation of R&D&I Results**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Process does not exist nor is one documented for the exploitation of results and technology transfer	Clause #6.4 Technology transfer, exploitation of results and intellectual property	*IP and exploitation of results* Quality Manual Section 7.3 (Design and Development)	A) Address Technology transfer, intellectual property and the exploitation of results. B) Create a new procedure (called "*Technology transfer, intellectual property and the exploitation of results"*) that will provide guidelines on the Tech transfer/exploitation of R&D&I results process. The procedure will be broken up into 3 sections: *Technology Transfer, Protection and exploitation of the results of R&D&I activities, and Intellectual Property Rights.* B1) Establish a systematic way to maintain and document a **technology transfer system** of the CSO's own technology and for integrating external technologies. B2) Establish a systematic way for assessing the viability and opportunity to **protect and exploit new R&D&I results** obtained. The basic activities involved in the protection and exploitation of results process are shown in *Figure G-4.4* B3) **Intellectual property rights (IPR)** Define a set of general principles related to the IPR of R&D&I work performed for clients (see *Figure G-4.5*).	A) Technology transfer, intellectual property management and the protection of proprietary material generated during R&D&I activities is a critical component of research and development. The process to commercially exploit research varies widely. For instance, it can involve licensing agreements or setting up joint ventures and partnerships to share both the risks and rewards of bringing new technologies to market. There are also many methods for protecting intellectual property from infringement, such as patenting or copyrighting. Specific details on the mechanism of the technology transfer and the intellectual property protection and exploitation process are not provided in the standards, and are also out of the scope of this thesis. B1) *Technology Transfer* UNE 166002:2006 clause 4.45 provides only general ideas on the **mechanisms for technology transfer**: i) Intellectual and industrial property (e.g., patents, utility models, etc.) ii) Technology acquisition and sale contracts iii) Technical assistance iv) Creation of joint ventures v) Cooperation and partnerships to undertake R&D&I projects vi) Technology transfer from the university/R&D&i bodies to the organization B2) *Protection and exploitation of the results of R&D&I activities*

				This generic process is adopted from the aspects provided in Clause 4.4.9 of UNE 166002:2006. Like the technology transfer process, the does not provide specific details on the process involved. B3) This section outlines general legal principles for intellectual property rights (IPR) related to the output of R&D&I activities performed for clients. These principles are directly taken from the guidelines provided in EARTO:2000 sec 2.2, and are "meant to ensure the satisfactory handling of issues related to IPR" (EARTO:2000 sec 2.2). These can be used by an organization as a guideline for preparing a legal IPR contract with the client before research work is carried out. However, it is recommended though, that specific conditions dealing with IPR be established with professional legal counsel.

H-7 Manufacturing, Receiving, Shipping; Purchasing

Table H-7.1: **Gap Closure Table - Manufacturing, Receiving, Shipping; Purchasing**

Gap(s)	Integrated MSS Requirement(s)	Area(s) of MS affected	Necessary Action Plan for Gap Closure	Rationale/Remarks
Retention period for client supplied research items not defined (e.g. products, materials, samples, specimens)	Clause #7.2 (Handling of product, customer property and research items)	*Customer property and research items* Control of Customer-Supplied Product (QASP 005)	A) Add line in QASP-005 specifying retention period for client supplied research items : at least three months from the date results were delivered to client	A) EARTO(2000) sec 4.8: Handling of research items. For legal reasons, or in case of a dispute, it might be advisable to keep the items for a longer time.
Approved vendors selected on basis of their ability to meet contractual requirements and quality assurance requirements, but selection of providers based on needs of R&D&I management unit not specified as a criteria in Quality Manual.	Clause #8.1 Procurement and subcontracting work	*Purchasing- Select and evaluation* Quality Manual (section7.4.1: Purchasing process)	A) Change last sentence in first paragraph of *Quality Manual sec. 7.4.1: Purchasing process* to: "*Approved vendors are selected on the basis of their ability to meet contractual requirements: including quality and R&D&I system, specific quality assurance and R&D&I management unit requirements as appropriate*".	A) UNE 166002:2006 requirement that personnel subcontracted and/or products acquired meet the requirements indicated by the R&D&I management unit.